

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Monday,
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The InterContinental Harbor Court
550 Light Street
Baltimore, MD

[Transcribed from PCORI webcast.]

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Grayson Norquist, MD, MSPH
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Harlan Weisman, MD
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AGENDA

Page

1. Welcome, Approval of January Board Meeting	
Minutes, and Executive Director's Report	6/11
Growing the PCORI Staff	13
New PCORI Office Space	20
Looking Ahead - The Next Six Months	23
National Priorities & Research Agenda	26
Funding Announcements/Funding Cycles	32
Patient and Stakeholder Engagement	41
2. Program Development Committee Report	46
PCORI Pilot Projects Grants Program Update	47
Update on Plans for Analysis of Public	
Comments Received on Draft National	
Priorities for Research and Research Agenda	89
Developing PCORI Funding Announcements	106
3. Public Comment Period	133
4. Break	166

AGENDA [Continued]

	<u>Page</u>
5. Finance, Audit and Administration Committee Report	166
Standing Committee on Conflict of Interest	
(SCCOI) Appointments	167
GAO Oversight and Compliance	182
2011 Financial Statement Audit	182
Managing Cash Flow	192
6. Lunch	210
7. Methodology Committee Report	211
Finalizing the Methodology Report	213
Board-Methodology Committee Engagement	238
Beyond the Methodology Report	241
Revising the Working PCOR Definition	256
8. Public Comment Period	287
9. Break	293

AGENDA [Continued]

Page

10.	Communications, Outreach and Engagement	
	Committee Report	293
	Update on Public Feedback Received on Draft	
	National Priorities for Research and	
	Research Agenda	296
	Report on National Patient and Stakeholder	
	Dialogue	297
	Report on Clinician Focus Groups	304
	Update on Stakeholder and Community	
	Engagement Events at Board Meetings	311
11.	Wrap up and Adjournment	337

P R O C E E D I N G S

[8:45 AM]

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2
3 CHAIRMAN WASHINGTON: Good morning and
4 welcome. This is the Ninth Board Meeting of the
5 Meeting of the Board of Governors of the Patient-
6 Centered Outcomes Research Institute. Today's
7 meeting is available via a live webcast on our
8 website at www.PCORI.org and webcasts will also be
9 archived for those of you who won't be able to stay
10 tuned the entire day on our website after this
11 meeting.

12 I want to again thank everyone for joining
13 us today; those are you who are joining us remotely
14 as well as the participants who are here in the
15 room and obviously a hearty thanks to my colleagues
16 on the Board.

17 In thinking about the meeting today, it
18 dawned on me that this month will mark actually the
19 second anniversary of the Patient Protection and
20 Affordable Care Act. March 23rd is when the
21 statute was signed into law for the nation and it
22 was that statute that I think stipulated that

1 within six months, this GAO was to appoint the
2 Board of Governors for PCORI, and so, it's actually
3 been less than two years; to be exact, it's been a
4 little over 17 months since we as a group have gone
5 on working together in collaboration with many,
6 many others to form what is now the Patient-
7 Centered Outcomes Research Institute.

8 And I raise this so that we can put into
9 some context the discussion that we're going to be
10 having today and discussions that we're going to
11 have going into the future because I want to
12 underscore that while we have a great deal of work
13 to do, we've made substantial progress over the
14 last 17 months. If you go online, which I've done
15 multiple times, I mean, there is PCORI, there is a
16 website.

17 So, first and foremost, we have created a
18 new institute literally from whole cloth for the
19 nation, and in creating this new institute, along
20 the way, we've had to establish new policies and
21 bylaws and procedures for governing ourselves as we
22 conduct our daily basis and go about achieving our

1 mission.

2 We have opened an office so that there is
3 concrete evidence of our existence, and, as I
4 mentioned, a website, which also serves a worldwide
5 symbol that we are now in business. And, most
6 importantly, particularly over the last six to nine
7 months, we've recruited superb staff and we believe
8 that we have recruited the best and the brightest
9 individuals in each of their respective areas.

10 What we're going to be talking about this
11 morning relates to the other two areas where I
12 think that we have also made significant progress
13 as we look ahead and look at where we are now. One
14 is that we really have advanced our mission. We
15 have established a mission statement and I'm just
16 going to reiterate it for those of you who have not
17 heard it. This is not for the Board, but for
18 others. PCORI mission, the Patient-Centered
19 Outcomes Research Institute helps people make
20 informed health care decisions and improves health
21 care delivery and outcomes by producing and
22 promoting high integrity, evidence-based

1 information that comes from research guided by
2 patients, caregivers, and the broader health care
3 community. And, indeed, we have been working and
4 making progress in advancing each of our mission
5 areas, and to reiterate, they are engaging patients
6 and other stakeholders, providers, caregivers,
7 clinicians, researchers, policymakers to conducting
8 PCORI patient-centered outcomes research we've been
9 doing. Disseminating research finding, we've been
10 organizing ourselves so that we're in a position to
11 have impact through dissemination and communication
12 of the research that's conducted. We similarly
13 have been working on how do we lay the foundation
14 and strengthen the infrastructure for not only
15 conducting PCOR, but also for more effectively
16 meaningfully engaging patients as well as
17 infrastructure for more effective dissemination.

18 And then, finally, underpinning everything
19 that we undertake across our mission areas. We
20 have an outstanding group that's been spearheading
21 our activities to advance rigorous methods, again,
22 in all of our mission areas. And so, our

1 discussions today just continue our efforts to
2 fine-tune what we're doing in these respective
3 mission areas and then, secondly, our discussions
4 also continue to focus on our desire to strengthen
5 our governance and improve the excellence of our
6 operations looking across the Board at how we do
7 business to ensure that we are, in fact,
8 incorporating best practices and optimizing the
9 opportunities we have to work with many across the
10 nation and to use the resources that's been
11 entrusted to us.

12 And so, yes, we do have miles and miles
13 and miles to go before we sleep and the woods at
14 some point have been dark and they will be dark and
15 they will be deep and sometimes they will even be
16 lovely, but our progress and our ongoing efforts
17 underscore our commitment to keeping the promises
18 that we have made as a board and the promise that's
19 held in the statute for us as an institute to
20 promote better information, better decisions, and,
21 ultimately, better health in the nation.

22 And so, I want to open the meeting by

1 thanking all, particularly my colleagues on the
2 Board of Governors, but everyone that has
3 participated with us up until this point and we
4 look forward to continuing to work with you in a
5 collaborative way to be more effective going into
6 the future.

7 And so, with that as an opening, Joe, I
8 turn it to Dr. Selby.

9 DR. SELBY: Thank you, Gene. Good
10 morning, everyone. I guess you would call this the
11 report from the dark and deep and often lovely
12 woods. I'm going to report to you on the fact that
13 I found a number of fellow travelers in the last
14 couple of months and the trip was getting ever more
15 interesting.

16 But, first, I want to start as I usually
17 do by acknowledging the Board of Governors and the
18 Methodology Committee for the help and support that
19 you all provide. I think I'm finding that you are
20 providing this help and support in new ways as our
21 staff increases in addition to the work that gets
22 done through committees and working groups and we

1 even form new ones as time goes by. Increasingly,
2 the Board is lending their assistance in the form
3 of one-on-one discussions, conversations, and
4 advice not only to me, but to a number of our
5 staff. So, we're continuing to be grateful. I
6 talk everywhere I go about how exceptional
7 the -- [off microphone] -- let you know that we're
8 aware at least of some of the honors that come your
9 way and here are three that we just became aware of
10 in the last couple weeks.

11 Dr. Debra Barksdale received an award from
12 the Delta Sigma Theta Sorority. They have an
13 annual Queen of Hearts Gala, and Hearts refers to
14 cardiovascular disease and she was given an award
15 for outstanding research contribution on
16 cardiovascular disease in African Americans. Dr.
17 Christine Goertz is this year's Chiropractor of the
18 Year, Outstanding Chiropractor of the Year in the
19 U.S. named by the American Chiropractic
20 Association. And Dr. Freda Lewis-Hall, who will
21 this Saturday receive the 2012 Alumni Award for
22 Distinguished Post-Graduate Achievement in the

1 fields in medicine and health care leadership from
2 Howard University's Board of Trustees.

3 It wouldn't surprise me if there was
4 another award or two that we're not aware of, but I
5 just thought that was worth mentioning and say we
6 do appreciate how fortunate we are to be able to
7 work with all of you.

8 So, this morning, I'm going to rather
9 briefly talk about the growing team going through
10 the dark, lovely woods. The office space, it's
11 more than concrete, actually, Gene, and then
12 looking ahead, the National Priorities for Research
13 Agenda, funding announcements, big news on funding
14 announcements, and our plans for patient and
15 stakeholder engagement.

16 We have added a number of key staff and I
17 can say that while for the last eight months I've
18 been celebrating the extraordinary Board and the
19 Extraordinary Methodology Committee, I can now say
20 that we have a sizable extraordinary staff. These
21 folks have come very excited about PCORI's mission,
22 very competent, very accomplished. It's a pleasure

1 and a privilege to go to work every day, and I'll
2 start at the top.

3 Pam Goodnow came to us from the National
4 Academy of Sciences and before that a number of
5 years at GW, where she was a comptroller and she
6 was a chief financial officer at NAS and then
7 comptroller at GW, and she knows really in great
8 depth the whole grant-making and grant-receiving
9 worlds, the world of federal audits. And it's just
10 a joy to have her here. She's unable to be here
11 this morning because of a family issue, but it is
12 really wonderful to have somebody with her
13 experience on hand every day to guide us in this
14 area.

15 Susan Hildebrandt is here. Susan?
16 There's a hand raised. Susan, we're delighted to
17 have and Susan will be PCORI's director of
18 Stakeholder Engagement. Susan comes to us after
19 19-plus years at the American Academy of Family
20 Physicians, where she has represented clinicians
21 and interacted with other groups of clinicians and
22 I think just makes a perfect person to engage

1 clinicians and other stakeholders in the work of
2 PCORI in making sure that their voice is heard as
3 we put research together and conduct it.

4 Judith Glanz will be PCORI's director of
5 Patient Engagement and Judith comes to us from most
6 recently AARP and before that, the Campaign for
7 Tobacco-Free Kids, and Judith will head up here in
8 D.C., our patient engagement efforts.

9 And, Judith, did you raise your -- yes,
10 both hands. Good, thanks.

11 And next is Sue Sheridan. There's Sue.
12 Sue comes to us from Boise, Idaho, and, in fact,
13 the plan is for Sue to continue coming to us from
14 Boise, Idaho. Sue's position will be deputy
15 director of Patient Engagement. So, we have two
16 people, two high-level leadership team individuals
17 managing patient engagement, and we see Sue's role
18 as somewhat complementary to Judy's in that Sue has
19 been for many years linking patients together
20 across the world, internationally, using a lot of
21 virtual methods, as well as a lot of travel and
22 she'll continue to do that with PCORI. And if

1 Judy's role is substantially to be at the Center,
2 and to be able to relate and engage to
3 organizations that represent patients, Sue's is to
4 connect us to the patients well out beyond the
5 Beltway, across the country.

6 Just one more word about Sue, she has in
7 her previous life founded two organizations. One
8 is called PICK, which is Patients of Infants and
9 Children with Kernicterus, and the second is CAPS,
10 which is Consumers Advancing Patient Safety. So,
11 she has brought patients together around different
12 causes already and we really look forward to
13 working with Sue.

14 I'm very happy to report that Gail
15 Shearer, Gail, who is a familiar face because Gail
16 has been with us as an independent consultant since
17 almost the beginning, since long before I was here,
18 February. She's a fount of knowledge in I would
19 say responsibility. She just keeps an eye on PCORI
20 and she'll be joining us on staff as a senior
21 advisor and among her charges is to just make sure
22 that when PCORI needs a policy, it gets developed,

1 and when it gets developed, it gets adhered to.

2 She also does a whole lot staffing the Methodology
3 Committee.

4 And last, Martin Duenas. Martin, this is
5 Martin's first adventure with PCORI this weekend.
6 Martin will be coming to us shortly from the
7 Juvenile Diabetes Research Foundation in New York,
8 where he was the director of Financial Operations
9 there in Grants Management and he will be in charge
10 of contracts management at PCORI and he brings a
11 wealth of expertise. I'd say his expertise spreads
12 well beyond contracts management, but it's always
13 nice to have somebody who's over-trained and over-
14 experienced. He also has a bundle of energy.

15 So, those are the new folks this month and
16 just let me say again how fortunate we are to have
17 all of them with us.

18 So, here is our ever-changing
19 organizational chart. Just the notation that there
20 are a couple slots still open; the Chief Science
21 Officer and the Director of Information Technology
22 are positions that are posted and we're not quite

1 to the stage of interviews yet, but those are two
2 positions we have our eye on. Human resources is
3 another area that are determining whether to add an
4 individual on staff or to continue contracting and
5 the rest of it is as you see.

6 Just a comment about this, the three boxes
7 in orange, and you've heard this before, constitute
8 our engagement team. It's actually with Sue
9 Sheridan's addition. That's four high-level
10 people. Now Bill Silberg runs communications, and
11 those folks are our engagement arm, and I think we
12 set out to prove that we were serious about
13 engagement and we have the scientists, we are
14 interviewing scientists on a rather frequent basis
15 these days, and I hope next time to be able to name
16 a number of additional scientists we've added, but
17 the point here is that these scientists and the
18 engagement team have to work together.

19 The scientists need to be engaged and it's
20 the engagement folks that make sure that they are.
21 The process of engagement needs to be studied, and
22 so, part of us being a learning organization is, in

1 fact, figuring out whether what we're doing in the
2 name of engagement is actually effective. So, the
3 scientists support engagement and engagement
4 supports science and that is one of the ways that
5 we will distinguish ourselves and our research and
6 it's one of the ways in which we intend to be a
7 learning organization.

8 So, just the next steps in hiring, I've
9 already mentioned the Chief Science Officer,
10 scientist interviews underway. Research
11 associates, I think we will have a number of
12 research associates added to PCORI's staff to
13 support Board activities, Methodology Committee
14 activities, and staff activities by May. The same
15 on the engagement side. We've told folks who came
16 to join the Engagement Team that now they need to
17 turn around and recruit staff to do the work to
18 expand our digital engagement with patients and
19 stakeholders to build up the communications and to
20 begin convening meetings of these folks. So, they
21 will need help. And in Operations, I've told you
22 we're looking for Director of Information

1 Technology, and I expect Martin and Pam Goodnow to
2 build up the finances in Grants Management staff.

3 Okay, Gene had said something about we
4 have a place and it's concrete. Well, it's
5 actually concrete, glass, wood, and carpet already
6 and it's not ready quite to show you the inside,
7 but I can tell you that we'll actually be in
8 residence there at 1828 L Street by the next time
9 we meet, by our May meeting. That picture on the
10 bottom is just of the foyer on the first floor, but
11 this is a lovely, not new, but lovely, very green
12 building and our offices will be on the ninth
13 floor, and we're really looking forward to the
14 move. It's designed to be very welcoming and
15 stakeholder and patient-centered environment.

16 DR. DOUMA: Can I --

17 DR. SELBY: Yes.

18 DR. DOUMA: A question. I just wanted to
19 ask a question. The Director of Information
20 Technology, will the roles and responsibilities
21 include both internal and external Information
22 Technology or is this focus on the internal?

1 DR. SELBY: No, to the extent I understand
2 exactly what you mean, I think this is going to be
3 a very high-level person who knows the entire field
4 and will help us make decisions, critical, as you
5 know, decisions and adheres always whether to hire
6 staff to do a particular task or whether to engage
7 through contracts so that you can get a broader
8 level of expertise for the amount of time and that
9 you need. So --

10 DR. DOUMA: Just to clarify, by external,
11 I meant working with all the development of
12 databases that we then can use for research, will
13 that be part of the portfolio of this person?

14 DR. SELBY: It would fall under this
15 person.

16 DR. DOUMA: Yes.

17 DR. SELBY: To the extent that we go that
18 direction.

19 DR. DOUMA: Right.

20 DR. SELBY: Harlan?

21 DR. WEISMAN: Harlan Weisman. I had a
22 similar question. So, what people call health

1 informatics, health information databases,
2 analytics, data analytics and so forth, is that
3 what we're talking about or are we talking about
4 somebody who helps us run our internal IT
5 infrastructure, which are two different types of
6 roles, I guess?

7 DR. SELBY: Well, it's more than just our
8 internal IT infrastructure, although, that's
9 important. Ultimately, we'll very likely bring out
10 website in-house and part of engagement, a
11 substantial part of engagement will be electronic
12 means of communication, means of rapidly surveying
13 very large numbers of patients across the country
14 and that will generate databases that this person
15 would be most likely be managing. Now, whether we
16 bring other databases in-house to analyze, I think
17 that's not decided yet.

18 DR. WEISMAN: What I meant Joe, was not so
19 much do we construct our own databases, but that's
20 particularly in outcomes research an important part
21 what outcomes will be and the construction or
22 advocacy of construction of interoperable databases

1 that can be utilized for PCOR as something having
2 somebody who can inform us, I guess similar to what
3 some of the other roles are. It would be
4 important, but the kind of individual who
5 specializes in that wouldn't be a classic IT
6 infrastructure person, I guess is what I'm saying.
7 So, they're almost different descriptors, job
8 descriptions. By the nature of my asking the
9 question, I think that's an important thing, for us
10 to build expertise in, so that's why I'm asking the
11 question.

12 DR. SELBY: Okay, okay. Let's see, is
13 Anne, let me just call on you, Anne. I want to
14 call on Anne Beal, who's had a little more hands-on
15 at this job description to see if she wants to add
16 anything.

17 DR. BEAL: Yes. Hi, Harlan. Yes, so, we
18 have someone who we're thinking about from an IT
19 perspective who's dealing with data, data
20 infrastructure; also, our infrastructure internally
21 with regard to Finance, Communications, as well as
22 Grants Management. What our thinking is, is that

1 this is a high-level person who's able to address
2 just the issues that you're talking about because
3 some of the other things in terms of just our IT
4 inside the building, that we can easily purchase.
5 That's sort of capacity. So, we're really thinking
6 about this as being the high-level person who can
7 help from a strategic perspective, really
8 addressing what the IT needs are for PCORI.

9 DR. SELBY: Sherine just reminded me, too,
10 that on a slightly different front, but not
11 unrelated, is work coming from the Methodology
12 Committee and also of great interest to the Program
13 Development Committee, and that is this notion of
14 building or supporting or catalyzing or finding a
15 CER infrastructure, as you said, for repeatedly
16 doing Patient-Centered Outcomes Research. So, that
17 might be a research network built at its core from
18 electronic health record data, but augmented with
19 patient reported data.

20 So, that's a topic that will be one of our
21 early advisory groups, and in July 2nd and 3rd, the
22 Methodology Committee, the PDC, anyone who's

1 interested will be invited to a workshop where we
2 kick that off, beginning to understand what role
3 PCORI can play in advancing the nation's ability to
4 do Patient-Centered Outcomes Research.

5 Steve?

6 VICE CHAIRMAN LIPSTEIN: Steve Lipstein.
7 Joe, I think we'll have an opportunity later in the
8 agenda because when the Methodology Committee does
9 the report, Chapter 4, my favorite chapter of the
10 Methodology Committee Report, really gets at this
11 whole issue of patient-centered datasets and the
12 kinds of data, Harlan, that you were talking about.
13 So, Sherine, when we get to Chapter 4 in the
14 discussion later today, let's bring this subject
15 back up for Board discussion because I think it'll
16 be an opportunity also to get these two subject
17 issues, okay? So, that way we can keep pushing on
18 with this, but this is a great topic for Board
19 discussion.

20 DR. GABRIEL: So, I can certainly comment
21 on it. Just as a reminder, that's Chapter 4 to
22 question mark, because the chapters haven't been

1 built out yet.

2 VICE CHAIRMAN LIPSTEIN: Right.

3 DR. GABRIEL: But we can certainly comment
4 on it. Actually, this is a very important and very
5 exciting area that I hope we can get as much
6 engagement as we can from PDC and others for the
7 workshop later this year.

8 DR. SELBY: Okay, I just want to give
9 everyone a brief calendar, nothing too surprising
10 here, I don't think, but among the many activities
11 that are going on now and over the next few months
12 are the public comment period for the National
13 Priorities and Research Agenda is still open. It
14 closes in about 10 days. And clinician focus
15 groups have been wrapped up and are being
16 summarized. On February 27th, we held the National
17 Patient and Stakeholder Dialogue here in D.C., and
18 that will be reported on later this afternoon from
19 the COEC Committee.

20 The public comment that we've received
21 from all sources, including from the National
22 Dialogue, including from our website, will be

1 analyzed by a committee of the PDC and reported
2 back along with suggestions for revisions to the
3 Priorities and Research Agenda to the Board at a
4 meeting. We have not identified a date for it yet,
5 but it will be likely a public webcast meeting, a
6 virtual meeting, but webcast, and the Board will
7 hear the report and hopefully adopt the Priorities
8 Research Agenda.

9 Shortly thereafter, mid-May, broad funding
10 announcements are going to be issued and they'll be
11 related to the first four priorities and you're
12 going to hear more about that from Dr. Kuntz
13 shortly in the PDC Report. Those applications will
14 be due sometime in late July and we aim to have a
15 large amount of funding awarded before the end of
16 2012 related to those first four priorities, and
17 you'll hear about priority five in the report from
18 the PDC, as well.

19 We anticipate that 2012 will be a year of
20 engagement with patients, patient groups,
21 clinicians, and other stakeholders, and they will
22 be in the form of conferences on specific topics,

1 they'll be in the form, as for example, the EHR
2 workshop in July, brainstorming sessions where we
3 begin deliberating on whether there are specific
4 areas that may deserve special emphasis from PCORI
5 that PCORI may want to focus on and advisory
6 groups. Some are named in the statute and others
7 may evolve as our discussions advance. And we
8 anticipate that at some point, hopefully late in
9 this year, PCORI will identify one or more areas
10 where we would release a funding announcement for
11 specific type of research that was deemed by
12 stakeholders to be of particular importance and
13 relevance to PCORI.

14 The Pilot Projects, you'll also hear from
15 Dr. Goertz shortly about progress in the review of
16 Pilot Projects. The reviews are back from NIH from
17 the Center for Scientific Review. They're being
18 processed. The Board will hear a report and make
19 final decisions on awardees, which will be
20 announced early in May.

21 And last, but by no means least, the
22 Methodology Report is due to the Board and I have

1 every confidence will be delivered to the Board on
2 May 10th. Public comment period will ensue 45 to
3 60 days and beginning in mid-July then, the input
4 will be analyzed and the Methodology Report revised
5 and the revised report will be submitted for
6 adoption to the Board by August. So, we will have
7 version one of the Methodology Report by mid-
8 August.

9 CHAIRMAN WASHINGTON: I have a question
10 for us, and that is: Do we know what the official
11 date is right now for submission of the Methodology
12 Report? Did we establish what the deadline is?

13 DR. SELBY: May 10th is the day. The
14 legislation says that the Methodology Committee
15 needs to submit to the Board a Methodology Report.
16 It's not very detailed. In fact, there are no
17 details about what the Board with it aside from
18 sending it out for public comment, but our
19 intention would be to get it out for public comment
20 shortly.

21 CHAIRMAN WASHINGTON: Okay, Steve has a
22 question.

1 VICE CHAIRMAN LIPSTEIN: So, Gene, there
2 were a couple of things we were thinking about as a
3 board. One was that once we receive it from the
4 Methodology Committee, we don't have to approve it
5 at that point. What we want to approve is approved
6 to send it out for public comment. Then when we
7 get it back, it will probably flow back to the
8 Methodology Committee with all that input and
9 they'll probably make recommendations for revisions
10 or changes and then we'll have a second take at it
11 as a board before it receives final approval. So,
12 it'll probably play out across the summer. Is that
13 what you're thinking, Joe?

14 DR. SELBY: Yes.

15 VICE CHAIRMAN LIPSTEIN: So, we'll approve
16 it for public comment, it'll then go through
17 iterations and changes, and then we'll probably be
18 looking at a formal approval of it probably in the
19 fall.

20 MR. BARNETT: When is our Board meeting in
21 May?

22 VICE CHAIRMAN LIPSTEIN: The 20th. That

1 weekend of the 20th.

2 MR. BARNETT: So, it's not for a couple of
3 weeks after the May 10 deadline. So, it won't be
4 until then, until late May that we will review it
5 and then approve it to send out for public comment.
6 Is that the timeline?

7 DR. SELBY: Well, we hope the review
8 process will begin on the 10th. So that by the
9 time we get to the May 20th meeting, we'll have a
10 very clear idea of what we think.

11 MR. BARNETT: Perfect.

12 DR. SELBY: Yeah.

13 VICE CHAIRMAN LIPSTEIN: And given the
14 iterative nature of what the Methodology Committee
15 has laid out, we're going to get an opportunity to
16 really participate with them in a very organized
17 and I hope very participative way between now and
18 then via workshops, phone calls, and I think they
19 have laid out an outline for the report. Like when
20 I said Chapter 4 through question mark, and that
21 was my favorite part, that's the part that deals
22 with robust datasets for clinical research, and so,

1 we'll all have an opportunity as Board members to
2 participate in that area of support development
3 that we think is really kind of important to us.

4 DR. NORQUIST: Greg Norquist. I just had
5 a comment, Joe. One of the things we talked about
6 is learning from what we've done in evaluation.
7 So, we spent a lot of time getting public comment
8 on our priorities and stuff. I hope we don't just
9 put this Methodology Report out to public comment
10 without learning maybe there's a different way we
11 want to do it to get our input. So, I hope we're
12 learning from what we're doing right now, but when
13 we put this out, we don't just issue it, that we
14 rethink how we get public comment.

15 DR. SELBY: Good, thanks. And thanks,
16 Steve, for mentioning that. The importance of the
17 work that the Board and Methodology Committee do
18 between now and May 10th, that's a point the
19 Methodology Committee has made repeatedly for us to
20 be engaged with them so May 10th doesn't deliver a
21 bunch of surprises.

22 So, funding announcements, and as I

1 alluded to before. We see the first four
2 priorities so this is assessing options for
3 prevention screening and treatment, improving
4 health care systems, communication and
5 dissemination research, and research on fairness
6 and addressing disparities. Those will be
7 released, that's the yellow box, in mid-May and
8 applications are due in July. We also though,
9 anticipate, that for the fifth announcement, we
10 will see -- the fifth announcement is an
11 infrastructure priority and it has two broad
12 components that we're thinking of now.

13 One is this building an infrastructure for
14 comparative effectiveness for Patient-Centered
15 Outcomes Research and the second is analytic
16 methods. So, there will be a funding announcement
17 that will take a little bit more time because most
18 importantly, we want to get the input of the
19 Methodology Report. One of the purposes of that
20 report is to identify gaps that need to be
21 addressed.

22 The issue of research infrastructure is

1 particularly complex. There are a lot of efforts
2 already in the field and we need to make some sense
3 about what those efforts are and how PCORI funding
4 could augment support, catalyze the next step in
5 those efforts.

6 So, that's why the delay and you'll hear
7 more about our plans for developing plan number
8 five later on this morning. And then the other
9 targeted announcements that I mentioned, I
10 anticipate those no sooner than the last quarter of
11 2012.

12 DR. DOUMA: Joe?

13 DR. SELBY: Yes.

14 DR. DOUMA: With regard to the first four
15 priorities, if you go back to the previous slide,
16 the yellow box is when those four come out?

17 DR. SELBY: Yes.

18 DR. DOUMA: Will they also be coming out
19 every six months after that and --

20 DR. SELBY: Well, the way that the PDC has
21 seen it thus far, those will be the equivalent of
22 standing announcements with submission dates every

1 four months. So, you could apply under this
2 standing announcement. These announcements will be
3 quite inviting in terms of the kinds of studies
4 that we'd consider. You could apply in November.
5 If you don't apply in November, I mean, you could
6 apply in July, you could apply in November, you
7 could apply the next March.

8 DR. DOUMA: But I presume based on the
9 learning proposition that we were talking about a
10 moment ago, it seems like the announcements would
11 modify from time to time as we learn from what were
12 coming back. By saying they're standing, they're
13 not static.

14 DR. SELBY: That's right. I think it's
15 very predictable, particularly in the early going
16 and likely in an ongoing way, we will modify them.

17 DR. DOUMA: I just suggest that it would
18 be nice to have to have a time on it sort of like
19 this to when if there are any modifications to the
20 standing ones that people know that's when they're
21 going to come out so they'll look for them.

22 DR. SELBY: That's a good point.

1 CHAIRMAN WASHINGTON: Francis? Yes,
2 Francis?

3 DR. COLLINS: Joe, can you clarify in
4 terms of the clinical research data network's plan
5 for a targeted announcement in mid-July, how does
6 the timing of that fit together with brainstorming
7 workshops on that very topic?

8 DR. SELBY: It has gotten a little tight,
9 Francis. At first, it looked like the workshop was
10 going to take place in June, but I think schedules
11 conspired to push it to early July, and so, that
12 makes it very tight. And as you'll hear, there's a
13 lot of discussion and work that we can do
14 preparatory to that workshop particularly in
15 collaboration with colleagues at NIH and AHRQ and
16 others to get our arms and our minds around this
17 vast field. I mean, I know you know this. I'd
18 just emphasis though that there's a lot going on in
19 this area, it's an area where we all have great
20 hopes that electronic health record data and other
21 data can be harnessed and linked and we can deal
22 with the privacy issues involved, we can find ways

1 to add patient-reported outcomes to these research
2 networks or databases and really, as has been said
3 here, have a reusable resource for efficiently
4 conducting important studies. But they're costly,
5 not all of them work out, and there are a lot of
6 players in the field. PCORI couldn't really by
7 itself fund a national infrastructure if it had its
8 heart set on it, so, I think there's a lot of
9 strategizing and just a lot of getting this full
10 appreciation of what's going on that can happen
11 even before the workshop.

12 DR. CLANCY: Joe?

13 DR. SELBY: Yes, Carolyn?

14 DR. CLANCY: Just building on Francis'
15 point, I'm very, very excited about this workshop,
16 which I believe is now going to be held July 2nd
17 and 3rd. I would hope that we're not just
18 rehashing what we already know and what we need to
19 know. And so, having been in a place for the past
20 several years where we were like slamming the
21 research community, I'm wondering if say August 1
22 to allow some time, if you might consider to that,

1 to allow some time for digesting.

2 Now, it could be that we end two days of
3 workshops smarter, but not having any breakthroughs
4 about what we might ask for, but it could also be
5 that there's a fabulous idea that, frankly, we'd
6 want to vet with other Board members, the
7 Methodology Committee, and so forth. So, I don't
8 want to preclude that possibility and also put the
9 communications folks in the position of saying
10 needing to blast out an announcement somewhere
11 saying we were trying for July, but it didn't --
12 predictability is really important to researchers,
13 who also take summer vacations.

14 VICE CHAIRMAN LIPSTEIN: Joe, if I could
15 weigh in here --

16 DR. SELBY: Thanks, Carolyn.

17 VICE CHAIRMAN LIPSTEIN: Because what I
18 think Francis and Carolyn are both pointing out is
19 a really important issue, especially for priority
20 number five, which, Francis, you taught me a new
21 phrase last week, foundational framework.

22 And this infrastructure development could

1 become the foundational framework for a lot of what
2 we want to accomplish over the next seven years,
3 but, Carolyn, I think it's really important that
4 what the research community may already know, and I
5 appreciate the concern about rehashing old work,
6 the provider community is just learning, and if we
7 really want to have credibility for our work and
8 dissemination of what we find as a result of that
9 work, creating these foundational frameworks in
10 cooperation with the provider community is very,
11 very important and what I mean by that is that the
12 research community for a long time has been using
13 datasets to do comparative effectiveness or
14 outcomes research that the provider community has
15 found suspect. And so, if we can build these
16 frameworks together so that we agree from the
17 outset that they have credibility, that they really
18 are patient-centered datasets, then I think the
19 research we do using that research will have far
20 greater credibility.

21 And so, while I have learned as a result
22 of serving on this Board that there's a lot of work

1 that's already taken place in this regard, it is
2 not widely known and it needs to be communicated
3 and we need a real participative approach here
4 because, as Joe just mentioned a minute ago, by
5 using electronic medical record capability, by
6 using real-life patient datasets, we know a whole
7 lot more about patients than we have historically
8 known from the use of administrative datasets and I
9 kind of view this work in July and August, Carolyn,
10 as our opportunity to get everybody on board and
11 everybody excited about this so that in the
12 provider community, whether I'm speaking now as a
13 stakeholder representing health systems or
14 hospitals or large groups of physicians, we can all
15 catch up and participate this in a meaningful way.

16 DR. SELBY: Steve, thanks. I appreciate
17 your saying that, and I'd just like to go on record
18 as saying that if the providers, the ultimate
19 owners, if you will, of the data don't get involved
20 and motivate collaboration, it probably won't
21 happen just with the researchers. So, I'm glad you
22 said that.

1 My time is just about up, but I don't want
2 to shortchange the notion of patient and
3 stakeholder engagement. So, you've met our
4 engagement team and this is our plan. Step one is
5 to begin building communities of patients and
6 stakeholders, and these are very large numbers of
7 both, of patients and also stakeholders,
8 clinicians, and others through a variety of means,
9 including our website, social media, face-to-face
10 meetings, so that we can have ongoing dialogues,
11 bidirectional dialogues so that we can ask
12 questions of the community so that the community
13 has ways of getting to PCORI with their questions.
14 We want to strengthen ties with advocacy
15 associations, professional clinical organizations,
16 purchaser organizations, and the research
17 community, and that is some of the early work of
18 our engagement team.

19 Refining the PCORI Research Agenda means
20 getting stakeholders to the table to talk with
21 PCORI about what is important to study. We've
22 defined patient engagement from the point of view

1 of setting the agenda, prioritizing questions as a
2 hallmark of PCORI, and 2012 is the year when we
3 being doing that, Multi-Stakeholder Workshops
4 focused on the National Priorities, Multi-
5 Stakeholder Advisory Panels, and again, the use of
6 social media and surveys are some of the ways that
7 we will obtain that input in 2012.

8 DR. WEISMAN: Hey, Joe?

9 DR. SELBY: Yes?

10 DR. WEISMAN: We've gotten through
11 feedback at various sessions that we've conducted
12 already with stakeholders that there's a lot of
13 interest in our utilization of advisory committees
14 as it relates to the Research Agenda and our
15 priorities, but other issues in the legislation
16 certainly encourage us as sort of mandates to use.
17 Can you talk about when you anticipate the first
18 set of advisory committees and what the process
19 will be in terms of deciding what those advisory
20 committees are?

21 DR. SELBY: I certainly can't give you
22 dates yet. I will say one thing: I think it's our

1 strong feeling that out of this July 2nd and 3rd
2 workshop will come the origins of an advisory
3 committee on research networks, and that has a lot
4 of aspects that we'll need advice on, both on just
5 strategies for building a comprehensive network,
6 but also strategies of engaging patients,
7 strategies for engaging systems for dealing with
8 issues such as privacy, for protecting privacy, but
9 enabling research, and for questions like how do we
10 use these networks then to heighten patient
11 engagement in the research process?

12 And here, I'm talking not simply about
13 conducting the research, but if there's a trial to
14 be done of an important question, patients have
15 said it's an important question: How do we
16 leverage this network to enhance participation?
17 All those kinds of activities would be, I think,
18 topics for an ongoing advisory committee on that
19 topic.

20 Another area where we're mandated to have
21 an advisory committee is in clinical trials, and I
22 think we've modified that to say clinical trials

1 and observational studies because oftentimes, the
2 question is: What is the proper role of one versus
3 the other? So, that's the second advisory
4 committee.

5 A third advisory committee that's
6 mentioned in the legislation that we have our eye
7 on is an advisory committee on rare diseases. Rare
8 diseases are called out, rare diseases are great
9 concern to patients, rare diseases are hard to
10 study and are understudied and we and others are
11 very interested in advancing research in that area
12 and figuring out what a patient-centered outcomes
13 Research Agenda can contribute in that area. So,
14 those are three of the early ones, Harlan.

15 DR. WEISMAN: And you anticipate those
16 would be 2012 events?

17 DR. SELBY: I certainly hope so.

18 DR. GABRIEL: Another one worth mentioning
19 that came up in last night's discussion actually is
20 on dissemination and implementation and we've got
21 an effort that Methodology Committee and COEC,
22 collaborative effort to move that forward, and I'm

1 pretty confident that we'll be proposing an
2 advisory committee on that topic, as well.

3 DR. SELBY: And I think we're going to
4 return to some of these topics, Gene. So, with
5 your permission, I'll close and --

6 CHAIRMAN WASHINGTON: Okay, let's just
7 hear from Allen. He has been --

8 DR. SELBY: Oh, sorry.

9 DR. DOUMA: No, I just wanted to
10 reinforce, I think this slide is particularly good.
11 I love it. I love what you're doing. The last one
12 in particular because of my background, the use of
13 social media and using online surveys, I just want
14 to reinforce that because of our optics, because of
15 who we are, we need to make sure that whenever
16 we're working and doing that sort of thing that our
17 surveys are vetted as, created as a research
18 instrument and has as much validity in the research
19 mode as it does in your classic survey modes, which
20 sometimes are a little bit sloppy.

21 DR. SELBY: Thanks.

22 CHAIRMAN WASHINGTON: Thank you, Joe.

1 Next on the agenda we have a report from the
2 Program Development Committee, the committee that's
3 chaired by Dr. Richard Kuntz. For those of you who
4 new out our ongoing proceedings, again, just to
5 give you a little context, this is the committee
6 that in particular is focused on conducting
7 Patient-Centered Outcomes Research, so, despite its
8 name, the principal focus of this group is how do
9 we, in fact, advance our Research Agenda?

10 Dr. Kuntz?

11 DR. KUNTZ: Thanks, Dr. Washington. Good
12 morning, everyone. On behalf of the Program
13 Development Committee, I'd like to spend the next
14 hour-and-a-half reviewing updates in our PDC
15 Report. The agenda will be fourfold. We will
16 review the PCORI project grants initially with Dr.
17 Goertz and Ms. Hunt. We will then review the
18 analysis of public comment, specifically about
19 where we stand with the National Priorities in
20 Research Agenda. We'll then go over a little bit
21 about the processing for the PFAs, the PCORI
22 Funding Announcements. That, again, will be done

1 by Christine and Gail. And then at the end, we'll
2 review the Dissemination Workshop and Workgroup
3 with Dr. Clancy.

4 To begin with, I just want to point out
5 that last Thursday, Dr. Washington appointed a
6 group to be on the Selection Committee for the
7 PCORI Pilot Projects and this is the list of those
8 who will participate in that process. And so, we
9 really are moving along with the Pilot Project
10 Grants. We received the applications, they have
11 been processed and reviewed, and now the selection
12 part begins and this will be the committee that
13 will start to do that process and then prepare a
14 report and a selection group back to the Board.

15 And, with that, I'll turn it over to Dr.
16 Goertz to talk a little bit more about the PPPs.

17 DR. GOERTZ: Great, thank you. Just a
18 reminder of our deliberation process from this
19 point forward, what we have been working on over
20 the last couple of months is basically to come up
21 with some specific criteria to be considered by the
22 PCORI Selection Committee when we're determining

1 what might be an appropriately balanced slate of
2 awards, and now that we've come up with that
3 information, PCORI staff is working to look at the
4 applications, looking at the scores, and our other
5 criteria and looking at different ways where we
6 might want to consider the applications based on
7 some of the criteria that are important to us, and
8 I'll be showing that criteria in the next slide.

9 The next phase will be for the PCORI
10 Selection Committee, which membership was just
11 announced. We will need to review the materials
12 and, again, consider the balance of, first of all,
13 always looking at the priority scores, but looking
14 at whether there might be some other criteria that
15 are important for us to consider, as well, and then
16 this committee will be preparing a recommended
17 slate of selected projects for funding
18 consideration to the entire Board. When, at that
19 point, the Board will meet to consider the slate
20 and based on the priorities that have been
21 developed and then request additional information
22 or options as required and then, ultimately,

1 approve a final slate of selected projects for
2 funding.

3 The next slide.

4 VICE CHAIRMAN LIPSTEIN: Christine, you
5 did something with me that I think that the whole
6 Board could benefit from, and I don't know, Gene,
7 how to do this, but Christine gave me a brief
8 tutorial on scoring and percentiles because I
9 didn't understand how you could get the same score
10 in a different percentile. And for those of us who
11 are less familiar with NIH study sections and that
12 kind of stuff, could we have a tutorial for those
13 of us on the Board -- I don't know if Larry, you
14 know the stuff, but for those of us on the Board
15 who have never done this, could we like maybe have
16 a phone tutorial on scoring and percentiles and
17 stuff like that?

18 DR. GOERTZ: Yes. I think that's a great
19 idea. I'd be happy to help with that.

20 CHAIRMAN WASHINGTON: Yes, we'll keep you
21 all after school one day.

22 [Laughter.]

1 CHAIRMAN WASHINGTON: We'll cover it.

2 DR. GOERTZ: You can write it on the Board
3 100 times.

4 CHAIRMAN WASHINGTON: I think that's an
5 excellent idea, Steve.

6 DR. GOERTZ: So, obviously, with our
7 balanced criteria, the priorities score is the
8 number one criteria that we'll be looking at. I
9 believe we've received all of the priorities scores
10 or most of the priority scores from NIH at this
11 point and are beginning to compile that information
12 as we speak.

13 The other criteria that we thought might
14 be important, that the working groups thought were
15 important were area of interest, population,
16 methods, geography, discipline of the PI, seniority
17 of the PI, condition, and then stakeholder and
18 patient involvement. Some of those criteria are a
19 little bit easier to operationalize than others,
20 not surprisingly, but we are working to find a way
21 to operationalize each of those criteria in a
22 meaningful way and these are the things that the

1 Selection Committee will be considering as we move
2 forward.

3 CHAIRMAN WASHINGTON: Can we take a
4 question now, please?

5 DR. GOERTZ: Absolutely.

6 DR. SIGAL: Ellen Sigal. So, many of us
7 do understand the NIH criteria and the scoring. I
8 thought that we though had the ability to really
9 put our own metrics into that. So, I'm just a
10 little bit confused about why we are almost redoing
11 it, but some of these considerations one would have
12 thought would have been part of the scoring.

13 DR. GOERTZ: We're absolutely not planning
14 to redo the scoring and our metrics did go into the
15 review criteria that NIH used when evaluating the
16 applications, the training that the reviewers
17 received were based on our review criteria, which
18 some of those criteria were similar to the things
19 that NIH uses and some of them were quite
20 different. For instance, we added a whole entire
21 criteria on patient engagement, stakeholder
22 engagement, which is not part of the normal

1 criteria. So, many of those things are, in fact,
2 included. So, all of those levels, when it comes
3 to environment and expertise of the PI and the
4 novelty and the soundness of the approach, the
5 significance, all of those things are built into
6 the review process.

7 However, for instance, it's possible that
8 since we have eight areas of interest, what if all
9 of the top 40 applications end up being within one
10 area of interest. In that case, we may want to
11 look at including some other applications and to
12 pull from other areas of interest just to give
13 balance.

14 DR. GOERTZ: Yes, Francis?

15 CHAIRMAN WASHINGTON: It was suggested
16 that I have you turn your card up so that I don't
17 forget who's coming next, and so, if you would.
18 And I have Dr. Douma and then Weisman, Collins, and
19 Selby.

20 DR. DOUMA: It seems like it's really
21 important that we do research across the care
22 continuum from primary care through end-of-life

1 care, and I'm not sure, I don't know, and this is a
2 question part: Is that being taken into
3 consideration in our scoring? And, if not, I don't
4 know what "area of interest means". Would that be
5 included under that bullet?

6 DR. GOERTZ: It may partially in that
7 some of the areas of interest focused on some
8 diverse populations, but not necessarily.

9 DR. DOUMA: Then what does "area of
10 interest" mean?

11 DR. GOERTZ: There are eight different
12 areas of interest that were written into our
13 program announcement.

14 DR. DOUMA: Okay. Okay, yes, I had
15 forgotten that was the nomenclature. I just
16 suggest if we can across the care continuum, I
17 think we'll benefit from that.

18 DR. GOERTZ: Thank you.

19 DR. WEISMAN: You caught me with a muffin
20 in my mouth. Good to have that webcast.

21 [Laughter.]

22 DR. WEISMAN: No, I'm skilled at this.

1 [Laughter.]

2 DR. WEISMAN: I think, Christine, I
3 understand these things, but there's been a lot of
4 input to us on the importance of transparency and
5 openness in all aspects of what we do, including
6 the criteria that we developed to choose what we
7 fund, and I'm wondering whether beyond these
8 checkboxes whether it would be worthwhile to
9 elaborate what each of them are and what the
10 Balance Committee will be doing versus what the
11 scoring groups did, so that people really
12 understand the process that we will be following.

13 DR. GOERTZ: We are absolutely committed
14 to that level of transparency. Every single one of
15 these criteria either does or will have a very
16 clear and concrete operational definition and that
17 will absolutely be made public, as will the method
18 behind the madness, the way that we're approaching
19 all of it will be completely transparent.

20 DR. WEISMAN: Before or after the fact?

21 DR. GOERTZ: Before, during, and after.

22 DR. WEISMAN: Good.

1 CHAIRMAN WASHINGTON: Dr. Collins then Dr.
2 Selby.

3 DR. COLLINS: A little preamble here
4 because Steve raised a question about how do we do
5 percentiles and priority scores. A very quick
6 version of this, but we can have that full tutorial
7 later if you really want. So, basically, the way
8 that NIH does this is that applications that go to
9 a chartered study section that meets repeatedly
10 that sort of has a membership that has established
11 a certain way of deciding what they like and what
12 they don't, then you get a priority score and then
13 that's percentiled against the way that study
14 section has behaved in its last three meetings in
15 order to expand the denominator.

16 For the PCORI reviews, however, this was
17 not the case because these are special panels. So,
18 every panel was just percentiled against itself.
19 So, that means if an application was ranked number
20 three in terms of priority scores out of 100, it
21 would have been ranked at the third percentile.
22 So, very direct assessment that should be pretty

1 transparent when you see the PCORI reviews that CSR
2 puts forward.

3 Now, just in terms of this business of
4 balance, I just, again, want to advocate that this
5 be done with great care, that, after all, the study
6 sections consisting of people with substantial
7 scientific expertise with review criteria that have
8 been very carefully established, many of which
9 already have included some of the bullets you see
10 here, such as stakeholder and patient involvement
11 and you wouldn't want to have this sort of doubly
12 jeopardized, and also, I think, done in a fashion
13 that the community will look at as probably the
14 most credible evidence of what should be funded and
15 what should not.

16 Certainly, when one jumps in and begins to
17 rearrange the decisions about what's getting
18 funded, it will have to be done transparently and
19 with very clear justification. I would just flag
20 one of these elements, and I've said this before in
21 a phone call, but I'll say it again, as being
22 particularly troubling, and that's the one of

1 geography. If an investigator has a special
2 population that is geographically important, that
3 ought to be covered in other ways, but we at PCORI
4 ought to represent the fact that we're a
5 meritocracy and the geography, while it may in fact
6 be important politically in certain circumstances,
7 I think it should not be something that we pay a
8 lot of attention to in terms of figuring out how to
9 fund the best research.

10 CHAIRMAN WASHINGTON: Okay. I'm going to
11 ask you to place your cards down once you finish.

12 [Laughter.]

13 CHAIRMAN WASHINGTON: Okay, so, Dr. Selby
14 and then Dr. Normand and then Sharon.

15 DR. SELBY: Right. Just kind of a
16 fundamental point, I think, about the notion of
17 seeking balance. When a study section is
18 reviewing, when a reviewer is reviewing a
19 particular proposal, they have no clue what else is
20 being reviewed by others and other study sections,
21 they have no clue how the final distribution is
22 going to play out. And so, there is no way in

1 which they can be expected to create balance on
2 their own.

3 As this slide shows, by far, the most
4 important characteristic we look at is the priority
5 score that comes from the study section, but as
6 Christine mentioned, it's conceivable that you
7 could have a real disturbing imbalance, and, for
8 example, not include anything that had to do with
9 aging or with a vulnerable population just as one
10 example simply because reviewers didn't know what
11 others were seeing and our role here is to take a
12 look at the balance that results from looking first
13 at those with the very highest scores. So, we're
14 not in any way, and we'll take care over and over
15 again not to repeat or undo anything the study
16 sections did, simply to look at things that they
17 couldn't possibly have seen from their vantage
18 point.

19 DR. KUNTZ: Sharon-Lise?

20 DR. NORMAND: Sharon-Lise Normand,
21 Methodology Committee member.

22 So, I just wanted to sort of do a little

1 math for you guys. If there were two cells for
2 each level, you've got more than 128 cells to
3 populate 40 applications. So, first of all, I
4 think this is a lot of aspects over which to
5 balance and that's just the practical standpoint.
6 So, I wanted to make that point and I think Dr.
7 Goertz said there were eight levels; areas of
8 interest had eight levels. So, I give you the
9 minimum number. So, start cutting back is my first
10 recommendation.

11 But I think more important than that, I
12 just thought it would be important just to give you
13 the thick of the scope of the problem you're trying
14 to deal with, we call big piece, small end problem.
15 But from a more practical standpoint, I think I
16 have trouble with this balancing issue from the
17 perspective of somebody who has served on study
18 sections. Like almost everybody in this room, you
19 look at these things, and, again, it's in your head
20 when you're clicking off the box. So, the
21 discipline, the seniority, the conditions, all of
22 that is integrated in the reviewer's head when

1 they're scoring and it is true, as Dr. Selby says,
2 that other study sections aren't seeing what other
3 people are doing, so, they can't balance, but why
4 should we balance is the question I have. And
5 someone cares about this, but the fact if the top
6 40 or 50 studies didn't have anything to do on the
7 aging, they will next time. So, I guess I'm sort
8 of looking at this thinking why do we need to go
9 through this phase?

10 CHAIRMAN WASHINGTON: Okay, -- [off
11 microphone].

12 DR. SIGAL: Ellen Sigal. So, I, too, have
13 very huge concerns about this and I would have
14 hoped that our metrics for establishing these
15 grants or these procedures would have incorporated
16 a lot of these issues prior to this, but I served
17 on NCAB, the National Cancer Advisory Board, for
18 years and it's the only advisory board, I think, by
19 statute that basically has to review all the grants
20 and has the authority to say yes or no. And when
21 there was disagreement with the grants, we did this
22 in public session and it was very open. So, even

1 though we have our criteria which may be open and
2 we will explain if the discussions will be closed,
3 and I'm concerned about this. It doesn't feel
4 right to me and I would hope that next time when we
5 do this, that our grants will be or our review
6 process will incorporate all of these metrics for
7 distribution all these priorities that we think are
8 important, but this should be by merit. So, I am
9 very worried about transparency.

10 DR. ZWOLAK: I'd like to express some
11 similar concerns and ask you the question about
12 whether you have decided either qualitatively or
13 quantitatively how much maximum impact this would
14 have as compared to the priority scores.

15 DR. GOERTZ: The priority scores are
16 absolutely the most important criteria. Just to
17 give you a sense, for instance, with the
18 stakeholder and patient involvement criteria, that
19 was one of the our review criteria, and so, the way
20 that they were operationalizing that is to look at
21 the score, the NIH score for that particular
22 criteria because we didn't want, for instance, in

1 the top 40 was to have everybody have a very poor
2 stakeholder criteria and the reason we wanted to
3 look at that is because this was a new criteria, we
4 didn't know how that would work.

5 So, with many of these, I don't think it's
6 necessarily that we'll be taking things out of
7 order, but just looking at how our portfolio
8 balances or how it shakes out when we're looking at
9 some of these things that we think are important to
10 us and then if there's an application that seems to
11 meet a lot of criteria that may fall slightly below
12 the funding line, we have the option of perhaps
13 thinking about moving that up and considering
14 funding that, also, but I do want to assure you
15 that PDC has been talking about this a great deal
16 and members of the Selection Committee, as well,
17 and it will be a very transparent process.

18 It is not intended in any way to
19 invalidate or to trivialize the priority score,
20 which was absolutely our top criteria when we're
21 looking at these applications, but more to say here
22 are some things that we have said are important to

1 us and we're interested in looking at, how the
2 natural process worked when it comes to some of
3 these things and as we move forward.

4 CHAIRMAN WASHINGTON: Dr. Levine?

5 DR. LEVINE: So, I'm going to ask a first
6 grade level question, which is: When you use the
7 term study section, is that the same as the
8 Selection Committee?

9 DR. GOERTZ: No, no, that's the review.
10 The study section is the review as a Selection
11 Committee is that the group of people that was on
12 the slide that Rick discussed, which are members of
13 the PCORI --

14 DR. LEVINE: Balancing.

15 DR. GOERTZ: -- Board and the Balancing
16 Committee and Methodology Committee.

17 DR. LEVINE: So, the study sections are
18 NIH staff?

19 DR. GOERTZ: The study section were
20 reviewers that --

21 DR. LEVINE: Oh, okay.

22 DR. GOERTZ: -- that were selected by

1 PCORI and NIH.

2 DR. LEVINE: Okay. Thank you.

3 DR. COLLINS: But they are not NIH staff.

4 DR. GOERTZ: Right.

5 DR. COLLINS: NIH staff runs the study
6 section, but the reviewers --

7 DR. LEVINE: So, staffs it.

8 DR. COLLINS: -- are, in fact, experts.
9 Scientists from the community and stakeholders.

10 DR. LEVINE: So, the term really means a
11 peer review committee?

12 DR. COLLINS: Yes.

13 DR. LEVINE: Study section.

14 DR. GOERTZ: Yes.

15 CHAIRMAN WASHINGTON: Okay, I'm going to
16 hear from everybody before we go back. So, I want
17 to hear from Kuntz first and then Dr. Weisman.

18 DR. KUNTZ: I just wanted to accelerate
19 the discussion and maybe we can take this offline a
20 little bit, but we did discuss before a method to
21 reduce the impact of this balancing part and that
22 was that we were always looking for exceptions to

1 the rules to why we would be out of order, why we
2 would award a grant out of order, and one of the
3 options was to potentially identify a priori all
4 these areas, what would identify unusual clusters
5 of grants in certain areas, and that would be a
6 binary rule that would make someone look at this.
7 So, if we saw, for example, 70 percent of grants
8 coming from California, we'd say there's a problem
9 there and then that might compel us to go down to
10 the next order, but rather than to develop an
11 equation that solves for balance, which would then
12 be something competitive with our part.

13 So, I think that we can potentially
14 describe the secondary screen which looks for
15 egregious or unusual clusters in these areas just
16 to make sure that we don't have massive or major
17 imbalance rather than to say that we're trying to
18 solve for balance as a secondary part of the
19 equation from the score.

20 CHAIRMAN WASHINGTON: Before we go to Dr.
21 Becker, I just want to say, Rick, while I strongly
22 support this part of the process, 70 percent from

1 California is okay.

2 [Laughter.]

3 MR. BECKER: That's the expected.

4 CHAIRMAN WASHINGTON: Dr. Becker?

5 MR. BECKER: So, Larry Becker, member of
6 the Board. So, in a related question, could you
7 describe under the Board of governors' needs to
8 consider, what is it that we're deciding when we
9 make our recommendation and presumably vote?
10 What's the role there?

11 DR. GOERTZ: As far as what you'll be
12 voting on, I don't --

13 MR. BECKER: Why isn't it simply yes, go
14 ahead? What's the decision point?

15 DR. GOERTZ: Well, it very well may be
16 yes, go ahead. In the end, somebody has to make a
17 decision, the ultimate decision about what's going
18 to be funded or not, the official decision, and we
19 made the decision at other Board meetings that it
20 would be the Board that made that official decision
21 about what we're going to be funding. So, what
22 you'll get is a recommendation from the Selection

1 Committee on what to fund that the Board can either
2 vote yes or no to.

3 CHAIRMAN WASHINGTON: And so, Larry, when
4 this was discussed, we discussed whether or not in
5 appointing the Selection Committee whether or not
6 they had authority just to prove it and proceed.
7 And we decided as a board that, yes, we wanted them
8 to present a recommendation for a slate. Not that
9 we'd go through, but essentially at that stage, the
10 expectation is that it's done, but there may be
11 some unexpected reason why the Board decides in a
12 particular area that this doesn't work for them.
13 So, it's a decision we've already made regarding
14 process. Okay.

15 Dr. Weisman?

16 DR. WEISMAN: Harlan Weisman, member of
17 the Board. I have a couple of points I wanted to
18 make, but one of them just real briefly is I agree
19 with what Sharon-Lise says. This is over-
20 parameterized. This is too many things to really
21 do other than qualitatively, which I think is
22 probably what you were saying, Rick.

1 The other thing, I recall, Carolyn, you
2 saying that in reviewing priority scores, the
3 precision, although we aren't measuring caps or
4 anything that a score plus or minus 5 or 10,
5 they're actually not going to be that different
6 from each other in terms of the view of the peer
7 review process. So, there's some looseness there,
8 and we have an arbitrary cut point of 40, is that
9 correct?

10 And one of the things that I was
11 wondering, Christine, or maybe just saying it
12 overtly is this doesn't have to be a subtraction
13 process, this can be an addition process for
14 rebalancing and that what would be bought in are
15 not things from the bottom of the priority scores,
16 but things right on the edge of the 40 that would
17 have been within the range of precision of the
18 scores anyway and that would allow this more
19 qualitative type of ranking that would respect what
20 was done when the priority scores were done and
21 maybe adding several just below the line, which is
22 an arbitrary line anyway and would allow to us to

1 achieve both sets of goals. One is to recognize
2 the process that was followed in giving the
3 priority scores, but also recognize that perhaps
4 there could be from the reasons that, Joe, you
5 said, that unawareness on the part of people in
6 terms of balance across the groups, something
7 egregious may have occurred, as Rick said, that
8 could be rebalanced and while maintaining the
9 integrity of the process.

10 DR. GOERTZ: Go ahead.

11 DR. WEISMAN: Yes, since I quoted you,
12 maybe I misquoted you.

13 DR. CLANCY: No, no, what I said it is a
14 human endeavor and sometimes it is possible to
15 overinflate the statistical distinction between say
16 a 3.2 score and a 3.3, or a 3.4 that was the
17 comment I made, not that I didn't think peer review
18 was important. The other thing --

19 DR. WEISMAN: No, I didn't suggest that.
20 I actually meant what you just said.

21 DR. CLANCY: Okay.

22 DR. WEISMAN: Just for clarity.

1 DR. CLANCY: All right.

2 DR. WEISMAN: But would you agree that if
3 you're right on the edge and just off, you could
4 have easily been just over the edge?

5 DR. CLANCY: Yes. Yes.

6 DR. WEISMAN: Okay, that's what I meant.

7 DR. CLANCY: Sort of like pools, right, in
8 standards of error and stuff like that. Sorry,
9 that's where my mind is these days.

10 The other point I would just make in the
11 spirit of a learning organization, a big, big part
12 of this discussion and decision process will, I
13 think, focus the Board in terms of how we choose to
14 specify or not for future announcements how to make
15 allocations. We may say, for example, for this
16 particular announcement, we want 20 percent set
17 aside for new investigators or here are criteria
18 and we're really going to wait stakeholder
19 engagement. I don't recall that there was quite
20 that much specificity in the earlier announcement,
21 but I think going through this exercise will
22 actually help particularly people who don't live in

1 this world.

2 DR. WEISMAN: I had one more --

3 CHAIRMAN WASHINGTON: Harlan, we're going
4 to need to rotate around.

5 DR. WEISMAN: Okay.

6 DR. GOERTZ: Do you want me to your answer
7 your question?

8 DR. WEISMAN: Yes, just one last point,
9 and you probably already answered it, when it's
10 presented to us, no matter how it occurs, after the
11 Board presentation, will we have full visibility at
12 that point of the process including what the
13 original 40 was and what the recommended is?

14 DR. GOERTZ: Absolutely, and just to
15 quickly answer your second question about can we
16 reach down and fund more than 40? I think at the
17 last at least two Board meetings, we have discussed
18 the possibility that the Selection or Balancing
19 Committee may come back to the Board with a
20 recommendation that would have more or less than
21 40, but we were thinking it might be more than 40
22 based on the fact that we had so many applications

1 submitted. And so, that's always been something
2 that we hope -- I don't think we've ever had a
3 vote, but nobody ever said no when that concept was
4 presented, and so, I think we're moving forward
5 with the belief that that would be acceptable to
6 the Board if we ended up with more than 40
7 applications or less than 40 applications for that
8 matter based on priority scores and other
9 considerations, but mostly priority scores.

10 CHAIRMAN WASHINGTON: Okay, Dr. Barksdale,
11 then, Dr. Norquist.

12 DR. BARKSDALE: Debra Barksdale, member of
13 the Board.

14 Christine, I have a question related to
15 how you envision these criteria being used in terms
16 of are they to be ranked or weighted or will the
17 most senior PI always win out, those kinds of --

18 DR. GOERTZ: No, I think it was actually
19 more in the other direction that we were interested
20 in, in new investigators and considering who might
21 be new investigators or -- again, we really -- when
22 we put out this program announcement, we were very

1 interested in attracting non-traditional
2 investigators, and so, if we were looking at that,
3 it would be looking at more, and the way that we're
4 operationally defining seniority of the PIs whether
5 somebody has been the principal investigator of a
6 federal grant or not. And, again, I don't see this
7 so much as divvying it up, but, perhaps if we're
8 trying to make a decision between two applications
9 where all the other criteria are the same; we might
10 consider someone who is more of a junior
11 investigator.

12 CHAIRMAN WASHINGTON: Okay, Norquist. I'm
13 just going to start calling last names. Then
14 Krumholtz.

15 DR. NORQUIST: Yes, I'm Greg Norquist,
16 member of the Board. So, I'm chair of this
17 committee and now I'm having second thoughts about
18 it.

19 [Laughter.]

20 DR. NORQUIST: But let me just say you're
21 kidding yourself if you don't think this goes on
22 all the time at NIH. I spent 15 years at NIH and

1 what happens is you get the scores in from the
2 review groups, the divisions sit there and they go
3 over all this and they have project officers how
4 help them try to figure out what the balance is and
5 what to do and then they go to the council, which
6 is like this Board, and they say here are the
7 scores, here's what we've done, we've looked at
8 this, this one is way out of line, but it's so
9 interesting, we really want to pick this up. And
10 then, you have council members kind of divvy around
11 and say oh, no, you shouldn't fund this, we want
12 you to fund that, this kind of thing, and that's
13 all done closed because you cannot expose these
14 individual grantees and the issues about their
15 grants and other stuff to the public, and everybody
16 understands that.

17 Then it comes back, the director makes the
18 final decision after Dr. Collins or the Congress
19 gives them money enough to do it and then they make
20 certain decisions about what to fund and then
21 later, they'll say there was a lot of good stuff
22 that we missed, let's come out with a targeted

1 announcement in this area and pick this up.

2 So, what I think this group is going to do
3 is basically we're going to look at this. We're
4 not going to go out of control and say, oh, we
5 don't think anything that these review groups did
6 is any good and we're going to pick this. We're
7 going to look for the things that are way out
8 there. We should learn. I absolutely agree with
9 Carolyn, one of the things we should learn if you
10 believe that review processes are prefect, no
11 offense, Dr. Collins, but it's human behavior, they
12 just don't actually work -- I mean, always well.

13 I've sat in on many of these and things
14 happen and groups get a little out of control and
15 stuff, and, so, you have to be prepared for that
16 and you have to look across. In general, they do a
17 very good job as best they can because when people
18 complain about them, I always say they are us,
19 because we're the ones sitting there and doing it.
20 So, it's us at fault sometimes.

21 So, I think what we will do, I hope, the
22 committee actually hasn't met as a group yet, which

1 we're going to do tonight actually after the talk
2 to start talking about this is we will come up with
3 in some sense about how to look at these
4 applications, we will present them to you the ones
5 with some evidence of where we think we would go
6 down to a funding line, it'll make your job a lot
7 easier than looking at the 400 applications that
8 were actually scored.

9 So, but in the end, the Board will make
10 the decision of we will say yes to this number, we
11 might want to go down a little bit, we will present
12 you some options. That's the way I see this
13 process, and I think we can learn a lot about how
14 we do it right the next time, perhaps.

15 CHAIRMAN WASHINGTON: Last comment on this
16 particular matter from Krumholtz.

17 DR. KRUMHOLTZ: Thanks, Harlan Krumholz.

18 To me, I think it's important to think
19 about what this means in terms of our strategy and
20 if we are emphasizing this transparency, to the
21 degree to which you can pre-specify what it is
22 you're doing and how you're waiting, I think, will

1 go a long way because what you really want to do is
2 promote the idea of fairness.

3 And you're right, Gray, I mean, there is a
4 lot of latitude, but you're just going to
5 substitute one group's for the others' if you start
6 moving people, one group's sort of proclivities for
7 another. And the other thing is that all of us
8 know a lot of these investigators, and that, I
9 think, is a danger with this process if we're less
10 than explicit about how we're managing it. If we
11 want to encourage junior investigators, at least
12 going forward in thinking about policy, then give
13 them some credit. At the NIH, they'll change
14 funding lines for the early-stage investigators. I
15 mean, I think that we should really ensure to the
16 extent possible that we have emphasized
17 explicitness and fairness. I know you guys are,
18 but just thinking in advance pre-specifying to the
19 extent possible.

20 The second thing is that if we're true to
21 what we're about, then we really need to be giving
22 disproportionate credit to those who have truly

1 engaged patients and caregivers in their conception
2 and in operations of their proposals.

3 So, that's the other thing which may or
4 may not have been adequately incorporated into the
5 review process. We tried, we had people on the
6 review panels, but those are the areas where you
7 can be very explicit about the importance of that
8 and that we will not fund any pilot grants unless
9 we are convinced that there's authentic, genuine,
10 and important substantial engagement by
11 stakeholders in those where it's appropriate. Some
12 of ours are actually more methodological, but in
13 those areas where we are targeting that, that that
14 is a strict criteria that we're now doing a check
15 on that was on top of what the review panels did,
16 but, overall, you guys have heroic work ahead of
17 you and we know you're going to do a great job.
18 So, these are just, I think, guidance statements
19 around it.

20 It is a pilot grant, after all, we're
21 going to learn a lot, it's going to help us in the
22 next step and we're going to have confidence in

1 what you do because we know how seriously you're
2 taking it, but these are just some of the potential
3 issues, I think.

4 DR. GOERTZ: Thank you.

5 CHAIRMAN WASHINGTON: Thank you,
6 Krumholtz.

7 Goertz do you want to wrap it up or are
8 you finished?

9 DR. GOERTZ: Absolutely. Next slide.

10 Just really briefly, the timeline that
11 we're on, which everyone has seen before, the
12 Selection Committee will be meeting sometime I
13 think in late March or very early April is what it
14 looks like. We'll be presenting the slate to the
15 Board shortly after that and then it will be a
16 PCORI staff function to start working on some of
17 the Grants Management issues and we hope to make
18 announcements regarding award in May.

19 Then, if I could turn this over to Gail,
20 to just really briefly to talk about some of the
21 ways that we're reviewing our peer review
22 experience because this is our first time out of

1 the box, we wanted to make sure that we were
2 capturing some information about it in a number of
3 different ways.

4 MS. HUNT: Gail Hunt. This is part of our
5 being a learning organization, which we've said 100
6 times that we want to do. So, we want to learn
7 from this experience, as Christine said. So, in
8 order to do that, we've done a couple of things.
9 One is we gave a survey instrument out to both the
10 stakeholder and the scientist who did the reviews
11 to kind of get insight into the review experience
12 so that we can use this for the future when we do,
13 for example, reviews for the next round of
14 proposals that we're talking about.

15 We also had 10 randomly-selected reviews
16 where we had people from PCORI go in as observers
17 and essentially observe the process of the NIH
18 review to get an idea of how, for example, the
19 patient and stakeholder person was a part of that
20 actual review. And now we've gotten the data on
21 preliminary and final scores for the applications,
22 including information on the six PCORI review

1 criteria, and as we've just spent an inordinate
2 amount of time talking about it, we will use that
3 as the primary cut point for our decisions based on
4 the Selection Committee.

5 The only other thing I wanted to mention
6 is that because we're a learning organization, we
7 really want to think about how we do the next round
8 of reviews when we've got our first full proposals
9 that are ready to be going out, the RFPs going out
10 in the middle of May, and so, we want to take a
11 look at how we should be doing this review process,
12 whether it should be done by, for example, outside
13 reviewers, the review first that's hired, whether
14 it should be done by NIH and AHRQ in combination or
15 in some way that maybe best meets the needs of
16 PCORI because we want to be sure that this review
17 process is branded as a PCORI review process. We
18 own this going forward, so, we want to be sure that
19 everyone knows that and that that's really clear.

20 CHAIRMAN WASHINGTON: Sigal has a comment
21 or question.

22 DR. SIGAL: Ellen Sigal. Gail, I'd be

1 specifically interested in the survey and whether
2 you targeted a separate survey for the patient
3 groups that were involved and the patient reviewers
4 because, often, they can be marginalized and
5 whether this was just sent out to all the reviewers
6 or whether you targeted the patient reviewers.

7 MS. HUNT: Christine, will --

8 DR. GOERTZ: Yes, there was actually a
9 separate survey that was given to the scientific
10 reviewers and to the stakeholder reviewers so we
11 could gauge their experience, and also in the
12 observational work that we did in the review
13 meetings, most of that observation was geared
14 towards to what impacted the stakeholder reviewers
15 had, to what extent -- were they listened to and
16 respected when they spoke and what applications
17 were they on, again, so that we could get some of
18 that information about their impact on the review
19 process.

20 CHAIRMAN WASHINGTON: Okay, Hole-Curry and
21 then Douma.

22 MS. HOLE-CURRY: Leah Hole-Curry, Board

1 member.

2 Thanks, this is great. So, an observation
3 and a question. My observation is it's very hard
4 for organizations to be learning organizations if
5 someone isn't operationalizing that component. So,
6 looking at Joe, I would ask that we consider a
7 staff member that specific responsibility is
8 continuous quality improvement, learning
9 organization, whatever it is. I know just in terms
10 of the PDC meetings and listening to you all and
11 how hard it was to incorporate this evaluation in,
12 even though we have said at each Board meeting how
13 important this is to learn from, how hard that has
14 been to do. So, if this is important to us, I
15 sincerely think that we have to consider making
16 that an operational responsibility somewhere.

17 And then, secondly, so, this is great, I'm
18 very excited about this. What is the plan for
19 bringing the results of this either back to the
20 Board or a subcommittee or is it an evaluation
21 report? How might that be completed?

22 DR. GOERTZ: There will definitely be an

1 evaluation reported. When we first started talking
2 about the Pilot Projects Program, we said that one
3 way that it was going to be a pilot project was to
4 find out what all the learning experiences were
5 going to be along the way and there have been very
6 many, and so, we have been compiling those, and so,
7 part of that will be the data that we get from the
8 surveys and from the observational studies that we
9 did during the review process. So, absolutely,
10 that will be coming back to the Board.

11 MS. HOLE-CURRY: Great. Not too fine of a
12 point on it, but if we're getting our next cycle
13 moving out soon, we'll need the information, at
14 least as much as we can as we continue to learn,
15 especially if we have continuous grant proposals
16 going out, we can incorporate learning as we go,
17 but --

18 DR. GOERTZ: Right, and certainly there
19 are a lot of learnings that came about in the
20 development of the program announcements, for
21 instance --

22 MS. HOLE-CURRY: Right.

1 DR. GOERTZ: That we'll want to make sure
2 that we consider as we're moving forward.

3 MS. HOLE-CURRY: Great, thank you.

4 CHAIRMAN WASHINGTON: Douma and then
5 Normand.

6 DR. DOUMA: Allen Douma, Board member.
7 What I had to say is really a follow-up to the last
8 statement Leah made. I think it's critical that as
9 soon as possible to actually have a timeline and
10 see how that dovetails with the next evaluation or
11 review for the next set of grants and I think
12 timing is really tight in all of this, so, perhaps
13 that information can be communicated across to the
14 review process before it actually comes and gets
15 vetted by the Board because we might lose a couple
16 of months if we wait for that.

17 MS. HUNT: Yes, I think that we'll
18 definitely have those things, we'll want that to
19 get out the staff, for example, who are in the
20 process of developing what the review process will
21 be for these grants, the RFPs that are going out in
22 mid-May.

1 DR. DOUMA: Yes, just again reinforce it
2 by getting some dates on it. Dates are magical
3 when it comes to getting things done.

4 DR. GOERTZ: We will do that.

5 CHAIRMAN WASHINGTON: Normand?

6 DR. NORMAND: Yes, Sharon-Lise Normand,
7 Methodology Committee member.

8 So, great job. I am interested to hear
9 the results. The point I guess I wanted to make is
10 for the new grants that are coming down the line,
11 to me, it would make sense if this is the road
12 we're going to take is to appoint people to review
13 committees, a PCORI Review Committee, and I don't
14 know if you had discussions about that yet of
15 pulling together review committees quickly to do
16 the pilot grants, but I think there's an ownership
17 if you belong to, you know, the blah, blah, blah
18 review committee.

19 And so, I don't know if there's a process
20 in place to select who's going to serve a two-year
21 term on the PCORI, this, that, and the other thing.
22 And just like we talked about PCORI scholars, I

1 think it's also good to get in place some
2 committees that are the PCORI committees.

3 CHAIRMAN WASHINGTON: Okay, that's an
4 excellent thought. Okay, Selby.

5 DR. SELBY: So, a couple of things.
6 Sharon-Lise, thank you, that's an excellent
7 suggestion. Associated with the Pilot Projects, we
8 had a solicitation online for both scientific and
9 stakeholder reviewers and 300 stakeholders,
10 patients, and other stakeholders and 600 scientists
11 applied. So, we called that the beginnings of our
12 reviewer community.

13 Your idea though is a brilliant one. The
14 notion of a standing study section, I think there
15 has been some question about whether we would
16 continue working with the Center for Scientific
17 Review over time and sort of establishing a
18 standing study section if we do it with the CSR
19 next time, would kind of imply that we were going
20 to continue with them. But I think we really need
21 to get moving on that quickly. I love the idea
22 because it's going to be critical to introduce

1 PCORI's unique review criteria and they're going to
2 be more of them next time than there were this last
3 time, to all reviewers and then we can evaluate
4 whether they are able to apply those criteria.

5 To Leah's point, I completely agree. I
6 think we will continue always evaluating the review
7 process not so much to see if it went well. I
8 mean, CSR handled a very large number of
9 applications really flawlessly from the point of
10 view of moving them through the process. The
11 evaluation is to see whether the steps we took to
12 make it more patient-centered were beginning to
13 take hold, and, if not, what changes can we make so
14 that a year from now, we can say the reviews that
15 PCORI does really differ and they really are
16 generally patient-centered. So, I completely
17 agree.

18 CHAIRMAN WASHINGTON: Is that the end of
19 your report, Goertz?

20 DR. GOERTZ: Yes, thank you.

21 CHAIRMAN WASHINGTON: Okay, thank you.
22 Great work.

1 Rick, just a time check, we've got a
2 little under 40 minutes. I know you have two
3 topics, so, keep that in mind.

4 DR. KUNTZ: Right. I did mention to
5 Christine this morning that we were going to bring
6 up a lot of topics that would generate discussion,
7 and I said how fast can you get through this first
8 section, and she said five minute tops.

9 [Laughter.]

10 DR. GOERTZ: I did not.

11 [Laughter.]

12 DR. KUNTZ: So, we're moving on now to the
13 public comment process and timeline for what we're
14 doing for the National Priorities in Research
15 Agenda, and I want to bifurcate the two
16 discussions. The discussion we'll have here is
17 about what the PDC is doing about the process for
18 incorporating comments, and we want to make sure
19 that everybody is aware, the public, that we take
20 all of the comments that are solicited through a
21 variety of different vehicles very, very seriously
22 and we want to outline some of the processes that

1 we're doing to demonstrate our accountability in
2 processing these comments into the final shape of
3 the NP and the RA going forward.

4 I think Dr. Levine will talk later, either
5 today or tomorrow, about the methods for receiving
6 comments, and that will also complement the efforts
7 that we've tried to do to incorporate public
8 comments in a serious and formal fashion that would
9 be both transparent, but also effective.

10 This is a high-level overview of the
11 public comment process and timeline. Due on March
12 15th is the close of the public comments. So, at
13 this point, we will start to aggregate data from
14 the variety of different vehicles, to include
15 websites, mailed comments, stakeholder events, the
16 media, and the PCORI Pilot Project experience
17 itself to really start to incorporate and identify
18 important themes.

19 We will then move on to number two, which
20 is the suitability of the themes to determine
21 whether the themes really fit PCORI's mission and
22 also our evolving vision statement. That will have

1 a deadline of March 27th.

2 Number three will be --

3 DR. WEISMAN: Can you say more about what
4 that suitability of themes means? I mean, if I
5 were a skeptic, I'd say does it give you the
6 ability to throw out things you don't like?

7 DR. KUNTZ: Well, I think what we have to
8 do, Harlan, is align comments with those that we
9 are soliciting and also those that meet a lot of
10 the objectives and goals going forward. We will
11 have a formal process in trying to determine those,
12 but we also have a moving process in developing our
13 final objectives, our strategies, and so on. So,
14 it'll be somewhat like changing cars in a moving
15 vehicle to some degree and we aim to really
16 formalize this process to at least categorize the
17 comments into big buckets to demonstrate those that
18 we think are on track with respect to what PCORI
19 aims to do and those that might be outlier
20 comments.

21 DR. WEISMAN: And so, what you're calling
22 outliers, those would be publicly open, not

1 identifying the individual, but identifying the --

2 DR. KUNTZ: That's correct.

3 DR. WEISMAN: -- comment or at least the
4 idea of it and then the rationale for discarding
5 it.

6 DR. KUNTZ: We would expect to get a lot
7 of comments about health care in general that might
8 be outside the scope of what we're trying to define
9 PCORI to be.

10 VICE CHAIRMAN LIPSTEIN: I think, Harlan,
11 if we let Rick finish the presentation, I think
12 it'll become clear that they tried to categorize
13 and find commonality of themes. So, as opposed to
14 things we heard one time from one person. Let's
15 let Rick finish then we'll open it up for questions
16 and comments because I think once he gets through
17 the whole process, it may answer some of those
18 questions.

19 DR. KUNTZ: Then moving on to the third
20 component, which will be performed by the staff and
21 I'll talk about how this is done and how all
22 members of the Board can engage in these processes.

1 Will be to conduct the initial evaluations of these
2 processes and evaluate the impact of the changes
3 based on the themes that we are developing for the
4 National Priorities and Research Agenda and for the
5 overall PCORI mission. So, this will be the
6 processing component.

7 We'll then have a voting process that will
8 originate in the PDC scheduled committee meetings
9 on April 9th to vote on the incorporation of
10 themes. So, this will be, again, Harlan following-
11 up on that process, that once we get the
12 categorization, the evaluations we'll put into a
13 format that can be voted on to make sure that we
14 align those comments, again, with the idea of
15 modifying our National Priorities and Research
16 Agendas with respect to the feedback we get from
17 the public.

18 We will then have a voting conference to
19 reach consensus on recommendations. This will be a
20 separate meeting two days later at the PDC on a
21 face-to-face meeting that we have scheduled April
22 11th to drive the kind of language we want to put

1 in for the recommendations overall and then on
2 April 17th, we will solicit the recommendations to
3 the Board in an open meeting being planning on the
4 17th.

5 If you look in the right column, you see
6 that the PDC and staff is labeled here and what we
7 tried to do is just basically connect these events
8 to meetings that we have scheduled at PDC, but I
9 want to point out that all of these events are open
10 entirely to the Board for participation both on the
11 phone calls and also the face-to-face meetings for
12 anyone who wants to be involved in this process.
13 It's merely, again, the vehicle for meeting is
14 going to be our PDC schedule overall. And maybe,
15 Steve, with that, we can break and see if there are
16 any comments.

17 VICE CHAIRMAN LIPSTEIN: Yes, I would, and
18 just one comment. The asterisks here are really
19 important because one of the things we've been
20 trying to do is when we get into Board meetings not
21 rehash what the committees have already done, and
22 one of the best ways to do that is to allow Board

1 members and Methodology Committee members to
2 participate in each of these steps so that you feel
3 like your voice was heard before we get to the next
4 Board meeting.

5 Harlan, did you want to weigh in now? The
6 other Harlan. I didn't mean that. Harlan
7 Krumholz.

8 DR. KRUMHOLZ: Thanks, Harlan Krumholz.

9 I just wanted to go behind what Rick said.
10 First of all, Rick, I know you didn't mean we're
11 really going to discard in the sense of we're
12 actually going to listen and take into account all
13 the comments that are given to us. Some are going
14 to flow directly into whatever we're going to
15 produce next, some are going to be put aside and
16 considered as an ongoing basis, but I think it's
17 important to say that there's no censoring going on
18 here. In fact, all those comments are going to be
19 available and there's a reflection that's going to
20 occur with all of them.

21 What is important, I think for those who
22 are thinking about commenting in the last 10 days

1 is that we're not looking so much for individuals
2 to come forth and to promote their own singular
3 cause as we are trying to get them to reflect back
4 on the general overall themes and importance of the
5 kind of work that PCORI's capable of doing and
6 helping inform us with respect to those activities
7 that we may pursue. So, as we look through and
8 distill the comments that we've gotten, we're not
9 looking to actually tabulate votes around whether
10 or not one cause got more votes than another, but
11 we're looking to try to understand how are people
12 trying to help us position ourselves in the best
13 way possible that will allow us to support
14 activities that will produce knowledge that will
15 have meaningful importance to patients.

16 And so, there are some important decisions
17 that the PCORI Board has to make in putting forth
18 agenda and priorities that are very germane to
19 that, how we should be spending our time, how we
20 should be devoting our money so that we can ensure
21 that we are being positively and constructively
22 disruptive to the current research architecture and

1 that we are generating a way of doing work and a
2 way of incorporating input and a way of producing
3 knowledge that's different than what has been
4 traditionally done.

5 Not in any way to denigrate very good,
6 important, traditional work, but we are here to
7 complement that work that's being done by others
8 and need to take a path that produces a sort of
9 fresh look at the way in which that could occur and
10 to strengthen the overall research infrastructure
11 that occurs throughout the country so that, I mean,
12 just building on what Rick said, all of these
13 comments are going to be brought and sometimes
14 people are promoting particular cause or agenda,
15 which is fine. We want to listen and understand
16 and appreciate that, but we're particularly going
17 to be driven in the comments which I think will be
18 most influential or those who are able to step back
19 a little bit from a particular cause and help us
20 think about how we can configure the overall
21 organization's activities to be constructive and
22 positive going forward.

1 CHAIRMAN WASHINGTON: Gabriel.

2 DR. GABRIEL: Sherine Gabriel, Methodology
3 Committee.

4 So, this is in the vein of being a
5 learning organization and kind of learning from
6 what we've already done, within the Methodology
7 Committee and with the Board, we've already put
8 forward the definition and have gone through the
9 process of soliciting public comments,
10 understanding where responses and changes were
11 needed and where they weren't and that process, I
12 think, could be informative to what's going on
13 here.

14 Likewise, as we're moving forward our
15 recommendations, we've developed a preliminary
16 voting process of voting, a process to reach
17 consensus regarding our recommendation for
18 methodologic standards and then, of course, the
19 public comment period for the Methodology Report.
20 So, I'm just making a suggestion that we kind of
21 connect the dots and particularly get the staff
22 working on all of these processes, talking to one

1 another so that we're not reinventing the wheel
2 internally and unnecessarily.

3 CHAIRMAN WASHINGTON: Weisman.

4 DR. WEISMAN: Yes, this is Harlan Weisman,
5 and I have I think a question for Harlan Krumholz.
6 Just understand it, I'm fully on Board with the
7 direction we're going and the priorities and
8 Research Agenda, but, again, I think it's important
9 to play a little bit of devil's advocate in this or
10 at least to fully understand the implications of
11 what we're saying.

12 Harlan, pretend for a second -- I don't
13 think this would happen, but pretend for a second
14 that people said you know what, we've heard your
15 vision of the future, we've heard your new way of
16 doing research, but, actually, we'd like the
17 approach that's been standard in the past and what
18 we're really hoping is that PCORI would pick up
19 from what the IOM left off with their specified
20 100. Pick the top five that decide on and run with
21 it. And let's say that that was if not a vast
22 majority, a large plurality, what would we do with

1 that?

2 DR. KRUMHOLZ: Oh, I think we'd listen
3 very carefully to what people are saying, we'd try
4 to understand the perspective that they're bringing
5 to it. It would be up to us, I think, to reflect
6 on where we can make our greatest impact and to
7 understand whether we, even in the course of
8 soliciting input for our priorities and agenda,
9 have been able to frame the possibility that wisdom
10 resides outside of the Institute of Medicine.
11 That, in fact, throughout the entire country, there
12 may be people facing challenges that were unable to
13 sort of bubble up to that esteemed group that met
14 that set those priorities and that what might be
15 most important is that we construct teams where
16 patients and caregivers have a fundamental,
17 important, substantive role in influencing the
18 design, implementation, and dissemination of
19 research.

20 And that, those teams are also including
21 researchers and clinicians and others who might be
22 involved and that we at least are given a chance,

1 and I'm just promoting this as my view, that we're
2 at least given a chance to say that we could
3 construct a world in which that becomes standard
4 operating procedure. I believe the IOM put
5 together their report thinking about conventional
6 research, in thinking about the usual way that
7 things are done.

8 Now, they did point to important content
9 areas, and I very much hope that when we open
10 applications that people will pay attention to
11 those content areas and if they can pull together
12 the right teams and if they can ask the right
13 questions and if they can show us that within three
14 to five years, they can produce important
15 knowledge, I guarantee that we will pay a lot of
16 attention to those content areas, but that that's
17 only facet of what we're trying to do and what I've
18 reflected on in the pilot grants is by opening it
19 up to a broader range rather than just
20 circumscribing it, people reflected back to us that
21 the process of applying changed their view about
22 how research might be done and brought together

1 people who wouldn't otherwise be talking to each
2 other and I'm worried if we circumscribe too much
3 or if we kowtow too much to prior efforts that may
4 not have had this in their mind when they developed
5 their priorities, then we will be losing an
6 opportunity to help set a new approach to the way
7 in which knowledge is generated.

8 DR. WEISMAN: So, does that mean then we
9 would listen to that input, but ultimately reject
10 that input if it wasn't consistent with the
11 direction we already want to go in?

12 Again, I'm playing devil's advocate.

13 DR. KRUMHOLZ: I think it's up to the
14 Board to reflect.

15 CHAIRMAN WASHINGTON: Steve.

16 VICE CHAIRMAN LIPSTEIN: I want to answer
17 that one for you, Harlan. I think, Harlan, your
18 construct is a little bit incomplete in that what
19 likely happens, what, in fact, does happen is you
20 will have a group of people who will say we should
21 pick up where the IOM left off and follow their
22 guidance and you will have an equal number of

1 people who will say just the opposite, who will say
2 we should start fresh, we should take into account
3 what they did, but we should also solicit
4 perspectives that go well beyond the Institute of
5 Medicine.

6 The same exact thing actually happened
7 when we issued our National Priorities. Some
8 people said that they weren't specific enough and
9 some people thought they were perfectly on target
10 or too general or appropriately general, and so,
11 what I think our Board is going to need to do isn't
12 to accept or reject, but it's going to be to listen
13 to all the input we get, and so, if somebody, for
14 example, said our National Priorities weren't
15 specific enough, what we say to that person is
16 we're also listening to that other voice which says
17 that they were appropriately broad and general so
18 as to incorporate lots of input and lots of ideas
19 and lots of perspectives. Not that we're ignoring
20 or discarding the people who wanted us to be more
21 specific, but that we were also listening to other
22 people.

1 I think in your example, yes, we would
2 listen to the people who would advocate for our
3 following on with the IOM, but we are going to hear
4 other voices, too, and then the role of our Board
5 of Governors is to hear all of those voices and to
6 use our best judgment.

7 CHAIRMAN WASHINGTON: We have a little
8 over 20 minutes and Rick just reminded me that one
9 of our key spokespersons has to leave. So, we're
10 going to forge ahead. Rich discussion definitely
11 food for thought as we move forward.

12 So, Rick?

13 DR. KUNTZ: Thank you, Gene. I want to go
14 to the next two slides to just recognize that these
15 scorecards for how to incorporate and how to
16 process the comments coming in have been developed
17 by our very talented staff, and they'll develop a
18 few more.

19 I just want to show you two slides of
20 these kind of scorecards, which we will all be
21 looking at, at both it's a complete view of the
22 comments, as well as a summary of where those

1 categories are to address these issues we just
2 talked about how we can be aligned on them.

3 And so, a scorecard like this will
4 indicate what themes are rising from the
5 stakeholder groups, which stakeholder groups,
6 whether or not they occurred in time, following a
7 specific event, for example. Did they originate in
8 certain parts of the country, and we'll start to
9 get more of the dimensions and metrics associated
10 with where these comments come from, the magnitude
11 of the comments, the magnitude of the themes, and
12 so on.

13 The next one is a dashboard which can be
14 drilled down to show the individual comments that
15 are made that contribute to the overall themes seen
16 in the summary comments going forward. I think we
17 want to let the staff with their expertise have a
18 lot of latitude to develop the scorecards. These
19 are experts in the areas in processing this
20 information. I think it'll be very, very valuable
21 for us as we go through the process of
22 understanding what is a public comment and how are

1 we going to process it? But I also just want to
2 reiterate the theme that PCORI takes very seriously
3 all the public comment we're eliciting and we will
4 try to process it to the best of our ability in a
5 transparent way, but also meets our timelines.
6 It's really critical that we get these timelines
7 out, that we process our National Priorities and
8 Research Agendas so that we can process a PCORI
9 funding announcement by mid-May.

10 I'd like to move on to a little bit more
11 on the details of the PCORI funding announcement
12 and as I said, these funding announcements will
13 evolve with the feedback about the National
14 Priorities and Research Agenda. So, it's going to
15 be a little bit of an iterative process as we get
16 smarter and try to understand how the data works
17 because they will have a direct impact about what
18 the final PCORI Funding Announcement, which we're
19 aiming for May, will have to go out.

20 So, like I said, we are still geared for a
21 mid-May release. The PFAs will definitely solicit,
22 the solicitations will be based on the response

1 about the National Priorities and Research Agenda,
2 as I said, it was baked in, and I had to just step
3 back a second and say that this is a very exciting
4 moment for us. We have really been evolving over
5 the last year-and-a-half, we have established our
6 first set of National Priorities and Research
7 Agendas, we are getting enthusiastic response back
8 from the public about these comments, we have
9 actual timelines and processes to process these
10 programs, and we are still on track to send out our
11 first PFAs, which is really the first publicly-
12 processed PFAs going forward in addition to the
13 accomplishments we've made in the PCORI Pilot
14 Project Grants.

15 This is just a high-level overview of the
16 Gantt chart associated with how the staff will help
17 us drive the processes to get these announcements
18 out by mid-May. We reviewed earlier in Joe's
19 presentation the five priorities that we've aligned
20 on for National Priorities to link up with PFAs
21 with. The first four priorities will be focused on
22 PFAs that will be generated by May 15th and the

1 fifth priority, which deals more about the
2 infrastructure research and the definitions of
3 PCOR, which has a heavy component of the
4 Methodology Committee, will come out a month or two
5 after that going forward.

6 I know I'm kind of zipping through here
7 pretty quickly, but I think that this is kind of
8 high-level review and the point of this slide is to
9 demonstrate that I think we do have a buttoned-up
10 process with our staff that is really starting to
11 develop the Gantt charts and lay out the ways that
12 we interact. If you look at the green and red
13 stars, it shows that basically we do have hardwired
14 meetings both with PDC and also the Board of
15 Governors and the Methodology Committee meetings,
16 as well, which isn't on here, to show that each of
17 these is integrated into the process with the staff
18 with respect to either the feedback to pull off
19 this PFA that we're sending out in mid-May.

20 A little bit more detail about the plans
21 for priorities one through four and this shows that
22 we are still in the process of hiring our research

1 scientists. I'll show you a little bit more detail
2 in the next slide. We are going to use CROs and
3 we're in the process of getting a few on board. We
4 have an open competition that's very transparent
5 and our applications are leaning towards using the
6 Center for Scientific Review. We had a very, very
7 good experience, I think, in general with the PCORI
8 Pilot Project Grants and at this stage, this seems
9 to be how we will be leading in the first round of
10 our PFAs to use CSR for the review process. And,
11 again, all of these applications will be branded
12 and really administered by PCORI, by both the staff
13 and also the Board of Governors and Methodology
14 Committee.

15 Here's an overview of the engagement of
16 the Board and the staff with the priorities and you
17 can see the principal Board and the Methodology
18 Committee members who are associated with each of
19 the five priorities. We do have a lot of
20 opportunity for more Board members here to help
21 participate, especially in the areas of the first,
22 third, and fourth National Priorities. So, I would

1 encourage individuals if you have time and have an
2 interest to sign-up and to start to get engaged in
3 the process of developing these PFAs going forward.

4 And, with that, I think we want to expand
5 a little bit more on priority number five. Again,
6 this is bifurcated into -- we initially called this
7 Accelerating PCOR and Methodological Research. It
8 really is about the Methodology Committee and their
9 efforts to really establish CER and PCOR methods,
10 and we'll hear more about that as the report comes
11 out over the next month or so. And, in addition,
12 this subsumes the data infrastructure that we had
13 talked about earlier, that is the IT issues are
14 linked with existing and new databases and the
15 potentials for developing network systems going
16 forward.

17 So, with that, I'll turn it over to Dr.
18 Goertz.

19 DR. GOERTZ: Thank you, Christine Goertz.

20 CHAIRMAN WASHINGTON: I'm sorry, Douma has
21 a question.

22 DR. DOUMA: Yes, Allen Douma, Board

1 member. Just it may be a semantic issue, but we're
2 always in such a hurry that I want to make sure we
3 didn't miss it, and it may be semantic in the sense
4 that you have a draft Board PFAs and the Gantt
5 chart, end of April, they're done. You also have
6 finalized PFAs, end of April, they're done. Is
7 that simply the finalized PFA as part of the
8 drafting process?

9 DR. KUNTZ: Yes.

10 DR. DOUMA: Okay, so, it's at some point -
11 -

12 DR. KUNTZ: Absolutely, yes.

13 DR. DOUMA: At some point, the draft is
14 done and we're looking to approve it?

15 DR. KUNTZ: That's correct. So, the
16 approval will occur before May 15th. We're still
17 aiming for the May 15th delivery, yes.

18 DR. DOUMA: Okay.

19 DR. KUNTZ: Thanks for pointing that out.

20 CHAIRMAN WASHINGTON: Lipstein.

21 Joe Selby, can you go back a slide?

22 Whoever had the slide, clicker. That one.

1 If you want to be on one of those groups
2 that Rick just invited us, who do you call? I
3 mean, do I call Mike Lauer or Carolyn or Gray or
4 Arnie or Harlan or who do I call?

5 DR. EPSTEIN: Can't you just call
6 everybody?

7 [Laughter.]

8 VICE CHAIRMAN LIPSTEIN: Arnie, you have a
9 way with words.

10 DR. SELBY: You can call Rick or you can
11 call Melissa Stern.

12 VICE CHAIRMAN LIPSTEIN: Melissa Stern,
13 thank you.

14 DR. KUNTZ: And, by the way, Ellen's on
15 the first one with me, just to acknowledge your
16 participation.

17 CHAIRMAN WASHINGTON: Okay, Christine and
18 we have public comment in 45 minutes, so, this is
19 points of clarification before we move on.

20 In 15 minutes, that's right. Okay, so --
21 [off microphone] -- Barksdale.

22 DR. NORMAND: Sharon-Lise Normand,

1 Methodology Committee.

2 Clarification, I'll underline it since
3 this is only a question of clarification and I
4 won't deviate from it. The purposed plan for
5 priority number five, Rick, you say clinical
6 research data infrastructure. I just want to
7 clarify, priority five could be much broader than
8 just data infrastructure, is that correct?

9 DR. KUNTZ: Yes, I'm sorry, I didn't make
10 that clear.

11 DR. NORMAND: Yes.

12 DR. KUNTZ: It was two parts. One is
13 going to be the overall Methodology Committee's
14 contribution to defining CER/PCOR.

15 DR. NORMAND: Okay.

16 DR. KUNTZ: Yes, which that in the second
17 part was the infrastructure.

18 CHAIRMAN WASHINGTON: Weisman.

19 DR. WEISMAN: Okay, this is a point of
20 clarification for you, Gene. We went through this
21 really quickly and I understand why.

22 And I think there's substantive issues in

1 some of this and I'm uncomfortable with some of it
2 and we don't have time now to discuss it, so --

3 CHAIRMAN WASHINGTON: Okay.

4 DR. WEISMAN: What's the method by which
5 we can get further clarifications of the process
6 and methods? This is probably the most important
7 thing that we will have done thus far and I just
8 feel it's going really quickly.

9 CHAIRMAN WASHINGTON: Okay, [off
10 microphone] -- this morning's session, and I will
11 be able to follow-up.

12 DR. BARKSDALE: I really do have a quick
13 clarification question. On slide 17 in the
14 package, there's abbreviation CRO and I deduced
15 that that's Contracted Research Organization. What
16 is the CSR?

17 DR. KUNTZ: The Center for Scientific
18 Review, which is at the NIH.

19 CHAIRMAN WASHINGTON: Okay, Goertz.

20 DR. GOERTZ: Okay, thank you. Christine
21 Goertz.

22 So, as Rick had said, that priority number

1 five is we're really envisioning it as being
2 divided into two separate areas. One is the CSR
3 methods and the other is something that we're
4 calling Clinical Research Data Infrastructure. And
5 since we're calling this out because the process
6 that we're proposing for this one is just a little
7 different than the process for the others and that
8 the program announcement would be written by
9 PCORI's staff and assisted by AHRQ, NIH staff, and
10 the Methodology Committee. And this would be a
11 separate funding announcement from that, from the
12 analytic method. So, I think with the other
13 priorities, we're looking at one funding
14 announcement, at least in this initial round. With
15 this one, there would actually be two funding
16 announcements.

17 And the solicitation and review process
18 for this particular effort would be managed by both
19 AHRQ and NIH through contracts from PCORI to both
20 of those organizations. We are looking at this
21 more of a focused competition with clear data and
22 governance requirements, including engagement of

1 relevant stakeholders. So, as we know with the
2 Pilot Projects Program, that was a rather general
3 announcement; we anticipate that this to be a much
4 more specific type of announcement and that the
5 funding would be through a cooperative agreement
6 mechanism which means that PCORI's staff and AHRQ
7 and NIH staff would have substantial involvement in
8 the research as it moved forward, as is normal with
9 cooperative agreements.

10 Can I have the next slide, please?

11 The rationale for contracting with these
12 federal agencies for this particular initiative is
13 really a multi-folded. First of all, they have
14 years of experience in this particular area that we
15 feel will be really invaluable when it comes to
16 writing this particular funding announcement. They
17 also have a much better idea of the gaps and
18 opportunities in this particular area of science
19 which allows our program announcement to really be
20 specifically targeted towards those gaps and
21 opportunities. We also have a current knowledge of
22 the state of the science based on work that they

1 have funded and are continuing to fund in this
2 particular area so that we are making sure that the
3 work that we do here really does fill a gap that
4 exists.

5 And, again, looking at a cooperative
6 agreement where the grantees would be working
7 together with PCORI, AHRQ, and NIH. Obviously,
8 AHRQ and NIH have a great deal of expertise in
9 running these cooperative agreements, which, again,
10 are a little bit different. They are very, very
11 different from writing a check and asking for a
12 quarterly or annual report. It really is
13 substantial involvement with the scientists within
14 those particular organizations.

15 And then, last, just a reminder that our
16 statute specifically encourages us to contact with
17 AHRQ, NIH, and other federal funders of Comparative
18 Effectiveness Research, as we're moving forward and
19 this is a particularly nice opportunity to do that.

20 Next slide. Then the second RFA for this,
21 again, would be in close collaboration with the
22 Methodology Committee. We still see AHRQ and NIH

1 having substantial involvement in this particular
2 initiative. We see this one as being more targeted
3 than priorities one and four, but probably not
4 quite as targeted as that for the research data
5 infrastructure and it's not as clear that this
6 would be a cooperative agreement though, again,
7 depending on how it finally gets conceptualized, it
8 certainly could be.

9 I'd be happy to answer any questions.

10 CHAIRMAN WASHINGTON: I have Weisman first
11 and then Lipstein.

12 DR. WEISMAN: There's another federal
13 agency that's involved in this and that's the Food
14 and Drug Administration, and they also have efforts
15 in this regard of databases, data analytics,
16 comparative effectiveness, and I'm not suggesting
17 that we complicate things with cooperative
18 agreements, but I've been asked the question and I
19 don't really know the answer about how do we
20 formally engage FDA in thinking about this because
21 they certainly, not sponsor, but encourage this
22 kind of research and are highly influential in this

1 regard and it would be nice to think that we could
2 get aligned with them, as well.

3 VICE CHAIRMAN LIPSTEIN: Steve Lipstein.
4 I want to first make a comment as Vice Chair and
5 then make a comment as my stakeholder
6 representative, representing hospitals and health
7 systems.

8 As Vice Chair, I think it's really
9 important as we go into this next stage of work
10 that since a lot of the work that we're describing
11 has been assigned to the Program Development
12 Committee and the Methodology Committee that so we
13 don't get to May with the Board being uncomfortable
14 with the process or the opportunities for input.
15 We really have to figure out a way for those that
16 are on the other committees, either the Finance and
17 Administration Committee or on the Communications
18 Outreach and Engagement Committee, to participate
19 in this process before the next Board meeting. In
20 other words, we otherwise will just rehash a lot of
21 work that's taken place, a lot of important works.
22 So, we have to incorporate that involvement between

1 now and then. So, that's my vice chair comment.

2 My stakeholder comment is --

3 CHAIRMAN WASHINGTON: Steve, can I just
4 interject? On that point, I mean, it's similar or
5 the same question that Harlan has raised and we may
6 have some time later in the day where we can resume
7 this discussion, but so noted from both of you. In
8 fact, I detect from Harlan that you're not sure
9 what your level of concern is because you haven't
10 had enough time to discuss it, and so, we need to
11 figure that out actually before we leave the
12 meeting.

13 What I would say to those that are
14 listening, because we will continue the discussion,
15 if you have comments, please do send them to us,
16 because that's why we're discussing it now and our
17 concerns, to us at our PCORI website.

18 VICE CHAIRMAN LIPSTEIN: Great. And,
19 Christine, could you go back a couple slides or
20 Rick? Rick, who's got the clicker? No, wrong way.
21 Right there.

22 This is really exciting that we're going

1 to get AHRQ and NIH together to help us on this
2 fifth priority, which is what Francis calls the
3 foundational framework, and this is where I would
4 really like to see us engage with health systems in
5 particular who have access to a lot of information
6 and importantly, the point I wanted to make was not
7 just one health system in one geography, but if we
8 could work with three or four health systems in the
9 same geography --

10 CHAIRMAN WASHINGTON: [Off microphone.]

11 VICE CHAIRMAN LIPSTEIN: Never mind.

12 Never mind.

13 CHAIRMAN WASHINGTON: We have Douma and
14 then Zwolak. Did you have your hand up, Francis?
15 Okay.

16 DR. DOUMA: Yes, I just want to comment
17 based on two colleagues who are, your organizations
18 AHRQ and NIH are just tremendous and your abilities
19 are tremendous, but I think it's important that we
20 don't sort of go down the slippery slope in which
21 we lose our identity because of the work we do with
22 you guys and building on what Harlan Krumholz has

1 been saying, we need to figure out how we are
2 different, even when we're doing cooperative
3 agreements, and it's easy not to do that
4 particularly in the timeframe that we're in.

5 CHAIRMAN WASHINGTON: So noted. Okay.

6 DR. ZWOLAK: Bob Zwolak, Board member.

7 A quick question. Later this morning,
8 we're going to have a discussion by the Finance and
9 Administration Committee, and when I hear this
10 tremendous report about the upcoming announcements,
11 the question I have is: Is Finance Administration
12 and the Board keeping up with you in terms of the
13 number of dollars we're going to assign to the PFAs
14 for the one to four category and the number of
15 dollars we're going to assign for number five and
16 so forth? And so, what do we have to do to keep up
17 with this program?

18 DR. SELBY: A couple of things. First, I
19 think the FAC is keeping up with us on this. Some
20 of this is fluid; some of this it has to be said
21 awaits the comments on the National Priorities and
22 the Research Agenda itself. So, that's why we're

1 anxious to get those comments analyzed and have
2 that input by April 15th. If we say we're issuing
3 funding announcements in mid-May, they need to be
4 based on the revised agenda and priorities, no
5 doubt. But I think, as you'll hear shortly, the
6 FAC is doing some heavy lifting on thinking about
7 spending.

8 CHAIRMAN WASHINGTON: Okay.

9 DR. COLLINS: Francis Collins, Board
10 member.

11 Just a couple of quick responses to things
12 that were said. To Harlan Weisman, I think, yes,
13 the FDA does have some critical resources and
14 skills and we will definitely want to tap into
15 those two things, like the sentinel network, for
16 instance, and I think both AHRQ and NIH have very
17 strong, positive relationships with the leadership
18 of FDA and we'll make sure to capitalize on those.

19 And with regard to Allen Douma, I totally
20 agree with you that while I think NIH and AHRQ can
21 bring some capabilities to these different RFAs or
22 PFAs for the fifth priority here, we very much want

1 to incorporate into that the PCORI view of patient-
2 centeredness. That'll be good experience for
3 everybody. I think it is true that the statute
4 encourages this kind of collaboration and I think
5 we can through the process of that collaboration
6 actually get more done than any of the three
7 organizations could do by themselves, and in a way,
8 that's really a good thing for the taxpayers to
9 see, that we are willing to roll up our sleeves and
10 work together. And, certainly, speaking for NIH,
11 and I'm sure Carolyn would say the same for AHRQ,
12 that's entirely our intention.

13 DR. CLANCY: Ditto.

14 CHAIRMAN WASHINGTON: Thank you. So,
15 we're going to move to wrap-up.

16 DR. KUNTZ: We had a final comment made by
17 Dr. Clancy about the PCORI Dissemination Workgroup.

18 DR. CLANCY: Great. So, you'll recall the
19 Dissemination Workgroup actually made its initial
20 kind of stage setting presentation at the last
21 Board meeting in Jacksonville. The members of the
22 committee, a really fantastic group, I just have to

1 say, are shown on this slide, and you may recall
2 that one of the proposals we made at the last Board
3 meeting was that starting with the initial funding
4 announcements, that we would include some
5 dissemination accelerating components. I will be
6 totally honest and say when I did my part, we had
7 no idea what that meant. So, what we are showing
8 you today for the first time is version 1.0. This
9 will not be your last time to comment on it, but I
10 just wanted to show you we started down the path of
11 developing a checklist. This has not even been
12 extensively vetted within the workgroup just
13 because of the timeframe coming up to this Board
14 meeting, but we do have a particular sense of
15 urgency about it.

16 The other thing I will just make a comment
17 on, which is separate; is that a number of you had
18 comments about how AHRQ makes investments and I was
19 trying to explain that we have an approval process
20 that we need to go through with the administration
21 and so forth. And so, on April 13th -- I just
22 confirmed this with Sharon, at the next meeting of

1 AHRQ's National Advisory Council, in the afternoon,
2 and you'll all get information about it and the
3 meetings are webcast, so you can tune in if you're
4 interested, we will be presenting in a public
5 session all about the investments that AHRQ is
6 making thus far with our 16 percent that comes
7 directly to AHRQ.

8 So, next slide, please.

9 UNIDENTIFIED SPEAKER: [Off microphone.]
10 Everybody is asking me who Howard Holland is.

11 DR. CLANCY: Who is Howard Holland?
12 Howard Holland directs the Office of Communication
13 and Knowledge Transfer at AHRQ and you may recall
14 that that office is explicitly mentioned in the
15 legislation, however, dissemination is not just
16 limited to his office, but if you ever meet him,
17 you won't want to deal with Gene or me again. He's
18 a wonderful, wonderful guy.

19 UNIDENTIFIED SPEAKER: [Off microphone.]
20 Speak for yourself.

21 [Laughter.]

22 DR. CLANCY: Well, I will speak for

1 myself.

2 So, this is a proposed checklist over two
3 slides. Now, at every meeting, we talk all about
4 how we are all about stakeholder engagement. We
5 generally don't get too specific or detailed about
6 what that means and I can tell you from long
7 experience, and I think Francis would agree, that
8 if you write into an announcement stakeholder
9 engagement is important, you can absolutely predict
10 you will euphoric responses back that say
11 absolutely, every morning, I wake up thinking about
12 stakeholder engagement, and so forth.

13 We wanted to and thought that we could go
14 a little bit further than that and the hypothesis
15 here is that engaging relevant stakeholders, and
16 you'll recall the case studies we presented from
17 RAND, engaging them from the get-go in essence is a
18 way not only to live up to this Board's aspirations
19 about engagement, but also a way to prime the pump
20 for dissemination. This is a hypothesis we will
21 get to test.

22 So, here are the specific ideas that we

1 thought would be included. The first is to
2 identify the stakeholders: patients, caregivers,
3 clinicians, communities, policymakers, and
4 institutions relevant to your proposed study. A
5 second relates to engagement. Describe at which
6 points in your proposed study stakeholders will be
7 engaged. Some people think engagement is a once-a-
8 year meeting, other people think it's weekly calls
9 or meetings. It's kind of important to know what
10 people have in mind.

11 In terms of engagement, describe how you
12 will engage stakeholders at each identified point
13 during the study and at its conclusion. We have
14 heard from some stakeholders, for example, who said
15 they felt terribly involved during a study,
16 obviously, not a PCORI study because we haven't
17 gotten to that point yet, but were surprised to
18 find out that they were not consulted and had no
19 input whatsoever into publication of papers, for
20 example.

21 And the fourth area here talks about a
22 governance plan. How will you develop a plan for

1 the project that articulates specific role and
2 responsibilities for the research team, stakeholder
3 groups, and defines rules for decision-making,
4 especially in the context of different opinions.

5 Next slide, please. Which brings us to
6 contract management. Describe how conflicts true
7 and perceived will be managed. In terms of study
8 results, describe how you will convey study results
9 to stakeholders and to study participants. And in
10 terms of assessing, thinking about from the get-go
11 about barriers to effective dissemination and
12 uptake, please describe how you will assess
13 barriers and facilitators to incorporating the
14 results into practice beyond communicating the
15 study results. After all, in health care, we get
16 to learn over and over again that knowledge is
17 helpful, but it's necessary, but not sufficient the
18 actual skills.

19 I can know I need to take an inhaler. If
20 I don't know how to use an inhaler, I don't get the
21 benefit. Similarly, if we're funding studies that
22 would require fairly complicated changes in

1 practice or how health care is delivered, we think
2 it's very important that the team is thinking about
3 that from day one, when they get their check. So,
4 again, this will not be your last opportunity to
5 comment, but we wanted to get this in front of you
6 because we feel pretty urgent about getting
7 something like this, more specificity into these
8 initial announcements.

9 So, I will stop here, ask Sharon if she
10 wants to add anything, and, again, I want to be
11 respectful that the members of the Dissemination
12 Workgroup, given the timeline here, have not have a
13 chance to vet this yet, but we will be doing that
14 very shortly.

15 CHAIRMAN WASHINGTON: Anything to add?

16 DR. LEVINE: No, I don't. I think she did
17 a great job.

18 CHAIRMAN WASHINGTON: Okay.

19 DR. LEVINE: Thank you.

20 CHAIRMAN WASHINGTON: Please move to wrap-
21 up.

22 DR. KUNTZ: Sure. That's our last slide,

1 and, again, in respect of time here, I'll be very
2 brief.

3 I'm very excited and I know our PDC is
4 about the progress paid for the PPP so far. This
5 has been a learning process as we have moved along,
6 but we're making good progress, and I think the
7 Engagement staff has been fantastic.

8 I thought we had a great discussion early
9 on about the other issues that are important to
10 boil up, and that is how we value applications and
11 how we process public comments. I think it was a
12 really rich discussion. I'm also really excited on
13 behalf of PDC about getting the PFAs out. It looks
14 like we're on track for May 15th and we're really
15 incorporating some very complicated dynamics right
16 now, including the evolution, modifications of the
17 Research Agenda on National Priorities,
18 incorporation of public comments into something
19 that's going to basically still deliver in the
20 middle of May, which is great.

21 And I just think, final comment, I know
22 there are concerns about going through some of

1 these slides very quickly and I think we had to
2 have a process to get everybody's views on this.
3 But, in general, I think we have to start to let go
4 of some of the operations associated with what
5 we're doing and get more trust into the staff who
6 are actually trying to deal with the processes
7 going forward.

8 There are many ways to skin a cat.
9 There's no question about it. We have a very, very
10 talented staff here who have done a good job in
11 really making the trains run on time and getting
12 these processes moving. So, I think it's important
13 for us to understand how we're going to evolve our
14 role over time to deal with the bigger issues of
15 the Board and Methodology Committee and start to
16 really handoff these process programs to our staff
17 going forward. And with that, I'll conclude my
18 comments.

19 CHAIRMAN WASHINGTON: Thank you, Rick, and
20 to other members of the committee who presented and
21 thanks to the entire group for just a Herculean
22 effort. It's a quite a bit here, which is one of

1 the reasons where is such stimulating discussion
2 and we didn't get to complete the discussion.

3 We're going to move into the public
4 comment period, but I would like to ask Harlan
5 Weisman and others who might have questions to
6 begin to just think about formulating them because
7 just looking at the list, we're probably going to
8 have some time, Rick, and if you don't mind, I'd
9 like to come back to it when we finish the public
10 comment period. Not that we will exhaust all your
11 questions, but at least maybe we can move the ball
12 a little further down the field and pick it up at
13 another stage. Not today, but in terms of some
14 Board deliberations.

15 Okay. We're -- [off microphone] -- moving
16 into the public comment period and we have five
17 individuals that have signed up at this point, and
18 so, I'm going to turn this over to Richard for you
19 to introduce the program and the presenters.

20 MR. SCHMITZ: Thank you, Dr. Washington.
21 I want to start by reminding those participating by
22 webcast that there's a teleconference number that

1 you can dial into if you would like to provide
2 comment and that is provided on the website. We
3 will hear first today from individuals who are in-
4 person and then we will check to see to see if
5 there is anyone by teleconference who wants to
6 provide comment. I want to remind everyone that
7 individuals are asked to limit their remarks to
8 three minutes. We'll use the standing microphone
9 for the public comments. If there's anyone that
10 has a disability that would like to provide comment
11 where they're sitting, we will bring a handheld
12 mike to you upon request. Any written testimony
13 should be submitted to PCORI by e-mail at
14 info@PCORI.org.

15 The first commenter today is Larry Kimmel
16 of Hopewell Cancer Support.

17 MR. KIMMEL: Good morning.

18 CHAIRMAN WASHINGTON: Good morning.

19 MR. KIMMEL: I'm Larry Kimmel and I'm here
20 on behalf of Hopewell Cancer Support, a Baltimore-
21 based non-profit, whose mission is to create a
22 community for all people with cancer, their

1 families, friends, that encourages an exchange of
2 information, the development of support systems,
3 and hopefully in a setting of hope.

4 I want to thank you for allowing me to
5 speak before you today and I hope that my comments
6 on behalf of Hopewell can further your efforts,
7 which is obviously very important, very open, and
8 considerate of all the stakeholders who are
9 involved in this.

10 I am and have been closely connected to
11 Hopewell almost since it was started. I'm a
12 retired educator and have known Hopewell from
13 different vantage points over time. I'm a two-time
14 cancer survivor, colon cancer and prostate cancer,
15 thus, a participant at Hopewell and also as a
16 volunteer for a lot of Hopewell initiatives and
17 events.

18 In looking at PCORI's priorities, we were
19 as an institution particularly interested in
20 priority three, supporting shared decision-making
21 between patients and their providers.

22 Since 1993, more than 9,000 individuals

1 have accounted for more than 90,000 visits to
2 Hopewell, where through varied programs, lead all
3 by certified social workers, people with cancer in
4 their families learn about excess treatment for,
5 cope with, recover from, and live with cancer.
6 Though people who have cancer have opportunities
7 every time they visit Hopewell to learn from each
8 other, there is a program there called House Call
9 Educational Series, and this is when health care
10 professionals, largely oncology physicians, will
11 come and interface with patients, participants at
12 Hopewell over a period of time, and since January
13 of 2010, we've had well over 100 professionals
14 participate in this program.

15 And the long and the short of it is that
16 this changes the whole character of decision-making
17 for participants and also for the professionals who
18 come and participate in Hopewell. It's a wonderful
19 collegial kind of experience and it really does for
20 Hopewell patients, if you want to call them that,
21 they become participants in the process of making
22 decisions and knowing where it is that they would

1 like to go and be.

2 And we feel this model is one that offers
3 really a lot of hope for the individuals, both
4 physicians, the professionals, and also the
5 participants, it opens up that kind of a dialogue
6 that's really critical and it ensures, we think,
7 shared decision-making in the progress of
8 participants. So, we think we have something
9 working and we wanted you to know about it and we
10 wish you well in your major project. Thank you
11 very much.

12 CHAIRMAN WASHINGTON: Okay. Thank you,
13 Mr. Kimmel.

14 MR. SCHMITZ: Our second commenter is Tony
15 Coelho, Partnership to Improve Patient Care.

16 MR. COELHO: Hi, I'm Tony Coelho and the
17 chairman of the Partnership to Improve Patient
18 Care, also known as PIPC. I'm pleased to hear
19 today that PCORI is striving to identify a
20 transparent, open process. What is most important
21 to us is that PCORI is responsive to the
22 stakeholder input you receive particularly from

1 patients. We are hopeful that the process you are
2 articulating today will meet that goal. I think
3 you all know that PIPC has concerns with the
4 Board's draft Priorities and Research Agenda, which
5 I'll touch on in my comments.

6 PCORI was created to be different and when
7 I say different, I don't just mean that researchers
8 have to check a box showing plans to collaborate
9 with patients in their funding applications to
10 PCORI that seems to reflect your bottom-up approach
11 to selecting research questions.

12 The statute envisioned a process that is
13 guided by and responsive to stakeholders with you
14 as a stakeholder Board bringing the views and
15 concerns of your representative group. The statute
16 specifically authorized additional resources to
17 support the patient representatives on the Board as
18 well as the expert advisory panels to assist in
19 identifying research priorities and the Research
20 Agenda. These elements make PCORI fundamentally
21 different because the priorities and subsequent
22 agenda are to be developed in this stakeholder

1 dialogue. On that note, PIPC appreciated that the
2 Board held its recent stakeholder dialogue in
3 Washington, a process we hope you will continue in
4 the future.

5 I want to reiterate the concern that broad
6 priorities in Research Agenda topics undermine the
7 ability to meaningfully provide input. PCORI seems
8 worried about focusing its research in one area
9 versus another for fear that it would offend those
10 left out of its research. I want to remind you
11 that at some point you'll have to make those tough
12 decisions because at some point, you'll have to
13 choose a specific research question. If you have a
14 transparent process for working with stakeholders
15 to come up with those questions, your final
16 decisions will be trusted and accepted.
17 Alternatively, if PCORI leaves a specific question
18 for the research community to come up with and uses
19 a closed-door review process for selecting
20 questions to fund, your credibility could well be
21 lost.

22 I would reiterate the comments made by

1 Marc Boutin from the National Health Council about
2 the need for a clear and predictable timeline that
3 stakeholders can rely on to plan their engagement
4 with PCORI. I understand that Shawn Bishop, who
5 played a lead role in drafting your authorizing
6 statute also provided comments and noted that the
7 importance of holding events like your stakeholder
8 dialogue before you come out with the draft
9 priorities and agenda so that you can get the
10 specificity as a board. A transparent, predictable
11 process will ensure you get the input you want and
12 will make PCORI's work credible to patients and
13 their providers. I believe that you all have the
14 best intentions for PCORI and I can appreciate that
15 a diverse stakeholder Board, such as yourselves, is
16 going to struggle as you build this operation.

17 PIPC stands ready to assist you in any way
18 we can, and our members look forward to
19 participating in the process articulated by PCORI
20 to identify research priorities and a Research
21 Agenda. I want to congratulate your new staff and
22 let them know that we look forward to looking

1 closely with them in this endeavor, and, as always,
2 I thank you for your important work.

3 CHAIRMAN WASHINGTON: Okay, thank you, Mr.
4 Coelho.

5 MR. SCHMITZ: Yes, our third public
6 comment is Paul Zimmet of Parkinson's Disease
7 Foundation.

8 DR. ZIMMET: Hi, I'm Dr. Paul Zimmet. I'm
9 a person with Parkinson's Disease and a health care
10 provider, and a dentist.

11 Through my profession as a member of the
12 Board of Dentistry and the Board of Health Care
13 Professionals for the Commonwealth of Virginia, I'm
14 also a husband, father, and a grandfather. I've
15 lived as a patient with chronic, debilitating,
16 neurological disease, a member of the health care
17 community, and a government appointee, which
18 provides me with a unique perspective of looking at
19 PCORI and what it's trying to achieve.

20 Last Monday, I had the opportunity to
21 attend the all-day national meeting in Washington,
22 D.C. Prior to attending the meeting, I studied the

1 mission of this organization and reviewed the Draft
2 National Research Priorities, and after doing this,
3 I'd like to offer two points of commentary, both of
4 which center on the issue of clarity.

5 First, it's not clear to me as to what
6 PCORI is doing and how it intends to go about doing
7 it. Sure, I can give you definitions of stated
8 objectives, but what is lacking is explicit
9 language on the process of how PCORI is going to do
10 this work and clarity on how it's going to happen.
11 For example, is PCORI going to first conduct
12 analysis of all the existing studies on patient-
13 centered outcomes, use this in developing initial
14 consensus and to look to funding these studies that
15 add value to the existing body of knowledge and
16 guidance to health care providers? I don't know.

17 Second, it's been made clear to me that
18 PCORI will remain patient-centered. The
19 organization has been struggling since its
20 inception on how to both defines, as well as, plans
21 to lead in the area of patient involvement. A good
22 first step is to be sure the differences between

1 patient-centered and patient involvement is clearly
2 understood and articulated and incorporated in all
3 of PCORI's work.

4 As you're well aware to date, patient-
5 centered research has been developed and conducted
6 without authentically engaging patients in the
7 research process. For PCORI to be a true leader in
8 the area of patient-centered research, it must
9 include patients on all levels of the process.
10 This means turning to groups and individuals that
11 have taken the lead in this area, such as the
12 Parkinson's Disease Group Foundation, PDF's
13 Advocates and Research Program, now in their fifth
14 year. For over 130 PDF research advocates like
15 myself from across the nation bringing our unique
16 perspective and insights, people touched with
17 Parkinson's in the researching process. We ensure
18 the Parkinson's communities have a say in research
19 priorities and how these priorities are
20 implemented, as well as educate our peers about the
21 importance of engaging in the research process.

22 A central piece of the program is multi-

1 day learning institute and I'm sure a PCORI
2 representative would be welcome to attend one of
3 these trainings, one of which starts Wednesday in
4 Atlanta.

5 Last Monday, most of those representing
6 the patient voice were representatives from
7 specific disease organizations and only a very few
8 were actual patients. I'm not saying there's no
9 place for these organizations, just the patient
10 involvement means going directly to the source.
11 Patients need to be involved in the process,
12 whatever the process is and whatever the process is
13 along the continuum. Patient involvement brings an
14 important perspective that only someone who
15 actually has it and knows it can understand.
16 Patient involvement brings some real-world
17 clarities to what PCORI is trying to do. The
18 patient would help greatly inform an explanation
19 into what exactly is going on. Thank you.

20 CHAIRMAN WASHINGTON: Okay. Thank you,
21 Dr. Zimmet.

22 MR. SCHMITZ: Brian Lyles, People's

1 Community Health Centers.

2 MR. LYLES: Good morning. I'd like to
3 join all of the other Baltimore-based organizations
4 in welcoming you to Baltimore. I represent
5 People's Community Health Centers, which is based
6 here in Baltimore.

7 We are a network of eight community health
8 center sites with a 40-year-history of having a
9 holistic approach to patients and people providing
10 quality primary care to a largely uninsured and
11 underinsured population as part of our mission
12 since the late 1960s. People's Community Health
13 Centers began as a very people-centered grassroots
14 effort in an era when many free clinics were
15 started and, today, we're still here. We are now a
16 federally-qualified community health center, but
17 with the same mission, serving over 16,000 patients
18 annually throughout our locations in Baltimore City
19 and northern Anne Arundel County, regardless of
20 their ability to pay.

21 In fact, we provide more uninsured
22 patients with primary health care than any other

1 institution in the State of Maryland. We'd like
2 you to know that community-based organizations like
3 ours represent an opportunity to interact with
4 professionals who work with special populations and
5 real-life concerns on a daily basis. We know our
6 community of patients, dedicated staff,
7 institutional partners combined with our years of
8 hands-on experience and people-centered health care
9 could play in a valuable role in PCORI-sponsored
10 research projects and we look forward to the
11 opportunity to work with you not only to find
12 solutions, but to help in this early stage in
13 generating the questions that need answers
14 regarding the delivery of services, workforce
15 development issues, reimbursements, and cost
16 management that, again, we deal with on a daily
17 basis. Thank you.

18 CHAIRMAN WASHINGTON: Thank you, Mr.
19 Lyles.

20 MR. SCHMITZ: That's all of the
21 preregistered commenters for the 11:00 a.m. period.
22 So, I wanted to check with the teleconference

1 operator, Debbie, to see if there's anyone on the
2 phone who wants to provide comment.

3 OPERATOR: There are no comments in the
4 cue.

5 MR. SCHMITZ: All right. Dr. Washington,
6 would you like to see if there are others in the
7 room who would like to provide comment at this
8 time?

9 CHAIRMAN WASHINGTON: Yes. Yes, please.

10 MR. COHEN: Yes, thank you. My name is
11 Perry Cohen, and I've talked to you before. So,
12 I'll skip the introductions.

13 But I wanted to talk a little bit about
14 the clinical research infrastructure, which I know
15 you must have thought of this, but nobody mentioned
16 it, so, I'll mention it. The Office of the
17 National Coordinator for Health Information
18 Technology is doing a lot of work in that area.
19 So, interoperable data exchange standards and the
20 like and including -- but these are mostly
21 organized on a regional basis with a major medical
22 center as a core. And I would like to put in a

1 pitch for also considering the patient and
2 scientific point of view which would organize the
3 whole data system, the whole national data system
4 along a specialty disease-oriented focus, which has
5 a lot of advantages. Not only does all the science
6 and the professions organize that way already, we
7 also have the patient advocacy groups and you need
8 the specialization to use the specialization for
9 developing new treatments and scientific
10 innovation.

11 So, Carolyn Clancy asked me to write up
12 some of the comments that I gave on Monday, which I
13 will do, and I wanted to add one more point, and
14 that is on the grant announcements that you
15 considered, on review, the pilot grants, have you
16 considered if you have a lot of meritorious
17 proposals, which I expect you will have out of 800
18 that have been submitted, maybe more than 40, if
19 it's an area of strategic importance that you could
20 add money to the pot to pick up those strategic --
21 so we don't have to wait for another grant process
22 and take into consideration the people who are

1 writing these grants. It's not easy.

2 So, that's my comment. Thank you.

3 CHAIRMAN WASHINGTON: Thank you, Mr.
4 Cohen.

5 MS. WILLIAMS: Good morning, my name is
6 Chris Williams and I appreciate the opportunity to
7 provide public testimony today. I'm here as a
8 patient with Chronic Fatigue Syndrome and as a
9 board member of the CFIDS Association of America,
10 whose mission is to make CFS widely understood,
11 diagnosable, curable, and preventable.

12 I spent 30 years in the federal government
13 in health policy and health services research,
14 including a few years at AHRQ. In August of 2008,
15 I had a sudden onset of flu-like symptoms that
16 never went away. After seven frustrating months of
17 having doctors telling me they didn't know what
18 wrong with me or I wasn't tired enough to have CFS,
19 I finally found a physician with expertise in CFS,
20 who determined that I had seven of the eight
21 symptoms that is established by the CDC.
22 My illness significantly affected my personal and

1 professional lives. I was no longer able to travel
2 for business, needed to work at home on a regular
3 basis, and really had no ability to do after-work
4 activities. I was relieved to be able to retire
5 from the government in June of 2011.

6 The CDC estimates that as many as one
7 million people in the U.S. have CFS, yet most
8 researchers believe that only 20 percent of
9 patients are diagnosed. In the U.S., CFS results
10 in \$9 billion in lost productivity and \$15 billion
11 in direct medical costs annually. The average
12 duration of illness is five years, but if not
13 diagnosed within two years, chances of recovery are
14 low. Twenty-five percent of patients are on Social
15 Security disability, and many are ill for decades.
16 The toll and costs of CFS to individuals, families,
17 and society is profound.

18 The CFIDS Association is focused on
19 research and has established a bio bank and
20 research institute Without Walls, a virtual network
21 of CFS researchers, some funded through our
22 organization.

1 We are working to find a biomarker and
2 effective treatments for this debilitating illness.
3 Yet, there is much more that needs to be done. We
4 believe that PCORI can make an important investment
5 in two of our National Priorities by working with
6 the CFS patient and provider communities.

7 First, improving health care systems. CFS
8 patients are chronically ill. This is a complex
9 illness that affects multiple systems of the body.
10 It is critical that care for patients is
11 coordinated across primary care providers,
12 specialists, and allied healthcare professionals
13 who may treat the same patient for different
14 manifestations of the illness. Education of
15 providers must be part of this improved healthcare
16 system.

17 Second, communications and dissemination.
18 These patients and families want to and must be
19 part of their own treatment plans if they're going
20 to improve. Working with CFS patients and families
21 could serve as a model for engagement with other
22 patients with chronic illnesses.

1 In both of these areas, lessons learned
2 with the CFS patient and provider communities can
3 be applied to other chronically ill patient
4 populations. Thank you and we look forward to
5 working with you.

6 CHAIRMAN WASHINGTON: Thank you, Ms.
7 Williams.

8 MR. SCHMITZ: That's everyone that has
9 indicated they would like to provide comment.

10 CHAIRMAN WASHINGTON: I'd like to thank
11 all of our presenters for taking the time to join
12 us today and also to share your thoughtful and
13 quite helpful comments. We continue to highly
14 value them and we are working to incorporate your
15 perspectives and your voices into all of our work
16 across the spectrum. Particularly of research,
17 but, ultimately in our work that's designed to
18 improve decision-making in the care setting. So,
19 thank you for participating.

20 It's now 11:30 and I realized that we've
21 had a long morning with no break, and so, we are
22 scheduled right now for a 15-minute break. I don't

1 see where we're going to have another time to come
2 back to this on the agenda, but what I want to ask,
3 are there other Board members besides Harlan who at
4 this point have concerns because I take a
5 presentation like that to mean this is the
6 direction that the group is proposing to go and our
7 general protocol has been it's a general green
8 light, proceed, and we'll incorporate suggestions,
9 comments, and we'll address concerns, and that's
10 the way I've interpreted this discussion, that
11 there is general agreement. But I want to be
12 responsive to Dr. Weisman's concerns and I want to
13 arrange for those to be heard, one being a public
14 setting, given the rest of the agenda, particularly
15 to the leadership with Rick and Joe and with me.
16 Unless we have some time later on today, I just
17 know that there are a host of really tough issues
18 that we're going to be dealing with, and I don't
19 see -- I thought maybe we'd have some time here.

20 So, are there others? And I'm not putting
21 you on the spot, Harlan, but I'm trying to
22 identify. Okay, so. Okay.

1 MS. HOLE-CURRY: Leah Hole-Curry, Board
2 member.

3 Does that mean we're not coming back to
4 Steve's suggestion about process? I think there
5 were two that were potentially specific concerns
6 about the presentation, but a broader
7 acknowledgement that we haven't done enough
8 internal prep for people to come and be able to
9 express their concerns.

10 CHAIRMAN WASHINGTON: Yes, okay.

11 DR. WEISMAN: My comment is more or less
12 like Leah's. To me, it's less a set of questions
13 that I'd like to have answered this morning than to
14 really get clarity where we're delegating as a
15 board and where we're participating in terms of
16 decision-making because one of the rationales for
17 the Board is that we're a diverse group with
18 diverse experiences and perspectives and that the
19 constructive discussion and debates that we have
20 adds value to the process.

21 I have tremendous trust and respect,
22 admiration, and I genuinely like everyone on the

1 Board and on the Methodology Committee and the
2 staff and it's not a question of that, it's a
3 question of if we're being asked to consider and
4 vote or approve of something, I think me, as a
5 board member, I feel an obligation to the people I
6 represent, which is the American public, that I
7 understand enough of the issue at hand that I can
8 provide a vote or give a vote that has adequate
9 thought given to it, and it's not a reaction or
10 it's not just because I like somebody, I want to
11 vote for their ideas, it's because it requires
12 consideration.

13 I absolutely agree with Rick that we have
14 to delegate operational responsibilities to our
15 staff and to our working groups and to our
16 committees certainly on the tactical issues, but we
17 talked about some things today that are
18 fundamentally about who we are or how we're going
19 to project who we are going to be and visibly,
20 publicly, and those are things around how we
21 respond to feedback and how we incorporate feedback
22 and, you know, the openness by which we operate.

1 When it involves that kind of setting strategic
2 direction or it involves philosophical stances, my
3 own view is that that isn't something that the
4 Board delegates, but that's something that the
5 Board considers and in considering it, it has to go
6 beyond the 12 point PowerPoint.

7 Speaking for myself, that's my own
8 feeling. How we do that, whether it's more in-
9 depth briefing, I don't know, but I don't feel that
10 on some of these issues, which are of such
11 importance -- and I want to say one other thing, I
12 really am impressed with the work that the PDC and
13 other working teams have done on these
14 presentations. I'm not saying there's anything
15 wrong in it, I'm just saying I don't fully
16 comprehend it, understand it, and it's of such
17 import that I feel like I need to know more. I'll
18 just stop there.

19 CHAIRMAN WASHINGTON: Leah, do you want
20 to add anything because I want to comment on
21 process. No.

22 Well, we have a process has been working.

1 The aberration here is that we don't have enough
2 time on this particular topic. So, we have a
3 process. The process has worked up until this
4 moment.

5 So, you're raising the question now about
6 how do we deal with situations where there is a
7 topic where a board member or multiple Board
8 members feel that we need more discussion, and I
9 think the question becomes: Do we need more
10 discussion in the public setting because, Harlan,
11 it's my impression that if we voted -- I mean, I've
12 learned to read the group. The overwhelming
13 majority would say proceed, but we now are
14 addressing the question of how do we address your
15 additional concerns and needs at this point?

16 DR. WEISMAN: By the way, if you took a
17 vote, I would vote yes, too, but I would do it with
18 the reservations that I've expressed.

19 CHAIRMAN WASHINGTON: Okay. Okay, so,
20 just by process, I'm saying we don't need a new
21 process, we need a modification that says in
22 situations where there seems to be overwhelming

1 support for a proposal to move forward, but we
2 haven't allowed sufficient time for a discussion
3 from the perspective of a board member or multiple
4 Board members, what should that next step be?

5 Mr. Lipstein, do you have the answer for
6 me?

7 VICE CHAIRMAN LIPSTEIN: I do. And it's a
8 practical answer. We are going to be working
9 concurrently over the next few months on five
10 different PCORI funding announcements in each of
11 our priority areas and it's going to involve an
12 incredible amount of work that were we to do all
13 that work in public session together, we would be
14 meeting continuously from now until May. So, what
15 we have to do is divide up the workload and then
16 the way I'm approaching this is as we divide up the
17 workload, there's one of those five public funding
18 announcements that I would like to work on
19 personally and I will devote my energy to that
20 while I will have to have confidence and faith and
21 trust in my fellow Board members and Methodology
22 Committee members to work in the other four

1 priority areas.

2 When we get together in May, we're going
3 to combine our work effort, but it's the only way
4 that we can make progress in a meaningful way in a
5 short amount of time and as some of my Board
6 members know, and I'm looking around the room, and
7 some of you, you want us to accelerate our pace of
8 work, not slow it down. So, we're going to have to
9 divide up the workload and figure out a way to
10 really have confidence in each other's work
11 products. And I think that that's why I would be
12 expressing the same concerns that Dr. Weisman is,
13 but I realize that I have to devote my energies to
14 the areas that I think my stakeholder group will
15 find the most important.

16 DR. WEISMAN: I think we're abrogating
17 some of our responsibility as Board members. The
18 PFA -- the National Priorities and the Research
19 Agenda are the two biggest things right in front of
20 us and there is no thing in May for that, that's a
21 done deal, and if I'm being asked to approve it, I
22 just feel like I don't have -- and I'm not saying

1 it has to be a board discussion, but maybe there
2 has to be more meat or material that if I have
3 specific questions, I can e-mail it to Rick or
4 somebody else, but I just feel like the PowerPoints
5 and the speed by which we went through it and it's
6 of some importance, this is going to say who we
7 are. I don't see how my working on a committee
8 solves that problem. Personal opinion again.

9 CHAIRMAN WASHINGTON: Okay. Well, my
10 proposal is, is that the modification be if there
11 is a board member or a set of Board members who
12 don't feel like they've adequately been able to
13 express themselves that they be provided an
14 opportunity to have a meeting, whether it's by
15 phone or in-person with me, with Joe, and whoever
16 is the program head or leader of that specific
17 area. And so, that's my proposal because I do
18 understand the process question that you're asking
19 far beyond the specifics of it.

20 DR. WEISMAN: Thank you.

21 CHAIRMAN WASHINGTON: So, I'd like some
22 comments on that as a process proposal.

1 DR. DOUMA: I always like it when you open
2 up to us being able to call and talk to you. It's
3 always been elucidating. I would suggest though
4 that minimize or decreasing the amount of phone
5 calls that we could look at two things that are
6 just process variables, that is, perhaps, have more
7 information prior to a board meeting. The decks
8 are really talking points versus explanations and
9 with those explanations, if a committee could add
10 what are you actually looking for the Board to do?
11 Is there a vote? Is there an agreement? What is
12 it you're looking for us to do?

13 And the other thing, I'd please request
14 that we get these a longer timeframe before the
15 Board. I mean, I was on travel the last two weeks
16 and I'm just catching up with stuff. So, and
17 that's a challenge a lot of us have, I think.

18 CHAIRMAN WASHINGTON: Any comments on the
19 proposal -- [off microphone]? Joe Selby.

20 DR. SELBY: A couple of things. I just
21 want to say that this process of repairing the
22 funding announcements is going to be a very

1 concentrated process and I think we will, as we
2 sink our teeth into it, have and find opportunities
3 to go buy it with Board members, but one thing, and
4 you'll also recall that these funding announcements
5 are likely to like fairly broad because they'll be
6 roughly consistent with our Research Agenda.

7 So, it isn't like we're going to be making
8 explicit decisions, but one thing I want to draw
9 everyone's attention to because I think this is a
10 way for Board members to have input is that the
11 funding announcements will call for proposals that
12 align with our Research Agenda, but the funding
13 announcements are also likely to have a set of
14 exemplary questions, which in no way do they define
15 the scope of what we're going to fund, but they are
16 meant to jog people's thinking and they're meant to
17 reflect some of the kinds of ideas that we think
18 are important.

19 So, I think that in particular as a multi-
20 stakeholder Board, you getting to the folks that
21 are putting these PFAs together, your ideas were
22 example questions. No special considerations, just

1 they would be in the PFA and they would remind
2 reviewers of the kinds of things under each
3 priority that would be of interest. So, that's one
4 very specific way, Harlan, for Board members to
5 have input.

6 CHAIRMAN WASHINGTON: Okay, but, again, in
7 this case, there's a more general question that's
8 on the table and I have a proposal. Specifics
9 aside because even with preparation, even with
10 materials being sent in advance, we could still be
11 in this same situation where because you -- well, I
12 don't want to pick on you, but because you were
13 away for two weeks and you arrive, you feel like
14 you don't have enough information to make the
15 decision and unless I hear otherwise, the proposal
16 is going to be, given that we have a limited amount
17 of time in public session, that we will -- the only
18 modifications that we will arrange for that Board
19 member or group of Board members to have some
20 meeting or session I would say with me or with
21 Steve.

22 That'll minimize my efforts along with Joe

1 and the particular programmatic leader. And I
2 don't think we need to write that, Mr. Barnett,
3 anywhere, but that's what we're agreeing on as
4 procedure.

5 And so, in this case, I certainly
6 registered from Harlan that he would like to have
7 such a session.

8 Leah, you are on the PDC. Would you still
9 like in, this particular case to --

10 MS. HOLE-CURRY: Perhaps, that's
11 illustrative of how fast we're all working that
12 even members on a committee who do regularly
13 participate don't always fully get each of the
14 components.

15 CHAIRMAN WASHINGTON: Great, okay. So,
16 would you like to include it in this particular
17 [off microphone] --

18 MS. HOLE-CURRY: Please.

19 CHAIRMAN WASHINGTON: Okay. Well, Rick we
20 are wrapping up the morning on your last words.

21 DR. KUNTZ: Well, first of all, I'm very
22 sensitive to all the comments that were made here,

1 and I think it is a time issue. I think we're
2 moving at breakneck speed, a lot of decisions being
3 made, and we're constrained by the time we meet
4 together.

5 I just want to point out that we do have
6 really regular PDC meetings and that is a great
7 opportunity for anybody to be engaged on a regular
8 basis. So, there are a lot of opportunities to
9 join in and we have really scheduled, we've got
10 some tight meetings coming up in the future. So,
11 we're looking for ways that we can find time to
12 meet together, that's one vehicle.

13 CHAIRMAN WASHINGTON: Okay, last word from
14 Douma.

15 DR. DOUMA: Yes, a quick follow-up on
16 requests. It would be really nice to have a simple
17 place that we could all go to find out where, when,
18 and how to contact or call into the meetings,
19 whether it's PDC or otherwise. And, also, it'd be
20 great, sometime soon, to have a list of staff and
21 perhaps some of the questions would be addressed to
22 a staff person, but, at this point, other than

1 sending an e-mail that I guess what it is. I don't
2 have like a staff directory and that would be
3 helpful, as well.

4 CHAIRMAN WASHINGTON: Okay. This has been
5 a terrific discussion this morning, very engaging,
6 and I think very useful for all of us. And, so,
7 thank you. We are going to take a 15-minute break
8 and resume at Noon. We're going to stay with that
9 plan and we'll count on Carrie and the group to
10 make it happen when we return.

11 [Recess.]

12 CHAIRMAN WASHINGTON: Welcome back
13 everyone to the next session of the Board of
14 Governors meeting for the Patient-Centered Outcomes
15 Research Institute. And next on the agenda is the
16 report from the Administration and Finance
17 Committee, which is chaired by Mr. Kerry Barnett.

18 MR. BARNETT: Mr. Chair, the best thing
19 about this committee report is that it is going to
20 be an easy one for me, because I don't have to do
21 any of the heavy lifting. I'm going to turn to
22 Larry Becker and he's going to present some

1 information and an action item relating to the
2 Standing Committee on Conflicts of Interests, that
3 he's been working with very closely and will come
4 up to the table and talk a little bit about the
5 current audit process. Just give the Board a quick
6 update as well as the substance of some
7 conversations with the GAO and their oversight
8 activities. And then, it will be back to Larry to
9 talk, to sort of kick-off that discussion about
10 kind of, big picture cash flow issues and exactly
11 how we are going to approach that, which is
12 particularly important given all of the activity
13 that we've just been hearing about, because very,
14 very soon we're going to have to attach it in time
15 for those funding announcements -- we're going to
16 have to begin to attach specific dollar amounts to
17 them. And we just want to make sure that we have a
18 pretty clear understanding of what our cash flow
19 strategy is in that regard.

20 So, with that I will turn it over to
21 Larry.

22 MR. BECKER: Thank you very much. This is

1 Larry Becker, a member of the Board.

2 So, at our last meeting we talked about
3 the structure of the Standing Committee on
4 Conflicts of Interest. You already approved the
5 membership on that committee of Sherine and Bob and
6 myself. And over the last, roughly two months
7 since our last meeting, we've been working
8 diligently trying to fill the other four slots on
9 the committee with 75 percent success, by the way
10 in doing that. We are still looking for the member
11 of the committee that would represent the media
12 perspective.

13 As we do this, we have found three
14 members; an ethicist and two consumer members of
15 the committee. We've also found a law firm that
16 would counsel us, but not be a specific member of
17 the committee, just to advise the committee. And
18 so, what I wanted to do is just briefly present to
19 you the folks that we had found and agreed to
20 serve.

21 Bernie Lo, from UCSF, has very graciously
22 agreed. Joe had a long conversation with him. I

1 did as well. He's agreed to participate and I
2 remember in our very first meeting when we set up
3 the ad hoc committee, his name came up from
4 multiple people around the table as a potential
5 participant. So he's very graciously agreed to
6 participate. In your package, by the way, you've
7 got his CV and I stopped counting at 200
8 publications. So he has done a fair amount of work
9 in this area.

10 The second person for your consideration
11 is a gentleman by the name of Art Levin. Art, by
12 the way, you might recall participated in our New
13 York meeting. He came to the meeting and he also
14 came to the stakeholder roundtable that evening.
15 And Art, as you can see, has spent considerable
16 time in both in the area of consumers. He's worked
17 with NQF on quality measures, he's worked with the
18 NCQA on performance measures, and so, you also have
19 a resume for Art in your package, and he, too, has
20 agreed to serve.

21 The third person who has agreed to
22 participate is Annette Bar-Cohen. She is in the

1 Washington, D.C. area. She's helped, as I
2 understand, has been very gracious with her help
3 around getting some of the members for the --
4 Christine's gone, but members for the groups that
5 looked at the grants themselves, to get patient
6 consumers that would participate on those groups.
7 And, she was very thankful to be asked. She was
8 very cautious, very careful about thinking about in
9 terms of time commitment, because she's got a fair
10 number of things on her plate. But, again, an
11 individual that we think can represent the consumer
12 population. And, again, I don't think it's in your
13 package, her CV, but we will get that to you. That
14 came in, I think, Friday night.

15 And Gail, Gail Shearer has been immensely
16 helping in vetting through all these people and
17 getting all of these people, and we're together
18 trying to find somebody who might help us find that
19 fourth or seventh member of the committee in the
20 media area.

21 We've asked several people, and in fact,
22 to do this and we've been turned down, I believe

1 three times now. And so, I'll give you an example.
2 Many of you might know Milt Freudenheim, was
3 somebody that we talked to. He's retired, except
4 that he's on contract for the New York Times to
5 right some pieces and he felt that would be a
6 conflict of interest, and so, it's sort of -- it's
7 been particularly difficult and what I'm hoping is
8 that by the time we get to our first meeting we
9 would, in fact, be able to find an individual and
10 we have to figure out a way to get this Board to
11 approve that seventh member once we have identified
12 them.

13 Yes, go ahead.

14 DR. SIGAL: Ellen Sigal, the Board. Just
15 a quick question. The process that you went
16 through, because I don't know if you asked other
17 Board members for recommendations, but just the
18 process your committee went through to select
19 people for this.

20 MR. BECKER: So, I went to the staff to
21 get names and maybe I should have gone out to
22 everybody with a letter to say, "Give me whatever

1 names you can come up with." I didn't do that, so
2 that's on me. But, I guess, from my perspective,
3 we put this out there and I would have hoped
4 people, if they had thoughts they would have come
5 after the last meeting.

6 CHAIRMAN WASHINGTON: Okay. I see a few
7 hands. Levine.

8 DR. LEVINE: Just Ellen -- Gene, you did
9 make a request at the Board meeting that if anyone
10 had names or suggestions --

11 UNIDENTIFIED SPEAKER: At the last Board
12 meeting?

13 DR. LEVINE: Yes, suggestions to forward
14 them and several of us did.

15 MR. BECKER: Allen, did you want -- okay.
16 And then finally, so we've gotten a letter from
17 Harris Beach.

18 We went out and we looked for law firms.
19 We looked for university lawyers, we looked at
20 Washington lawyers. We got turned down by
21 Covington, for example, and I asked Covington if
22 they could come up with another Washington law firm

1 and they looked around and felt that there were all
2 kinds of conflicts, so we did come up with Harris
3 Beach and the individual Karl Sleight. Whose part
4 of that counseled the New York State Ethics
5 Commission, and he's been involved with various
6 private sectors, as well as, public sector
7 counseling in the area of ethics both legislative
8 and non-legislative in this State of New York.

9 MR. BARNETT: Just to clarify on that
10 Larry.

11 MR. BECKER: Yes.

12 MR. BARNETT: He would be counsel to the
13 committee as opposed to being a member of the
14 committee?

15 MR. BECKER: Yes. Correct. Because, oh,
16 by the way when I had the conversation with
17 Covington, they advised me that we probably
18 wouldn't find somebody who would sit literally on
19 the committee for professional reasons.

20 Yes. Francis.

21 DR. COLLINS: Sorry, could you clarify one
22 more time and my apologies if it's already been

1 stated many times to the Board, the exact charge to
2 this committee, what are they asked to do? Is
3 there a written out, sort of, charge that they are
4 addressing?

5 MR. BECKER: Yes, so at the last meeting
6 we put forth a series of guidelines around conflict
7 of interest and what the committee charge would be
8 relative to answering questions relative to who is
9 eligible for funding, because there are a series of
10 situations where there might be conflicts of people
11 who would apply, for example, your wife. Could
12 your wife be part of that and how far down the
13 train and how far away would somebody have to be to
14 be eligible?

15 So, we went through that and that's in the
16 guidelines for the committee.

17 DR. COLLINS: And would this also apply to
18 when the Board is in conflict in making decisions,
19 because we are talking about an opportunity in the
20 not too distant future where the Board is going to
21 be asked to sign off on the first set of pilot
22 Projects. How will that play out in terms of

1 whether or not there are conflicts that need to be
2 acknowledged and disclosed and potentially result
3 in people leaving the room during various
4 conversations? Is that all part of this
5 committee's role? How are going to handle that
6 question?

7 MR. BECKER: And Kerry chime in here, but
8 I think that's a separate process. I think that's
9 in the law itself about recusal for the Board,
10 itself.

11 MR. BARNETT: That's correct. We have in
12 place a conflict of interest policy that applies to
13 the Board, but the recognition after having some
14 number of kind of working group meetings, there's a
15 recognition that there's still going to be some
16 kind of thorny policy issues that would need a
17 broader, deeper set of analysis, and even tact, and
18 in some cases, a Court of Appeals, almost. And
19 that was the purpose of creating this separate
20 committee.

21 VICE CHAIRMAN LIPSTEIN: But -- Gene, I
22 think Francis is raising a point here, that we need

1 to come back to and I'll tell you what it is, is
2 that for example, in the final 40, we haven't
3 scrubbed those 40 for how many that I submitted
4 personally. And so, we haven't a process in place
5 that says we're going to scrub the current Pilot
6 Projects process for conflict of interest, so if
7 there are any that are identified, they get
8 referred to the proper committee.

9 MR. BECKER: Right.

10 VICE CHAIRMAN LIPSTEIN: Or included in
11 the proper process. So, I think what Francis is
12 saying, we have to do some of this in real-time.

13 Is that what you were suggesting?

14 DR. COLLINS: You got it.

15 VICE CHAIRMAN LIPSTEIN: Okay. I'm hoping
16 I won 10 of the top 40, but you know, we haven't
17 scrubbed the process yet.

18 CHAIRMAN WASHINGTON: Okay. But let's
19 also keep in mind that first of all, as Board
20 members we are prohibited from applying, one. Two,
21 we were also prohibited from providing any
22 consultation or advice in any form to any member in

1 your institution. Now, I know Francis asked a
2 slightly different question, but let's keep in mind
3 that we have honored some process up until now and
4 the implicit assumption Francis, at least, I'm glad
5 you're raising it, was that when we got to that
6 point where you felt it was more of an honor system
7 that there was a conflict of interest and you
8 needed to be recused, then you would do that.

9 We may want a specific process that says,
10 "If you're institution has a grant that's in this
11 slate, then you have to step out while the rest of
12 the Board members -- ," there are others that do
13 that. So it's a good point, but I just want to --
14 we have thought about it up until now, but we
15 should come back at some point to the specific
16 question that Francis is raising.

17 MR. BARNETT: And Gene, I think
18 immediately prior to that Board discussion, where
19 we start to make some of these decisions, we'll
20 spend some time reviewing what those conflict of
21 interest requirements are, so if people need to
22 make declarations of conflict of recuse themselves

1 they can do so at that time.

2 CHAIRMAN WASHINGTON: And going back to
3 your original question Francis, I would see that we
4 could consult this group about their opinions,
5 about this kind of question and issue, given that
6 there's some real expertise on it.

7 MR. BECKER: Right.

8 CHAIRMAN WASHINGTON: In terms of ethics,
9 as well as, conflicts of interest.

10 MR. BECKER: And there were two provisions
11 in the guidelines that we approved, and one of them
12 was that the PIs had to sign that they weren't
13 getting advice from a board member and a board
14 member wasn't going to be a beneficiary of whatever
15 the grant was. And then, the second thing was what
16 you just said and we left the spot open so that
17 some question to be determined, could be referred
18 to this committee.

19 So, with that I would -- Allen.

20 DR. DOUMA: Just to follow-up. I think I
21 understand pretty well when we're recusing
22 ourselves, when we have some direct relationship to

1 a research project and funding. My question is, if
2 for example, I'm in the infrastructure building
3 business, which I'm not. But if I were, should I
4 recuse myself when we're voting on the percentage
5 of our funds that go to infrastructure building?

6 MR. BARNETT: It's a good question Gene,
7 if I could just suggest that we probably don't have
8 time to start to discuss specific ethics questions
9 that are going to come up in the context of these
10 grants. We probably have to instead, focus on the
11 action item before, but we can take that offline
12 and sort of talk it though if you'd like, but I'm
13 just a little worried that we're going to wind up
14 in a 20 minute discussion with what ifs.

15 DR. DOUMA: That's fine with me.

16 CHAIRMAN WASHINGTON: Okay. So, Steve
17 your card is down now.

18 VICE CHAIRMAN LIPSTEIN: Oh, I'm sorry.

19 MR. BECKER: Okay, so I guess I would now
20 ask for a motion to accept the nominees of Bernie
21 Lo, Arthur Levin and Annette Bar-Cohen as members
22 of the committee and Harris Beach as the counsel to

1 the committee.

2 DR. CLANCY: So moved.

3 MS. HUNT: Second.

4 CHAIRMAN WASHINGTON: It's been moved and
5 there's a second, any further comments?

6 [No response.]

7 CHAIRMAN WASHINGTON: All in favor?

8 [Chorus of ayes.]

9 CHAIRMAN WASHINGTON: All opposed?

10 [No response.]

11 CHAIRMAN WASHINGTON: Okay, so the motion
12 carries.

13 MR. BECKER: Thank you very much.

14 CHAIRMAN WASHINGTON: Yes, we have a
15 comment here from Carolyn Clancy.

16 DR. CLANCY: I want to make a very brief
17 comment to say, wow, I thought you did a fabulous
18 job. I made no suggestions whatsoever just in the
19 crush of time, but you couldn't have done better.

20 MR. BECKER: Thank you.

21 CHAIRMAN WASHINGTON: That's great.

22 Gabriel.

1 DR. GABRIEL: Sherine Gabriel, also a
2 member of this group. Just to comment, Allen's
3 question -- I think we have a pretty low bar for
4 referring questions of that sort in the conflict of
5 interest area to this committee. It's perhaps a
6 good example of the kind of question that should be
7 taken up.

8 CHAIRMAN WASHINGTON: Please carry on,
9 Kerry, Larry.

10 MR. BARNETT: If I may just make one
11 closing comment. The biggest challenge that we're
12 going to have with this committee and Larry and I
13 have already talked about this, is it is a
14 committee and it takes time to get people together
15 and so, the biggest concern is that it's going to
16 be difficult for this committee to be able to very
17 quickly spit out answers to specific questions.
18 Instead, I think there's going to have to be a more
19 thoughtful iterative process, but over time it will
20 result in sort of case law if you want to think of
21 it that way where we have a greater and developing,
22 and even, evolving understanding of how we're going

1 to operate. And I think this committee is just
2 going to play a critical role in that regard.

3 So if that could be the last word on that,
4 then we're going to turn to Anne and Anne is going
5 to talk just very briefly about the GAO compliance
6 process and where we are in the audit.

7 DR. BEAL: So this discussion is just an
8 update to inform the Board of our current status,
9 but as a reminder the GAO is responsible for both
10 financial and programmatic audit of PCORI. The
11 financial audit occurs on an annual basis, while
12 the programmatic audit occurs every five years.
13 And so, we are now in the middle of undergoing the
14 process of the financial audit.

15 And so, as part of that process we have
16 engaged an external auditing firm and sat down and
17 spoke with them, as well as, with GAO. And so,
18 what GAO is going to do is actually review the
19 process of the audit and not necessarily do a
20 direct audit of us. The other to note is that
21 since we really came into creation in September of
22 2010, what this means is the financial audit

1 process is going to cover all of 2011 plus that
2 little tail end of 2010 and then going forward it
3 will be on an annual basis.

4 And so, the report that needs to be
5 submitted by GAO needs to go in on April 1st. The
6 other thing that needs to be noted is that one of
7 the questions that we've had, which really relates
8 to the criteria by which we report with respect to
9 the audit is whether we are a governmental agency
10 or not and what it means with respect to whether we
11 need to adhere to A122, A133, et cetera. As we
12 know, we are an independent non-governmental agency
13 and so, have really asked for a very specific
14 clarification on that to see whether we really must
15 abide by some of these reporting requirements.

16 What we have decided internally, as an
17 organization because the early indications are, in
18 fact, that we will probably not have to adhere to
19 some of these reporting requirements, is that we
20 would still have in terms of our own processes and
21 reporting, essentially adopt the most stringent
22 criteria that are available, because there is a

1 little bit of ambiguity around that. But as I
2 said, the preliminary reports that we're getting
3 from some of our discussions with staff at the OMB
4 is that we probably will not have to adhere to some
5 of these, but it is still, I think internally,
6 we've made the decision that we will probably go
7 for the most conservative and stringent approach in
8 terms of our own accounting.

9 And so, this is just information about
10 McGladrey and Pullen who is the auditing firm that
11 is overseeing our process and the field work has
12 already begun. We are in the final stages of this
13 and the plan, currently, is for it to be completed
14 by March 12th, so that they can then get the
15 information that they need regarding our financial
16 audit over to the GAO and the GAO ultimately needs
17 to review all of those materials and then submit
18 them to Congress by April 1st. And so, our plan
19 was to give them at least two weeks' time to be
20 able to do this and we are definitely on target for
21 them.

22 And I think that is it.

1 CHAIRMAN WASHINGTON: Thank you Dr. Beal.

2 MR. BARNETT: And unless there are any
3 questions on that, we'll go back to --

4 DR. DOUMA: I have a question.

5 CHAIRMAN WASHINGTON: Yes.

6 DR. DOUMA: Actually, this time I'm on
7 this committee and in the committee there was a
8 discussion about concern, perhaps, about the March
9 12th to April 1st timeframe, and the question was
10 brought up as, what involvement of the Board and/or
11 the committee should take place during that three
12 week timeframe and do we have a process for that?

13 DR. BEAL: That is a good question. So,
14 we have been talking about that with Larry, because
15 the audit will have to come back to us and then,
16 we'll have to review it and so, I think we're going
17 to plan to have an off-cycle meeting in order to
18 undergo just that process.

19 DR. DOUMA: Do you think it is acceptable
20 for us to give the GAO the information we have on
21 March 12th with the provision that we haven't
22 approved it yet, but it will give them a little

1 jump on getting their evaluation done? Or do we
2 have to wait until we've actually finally approved
3 by the Board?

4 VICE CHAIRMAN LIPSTEIN: Allen, the
5 purpose of the audit is an independent point of
6 view, so the notion that we actually approve the
7 audit is not the right wording. In other words,
8 we'll see the audit, but the audit is an
9 independent audit. So, are you asking about just
10 review prior to submission or some kind of an
11 approval process at the Board level? Because the
12 Board is going to receive the audit, but we don't
13 approve it, it is what it is.

14 MR. BECKER: Well, I respectfully
15 disagree. And I believe that we have to approve
16 it, because once we approve it, it closes the
17 audit. And therefore, any events of materiality
18 that occur after that closing, goes to the next
19 audit cycle. Until we approve it and close it,
20 other things could enter into there and that could
21 create a problem for GAO or Carolyn's not sitting
22 here, because I know with NQF, we had exactly that

1 problem and we ended up with someone from the
2 government --

3 VICE CHAIRMAN LIPSTEIN: So you are
4 talking about an official endpoint to the audit?

5 MR. BECKER: Correct.

6 VICE CHAIRMAN LIPSTEIN: Okay. That's
7 okay. I just didn't want anybody to get the
8 impression that we would actually review, change
9 it, modify it and then sign off on it.

10 We're just talking about an endpoint to
11 the audit protocol.

12 MR. BECKER: Yes.

13 VICE CHAIRMAN LIPSTEIN: I understand.

14 MR. BARNETT: I think the word is "accept
15 the audit" as opposed to "approve the audit."

16 VICE CHAIRMAN LIPSTEIN: That's right.

17 DR. WEISMAN: You know, I've served on
18 boards before and boards do review the audits and
19 do vote to accept it or not. I mean, there are
20 things that can come up during an audit, and we,
21 the Board is responsible for the organization from
22 that formal sense and whether there are questions

1 that we have back to the auditors or other things,
2 those are things that happen. We want it to be an
3 independent process, but also something that we
4 accept.

5 MR. BARNETT: Let's put the issue to the
6 group. What we would certainly intend to do is
7 have the Finance and Audit Committee review the
8 audit in some detail and to the extent there's any
9 iterative process that needs to occur, whether it's
10 clarification or pushing back on anything or
11 anything of that sort, we would intend to do that.
12 And so, let me just ask the Chair and the rest of
13 the Board whether you want there to be an
14 additional step, which would be a formal vote to
15 accept the audit by the full Board prior to the --
16 what would it be Anne? Prior to the April 1st
17 timeframe or whether that could come after that.

18 CHAIRMAN WASHINGTON: Well, for the boards
19 that I'm on, the best practice would be that the
20 committee makes a recommendation to the Board to
21 accept the audit.

22 MR. BARNETT: Right.

1 CHAIRMAN WASHINGTON: In which case, I
2 think, we aspire to best practices that it should
3 come as a recommendation to the Board.

4 MR. BARNETT: Yeah, the only question
5 would be if you wanted it to come to the Board
6 prior to the April 1st submission, right Anne?

7 DR. BEAL: Mm-hmm.

8 MR. BARNETT: That's the magic date.

9 DR. DOUMA: Well, it's even more than
10 that. It's prior to the GAO saying this what we're
11 going to be looking at, because until -- do they
12 need our acceptance before they actually evaluate
13 the information?

14 VICE CHAIRMAN LIPSTEIN: Given the timing
15 here, I think we have to delegate this to the FAC
16 and they'll report out at our meeting in May, but
17 unless there is a member of the Board that thinks
18 that they wouldn't be comfortable with the FAC
19 reviewing and accepting this on our behalf.
20 Because, you know, April 1st is soon. Like three
21 weeks away.

22 DR. WEISMAN: Right.

1 CHAIRMAN WASHINGTON: Okay, there are two
2 questions. One is what our general policy might be
3 and we can always modify that in terms of
4 delegating the authority in this particular case
5 versus what it would be in this specific case and
6 you're proposing that in this specific case we
7 delegate the decision-making, officially, to the
8 FAC to essentially approve the audit.

9 VICE CHAIRMAN LIPSTEIN: Accept the audit.

10 CHAIRMAN WASHINGTON: Accept the audit,
11 right.

12 VICE CHAIRMAN LIPSTEIN: And the reason,
13 Gene, is that it's March 5th and you're telling me
14 that we've got an April 1st deadline.

15 CHAIRMAN WASHINGTON: I'm certainly
16 comfortable with that. Others? We have a proposal
17 on the table, you know, since we don't have an
18 official policy yet one way or the other, I don't
19 think we need to vote, but so -- [off microphone] -
20 - that we support in this case, that approval --
21 acceptance would be at the level of the FAC.

22 DR. DOUMA: And let's just check with the

1 GAO, that it's okay with them.

2 MR. BARNETT: Again, a friendly amendment,
3 with a subsequent report to the full Board. And in
4 the interim, if upon reviewing the audit, if there
5 were any particular issues that we felt was
6 sufficiently of concern we would then take that to
7 the Chair and Vice Chair and possibly to the full
8 Board for review if that seemed to warrant it in
9 the interim.

10 CHAIRMAN WASHINGTON: Okay. That's what
11 we'd like for the minutes to reflect as the
12 decision in this case.

13 VICE CHAIRMAN LIPSTEIN: [Off microphone.]

14 CHAIRMAN WASHINGTON: No, we don't feel
15 like we need one for that because it's not an
16 official policy yet.

17 MR. BARNETT: Anne, do you have anything
18 further on that?

19 DR. BEAL: No, I was just looking for when
20 our next meeting is, but I know we have gone
21 through the calendar to execute this.

22 MR. BARNETT: Okay. So then Mr. Chair,

1 we'll go back to Larry on a completely different
2 subject relating to our kind of broad strategy
3 around cash flow, given the grant cycles coming up.

4 MR. BECKER: Thank you. So, as Kerry
5 mentioned, managing the cash flow. So, as we've
6 seen this morning as we talked about the grants,
7 there are going to be a series of grants over a
8 prescribed period of time and those grants will be
9 of varying lengths. So some of them could be a
10 year, some could be two years, some could be three
11 years, some could be five years. And there will be
12 multiple grants, as we've seen this year. We've
13 had two grant cycles and we might have three
14 funding cycles in a year, and so -- and that
15 process as we've experienced, takes some time to
16 work through.

17 And so, considering those strategies and
18 how that cycle works, funding those multiyear
19 grants there are varies cash flow that occur in
20 those grants. Now, let me just say that the
21 numbers you see on this slide are purely
22 hypothetical for the purposes of teeing up the

1 conversation that we want to have. And that is,
2 that some grants might pay 50 percent up front, 25
3 percent in the second year, and 25 percent in the
4 third year. It might be 25 percent up front, 40
5 percent and 40 percent on the back two years or
6 over five years. And so, with those kinds of
7 variables in the discussion and we look at our
8 funding, the money that we get from the Affordable
9 Care Act,

10 We'll get an amount of money. There will
11 be some amount of money that will go towards
12 operations, and again, just placeholders to get to
13 the math here to demonstrate the point, so don't
14 look at 20 percent or any of the other numbers as
15 numbers that are dyed in the wool and cast in
16 concrete. But in 2012 we might have \$90 million
17 that would go towards grants. And as I mentioned,
18 those go out in various amounts so 50 percent of
19 that might go out in year one.

20 So the question becomes, do we as an
21 organization, take a process that enables us to
22 spend \$90 million on just the grants that we grant

1 in the first year or do we take \$90 million and
2 grant twice as many. So in the 50 percent model,
3 right, you could have \$45 million of grants and you
4 could hold the \$45 million for those grants that
5 get paid in the next year, or the alternative is to
6 say as this example, where you could put out \$90
7 million of grants knowing that you would then fund
8 the balance of those grants with dollars that came
9 in future years.

10 So, you could get more started more
11 quickly under this scenario versus a scenario that
12 said just the \$45 million in 23 and 23 and then
13 when we get to 2013 we have the next amount of
14 money that starts the next set of grants.

15 So, if I have ably communicated that, what
16 we really want to do is to have a discussion among
17 the Board about which approach we ought to take.
18 So, should we plan to make grant commitments ahead
19 of funds available and let's just start there and
20 let me stop and clarify anything that I said or
21 simply dive into the conversation?

22 CHAIRMAN WASHINGTON: Could you go back

1 two slides? Please.

2 MR. BECKER: I can. I think I can.

3 CHAIRMAN WASHINGTON: And then we'll start
4 recognizing. Let's identify this for now as Option
5 A. Option A is the multiyear cash flow.

6 MR. BECKER: Right.

7 CHAIRMAN WASHINGTON: Okay. And then
8 Option B is annual cash flow.

9 MR. BECKER: Right.

10 CHAIRMAN WASHINGTON: So, we're talking
11 Option A versus Option B for the discussion
12 purposes.

13 MR. BECKER: Right. Thank you.

14 CHAIRMAN WASHINGTON: And we have Dr.
15 Clancy and then Kuntz and Collins.

16 DR. CLANCY: So, as Larry knows from
17 another conversation, I'm a huge fan of Option A.
18 We've got incredible opportunities ahead of us.
19 We've got a mandatory funding stream. We have some
20 people asking questions about why, perhaps, we
21 haven't funded more now. So I would be a huge fan
22 of that.

1 I would also point out that there is
2 potentially an unintended consequence of Option B,
3 which is that if I were a grantee under that option
4 I might actually try to frontload year one even if
5 I knew there was not an ice cube's chance -- I'll
6 stop there, of actually being able to spend all the
7 money in that year.

8 So, I think it will actually have a
9 negative reverberating effect, but that's all I
10 wanted to say was that many of the people whom we
11 are hoping will apply, the best and the brightest,
12 They're called that for a good reason and they will
13 figure that out rapidly.

14 CHAIRMAN WASHINGTON: Dr. Kuntz and then
15 Dr. Collins, then Norquist and Zwolak.

16 DR. KUNTZ: Well, Rick Kuntz here, member
17 of the Board. I'm glad we're bringing this up and
18 trying to understand what the parameters are for us
19 to be able to predict and I suggested earlier that
20 we start to have a communication, at least between
21 the PDC and the Finance Committee so that you can
22 ask what parameters we need to have in order to be

1 able to understand the grant parameters and try to
2 find this understanding. It may include things
3 like, what is the gating process going to be for
4 grants. I guess we assume it's going to be three
5 times per year. The other is going to be the award
6 sizes, are we going to prescribe them up front or
7 ask them in an RO-1 type scenario. And then, all
8 of those parameters we talked about.

9 And the other thing is, just from an
10 accounting perspective, I'm still a little bit
11 confused the statement of cash flows, is that going
12 to be the flow that goes into grants under a
13 statement of cash flows or is this going to be more
14 predictive under another accrual system? So, I'm
15 not quite sure what you mean when you talk about
16 cash flow specifically and my guess is what -- and
17 because we don't know how to allocate future
18 increases in revenues, you know, going forward so,
19 it's a minor accounting issue, but I'm not quite
20 sure the right word is the statement of cash flows
21 for what goes into the funding part.

22 DR. COLLINS: So this is very much, oh

1 yeah. Francis Collins, Board member.

2 This is relevant to something that Rick
3 just said. If you are going to go with Option A
4 and I agree with Carolyn, that makes a lot of sense
5 in terms of trying to get our Research Agenda up
6 and going as vigorously as possible. I think one
7 consequence of that is then when you make a grant
8 award, you're probably making it year-by-year,
9 because otherwise you are potentially at-risk of
10 making a commitment that you don't have. But
11 that's okay, because don't' we also expect our
12 awardees to provide something in the way of an
13 Annual Report of Progress and they should not
14 assume that just because you got a three-year
15 award, you're actually going to get all three years
16 if it turns out that you don't do any work. So
17 this would pretty much then, put you into a
18 scenario where you give a grant award that says,
19 "Predicated upon the availability of funds, here is
20 what you will get on year one, two, and three. But
21 we will expect to see a progress report from you
22 before we make that second and third year."

1 And again, it's based on the availability
2 of funds because we can't entirely predict the
3 future.

4 CHAIRMAN WASHINGTON: Norquist and then
5 Krumholz and Zwolak.

6 DR. NORQUIST: Yeah, Gray Norquist, on the
7 Board. I agree with Francis. I think you have to
8 go this route if you're going to get things out and
9 if we're going to the number of funding
10 announcements, there's no way if we don't do it
11 this way. But, you're absolutely right because the
12 key issue here is all grantees, and most people
13 know this, it's always availability of funds. We
14 could lose it all and then the whole thing would be
15 down and then what we are doing.

16 But the other good thing about it, is it
17 really puts the grantee on the spot because it
18 makes them do something at the end of their first
19 year because if you frontload and you kind of
20 guarantee them, then we're going to have all of
21 this, kind of, you know, stick approach with them
22 and I think it's very easy to say, "After the first

1 year availability of funds and progress and what
2 you've told us what you were going to do at this
3 point." Because often when I was at NIH, we would
4 have these large clinical trials and we'd get stuck
5 at the second year and we'd go, "Dang. Nothing's
6 happened. Do we keep putting money into this or do
7 we stop and cut bait at this point?"

8 And some of the rules have changed about
9 that. If you don't get a certain amount of
10 participation now, you cut. So I don't think this
11 is unusual that people wouldn't be aware of this
12 and I think what's much more important right now is
13 to get this money out and start funding things and
14 the only way it's going to work is with Option A.

15 CHAIRMAN WASHINGTON: Okay, Krumholz and
16 then Zwolak.

17 DR. KRUMHOLZ: Okay, I just want to make
18 the point that even if we had the funds in the
19 bank, that doesn't mean that we would necessarily
20 give it the next year without satisfactory
21 progress, and so, I don't think it precludes that.
22 I do think by the way of the satisfactory progress,

1 again, we should build in that we should be
2 interviewing the patients at an annual basis to see
3 about how they understand and are participating
4 actively in the research itself and that should be
5 part of the evaluation. Not just a report that is
6 submitted, but actually talking to the people who
7 in the application were intended to be part of that
8 process to guarantee that.

9 I just want to strongly come out with
10 everyone else in saying I think we should go with
11 the first, and in part, I think, because we keep
12 hearing about the possibility that people may want
13 to undermine our funding. Our funding is fairly
14 firmly embedded, but there's not guarantee for it
15 going forward. The best guarantee that we can have
16 is to fund a large number of important
17 consequential research projects that people are
18 excited about and that if we stop early, will lead
19 to the nonperformance of that production of
20 knowledge, which people are actually anticipating.
21 So if we've done a really great job funding the
22 right projects and getting people to anticipate

1 their results, and that money is predicated on our
2 continued existence rather than money we had in the
3 bank that we can just dispense with, it will ensure
4 our continued -- it puts pressure on us. I just
5 wanted to say that.

6 You're talking about the pressure on the
7 grantees, I want to put the pressure on us to make
8 those wise investments and then have people in a
9 position to say they want us to be able to finish
10 funding those projects because they are so
11 important. That's where the pressure should lie.

12 CHAIRMAN WASHINGTON: Zwolak.

13 DR. ZWOLAK: Bob Zwolak, Board member.
14 I'm also a very strong supporter of Option A for
15 all the reasons stated, but in addition when you
16 think about the timeline of doing the research,
17 even with Option A, the dollars aren't really going
18 to start to flow out the door very much until 2013,
19 2014. A year or two to do the research, analyze
20 it, and get it published, we're looking way down
21 the road at 2015, 2016 before our most impactful
22 studies are published. And if we go in slow mode

1 it's going to be 2017 or 2018 before we get much
2 important out there. So, I think it's almost
3 imperative to do Option A.

4 CHAIRMAN WASHINGTON: Mr. Becker.

5 MR. BECKER: I think we got our answer.

6 CHAIRMAN WASHINGTON: Okay, now do we need
7 a motion?

8 MS. HUNT: So moved.

9 DR. CLANCY: Second.

10 MR. BECKER: All in favor of Option A?

11 CHAIRMAN WASHINGTON: Any further
12 discussion? All in favor?

13 [Chorus of ayes.]

14 MR. BECKER: Wait a minute. Francis has a
15 comment.

16 DR. COLLINS: Just to be sure what the
17 motion is, we're going with Option A, but are we
18 also specifying this notion that the first year is
19 half of the total or is that still a topic for some
20 discussion?

21 MR. BECKER: Yes, that's a topic for
22 discussion.

1 DR. COLLINS: Okay, good.

2 MR. BARNETT: I think that will vary with
3 the specific grant.

4 MR. BECKER: Right.

5 DR. COLLINS: Got it, I just wanted to
6 clarify that.

7 MR. BECKER: Right. With the notion that
8 Gray and Harlan had about requirements after years
9 one, two or how many every year, each year.

10 CHAIRMAN WASHINGTON: Douma and then Gray.

11 DR. DOUMA: This is really a question
12 because of my ignorance in this field, but it's
13 also important that we have very well-defined
14 processes that when somebody reports and what they
15 report in the first year before they get the second
16 year. Clearly, we don't want to have a break in
17 funding and so, I don't know what the standard
18 protocol is so we need to have -- particularly
19 there are going to be a lot of people, perhaps like
20 me who don't know what the standard protocol is and
21 we need to be very precise so we don't have
22 somebody whose funding breaks down for 90 days and

1 the research project goes away because they had to
2 fire everybody.

3 CHAIRMAN WASHINGTON: Got you. Gray.

4 DR. NORQUIST: Yeah, I was just going to
5 add on that, what that means is we need some
6 scientific staff and some Grants Management people
7 in place very quickly because the Board is not
8 going to do that. That's going to be an individual
9 thing where somebody is going to be following that,
10 so we better start as soon as we can to get those
11 scientists and Grants Management people on, that's
12 going to be key here.

13 [Off microphone discussion.]

14 CHAIRMAN WASHINGTON: The last word to
15 Hunt and then we're going to turn it back over to
16 you Kerry.

17 MR. BECKER: We've got the motion on the
18 floor, I think.

19 CHAIRMAN WASHINGTON: Okay.

20 MR. BECKER: So we have Gail comment on
21 that.

22 CHAIRMAN WASHINGTON: Are you commenting

1 on Option A versus Option B or are you moving onto
2 something else?

3 MS. HUNT: No.

4 CHAIRMAN WASHINGTON: Okay. So there's a
5 motion, moved, second, all in favor?

6 [Chorus of ayes.]

7 CHAIRMAN WASHINGTON: Okay. All opposed?

8 [No response.]

9 CHAIRMAN WASHINGTON: okay, you have your
10 answer.

11 MR. BECKER: Okay, thank you very much.

12 MR. BARNETT: Gene, just a quick follow up
13 on that vote. I just want to make it clear that
14 the next step now, as Larry indicated, those
15 numbers are there for illustrative purposes only,
16 so the next step is working with Anne and Joe and
17 the Finance staff and PDC to begin to create a
18 proposed cash flow model that has some real numbers
19 to it. And it is on that basis that we will start
20 to get a sense of the size of the various grants
21 programs in which year.

22 CHAIRMAN WASHINGTON: Hunt and then we're

1 going to ask you, Barnett, to wrap up the report.

2 MS. HUNT: I just --

3 CHAIRMAN WASHINGTON: Go for it.

4 MS. HUNT: It wasn't on this. It goes
5 back to something that Harlan said. I just wanted
6 to close the loop on this question of asking,
7 calling up some of the patients to find out how
8 much they really were involved during the process
9 of the actual grant. Who is going to be doing the
10 calling? Is that the staff that are calling up or
11 are you sort of doing -- expect people to do a
12 self-report, like we called patients and they said
13 this. So, I just wanted to be clear on that.

14 DR. KRUMHOLZ: Well, of course, this is
15 something that will be considered and Judy is going
16 to, I think, play an important role in leading.
17 But it would have to be a standardized assessment
18 that we felt was reproducible. It would have to be
19 authentic and genuine with respect to trying to
20 ensure that we are reaching out. It should not be
21 considered, like don't tell on your investigators
22 or anything.

1 It would need to be welcoming and
2 collegial and in a way just to try to learn from
3 the experience that they've had, but also inform us
4 about whether they're authentically involved in the
5 research and can they discuss fluently what their
6 talking about in language that they can use, but
7 really is someone gets on the phone and clearly
8 doesn't even really understand what's going on
9 or -- we've got -- probably not that you're going
10 to say, "Okay, we're not funding you." It will
11 elicit another call and a discussion and some
12 assessment. This is part of what's new about us, I
13 think, if we're going to try and pursue this kind
14 of work. We're going to have to develop these
15 kinds of methods, as well. And maybe, Sherine and
16 your group can think about, how do we do this in a
17 reliable, reproducible way and how can it inform us
18 going forward?

19 So, Gail, I really don't have the answers
20 about it except that I want to cite it as an
21 aspiration, that if this is what we want to do,
22 then we want to make it clear this is another facet

1 and people will be evaluated on the substance and
2 content and progress traditionally, but also on
3 their success on incorporating the various members
4 of the team in the work that they are doing.

5 CHAIRMAN WASHINGTON: Okay, excellent
6 suggestion. Mr. Barnett, you're going to wrap up.

7 MR. BARNETT: Yeah, I think that concludes
8 our report.

9 [Laughter.]

10 CHAIRMAN WASHINGTON: Okay. Well, thanks
11 again to all the members of your committee and
12 particularly to Larry for carrying the ball on two
13 of these major issues. You have direction and
14 support to move forward.

15 MR. BECKER: Thank you.

16 CHAIRMAN WASHINGTON: That wraps up our
17 discussion for the morning having completed reports
18 from the executive Director and well as from the
19 program Development Committee and now the Finance
20 Administration Committee.

21 So, we're going to take a break and we
22 will return at 1:45, and we will start precisely at

1 1:45 where in the afternoon we will hear the report
2 from the Methodology Committee and we'll hear a
3 report from what we call COEC, Communications,
4 Outreach and Engagement Committee, and we'll also
5 have another public session this afternoon.

6 Enjoy lunch. See you at 1:45.

7 [Whereupon, a luncheon recess was taken.]

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

[1:45 PM]

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3 VICE CHAIRMAN LIPSTEIN: So on behalf of
4 Dr. Washington and the Board of Governors, perfect
5 timing Gene, we've started up our afternoon session
6 of the Board of Governors meeting. And as you can
7 see by our agenda, we are devoting the majority of
8 our afternoon to a report of all the activities of
9 the Methodology Committee. So, Dr. Washington,
10 unless you have any other information that you
11 would like to share, I was going to turn it over to
12 Dr. Gabriel.

13 CHAIRMAN WASHINGTON: That sounds great.
14 Please continue.

15 VICE CHAIRMAN LIPSTEIN: Sherine, you're
16 on.

17 DR. GABRIEL: Okay, I don't have the slide
18 changer, but -- if somebody has it, pass it down.

19 Okay, well thank you very much Steve and
20 Gene. I'm happy to present an overview of the
21 activities of the Methodology Committee. Some of
22 my colleagues are just coming in from lunch here,

1 but Jean is here as always and that's great and
2 David's here.

3 Let me just go over to my next slide. So
4 this is the agenda. I'm going to give you a sense
5 of what we're doing, the last steps to finalize out
6 Methodology Report that is due to this Board on May
7 the 10th. Again, remind you of some of the work
8 that we've done and we are doing to ensure that
9 there's communication and engagement between the
10 Board and the MC. I'll share with you some initial
11 discussions that we've had on the MC, as to what
12 happens after May 10th, like Dave was saying this
13 morning. So what are we going to be doing on May
14 11th after we submit the report? So, I'll give you
15 a sense of our discussions towards that and then,
16 David Flum, who has led a group of both Methodology
17 Committee members and Board members to finalize the
18 PCOR definition.

19 Just with respect to that, you'll all
20 recall -- I don't remember how many months ago when
21 we first put forward the initial PCOR definition,
22 we asked for a vote of this Board to endorse it as

1 a working definition pending the public comment
2 period and the edits we anticipated making and
3 follow up of that. All of that's now complete, so
4 we will be looking for a vote of this Board to
5 endorse the PCOR definition, now with the public
6 comments all in place.

7 Okay. So, I'll do the first three parts
8 and then David maybe will change places or you can
9 come up here and lead us through the last couple of
10 slides.

11 So finalizing the report. Many of you, I
12 think, participated in -- I think it was the third
13 teleconference, the Methodology Committee with the
14 Board led by Mark Helfand began to give you a sense
15 of what the report would look like and there's an
16 outline of the report that was distributed at the
17 time. A briefing document that I was not allowed
18 to reattach with the packet for the Board today
19 because I was told you already had it, so that's a
20 good thing if anybody wants to take another look at
21 that, you're welcome to it.

22 But this is what the report will look

1 like. Chapter 1 will be an introduction. There
2 will be, "What is PCOR?" And that will be based on
3 our definition. We'll hear a little bit more about
4 that later. Why do we need to do this and
5 obviously talk about responsiveness to the statute.
6 Who is the audience for the report? What are the
7 goals? What is the report trying to do? What it
8 cannot do in this first version of the report?

9 And then, Chapter 2 will talk about the
10 standards. So this is the methodologic standards
11 for PCOR. What are standards? What are the
12 categories for rating potential standards? And the
13 process that we are beginning to go through to
14 select those standards.

15 All of Chapter 3 is really dedicated to
16 patient-centeredness. How does it apply in
17 research prioritization? Identifying questions,
18 design of studies. The whole PICOTS set of
19 categories: population, intervention, comparator,
20 outcome, timeframe, setting. So, we're talking
21 about instilling the patient viewpoint in patient-
22 centeredness in every stage of the process and what

1 do we really mean by that and then,
2 dissemination/implementation. This is something
3 that a fair bit yesterday evening. We have begun
4 to work on that really, under Brian's leadership
5 and collaboration with Sharon Levine's team and the
6 Communication Dissemination Group headed by
7 Carolyn, and we have a plan for how
8 dissemination/implementation is going to roll out
9 following the report and you will hear more about
10 that in subsequent meetings. What methods make
11 research more patient-centered and how is patient-
12 centeredness balanced? How do we balance the whole
13 notion of patient-centeredness with feasibility and
14 other stakeholder concerns? So a lot of that will
15 be in Chapter 3. Some of it has already been
16 written.

17 Chapters 4 to I don't know how many we'll
18 end up having in here. We're waiting -- of course,
19 we have 15 contractors that are busily working on
20 their research product and we'll be getting those
21 in a matter of weeks. You will be seeing some of
22 the early results of that if you stay on for our

1 workshops, the results of some of it anyway.

2 And, that's really what those chapters
3 will contain; the standards for selecting,
4 designing, and conducting research. And then we'll
5 have a final chapter just talking about future
6 plans. What the public comment period will be
7 like. Again, this is really where the
8 dissemination and implementation plans will be
9 outlined. And then, our plans for updating the
10 report, we've got -- we've tried -- I'm not sure
11 we've done a terribly great job of expectation
12 management. This is really the first -- this is
13 really version one. We're going to have, I think,
14 a great version one, but all of the answers to all
15 of the questions regarding methodologic standards
16 for PCOR will not be answered in this first report.
17 And so, our plans for updating will be a key part.

18 So, that's basically what it will look
19 like. Again, for those of you who participated in
20 the last call, you've got to a sense of this, but
21 just to give you a visual of what a section might
22 look like, and again, we don't have a lot of the

1 content. The content that we can write we're well
2 on our way to writing it, but the pieces that are
3 being written by our contractors are still pending,
4 so none of this has been populated yet.

5 But this is just an example of what it
6 might look like. So a sample section: "Endorsed
7 Standards and Actions Related to Missing data."
8 Missing data is a big problem in research, in any
9 research regarding human health. And a little bit
10 of a background section, what the recommended
11 standards are based on what the contractors have
12 produced or what we have produced, and the
13 rationale for the standards. So, as I'll mention
14 in an upcoming slide, we have a process that we've
15 put in place once the standards are recommended by
16 the contractors or by others, for us to go through
17 them and vet them and actually vote on them in a
18 systematic process to put those forward that we
19 feel ought to be in our first report.

20 And then, some recommended action. So,
21 you know, we might encourage training in a certain
22 area or we might encourage dissemination of certain

1 software and so on. So, again, we're kind of
2 making this up, but just to give a sense of what
3 the chapter sections will look like.

4 This is just the report writing process
5 and I think you're familiar with many of these
6 time-points. So, we have the workshops in a day or
7 so, and again, we invite any of you to come and
8 observe to get a sense for what the material being
9 produced by the contractors is going to look like.
10 Shortly after the workshops are completed, our
11 Deloitte staff will be reviewing the materials.
12 Everything is going to be transcribed and is it
13 webcast or audio?

14 UNIDENTIFIED SPEAKER: Audio.

15 DR. GABRIEL: Audio. So at least
16 everything will be captured and we will provide a
17 summary, so for those of you who aren't able to
18 attend, you'll be able to take a look at a summary
19 of what went on and what the initial contractor
20 reports look. We will review a draft or summary of
21 these draft recommended standards. We'll begin to
22 do that in April and then we'll be looking for

1 input from the Board shortly after that on this
2 initial drafted report and then, of course, May
3 10th you will receive the final report and look for
4 input and approval for public comment by our Board
5 meeting May 22nd or something like that. I got
6 that right.

7 So, I'm going to go through these in a
8 little bit more detail, these four steps.

9 So the first phase involves the two
10 workshops as I mentioned where the findings of the
11 research groups that we contracted with will be
12 shared in order to facilitate our first report. We
13 will have 15 reports in total that will be
14 delivered to us in March that will outline findings
15 and recommendations from each research team and as
16 I mention, I think, before to this Board a couple
17 of times, it wasn't a matter of simply contracting
18 with these groups and sending them off and saying
19 come back in March and we'll look at the report,
20 but every work group the MC has been meeting with
21 these contractors by phone weekly or every other
22 week to just be sure that what they're producing

1 will really align with the needs of the report.

2 And so, they've been working very hard to
3 keep that on track.

4 The next step is really a consensus
5 process -- voting process and we've defined an
6 approach to select the standards and
7 recommendations for inclusion in the May report and
8 I didn't go through this in detail, but it's
9 basically three steps. The first and the largest
10 amount of work really still resides with the
11 working groups so the Patient-Centeredness Working
12 Group, the Research Methods Working Group, and so
13 on.

14 And they will screen the recommendations
15 that are coming from the contractors and really
16 have a deep discussion and reach internal consensus
17 on which recommendation coming from those reports
18 they're going to put forward as recommendations
19 that are sort of ready for prime time. These are
20 ready to be included in the May report. And we've
21 agreed to set a pretty high bar for those, so it
22 really has to meet all of our criteria to be

1 included. If it's incomplete in some way or
2 another, if more research needs to be done, or if
3 there are some questions about what has been done,
4 we will reserve those, we'll put those aside and
5 look at revamping them for version two.

6 So, we're trying to set a pretty high bar
7 so that the recommendations that do come through
8 really have met the highest standards.

9 So, the work groups will say, yes, it's
10 ready to move forward, no, it's not. The no's will
11 probably be -- will be set aside for inclusion --
12 consideration for inclusion in version two, and the
13 yeses will be submitted to what we call a pre-vote,
14 so then the whole committee -- first step was just
15 the work group, second still would be the whole
16 committee -- then will look at the standards and
17 we've created a standardized template where each
18 standard will be summarized in exactly the same
19 way, and then the full Methodology Committee will
20 conduct a pre-vote by e-mail.

21 Where we agree, those will go in the
22 report, where we don't agree, they will be put

1 aside for a discussion, and then we're going to
2 have a face-to-face meeting on April 3rd where
3 those recommendations from the working groups, from
4 the contractors, where there has been disagreement,
5 will be put to discussion, almost like a study
6 section format. We'll have maybe 15, 20 minutes
7 per standard. We'll review them and after that
8 discussion we'll come to consensus on what
9 standards are to be included in the first report
10 that you all will eventually see.

11 DR. WEISMAN: Sherine, could I ask you a
12 couple questions about the methods? The consensus
13 process you're following to get -- you used the
14 word consensus but you've also used the word vote.
15 Have you actually formalized what a consensus --
16 how you get to consensus? And is there a process
17 also whether some things are voted --

18 DR. GABRIEL: Right. So, that's a good
19 point. So, the first step is internal consensus
20 within the workgroup. So, that's essentially
21 unanimous. We want to be sure that everybody in
22 the workgroup agrees that these four or six or

1 eleven standards are ready to be moved forward.

2 When I said vote, we will consider
3 agreement two-thirds or more, agreement will be
4 considered a yes in our voting, so when we vote at
5 the end of the day, the Methodology Committee, if
6 two-thirds of us agree, we'll be putting it
7 forward.

8 And, again, putting it forward means we'll
9 be putting it in the final report that will get
10 reviewed by this group, but we just wanted to be
11 sure that we had enough of a vetting process before
12 you saw it that you could feel confident that it's
13 had a full review at the level of the workgroup and
14 at the level of the full committee.

15 DR. WEISMAN: And will you list the
16 candidates that don't -- the methods that don't
17 make it? Will they also be in the report?

18 DR. GABRIEL: Absolutely. You'll see it
19 all.

20 CHAIRMAN WASHINGTON: Douma?

21 DR. DOUMA: Just a little variation on
22 that. I was going to ask that, but also, will we

1 be seeing any recording of the deliberations, what
2 the concerns are, so we can look at those moving
3 forward? Not just us, but -- is that going to be
4 made public?

5 DR. GABRIEL: Yep. So, we will be, even
6 at the very first step when the working group comes
7 to internal consensus and puts forward their
8 recommendations, there will be a justification
9 attached to that and then at the later step, after
10 the April 3rd face-to-face meeting, we'll have a
11 written report there as well.

12 So, but very good comments. So, the next
13 two steps, and there are only four in total that I
14 wanted to go over, are, you know, drafting and the
15 revising of the reports. So, after we've all
16 agreed what needs to be in there in terms of
17 recommendations, we have a report writing team,
18 some of whom you've already met, but are interim
19 researchers and are writers.

20 We have four experienced report writers
21 that have really been brought on Board to help us
22 get the words together and develop the report, and

1 so once we're in agreement on what needs to be
2 there with respect to recommendations, they will
3 help us do that and this group has been meeting
4 already with us and with our Deloitte staff, so
5 they're pretty much up to speed.

6 And then May 10th, leading up to that,
7 we're going to be preparing it for your review and
8 approval and hopefully to be posted for public
9 comment shortly thereafter, I guess. It's
10 delivered to you on May 10th, May 22nd, that's when
11 you'll decide whether it's ready for Board approval
12 or for public comment.

13 So, those are kind of the last four steps
14 and I'll maybe just stop there, if there are any
15 other questions, and then I'll go on.

16 CHAIRMAN WASHINGTON: It's a good place to
17 pause. Collins?

18 DR. COLLINS: So, thanks. That's very
19 helpful. Sherine, can you just remind us in terms
20 of the audience, for the recommendations about
21 standards, what is the expectation about what the
22 investigator community will do once these have been

1 produced? And what are the expectations about how
2 PCORI will use those standards in terms of
3 reviewing grants or making other decisions about
4 how to spend our resources?

5 Does this all fit together somehow? And
6 how do you both make full advantage of the hard
7 work that's gone into this without having it become
8 a little bit too heavy handed and top down in terms
9 of squashing creativity?

10 DR. GABRIEL: Yeah. So, the statute
11 actually advises that these standards are to be
12 used in our review, so in the review of grants, as
13 we decide what gets funded and what doesn't get
14 funded, these standards ought to be looked at once
15 it's all approved, and so applications will be
16 judged based on the degree to which -- at least in
17 part, based on the degree to which they adhere to
18 the methodologic standards for PCOR as we've all
19 agreed to them.

20 So, in terms of what we're going to do
21 with them as an institute, that's one of the key
22 intersections between developing the standards and

1 then funding PCOR research, so that's one step.

2 And, you know, as I'll mention in the
3 beyond the report comments that I'll make a little
4 bit later, what we really hope, in sort of echoing
5 Dr. Washington, is that once these -- once we move
6 forward and really do develop standards that we're
7 all comfortable with, that they become adopted as
8 standards, not just a part of the review of PCORI,
9 but they're really adopted much more widely by the
10 broader scientific community as the way to do high
11 quality, high integrity research in this area. So,
12 that's where the dissemination piece comes in.

13 DR. COLLINS: Can I quickly follow up?
14 So, in circumstances where you have a grant
15 application that actually is proposing a new
16 approach to developing standards for something
17 like, say, missing data, which was one of the
18 examples you used --

19 DR. GABRIEL: Right.

20 DR. COLLINS: -- if you've already
21 established, well, here is the standard, does that
22 mean that grantee is no longer welcome?

1 DR. GABRIEL: No. That's why we've got a
2 priority five, and I think actually Joe mentioned
3 this this morning, one of the goals of the
4 Methodology Report is to understand what's known
5 with respect to PCOR methodology and understand
6 where there are gaps and where new research is
7 needed, and that gaps piece is going to drive what
8 we will propose for a methodologic Research Agenda
9 under your priority number five.

10 So, yeah, we've got to marry those two.

11 CHAIRMAN WASHINGTON: Sigal and then
12 Lipstein, is yours still up? Okay, Lipstein.

13 DR. SIGAL: So, Sherine, thank you very
14 much. It's a thoughtful presentation. So, my
15 question is a follow up on Francis' comment. So,
16 because we don't know exactly what we're going to
17 be studying and because we have complex work and
18 complex patient populations, is there enough
19 flexibility in these guidelines. So, as an
20 example, in our outreach last week we heard a lot
21 about mental illness, we heard a lot about
22 adherence, comorbid conditions, underserved

1 patients, rare disease. So, is there enough
2 flexibility built into this for the kind of studies
3 that we ultimately may do?

4 DR. GABRIEL: So, I mean, you bring up a
5 good point. I keep referring to standards because
6 that's what the statute -- the language of the
7 statute used, but when we talk about it internally,
8 we use words like guidance, and I think that's
9 probably a more reasonable approach. Based on
10 what's currently known, this is the best advice
11 that we can come up with in terms of
12 recommendations for doing a certain kind of
13 research.

14 But you're absolutely right, there has to
15 be some flexibility both for new research and for
16 the kinds of novel things that we hope to be
17 funding.

18 CHAIRMAN WASHINGTON: Lipstein.

19 VICE CHAIRMAN LIPSTEIN: Sherine, I guess
20 I have two questions. The first one is, when I
21 look at the outline that you presented earlier and
22 it talks about how you develop the standards,

1 patient-centeredness, standards for selecting,
2 designing and conducting research, future plans and
3 directions, and then I kind of ping that up against
4 our National Priorities. So, I'm wondering, for
5 example, would the Methodology Committee, either in
6 this first report or in subsequent reports, need to
7 identify, here are the standards that applied at,
8 say, comparative clinical effectiveness research,
9 priority number one? Priority number two is
10 patient-centered outcomes research -- different set
11 of standards, different set of guidelines. Number
12 three, dissemination research, different set of
13 guidelines. Number four, serving vulnerable
14 populations, eliminating disparities. And then,
15 ultimately, number five, you know, creating a
16 robust data infrastructure or developing PCOR
17 infrastructure.

18 So, question number one is, do the
19 standards go specific with the priorities? And I
20 guess -- and then coming back to a related question
21 is, when the Methodology Committee basically opines
22 and says, yes, there's missing data in every kind

1 of analysis we might do, but if you're missing data
2 elements A, B, and C, it's not going to be credible
3 outcomes research unless it's a complete data set.

4 So, those are my two questions.

5 DR. GABRIEL: So, the first question, the
6 answer is really yes and no. So, of course, we
7 started going down the Methodology Report
8 preparation path before the priorities were out, so
9 it wasn't like many things we do, we do things
10 concurrently that, you know, in the best of all
11 worlds should be done one after the other. So, the
12 report isn't written aligned with the five
13 priorities, but I'm willing to bet that there is
14 really good alignment anyway, it's just not -- it
15 may not be as obvious as if we'd had the time to do
16 one after the other.

17 But I'm quite certain that actually all
18 the elements that are in the priorities will be
19 addressed. I mean, obviously, most of it is CER.
20 Obviously, we are talking about the importance of
21 how to bring in vulnerable populations.

22 We mentioned this morning the work that's

1 underway to help understand the EHR issues and how
2 do we use EHR data more effectively for CER work,
3 and, you know, we're putting together this workshop
4 in July to understand what's been done, what's not
5 been done, and what makes sense, how would we move
6 forward in this area to build networks, what kind
7 of infrastructure makes sense given everything
8 that's already been done, what training might make
9 sense, what standards are needed.

10 And so we're doing all of the same things,
11 they're not in perfect alignment because they
12 didn't -- the sequence wasn't perfect, but I really
13 don't think it would be difficult to do that
14 crosswalk once we're completed.

15 CHAIRMAN WASHINGTON: Douma?

16 DR. DOUMA: Freda's ahead of me, by the
17 way.

18 CHAIRMAN WASHINGTON: Okay, Lewis-Hall.

19 DR. LEWIS-HALL: Freda Lewis-Hall, Board.
20 I just have one quick question, which is, in
21 noticing the public comment period that follows all
22 of this hard work, I was thinking, you know, this

1 report is inherently very technical and the
2 question is, what, if anything, do you think we
3 could do or what's planned for us to do that might
4 make it easier for, I guess, less technical people
5 to understand this and to be able to respond to it?

6 DR. GABRIEL: Yeah, well, it is going to
7 be technical, at least in part. You might
8 remember, or maybe you won't, but our original --
9 our vision was to begin with this audience, maybe,
10 and then move on to the scientific community, the
11 provider community, and the patient and the public,
12 and we had initially proposed, you know, once we've
13 got it all together, to create an interactive tool
14 that, depending on the audience, you would see the
15 material presented perhaps somewhat differently.

16 Now, we haven't done that work, but that's
17 still in the plans. I mean, it's technical but not
18 every consumer of the report needs to see all the
19 technical pieces. Every single one of our
20 recommendations is going to have relevance to
21 people, but it will have to be presented in a
22 different way.

1 Now, we haven't done the work yet of sort
2 of redefining the report based on the audience, but
3 we hope to be doing that.

4 DR. DOUMA: Gene?

5 CHAIRMAN WASHINGTON: Douma.

6 DR. DOUMA: Yeah, my comment statement is
7 actually from the same number four that Freda was
8 talking about. If you read it, it says that the
9 Methodology Report will be posted for public
10 comment. It sounds really passive to me. It
11 sounds not very -- perhaps not very effective
12 regardless of which audience we're trying to reach.
13 And what I would like to see here at some time this
14 written to say, "At this point we will implement
15 our distribution and dissemination plan for the
16 Methodology Report in order to get 10,000 comments
17 from various audiences" and really actually have
18 some goals, objectives, things we can strive for,
19 and if we're not reaching them, because it would be
20 some time period, that we have the ability to crank
21 up our marketing plan, so to speak, in order to
22 reach some significant goals.

1 Because if we only get feedback from 50
2 people or 100 people, then we have to call into
3 question the selectivity of those people makes it
4 invalid, almost, what they're saying because we
5 can't sum them up.

6 Anyway --

7 DR. GABRIEL: Good point. Before I go on,
8 I just -- maybe I could -- oh, I'm sorry.

9 CHAIRMAN WASHINGTON: Weisman had a
10 comment related?

11 DR. WEISMAN: Yeah, just a question. I
12 guess it is related. What about what happens after
13 Board approval? Is there plans to publish this as
14 a book? As a set of articles? Because in order,
15 you know, the classic approach in academia, of
16 course, would be to be able to cite something that
17 you're using and to have that kind of impact. What
18 has been the thoughts of the committee on that?

19 DR. GABRIEL: Well, that's a good
20 question. I'm not sure if we've actually talked
21 about that at length. I mean, we've obviously
22 talked about, you know, publishing bits and pieces

1 of it, but I can't tell you that we have a real
2 plan.

3 DR. WEISMAN: It is a scholarly piece of
4 work.

5 DR. GABRIEL: Yeah, and I think, you know,
6 part of our dissemination and implementation plan,
7 which, again, hasn't been fully fleshed out yet
8 because it's sort of a subsequent step, and you'll
9 hear more about it next meeting, will involve
10 publications, will involve participation in
11 conferences, will involve posting it, you know,
12 will involve other workgroups, but I can't tell you
13 that we have a publication strategy in place yet,
14 only that I take your point. This is something
15 that ought to happen.

16 And, you know, I was just going to say,
17 before I wrap this up, I just wanted to invite
18 other members to come, and Sharon-Lise, I know, has
19 a comment, but others as well.

20 CHAIRMAN WASHINGTON: Normand.

21 DR. NORMAND: Sharon-Lise Normand,
22 Methodology Committee member. So, just to follow

1 up on that, I think the other thing, I know the
2 other aspect that we're working on is this
3 translation tool, which is different from a
4 publication, but something that we are thinking a
5 lot about so that it reaches many different users,
6 and rather than thinking of the usual publication
7 type of article, not that we've ruled that out, but
8 we certainly have been thinking more about a
9 translation tool using very different formats and
10 getting it to people who would be unlikely to go
11 and read a book on standards or methodology, so
12 that's the one item I would --

13 DR. GABRIEL: Yes, thank you for bringing
14 that up. So, maybe if I could just invite other
15 members of the Methodology Committee to comment and
16 add to what we just said. Is that all right?

17 CHAIRMAN WASHINGTON: Sure.

18 DR. GABRIEL: Brian?

19 MR. MITTMAN: Just one quick comment in
20 response to Allen's note about comments. One of
21 the key strategies for the outreach in receiving
22 comments is to work with some of the professional

1 associations and in some ways delegate at least
2 some of the responsibility to them to reach out to
3 their members and perhaps collate comments, so I
4 think we've been in the process of actively
5 identifying the key stakeholder groups and the
6 representative groups so that we ensure that we're
7 in touch with them and that they're on Board and
8 will help us with that review process.

9 CHAIRMAN WASHINGTON: Okay? Please
10 continue.

11 DR. GABRIEL: So, the next couple of
12 slides really just speak to Board engagement. I'm
13 sorry this is such a messy slide. Next time we'll
14 have to think of something a little bit different,
15 because I'm sure there will be things added to it.

16 So, our goals with respect to engaging
17 with this group are to be as transparent as we
18 possibly can, to collaborate and to coordinate our
19 activities, and the stuff in the green boxes are
20 the new engagement activities since the last Board
21 meeting and the stuff not in the green boxes is
22 what I shared with you last time.

1 So, since we met last, we've also gained
2 the support of two committee members in kind of
3 framing the PFA, so I'm talking about things that
4 we're doing together. Gail, actually, prepares
5 these wonderful weekly status reports that she
6 shares with Joe and Anne, and it's really been a
7 nice way to sort of give the staff at the
8 leadership level an update of, here are the things
9 that we've been working on this week and it's
10 really been a good way to sort of keep tabs.

11 And all of this information, by the way,
12 once evidence is up, will be in a board site where
13 you can go and kind of check on, okay, what's the
14 Methodology Committee been doing this last week or
15 the week before that. We're, of course,
16 participating in the pilot selection process and
17 other activities. These teleconference calls that
18 we've had with Mark, under Mark Helfand's
19 leadership in his role as the Assimilation Group
20 chair, I think, have really helped by sharing with
21 the Board our interim thoughts on how the report's
22 coming together, what the outline looks like, and

1 as Sharon-Lise reminded me, this translation tool,
2 the statute requires us to produce a translation
3 table and we kind of see it as a translation tool
4 where an individual -- it could be an investigator,
5 it could be a patient -- at some point can look at
6 this tool and look at the kind of research that
7 they have a question about and then match that to
8 the kinds of methods and approaches that might be
9 advisable or less advisable and why, and that's
10 basically what the translation tool will look like.
11 And there are some in the literature, some examples
12 already in the literature.

13 And we're collaborating, as I've mentioned
14 a couple of times, and this is something Brian is
15 leading from the Methodology Committee, working
16 with Board members to develop a dissemination plan,
17 and he's mentioned a little bit about that.

18 So, we're continuing to do more and more
19 to ensure engagement and I think there's a box
20 that's hidden there that just talks about our
21 participation in a scientific publications
22 committee.

1 So, more and more we're doing more things
2 together, which I think is a really good thing.

3 So, next steps with respect to engagement,
4 the case study teleconference, that already
5 happened in follow up to the January Jacksonville
6 meeting. The green things are the Board engagement
7 steps. We will either have you at the workshop, if
8 you're able to make it, or share executive
9 summaries of the workshop and contractor reports
10 shortly after the workshop so you'll see those
11 preliminary reports, have a sense of what's
12 happening there, and then hopefully we will get
13 input from you as we're revising our report, and
14 then May 10th we're submitting it to the Board and,
15 again, we'll be hopefully posting it for public
16 comment or maybe, I take your point, change that
17 language as the first step in our dissemination
18 process, and then we will discuss and approve a
19 more detailed dissemination plan shortly after
20 that.

21 So, the last couple of slides before I
22 turn it over to David to talk about the definition

1 just gives you an idea of what discussions we've
2 had within the Methodology Committee regarding, you
3 know, what happens after the report. You know, I'm
4 not great at visuals, but it was the best I could
5 do.

6 So, following the release of this first
7 report, our goals will be to enhance adoption of
8 the recommended standards, a push for research,
9 methodologic research to fill the gaps that will
10 become even more clear after we put together this
11 report, and really have the Methodology Committee
12 act as a convener, that is, bringing together
13 others around the country that have thought about
14 these things to help us improve the report and
15 improve the recommendations going forward as a
16 communicator, to share what we've learned, whether
17 it's in the scientific literature, in the lay
18 literature, through a translation tool, you know,
19 through novel means of communications.

20 I think Robin was sharing some ideas about
21 some novel communication approaches that she became
22 familiar with at another meeting through -- it was

1 a fellow who was actually a poet, right? And
2 actually the same individual was -- it just so
3 happened when she shared it, I learned the same
4 individual was brought on at Mayo as kind of an
5 innovative, out of the box approach to sharing
6 difficult concepts in an unusually way. People
7 have suggested video games, obviously social media,
8 so what are the ways we can imagine to communicate
9 what we're developing as effectively and
10 efficiently and maybe using novel approaches going
11 forward, and as a catalyst, so can we serve as a
12 catalyst to ensure that these practices and
13 standards that we're putting forward are because of
14 their scientific integrity, because of the
15 effective way we're communicating them, are really
16 catalyzing more research in this area and just
17 being very widely adopted.

18 So, obviously, you're our first audience.
19 Beyond that, it's the wider stakeholder community,
20 really, across the country. And so, how are we
21 doing that? The committee member feedback
22 sessions, I'll just share with you, Sharon-Lise and

1 I have started -- we thought we'd be done by now,
2 but we're only halfway through -- meeting with our
3 committee members one-on-one, or I guess it's two-
4 on-one, to really get a sense, individually, how
5 they think the process has worked over the last
6 year, what we can do differently, what we can do
7 better as we go forward.

8 We'll also be asking them to complete a
9 survey tool, an anonymous survey tool to, again,
10 understand from the perspective of each and every
11 one of our Methodology Committee members, get
12 feedback as to what we can do to improve our
13 process going forward.

14 I've mentioned the dissemination
15 implementation plan that we'll be developing going
16 forward along with Carolyn's group and the COEC.
17 We'll bring all of the feedback from these
18 committee member feedback sessions and the surveys
19 and some of our initial discussions. After the May
20 report is out for public comment we're going to
21 plan kind of a mini retreat where we take the
22 feedback that we've heard from our members and

1 really use it to drive our plans going forward.

2 We've already produced, as you all know,
3 kind of a blueprint for the next couple of years
4 and we'll be revising that based on the input that
5 we get from our Methodology Committee members.

6 And we're planning to engage, I think as
7 Brian mentioned just a bit ago, professional
8 societies and other stakeholders using advisory
9 groups and other sorts of activities to look at
10 areas that are particularly challenging and,
11 obviously, the one that we've talked a lot about is
12 electronic data systems, implementation,
13 dissemination is another one, novel delivery tools,
14 how are we going to get this somewhat technical
15 information and really assemble it in ways that a
16 variety of different audiences can understand it
17 and consume it and use it. And then on the health
18 systems standpoint, are there systems, engineering
19 principles, or experts that can help us drive some
20 of these standards into our health systems? And
21 these are just ideas, but they're the kinds of
22 things we are starting to think about in terms of

1 serving as a convener, communicator, and catalyst
2 to push our standards forward and improve -- know
3 what to do so that version two is even better.

4 And then the last one I'll mention is the
5 first annual PCOR conference. I think all of us on
6 the Methodology Committee, and this came up again
7 last night around the Board, see the importance of
8 really sort of stepping up and kind of taking the
9 podium, if you will, and saying, we are the PCOR
10 leaders, and one way to do that is to really hold
11 the first annual conference and serve as the
12 convener for those around the country.

13 Some of these conferences are popping up
14 already and I'd rather we're at the helm rather
15 than invited to speak or even worse, sometimes not
16 even invited. So, you know, we'd like permission
17 from the Board to start thinking about this, at
18 least from a methodology point of view and, you
19 know, just start with the easy stuff, you know,
20 let's get a date in place, let's get a simple
21 agenda in place, let's get a venue in place and
22 really plan for this. It won't happen in the fall

1 if we don't get moving.

2 CHAIRMAN WASHINGTON: Could we pause for a
3 minute?

4 DR. GABRIEL: Yeah, I think --

5 CHAIRMAN WASHINGTON: We have Collins and
6 then Lipstein and then Douma.

7 DR. COLLINS: So, just a process question.
8 I appreciate your putting forward these ideas about
9 advisory groups and its potential considerations.
10 It would help me, I think, to know what exactly is
11 the process by which the Board decides on advisory
12 groups? And have we decided on some already?
13 Could you just give us a quick snapshot on what
14 that process could look like? Because this is a
15 mechanism that could potentially be valuable in
16 quite a number of places and we want to be very
17 thoughtful about how we set these up so that they
18 actually fill the gaps that most need filling and
19 don't end up conflicting with each other.

20 CHAIRMAN WASHINGTON: Okay, I was just
21 confirming with Joe that to date we do not have a
22 clear process for setting these up across the

1 organization. We've expressed intent, and that is
2 the plan.

3 VICE CHAIRMAN LIPSTEIN: We don't have a
4 clear process, I remember because I led this panel.
5 Early on we developed a panel of guidelines for
6 advisory panels so that whenever we did want to
7 begin to establish them we had some general ground
8 rules to follow. So, there is a document somewhere
9 in -- Joe, you're looking at --

10 DR. COLLINS: Archives.

11 VICE CHAIRMAN LIPSTEIN: There's a
12 document somewhere in PCORI land with guidelines
13 for the creation of advisory panels. We ought to
14 dust it off, Francis, and bring it back.

15 DR. COLLINS: Yeah.

16 CHAIRMAN WASHINGTON: Okay. Good point.
17 I have Lipstein and then Douma.

18 VICE CHAIRMAN LIPSTEIN: So, breaking with
19 a little bit of our tradition, Sherine or Sharon-
20 Lise, I want to think out loud for a second. So,
21 Joe and I are going -- I invited Joe or I asked Joe
22 to come meet with a group of stakeholders from

1 health systems in May, I think it is, April or May,
2 and these are 30 really large health systems and so
3 imagine that Joe was very, very effective at
4 saying, we want to create these robust, PCOR
5 networks for both data or investigation or research
6 or however we want to do it, and imagine that in
7 this room, I'm just going to cite five that I can
8 think off the top of my head -- Kate Walsh will be
9 there from the Boston Medical Group and Steve
10 Safyer from Montefiore in the Bronx and Kevin
11 Lofton from Catholic Healthcare Initiatives in
12 Denver, and you've got Charles Sorenson from
13 Intermountain and you've got Tom Priselac from
14 Southern California. So, I picked five disparate
15 geographies. If we wanted to get those five
16 organizations to work together to develop a network
17 of either investigators or to put research or data
18 together for the purposes of achieving our five
19 priorities and I said something like, well, I have
20 17 new best friends on the Methodology Committee
21 who want to work with you to figure out how to do
22 this.

1 I don't know how that works. I mean, I
2 don't know how we get the expertise that they might
3 need to develop something that's truly novel and
4 innovative in the way of a network to do research,
5 and unless it results in a grant application, how
6 it would ever come to our attention. And since I'm
7 not allowed to help them develop a grant because
8 that would run afoul of the conflict of interest
9 rules, how would we take an idea like that and do
10 something with it? And so that's what I wanted to
11 just think out loud briefly about, Gene, if we
12 could.

13 CHAIRMAN WASHINGTON: Sure. I take that
14 question as a question to the Board, not just to
15 Sherine. So, those of you who don't currently have
16 your thinking caps on, please pull them out and put
17 them on.

18 DR. GABRIEL: I mean, I would just suggest
19 that we need to understand from leaders such as the
20 ones you mentioned exactly what their needs are and
21 what the barriers are, and I think that's one of
22 the goals of these advisory groups. We need to

1 listen, probably, more than anything else as a
2 first step.

3 VICE CHAIRMAN LIPSTEIN: Harlan, to add to
4 that, I think this group of five might know what
5 the goal is, but they certainly wouldn't know what
6 their needs were and that's what, Harlan, maybe you
7 can help us with that.

8 DR. KRUMHOLZ: Well, I think there's two
9 distinct issues here. One is where we target a
10 specific kind of network or group that we're trying
11 to foster where we, as a group, have come together
12 and said, for example, we want to emphasize
13 longitudinal prospective collection of data that
14 brings forth the voice of the patient, that's going
15 to ensure that we're doing that. Another might be
16 that we say we want to leverage, like you showed a
17 long time ago in St. Louis, the FRED database where
18 we say we want to create a series of resources from
19 existing data that might be leveraged for wider use
20 that might build beyond the traditional use of
21 claims data and might overcome some of those
22 limitations and have outcomes.

1 We would target that. To me, that's some
2 of the targeted opportunities that we might have
3 and we might want to put together an advisory
4 group, we might want to be very agile in trying to
5 move rapidly in trying to develop that and see if
6 we can seek people to make applications.

7 Another way, again, is in the broad-based
8 portfolio of the infrastructure where people might
9 coalesce and say they might pitch to us an idea
10 where we're ready to catch it and we want to
11 encourage that group to work.

12 Now, the Methodology Committee is so busy,
13 I wouldn't want to promise their ability to work
14 closely with any single group in the country. On
15 the other hand, I think there are people like the
16 Methodology Committee members around the country
17 and if a group coalesced that had the reach of the
18 one that you just described, they could bring
19 together that kind of expertise, bring together
20 patients, bring together the people within those
21 organizations, and we ought to be prepared to be
22 able to support proposals that are -- maybe even

1 formative, pilot proposals, I'd like us to think
2 about planning grants for opportunities like that,
3 where we can fund those groups to make the next
4 steps together that might then lead to an ultimate
5 proposals.

6 Then, Joe, you know, you and I have talked
7 about how with a pilot proposal then someone might
8 petition to put in a large grant and then the group
9 could continue. NIH does this all the time, go
10 above a certain amount, somebody can pitch it, but
11 they're not going to go through the regular
12 mechanism because it's such an audacious goal that
13 we have the opportunity to -- you petition it, it's
14 bigger than usual, and we have a chance to vet it
15 through some mechanism that Joe would set up
16 internally.

17 So, I think there are different kinds,
18 ones that might emanate from us where we're
19 particularly looking for that and we're saying, who
20 can do it, and another might be where we are
21 looking for new and novel ideas we couldn't even
22 envision, we're ready to catch it, and the catch

1 might be petition for doing it or a planning grant
2 that lets you get started and pull together the
3 expertise that you need in order to get to the next
4 step.

5 CHAIRMAN WASHINGTON: Douma?

6 DR. DOUMA: I just want to say that seeing
7 systems engineering up on your list is just so
8 wonderful. I think that's going to be key to a lot
9 of the -- we were talking about it yesterday, it's
10 going to be key to a lot of different -- of the
11 various challenges we've been facing and as an old
12 engineer who went to medical school not
13 understanding why medicine was 50 years behind
14 everybody else, it's great.

15 I also, with regard to the PCOR
16 conference, and I'm not in the middle of this, I am
17 seeing stuff popping up all over the place. My e-
18 mail is filled with workshops, conferences, et
19 cetera, et cetera, and I think the earlier the
20 better. And I would like us to give a great sense
21 to our communications people and our meeting
22 management people that at least by the next meeting

1 we've got something fleshed out pretty thoroughly
2 across the Board with regard to PCORI.

3 DR. GABRIEL: I couldn't agree more.

4 CHAIRMAN WASHINGTON: Could I just pick up
5 on that point since that was a question to you --

6 DR. GABRIEL: Yes.

7 CHAIRMAN WASHINGTON: I am -- we're going
8 to commit that by the next meeting, Joe, right,
9 that we will have fleshed out plans. We will have
10 even, by then, surveyed for possible dates and
11 sites for a PCORI first annual meeting.

12 DR. SELBY: Yes.

13 CHAIRMAN WASHINGTON: Okay.

14 DR. GABRIEL: Yes, and I would say if
15 Board members have ideas about a luminary or two or
16 three that could serve as a keynote, we need to
17 identify those folks early because their schedules
18 really get filled up.

19 So, I'm now going to turn it over to Dave,
20 if you want to come over here and talk about the
21 definition work, and we'll be looking for a vote of
22 the Board.

1 I guess there are only two slides, so I
2 could even do it for you if you want.

3 DR. FLUM: That sounds great. So, Dave
4 Flum, Methodology Committee. Thank you very much
5 for giving me the opportunity to share this work.
6 This work started a year ago, so we're -- this is
7 now a year-long process that's been really
8 inclusive to help do one of the formative
9 activities for PCORI, which is to really define
10 something that had yet to be defined at the time of
11 the creation of the institute.

12 I've had the opportunity to shepherd this
13 group that's involved, both Methodology Committee
14 members and also some members of the Board. You
15 see the Board members and the workgroup members
16 that are listed there.

17 This has really been an iterative process
18 that took the thoughts of the group a year ago and
19 then refined them through a process of public
20 input, very formalized public input, with
21 opportunity for the public to respond both to
22 questions we posed to them about the degree to

1 which they understood what we were trying to get
2 at, and also public comments.

3 We received 568 non-duplicated comments
4 that were collated by the NORC group and then
5 turned into about 12 distinct themes that emerged
6 that we were able to sub-classify all the comments
7 back and then consider them in definition revision.

8 NORC also conducted six focus groups
9 nationwide that involved a diverse group of
10 patients. Those focus groups identified themes,
11 many of them that were different from the themes
12 that emerged from the public comment period. All
13 of that was assimilated into a refinement process
14 by this group.

15 This was genuinely a consensus activity,
16 so there was no voting that took place, by the end
17 everybody agreed that the definition and then the
18 revision of the definition met their needs and met
19 the institute's needs. And so what we're preparing
20 to show today is the last step in that process of
21 creating a draft definition that we're hoping moves
22 from a draft or a working definition, to the

1 definition, acknowledging that definitions can be
2 considered for change over time as the needs meet.

3 But I want to just describe the very last
4 step to you, which was from an update from the last
5 time we got together, the product of several more
6 consensus calls where, based on the NORC comments
7 and the public comments, there were several changes
8 that were made to the definition.

9 The next slide, actually, is the
10 definition and because I don't like PowerPoint very
11 much, this is the only other slide you see. But I
12 suggest we all take a moment and read this
13 definition, because this is the current definition
14 of patient-centered outcomes research. And for
15 those who are viewing this on the web or on the
16 phone, I'll just read it, if you can indulge me in
17 that.

18 "Patient-centered outcomes research helps
19 people and their caregivers communicate and make
20 informed healthcare decisions allowing their voices
21 to be heard and assessing the value of healthcare
22 options. This research answers patient-centered

1 questions such as: given my personal
2 characteristics, conditions, and preferences, what
3 should I expect will happen to me? Two, what are
4 my options and what are the potential benefits and
5 harms of those options? Three, what can I do to
6 improve the outcomes that are most important to me?
7 Four, how can clinicians and the care delivery
8 systems they work in help me make the best
9 decisions about my health and healthcare?"

10 "To answer these questions, PCOR assesses
11 the benefits and harms of preventative, diagnostic,
12 therapeutic, palliative, or health delivery system
13 interventions to inform decision-making,
14 highlighting comparisons and outcomes that matter
15 to people; is inclusive of an individual's
16 preferences, autonomy and needs, focusing on
17 outcomes that people notice and care about such as
18 survival, function, symptoms, and health related
19 quality of life; incorporates a wide variety of
20 settings and diversity of participants to address
21 individual differences and barriers to
22 implementation and dissemination; and, lastly,

1 investigates or may investigate optimizing outcomes
2 while addressing to burden to individuals, resource
3 availability, and other stakeholder perspectives.”

4 The definition has two parts, the first
5 part is really considered for the public, if you
6 will, the second part is intended to clarify for
7 investigators and other stakeholders who need more
8 details and not the how-to of PCORI, if you will,
9 the how-to of PCOR, I should say.

10 The highlighted components of this
11 definition in yellow are the things that really
12 changed substantively from the first set of
13 definitions, and I'd like to just highlight those
14 changes so that you understand what the public
15 process involved.

16 The first change, we'll start with the
17 first sentence, many of the themes that emerged
18 from the focus groups and the public comment
19 emphasized that for the public that was at least
20 involved in this process, one of the major
21 shortcomings of the way investigators or research,
22 I should say, is used or intended, misses the boat

1 in terms of communication, either because it fails
2 to adequately deliver the information in a way that
3 people can understand health literacy, numeracy,
4 but also that the goal from a patient's perspective
5 is not just have a data dump of research or sheaf
6 of papers, but information that they can
7 incorporate into the decisions that they need to
8 make.

9 Communication was as important as
10 healthcare decisions and that aspect of adding
11 communication into the first line of the definition
12 was felt to be important by many stakeholders.

13 The word potential, added to benefits and
14 harms -- benefits and harms were words that, this
15 is in the second question, benefits and harms were
16 words that lots of folks had trouble with. Harms,
17 risks, were, by some, viewed interchangeably but
18 others viewed as having different meaning, adding
19 potential signal that there's a lot of uncertainty
20 in every healthcare decisions, both on the benefit
21 side and the harm side, and that seemed to be
22 responsive to the public comments that made the

1 information sound a little more doom-ful.

2 Question four has been totally changed.

3 There was lots of concern about what we meant when
4 we talked about the healthcare system. A
5 healthcare delivery system was not something that
6 was understood by many of the people who responded
7 in the public comments and during the focus groups.

8 By changing it to "clinicians and the
9 cared delivery systems they work in" we were hoping
10 to signal that we weren't talking about necessarily
11 what some people first viewed that term, health
12 system, were responding to. Many felt that when
13 you add the words "health system," it just meant
14 the insurance company.

15 The second part of that sentence also
16 refines the idea that the information is intended
17 to help people make the best decisions about their
18 health and their healthcare.

19 The last two comments are on the second
20 half of the definition. There was considerable
21 interest in including the word palliative or
22 palliative interventions as a distinct form of

1 interventions that were neither preventative,
2 diagnostic, or necessarily therapeutic. It's a
3 subtle point, but palliative is considered by many
4 to be in a separate category.

5 And, lastly, the last bullet under the
6 how-to of PCOR was the word "availability" after
7 "resources." Actually, regrettably, this was part
8 of the initial definition to have the words
9 "resource availability" included, and it was simply
10 a matter of editing that it was not included in the
11 definition that went to the public, but the take
12 home message about the last bullet is that by
13 including the issue of resource availability as one
14 of the many issues that patient-centered outcomes
15 research includes, specifically by including it in
16 the context of the way in which it becomes a
17 barrier or a means to achieving successful patient-
18 centered outcomes, many felt that this was
19 something that PCOR should be inclusive of.

20 The last question that came up repeatedly
21 was the extent to which PCOR and CER are
22 synonymous. I think all the members of this

1 workgroup have felt that this definition of PCOR is
2 certainly inclusive of traditional comparative
3 effectiveness research, but also allows for a lot
4 more room for a lot of other areas that may not
5 traditionally fall under comparative effectiveness
6 research definitions that have been offered in the
7 past.

8 Now, I suspect many of you have words that
9 you see here that you disagree with or you'd like
10 changed or maybe that you're not 100 percent on
11 Board with. I'll reflect what I started with,
12 which is this was a consensus process by which the
13 main concepts, if not the specific words, by many,
14 many different individuals, including the voices of
15 hundreds of people from the public have been
16 included, so I'd encourage you to, as you consider
17 this definition as your moving-forward definition,
18 reflect that and respect that process which has
19 been genuinely the first time that PCORI has
20 exploited the use of the public's perspective in
21 creating its work, and I think it's important that
22 we take advantage of that opportunity here.

1 Thank you very much.

2 CHAIRMAN WASHINGTON: Okay, David. Before
3 we open it up for Dr. Flum to questions and
4 comments, I take this as a recommendation from the
5 working group at this point.

6 DR. FLUM: That's correct.

7 CHAIRMAN WASHINGTON: Okay. [Off
8 microphone] -- specific request.

9 Okay, first Sigal and then Epstein and
10 Collins and Douma and I'll work my way to this
11 side.

12 DR. SIGAL: So, this is the first time I'm
13 seeing question four. I guess I just missed it. I
14 don't understand it. It's complicated and I don't
15 understand what it really means. The first three
16 questions are good, I've seen them before, they're
17 tangible. This, to me, is very convoluted.
18 Patients go to physicians, the healthcare system,
19 we know, has issues, but this is just -- doesn't
20 seem to be something primary for a patient. They'd
21 want the best answers for them, but fixing the
22 healthcare system -- needs to be fixed for them,

1 but I just have a hard time with this. I don't
2 know what it means and it's very complicated to me.

3 DR. FLUM: So, this is Dave Flum again.
4 Let me offer a point of clarification then. This
5 question, and its modification, came from a set of
6 public comments that we heard about things that the
7 patients would like to know about where to go to
8 get their healthcare. This often comes up as,
9 should I go to the big university hospital or can I
10 go to my local -- is this something I can go to the
11 local clinic for. Is it better to be in an HMO or
12 an integrated care delivery system? Or should I go
13 to my doc who I've been seeing who works out of his
14 office? Questions that often come to bear by --
15 when patients are trying to figure out what is the
16 way to navigate their course in the healthcare
17 system, and it reflects the fact that people, I
18 suspect, think that there's a role that the
19 healthcare system and their doctors play and their
20 clinicians, I should say, play in helping them make
21 the best decisions and getting them the best
22 outcomes. It's the only question that refers to

1 the system.

2 DR. SIGAL: Look, I live in the world of
3 cancer and where 85 percent of the people are
4 treated in a community setting and if there were
5 one recommendation I would make is get a second
6 opinion at an academic center. But, having said
7 that, this doesn't say that to me. This is -- I
8 don't know what it says, but maybe it's a question
9 we have to answer, and I think it's a legitimate
10 question for PCORI, but for me on these very basic
11 questions that are really important, I just -- I
12 find it just convoluted. I'm sorry.

13 CHAIRMAN WASHINGTON: Okay. Epstein and
14 then Collins.

15 DR. EPSTEIN: Hi, Arnie Epstein, BOG. I'm
16 going to follow up Ellen's. I'm really respectful
17 of the process. It sounds like it was careful and
18 deliberative and sought outside opinion. I
19 certainly like those first few questions, Harlan
20 mentioned them, I think one of our first meetings,
21 and I found them engaging then and I find them
22 engaging today.

1 I'm really troubled by the fourth question
2 and the top, which is focused, and the issue for me
3 is not whether decision making is important, it's
4 central, that really ought to be there. The issue
5 for me is that I think that there's a lot to do
6 with patient-centered outcomes, which does not
7 mediate through direct patient decision making, and
8 to lose that emphasis as part of our research, I
9 think, would be a mistake, and I'm thinking of the
10 many, I'll name some studies of nurse extenders who
11 can help patients with chronic disease after they
12 leave the hospital, IT aids to help patients, you
13 know, keep track of their medications and other
14 aspects that are important, the whole service of
15 health services. And to not see that included as
16 part of patient-centered outcomes research to me
17 seems like we're going to be losing too many
18 valuable things.

19 DR. FLUM: I would just offer you to
20 consider the first bullet under PCOR really writ
21 large talks about assessing the benefits and harms
22 of everything from health system interventions of

1 the very type you just described. This is in the
2 first bullet of the operationalized component, the
3 definition.

4 This definition can hold an awful lot
5 underneath it and although we might make other
6 questions, including the types of questions you
7 just asked, we thought that we were covering that
8 in bullet one.

9 DR. EPSTEIN: Since I didn't get it and I
10 don't get it now, maybe we could cover it a little
11 differently. It says "interventions to inform
12 decision-making." This is not about decision-
13 making. Decision-making is really important, so
14 don't hear that I wouldn't say it's first and
15 second, I'm saying, we don't want to lose things
16 that are really very important predictors or
17 remedies for patient outcome merely because they're
18 not mediated through conscious decisions.

19 CHAIRMAN WASHINGTON: Joe has a comment
20 relating to this specifically.

21 DR. SELBY: Yeah, I just -- a couple
22 things. First of all, with respect to your most

1 recent comment, Arnie, I don't think that that
2 bullet that starts "assesses the benefits and harms
3 of preventive," et cetera, speaks only about
4 interventions meant to inform decision-making. So,
5 I think you're just reading that wrong.

6 It assesses the benefits and harms of
7 health delivery system interventions in order to
8 inform decision-making, but it's not interventions
9 to inform decision-making, it's assessing
10 interventions so that decisions can be made.

11 So, you know, I do take your point that
12 sometimes even patient-centered research might not
13 be about informing decision-makings, but that's not
14 what this first bullet says. It doesn't go to the
15 extreme that you suggest it does.

16 CHAIRMAN WASHINGTON: David, and then
17 we've got to move on to the --

18 DR. FLUM: And because we're not obviously
19 going to sort of have a debate about each word, I
20 would just say that there was a considerable
21 discussion, Dr. Epstein, about your point. One of
22 the considerations was actually that really

1 everything is a decision made, and it may not be by
2 the patient, it's true, but it may be made by the
3 system, about whether or not to pay for those
4 nurse, whether or not the healthcare system will
5 include health extension at home or any of the
6 things actually mentioned, but implicitly there is
7 a decision being made between the alternative
8 status quo and any of the components that may be
9 important that may be not mediated by the patient
10 making the decision, but certainly somebody is
11 making the decisions.

12 CHAIRMAN WASHINGTON: So, Collins and then
13 Barksdale.

14 DR. COLLINS: So, as one who's, I guess,
15 advocated that we just need to come up with a
16 decision and move this forward or face
17 embarrassment after all these months of trying to
18 decide on the decision, I'm loathe to weigh in, but
19 I will anyway. I'm just a little troubled by that
20 very first sentence in bold because that's the
21 thing that people will look at and perhaps won't
22 dig any deeper down into the document.

1 "PCOR helps people and their caregivers
2 communicate and make informed healthcare decisions
3 allowing their voices to be heard and assessing the
4 value of healthcare options." If you just read
5 that, I think you'd be wondering, is this a
6 platform that's focused primarily on communication
7 or is it focused on research? And I think you
8 might think it was the former.

9 So, I get it about why communication is
10 important, but if that sentence is really
11 encapsulating the main idea of what PCOR is, I
12 think it is skewed very heavily in the direction of
13 the communication function and it doesn't emphasize
14 the primary function, which is to do research.

15 CHAIRMAN WASHINGTON: Okay, Barksdale?

16 DR. BARKSDALE: My comment was related to
17 the word caregiver and I know that we've spent a
18 lot of time on the call discussing what we meant by
19 caregivers, and it's my recollection that we went
20 with the broader notion of a caregiver, not as the
21 member of the family, for example, but caregivers
22 including clinicians? Am I confused?

1 DR. FLUM: You're not confused. There's a
2 rationale document that accompanies this that can
3 help sort of translate some of the words by the
4 intended meeting. It may be, by the way, a
5 wonderful opportunity to have lots of these points
6 of clarification further made.

7 You made the point, I believe, that it was
8 your desire that caregiver reflected anybody who
9 helps care for you, including your doctors, but
10 also family members and other clinicians and other
11 non-clinicians necessarily. By keeping the
12 language broad here we have the opportunity to
13 define that -- to further refine that, define that,
14 and clarify that in any way we want.

15 I think the rationale document is a great
16 opportunity to cover a lot of these issues, though.

17 CHAIRMAN WASHINGTON: We have Douma then
18 we have Hole-Curry, Becker, Weisman. So, Douma.

19 DR. DOUMA: Yeah, I just want to report
20 that, what, ten days ago when we had the committee
21 meeting I was given permission to actually vet this
22 at a presentation, which was about, I don't know,

1 six, seven days ago, and it went off very well.
2 There were several hundred people and they were all
3 in the population health arena, so they're geared
4 toward thinking this way in the first place, so
5 some of the nuances that are being brought up by
6 the more clinical folks were not addressed there,
7 but I do want to do number four, particularly
8 because there's a lot of push back on that.

9 I think that is one of the most
10 significantly different phrases that we're seeing
11 in our definition versus what we're used to. What
12 we're used to is we're trying to collect, gather
13 good research information that could be used by
14 clinicians and the delivery system to really make
15 great choices for me, I'll just personalize this,
16 versus what we're trying to say is that, yes,
17 that's true, but I am, in the final analysis, as
18 Joe was talking about, I'm the decision maker
19 whether or not that particular piece of information
20 actually applies to me.

21 And so, we turn it around a little bit to
22 say, the system needs to engage me in making that

1 decision, although we realize that in many
2 circumstances it's a piece of information
3 clinicians use and they make decisions and it's by
4 default it's accepted.

5 And it's maybe unconscious that I'm making
6 the decision, but by me not saying no, I'm saying,
7 yes.

8 CHAIRMAN WASHINGTON: Okay, Hole-Curry and
9 then Becker, Weisman, Clancy.

10 MS. HOLE-CURRY: Leah Hole-Curry, Board
11 member. Thank you to everyone on the committee, I
12 saw it was a big committee, for doing this work.

13 So, what I brought with me in prep for
14 this Board meeting was the July 15, 2011
15 announcement that we put out about our working
16 definition and then I compared it against this
17 document and I did read the rationale or discussion
18 document that went with it.

19 So, my first question is just an easy one.
20 Is it our intent if this passes to include the
21 discussion or rationale document of the final --
22 when we publish? I think it includes a lot of

1 valuable information and I would suggest that that
2 be on the table as well.

3 DR. FLUM: So, that was the intention of
4 the group. Yeah.

5 MS. HOLE-CURRY: Okay, great. And then
6 the second one is, I guess I just want to stress
7 from a process point how much work went into the
8 first one and then all of the iterations, so I
9 really would look to either the group or the chair
10 and vice chair to help us figure out, process wise,
11 how to vote this through or not vote it, because I
12 get that there's -- that words mean something, but
13 we've also been at this a really long time and I
14 think that we should be able to vote on this as a
15 whole. That would be my proposal.

16 CHAIRMAN WASHINGTON: That is the intent.
17 I framed this discussion by saying that there was a
18 proposal on it. What I didn't say, more
19 explicitly, I will say now. We're going to vote at
20 the end of this discussion.

21 Becker, Weisman, Clancy.

22 DR. FLUM: Sherine, did you want to --

1 DR. GABRIEL: I was just going to suggest
2 at some point to just summarize quickly the work
3 that has gone on in case people don't really
4 recall, you know, the NORC step and the focus group
5 step, just to ensure that everybody around the
6 Board table hears that again.

7 MR. BECKER: So, I wanted to comment, too,
8 on number four. I'm a lot where Allen and Arnie
9 are. I read the NORC work. I recollect the
10 comment about people misinterpreting it and
11 thinking about it in terms of health plan. I get
12 that. But what is, to me, significantly changed in
13 number four is outcomes.

14 In parallel with number three -- number
15 three talks about, how can I improve the outcomes,
16 my outcomes? Number four, in its earlier stage,
17 was, how can the health system -- I understand the
18 misinterpretation maybe of those words -- help me
19 get to the outcomes. And here it is simply about
20 the decision and it takes the system off the hook
21 for the outcomes.

22 And so, I have trouble with number four,

1 because now the outcomes are totally on me and not
2 in concert with my clinicians, providers, et
3 cetera.

4 CHAIRMAN WASHINGTON: Okay, Weisman and
5 then Clancy.

6 DR. WEISMAN: Well, I've been part of this
7 as part of the working group and, you know, number
8 four is problematic only because it takes a lot of
9 work to talk about what we mean, but this thing has
10 been wordsmithed. I think this thing has been
11 written forwards and backwards and sideways,
12 seriously, in all different ways. It usually ends
13 up about where it is with some wordsmithing.

14 Some of the things we're going to have to
15 explain to some people some of the time, you know,
16 some people are going to get some parts and not
17 others, but I think it does -- my own feeling is
18 that it does the job that we intend it to do within
19 the limits of people arguing about words.

20 Larry, I really like what you said, I like
21 what some of the other comments were, but I can't
22 even think about the idea that this thing goes back

1 to the working group and we rework it. Maybe we
2 evolve it over time.

3 You said something really crucial, you
4 said you compared it to a document of last July,
5 July 2011, and it's now 2012 and we're moving
6 closer to July of 2012 than we are distance from
7 2011. And a lot of people are wondering what are
8 we doing with all the information we're gathering.
9 It's been quite extensive, as Sherine said. That
10 was just a comment.

11 The other comment I wanted to make is, I
12 think you have another document that's really nice,
13 which is that you outlined the comments, summarized
14 the comments that we received from the various
15 stakeholders, wrote -- there's then a statement
16 about how we're either making the decision to
17 incorporate or not incorporate that feedback, and
18 then there's further elaboration on what we're
19 doing with that feedback, either to accept it and
20 incorporate it and make changes or to not accept
21 it, which I think is an absolutely wonderful model
22 for what we were talking about earlier in the day

1 about how we take in stakeholder feedback.

2 And I was just wondering whether you could
3 comment on that process? It's short and to the
4 point, but it's very effective.

5 DR. FLUM: So, we -- if I can, this is
6 Dave Flum, we modeled that response off of CMS's
7 response system, so every comment, every theme, I
8 should say, from the comments in the NORC process
9 was distilled into a sort of recommendation by the
10 public and we responded to whether or not that was
11 going to reflect into a change in the definition
12 and the rationale for either including it or not
13 including it. They're about a paragraph long,
14 they're written in as close to lay language as we
15 can get with this stuff, and it's intended to be
16 posted on the web.

17 The rationale is intended to be posted on
18 the web as well and the whole process can result in
19 a publication and scientific journal as well, but
20 our primary response to the public that reflects
21 the degree to which the public's voice has been
22 integrated into this definition would be the web

1 response, I think.

2 DR. WEISMAN: Thanks.

3 DR. CLANCY: David, I want to actually
4 join with everyone who saluted the process. The
5 scheduling challenges alone for this rather large
6 group are close to giving me a headache. And I
7 want to say, bravo. I think it's wonderful. I
8 speak from the perspective of someone who's spoken
9 to a lot of different audiences, not just my large
10 extended family, although I've mentioned them, but
11 very diverse audiences in terms of their
12 understanding about what this means, that it's
13 about end results that matter to me, and so forth,
14 and I think this works.

15 And, Arnie, I actually say that there is a
16 distinction between number four and that first
17 bullet. I think the first bullet does encompass
18 some of the issues that you were identifying.

19 I read number four as being, A, more
20 understandable, and B, something about what is the
21 obligation of clinicians and the systems or
22 organizations in which they work to make something

1 like, I'll put this in quotes "shared decision
2 making" actually possible, right? We talk about
3 that a lot in almost musical tones. We're almost
4 on our feet. You know, we get very, very excited.

5 In real life, it doesn't happen. In fact,
6 people, you know, often get out the door and aren't
7 clear where in god's name their parking ticket is
8 much less what is going to be coming next and so
9 forth. We haven't done such a great job.

10 So, I'm incredibly enthusiastic about this
11 and plan to use it early and often.

12 CHAIRMAN WASHINGTON: Okay, Norquist are
13 you up or down? Norquist will be the last comment
14 and then we're going to call the question.

15 DR. NORQUIST: Yeah, so this is Gray
16 Norquist. I can't help but having acted like a
17 psychiatrist all day, so I have to say something
18 about them. So, it's okay to have --

19 [Laughter.]

20 DR. NORQUIST: No, no, I was going to say,
21 you know, the sense is that I have -- actually,
22 Sherine and I were kind of talking -- it's okay to

1 have disagreement, you know, and I think we need to
2 stop worrying that everybody's going to agree.

3 I'm okay. I was on the committee so I'm
4 okay with it, but I think, I get the sense that
5 people want to have us all agree, but that's okay.
6 I think that's the spirit of what we are. So, I
7 hope people understand that.

8 CHAIRMAN WASHINGTON: Krumholz?

9 DR. KRUMHOLZ: As somebody who has been
10 involved from the very beginning, I do want to say
11 this is extraordinarily difficult. I want to
12 commend David. I want to say that, Arnie, you
13 know, the thing is, it is hard, but these are
14 questions such as, so it's not exhaustive with
15 respect to the scope and so it provides some
16 examples that do focus on the decision-making.

17 I'm not saying you're wrong, I'm just
18 saying where we are now I don't think excludes the
19 point you made. If it had been incorporated
20 earlier, we might have been able to act on it a
21 little bit better, but it's been through so many
22 different iterations.

1 And I think the part that Francis said
2 does, if anything that I've heard, did give me a
3 little pause, David, I don't know, just to make
4 sure that we are talking about this through
5 scholarship, I mean, that it is research. And
6 maybe it's obvious enough, but of everything I
7 heard, that's what I thought, um, you know, maybe.
8 Because there are a lot of things that can help
9 people communicate and make informed decisions, but
10 it is really through research.

11 The only thing is, it does say patient-
12 centered outcomes research and if people don't just
13 see that as a name but actually see that it says
14 research, it may be the one thing that signals to
15 them.

16 But I am very loathe to think that we
17 would bounce it back rather than say this -- this
18 isn't something necessarily any one of us would
19 write but we could all live with given that that's
20 sort of what we've got as a group and the need to
21 move forward.

22 But that was the one thing that I was a

1 little bit thinking about.

2 DR. LEVINE: I promise it will be brief.
3 I think one of the -- what's not written, but I
4 think intended, is that the first -- what bridges
5 the first sentence and the second are the words "by
6 doing," so that we communicate or, it helps people
7 communicate in making informed health decisions and
8 allows their voices to be heard in assessing the
9 value of options by doing research that answers
10 patient-centered questions such as -- and maybe
11 that could be put into the document that goes along
12 with it, if we don't, I mean, I -- by the way, I
13 agree with Carolyn, that this -- you know, David
14 has essentially done a Talmudic scholar's worth of
15 work in terms of how many angels can fit on the
16 head of a pin, but I think that clearly was the
17 intention, is that the vehicle to do that is
18 research that answers patient-centered questions.

19 It's just missing those two words.

20 CHAIRMAN WASHINGTON: Thanks.

21 DR. CLANCY: We are not going to step
22 away. People are confused about patient-centered

1 care versus patient-centered outcomes. That will
2 persist for the life of this institute even if it's
3 eternal, I guaranty it.

4 CHAIRMAN WASHINGTON: Well, this
5 represents an extraordinary amount of work and I
6 actually also think it represents a culmination of
7 a remarkable process, and so I want to commend
8 David, the working group, but I also want to
9 commend all the various stakeholders that have
10 provided us with input over the last, almost, nine
11 months. And so, the question on the table is, all
12 those in favor of approving this definition as it
13 is, raise your hands.

14 [Show of hands.]

15 CHAIRMAN WASHINGTON: Okay. It's going to
16 be easy for me to count those opposed. Okay. All
17 those opposed?

18 CHAIRMAN WASHINGTON: One, two, okay.
19 Three, okay. And abstaining.

20 DR. SIGAL: Can we abstain?

21 CHAIRMAN WASHINGTON: Okay, I mean, I
22 don't know if we need to get this official, but I

1 think we should. Do you want to be abstained?

2 Because we're don't have a category of abstain.

3 DR. SIGAL: For some reason, this is the
4 first time I saw this and I'm not comfortable with
5 it, but, again, I was so -- yeah, abstain.

6 CHAIRMAN WASHINGTON: So, we have two
7 opposed, one abstention, the motion carries. Thank
8 you, again, to everyone involved including the
9 Board.

10 DR. GABRIEL: That's the end of my report.
11 Thank you.

12 CHAIRMAN WASHINGTON: Okay.

13 [Off microphone discussion.]

14 CHAIRMAN WASHINGTON: For the next public
15 comment period.

16 [Off microphone discussion.]

17 [Applause.]

18 MR. SCHMITZ: All right, thank you, Dr.
19 Washington. We now have a 30-minute public comment
20 period scheduled. Just as a reminder, we'll hear
21 first from those in the room who are pre-
22 registered, then we will check the teleconference

1 to see if anyone participating by phone wants to
2 provide comment. Individuals are asked to limit
3 their comments to three minutes and written
4 testimony should be submitted to PCORI by e-mail at
5 info@pcori.org.

6 The first commenter is Ellen MacKenzie at
7 John Hopkins School of Public Health.

8 DR. MACKENZIE: Thank you very much for
9 this opportunity to make a few comments. I'm Ellen
10 MacKenzie, I'm a professor and chair of the
11 Department of Health Policy and Management at Johns
12 Hopkins Bloomberg School of Public Health right
13 here in Baltimore. I'm also a former Board member
14 of the National Trauma Institute and it is that
15 institution that I'm representing here today.

16 I'm a health services research who has
17 spent the past 30 years working with trauma
18 providers to improve our understanding of trauma
19 outcomes with an emphasis on developing programs
20 and policies that make a difference in these
21 outcomes.

22 As you move forward with the work of

1 PCORI, I ask that you remember that trauma is the
2 leading cause of death among our children and young
3 adults and requires your serious attention.

4 Overall, injury is the fourth leading
5 cause of death -- the fourth leading cause of death
6 over all ages and the leading cause of death among
7 children and young adults. And data from AHRQ has
8 shown that trauma-related disorders are
9 consistently among the five most costly conditions
10 for our country.

11 In 2008, direct healthcare expenditures
12 for trauma -- related to trauma were outranked only
13 by heart disease, and by a slim margin, by cancer.

14 Attention to the priorities on comparative
15 clinical effectiveness that PCORI has proposed are
16 critical to reducing this burden. As with most
17 other areas of medicine and surgery, direct head-
18 to-head comparisons of specific acute care
19 treatment options are sorely needed to improve our
20 understanding of which treatment works best for
21 which person under what conditions. Often these
22 comparisons are challenging in trauma specifically

1 as they require comparing different surgical
2 approaches or very often surgical versus non-
3 surgical approaches.

4 And all of this must be done within the
5 context of a very challenging patient as well as a
6 challenging treatment environment. Decisions in
7 trauma are often needed quickly and there is little
8 time to consider alternatives. The need for good
9 evidence is sorely needed.

10 But we know that even with optimal acute
11 care that long-term outcomes are not often good.
12 Our own work, for example, has shown that only a
13 little over 50 percent of individuals who've
14 suffered a bad leg injury are back to work in two
15 years. Rates of return to work are even lower for
16 those suffering traumatic brain and traumatic
17 spinal cord injuries.

18 These outcomes are complicated not only by
19 the physical impairment associated with the injury,
20 but by the psychological consequences including
21 high rates of anxiety, depression, and poorly
22 managed pain.

1 Identifying these individuals who are at
2 risk of poor outcomes early in the recovery process
3 is critical and is the critical first step, and we
4 really don't know how to do this.

5 Coordinating a wide range of post-acute
6 care services and ensuring that patients have
7 access to these services and are motivated to use
8 these services is the next critical step.

9 Collaborative care models that foster
10 interaction between informed activated patients
11 with prepared, proactive practice teams, have been
12 shown to be effective in managing complex medical
13 conditions. These types of models must be
14 developed and evaluated specifically for younger
15 trauma population if we are to have a chance of
16 improving recovery.

17 We request that PCORI recognize that
18 trauma is a huge problem facing our country and
19 ensure that you will include it among your
20 priorities. It has been shown over and over again
21 that funding for trauma research and trauma
22 outcomes research is nowhere near commensurate with

1 the magnitude of the problem.

2 And from a personal standpoint I can't
3 tell you how frustrating it is for me as a health
4 services researcher and health outcomes researcher
5 to work with young, very motivated, bright
6 clinicians who are working in trauma and have a
7 great research idea and then we sit down and say,
8 all right, who's going to fund this. The funding
9 opportunities for trauma outcomes research have
10 always been very limited and hopefully this will
11 change. Thank you.

12 VICE CHAIRMAN LIPSTEIN: That's Professor
13 MacKenzie from Johns Hopkins, my alma mater. Thank
14 you.

15 CHAIRMAN WASHINGTON: Thank you, Dr.
16 MacKenzie.

17 DR. DOUMA: And my alma mater too.

18 MR. SCHMITZ: That concludes the number of
19 individuals registered to comment on site, so we
20 will turn to the teleconference to see if there's
21 anyone on the phone who wishes to provide comment.

22 OPERATOR: There are no comments in queue.

1 CHAIRMAN WASHINGTON: I also think that
2 with two alums from Hopkins that Hopkins should be
3 disqualified from applying for any PCORI money.

4 [Laughter.]

5 VICE CHAIRMAN LIPSTEIN: There's more than
6 two.

7 CHAIRMAN WASHINGTON: Oh, there's more
8 than two? Oh, for sure.

9 Okay, anyone else? I mean, that didn't
10 register that would like to comment?

11 Okay, because we have agreed that we do
12 not want a break during a period when there's a
13 public comment, in case someone wants to present,
14 I'm going to ask Dr. Levine, if you are ready to
15 move on? Okay.

16 And, again, if we identify someone,
17 Richard, in the time allowed, we will stop.

18 [Pause.]

19 DR. LEVINE: Thanks. And this is the
20 report from the COEC and I think I have to
21 apologize to the committee members and acknowledge
22 that given how fast things have been moving, there

1 are things in this report that have occurred since
2 our last committee meeting two weeks ago, and so,
3 some of my colleagues will be seeing this for the
4 first time also, though many of them have
5 participated in this work along with me.

6 And just, again, a reminder of the heroes
7 of the COEC, and we always put Gail Hunt's name in
8 italics because in spite of her non-voting status,
9 she's been one of the most loyal attendees at our
10 committee meetings and a tremendously valuable
11 contributor.

12 So, I'm going to briefly cover, today,
13 public feedback on the Draft National Priorities to
14 remind folks about that process, again, not the
15 content, to give you some additional opportunity to
16 see what actually happened at the February 27th
17 meeting, for those of you who weren't able to do
18 it.

19 I want to briefly report on the clinician
20 focus group that took place in February. This will
21 just be highlights of this and the full report will
22 be provided to the Board, and these are clinician

1 focus groups on the Priorities and Research Agenda,
2 process for incorporating input into the revisions
3 of the Priorities and Research Agenda and, again in
4 the spirit of continuous quality improvement and
5 being a learning organization, the committee's
6 thoughts about evaluating what we have done in
7 terms of stakeholder and community engagement
8 events associated with Board meetings, collecting
9 feedback, not just from Board members, but from
10 others, and then bringing forward some
11 recommendations about thinking about this going
12 forward, which will, I think and hope, have some
13 opportunity to inform our conversations about our
14 Board meetings in 2013 and going forward.

15 And finally, just a reminder to everyone
16 in the room about connecting with PCORI.

17 CHAIRMAN WASHINGTON: Just a process
18 question. We were scheduled to break at 3:45.
19 Now, we can plan to take two of these, if we want,
20 and have our break and reconvene, or we can work
21 through them and have you step out as needed.
22 What's your preference, break?

1 UNIDENTIFIED SPEAKER: [Off microphone.]

2 CHAIRMAN WASHINGTON: Okay.

3 DR. LEVINE: Okay? So, all in favor?

4 CHAIRMAN WASHINGTON: [Off microphone] --
5 hear from the others, yours count for more this
6 time. I was counting nods of heads too though.

7 DR. LEVINE: So, as I think was previously
8 mentioned today, we have ten days left from today -
9 - from tomorrow in the public comment period. The
10 primary modality for submitting responses or
11 reactions and thoughts about the Priorities and
12 Research Agenda is through the website though we
13 are providing opportunity for feedback by mail and
14 we distributed it at the stakeholder event. We
15 distributed the information with a mail address and
16 the website is there, the website address with
17 /prioritiesagenda.

18 To date, we have received, actually, I
19 think it's 115 comments through March 1st -- or
20 through yesterday, sorry, and I'm going to show you
21 just a quick summary of where the comments are
22 coming from, both in terms of stakeholder group and

1 geography. And this is a bar graph on stakeholder
2 type. You can see that the largest number of
3 comments, 36 or 37, have come in research
4 community, 27 from physicians, and I'm guessing at
5 where those bars stand between numbers looks like
6 about 23 from patient advocates, and 14 from
7 patients themselves, individual patients.

8 I would say also that people had the
9 opportunity to identify themselves or to mark off
10 more than one category, so these numbers don't
11 necessarily add up to the whole.

12 And this is a geographic representation of
13 where the comments came from. As you can see, they
14 tend to add, congregate, aggregate in large
15 population centers and our hope is that by --
16 through contact, and we know that generally in the
17 last ten days of an open comment period we get -- a
18 lot of people wait until the very end to submit
19 comments, so we're hoping that actually this
20 pattern will shift as we've worked with national
21 organizations with local affiliates to try and get
22 feedback from less than the most concentrated

1 population geographies.

2 The stakeholder event, the patient and
3 stakeholder dialogue on February 27th, which, just
4 to remind the Board, this was Gene's idea when we
5 first began to get a sense of the variety and
6 diversity of feedback we were getting about the
7 approach taken on the Priorities and Research
8 Agenda and I believe this was in December, Gene
9 said, we need to open this up.

10 We clearly need to really put on steroids
11 the opportunity for people to engage with us around
12 this and for us to explain the rationale and to get
13 feedback on this. And in an almost amazingly short
14 period of time, staff and -- PCORI full time staff
15 and Board members put together an event, which
16 attracted 900 individuals who preregistered, 400 in
17 person, 530 by webcast or phone, and the actual
18 participation had a much smaller fall off than is
19 usually the case.

20 Usually when you put on a large meeting
21 you expect 15 to 20 percent no shows, 850 people
22 actually participated. The archived webcast is on

1 PCORI.org under the Past Meetings and Events page.
2 And the day -- I think you've all seen the agenda,
3 Joe led it off, Harlan Krumholz spoke to the
4 National Priorities and set a context for why the
5 Board -- or the PDC and those involved actually
6 went down the pathway of this approach to the
7 Priorities and Research Agenda.

8 And a couple of statements that Harlan
9 made, which were resonated with the patients and
10 patient advocates were, one, our true north is our
11 patient, and one of the patients who was blogging
12 while the day went on made the comment that
13 Harlan's comments represented a pledge of
14 allegiance to patients the likes of which this
15 individual had never heard, and I just thought that
16 was a very touching comment and a way of
17 encapsulating the passion that Harlan unleashed on
18 that audience.

19 Also, we had two panels. The first was a
20 Patient and Caregiver Advocates Panel. These were
21 really representatives of large patient and
22 caregiver advocacy organizations. As you can see:

1 American Cancer Society, Autism Speaks, NAMI, and
2 the National Alliance for Hispanic Health, and the
3 National Health Council.

4 Those organizations represent more than
5 130 million individuals who are affected by the
6 conditions the organizations represent, which they
7 made the point several times.

8 The second panel of clinicians and payers,
9 clinicians: American Academy of Family Physicians,
10 the AMA, American Nurses Association, and payers --
11 AETNA and the National Business Group on Health,
12 and industry, a spokesperson representing pharma.

13 And I'm going to just take two minutes for
14 you to be able to see:

15 [Video shown.]

16 DR. KRUMHOLZ: I want to welcome you --
17 the notion that we've got is that we are problem
18 solvers together. Our accountability is to
19 patients. Ultimately we're going to be listening
20 to a lot of stakeholders, but our true north is
21 going to be patients, patients and their
22 caregivers, and in this conception, I think maybe

1 we have a chance to turn the world upside down just
2 a bit.

3 UNIDENTIFIED SPEAKER: It also provides an
4 opportunity for the patient and consumer
5 communities to collaborate with the scientific
6 community in really designing robust and responsive
7 research projects that will result in answers to
8 the pressing questions we have.

9 UNIDENTIFIED SPEAKER: Congress envisioned
10 that PCORI would carry out its mission in a unique
11 way. At its core, PCORI is an agenda setting body.
12 Patients have a different view of what the
13 priorities would be from researchers and that they
14 should be involved in the very initial stages of
15 setting the Research Agenda.

16 UNIDENTIFIED SPEAKER: As one of our
17 patients so eloquently stated, an outcome is how I
18 end up. That's what they care about.

19 UNIDENTIFIED SPEAKER: In the past ten
20 years I've seen increasing awareness of the value
21 of patient input to policy and regulatory decisions
22 and what I see is a major paradigm shift from an

1 expert-dominated medical decision-making where the
2 patient's role is a passive recipient of the
3 treatment to a truly patient-centered healthcare.

4 UNIDENTIFIED SPEAKER: Members of the
5 public, patients and consumers, can be a force that
6 can make these reforms succeed if they are
7 utilized. And the time is now to begin that
8 communication.

9 UNIDENTIFIED SPEAKER: I hope that there
10 is rigorous enforcement of meaningful patient
11 involvement in leadership teams receiving the grant
12 funding.

13 UNIDENTIFIED SPEAKER: We need to move
14 away from token patientism and while the diseases
15 that we all represent are critical, we need to find
16 ways to really represent patient -- not centered
17 research, its patient-driven research.

18 DR. KRUMHOLZ: This is going to be
19 research done differently. How? Because in the
20 governance, design, implementation, dissemination
21 and application of this research, patients are
22 going to be involved at every step. And in order

1 to get funded by us, on your team you're going to
2 need patients, clinicians, and researchers,
3 authentically and genuinely working together.

4 [End of video.]

5 [Applause.]

6 VICE CHAIRMAN LIPSTEIN: Hey, Gene, seeing
7 Harlan Krumholz wrapped in the American flag.
8 Harlan --

9 CHAIRMAN WASHINGTON: I'm going to start
10 recognizing him as Mr. President.

11 DR. LEVINE: The impact, as you can tell,
12 was quite powerful. The morning was a combination
13 of PCORI Board members, Harlan, in particular, and
14 the two panels, and the afternoon was three hours
15 of public comments. We had 46 individuals, in
16 person, who made statements. For those of you who
17 didn't -- we didn't -- this is hot off the press.

18 They've been editing up through lunchtime
19 to get you brief clips, but Lisa Simpson was one of
20 -- the President of Academy Health, Shawn Bishop,
21 one of the staff folks in Congress who helped to
22 write -- had a substantial hand in writing the

1 legislation, and, of course, Perry Cohen who is
2 well known to all of us and to whom many people in
3 the audience actually expressed a debt of gratitude
4 to Perry for his comments that day.

5 We had eight individuals making comments
6 on the phone. Ninety percent of people who filled
7 out the evaluations felt the event was informative,
8 which I think is quite stunning. And 85 percent --
9 just below 85 percent felt the panel discussions
10 helped provide context for the Priorities and
11 Research Agenda.

12 In addition to the website and the
13 stakeholder dialogue, we reviewed in Jacksonville
14 the results of the patient and caregiver focus
15 groups, which were not specifically focused on the
16 Priorities and Research Agenda, though the
17 conversation in those focus groups actually had
18 elements of what had already been formulated
19 inserted into it.

20 And then in February, there were nine
21 clinician focus groups in four cities with 58
22 participants to get -- and this is really the first

1 detailed feedback from clinicians around the
2 Priorities and Research Agenda. And to look at the
3 Priorities from the clinicians perspective, their
4 understanding and reaction to PCORI's proposed
5 priorities, as well as their general opinions about
6 PCORI's work and whether they actually understood
7 who we were and how we were relevant to their
8 lives, and ultimately to try and better understand
9 the practice needs, clinical issues, and how this
10 research is going to -- could be helpful to them in
11 their pursuit of their mission as practitioners.

12 This is, again, a geography -- San
13 Francisco, Chicago, Philadelphia, and Birmingham,
14 Alabama. Advanced practice nurses, cardiologists,
15 integrative healthcare practitioners, PAs, RNs,
16 primary care physicians, a mix of nurses,
17 psychiatrists, and orthopedists. And for many
18 reasons, we kept the specialists separated so that
19 we could get some sense of whether there were
20 differences among the specialties in terms of how
21 patient-centered outcomes research, what their
22 attitudes were and how much utility they saw in it

1 for their clinical practice.

2 And when you all get -- and this report
3 will be posted on the website, but you'll see that,
4 in fact, there were substantial differences among
5 the specialties in terms of avidity for patient-
6 centered outcomes research and their sense of
7 utility in their practice.

8 And these are just some of the findings
9 from the clinician focus group. Again, these are
10 very high level and quick and dirty, assembled in
11 the week prior to our Board meeting.

12 Clinicians have mixed feelings about the
13 research. They use and appreciate research, but
14 have concerns about corporate agendas, about the
15 issue of FDA approval times, they are split on
16 whether it's too fast or too slow, and feel several
17 steps removed in clinical practice from actual
18 research activity.

19 They voluntarily articulated the need for
20 many of the concepts behind comparative
21 effectiveness research and patient-centered
22 outcomes, but this is not the language they use and

1 the language required some explanation.

2 In terms of impressions of PCORI, one of
3 the biggest stumbling blocks is the perception that
4 PCORI is broad, overreaching, too idealistic to
5 have a meaningful impact. And, again, this is a
6 theme we heard from some of the patient focus
7 groups also.

8 Another communication challenge is, coming
9 from the clinicians interestingly, that how can we
10 ignore costs, the issues of access and payer
11 decisions that they feel overshadow discussions
12 about clinical outcomes. Again, split on whether
13 PCORI ought to be addressing them but articulating
14 that they become the 800 pound gorilla in the room,
15 unspoken and unaddressed.

16 Clinicians, similar to patients and
17 caregivers in the earlier focus groups, agree that
18 assessing options and communications are key
19 priority areas for PCORI. Clinicians also
20 prioritize improving healthcare systems, which
21 really means improving the conditions in their
22 working environment in terms of their ability to

1 achieve their own personal mission around
2 supporting patients and providing optimal patient
3 care.

4 In terms of advice for engagement, strong
5 preference for professional organizations,
6 professional societies as the preferred channel for
7 information. They trust their specialty societies
8 and believe information that comes from them.
9 They're willing to engage with PCORI if the
10 opportunities are convenient and very specific to
11 their practice setting in the patient populations
12 they're caring for.

13 They also like the idea of surveys,
14 they're easy, they're fast, they don't require them
15 to leave the office, but are willing to participate
16 in focus groups, again, if they have a sense that
17 the information is going to be used in a way that
18 ultimately is useful to them. And many underscored
19 the fact that ongoing communication is going to be
20 necessary, will take diligence on PCORI's part, but
21 without it, they're going to forget about us pretty
22 quickly.

1 This was the exercise of allocating
2 funding, you know, if you were running PCORI and
3 you were going to make funding decisions among
4 these priorities, the averages here really mask the
5 range of opinions. While the average of 17 percent
6 of funds would have been allocated to the
7 disparities, many individuals said it ought to be
8 part of everything else we do in addition to having
9 its own separate funding allocation. If we get all
10 the other stuff right, we will be addressing the
11 issue of eliminating disparities.

12 And, again, there was tremendous range
13 from the cardiologist who thought 75 percent of the
14 funding ought to go into assessment of prevention,
15 diagnosis and treatment options, to the
16 psychiatrist who thought that 80 percent ought to
17 go to addressing disparities.

18 And just one other point is, these
19 allocations were very similar to the patient and
20 caregiver focus group in terms of over -- again, on
21 average, representing funding.

22 And so, just once again, and I think we

1 talked about this earlier, the process of revising
2 the Priorities and Research Agenda, the PDC and
3 PCORI, and the PCORI Board, will review input from
4 the website, from the stakeholder dialogue, from
5 the focus groups, and from formal and informal
6 feedback that is being received by Board members
7 and staff at PCORI related events. There's a lot
8 of conversation going and many people have asked
9 for a mechanism to communicate that to staff so
10 that it can be incorporated into the work that
11 Deloitte will be doing on behalf of the PDC to
12 organize the feedback and put together the work
13 that will make the -- that will enable people to
14 understand what happened with their feedback and
15 how the feedback influenced the revised Priorities
16 and Research Agenda.

17 The report will be published on the
18 website, again, explaining how input led to changes
19 in the Priorities and then there will be a meeting
20 of the PCORI Board, a public meeting of the Board,
21 in April during which the revised Priorities and
22 Research Agenda will be presented.

1 April feels like it's tomorrow, but the
2 intent is they will be adopted in mid-April so that
3 they can, in time for the funding announcement in
4 May.

5 And, again, as I said earlier, in the
6 spirit of continual improvement, subsequent to this
7 Board meeting, Board members will receive a survey,
8 which I would -- we would really appreciate it if
9 100 percent of people filled out, on -- and this is
10 relating to our stakeholder and community
11 engagement events associated with Board meetings.
12 And these are the Board meetings we've held,
13 really, from the beginning through this Board
14 meeting.

15 We have -- we'll also be surveying
16 participants from our March 2011 through January
17 2012 stakeholder engagement events. We have
18 feedback from New York and St. Louis already. We
19 will be reaching out and surveying those who
20 presented to us and those who Board members met
21 with at the other Board meetings, to enable us,
22 again, to come back to the Board. We had hoped to

1 do this in May, I'm not sure that will be feasible,
2 hopefully we can, and to feed this into our
3 planning for the remainder of -- stakeholder events
4 for the remainder of 2012 as well as how we plan --
5 what we think we ought to be doing and can we be
6 doing creative things going forward, both in 2012,
7 second half, and 2013.

8 And, again, just a reminder about the
9 website address, the mailing list, just for people
10 to sign up on the mailing list. We have a Twitter
11 account for those of you who Tweet or follow
12 Tweets, and there is a separate portal for
13 providing feedback at any time, unrelated to the
14 Priorities and Research Agenda, and, again, a web
15 address for requesting speaker from PCORI for an
16 event in the community or for a professional
17 meeting.

18 And I will ask if any of the committee
19 members have any comments.

20 CHAIRMAN WASHINGTON: Okay. Start with
21 Sigal and then Hunt.

22 DR. SIGAL: Well, first of all, thank you

1 for your hard work and it's a good report and it's
2 interesting. I just have a specific question on
3 the patient and the patient advocates that
4 responded. So, I assume you mean patient --
5 individual patients? Okay, and in terms of the
6 advocacy organizations, do you have a breakdown of
7 whether they were disease specific or whether there
8 were big omissions? Because, you know, I know I've
9 been trying to get people to respond to this and
10 it's been a big task.

11 DR. LEVINE: We do have the information.
12 I don't have it here with me, but we do have the
13 names of all the organizations.

14 DR. SIGAL: Okay, and you did say you
15 proactively went out and tried to get more response
16 from groups too? Great.

17 DR. LEVINE: We're still doing that.

18 DR. SIGAL: Yeah, I know. Thank you.

19 CHAIRMAN WASHINGTON: Okay, Hunt and
20 then --

21 MS. HUNT: Yeah, Gail Hunt, Board of
22 Governors. Sharon, I know that we're just seeing

1 some of these numbers, you know, just literally now
2 and they're being updated. I'm concerned about how
3 few people have responded on the public feedback on
4 the draft Priorities and Agenda. One hundred and
5 one --

6 DR. LEVINE: It's 115, but, yeah.

7 MS. HUNT: Even if it's 150, it's -- and I
8 know that you say right before the 15th a bunch of
9 people will probably reply, and that's probably
10 true, but it's kind of -- the numbers are so small
11 and I'm concerned that the -- it's going to be the
12 big organizations that they'll will probably have
13 their letters in because I know that some people
14 are actually out there at the moment,
15 organizations, soliciting, let's get our letter in
16 to PCORI.

17 So, I'm concerned about it being a small
18 number and about they're just the big voices. And,
19 you know, I know that we can't, I guess -- we've
20 got these other things to rely on, the focus groups
21 and all, and we can go ahead, but I guess the sense
22 is that we need to, when we write this up, we need

1 to say that we understand that these are -- that
2 we're basing this, basically, on smaller numbers
3 and that we're not necessarily getting the voice of
4 the patient and caregiver in what we've got.

5 DR. LEVINE: It's a really good point and
6 I think the other point that will be made is, this
7 is the first iteration of National Priorities and
8 Research Agenda, and I think as we move forward and
9 our reach into the broader community over time gets
10 deeper and broader, hopefully that will result in
11 more familiarity, more interest in responding, and
12 I think how we behave in relationship to the
13 feedback we do get, will help to generate trust and
14 hopefully more interest in providing information.

15 CHAIRMAN WASHINGTON: Douma and then
16 Weisman and Clancy. Oh, Leah --

17 MS. HOLE-CURRY: Just for context, too, I
18 would say that the great thing about the
19 presentation, thank you, is also that it's not just
20 the online comments that we'd be referring to, but
21 the focus groups which did include actual patients
22 and the 800 or 900 folks that were at the

1 stakeholder focus event, which included, I think,
2 some patients. So, I think that's a good thing,
3 don't you?

4 MS. HUNT: Yeah, it's good that we had
5 those 800 or 900, but we didn't hear from 800 or
6 900 voices at that meeting saying, this is what we
7 think about the National Priorities and Research
8 Agenda. That's all I'm talking about is the input
9 to that.

10 CHAIRMAN WASHINGTON: Douma.

11 DR. DOUMA: Couple of responses. Ellen,
12 first of all, you can go online and see who's
13 actually signed up. I did that less than a week
14 ago and the vast majority of people are not
15 identifying with organizations, they're
16 individuals, so it's hard to tell.

17 Anybody? Anybody?

18 DR. SIGAL: Oh, so how do we classify
19 them?

20 DR. DOUMA: Oh, no, there's a separate
21 classification scheme and I didn't add those up.
22 There's just a list, you can see how they

1 identified themselves.

2 I am also very concerned about the small
3 number. I mean, hate to get too hyperbolic, but
4 with 200 million patients and 5 to 10 million other
5 stakeholders, we've got to figure a way, because
6 this is our third effort, really, and if we're only
7 getting a couple hundred people -- we've got to
8 have, and I'm not sure we did have, a communication
9 strategy or plan with regard to how to market this.
10 And we've got to learn from this experience -- and
11 decide, what are we going to be content with? Are
12 we going to be happy with 200 or is it 2,000? What
13 do we shoot for?

14 Because unless we've got something to
15 shoot for, we're not going to be able to measure
16 whether we're doing the right things or not. And,
17 so, I think we need to get more proscriptive, we
18 need to -- we just really need to have a
19 communication plan, measure against communication
20 plan, and every time we do it, adapt some of the
21 stuff we learned from the previous experience.

22 CHAIRMAN WASHINGTON: Is it related to

1 that? Krumholz, please.

2 DR. KRUMHOLZ: I just want to follow up
3 with Allen because I think that you're speaking of
4 the method, which is important, are we getting to
5 people in a way that they can contribute, but I
6 think the one thing that we may not have reflected
7 well enough with regard to the Priorities and
8 Agenda was laying out it conceptually, like, what
9 exactly would you say to it, because in deciding to
10 go in this direction, it may confuse people a
11 little bit because it's not saying, okay, there's
12 atrial fibrillation and cancer and this and that,
13 and maybe it was our fault, but we can work on the
14 methods, there's no question. Because I told
15 Carolyn, if I were to sit a family member in front
16 of a computer on the webpage and say, please
17 comment on this, they wouldn't know what to say, I
18 mean, you just wouldn't know how to manage it. And
19 there's the piece about how do we get them to the
20 computer to read -- to do that, but then there's
21 also the part about, when we went in this
22 direction, did we frame well enough what we were

1 looking for and how people might contribute to our
2 own evolution of thinking about this.

3 And I think our own thinking has continued
4 to evolve over time and the one thing that we could
5 do better going forward is that framing for people
6 about what kind of input might you give to this. I
7 mean, some people can give whatever they want, but
8 if someone who's a Tabula rasa is sitting down and
9 doesn't really have an idea about PCORI, it's hard
10 for them to engage in it the way we presented it
11 and that's what, I think, we need to work on.

12 CHAIRMAN WASHINGTON: Yeah, I think this
13 is an important point, and it's not just PCORI.
14 Remember, again, we're conducting this research for
15 the nation and I think this is a fundamental
16 question that all organizations are going to
17 encounter, and that is, again, it's basic: what is
18 the best, most effective way, in this case, to get
19 feedback? And that hasn't been defined. We don't
20 know even the basics about that, so that becomes a
21 research question.

22 I also think the point that Allen made is

1 one that at least I don't remember us discussing
2 is, what's our target? You know, we need to be
3 thinking about what makes sort of us feel that we
4 have in fact reached some penetration that
5 satisfies that we feel like we really do have
6 feedback.

7 DR. DOUMA: Can I quickly respond. I
8 agree totally with what both of you just said and I
9 think we just need to be much more proscriptive and
10 I just want to add a little nitpicky because I've
11 been involved with surveys for 35 years, the
12 survey, we've got to be careful about our survey
13 instruments themselves. This particular instrument
14 asks people whether -- it was basically a five-
15 point scale, three of those points were positive,
16 two were negative, that's not the way to ask a
17 survey.

18 We've got to be a little bit more rigorous
19 in the type of survey we do.

20 CHAIRMAN WASHINGTON: Next time all five
21 should be positive, right?

22 [Laughter.]

1 DR. DOUMA: Absolutely. If you're going
2 to do it, be blatant.

3 CHAIRMAN WASHINGTON: Okay, so we have
4 Weisman and then Clancy and Selby.

5 DR. WEISMAN: Yeah, I hate to disappoint
6 the Board, but this is not the most exciting thing
7 in peoples' lives although it is for us. So, I
8 mean, the fact that you're not having overwhelming
9 crowds in the streets, you know, cheering us on,
10 you know, there's a lot of other things going on.
11 There's the economy, there's elections, there's all
12 kinds of Academy Awards, there's lots of things
13 going on in peoples' lives, and this is important,
14 but I would say that we have had a fairly effective
15 way of getting feedback, particularly from
16 patients. You know, we've done focus groups.
17 Could they be done better? Yes. You know, I've
18 advocated for some quantitative market kind of
19 research kind of stuff that we can do, but, boy,
20 Joe's been on a road show forever. You know, the
21 only breaks you get off the road show are when you
22 come to a board meeting, right? And, you know,

1 other Board members have too. We've met with
2 patient groups.

3 You know, the heterogeneity among patients
4 is more narrow than I think it is among other
5 stakeholders in that they universally say that, you
6 know, they're not happy with -- by and large,
7 they're not happy with healthcare as it relates to
8 the information available to them that they don't
9 feel that people communicate with them effectively.
10 I mean, that's resoundingly what we hear over and
11 over again at the town halls that we had in New
12 York and St. Louis.

13 And I think the idea now, asking for them
14 to translate that into, how do you come up with
15 National Priorities, maybe we could do that better.
16 I'm not sure what else we could be doing, to be
17 honest with you, because we haven't done stuff yet
18 that shows them the value of what we can do for
19 them, and I think as we do that, as that momentum
20 builds, you know, maybe we will get more
21 engagement, but I do think we've done a reasonably
22 good job at hearing what's on the minds of patients

1 and I think a lot of what Harlan was addressing in
2 his inaugural speech then -- or, state of the
3 union, was addressing that for them.

4 DR. LEVINE: Right. And I think one of
5 the things that was very illustrative for me was I
6 talk to lots of folks in breaks in the morning and
7 it took most of the morning for people to actually
8 understand -- and these are people who are very
9 sophisticated and for whom this is their life, for
10 the most part, to really get what we were asking
11 and get what -- why the framework and how we
12 actually thought we might get from where we're
13 starting to actual answers to questions.

14 And I think the same thing was true in the
15 focus groups with the clinicians. Again, it took a
16 while for them to actually be able to engage and
17 answer the questions, and so imagine, you know,
18 people sitting down getting a note from a consumer
19 advocacy organization and saying, you know, go to
20 the website and let PCORI hear from you about what
21 you think, I think it's a tall order because we
22 were asking for a lot in terms of the feedback for

1 this.

2 Now, so what I take away from that is the
3 more targeted and specific the questions we want
4 feedback on, and the more relevant they are to
5 peoples' lives, the more likely we are to get a
6 more robust response. And I do think that our
7 ability to disseminate the request for help through
8 trusted organizations and building a network of
9 organizations who trust us enough to do this on our
10 behalf with their constituents, again, will help us
11 achieve what we really want, which is deeper and
12 broader understanding.

13 CHAIRMAN WASHINGTON: Okay. Clancy? And
14 then Lipstein, Norquist and --

15 DR. CLANCY: So, first I wanted to thank
16 Sharon and the committee for a terrific
17 presentation.

18 I will tell you, and as your own Sue
19 Sheridan, part of the wonderful engagement team
20 knows very, very well, in many areas, whether it's
21 quality, safety, a variety of things, all of which
22 are a little bit more proximal to peoples'

1 experience, it is hard to get people involved.

2 In general, they tend to be a narrow,
3 tight group of folks who are wonderful, but Sue
4 will tell you, this is why we call her a lot -- we
5 have in her prior life anyway -- it is difficult
6 and it's pretty abstract stuff and in addition to
7 that, I think it's fair to say that there's been an
8 unprecedented number of opportunities, I'm thinking
9 about proposed rules related to the Affordable Care
10 Act, for people to weigh in about stuff that's
11 going to affect them next year, okay.

12 So, I think that bandwidth issue is all
13 part of what we're doing. That said, I think from
14 what I understand, there were a lot of patient
15 groups who wanted this legislation to happen. We
16 have an incredible opportunity to reach out
17 directly, not just come to our website, that is
18 fairly passive, I mean, great if they do, but it is
19 abstract stuff. On some level there's a whole lot
20 of people, I think, want to hear what are the
21 priorities going to be and do they care about it.
22 To tell them that they get to do more work for free

1 to be engaged in potentially writing proposals, I
2 mean, this is all very, very downstream kinds of
3 stuff at a moment in time when there's a lot of
4 challenging issues right now today.

5 The other thing I wanted to just underline
6 in Sharon's presentation, in case it was too
7 subtle, was the word diligence. I think this
8 comment came from a focus group participant or I
9 can't remember if they said it or if that was your
10 interpretation.

11 I heard a lot of kudos for the meeting
12 last Monday, well-deserved kudos, but I also heard
13 people say, "show me." I'm thrilled to be here
14 today, but I want to be involved with you all
15 moving forward.

16 So, I think the stakeholder engagement
17 team here at PCORI will have their hands full and I
18 think that as a board we're going to have to figure
19 out how do we allocate resources, because the one
20 thing PCORI can uniquely do, and probably needs to
21 do uniquely, is to engage that. A lot of the other
22 functions, it's a little bit easier to outsource,

1 but if we're not doing that, then people are not
2 going to care.

3 CHAIRMAN WASHINGTON: Let's go to Selby
4 first because I skipped him.

5 DR. SELBY: Thanks, Gail. Yes, and those
6 people who said, "Show me," were all from Missouri.

7 So, I've also been watching the numbers
8 accumulate slowly and been -- I'm in full agreement
9 with all the people who've offered explanations for
10 why the numbers are low, and the question I've
11 had -- and so I've had a little bit of mixed
12 feelings, is whether efforts to gin up the response
13 rate more would wind up giving us a more or less
14 balanced -- biased -- more or less biased sample in
15 the end, and so I've been wanting to be careful
16 about those efforts.

17 But back at PCORI, others have also been
18 watching and we do have, I think, some strategies
19 in place, and I'd like to ask Bill Silberg, our
20 Director of Communications, to just speak briefly
21 on some efforts we're going to undertake in these
22 last ten days to see if we can't get the rates up

1 some.

2 MR. SILBERG: Great. Thanks, Joe.

3 And we also share the concern that the
4 numbers have been smaller than we might like and
5 are growing slowly, and I think all of the issues
6 that have been raised and the points that have been
7 made are part of that whole question.

8 That having been said, we are working full
9 tilt to do what we can in the next ten days to
10 accomplish, really, two things. One is to try to,
11 as broadly as we can, both on the professional and
12 the consumer side, do as much outreach as is
13 reasonable given the time we have so that we are
14 able to defensibly say, we made every reasonable
15 effort to get the word out.

16 If that didn't directly result in the kind
17 of numbers we would all like to see, you know,
18 there's only so much we can do about that, but we
19 don't want to be caught with anyone saying, how
20 come I didn't know, because I think that is a big
21 perceptual issue and we owe it to our various
22 audiences to do that. So, we are doing that in a

1 number of ways.

2 We now have all of our engagement team
3 engaged fully in a full court press to contact all
4 of the folks that they know with an eye not just
5 toward would you please individually send us a
6 comment, but to mobilize all of their
7 communications capacity to get the word out to
8 their constituencies because obviously we could
9 hire a thousand folks to make phone calls and we
10 wouldn't reach as many folks as if we could
11 mobilize all of our partners.

12 So, that's one piece. We're doing a lot
13 of this. We're also doing a series of targeted
14 online ads and alerts to both professional and
15 consumer media trying to get the biggest bang for
16 the buck. So, on the professional side, trying to
17 go out through places like Modern Healthcare,
18 American Medical News. We're working with the
19 Health Affairs listserv and blog on the consumer
20 side, WebMD, the AARP website.

21 We're really trying to get the word in
22 front of as many folks who will see it and try to

1 get back to us as possible.

2 In addition, we're trying to work with
3 what's called in the business, earned media, but
4 it's basically trying to get to folks who reach
5 these audiences, not through paid advertising or
6 just through personal calls, but really trying to
7 get our message in front of them through their
8 various communications vehicles, which are expected
9 by those audiences, so they have some resonance.

10 So, we really are trying to do everything
11 we can, but we hear you, we hear you totally, and I
12 think one of the important points to kind of leave
13 you with is just as much of the rest of what we're
14 doing is a piece along a road, it's a start or
15 maybe step two in a start, we see what we learn
16 here, as several have said, to contribute to an
17 ongoing conversation. Our real opportunities are
18 not just, we think, to try to do the best we can to
19 get as much comment and synthesize it based on this
20 one piece of PCORI's work, but to begin to set the
21 stage to do this over and over and over again in a
22 consistent and iterative process to build these

1 partnerships so that the next time we have
2 something important we want our communities to talk
3 about, we hopefully will not be having the same
4 conversation.

5 CHAIRMAN WASHINGTON: Lipstein and then
6 right next to him, Lewis-Hall, and then --

7 VICE CHAIRMAN LIPSTEIN: So, there are two
8 points, one that Gail made and one that Carolyn
9 made and I know we don't want to repeat, but there
10 are things that I think are worth emphasizing.

11 We do know now after two years of
12 experience with PCORI that there are organizations
13 that send a representative to every single one of
14 our meetings, so they have a voice which will be
15 heard loud and clear because they have a paid
16 professional on their staff whose 100 percent role
17 is to track PCORI.

18 And so we will hear from them. So, I
19 think we need to be sure that that voice doesn't
20 get magnified to the exclusion of other voices that
21 we want to hear from. And that was a key point.

22 Two was, Carolyn brought up a key point

1 too, which is, for the last two months, the medical
2 establishment has been really focused on what was
3 going to happen with the SGR, sustainable growth
4 rate fix, and then the offsets affected every other
5 aspect of our industry, and so we were all consumed
6 with writing testimony or feedback or opinions on
7 things that actually had significant dollar
8 consequences for the healthcare sector of the
9 American economy, which means we weren't focused on
10 PCORI, and so I think we need to keep that in mind
11 too, that the timing here is not great for getting
12 feedback.

13 But the third was, is that as Joe has made
14 his presentations and I've made three and, Allen,
15 you commented that you -- it's been very well
16 received. The National Priorities and the Research
17 Agenda have been very well received. The number
18 one criticism being that, you know, maybe we
19 weren't specific enough, which could also be
20 interpreted as we didn't give people enough to
21 shoot at.

22 And if you didn't give people enough to

1 shoot at, then maybe that explains a little bit of
2 the de minimis return in terms of feedback, but I
3 think we need to -- you know, when I saw this, I
4 didn't necessarily think it was an inadequacy of
5 interest or concern, it just meant there were a lot
6 of other priorities going, or, alternatively, that
7 people were very much -- people don't tend to write
8 in comments or provide feedback if they're in
9 agreement with you.

10 CHAIRMAN WASHINGTON: Okay. Lewis-Hall.
11 Then Norquist.

12 DR. LEWIS-HALL: Freda Lewis-Hall, Board.
13 Actually, I was going in a little bit of a
14 different direction, which is, I'm not sure people
15 know what to say along the lines of what Harlan
16 said, you know, I don't recognize this, I'm not
17 quite sure what this means to me, and I'm not sure
18 what to say even if I had something to say.

19 So, I think the reframing is really
20 important, one. The second thing is, we continue
21 to ask people to come to us to make the comments,
22 and we may want to -- you know, the reach is great,

1 but we're still saying, now that I've reached you,
2 please come to us, to our website, to our meeting,
3 you know, to our focus groups, or whatever. There
4 may be an opportunity for us to shift a little bit
5 and to literally go where people are and ask them
6 their questions there, and I think, Steve, you had
7 given the comment once, you know, why aren't we
8 roaming the halls of a hospital or a clinic or
9 where people are receiving care or in a drug store
10 or a mall, or wherever it is people are
11 congregating and ask them the questions if you
12 really want people who, you know, don't have a bias
13 or some acute interest in this.

14 So, I think we do have an opportunity to
15 evolve and grow in the way in which we do outreach,
16 both in simplifying our message, framing specific
17 questions that people can respond to that would,
18 you know, give them a way to give us feedback, and
19 then to go where they are and not to ask them to do
20 any more work than they are likely to be inclined
21 to do.

22 CHAIRMAN WASHINGTON: Norquist.

1 DR. NORQUIST: So, Gray Norquist, member
2 of the Board. So, I'll follow on with Freda
3 because one of the -- I didn't make it to the
4 February 27th but I got to watch it and keep the
5 recording of Harlan and everything on my personal -
6 - but the one comment that actually struck me the
7 most out of all the people who testify was a woman,
8 and I can't remember what organization she was
9 with, but stood up and said, this is all well and
10 good, I like this, but I hope one day we have a
11 meeting in which people are unlike us are here.

12 And so, I just want -- it's very hard. I
13 agree with Carolyn, it's very hard to get input and
14 I agree with Freda, you can't, you know, build a
15 place and assume that people are going to come
16 because they're not. I mean, they've got -- trust
17 me, they're not worried about the healthcare,
18 they're just worried about just surviving day to
19 day many of these groups.

20 So, I hope -- we now have an engagement
21 group and I hope we can work with them to really
22 get out of our little tower or whatever and get out

1 there and really try to figure out how we can get
2 them, but it's not going to happen this year, but
3 that could be something really different that no
4 other group has ever done to really try to reach
5 these people who underrepresented, who are
6 suffering with chronic medical conditions, who
7 really have something to input. Now, they may not
8 say it the way you want them to say it, but they
9 know what the problems are and they'll say it.

10 So, I hope we put some strong effort in
11 that and really try to reach the groups who are
12 suffering the most and, it's hard, but I think it's
13 worth it.

14 CHAIRMAN WASHINGTON: Dr. Levine, you want
15 to wrap up your report?

16 DR. LEVINE: I want to thank everyone for
17 their comments. I mean, this is really -- we are
18 at the beginning of a process and I'm the number
19 one fan of our new engagement team and I think the
20 capability and potential they bring to us in terms
21 of putting on steroids what our -- you know, what
22 we have been trying to do for the last year and a

1 half. And, again, to continue to learn from what
2 we're doing.

3 So, my ask of you is to fill out the
4 survey and be free. You all know exactly what
5 those questions are about, so there shouldn't be
6 any issue of framing or reframing, but give us your
7 thoughts about how we can actually make these
8 engagements in relationship to our Board meetings
9 meaningful. And to Freda's point, perhaps turn our
10 approach 90 or 180 degrees.

11 CHAIRMAN WASHINGTON: Okay, just in
12 wrapping up this session, again, I want to
13 acknowledge that this represents an amazing amount
14 of work on the part of not just those involved in
15 the communications and outreach and engagement
16 committee, but also other Board members and the
17 many stakeholders who, in fact, showed up for the
18 conference and are responding online.

19 And, importantly, last Monday was a big
20 success, I would say principally because in
21 addition to the Mr. President's speech, the staff,
22 and I really want to compliment the staff for a

1 phenomenal job in putting this together in a very
2 short period of time and I think that they, from
3 everything that I have heard, really reflects the
4 best of what PCORI is offering now and what we are
5 going to offer in the future as it relates to
6 patient and stakeholder engagement.

7 So, it feels good.

8 DR. CLANCY: Are you going to post the
9 video on the website? I mean, that would actually,
10 I think, capture peoples' attention. The video
11 from last Monday? I know there's a video of Joe,
12 but -- great. Great.

13 UNIDENTIFIED SPEAKER: Do you have a
14 screensaver?

15 CHAIRMAN WASHINGTON: Of Harlan? Okay.
16 We're going to pass that around.

17 We've come to the conclusion of the day
18 and I think every Board member would agree that
19 this has been an intense but highly productive
20 meeting today and so, again, I want to thank
21 everyone who came to join us and participate in
22 person as well as those on the line, and thank the

1 Board for your ongoing deep involvement day to day
2 in the life of PCORI and in ensuring that we
3 realize the promise that's inherent in our charge.

4 So, thanks, everyone, for your
5 participation. That concludes the meeting.

6 [Whereupon, the PCORI Board of Governors
7 meeting was concluded.]

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