BOARD OF GOVERNORS MEETING

Monday, November 19, 2012

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

[Transcribed from PCORI Webcast.]
PRESENT:

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

1. Welcome
   Consideration of May & September Board Meeting Minutes for Approval

2. Executive Director’s Report

3. Methodology Committee Update:
   Revisions of Standards and Recommended Actions
   Discussion and consideration for approval

4. Recess

5. Advisory Panel Charters
   Presentation on first three proposed panels:
   Patient Engagement, Comparative Assessment of Options, and Health Disparities
   Discussion and consideration for approval

6. 2013 Budget
   Discussion and consideration for approval
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PROCEEDINGS

[8:36 AM EST]

CHAIRMAN WASHINGTON: Good morning, everyone, and welcome to the Board of Governors Meeting of the Patient-Centered Outcomes Research Institute. We’re pleased to welcome everyone that’s here in person as well as those that are participating via our webcast proceeding.

This is our 14th public meeting, which includes 12 face-to-face meetings and two special Board webinars. For those of you who are joining us via the webcast, I want you to know that you can reach us online, today, via a toll-free number that’s listed on the Board meeting page on our website at www.pcori.org.

I’m also pleased to remind you that, as with all of our public meetings, today we will have a public comment period from 4:15 to 4:45 Eastern time and we have several individuals already registered, but if there are additional individuals who would like to register, if you’re on site, you can just walk up and register in person by 3:00
p.m., and if you’re watching online or listening on
the phone, you can alert the operator. And, as a
reminder, that number to call in is 1-800-875-3456.

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

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

UNIDENTIFIED BOARD MEMBER: [off
microphone – inaudible.]

UNIDENTIFIED BOARD MEMBER: [off
microphone – inaudible.]

CHAIRMAN WASHINGTON: Okay, I have a
motion and a second. Comments?

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

You felt my presence, I’m touched. Thank you.

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

[Chorus of ayes.]

CHAIRMAN WASHINGTON: All opposed?

[No audible or visual response.]

CHAIRMAN WASHINGTON: Okay, any abstentions?

[No audible or visual response.]

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

And September?

UNIDENTIFIED BOARD MEMBER: So moved.

CHAIRMAN WASHINGTON: Okay, it’s been moved, and second.
UNIDENTIFIED BOARD MEMBER: [Off microphone.]

CHAIRMAN WASHINGTON: Comments?
[No response.]

CHAIRMAN WASHINGTON: All in favor?
[Show of hands.]

CHAIRMAN WASHINGTON: All opposed?
[No audible or visual response.]

CHAIRMAN WASHINGTON: Okay, any abstentions?
[No audible or visual response.]

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

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

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

So, we do have an action-packed agenda, as usual. If you recall at our last meeting in
Washington, D.C. in September, we spent a good part of the first day on engagement. We’ve agreed, as a Board, that engagement is a strategic imperative for our activities, that it’s one of the ways that we distinguish ourselves and one of the ways that we make patient-centered outcomes research more patient-centered and more relevant.

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

But today we’re not going to talk as much about engagement, we’re going to talk more about methodology, hear from the Methodology Committee, talk about research that we are funding and are about to fund, and talk about the budget for next year.
But one topic that I really -- that this meeting can’t go by without mentioning is the workshop that was held in Washington, D.C. on October 26 to 28. It was entitled “Transforming Patient-Centered Research, Building Partnerships and Promising Models” and this was really one of the first manifestations of our engagement program. We brought a total of 170 persons, more than we had aimed for, actually, this meeting was oversubscribed. Patients and other stakeholders from 40 states were represented, this included patients -- individual patients, patients from organizations as large as the American Heart Association, patients who were engaged in research networks and other partnerships with researchers, 250 additional persons that attended the conference by webinar each day. Videos of these meetings are available at pcori.org, and happy to say that there was really outstanding attendance by the Board, five Board members, essentially the entire COEC, Communications Outreach and Engagement Committee, as well as a Methodology Committee members were
present and participated in the meeting.

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

[Video shown.]

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

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

We presented our proposed strategies for engagement, the same strategies that we had presented to the Board in September. In general, I think it’s fair to say that they were endorsed, but in almost every case there were some refinements.
that really had a ring of authenticity to them, that were offered throughout the day.

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

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

Another suggestion that came out of the meeting that we’re pursuing is the notion of PCORI ambassadors, patients who would be particularly
engaged with PCORI and represent us locally throughout the country.

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

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

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

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

   So, the methods are challenging and this
day will bring together experts and stakeholders to
review where we’ve gotten. We’ve actually been
pilot testing the prioritization process and we’ll
go over that and hopefully at the end have a clear
picture of how we’re going to implement research
prioritization.
So, those are the next two engagement -- major engagement events coming up.

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

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

This person will serve as the principle spokesperson and represent PCORI with all major stakeholder organizations, bring these organizations together to help plan and conduct our research, and they will work closely with the Board
of Governors, its COEC, and the Methodology Committee, to strengthen our ongoing relationships with the community and particularly to evaluate what we do in the realm of engagement.

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

So, Dr. Anne Beal has been overseeing and supporting the engagement work, among many other tasks that she takes on, and so, I’m also very happy to say that bringing on the Chief Officer for Engagement allows us to recognize Anne’s many contributions and to announce that actually she’s had a title change and she is now the Deputy Executive Director as well as Chief Operating Officer for PCORI and in that role she’ll be able to take on a number of tasks supporting me and the executive team as well as continue to oversee contracting, finance, communication, HR, and facilities.
So, Anne just celebrated her one-year anniversary with us and I’d like to congratulate her.

[Applause.]

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

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

So, now there are three positions at the officer level. The Chief Science Officer and the Chief Officer for Engagement are not yet in place. Anne, obviously, has been here for the year.
Active searches with search firms are underway for both of these and I think with PCORI’s future now just a little bit clearer and more solid, we’re very optimistic that in the next several months we’ll have these positions filled, so the Chief Science Officer and the Chief Officer for Engagement.

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

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

In addition, Dr. Lori Frank is our Director for Engagement Research and it reflects the fact that we take evaluation of our engagement activities very seriously. We think it’s in our
strategic interest to identify what’s working, to
demonstrate to the public and the research
community what works, and to refine it so that it
works better.

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

So, that’s the engagement -- that’s the
entire executive team.

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

Then, as I said, you’re going to hear
about the PCORI advisory committees, the first
PCORI advisory committee charters. In September
you instructed us to prepare charters and three
charters have been prepared and Dr. Beal will
present those to you next.

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

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

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

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

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

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

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

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

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

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

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

For those of you who had not heard, Dr.
Gabriel is now the new dean of the medical school at the Mayo Clinic, so we want to congratulate you, Dean.

[Applause.]

I’ll turn it over to you.

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

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

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

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

And so, what I’m going to propose is adoption of the standards and recommended actions and hope that the Board also agrees with us beginning a dissemination effort along with the COEC. Last night there was a lot of discussion about implementation and I think 7:45 this morning I got two slides that kind of helped highlight the
dissemination directions that the Methodology Committee, working with the COEC, hopes to move forward in order to disseminate the standards with the hope and the expectation, really, that these will change practice and will be a major driver for how research is done differently.

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

This is just a reminder slide, so, this slide you saw before at my last presentation, I think, back in May, just to give you a sense of how we got to the initial draft methodology report. As you know, there were a number of methodologic areas that were identified, working groups were assigned, we prioritized a variety of methods and methodologic questions to be examined, a lot of information gathering involving not only our team and the staff, but many external researchers and contractors, and then a process of internal review and deliberation and debate that led to the standards that you saw in May and that we received public comment for over the summer.
And I have to say, sometimes methodologic standards are a little bit dry, if you will, I don’t think ours are, but the topic can be, and I was a little worried about not receiving much public comment, and we -- those worries were soon vanished.

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

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

And here you can see on the right-hand side of the slide, the 12 areas, the 12 topics of
the standards, and just the number of comments in each. Everybody’s eye will go to the 143 under trials, but let me just point out that our specific standard with respect to trials was on adaptive trials.

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

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

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

So, basically there were five major themes
from the public comments. Most of the comments -- well, first of all, I’ll say that the majority of the comments were really very supportive of our standards. But the themes were as follows: many of them pointed to the importance of implementation, and, again, we talked about this a good bit last night and I’m actually excited about the proposed work that we hope to do with the COEC to disseminate and eventually implement these standards.

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

There were a number of gaps that were identified, many of them we knew and I think we
shared with the Board back in May that we couldn’t
cover, we didn’t intend to cover the entire
waterfront, but there were some important gaps, and
this is a reminder to remind you that this is
version one, so there will be additional work as we
go on to update, add standards, go through this
process again, and really continually improve the
methodology report and the methodologic standards
and actions.

And then accessibility. There were a
number of comments about accessibility of the
document. Parts of it were accessible to, I think,
a broad audience, but parts of it, especially the
analytics standards, were somewhat less accessible
and there was advice to improve that. And then
finally, feasibility of the standards to produce
patient-centered research findings. And, again, it
reminds me of our discussion not only last night,
but when the Methodology Committee met yesterday,
one of our primary agendas for the coming year is
to really build a program for evaluation to
determine -- to study and determine how these
standards really help us reach our ultimate goal of producing patient-centered research findings and information that people can use to make better decisions.

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

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

In a couple of situations, several,
actually, we solicited outside expertise, so sometimes the actual commenters themselves where we went back and said, you know, help us understand exactly what you meant by this. Other times it was the contractors that helped us write the initial set of standards, or at least informed the writing of the initial set of standards, just to make sure that we were understanding things as clearly as possible, particularly in the area of research prioritization, heterogeneity, diagnostic testing, and adaptive trials, those were the areas where we solicited external expertise to help understand and better respond to the comments.

And then the work -- at the end of all of that, the working groups drafted proposed revisions, and in October, we came back as a full committee to review everything the various working groups had proposed as a full committee, and on October 31st, which was what was supposed to be a face-to-face meeting, but thanks to Sandy we ended up doing it virtually -- Hurricane Sandy, that is, and anyway, it worked out very well, and we came
together, at least virtually, for a whole day and really went through everything and came up with a final set of standards.

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

So, whereas some of us didn’t agree on certain components of certain standards, we wanted to be certain that the level of disagreement or dissent didn’t rise to the level that, you know, it
couldn’t -- didn’t keep you up at night and it wasn’t enough that you would not endorse the entire set to come forward to this body.

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

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

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

So, just at a very high level, revisions
to the methodologic standards, 21 of our standards, I know you may recall that we started with over 60, 21 were revised, 14 of those were major changes with respect to the content, 7 of them I guess we call just wording changes, although I think some of those were substantive as well, 19 standards were either deleted, expanded, or consolidated, and 21 of the 60-some were unchanged. So, it really did end up, at the end of the day, to be some very significant changes. This is just a clip -- I’m not going to go through this line-by-line -- but it’s just a little bit of what we call our working document. So, we have a very detailed working document that specifies each standard, the summary of the revision, and how we -- how the standard ended up being changed. And so, just as an example, this is the causal inference standard, and what we heard from one commenter was that this particular standard focuses on point exposures and didn’t really address time varying treatments. And PCORI’s mission talks about longitudinal problems and
longitudinal outcomes and why is it that the standard really addresses an event that would occur only at one point and not something that might change over time. And we agreed with this, as we agreed with many of the comments, and you can see that the resulting standard really has been changed quite a bit to talk about, you know, prospect of studies and the fact that some exposures do change over time and that that should be specified and is included.

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

And here is a relatively minor, but I think also important, comment that we -- some of our standards talk about interventions, which
suggest a treatment or some sort of intervention,
but really to broaden that so that we’re talking
about exposures that might affect outcome of
patients, which could be interventions or other
things, and so we kind of changed the language
there.

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

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

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

Actually, before I go on, I just thought,
if I could ask Sharon-Lise if she had any comments
on the process.
CHAIRMAN WASHINGTON: Please.

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

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

Just a word on dissemination and
implementation of the standards. So, anticipating moving these -- we’re anticipating moving forward with dissemination and implementation. Again, as we discussed last night, we understand that adherence to these standards is not going to be entirely simple. It will require changes in the way we solicit research, in the way investigators design research, certainly in the way it’s reviewed and funded and monitored, et cetera. And that’s going to require a coordinated effort -- a multi-stakeholder coordinated effort, and so we hope to work with the staff and with the guidance of the COEC, including bringing together advisory groups as needed to really understand how best to disseminate and implement these and prioritize and stage our dissemination activity going forward.

And so, in addition to your consideration of the standards, we ask that you endorse our two groups to work together to continue the work that they actually already started yesterday, to develop an initiative for widespread dissemination and implementation of the standards and I think the
group also is asking to convene a new advisory
group for this initiative that will hopefully
involve some of you.

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

So, this is my last slide, if I may -- uh
oh -- this is the Methodology Committee vice chair,
Sharon-Lise Normand’s last meeting and I just --
last public meeting with the Board, and yesterday
at the Methodology Committee meeting we had a very
nice tribute. I didn’t actually know that she
could turn red, but she kind of turned a little bit
red, and we had, every single one of us, shared a
story about our experiences with Sharon-Lise -- all
but one. One of us actually shared an operetta,
which was lovely. Steve Goodman, who I’m sure you
all know is a very accomplished opera singer
actually created a little operetta just as a
tribute for Sharon-Lise and we played that, and we
really -- to a person, commented that we have
learned an incredible amount from Sharon-Lise and
we’ll miss her wisdom greatly and we will just miss
having her around. And so, it’s been wonderful.
Thank you very much for everything.

[Applause.]

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

Shortly after Sharon-Lise announced to me,
to Steve, to Joe, that she was going to be stepping
aside I sent her a note in which I expressed our
deep gratitude and heartfelt thanks for all that
she had contributed in terms of her wisdom and
insight and the knowledge, but I also commented
that because of Sharon-Lise, I mean, the bar had
been set very, very, very high, and that will be an
enduring and endearing memory of your legacy on the
Board. And, again, thanks. And just know that we
know where to find you. You can run, but you can’t hide.

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

[Applause.]

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

[Applause.]

CHAIRMAN WASHINGTON: Okay, with that, I’m going to open it up. There is a proposal on the table that we would first adopt these and the second part of this would be that we would endorse this concept, which Sherine, I don’t think it
really needs an endorsement, we would just encourage you to go forward and continue your work with the COEC and the Methodology Committee.

So, we’re going to focus on the changes that have been proposed and adopted and the current recommendation from the Methodology Committee that this be the current standards coming from the group.

Let me start with Dr. Collins.

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

Just two questions. So, first of all, you’re putting forward now the expectation that with these standards in place that there will be a desire to see researchers adhere to them and one of my questions is, how are you going to assess, going forward, whether in the real world of research these standards, A, are being adhered to, and B, that that’s actually working as opposed to real world experience, which sometimes leads you to need...
to revise what, in a more ideal kind of think tank approach, you might have hoped could happen?

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

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

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

One of the, I guess, fortunate things is that we have already -- PCORI has already funded research before the standards were implemented, and
so as I alluded to yesterday, we spent a good part of the day thinking about what we’re going to do in the coming months, and one of the key activities is going to be to develop an evaluation plan to assess exactly those questions. So, we’re methodologists, we’re going to do this -- we’re going to develop a research plan, if you will, to consider ways of determining, testing, evaluating, exactly how these standards are being used, have been used, compared to what happened -- what we’ve done in the past and to use that information to continually improve the process.

Now, I’m going to ask, I’m not sure exactly who, but --

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

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

MS. NORMAND: So, part of it is we had a discussion yesterday about -- so, first of all, we want to collect information from the peer review, so we’re going to -- the hope is to collect
information about patient representatives or participants. So, collect a lot of data on the review cycle, what’s happening there.

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

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

DR. GABRIEL: Yeah, Mike had proposed, actually, some experimental approaches that we’re going to consider and I’m also going to ask Brian
to comment on the implementation piece and then
we’ll get to the translation table question.

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

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

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

So, there’s a movement afoot to go ahead
and do this.

Now, PCORI is in a fabulous situation
because we’ve actually prospectively defined a set of standards for research that we certainly would like to see from our institute as well as potentially from other institutes as well, and given that we have defined the standards in a rather explicit way, we’re also in a position to engage in some experiments and so this is something that we’ve been talking about and thinking about is to use adherence to standards for applications or contract solicitations or contract responses, use these as our endpoint and see whether or not different approaches yield better likelihood to adhere to these.

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

DR. GABRIEL: Brian?

MR. MITTMAN: Brian Mittman, Methodology Committee. So, just to follow up and elaborate on my colleague’s comments, we have a good source of
guidance and how to go about designing studies to
evaluate the dissemination, implementation,
outcomes, effectiveness of these standards and that
is the field of implementation science and studies
of dissemination and effectiveness of other
standards for professional activity, namely
clinical practice guidelines. So, as the joint
Methodology Committee-COEC group gets together and
begins to think through the questions you’ve asked,
to lay out different kinds of studies, as Mike has
described, we will turn to that body of literature
for guidance and identifying methods, identifying
outcomes and measures and so on.

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

DR. SCHNEEWEISS: This is Sebastian
Schneeweiss from Harvard Medical School from the
PCORI methods committee. Many people of the methods committee, of course, very involved in these considerations, I just speak for many of us. We, in the methods report, we have provided a framework for a translation table and the considerations that have to go into building a translation table. While doing that, we realized this is a very difficult endeavor that we embarked here.

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

So, we had many follow on discussions internally in the methods committee and charted out several pathways forward here and I think yesterday the majority really thought that we need to understand better what the target audience is, what the consumers really want from a translation table because that will decide which way we will go of
the pathways that we have charted out here. So, that is certainly one of the first priorities for us to engage stakeholders from the entire spectrum to learn more about the uses of the translation table.

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

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

So, specifically the question would be is that we have not been able to even advise -- and I understand why, up until now -- that the standards not be part of our PFAs. As we go forward, we are currently going to be talking about PFAs and we have others that are going to go through. Will this be now required? Have we looked at what we’re looking at and what we’re doing and whether these are even amenable to what we’re trying to do? And will this just be a core requirement of any PCORI grant?
CHAIRMAN WASHINGTON: I would just say, I see that as a broader question for the Board. Please comment on it, but that’s why I was turning to Joe.

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

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

MS. SIGAL: Just a comment, and we’ll, I assume, discuss it at the full Board level, but it seems to me rather strange that we would have this
methodology report that we can’t adhere to with our own work.

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

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

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

DR. CLANCY: I think Joe may have just
answered my question. I was thinking through the practical steps, although it does strike me with the upcoming workshops you also have an opportunity to frame that in terms of what the report is proposing, if not totally finalized. I guess we’re recommending to or voting to adopt today the two early December workshops, and I also wanted to thank the Methodology Committee. Since I work closely with one of the members, I have probably a better inkling than some about just how much time it is.

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

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

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

MS. HOLE-CURRY: Okay.

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

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

CHAIRMAN WASHINGTON: That’s a good point.
MS. HOLE-CURRY: I think it is the primary
--

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

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

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

DR. SELBY: It is automatic, and the only
thing that's not is the good point you made that
it's not as simple as just instructing the peer
reviewers to grade each application on their level
of adherence. We have to go through the standards
one-by-one and figure out how to work with peer reviewers.

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

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

DR. WEISMAN: [Off microphone.]

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

Zwolack and then Lewis-Hall and then Krumholz.

DR. ZWOLACK: Bob Zwolack. First, I want to congratulate your group. This is spectacular. There’s a lot more clarity surrounding exposures
and I thought that overall the draft report was excellent, but this one is even better organized and much better, so I’d like to offer my congratulations.

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

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

We did receive many comments about that, you know, you could explain this better such and such a way, and we’re now going back to the process of doing that, and I think just as the comments
that we received on the standards and recommended actions have improved them, I think those comments will improve our explanation and hopefully make the entire document more accessible.

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

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

And so, along with the comments that we’ve received from the public and with external expertise in narrative medicine, we hope to improve those.
So, the first response to your question is that the report, we hope, will be that much better than what you saw in May just as the standards are that much better based on what we learned from the outside.

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

CHAIRMAN WASHINGTON: Absolutely.

DR. HELFAND: I don’t have a lot to add except that we were encouraged by the, sort of, interest people have in our doing a better job of exemplifying what we’re talking about, both on the level of, can you give me an example where a story where making missing data -- doing missing data right made a big difference in people’s lives, but
also on the level of, we keep talking about
listening to patients or listening to the people
and sort of how does that translate into research
methodology. How is that relevant -- you’re saying
that you want to hear stories, you want to hear
what people say about themselves, about their
illness. How does that -- how do researchers turn
that into changes in research design?

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

CHAIRMAN WASHINGTON: To that point,
Weisman?

DR. WEISMAN: Yeah, just --
CHAIRMAN WASHINGTON: Name.

DR. WEISMAN: Harlan Weisman, member of
the Board, and just a suggestion, maybe. At both
the workshop, but also at some of the visits the
Board has made to various groups around the
country, we have seen good examples of patient-centered research and how it has made a difference, and it might be worthwhile for the Methodology Committee, in looking for these narrations, to turn to whatever recordings we have of those interactions, including at the workshop where there were several groups already doing this kind of research where it made a difference.

CHAIRMAN WASHINGTON: Okay.

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

CHAIRMAN WASHINGTON: Lewis-Hall and then Krumholz.

MS. LEWIS-HALL: Freda Lewis-Hall, Board. I actually have three questions, two process and one on implementation. I’ll do the process ones first. It sounds as though, after public comment, these standards have changed, in some cases, quite dramatically. Is there any need to or intent to or was it not a part of our original design to reach back out for kind of this dramatically changed environment or is the feeling that we press ahead?
So, originally, I don’t recall, so I’m asking the question, I’m not sure we anticipated such dramatic changes in the standards as have been made as a result of some of the comments that we’ve received and then addressed.

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

MS. NORMAND: The answer is yes.

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

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

MS. LEWIS-HALL: So, then the second question is, again on process, there were a number of things that were not addressed, that were not actually standards, right, there were a lot of
comments that were about non-standard issues in the backdrop or the environment of research. How do we intend to address those moving forward?

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

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

    MS. LEWIS-HALL: Right.

    DR. HELFAND: -- but really were about the report that the standards were explained in. And until we revised -- we have looked at all of those and, of course, the AIR has looked at all of those, and the public’s looked at all of those. Every comment is out to the public. It came in -- was posted on the web 15 minutes after it came in for the whole summer.
So, the only way to respond to those comments, really, is to do something with them, that is, if we change the example on page 15, our response would be, we agree, we did that, and if we don’t, we would say why.

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

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

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

MS. NORMAND: And I just want to follow up, it’s Sharon-Lise Normand, on that. Just to underline, in case it wasn’t clear, for every comment, we have a response that we’re going to
post, just so you know, every single comment there will be a response to it, as Dr. Helfand indicated. We’re not going through all of them right now, but every single comment, there will be a --

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

MS. NORMAND: Exactly, exactly.

DR. GABRIEL: Absolutely every comment will be addressed.

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

So, any idea of how many researchers are able to meet these standards? How including patients in research might alter the ability to meet the standards? Or are those non-issues?
DR. GABRIEL: No, no, those are critical issues and, again, that sort of relates to maybe what Dr. Collins was asking a bit ago in our discussion yesterday about how do we build out a detailed evaluation plan. I mean, you heard Mike talk about experiments that we might be able to run to really demonstrate the impact of implementing these standards on the research.

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

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

CHAIRMAN WASHINGTON: Sharon-Lise wanted to --

MS. NORMAND: Yeah, I just wanted to --

Sharon-Lise Normand, outgoing Methodology Committee vice chair. I just want to emphasize the following, that there is nothing in our standards that hasn’t already been implemented successfully somewhere. So, these are all doable, and so really what we’re trying to do is to push the science and raise so that everybody engages in this type of research. So, just to be clear, it’s not that researchers won’t be able to do it, it’s out of their reach, that’s just not the case.

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

DR. SELBY: Only in response to Freda’s first question about will we put the revised standards out for another public comment. As we read the legislation we don’t think that it
suggests that, and it could get pretty circular and never stop --

MS. LEWIS-HALL: It’ll be 2015 before we get it.

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

DR. GABRIEL: Right, and the one thing to -- the one comment that I would like to add to that is that we did receive a number of comments on gaps, you didn’t address this and that, you need a new standard on this. Now, should we develop a brand new standard, I think that would have to go out for public comment. So, those sorts of
comments, we sort of reserve for version two, and I think that’s the category where I think it will have to go out for public comment, because it’s a brand new topic, not fix this.

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

DR. KRUMHOLZ: I just want to make two quick comments. One, first, I have to acknowledge the great works. That, I think, goes without question, but the issue of the implementation just got me thinking about these GIA standards and, you know, the Guideline Implementation Appraisals, and the degree to which, as written, it’s poised for adoption and use and it may be that we would benefit from thinking in the ways that some people have spent working with guidelines in trying to understand whether they’re ready for being implemented. And that doesn’t change the content. The content is fantastic. Just thinking about how does it get positioned in a way so that it can be used and checklists or whatever tools might be able to be used, you’ve got this -- I mean, you’ve got a
lot of ways in which it’s already being done, but just make it easier for people to use. And along those lines also with regard to being able to get this adopted and put into practice, I wonder if we should be thinking about standardization of that. So, with respect to our own grant-making, if this is just about training people on the peer review, I think we are going to fail to implement a standard approach to really looking at this. And the question is, can we get a prescreen so that there is a group of experts who go through the -- maybe they get graded first so that if people get filtered out early, for some reason or another, that there’s sort of a quick review. So, you’re left with a group of competitive grants and then those get a little deeper look in a very standardized approach that’s very much testing whether they’re in alignment with our own standards. And then that’s given to the peer review group with a little bit of annotation so that that helps them take it to the next level
of evaluation.

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

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

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

The second thing I’d like to state is that we’d also sort of want -- you know, again, we have this idea of experimentation that we’d like to be able to utilize. The third thing is, there are
standards and, as I said, these are all
implementable, so we didn’t pick anything -- I
would say, sort of unlike the guidelines, they’re a
little more rubber meets the road in terms of the
standards that we have proposed.

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

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

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

I think when you think about what you’ve
just said, that’s what’s going to be most important
to communicate. Where are those areas where there is great latitude? And where are those areas for which it’s nonnegotiable? And then that’s the -- I think the value of our standardized evaluation of the grants, and particularly if we’re trying to get grants from groups that may not traditionally be submitting grants or not have the great depth of experience, we want them to rely on this document to help guide them in the approaches that they may use.

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

CHAIRMAN WASHINGTON: Okay, good point.

We have five minutes and three comments. I’m going to limit it to three that were already -- Norquist, Hunt, and then final comment from Normand, and I’m going to call the question.

DR. NORQUIST: Yeah, this is Gray
Norquist, member of the Board. So, I actually read these, if you can believe that, on the plane, and so I would say to Freda that actually listening to the public does make a difference, it did make some reasonable changes. So, I would say that, and I would also congratulate you on your work.

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

And then I was going to do, Gene, you had five minutes and I wanted to make sure -- and I was going to make the motion that we accept the standards and then kind of move on from there. So, anyway --
CHAIRMAN WASHINGTON: Okay, well, we have a motion on the table, but can we hear from Gail and --

MS. HOLE-CURRY: Second.

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

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

Can you -- my sense, from reading the standard that you put in, you have stepped back from that. So, we would be in the position of stating one thing, which is that you will follow this, and the other is that we’re also saying you have to -- the proposers have to adopt the standards, have to be sure that they have the
complete standards, they meet the complete standards that you all have suggested, but it is at a lesser level and I mean, it’s maybe just because that’s where I focused, but it’s 4.1.1. I mean, I see the shaking of the heads, so you know what I’m talking about.

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

DR. GABRIEL: Yeah, so, yes, you’re referring to 4.1.1. We got a lot of comments about that and just to be clear, that reads “engage people representing the population of interest and other relevant stakeholders in ways that are appropriate and necessary in a given research context.” So, the stepping back might be in a given research context.

So, there were a couple of things that we heard and this was a subject -- this particular standard was a subject of lots and lots of discussion and debate and back and forth. One topic -- one comment was the initial standard, if
you remember, didn’t have other relevant stakeholders in the title and we heard a lot about, yes, of course, we’re the Patient-Centered Outcomes Research Institute, but there are other relevant stakeholders that you may need to bring in depending on the research context.

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

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

And so what you see here is the same set
of, you know, stakeholders should be engaged in the processes of formulating research questions, defining essential characteristics, monitoring study conduct, designing, suggesting plans. So, that’s all still there.

MS. HUNT: Gail Hunt again. Now it says, “stakeholders can be engaged,” not even should, so that’s the kind of thing I’m talking about in terms of stepping back and I think that it should be -- there should be something that talks specifically about patients and caregivers and their requirement to participate, and then other stakeholders too, and then talk about the other relevant stakeholders, but -- and also, the -- stepping back on the language.

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

So, this is saying, oh, you only need to do it if you deem it as appropriate and relevant,
and I think this will be something that people will just move right into that gap.

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

MS. HUNT: Mark?

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

DR. HUNT: Mark is going to die if he doesn’t get --

DR. HELFAND: No, that’s okay. Gail, the only thing I wanted to disagree with or correct, you know, it doesn’t say “if the researchers deem it necessary.” What I can tell you is that the thought behind these changes is that PCORI has a broader -- PCORI’s bigger than its methodologic standards. PCORI, let’s say, has an incredibly effective engagement activity with cardiac patients and a -- I’m just hypothesizing -- and a study comes along where there’s already a great group of
stakeholders for cardiovascular disease working with PCORI and a study comes along and says, as may have happened a few years ago, you know, maybe if you stop that Clopidogrel after one year you’re not doing the patents a great service. Maybe it should be continued two years, at least we’ve got some data to suggest that. And that group say -- engaged and everything says, PCORI, please, do a study to figure that out. And the study design is to go back into a database and reexamine it in a different statistical method and at what steps do the people want to be engaged in that particular kind of study if fast, retrospective analysis of the database? And that’s what we meant by the research context.

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

So, it isn’t leaving it up to the
researcher to decide engagement, yes or no, it’s allowing flexibility for the public as how they want to be engaged in different types of research studies and different -- in different contexts.

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

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

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

CHAIRMAN WASHINGTON: Okay, I thought we
were voting on the standards.

DR. SELBY: That’s what we’re called on to adopt.

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

MR. BECKER: What are we doing relative to Gail’s comment?

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

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

So, to me, what really matters is how we
implement this particular standard and to make sure that it’s implemented in alignment with, you know, PCORI’s mission, vision, and values, which we’ll do.

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

MS. NORMAND: Right, okay. Thank you.

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

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

And just wanted to mention one thing. You
brought in the new stakeholders or the other
stakeholders, that’s true, but when you look --
when you read it now, it sounds like they have the
option -- the proposers have the option of not
involving patients and caregivers, just involving,
say, primary care docs or cardiologists who are
stakeholders. They are definitely stakeholders,
but I think we’ve always talked about it as if
there were patients and caregivers involved as well
as --

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

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

At the same time, I am opposed to the
language change because I think to say “all ways,”
I mean, you’re putting -- it’s a quagmire for
reviewers and for investigators because, you know,
there are always alternative ways to do it and to say that they have to do it in all ways, I think would be really hard to implement.

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

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

UNIDENTIFIED BOARD MEMBER: This is Gray’s motion you’re talking about.

CHAIRMAN WASHINGTON: This is Gray’s
motion. And the motion is that we adopt the revised standards, not the specific, that are being recommended by the Methodology Committee. Are we clear?

CHAIRMAN WASHINGTON: All in favor?

[Hands raised.]

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

[Hands raised.]

CHAIRMAN WASHINGTON: Four. Abstaining?

[No visible hands.]

CHAIRMAN WASHINGTON: Okay, so the motion carries and we’ve adopted it.

Sharon-Lise has asked to make --

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

I will be remiss if I didn’t say the
following, I said this yesterday in the meeting with the Methodology Committee, we’ve all been parts of large groups and committees. I have to say that the Methodology Committee has been very, very delightful to work with. I can honestly say, there is no ego in that group. We come in, we listen to each other, there are no eyes rolling, everybody listens to everybody and it’s just been an endearing and creative group of people and I just want to say that I’m so grateful to have the opportunity to work with them. So, thank you again.

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

VICE CHAIRMAN LIPSTEIN: So, my name is Steve Lipstein. I am the not-yet-outgoing vice chair of the PCORI Board and I don’t want to talk about the Methodology Committee or its report, I’d just like to talk about Sharon-Lise for a minute. Because we vice chairs, we are kindred spirits. We
do everything that our chairs ask of us, but in Sharon-Lise’s case, she’s done everything that we could have asked of her and a whole lot more.

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

Sharon-Lise, thank you for everything.

[Applause.]
CHAIRMAN WASHINGTON: Thanks to the entire Methodology Committee for just a herculean effort and, I think, a tremendous outcome.

Break until 10:30.

[Recess.]

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

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

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

And so today, I understand that, in fact, we have a proposal for three advisory panels, as well as at least a proposal that we consider some additional ones going forward. So, we’re going to be looking for an endorsement of that idea as well.
And to present, we have our Executive Director, Dr. Anne Beal.

Thank you, Anne.

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

CHAIRMAN WASHINGTON: Beg your pardon?

Oh, Deputy Executive Director. That's right.

DR. BEAL: Yeah, right. I got you, Joe.

All right. So thank you Gene.

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

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

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

In addition, as we talked about how we would populate these panels, we wanted to make sure that we would pay a lot of attention to the diversity of interests and expertise and views that we would want to make sure are included in the panels, and we also talked about the fact that we
would want to compensate members for their time and that when people are appointed to these advisory panels, they would be appointed for one-year terms.

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

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

So, as we talk about the advisory panels that are in front of you today, there are two
specific questions that we want you all to consider. First is the scope of the work that’s outlined in the three advisory panel charters appropriate, and secondly, we’re going to have a discussion about additional advisory panels that we would like to develop in the first quarter of 2013. So, as we have today’s discussion, just recall that these are the specific questions that we would like to pose to you.

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

We would then submit a request to the Board for approval of an advisory panel charter, and that is the activity that we are engaging in today, and then the Board may either authorize the
charter or they may request revisions to the charters. So, that’s the discussion that we’re going to be having today.

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

Then once we’ve gone through that process and have selected a proposed slate of panels, we would then bring it back to the Board for the Board to then authorize and approve the nominees for panel membership and then also for the Board to select a chairperson to chair that panel.
So, the first three advisory panels that we are proposing, which we actually discussed at the last Board meeting, is the advisory panel on patient engagement, the advisory panel on comparative assessment of options, and the advisory panel on health disparities.

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

So, going into a bit more detail -- and as I say, you have the actual language in the appendix -- but one of the first ones that we thought was important to establish is the panel on patient engagement. Essentially, one of the things that we thought is that it would be very important to have a patient advisory board, if you will, which is really engaged to help us determine what are the patient engagement standards and what is the culture of patient-centeredness in all aspects of
PCORI’s research and dissemination activities.

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

In addition, as we’ve thought about it, there are other advisory panels that we’re going to be developing for the work of PCORI and for many of these advisory panels we’re going to ensure that we have patient representation on these other advisory panels. And so, some of our thinking is that for this patient engagement advisory panel that we would have patients who are able to serve on both advisory panels to be able to bring information back from the different advisory panels that we have to then this patient engagement advisory panel.

So, what we are proposing is that this be an advisory panel of between 12 to 21 members with...
an assurance that at least 75 percent, or a
supermajority, of the people who participate on the
panel be patients or caregivers or folks from
advocacy organizations, and then their balance be
people who represent perspectives from researchers
or stakeholders.

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

And so, we would be very interested in
having an advisory panel to help us with this
process towards getting to more specificity. So,
this is one in which the term would actually be for
two years and we would have its membership between 15 to 21 members, and in this case, at least 25 percent of the members will be patients, caregivers, and advocacy organizations. However, the balance or the majority of them would really represent individuals who come from either clinical research or other stakeholder backgrounds.

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

I think one of the things to highlight in terms of the work that we’re doing in terms of disparities is that historically a lot of the work in health disparities research has really been somewhat descriptive and what we really want to do is make sure that the focus of the work that we’re doing here at PCORI is really informing and identifying best strategies to eliminate disparities rather than to do studies that really describe the problems of disparities.
The other thing that I think is worth mentioning is that part of our emphasis on these panels as some of the first ones that we’re interested in developing is because, as Joe mentioned earlier, we just hired our program leads in these areas, and so part of the task that they’re going to be engaging in very early on is really developing the funding priorities and the funding strategies within each of these areas, and so they’re keen to have access to the expertise, which would be available through these advisory committees.

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

So, before we open it up for discussion, one of the things that we wanted to present to you all is that we now have these three charters in
front of us for advisory panels and would like to then focus on four charters that we would like to then bring back to you over the next two Board meetings.

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

As you all know, we currently have a number of proposals that are under review that we plan to be announcing within the next six to eight weeks, and so included among those may be projects that are focused on rare diseases. And so, as a result, if we have some projects that have scored
well that focus on rare diseases, then we would want to be able to have the latitude and the approval from this Board to be able then to develop the charters to be able to create the advisory panels for those.

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

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

So, with that, I’ll just take it back to
the questions, which is, again, asking about, is the scope of the work that is outlined in the materials that you have for the three advisory panels appropriate? And then we’re asking you to comment on our proposal for additional advisory panels for us to develop in the first quarter of 2013.

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

And I see quite a few. Why don’t I start with Krumholz and just work our way around to Collins -- no, I’m sorry, Kuntz. I meant Kuntz. Sorry.
DR. KUNTZ: Freudian slip there.

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

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

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

DR. BEAL: So, let me just make sure that I understand. So, are you saying that we should
change the profile of the patient engagement panel?

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

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

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

DR. WEISMAN: Can I make one comment?

CHAIRMAN WASHINGTON: Sure.

DR. WEISMAN: This is completely related.

CHAIRMAN WASHINGTON: Give your name, please.

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

CHAIRMAN WASHINGTON: Collins.

DR. COLLINS: Francis Collins, Board member. Two comments, one very straightforward, one much more general. So, the straightforward one
is the proposed panel on comparative assessment of options. That title just confused the heck out of me about what are you talking about. I think you’ve got to have a title there that really explains what it is this panel is doing, and I think it’s research priority, so why don’t you just say that?

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

And what you don’t want to do is to assemble panels and then essentially have them conclude that they’re window dressing and they’re not really being listened to. Help me with that in terms of how you would actually implement this in a
way that their advice is going to be synergized with all the other things PCORI’s trying to do.

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

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

I think one of the things, though, that we also have to keep in mind, though, is that because these are leading experts in the country around various topics, we want to make sure that they will be able to provide input and advice to us that is general and help with guidance and general directions, but then when we get down to the level of real specific funding announcements, that’s
where we would maintain a firewall to make sure
that they’re not precluded from applying to us.

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

CHAIRMAN WASHINGTON: Joe wants to add.

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

The other thing to be said, though, is
that these advisory committees advise us on more
than just what to study, they take a look at the
portfolio we’ve got, they help us think through
gaps and new directions, and particularly
important, they help us think about dissemination
when we have findings. So, they have a broad range
of responsibilities. Prioritization, we tend to
think of a lot because it’s early in the process.

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

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

Just to keep -- rather than going around
in an orderly fashion, to keep this group alert,
I’m going to just sort of jump around. I’m going
to look at my list and you’re not going to know
whether I’m going to call on Becker.

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

The second point, also to process, was
that -- and Carolyn whispered this in my ear before
she had to leave -- we both serve on NQF and she
was asking about a process diagram about how these
advisory panels will fit into the flow of
everything that occurs because, for example, at
NQF, we have got steering committees and various
kinds of advisory committees, and sometimes those
things get conflicted a bit. And so, really, a process diagram of how this all fits.

Thank you.

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

I just think it’s something that maybe we need to clarify. I mean, I know that you guys are sensitive to that issue, and also I think that it’s important to have the panels be able to talk to each other, not just so the staff staffs the health
disparities and they do their decisions and it comes to the Board, and then comparative assessment is doing its issues and it comes to the Board through the staff, but that there’s some connection among the advisory groups so that at least someone’s responsible for knowing that there’s not duplication of effort, for example, across the panels.

CHAIRMAN WASHINGTON: Okay, good point.

Levine and then Douma.

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

MS. HUNT: Is that a joke?

DR. LEVINE: If I could -- I was trying to come up with one but they’re just so much better
when you use psychiatrists that I don’t want to
dilute the impact.

CHAIRMAN WASHINGTON: Okay, Douma and then
Barnett.

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

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

DR. DOUMA: Okay, good.

CHAIRMAN WASHINGTON: Barnett.

MR. BARNETT: Kerry Barnett. My comment
was actually fairly similar to Gail’s. You know,
Anne, have you given some thought as to how to
integrate these panels? You know, if you look at
their charters, what they’re being charged with,
substantively it all touches a number of different
places, and I think in order to drive the highest
value work product, we don’t want them all marching
off in completely different directions from a
policy standpoint.

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

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

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

DR. BEAL: So, I will say that we had
actually thought about having patients on all of
the panels and then come back to the patient
engagement, but you all are talking about
essentially taking it to another level of coordination, so we’ll definitely think about that.

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

Okay, Zwolak.

DR. ZWOLAK: Bob Zwolak, Board member. I understand that these scopes have to be pretty broad, but my concern is how we actually shape these groups; how we assign them their tasks; who does; how they fit into the organization, and I’ll be very brief because my comments are a lot like what Francis just said. I just want to make sure that we continue to operate efficiently and the question is: who decides what they do? Who do they report to? Do they report directly to the Board? Do they coordinate? Does engagement coordinate
with CEOC? Does the comparative effectiveness integrate with methodology?

The reporting structure really troubles me.

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

CHAIRMAN WASHINGTON: Could I just clarify one point? It’s not input from the Board on the panel, the Board approves the panels. Okay, but
the expectation is that these panels and chairs
would really be reporting to the staff from day-to-
day, but we actually approve -- there’s nobody at
the Board level that -- at least I was anticipating
-- that any chair or Board -- I mean, panel member
-- would report to.

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

DR. BEAL: Exactly.

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

MS. SIGAL: Ellen Sigal, Board. So, I
think I understand why we have these panels, but I
must say that I’m a bit concerned about how it’s
going to work within the whole ecosystem and how it
really functions because, as an example, the
patient engagement, I mean, it’s going to take a
while to set it up, we already are committing major
resources for patient engagement. I don’t know how
it really interacts with ongoing things or things
that are planned, and specifically even the PFAs.
So, it’s just -- it may be just overwhelming to
manage these panels, to integrate them, and for
them to be useful.

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

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

What I can actually just point to is my
own experience having, as a funder, relied on
advisory panels before. They’re an excellent way to really help with refining of thinking, crystallization of thinking, to really just get input from a broad range of individuals who may represent different opportunities in terms of what they think about. And also I think the other thing that Joe talked about, which is very important, is as we talk about dissemination, really hearing from different types of organizations or entities who might be very eager to hear about the type of work that we are producing, so sometimes they help very much at the front end as we’re developing work to understand whether there’s a ready audience for the work that we’re developing.

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

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

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

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

Lewis-Hall.

DR. LEWIS-HALL: Freda Lewis-Hall, Board. Anne, I think you answered the question that I was going to ask but I want to maybe ask it in a little bit of a different way, and that is, it sounds like synthesizing comments that people have made, they were concerned about three things. You know, what are the real critical questions that we intend to
ask these boards, when and how? And then, what are we going to do with that? And then, the second is really around the who and whether or not we’ll have an opportunity to revisit or be made aware of who we’re proposing on these slates once we’ve -- okay, so we’ll approve each of the slates and you’ll bring us a slate for approval or a group of people that will get honed down and it will all be worked out over time?

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

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

DR. LEWIS-HALL: And then the third one is really the interconnectedness, and I’d really like
to suggest, you know, a real chart of how we expect them to work together and to work with us, because essentially we’re introducing, you know, near 60 people into an already large and complex environment to give ongoing advice and input, and that, you know, we’ve all had examples of amazing advisory boards that were highly productive, and everybody in the room has also been involved with advisor boards that were just disastrous in more ways than we can recount.

We want the first kind, not the second kind.

CHAIRMAN WASHINGTON: There’s a recurring theme here, Anne and Joe, of effectiveness of these advisory panels, and so with our Methodology Committee being composed of the best and the brightest in this whole area, we should be maybe thinking about how, in fact, do we measure, because these advisory panels, again, they’ve been created, and have been for years, all around the country and we tend to think of it as a way to enhance patient-centered research and ultimately patient-centered
care, way to test it in some kind of way, and so we should be thinking about a rigorous evaluation of this whole exercise that we’re about to undertake.

Hunt, please.

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

So, I think we should clarify that, that
they -- somehow we have input to the Board too, and also, could you just mention, this is a tiny thing, but who appoints the chair of each of these?

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

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

So, including Board, but not exclusive to Board.

So then, in terms of the question that you asked about the chair, that would be something that would be worked out at each of these committees --
with each of the committees, and then again working
with the staff to make those recommendations. But
then obviously then brought forward to the Board
for final approval.

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

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

Ultimately, it is to the Board, but there
would be situations where they would just work with
the staff, other times with the committee, and then
there would be times when I expect we might have a
chair presenting to this group. That’s what is to
be determined, Gail, is what I’m envisioning.

Is that --

MS. HUNT: [Off microphone.]

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

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

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

MS. BARKSDALE: And my second question, you might not be able to answer at this time, but during those monthly meetings, what will they be talking about? Would they be reacting to something specifically brought to them? Or will they be
generating ideas as an independent entity? I’m not quite sure what’s going to happen every month.

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

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

CHAIRMAN WASHINGTON: Just jump in, Joe.

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

They will be -- among the things that they’ll be doing are actually prioritizing research
topics that come through the process that we discussed last month and we will be discussing on December 4th and 5th. So, they will have real work to do applying a set of criteria to a set of questions and discussing, you know, why they scored them as they did. That will certainly be done in public.

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

CHAIRMAN WASHINGTON: Okay, we have Gabriel and Epstein.

DR. GABRIEL: Sherine Gabriel, Methodology Committee. I just wanted to underscore the importance of coordination and making sure the interconnectedness between all of our activities is in place. I mean, the last thing we want is a number of disconnected bodies. It’s just highly inefficient. And with respect to vetting, the
Methodology Committee has not had an opportunity to review these, so these haven’t been reviewed with us, and I think that we have a real opportunity to contribute not only on the evaluation side, which is a great idea, but contribute methodologic knowledge and methodologic input and even input in terms of the structure and goals.

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

CHAIRMAN WASHINGTON: Sounds great.

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

We had the example of the postmenopausal
symptoms, and if I had an advisory board there of people who were specialists in women’s health and OB/GYN, I would think they could teach us a lot about the ripeness of that area for further investigation.

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

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

DR. EPSTEIN: Sorry, I meant an advisory panel help the Board, making tough decisions about -- between areas in which they’re not going to have any expertise, per se, because no -- unless a
tightly appointed Board -- advisory panel around a specific area, it will be impossible.

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

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

DR. SELBY: I would -- first of all, I agree with you, Arnie, that the task of the
committee with the difficult name, that’s related
to our first priority, is the most challenging.
It’s the most challenging to us as a Board as well.
It’s the most challenging to the whole notion of
PCORI that nothing in the legislation says anything
about which directions we go.

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

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

Nonetheless, I think that as one -- having
-- for the Board to have as one stream of input
into what funding directions we take, an advisory
panel in this area is essential.

CHAIRMAN WASHINGTON: Normand?

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

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

CHAIRMAN WASHINGTON: Weisman.

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

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

At some point, you know, there is -- you have -- none of this is totally algorithm and method driven. There’s human judgment that always comes into this, and at some point we have to just say, these are all the inputs, and we were appointed, our staff was appointed to make some calls. But what would help me, maybe, and everyone’s talking about organizational flow and
governance, maybe you could just show how an idea flows through this system of workflow -- I’m sorry, workshops, internal deliberation, advisory committees, to end up as a priority. What is that process, that flow of things? Because then maybe I would understand how it all could come together. It’s just a suggestion, because right now I’m seeing a galaxy of different stars doing it sounds like the same thing, and I’m not seeing the constellation.

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

DR. LEVINE: So, three quick comments, if I can remember the third one. I don’t think we should lose your point, Gene, about an opportunity for a Board member to be an ex officio member of each of the advisory panels. I think that that will enable us as a Board to learn from -- second point, there must be a robust literature on best practices in organizations using advisory panels, and I think before the first meeting convenes, that we ought to have a sense of what that means in
terms of how this work goes on, and I assume somebody may be looking at that now.

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

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

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

DR. BEAL: I just wanted to respond to Rick’s comment about the composition of the patient
engagement panel, that the actual language in the charter says super majority. Our 75 percent was a goal that we have but we have flexibility. Simply super majority.

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

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

DR. KRUMHOLZ: Harlan Krumholz. I just want to be clear. As I listen to the discussion, the thing that I’m uncertain about as we develop that hierarchy of decision-making is to what degree does the Board get deep into this? If the staff feels that they need these advisory groups, we’re
mandated by the legislation -- I’m speaking in support of this -- that we say to them, here’s some concerns, you’re tapping into some of the expertise of the Board who are expressing some thoughts and potential landmines out there, but God bless.

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

I’m just wondering, but I’m having trouble calibrating, that’s why.
CHAIRMAN WASHINGTON: Okay. Douma.

Sorry, and then I want to comment on --

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

CHAIRMAN WASHINGTON: And so, following up on the point you just made, Harlan, I’d like to propose that at this point, this is not about a vote. We had already authorized or encouraged, endorsed the idea, and so the staff is moving through a process and it’s checking in with us for input, and ultimately will come to us for a vote, which is what it’s called for. And I’m just going to bring this to closure and thank all the Board
members for your comments to staff regarding these three.

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

DR. SELBY: I’ll just say one thing briefly. Each of these committees has natural sponsors on the staff; so for example, the one that’s dedicated to comparative effectiveness has a program director, David Hickam, who would oversee the relationships with that one. The patient engagement one, likewise, the disparities one,
likewise, if we go to one with improving health systems, likewise.

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

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

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

And rare disease, we are -- I would say, we’ve reexamined the legislation and with respect
to rare diseases, our read of the legislation is that if we fund a study, there should be a small advisory group for that study. If we fund ten studies, there should be ten small advisory groups. There is not a call in the legislation for one advisory panel on rare diseases, although we happen to think that idea has some merit.

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

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

DR. WEISMAN: Okay, Harlan Weisman, Board member. Maybe a suggestion, and it picks up from where Harlan was, because it sounds like you guys need this advice, you feel a compelling need for it, but, you know, we’re experimenting as we go. There’s no textbook that tells any of us how to set this up and getting this enterprise of PCOR going, is to not lock into a two-year timeframe. I mean,
it makes sense, and that probably should be the intent of what we expect, but in doing an experiment, you may find that one advisory committee or how it operates isn’t exactly what you were thinking it ought to be or that, you know what, these two advisory committees are basically doing the same thing so we want to continue but we want to bring them together.

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

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

CHAIRMAN WASHINGTON: Okay. So, Joe and Anne, to summarize, what you’ve heard from Board members, as their input, is the concern regarding
the amount of work and the need to coordinate at a
time when so much else is going on, taking on, you
know, another four. And so, you know what your
needs are and in that light we ask that you
evaluate what the next steps are going to be.

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

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

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

DR. BEAL: Okay.

CHAIRMAN WASHINGTON: Yeah, I just don’t
think we should segment it by committees, and we
won’t choose everybody, but we’ll be able to
explain it, we’ll know what the interests are.

Steve, does that sound --

VICE CHAIRMAN LIPSTEIN: Sounds good.

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

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

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

CHAIRMAN WASHINGTON: Okay.

MR. BARNETT: Frankly, just there are
about four or five issues that Anne’s going to
cover that are pretty significant to be brought to
the Board’s attention and then, of course, whatever
other issues arise. But my suggestion would be,
let’s just jump in and if we need to pen some of it
for later this afternoon, we can do that.

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

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

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

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

Last time around, the budget process really consisted of going around to the Board committees and saying, what are you thinking about
doing next year and how much money do you need to
do it, and then there was some thrashing that went
on behind the scenes and we had a budget.

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

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

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

The real focus of the discussion here this
morning and maybe later on this afternoon, I think,
needs to be far more about words than numbers. It has to be about to what extent is this budget, as it takes shape -- to what extent does it fit the strategies that we’ve been talking about as a Board and the activities and objectives that we see ourselves addressing in 2013. And we need to be on the lookout for any sort of a mismatch between what are expectations are and the resource allocation that you see here.

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

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

DR. BEAL: So, first I want to recognize the great work of Pam Goodnow, who’s our Director of Finance, who’s really been such an asset to the organization. So, I want to thank her for all that
she’s done to help pull this budget together. So, these are the key points that we’re going to talk about today in terms of, as Kerry said, as we thought about this budget we wanted to really make sure that we focus on key strategies and essentially strategic implications in terms of what it is that we’re discussing.

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

And so, as you’ll see here, what we then did is presented the overall budget as well as some
support for some of the different types of
questions that we want to raise with you.

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

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

But hidden -- or not hidden, but within
those numbers is essentially five key messages that
we want to make clear. So, one is that as we were
developing this budget, we really wanted to make
sure that it was aligned with the strategic goals
that we’ve set for the organization and that in
terms of thinking about what it is that we’re trying to achieve, we really want to think about many of the requests in here as really being the placeholders for saying these are the activities that we want to engage in.

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

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

And so, ultimately those monies will come
into us, but not within 2013. And so, all of the
adjustments that we’ve done in terms of the budget
and what -- the monies that we’re working on are on
this relatively conservative estimate that we will
have $147 million, and I’ll speak a little bit more
around that.

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

As you heard Joe mention earlier today, we
just hired our scientific leads. We are engaging
and bringing on our advisory panels to help us with
creating greater specificity in terms of our
scientific programs, and so what we wanted to do
was to essentially be able to build into our budget flexibility to be able to make investments in terms of our scientific work that we, at this point, cannot really anticipate but wanted to make sure that we have that flexibility in our funding.

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

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

So, again, this is the definition of performance-based budgeting and as I said, the really key take home message is that rather than looking prospectively -- I’m sorry, retrospectively
and saying, how did we do last year and what are
the adjustments that we want to make going forward,
that this is somewhat different in that we are a
developing organization, so we really don’t have
that retrospective information to be able to look
at that really helps to define where we are going
prospectively.

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

And the process that we went through to
really develop the budget was to go to each of our
directors and to say, what is it that you think are
your needs and activities for the upcoming year
both in terms of staffing and in terms of funding,
and then we built the budget in that way.
As Kerry mentioned, this was a significant departure from the process that we went through last year where we really tapped into each of the respective committees and asked the committees to be able to help create the budget.

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

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

It’s become abundantly clear as we’ve
really defined the PCORI way of doing research and talk about doing research differently, that we actually want to do this internally, and so we are now expanding our a capacity for proposal review and are developing that in-house capacity to be able to do that as well as recognizing that in terms of the ongoing follow up of these different projects that we are developing, that we’re going to have significant reporting from our awardees, that we’re going to want our scientific staff to be able to provide overview and oversight to them, that we want them to be able to pull out the lessons earlier rather than later, and also that we want them to essentially be a resource and provide guidance and to be able to take our awardees questions and be able to help them in terms of the process of really doing patient engagement research.

So, all this really means that as we’ve thought about particularly the staffing needs that we’re going to have in the scientific part of our organization, it is going to be a bit larger than
we had initially thought about a year, year and a half ago.

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

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

So, first the shift is that we would like to change the proportion of contractors who are doing the work of PCORI to really bring those people on board or bring people like them on board as full time staff for PCORI. And so, we’re
proposing that we actually increase our staff from 34 to 88. But at the same time reduce our reliance on contractors to take it from 38 down to nine.

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

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

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

DR. BEAL: Sure.

VICE CHAIRMAN LIPSTEIN: One of the reasons -- so, as we’ve worked with staff over the last couple years, one of the reasons we haven’t
been able to move to more of a staff model earlier is because the legislation that created us was a little bit in question and, as you know, it wasn’t until certain decisions were made by our judiciary that we were able to really get ourselves on a little bit more stable footing, and certainly now in the aftermath of the election, even more so.

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

DR. BEAL: Absolutely. Thank you, Steve.

So, the other thing that I’d like to point out from the budget, and you’ll see this particularly mapped out in the slides that are coming up, is that we had set a target for overhead administrative costs at 10 percent, and what I’m learning from Pam is that there are a very specific set of guidelines as to what can be counted as a administrative versus programmatic and we’ve done very careful accounting to make sure that things are appropriately allocated.
And so, what we’ve determined is that as we think about really what are some of the best practices, when you look at, for example, nonprofit organizations, in general they try to keep their administrative expenses at anywhere between 10 and 20 percent, and we had actually set a goal for ourselves at 10 percent.

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

And so, many of those are listed here, but in the broadest strokes what it is that we’re thinking is that we need to have the infrastructure that allows us to manage and coordinate all of the awards that were given, we need to have the infrastructure around dissemination of the work that’s being produced by PCORI, and particularly by the Methodology Committee, and we need to have also
the internal infrastructure in terms of financial oversight for the work it is that we are doing.

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

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

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

MS. GOODNOW: I’m sorry?

DR. BEAL: The researcher data mark.

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

DR. COLLINS: What is a researcher data mark?

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

DR. BEAL: Okay, so, one of the questions around this is, so it came from the staff who are
providing the support for the Methodology Committee. One of the challenges is that the Methodology Committee has not yet had a chance to review their portion of the budget because, as you know, they’ve been busy working on the revised standards. And so, a lot of what is being requested that comes specifically from the MC is actually right now a placeholder and they plan to be able to review this in detail within the next month or so.

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

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


DR. KRUMHOLZ: Is that what you were saying?

DR. BEAL: Yes. Okay.

So then in terms of the appropriations
that we’re expecting will come in, so as you know, PCORI has two lines of revenue that comes into the organization, so first are our appropriated dollars and then the second are the monies that come into the PCORI trust.

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

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

This is something, actually, that we’ve been working quite a long time with the FAAC is to try to get some real specificity regarding this, and so the bottom line, though, is that as we’ve looked at what our revenue assumptions can be for
2013 that we can rely on, we are working with a number of $147 million.

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

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

Now, with that said, the Methodology Committee has not yet had that opportunity to do that, but as we’ve also gone to some of the other committees, there were a lot of questions and particularly at the level of the COEC there were a number of questions in terms of the budget and the activities that we were proposing.
So, you all have your book that has all of the details in terms of what is being proposed for communications and engagement, and one of the things that there’s been actually about five different things that the COEC has asked us to engage in as ongoing activities for refinement of this budget. So, one is that while there are long lists of activities that we are proposing, they’re asking us actually to prioritize these lists into, if you will, Tier 1, Tier 2, and Tier 3 activities so that if we determine that there are some that are going to fall off, we’ve been able to determine which those are based upon the priorities.

In addition, similar to the conversation that we had around the advisory panels, much of this is new activity and so what they’ve asked us to do is to develop a project plan and work stream around these specific activities to make sure that we can achieve all of these within the timeline that we’re talking about as well as then to define what would be the measures of success for the different activities that they’re proposing.
Lastly, one of the things that came out of the discussions that we’ve had with the COEC is that we should definitely evaluate all of the activities to see that we’re having the desired impact from these various activities and that we may, in fact, need to adjust and change, not only based upon the learning that we have from this evaluation, but also to adjust and change as the environment changes and as the needs of PCORI changes.

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

DR. DOUMA: Yeah, Allen Douma, Board. I don’t want to interrupt but it’s with reference to language that was in a previous slide about the money, not the appropriation, but the other money –

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

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

And so, they’ve told us that based on their estimates at Treasury, between August 15th
and October 15th, they will give us some of those monies, they’ll be deposited into the trust, but then there is a six to eight month period of time because the excise tax return actually collects Federal Highway taxes and a lot of other taxes. So, the Treasury needs about eight months to decide whose money is really what, and so we’ll get some portion between August 15 and October 15th, on estimate, and then the rest of it in 2014 with that six to eight month lag.

UNIDENTIFIED BOARD MEMBER: Aren’t you glad you asked?

DR. DOUMA: Yeah, I’m really glad I asked.

So, will we -- going forward, will we -- our expectations be that this money is calculated on an annual basis and we get it with a lag, or we’ll also go back -- and the only reason this looks like it’s quarterly is because that was the end of that year? Is that correct?

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

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

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

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

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

DR. BEAL: Yes, because actually we’re going to then get into the real specifics of the
numbers and I think that having discussed the big
picture issues, I think, this is a natural time.
Or I could go into the numbers.

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

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

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

I know it means that when we do that at
the federal level, but when we do that at PCORI it
means that we’re giving you our best estimates of what we’re going to spend, and then you will find that during the course of the year there’s certain elements of this budget where the staff will have to come back and seek approval to spend individual amounts, like the investment in infrastructure is an example.

CHAIRMAN WASHINGTON: Sigal, please.

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

And I don’t know how that we’re supposed to over -- kind of agree to a budget that is that large that we may not spend or, frankly, may not need or hasn’t been fully vetted.
DR. BEAL: So, one of the things I think that Ellen’s comments points out that I think is important is that as we created this budget, it is definitely an aspirational budget, and as we thought about what are the activities, what are the things that we want to do, what are the goals that we’re trying to achieve here in the ideal world is what it is that we would like to be able to accomplish.

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

VICE CHAIRMAN LIPSTEIN: And, Ellen, when we go through, the way our decision-making matrix is structured, you will find that staff needs to
return to the Board for expenditures in excess of $500,000, so while we budget in the millions, there are other opportunities for the Board to look at the major categories of expenditure. But I also think, in picking our leaders, in picking our staff, we expect them not to be wasteful and to be prudent expenditures of the money and, at least in my experience working with them, I wouldn’t say they’re cheap, but they watch our dollars -- they watch our dollars as if they were their dollars, and so they have been very good stewards of our resources.

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

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

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

CHAIRMAN WASHINGTON: No, I was talking
about in five minutes.

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

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

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

DR. BEAL: Well, let me -- I’ll jump
ahead. So, essentially the bottom line, and this
is where Kerry is taking us, is that as we think
about what will be our outstanding commitments, we
have the monies that are from the pilot projects
that we’ve committed, we have the monies from the funding announcement that we approved in May, which is about to yield a number of projects that we will be approving in the next six to eight weeks, and then we’re going to have at least two funding cycles for the broad funding announcements in 2013 that will be paid for and committed within 2013.

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

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

MR. BARNETT: Yeah, absolutely.

CHAIRMAN WASHINGTON: -- on the table?

Okay. Since we have a couple minutes left, I’m going to hear from Weisman and, did you put your card down, Sherine?
DR. GABRIEL:  [Off microphone.]

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

DR. WEISMAN:  So, as an alternative to what Steve said, one thing that I suggested yesterday, at least at the COEC, is because it is aspirational and, in fact, we want to encourage them to have stretch goals, but it would be unlikely, in all probability, to hit every stretch goal, but some of them will, is that we put some kind of probability on the budget and say that instead of funding it 100 percent, which is unlikely that we’ll actually spend the money, we fund it -- I don’t know what the right number is, I’m just going to say arbitrarily we fund it at 80 percent with the idea that it gives you the latitude to keep going after everything, but not everything is actually going to pan out. And if, additionally, we could consider putting in a contingency part of this 80 percent budget which is releasable based on, you know, where we are. But
that does two things, one of them is, it’s more likely to be what our actual fund is, but two, it forces us to really think about our priorities and make sure that we really hit those priorities and not have the kinds of concern that Ellen has.

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

CHAIRMAN WASHINGTON: Okay. Gabriel and Levine.

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

CHAIRMAN WASHINGTON: Levine, last
DR. LEVINE: Last comment. And Ellen’s comments were really -- and the concerns and questions both she and Gray raised about the budget, we spent several hours yesterday talking through at the COEC, and Anne briefly summarized the requests that we made in terms of giving us more comfort with moving forward, including Harlan’s suggestion, the fact that we’ve asked for quarterly reports around where we are in terms of projections.

One of the concerns that we had, and this was reflected by a number of people, is the number of actual events or activities that are driving the size of the budget and whether, in fact, there’s sufficient opportunity, sufficient staff and sufficient opportunity to really, in a high integrity way, learn from each event in terms of -- rather than, for example, scheduling four events in four parts of the country that are the same, to ensure that we have a process in place to understand the metrics of success, whether we’re
meeting them, and what that means about the 
subsequent schedule.

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

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

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

[Whereupon, at 12:13 p.m., the meeting was 
recessed, to reconvene at 2:10 p.m., this same 
day.]
CHAIRMAN WASHINGTON: Welcome back to this meeting of the Board of Governors for the Patient-Centered Outcomes Research Institute also known as PCORI. And we are going to continue our discussion about the budget for 2013.

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

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

Kerry.

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

You know, I just want to start by saying,
and Anne, help me with this, this slide that’s been on the screen there shows a $10 million -- what looks like a net loss for the year. And several of you during lunch have commented on it. And that’s fully accurate, but of course accurate in a misleading way, because all that reflects is that in fact the operating revenue for 2013, that will come in in 2013, is projected to be actually $10 million less than the proposed expenses, but what that doesn’t take into account are two very important things. Number one, there’s a very substantial carryover of funds from 2011 and 2012 to the tune of $200 million? What’s the number, just roughly? Round numbers is fine. It’s a large number.

MS. GOODNOW: Opening cash, $233 million.

MR. BARNETT: Two hundred and thirty-three million dollars. And it also doesn’t take into account the fact that in -- that much of our 2013 revenue, as you heard from Pam and Anne earlier, is actually not going to come in until 2014. So, from a cash flow perspective, we have a very substantial
amount of resource to allocate and to work with, and I don’t want anybody to be confused about that. As we kind of open up the discussion and dialogue, I just wanted to sort of reset what I think we’re trying to do over the course of the next 20 or 30 minutes max, and that is to really identify what the next steps are for this budget to get us to a point where the Board feels comfortable approving the budget.

I don’t think there’s an expectation that at the end of 20 or 30 minutes there’s going to be an up or down vote on this particular budget, but we’ve already begun with a couple important, I think, do items for the staff. One of them is that the Methodology Committee, as you heard from Sherine, has not had an opportunity to fully vet the budget, and we’ll make sure that that occurs over the course of the next several weeks so we get all of your feedback and input.

And the second thing that we’ve heard loud and clear is kind of focusing on the COEC
discussion that occurred yesterday in some detail, a belief that we’re looking at some very substantial levels of activity relating to communications.

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

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

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

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

And where we decide that maybe we’re
spending some dollars in an area that may not be of
the highest value, we have the opportunity to pull
back in those areas as well. And so, in fact, when
we think about some of the communications activities, it is very important that the communications committee is basically getting a full download from staff at least on a quarterly basis, to provide an opportunity to kind of reevaluate those activities. The town hall meetings are the perfect example. After we have one or two of them under our belt, we’ll make decisions -- you need to make decisions -- as to whether or not we want more of them or fewer, whether they should be larger or smaller, whether they should be more robust or, frankly, less expensive. Those are all decisions that I think we need to be prepared to make on an ongoing basis and we shouldn’t feel like we’re tying our hands by decisions that we may be making today or in the near future.

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

CHAIRMAN WASHINGTON: Okay. We have a round of questions and then, Anne, I understand you
want to continue --

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

CHAIRMAN WASHINGTON: Okay, well, why don’t we go with Weisman first?

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

MR. BARNETT: What I think would be great is if the Board could, in an informal way, indicate that the budget that you’ve seen here today is directionally correct and at the same time identify those areas of kind of further analysis or further
refinement or further detail that might be good to do.

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

DR. WEISMAN: Thank you.

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

MS. SIGAL: So, Ellen Sigal, Board. I’m challenged by how it could be directionally correct if we’re concerned about certain line items or certain categories. I just don’t know how that can
be, I mean, unless we say it’s directionally correct with a caveat that we think one category may be excessive or needs to be re-looked at. I don’t know what we’re doing when we say it’s directionally correct. It just doesn’t seem to make a whole lot of sense to me.

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

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

MS. SIGAL: Well, I mean, for me, I’m one of 21, I have been very specific on concerns, in writing and vocally among the people. Now, I may be right, I may be wrong, it may be irrelevant, but
it would be very hard to vote on a budget and say
it’s directionally correct.

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

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

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

But we’re not voting on a budget today.

Rick?

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

CHAIRMAN WASHINGTON: Okay. [Off microphone.]

VICE CHAIRMAN LIPSTEIN: No, I think I also wanted to get a dialogue with Ellen just a little bit because I think I -- as I look through the budget, when I think of directionally correct, you know, programming the budget into categories of
the Methodology Committee, research, engagement, program development, evaluation, and then we did make a suggestion, and it is in your book under Item B, that for the line items above a million dollars, a certain threshold, that we would provide the Board with greater specificity, but I do think it would be helpful, since we all have different thresholds, perhaps, of materiality, how much detail per line item staff needs to provide to the Board.

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

And I think what I’d like to suggest is that we should give the staff direction so they’d know how to respond, which is, if we’re interested only in those line items above a million dollars as a threshold, then they know how to respond. If we’re going to ask them to respond for every
expenditure over a half a million or over $250,000, but that was the suggestion I made, and so I do think we need to give them greater clarity, because that’s -- we are scrubbing this in the Finance Administration and Audit Committee at a more detailed level than we scrub at the Board, and so I think we have to figure out as a Board how detailed we’re going to scrub so that staff can really -- we give them a fair shot at coming back and meeting our expectations.

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

Anne, would you present, please?

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

So, as Kerry said, this represents the budget for 2013 and while, based upon our revenues and expenses, there would be a deficit of $10
million. What we also highlighted in the asterisks at the bottom is that we do have monies carried over from 2012. So, this just represents the expenses and revenues for 2013.

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

DR. WEISMAN: Can I ask a clarification question?

DR. BEAL: Sure.

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

DR. WEISMAN: And how did you do that? And would looking at the phasing of bringing on new staff, would that help us in any way in terms of how we’re managing and seeing how we’re doing along the way? In other words, did you assume -- did you just divide it by four quarters or did you say -- did you frontload it, did you backload it? How did you do it?

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

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

DR. WEISMAN: Because the timing of
hiring, obviously, affects the budget?

MS. GOODNOW: Sure.

VICE CHAIRMAN LIPSTEIN: They didn’t hear it.

DR. BEAL: Sorry.

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

DR. BEAL: And then I’ll add, also included in that calculation were some of the fixed
costs associated with staff in terms of computers and benefits and things like that. So, that was also part of the calculus.

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

On the other hand, we have a burden, which is we’re actually doing a lot of science internally, more than other groups are, so while the 10 percent may or may not be right, I just wonder how you can actually develop a better benchmark to look at efficiencies because, you know, being about 10 percent then lower than 10 percent is really a function of the fact that we’re going to get more money. And I just wonder if
there’s a better way to measure efficiency rather than use a charitable granting agency’s 10 percent GNA as a standard.

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

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

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

And so, right now our operating model is
that the vast majority of our monies do go out the
door and we do have some internal program work as
well as in evaluation work, and so I think the 10
percent is a good benchmark compared to that.

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

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

CHAIRMAN WASHINGTON: Douma?

DR. DOUMA: Allen Douma, Board.
CHAIRMAN WASHINGTON: And then Clancy.

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

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

DR. DOUMA: Okay, so they’ll --

DR. BEAL: Yes.

DR. DOUMA: They’ll go hand-in-hand from month-to-month.

DR. BEAL: Exactly.

DR. DOUMA: Okay.

CHAIRMAN WASHINGTON: Okay, Clancy.

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

CHAIRMAN WASHINGTON: Carolyn Clancy.

DR. CLANCY: Sorry, Carolyn Clancy, Board
member. Just wanted to acknowledge Pam and Anne’s and the work of the committee, that hard work that went into it.

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

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

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

CHAIRMAN WASHINGTON: Excellent point.

Allen?

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

DR. CLANCY: You’re on it.

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

CHAIRMAN WASHINGTON: Zwolak.

DR. ZWOLAK: Bob Zwolak, Board. Contractors are expensive and if we’re talking about directionally correct, I think reducing the number of contractors is a key issue, but my question for you is, how did you decide what the
landing zone was? So, we go down from 38 to 9.

How did you decide what positions should remain at the relatively expensive contractor level and who we would -- why we wouldn’t replace them with hires?

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

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

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

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

DR. BEAL: Yes.

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

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

I think we’ve got a pretty good list of about a half a dozen items, areas that we need to
work on. Some of these, I think, need to be worked on very specifically between now and approval, but some of them are more ongoing, things like establishing key performance metrics and that sort of thing, but I think -- and Anne, you’re nodding your head, so I think you’ve got a good sense of what the next steps are -- and then we will figure out whether to bring this back to the Board at a telephone Board meeting between now and the end of the year, or if it can wait until February -- our goal would be not to have it wait until February.

CHAIRMAN WASHINGTON: Krumholz.

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

I mean, when I first started looking at pie charts, I said, well, god, the research, what is -- I mean, it looks like it’s about 75 percent,
but I don’t know how to benchmark that. I know these are activities we’re mandated to do, it’s about engagement and other important things, but just for the public to know, of this money, how much of it is actually being plowed into direct research versus other things? And that’s worth, I think, us, you know, having an appreciation for that balanced, because in the end, to me, that’s what I really want to know, which is, you know, what are we doing to report the research and then how much are we actually able to put into the research given that balance?

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

MR. BARNETT: Yeah, I think that’s a great point, and, you know, that’s a classic issue, I think, higher-level issue for the Board. You know, you’ve got three areas, you’ve got administration, you’ve got program, and then you have research. And having kind of general agreement as to how much of our budget should be expended in each of those
areas is sort of a fundamental budgeting question.

So, if anybody thinks that what’s been proposed kind of misses the mark, please surface that.

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

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

DR. CLANCY: So, since we don’t actually
set the categories by ourselves, I’ll just say we have less latitude and flexibility, but your comment -- or question actually builds on what I was going to suggest.

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

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

CHAIRMAN WASHINGTON: Good point.

MS. GOODNOW: And as far as those costs that are in the budget as programmed, there is actually a definition that nonprofits use so that
we can be recording those expenses systematically whenever you look at anyone’s financial statements. So, there are definitions and any particular costs that falls into a program category is one that can be directly related to the mission, and those that are in administrative, including things like the annual report or just plan -- the back office accounting people are in the administrative budget.

DR. KRUMHOLZ: This is Harlan Krumholz again. And to be clear, I’m not questioning the -- I mean, we have endorsed that and we are behind it. The question is about the allocation and how we, as a Board, think strategically about exactly how many dollars, and I think that Carolyn’s brought up a really good point. I mean, if you’re investing in dollars to develop the research proposals, should that legitimately be considered part of your research expense or not, but even with that we should know at the end, of the awards we’ve made, what percent of our total budget does that account for, just so we can sort of stay on target with that and give staff direction.
But this is not criticism at all of -- or of this budget allocation, but just starting to try to think about how do we keep track of it and how do we prioritize appropriately?

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

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

So, for example, patient engagement, it’s part of the Methodology Committee budget, it’s part of the COEC budget, there’s staff who are dedicated to it. And so to be able to look at an overall picture of all of the program and research expenses, or expenditures planned around patient engagement, as one example, but communication will attach to a number of things, it might give us a more nuanced picture of kind of the tapestry of how
things connect and, quite honestly, help to do what we’ve been trying to do, which is coordinate what are currently not intentionally, but by fiat, kind of siloed activities.

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

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

Would you introduce this next section, please?

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

Dr. Lori Frank is going to go first, and I believe Lori has presented to this Board before. Lori is our Director of Engagement Research, so she has a big job of working with staff, with the
Methodology Committee and others, on evaluating over time how our engagement activities are impacting the quality and the outcomes of our research.

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

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

Then Martin Dueñas, Director of Contracts, is going to update you on the submissions we’ve received and the review we’ve gone through for the responses to our first round of broad PFAs. I just want to say -- and at the end of that presentation we’re going to talk with you about our proposed approach to identifying those projects under each priority that we’re going to fund. Same kind of conversation we had with the Pilot Projects,
needing to account primarily for the scores that these applications receive, but also looking at other considerations important to the Board and important to patient-centered outcomes research.

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

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

MS. FRANK: Okay. Thanks very much, Joe, and I will move quickly through these slides in the interest of time. I thought about presenting them backwards so that we could rewind the clock, but I’ll just move quickly through them.
So, there are really two points I want to address with regard to our pilot projects. The first is the evaluation of our unique review process that did involve stakeholders for these, and the second is an update on the status of the Pilot Project management.

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

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

So, the Pilot Project call for applications addressed each of these eight areas and applicants were allowed to respond to one or more of these areas: informing the national priorities for PCORI; bringing together patients, caregivers, and other stakeholders across the research continuum; translating evidence-based care
into healthcare practice in a way that accommodates patient preference; identifying gaps in comparative effectiveness knowledge; evaluating specific patient-centered outcomes instruments; assessing the patient perspective when conducting research on behaviors, lifestyles, and choices; studying patient care team interaction when multiple options exist; and advancing analysis of CER data.

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

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

So, we asked some questions of the reviewers at the conclusion of the review process. We had 354 scientific reviewers and 45 patient and
other stakeholder reviewers, so there were about 3
stakeholder reviewers per panel for this.

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

This next slide addresses the question to
what extent were scientific reviewers receptive to
the comments made by stakeholder reviewers, and
what’s really striking here is the similarity in
response. The scientific reviewers are presented
on the left and the stakeholder reviewers are
presented on the right there, and in each case,
close to 90 percent of both groups reported that
the stakeholder reviewers thought that the
scientific reviewers were receptive to their
comments as did the scientific reviewers.

Turning the question around -- yeah,
sorry.
DR. DOUMA: Yeah, Allen Douma, Board.

What’s the breakdown of the stakeholder reviewers?

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

DR. DOUMA: Ah-ha, patients --

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

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

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

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

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

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

This next -- yeah.

DR. KRUMHOLZ: Harlan Krumholz. Just -- you’re going fast and I just want to distill this. So, what you’re saying is that the scientists didn’t feel the stakeholders were listening to
them, but the stakeholders thought the scientists listened to them?

MS. FRANK: Actually, no. So, there were similarities. So, this first question was, to what extent did the scientific reviewers listen to the stakeholders, and what we were pointing out here is the similarity --

DR. Krumholz: It’s similar, right, but when you reversed it, the scientists felt that the stakeholders were not incorporating them to the extent that the stakeholders thought that they were.

MS. FRANK: Essentially, but there’s the big don’t know piece of the pie there.

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

DR. Krumholz: I don’t want to slow you down, I’m just interested --

[Overlapping speakers.]

DR. Weisman: -- the groups that they didn’t -- they actually didn’t know who they were.
Do you know that?

MS. FRANK: We don’t know that and --

DR. WEISMAN: So, would it be safe to subtract or not or we just don’t know whether you could do that?

MS. FRANK: Yeah, I don’t think that --

MS. GOERTZ: Most of them did know. There are one or two review groups where it was unclear, but most of the review groups did know.

CHAIRMAN WASHINGTON: I’m sorry, Lori, but there seems to be some confusion.

MS. FRANK: Sure. Let’s clear it up.

CHAIRMAN WASHINGTON: Sharon -- I mean, Levine.

DR. LEVINE: So, the scientists were less confident that the stakeholders were receptive to their comments than the stakeholders felt they were actually receptive to their comments?

MS. FRANK: Yeah. So, if you look at the numbers, there are about two-thirds of the scientific reviewers who said that the stakeholder reviewers were receptive to their comments, to some
extent or to a great extent. What’s going on with
that other third? They said, I don’t know. So, it
was really only four percent of the scientific
reviewers who said that it was a small extent to
which the stakeholders were receptive to their
comments.

DR. DOUMA: And I think it’s really
important what you’re saying about the “don’t know”
is because presume scientists are more evidence-
based and they didn’t have the evidence because
they didn’t do a survey of the stakeholders.

MS. FRANK: Right. It’s an interesting
point, and then, of course, all the stakeholders
knew who they were, so we didn’t have a problem
with that piece of the data.

Okay. So, the next question was, compared
to other reviews you’ve participated in, to what
extent did having an emphasis on patient engagement
impact the overall scoring? And only 1 percent
said, to no extent. So, the vast majority, over 90
percent, thought that patient engagement impacted
overall scoring to some extent or to a great
extent.

Okay. On this we asked, how would you describe the degree of emphasis stakeholder reviewers placed on the patient perspective relative to that placed by scientific reviewers? So, if you go to the bars on the right, which represent the responses of the stakeholder reviewers, you see essentially a 50/50 split. So, about half of the stakeholder reviewers placed more emphasis on the patient perspective compared to what the scientific reviewers did by their report.

And about half thought that both types of reviewers looked at this in the same way.

Now, if you look on the left, about 27 percent of those scientific reviewers said, I don’t know, I’m not going to answer this because I don’t have the information. Of the rest there was also essentially a 50/50 split, but in this case, slightly more scientific reviewers thought both types of reviewers placed the same emphasis on the patient perspective -- slightly -- proportionately less scientific reviewers thought that the
stakeholders emphasized the patient perspective more than they did.

Okay, so Mike Lauer conducted some additional analyses of the scoring criteria, along with the colleagues noted at the bottom of this slide. The scoring criteria were the approach to the research question, the significance of the research question, stakeholder involvement, innovation of the research, and investigator qualifications.

And so what they found, using a mix linear model was that the approach really had the greatest association with the final score coming out of those review panels.

They also took those data and used a random forest method, a machine learning data classification method, and analyzed the data the same way, and here’s a comparison of the data from the prior slide with the random forest. So, random forest is represented with the orange bars, the blue bars represent what you just saw. So, the results are similar in that approach was associated
with the final score out of those review panels to
the greatest extent; investigator qualifications,
much less so. In the case of the random forest
analysis, the significance of the research question
and the innovation also appear as drivers of that
final score.

Okay, so --

DR. DOUMA: Are you going onto the next
subject?

MS. FRANK: I am. I don’t have to.

DR. DOUMA: Before you do, can I ask a
question?

MS. FRANK: Sure.

DR. DOUMA: How are we going to implement
or apply the results of this into what we do next?

MS. FRANK: Yeah, so I want to say there’s
more analyses we would like to do of this.

Martin’s about to share with you our Cycle I
reviews, and so we’ll have more review data then to
work with. Remember, these are just the scoring
data out of the Pilot Project round.

DR. DOUMA: Right. So, what you’re
saying, basically you don’t have enough data?

MS. FRANK: We would like to collect some more data, but there’s still plenty that can be done with the Pilot Project scoring data.

CHAIRMAN WASHINGTON: Okay.

MS. GOERTZ: You know, a lot of this -- we’re just presenting the data that we -- we had a pretty good sense of this after the review process occurred, and in fact, much of how we approached the next set of reviews that Martin is going to be describing is based on our general impression that we hadn’t been as stakeholder driven as we would like to be eventually with the review process, and that we probably hadn’t done the type of training that would be ideal about what it was that was important to us.

And so much of -- I think there are still many things that we can learn by continuing to look at the data, but sort of the gestalt of it we already knew and have already incorporated into our -- into the review process.

MS. FRANK: Thank you for that. Yeah,
there were a lot of learnings out of this and the
number of patient and stakeholder reviewers was
increased substantially for the PFA merit reviews.

CHAIRMAN WASHINGTON: Okay, Normand and
the Lewis-Hall.

MS. NORMAND: Sharon-Lise Normand,
Methodology Committee member. I wanted to ask --
maybe push a little bit more on that in terms of
Allen’s question in terms of -- how are the -- so,
yes, more analysis could be done, but what’s the
purpose of it?

Let me throw something out, and I’m not
saying this is right at all, so if we look at that
particular graphic that you currently have up, it’s
talking about which components weighed the most in
terms of the final scores. Is that the right
distribution as a Board that we want? Do we want
it mostly -- I’m not saying the approach should be
the heaviest weighed, but do we want the
stakeholder to be much more?

So, again, whose -- how can we utilize the
data? What are you -- can you give us some
examples of some questions that you’d like to answer with the data to go forward?

MS. FRANK: Yeah, that’s part of why I would really like the data out of this round that Martin’s about to discuss because the merit review criteria were refined for the PFA review. So, another question is, are we training the reviewers appropriately? Are we giving them the right information about the criteria? And then, yes, are they using the criteria in the way that we hope? Or should there be some explicit weighting as part of the instructions?

I would say, there’s a limit to what we want to conclude out of this based on this dataset.

MS. NORMAND: I’ll say one more thing, I’m sorry, it’s just that typically -- and I know you’ve done this -- is usually we have the questions and we collect the data, not get the data and then -- so, but, I just wanted to get the sense of the questions that you may have in your head proposed.

MS. FRANK: Yeah, so coming out of the
Pilot Projects, this was largely descriptive. So, it’s just an update, what did we learn out of it, and then is there something there that can inform the program going forward. And, you know, Martin has reviewed these and taken it on board as well.

CHAIRMAN WASHINGTON: I have a comment from Mike, Methodology Committee.

DR. LAUER: Thank you. Mike Lauer, Methodology Committee. We’re definitely looking forward to getting more data and exploring this further. But it was interesting, at the same time that we were doing this, I happened to be reviewing a big grant for the Medical Research Council of Australia, and I had never reviewed for them before, and they gave me very explicit instructions about how I was supposed to review their grant down to 35 points for this category, 10 points for this category, 5 points for that category, so they told me exactly what they wanted, what they cared about, you know, whether I agreed with that or not, and it was just interesting at the same time that I was reviewing that grant we had this.
So, it’s a possible mechanism. This could lend itself very well to a variety of experiments.

DR. LEWIS-HALL: Freda Lewis-Hall, Board.

I actually had two quick questions. One is, back to the stakeholder engagement, I guess Christine, you almost pre-answered it for me, but I just want to check my understanding of whether or not we had some conceived notions about what that data would have told us, and then whether or not we have any goals about how that should actually look and/or benchmarks against kind of other organizations that do this work so that we -- I’m assuming that we want to be kind of the best at it, so what that would look like against not just ourselves, but others as benchmarks.

And then the same, to Mike’s point, which is, do we have a notion about how we would actually set goals across those criterion and then figure out ways to meet those?

MS. FRANK: Right. So, we’re using this to help establish some hypotheses moving forward.

So, in this case we asked ourselves, what would
success look like? What do we want to move here?
So, that gets into some philosophical discussions,
which would take longer than we have right now, but
we’re very much looking forward to having some more
data and then working more on what implications
this has for our merit review criteria.

Okay, so the other piece I wanted to
address was our active portfolio management. So,
PCORI is very interested in making sure that we
learn as quickly as possible out of all of our
funded work and as part of this we’re pursuing very
active portfolio management with these Pilot
Project awardees.

So, we are partnering with Academy Health
to facilitate cross-learning, and as part of the
work, we’re also developing a framework for patient
and other stakeholder engagement in research.
Throughout, we’ll be eliciting the patient view of
research engagement.

With Academy Health, PCORI will be
learning specifically about facilitators, barriers,
and the impact of involving patients and other
stakeholders in the full cycle of research, developing this conceptual framework that I mentioned for PCOR.

We are very interested in the cross-learning possibilities here. There’s going to be lessons learned. We want to learn them quickly, as quickly as possible, and then disseminate them across the other awardees, for example, and obviously keeping an eye on the implications for the PCORI research agenda moving forward.

So, here’s a timeline. Back in the summer, we put out a request for proposal and received a lot of competitive proposals in response. Academy Health was selected. They got to work right away reviewing the Pilot Project content and starting on a literature review.

Through this fall, as the awardee contracts had been finalized, we’ve been working with Academy Health to identify topic or method themes that would make sense for grouping the awardees so that we can form reasonable subgroups to facilitate this cross-learning goal, and we’re
very much looking forward, moving forward, to
exploring options for communication among these
awardee thematic groupings and for planning for
subgroup convenings.

So, I mentioned that establishing a
contceptual framework is part of our goal, and as
part of that work, Academy Health has been
conducting a literature review. They’re well
underway with that.

They’ve developed a draft framework
already, which I’ll show a few points out of in
just a moment. As part of their work, they
obtained input from their own patient, consumer,
and researcher roundtable, and all aspects of this
work are completed with attention to patient
involvement.

So, using structure, process, and outcomes
to organize their framework, here are their
structure elements. Of particular interest are
number four and five: What does engagement
infrastructure look like? And what’s the training
needed to help use that infrastructure? Number
seven: How do we evaluate it?

And I’ll move through these very quickly.

For the process elements, all of these are of interest, but particularly looking at the culture of engagement, what does that mean and what does it mean to the different stakeholders involved? And are there specific areas across the research continuum where patient engagement is optimal, for example?

And then, last, but certainly not least, are the outcomes components. So, those four at the top are more near term outcomes: attitudes of researchers, clinicians, patients, other stakeholders towards engagement in research. What relationships are forming that weren’t there before?

The longer-term outcomes that we’re very, very interested in is: what is the impact on quality of the research and relevance of the research? Is there an impact on uptake of the research results? Will there be improvements in dissemination of an access to the research? Are
their policy implications? And of great interest to us, will there be improvements in health outcomes that are demonstrably associated with the engagement effort?

DR. DOUMA: Allen Douma, Board. Could you take, for example, concept appeal and take us through once we’ve measured -- that’s an outcome -- once we’ve measured it, what are we going to do with it?

MS. FRANK: I could. This is a draft framework and I’m just wondering about with reference to time if this might be a conversation we could better have after this particular framework has been refined with some more input?

DR. DOUMA: It’s certainly your choice.

CHAIRMAN WASHINGTON: Other comments? Questions?

[No response.]

CHAIRMAN WASHINGTON: Okay, well, Lori, thank you --

MS. FRANK: All right, thank you very much.
CHAIRMAN WASHINGTON: -- very much for this update. [Off microphone.] It’s going to be from Martin. Joe had to step out for an interview. And I’m going to ask you to just introduce yourself, Martin, to the group and to the audience and present.

MR. DUEÑAS: Good afternoon. I’m just looking at the technical aspect here. This is basically an update on the Cycle I funding and it’s basically an operational and process update.

As you know, we -- well, let me start with the questions that we’re going to ask of you. There’s two things that we’re going to do -- that I’m going to do in my presentation, one is just give you an update of what happened with the Cycle I PFAs that were launched, and the last part is going to be to show you the selection criteria that we’re going to use to select the applications that we want to fund.

So, that is the two questions, feedback regarding the selection criteria. And as has been mentioned from Lori’s presentation, we’re
collecting a lot of data, and I’m going to show you
some of that data that we’re collecting, and then
if there’s any ideas of any other data that we
should be collecting and any other questions that
you may want to ask.

This is another view of what I’m going to
discuss, so I’m going to go through this quickly.

As you know, May 22nd we released four
PFAs that are listed here. We did get about 500
applications and this is the timeline of where we
are in the process. June 15 is when we received
the letters of intent, and it has gone through a
process of internal control, a scientific review,
an impact review they just finished, as Joe
mentioned, last Thursday, November 15, and we’re
currently analyzing the data for -- to bring to the
Board for approval, so this is the last one there.

The applications we reviewed through the --
as Lori was mentioning, there is a complete new
review criteria, and I’ve been asked to mention
this, eight, because it’s important for you to
listen to. Impact on the condition on health of
individuals and populations was criteria number one. Number two was innovation and potential for improvement of research. Number three was impact on healthcare performance. Number four is patient-centeredness. Number five is rigorous research methods. Number six is inclusiveness of different populations. Number seven is research team and environment. Number eight is the efficient use of research resources.

So, all the applications were scored according to these eight criteria and the reviewers were trained according to these criteria. That was Phase I that involved only scientists as reviewers.

Phase II, we asked them to focus on impact and we pulled three of the criteria that we need to focus on, number two, number four, and number seven.

So, there were, out of the almost 500 applications that were received, there were 152 applications that moved into Phase II, about 32 percent of the applications.

So, there’s a lot of data collected during
these applications and it was the basic data, has
the organization and the project started, the
funding opportunity, the name of the PI, but also
the, if you see here on the right side, this line,
you see the study design, the analytical methods,
the specific aims, technical abstracts.

So, let me go through some of that data so
you can see what it looks like.

So, geographic data was collected. So,
these represent all the applications that we’re
moving to Phase II. It represented 30 states plus
Canada. This represents the population that’s
being studied in these applications. These
represent the conditions that are being studied and
they can pick multiple, that’s why you can see it’s
more than the methods being studied, the design,
and there’s a question, so before -- I can answer
the question before I go into the selection of
approach and action.

DR. KRUMHOLZ: So, I’m listening carefully
to you, but I just want to be sure that I
understand how this happened. So, to get to Phase
II, was there a target percentage that was identified? Or these are the ones that hit an absolute standard on the Phase I criteria?

And then, just to remind me, because I know we’ve said this before, the target number of grants from the 152 that we would expect to fund would be?

MR. DUEÑAS: So, the target was 109 and about $96 million.

DR. KRUMHOLZ: The target’s 109. And was there an attempt to get like 30 percent to get through the first phase?

MR. DUEÑAS: The top 10 percent, so, yeah, about 30 percent.

DR. KRUMHOLZ: But that was -- I mean, it was not an absolute -- it wasn’t an absolute, but you were going to take the top third?

MR. DUEÑAS: Correct.

DR. KRUMHOLZ: Okay.

MR. DUEÑAS: Which is what we did.

DR. KRUMHOLZ: Thank you.

CHAIRMAN WASHINGTON: Another question,
Martin.

MS. BARKSDALE: I have a question as well.

CHAIRMAN WASHINGTON: Name please.

MS. BARKSDALE: I’m sorry. Debra Barksdale, Board, the slide that looks at the focus on impact. Who were the reviewers for Phase I and Phase II different? Were there different types of reviewers?

MR. DUEÑAS: Yeah, good question. The first one was only scientific and it was a different panel than the Phase II. The first two included scientists and patient stakeholders. Completely separate.

MS. BARKSDALE: I find it curious in the criteria that you only chose -- there were only three listed for Phase II, and yet one on Phase I dealt with the impact as well. It’s a pretty significant impact, but it is not -- was not part of Phase II. I guess I don’t understand the logic.

MR. DUEÑAS: Yeah, so there was a lot of internal discussion of how do we move the -- how do we review the second phase? And the idea was to
review the impact, what was really that was going
to change practice? And I don’t know if Anne wants
to add anything, but it’s totally innovation.

And the three main things that we focus is
the innovation of the project, the patient-
centeredness is clear, and the last one is the
research team environment. What that meant is, are
you really involving patients into the process, so
that was just what we decided.

CHAIRMAN WASHINGTON: Collins?

DR. COLLINS: Francis Collins, Board. Are
you going to share with us what happened in terms
of the scores from Phase I and the Phase II scores
and how much reshuffling occurred?

MR. DUEÑAS: Not at this time. So, we’re
collecting all this data, we just finished -- we
just finished the review on Thursday, but we have
all that data that we will be presenting to you.

DR. COLLINS: And can you say again who
were the reviewers in Phase I and Phase II?

MR. DUEÑAS: Phase I were all scientific
reviewers. There were three reviewers per
applications. And Phase II, it was a complete new set of reviewers. There were two scientists, one patient, and one stakeholder per application.

DR. COLLINS: I think it would be very interesting to see -- I’m concerned like Debra that you’ve picked three of the review criteria out of your list of eight, it wasn’t obvious to me why those were the right three.

MR. DUEÑAS: It’s going to be fascinating to look at the data because, as you can see, for each application we can have eight data points from the overall score plus a data point in the second review, and then it’s going to have patient stakeholders. So, I’m actually excited to see the data as well.

DR. COLLINS: But your plan is that it’s the Phase II reviewers who determined who gets funded?

MR. DUEÑAS: So, we’ll talk about that in the last slide that we’re going to get to. Yeah, we’ll hold that question for a second.

DR. COLLINS: I just want to flag that if
you have a grant that scores extremely well in Phase I and somehow it gets dinged in Phase II, you should worry a lot about that.

MR. DUEÑAS: Noted.

CHAIRMAN WASHINGTON: Okay, please continue.

MR. DUEÑAS: So, if we go to the selection criteria, which Dr. Francis just alluded to, so, the selection criteria is going to consist of a Selection Committee that is similar to the one we did in Pilot Projects. Selection committee will be Board members and staff. The idea is to collect the highest scoring, so they select -- the three basic criteria that we're going to use is final score for Phase II is the main one, so the ones that scored the highest will be funded, but also we're going to look at conditions of population study. And then after that, we're going to bring the proposal to the Board for approval, so I don't know if that answered your question, Dr. Francis.

DR. COLLINS: One other question. Were the Phase II reviewers aware of the scores from
Phase I?

MR. DUEÑAS: Correct. Yes.

CHAIRMAN WASHINGTON: Dr. Normand, do you have any comment on that?

MS. NORMAND: It’s sort of an -- I’m just trying to understand the rationale for that. It’s not necessarily what I automatically would think of doing. And I’m sure there’s been thought put into it, but perhaps you can remind us of the rationale for that particular design to make them aware of the scores in the prior round.

MR. DUEÑAS: So, this model -- so, the statute requires to do peer review in a validated model. This model follows NIH editorial review and has been used many times. So --

DR. COLLINS: Say that again. This is not what our advisory councils do.

MR. DUEÑAS: Okay. So, you see --

UNIDENTIFIED SPEAKER: [Off microphone.]

MR. DUEÑAS: Dr. Francis doesn’t know everything that happens at the NIH. The editorial review --
DR. COLLINS: That’s not the right answer.

DR. DOUMA: No, I don’t think --

MR. DUEÑAS: The editorial review was used during the new stimulus money that came in. What they did is, because they had a lot of applications, they basically did this review where the first phase was a mail review where you send the applications to the reviewers and they will review it online, there were three applicants and the second, and then the Phase II, is exactly what we did, it will be a complete new set of reviewers that will focus on the impact of it, and literally just use the critiques from the Phase I in this course to sort of make a decision on the applications.

DR. COLLINS: There’s a relationship, but it’s certainly not the same in that you’ve changed the characteristics of the reviewers for Phase II compared to Phase I.

DR. CLANCY: Carolyn Clancy, Board member. Martin, just a quick clarification question. So, if Arnie submits a grant, and we know he didn’t,
and there are three reviewers and three scores, does the second committee see the three scores or do they see an average mean?

MR. DUEÑAS: They see all the scores.

DR. CLANCY: Great.

MR. DUEÑAS: They see the criteria and all the scores.

DR. CLANCY: I mean, off the top of my head, this doesn’t sound all that different than if someone submits a grant and does well but not well enough, and then they resubmit. That second committee knows what they got the first time.

MR. DUEÑAS: So, the second reviewers not only see the scores, they see the applications and everything else.

DR. COLLINS: Except in a resubmission, the grant has been rewritten. Here it’s the same proposal for both Phase I and Phase II reviewers. There’s no response to Phase I in order to get to Phase II.

CHAIRMAN WASHINGTON: Okay, Norquist.

DR. NORQUIST: Gray Norquist. So, I think
there’s some confusion. I would agree with Francis. That’s not the way exactly it was done. It’s just surprising to me because I didn’t know this is the way this was going to be done and I would also -- Francis was concerned about a good score, I would also be concerned of the reverse. If I had been a very high impact but didn’t do well with the scientific people, now I’m lost, so you’re biased toward not getting necessarily highly innovative -- I mean, you could argue that direction.

So, that worries me a little bit too, like who got missed in that first group that didn’t make it to the second. So, I don’t know. I’m a little concerned here about -- and then now you’ve got a third process, which is in a Board of Governor’s group that’s got to pull this all together and I hope I’m not in that group.

CHAIRMAN WASHINGTON: Thanks for volunteering.

MS. GOERTZ: Christine Goertz. One of the things that we had talked about in the PDC when we
last met, we were talking about this process, and there are several of us who are wondering if maybe the process shouldn’t be flipped and maybe have the stakeholder reviewers involved in the first round as well as the scientists so that we go first through the screen of is this exciting, you know, does it have high significance and also look at the science.

And so I think there are a lot of ways that this can be tweaked and improved upon as we move forward. And then just relative to the selection process, I think that the criteria that we have now makes sense at this particular phase of our development, but at some point this is going to get more complex because I think we’re also going to have to be paying more attention to gaps, and right now we haven’t funded much, so our portfolio is fairly wide open, but as our portfolio starts to fill in, I think we’re going to have to consider what we’ve already funded and where we already have investments in addition to some of these other things as we move forward.
CHAIRMAN WASHINGTON: Okay. I don’t see any more -- oh, Weisman.

DR. WEISMAN: Yeah, maybe a suggestion for the future for the next round also is that we have a Methodology Committee that is available to consult and help us on these kinds of methodologic issues, which this is, you know, grant selection and prioritization is a method, and we -- it would be a shame to not tap into the expertise of that group.

DR. SELBY: You know, I’m sorry I had to step out and miss the first part of this. It went faster than I thought. You guys really moved along.

We discussed with -- and I just wanted to say that we discussed this issue about having only scientific reviewers review in the first round and do it by mail back in Denver, and at that point we were anticipating something on the order of 1,300 and we knew we couldn’t do them all face-to-face.

We also discussed that -- and we had no patient or stakeholder reviewers in that phase, and
we discussed, in fact, that with the next round we
will have patient and stakeholder reviewers whether
we have one round -- whether we have one phase or
two, whether we do the first phase by mail or not.

And with respect to Phase II, we talked a
lot in the day before the reviews with the
committee co-chairs about this, and yes, we did say
to emphasize this time these three because the
applications they were reviewing were the top third
of those who had done well in the first review.

But we also said, because there’s a lot of
technical reviewers on here, if you see a flaw, if
you see something that in your mind makes this a
fatal flaw in the research, be sure and bring it up
because it can’t be patient-centered if it’s wrong.
It can’t really serve the interests of patients if
it’s wrong.

So, they did bring up methodologic issues
as well.

DR. WEISMAN: I meant the method of
actually conducting a two-stage review, sort of the
mechanics of it. But could you go back to that
slide? The one thing that concerned, I think other people said it, but if I heard them right, and it certainly concerned me, was going from seven to three in what seemed like maybe some arbitrary, you know, number one to me sounded like I’d like to know what stakeholders thought -- no, it was the review -- the one you had up for Joe, the one that was there when Joe was talking -- impact of the condition on the health of individuals in populations, I would have liked to hear what -- I mean, I would think stakeholders would have a point of view on that too. That was my only --

DR. SELBY: You know --

DR. WEISMAN: It’s not just a scientific issue, I guess.

DR. SELBY: Well, the way we implemented it, it was -- you know, that’s the one where prevalence and burden and costs come in substantially, costs both to the patient and overall cost to the country, come in.

We were really focused, in Phase II, on saying, is it likely that this research will make a
difference based on what’s known, based on preliminary data, based on requests from patients or clinicians for this information, based on the results of evidence syntheses, is there a need for this information? Is there an audience waiting for it? Because we wanted to select research that would be likely to be put into practice, change practice, improve outcomes. And we certainly wanted to focus on, is this a patient-centered question? And we certainly wanted to focus on, have you engaged -- have they engaged patients and other stakeholders in the process?

So, that was what we emphasized primarily in round two. But as I said, we did say, if you see a scientific flaw in this, bring it up because that -- you know, that’s overriding.

CHAIRMAN WASHINGTON: Kuntz?

DR. KUNTZ: Just a clarity question. Was the first -- is the first phase a screening process?

MR. DUEÑAS: A screening process --

DR. SELBY: Yeah, it’s a type of screening
process.

DR. KUNTZ: Does it reduce the number?

DR. SELBY: It reduces the number by two-thirds.

DR. KUNTZ: So, if it does that, I’m just trying to think of what the cumulative process is for, you know, working on the knowledge obtained in the first screen, because what you do is you erase the process and then it gets reevaluated on just three criteria at the end. There’s no cumulative use of the previous screen as knowledge other than the carry through with the score, right?

DR. SELBY: Well, and the pink sheets. And the pink sheets from the first round.

DR. KUNTZ: Were there instructions about how to process that and value? I mean, I’m just trying to think of like -- do the second people -- does the second screen take into account what Harlan just said, the rigorous review of the seven criteria and then they add emphasis on the three, or does it start from scratch and just relook at those three?
MR. DUEÑAS: So, it doesn’t start from scratch. The way they were trained is that look at the criteria, how it was reviewed before. So, they had that. Not only did they have the application, but they also had the pink sheet.

DR. KUNTZ: So, the general thrust was that there was a platform --

MR. DUEÑAS: Correct.

DR. KUNTZ: -- Phase I, that they built additional evaluation on, and that was instructed?

MR. DUEÑAS: Correct.

DR. KUNTZ: Okay.

CHAIRMAN WASHINGTON: Normand.

MS. NORMAND: Sharon-Lise Normand, Methodology Committee member. I just wanted to ask, on what basis or evidence of -- I’m still stuck on the second phase review having the so-called pink sheets and it’s sort of a different group of characteristic of people who are reviewing at that second stage and they’ve got all this information from the first stage. My initial reaction was, oh, my god, why are you doing that?
Why are you giving that information to them? And I’m sort of still there.

So, I’m trying to understand the -- how -- why did you feel the need to provide them with that? Can you just sort of -- just my automatic reaction, you shouldn’t have, but I’m willing to be -- I can be wrong, obviously, so help me think through -- what did that provide?

DR. SELBY: So, we know from the data we showed you in the pilots and we know from work that others at NIH have done over time that a traditional study section weights the approach, the analytic approach. It’s almost the only thing that matters. And, you know, from study sections, you go to study section and the game is to try to find a reason not to fund something, but usually based on methods.

And we’re trying to get away from that, so we tried to identify a group and we may change this strategy, but we tried to identify the subgroup of all the applications that would do pretty well in that more traditional kind of review. We did have
all eight criteria, but I bet you that if you looked, number five, rigorous research methods, would probably drive those scores in round one as it did in the pilots.

And then we said, starting with a group that’s done quite well in terms of the approach, please emphasis, please -- and this is hard. I mean, we really do want to shift the paradigm toward funding research that’s likely to have an impact. We don’t want methodologically elegant work that isn’t going to have an impact. So, that’s why we did exactly what we did. Please place an emphasis on the likelihood that this will change practice, place an emphasis on is this really important to patients, place an emphasis on have they engaged.

So, that’s the thinking, that it’s going to be very tough, no matter what we do, to break the paradigm. We don’t expect, probably, that it’s going to break it very much this first time. We’re anxious to see.

MS. NORMAND: So, I’m not disagreeing with
that, it’s a very -- in some sense, it’s a very
nerdy point. I’m just asking about providing the
score -- like, the pink sheets, to the second
group. What was the thinking behind that? That’s
the only -- this is the process that I’m asking
about in terms of that piece.

DR. SELBY: Again, you know, this may be a
function of how many we expected versus how many we
actually wound up with, but I think we were not
necessarily expecting the second round study
section to peruse the entire application quite as
carefully as the first round did.

And we also really, you know, frankly
didn’t want a whole lot of second guessing either.
That didn’t seem to make a lot of sense either.

MR. DUEÑAS: And that’s exactly right.
So, the idea is that we were expecting over 1,000
applications. So, the idea was to sort of give
them the critiques as the primary resource for them
and that access to the application, but only if you
have to, and that’s one of the reasons why they got
access to the pink sheet.
DR. SCHNEEWEISS: Sebastian Schneeweiss, methods committee. If you can go back to the bubble chart with those four big bubbles or five big bubbles, what I saw there that what is in this upper green bubble is CER, assuming that these proposals move proportionately on to be funded, right, that is 29 percent is actually the smallest absolute percentage of the research portfolio. Is that the research portfolio that we can expect from PCORI in the future, less than a third CER?

DR. SELBY: The denominators are switched here. The denominator is the number that were submitted and so the 61 -- it’s, by far, the largest group, 61 made it through versus 26, 35, and 30.

CHAIRMAN WASHINGTON: Okay. And then Collins after Douma.

MR. DUEÑAS: Which one?

DR. DOUMA: It’s the one -- yeah, it’s the one that shows up what’s next for us. We have a vested interest in that. No, you were just there. That one.
DR. SELBY: Okay, that one we haven’t actually gotten to speak to yet. That’s my job to speak to that one.

DR. DOUMA: Oh, okay. He’d already shown it.

CHAIRMAN WASHINGTON: Okay, Francis, please, first.

DR. COLLINS: Francis Collins, Board. I think the Board would love to see a simple plot of the average priority scores for each application for Phase I versus Phase II. Is R squared a large number or a very small number? If you have very limited correlation between the two reviews, then I think we really have to look very hard at whether this is a system that’s plucking out the right proposals for PCORI to support.

Because I would have expected that a Phase II process, when it is already informed by what happened in Phase I, is sort of like council where you’re trying to do some fine-tuning for what’s a high priority, I mean, that’s what we call it -- high program priority, low program priority, sort
of at the margin where something -- well, it’s all right at the borderline and do we want to fund this or do we want to fund something else and pull it up a little bit.

And if there’s a great deal of reshuffling going on here, i.e. if R squared ends up being pretty small, then I think you really have to look hard at this process about whether it’s doing what you need.

DR. WEISMAN: Francis, I don’t think that that’s true, I mean, based on what Joe said. Joe said they were shifting, so the assumption is everyone who made it through the gate, so to speak, had good methods. Now the criteria are based on these three factors and that his assumption is that the primary reason for making it through the gate was on methodologic rigor. That’s what he said.

DR. COLLINS: The first phase had those eight criteria, I presume they were all being evaluated on the basis of science.

DR. SELBY: But if we talk about the overall scores from round one versus round two, in
round one, the overall score is going to be driven mostly by criteria number five, that is the approach, the methods.

Then having truncated the distribution and really decreased the variants among the scores, we bring them to Phase II, and I think I’ll be happy if the correlation between the overall score in Phase I and the overall score in Phase II is no so high.

The components -- I’ll be happy if the component scores are close, but the overall score it would be nice to be driven by something other than just the method.

DR. COLLINS: I’m going to worry, as Gray was, about projects that actually were sort of in your worst 10 percent as far as Phase I, but get pushed into fundable range in Phase II, which means there were considerable concerns --

DR. SELBY: They don’t get to Phase II.

DR. COLLINS: No, I mean, they still made it to Phase II because they’re in your top one-third, but they’re at the worst part of your one-
third.

DR. SELBY: This may comfort you a little bit. As many as half or more, and this is, again, it’s a function of the small numbers, but half or more than half of the projects, I think, in each area, are going to get funded, so -- from the Phase II review. It’s --

DR. COLLINS: No, I got that.

DR. SELBY: Okay. So --

DR. COLLINS: I’m still worried about major shifts when you go to the second phase when Phase I was supposed to be your rigorous and scientific --

DR. SELBY: We certainly are going to study that and we’ll have to -- if we see it, we’ll have to decide whether it’s a good thing or a bad thing.

CHAIRMAN WASHINGTON: Kuntz and then Clancy.

DR. KUNTZ: Rick Kuntz, Board member. I’d love to extend the linear regression discussion some more.
[Laughter.]

DR. CLANCY: I like the random forest myself.

DR. KUNTZ: And I think what Francis is saying is we do have consistency between two different groups that value things high, and because I think that there are a lot of moving parts in this process here and one is that you’re putting a lot of faith in the second group and actually judging merit, which is a new composition of people who may not understand methods. So, if the first group is more scientific and the rigor has been established through some score, well, first of all, it would be hard to correlate because they’ll all be high scores, so you may reduce the ability to correlate because you don’t have any variance on the first component.

But the second part would be, that’s where the experiment is. Take a novel group of individuals with a reduced set of criteria; can they still judge highly scientifically meritorious grants? And we should test that to see if what
people valued on the front end by the scientists were still somewhat valued at the back end, because it isn’t just -- it isn’t a process of we only get the most rigorous studies first and then from then you pick the best. There’s a lot of questions as to whether or not the group -- it’s an experiment. You know, can this group still pick meritoriously, scientifically rigorous studies?

CHAIRMAN WASHINGTON: [Off microphone.]

DR. KUNTZ: Only if you make a huge assumption that there’s equivalent worthiness of the people who made it through the screen --

DR. WEISMAN: The screen is on scientific grounds and then the second group has a different set of weighting of the criteria.

DR. KUNTZ: If we can make the assumption that those are completely orthogonal viewpoints, that we’re satisfied with the merit, they’re all of A+ level, and the second part is now completely a separate -- I’m sorry for using this matrix terms, but a completely different dimension. But have we all agreed on that, that the second value of those
three criteria are what you’re going to basically use to judge the grants at the end assuming that you’ve made this kind of rigorous threshold at the beginning? I think it’s complicated.

CHAIRMAN WASHINGTON: I see a few hands, but can we hear from Mark Helfand? And then we’ll come back to the table. We have Clancy and then we have Krumholz and Gabriel.

DR. HELFAND: Well, I’m counting the hypotheses that are being generated and I think Joe’s hypothesis, it’s pretty reasonable, that those that went forward all scored high in methodology is, I understand, would be very easy to test, right, there is a score for each component. So, if that’s true or not, you should be able to answer that quickly.

And then the second concern about the relationship between the overall score in the first versus second, however you do it, correlation or whatever, should be pretty easy to test.

So, since, you know, once you get too many hypotheses, then we don’t know what to do, I wanted
to get a few out there on the table before we get 100 more. And I think, you know, the concern that I would look at is whether you -- your goal is to achieve, it says, more impact by the second phase, but you have kind of a new process and it’s -- there’s no representation, there’s only two or three people trying to represent a bigger community or set of communities than the research community alone.

And so I would worry about whether, instead of more impact, the half that went on after that process were more neutral, less risky methodologically or as far as their hypothesis or their goals, whether they had less chance of ruffling feathers, whether -- the difficulty in that process was not so much more impact, but more uncertainty about what research should go forward. And usually when people have more uncertainty, they get more afraid of risk and they pick more conventional or studies that won’t ruffle feathers. And finally, whether it’s less diverse, and I mean, you know, geographically and population wise than
the bigger ones.

Those are the four things that I’d add. And the limit on hypotheses for this is six, so I think I’ve closed the door on anyone else.

DR. CLANCY: Carolyn Clancy, Board member. It’s possible I’m missing something and I will disclose one bias. Having sat in many, many study sections and reviewing a lot of health services research papers, I will say that there’s no shortage of papers that are methodologically rigorous and you get to the end and you think, “and?” or “so what?”

I think PCORI wants to fund work that is rigorous and relevant, and it is a tough position to be in review groups where people have said this, where they’ve said, I don’t even know these methods but I’m going to assume they’re flawless. But this is a really important question, and I think that’s what the design was here.

And we have been encouraging the staff to be bold and edgy, so I’m not sure they ought to correlate. If they do, I suppose that means that
previous data from NIH study sections and from our
own pilots that says that approach ultimately
swamps everything else in terms of what this
overall score turns out to be, perhaps was flawed.

But I actually think this was not a bad
thing to do.

CHAIRMAN WASHINGTON: Thank you, Dr.
Clancy. Krumholz and then Gabriel.

DR. KRUMHOLZ: Harlan Krumholz. I guess
at the end, I want to get back to what Rick said,
the issue is, did that first screen say that these
are good enough, and then we don’t care if they
correlate. I mean, first when Francis told me that
I was thinking it is important, but actually, if
all those are good enough, if you think you can
make valid inferences from all those study designs,
then maybe I don’t care about the distribution of
quality among the top third. And the question, I
think, Joe, would be, how might you later sort of
follow up on that by sort of taking a deeper dive
into the differences in the quality of the methods
of those and were they meaningful differences or
did you really then get to a group that said, you
don’t have to worry so much about the methods,
these are all good enough, now let’s choose among
this group of 32 percent that were left?

And I think that’s really the question,
but I do -- I wasn’t in Denver, but I do remember
at times we have discussed this idea about could
you get to good enough, and now people could focus
on the issue of impact, as Carolyn said?

CHAIRMAN WASHINGTON: Okay. Gabriel.

DR. GABRIEL: So, I like the idea and I
understand the merits of the two-phase approach,
but I guess I wanted to get back to something that
Christine said. If there’s an initial screening
phase, it just seemed to make a good deal of sense
to me to have that screening phase be what are the
important patient-centered questions. And then as
a second phase, look at the methods.

Because at the end of the day, if you have
-- you know, and we’ll end up, perhaps, in a
similar place, but then those that don’t get
funded, we have an opportunity to go back to those
applicants and, you know, maybe pair them up with some methodologists and move forward on those important patient-centered questions in a more methodologically rigorous way.

I just wonder what happened to that because that really seemed to make a great deal of sense to me.

DR. SELBY: [Off microphone] -- last Thursday that you can -- it’s kind of the researcher’s perspective, maybe, versus the patients -- the traditional researcher’s perspective, not yours, versus the patient’s perspective, yours or Christine’s, which is just give me the good science and we’ll pick out those that are patient-centered, versus, just give me the patient-centered and then we’ll pick out the good science.

And I agree with you that if all goes well, we’ll wind up at the same place.

DR. GABRIEL: And help the others or some of the others.

MR. DUEÑAS: And just to say, we’re going
to include patients in the Phase I for the next cycle.

CHAIRMAN WASHINGTON: Okay, well, we’ve been talking about Phase I and Phase II. I’m glad it’s Joe’s opportunity to tell you that there’s a Phase III to this. So, Joe, will you --

DR. SELBY: Yeah, here we go. So, now we will have the applications ranked by the overall score from Phase II, that’s what we’re going to work with, and we have, and I think Martin probably showed you -- we have a lot of data that was collected on these that we can examine and you will recall from the Pilot Projects that we examined a number of variables and we actually set some criteria that we wanted a certain degree of balance, if you will, with respect to variables like vulnerable populations, the disease studied -- we didn’t want it to all be in one condition, for example.

And I think the same thing goes here.

Last time we appointed a committee primarily composed of Board members with a Methodology
Committee member, and staff generated data that the committee looked at, and last time it worked out remarkably nicely that everything tended to kind of balance out on its own and we were able to just take the top 50 scores.

This time we’ll hope for similar turn of events that if we take the top number we can fund within each priority area, that we’ll get that balance.

But we will have the committee again, we’ll look at those variables, and we’re proposing that we essentially make the final selection on three criteria. First and foremost, the final score from Phase II, so that’s in bold, that’s the overwhelming driving determinant of what we fund.

But we will consider carefully the condition studied, and if it appears that there is a severe imbalance in one direction or another, based on what we’ve seen at the end of everything that came in and at the end of Phase I, I think we’re going to see a pretty nice balance across the conditions.

And the same goes with the second one,
populations studied. If we saw, you know, some obvious vulnerable populations just completely left out, we would, perhaps, look below the pay line to see if there’s a good, high scoring study, that might bring that population in.

But that’s what the committee would be asked to do. We’d be doing it in the next three to four weeks, and we’ll come back to the Board in a December -- probably our December 18th telephonic Board meeting, which we’ll turn into a webcast, and we’ll present -- the Board/Staff Selection Committee will present to the Board a proposed slate of proposals for funding at that time.

CHAIRMAN WASHINGTON: Before we go to questions, Joe, I would just also remind the Board that we more or less decided that the next “balancing group” for lack of a better word, especially with Dr. Normand at the table, would be composed of a different group of Board members, that it wouldn’t be anyone -- except for possibly the Chair of the previous round who would come with some experience from that round.
Seriously, that’s what we would be proposing as we think about constituting the second group.

Sigal?

MS. SIGAL: Ellen Sigal, Board member.

So, I have a little concern on the balancing and how we’re doing it because we were very specific that we were disease-agnostic, condition-agnostic, we wanted a very broad tent. That was what we did. A lot of us didn’t really agree with that, but that was what the judgment was.

Now, we’re basically saying, well, if there are too many from one disease we’re going to kind of reshuffle the deck. And it concerns me because we were very deliberate, very, very deliberate in not being specific. And now we are changing the deck chairs, and I don’t know how I feel about that. You know, maybe if there are one or two on the edge, but if there were five or ten outstanding grants on Parkinson’s but there are none in, I don’t know, Alzheimer’s, so we’re going to give one in Alzheimer’s that isn’t so good that
wouldn’t get funded a grant? I don’t know how that works. It just seems to question exactly how we’re doing these things.

DR. WEISMAN: The way it was done last time, Ellen, is they expanded the pool and took the ones on the border. Is that --

DR. SELBY: And we may be able to -- it may be possible to do that this time.

DR. WEISMAN: I thought we voted on it.

[Off microphone discussion.]

DR. SELBY: Last time we did -- we were able to improve the balance some by just taking a larger number. And I think, you know, the decision about the exact number to fund is, this time, given the somewhat smaller than expected total number submitted, has yet to be made, will be made in discussions with the committee.

But I would just say to Ellen, your -- I can see how you got to the conclusion that you got, but I think you could get to the opposite conclusion. If you wanted to be disease-agnostic, you’d say, we don’t want to focus all of our
research in any one area, so disease-agnostic is maybe the wrong definition, but we did decide we didn’t want to concentrate all of our resources in one or a few areas, and this would be consistent with that in saying, you know, if we, by the luck of the draw, wound up concentrating it all in one area, we’d like a little spread. So, not inconsistent.

MS. SIGAL: Just a point to that, maybe that’s correct, but if we -- you know, because we know who the likely candidates are going to be always by the nature of the population, but if we really want the diversity, then maybe we need to be -- and we are getting to that, we need to be a little bit more specific in getting other diseases or other rare diseases or other outcomes and be more proactive about that. That may be another way to approach it.

CHAIRMAN WASHINGTON: Norquist, is your card up?

DR. NORQUIST: Gray Norquist on the Board. So, what I would say is that we kind of lucked out,
you know, the last -- and the other thing, when you say condition, people are studying chronic, so it’s not as simple as just cancer or something often on many of these, and so I think you’ll find that may not be an issue. The only thing I would say is that -- whoever makes up the committee, is that you be sure that you have some a priori criteria. Don’t just say they didn’t hit a severe or whatever because trust me, the people who don’t get funded are going to have a lot to be upset about, and so I think we need to be very clear what our line is there about that.

CHAIRMAN WASHINGTON: Douma and then Hunt.

DR. DOUMA: The lexicon that Bob keeps bringing up may be of value here with regard to what we mean by condition. We can -- I’ve used it in a broader sense and a more narrow sense. In the broader sense, for example, chronic pain or chronic shortness of breath are conditions. Are we going to treat them the same way we treat diabetes or congestive heart failure?

DR. SELBY: I think right now they -- if
I’m remembering correctly, those are categories, so if something crossed diseases and was about chronic pain, yeah, there’s pain, so you see, those are separate categories right now.

DR. DOUMA: And those are the same categories we’re going to be using as conditions and choosing between?

DR. SELBY: Except it’s a much, much longer list. But you can see already that there is pretty good spread among those.

CHAIRMAN WASHINGTON: Okay. Hunt?

MS. HUNT: Hunt, Gail Hunt, on the Board. So, to this topic of conditions, are we really going to be looking at not just the conditions that are there, or -- I should say, are we just going to be looking at the conditions that we just saw listed there, or is it somehow a condition that sort of ties in with impact or devastation on the patient or, you know, condition that’s broader than just --

DR. SELBY: Now, we would definitely not try to go after particular conditions that had
greater impact because that was already done in the review. So, our principle last time that we’ll certainly adhere to this time is, we’re not going to second guess the reviews.

We look at criteria that were not considered criteria in that -- those reviews.

CHAIRMAN WASHINGTON: [Off microphone.]

So, I’m going to summarize where we are at this point. We’ve completed two stages of a three-stage process and we’ve had quite a bit of debate and discussion regarding the pros and cons of the approach that we’ve executed to date. But at this point, we are where we are, and with those comments, I hear more than just the suggestion, a strong recommendation that we, Joe and Martin, find a way to more rigorously assess going forward. In fact, even some retrospective analyses to test some of these hypotheses, as Mark said, so that we can have that data going into the future.

But looking ahead, there will be this next smaller group consisting of Board and staff, which will be looking at the impact scores, essentially,
from this phase, to come up with the recommended list of projects that will be brought to the Board within the next month, month and a half.

DR. SELBY: Month.

CHAIRMAN WASHINGTON: Month. Within the next month. It will be a web telecast.

DR. SELBY: December 18th.

CHAIRMAN WASHINGTON: Oh, it’s December 18th, it would be open to the public. Okay. And we will ensure that the Board, as soon as the information is available, that this information is both put on the web, or can we do that given that we’re talking about specific projects? Maybe we can’t do that before, but we’ll get as much information as we can to the Board as quickly as we can regarding the outcome of this next phase.

DR. SELBY: Last thing I’ll say is that we will be contacting a number of you to invite you to serve on the Selection Committee, and the last time we made sure that each of the Board committees was represented on the Selection Committee, typically by more than one person.
CHAIRMAN WASHINGTON: Sigal and then Zwolak has the last comment on this and we’re going to close this session.

MS. SIGAL: So, just a quick question. So, we’re going to get the recommendations. Are we going to see the ones right below the line? One of the things that I used to take great joy on when I was at the National Cancer Advisory Board, is that we got to see things that weren’t funded that were just below the pay line and it was quite interesting. Are we going to see that? Are we going to see those that almost got there but didn’t?

DR. SELBY: That’s an interesting question. With respect to choosing those that get funded, we found last time that it was a very satisfying and relieving exercise not to have to look at the proposals themselves or their titles or inadvertently see the investigators, and just to look at the distribution of their characteristics and make decisions about funding on the basis of characteristics rather than the projects
themselves.

But I think having said that -- and if we could get through it this time the same way, we would have no worries about recusals, we'd have no worries about conflicts that we missed.

But I think having said that, once we determine which ones we will fund, to take at those just below with an eye toward identifying promising projects that should be encouraged to resubmit or to tool up a little bit and resubmit is a very, very nice idea and I think that would be -- this is off the top of my head, but it sounds like a good idea and a very patient-centered idea to do that.

CHAIRMAN WASHINGTON: Zwolak, last comment.

DR. ZWOLAK: Bob Zwolak, Board. I think at one point in our genesis we were actually talking about trying to finish two full funding cycles in calendar 2012. It’s going to be one, it’s going to be four and a half months from the submission of the completed grants to the announcements.
So, the question is, what’s -- realizing this is kind of an alpha, what’s the eventual goal for turnaround from submission of grants to announcements?

DR. SELBY: This is a -- and Carolyn or Francis, correct me if I’m wrong -- but I think we have telescoped the NIH/AHRQ process a bit already. I think this is a bit quicker, four and a half months from the application deadline to the award date. That’s a little quick.

It’s tough when you do these broad announcements because you get so much and so there’s a lot of work to be done just putting the panels together and getting the reviews done, especially when there’s two phases of review.

When we get more targeted announcements, there will be fewer responses, there will be a smaller review committee, and I think we could pick up some ground there, but we haven’t had it as one of our priorities to speed this part of it up even further.

DR. CLANCY: Just one quick comment. Just
to be a tiny bit humble, I think any institute or 
AHRQ could do it once this rapidly. The challenge 
will be when you have to make it a repeatable 
process and continue that. So, actually staying on 
this timeline I think would be great.

CHAIRMAN WASHINGTON: Thanks for all of 
your comments and we’re going to take a break now. 
It’s 3:00 o’clock and we will resume at 3:15.
[Recess.]

CHAIRMAN WASHINGTON: Welcome back to 
this, it’s the last session of the day, meeting of 
the Board of Governors of the Patient-Centered 
Outcomes Research Institute.

In this session, we are going to address 
the question of funding for some initial priority 
targeted areas and I’ve asked our vice chairman to 
chair this session and also have the record reflect 
that I’m going to recuse myself from the 
discussion. It’s a personal interpretation of a 
potential conflict of interest.

VICE CHAIRMAN LIPSTEIN: Joe.

DR. SELBY: Yes.
VICE CHAIRMAN LIPSTEIN: I just did my thing.

DR. SELBY: It’s hard work. Steve, thank you very much for that and, Gene, thank you. And I want to reintroduce Dr. Kara Walker, who I had the pleasure of working with a lot on this particular budget. Really, the truth is, Kara led much of it and I’m going to do the Steve/Gene thing of having Kara sit directly across from me so we can maintain eye contact and if I need her assistance in answering a question, she’s there.

So, what I want to do this afternoon is present to you a rationale, or review a rationale with you for why PCORI should move rather quickly toward some targeted funding announcements. And targeted funding announcements mean, instead of submitting a call, a broad call, for research across a wide range of conditions, any condition, any treatment, any question, as we do now, that we dedicate some of our funding to a much more targeted or specific or focused approach where we concentrate on one question, which we’ve determined
is very high priority and very suitable for PCORI. I want to say, before going any further, that we are extremely proud of the announcements that are out, the standing announcements that I call broad funding announcements. We think that they provide an opportunity to get the best ideas of patients working with -- of researchers working with patients and stakeholders from across the country, ideas that we may never have thought of, ideas about conditions we might not have come up with, that we simply solicit good research, we review it, and prioritize it on its merits, not on the basis of what the question was in the beginning, not on the basis that they picked the disease that we favored.

So, having said that, we also see a merit in a targeted approach, which is to identify, in collaboration with stakeholders, patients, clinicians, and others, some very high priority areas that PCORI should concentrate research funding and resources in.

You know and you’ve heard, at the last
meeting in Washington and again earlier today when we talked about the advisory panels, that we are building a topic generation and research prioritization scheme process that we’re very pleased with how it’s developing. We’re looking forward to the day when it’s functioning and good ideas are coming out at the end of the process and coming to the Board -- high prioritized, good ideas.

But we’re not going to get there for, I would say, six months minimum before the advisory panels have been convened and actually gone through the prioritization process and generated these topics for us to consider.

And so, in our judgment, we think there’s a need to get on with identifying high priority topics. I’m going to talk to you about the process that we’ve put into place and gone through in this interim phase. I want to then show you the proposed topics that we’ve come up with, have a discussion with you, give you a little information about those three topics, and then, in fact, ask
for the Board’s vote on these topics.

There will be a somewhat larger list that you’ll see and I think that we are open to expanding the number of topics, modestly, that we could go after. But there are limits on how many targeted topics one can -- the staff can go after at one time.

So, the rationale, in part we respond to concerns that we’ve heard from virtually every stakeholder group that exists, from patients through researchers through industry through health plans and employers, concerns that, in fact, we did stay at such a high level that it didn’t seem to stakeholders that we were being consistent with the legislation which said, prioritize high priority topics and fund in those areas.

We’re responding to a Board directive, which we got late in the summer from the Board, to move forward with identifying several high priority, stakeholder vetted topics.

It gives us a chance to jumpstart and test -- what we’ve done allowed us to jumpstart and test
the longer-term topic generation and research prioritization effort that we’re putting into place. And, in fact, I’ll say that we’re working on in those workshops I mentioned this morning on December 4th and 5th.

Very importantly, it leverages stakeholder input that was gathered before PCORI really came on the scene, and so there were -- and lastly, this endeavor, allows us to build further on our engagement work.

MS. HUNT:  Hunt, I’m on the Board. What does stakeholder input from before PCORI’s existence -- what does that mean?

DR. SELBY:  It means that there were other stakeholder-driven processes that identified high priority topics.

MS. HUNT:  Okay.

VICE CHAIRMAN LIPSTEIN:  I think that will become apparent, Gail, as we go through the process -- through the process steps.

DR. SELBY:  So, you’ve seen something like this before, and this is an adaptation of our plan
for the long-term prioritization process, but this
is now modified to reflect what we did this time.

So, on the left, we began with reports of
prioritized topics that had come from a variety of
stakeholder groups, and we looked specifically for
topics that had been identified by at least two of
these processes or sources. And so, we created a
list, it turned out to be a list of 40 -- 40 or 41,
Kara? -- topics, that had been identified by at
least two of the processes we looked at.

Staff. PCORI staff then, we really did
not feel that this prioritization process was ready
to invite patients and stakeholders, non-PCORI
patients and stakeholders into yet because it had
not been vetted at all and there are challenges
about gathering information and prioritizing. So,
we used software that we plan to use going forward,
but there were staff who actually did the review of
these topics, and they reviewed them on two sets of
criteria.

The first, and we’re in the middle now,
the middle blue chevron, beneath that, the first
was PCORI’s review criteria, which you’re familiar
with, not all eight, but five of them -- patient
centeredness, the impact of the condition, that is
the burden, the innovation and potential for
improvement, that is potential for practice change,
the impact on healthcare, on healthcare
performance, quality, safety, efficiency, and
lastly, inclusiveness, that it either considers
multiple populations or goes after a particular
population that’s a vulnerable population.

So, those are traditional criteria
reviewed by that, and actually, slightly before we
reviewed by those, we reviewed by four criteria
that I’ll talk a little bit more about in a minute,
that were specifically developed for this high
priority, fast tracked process, this targeted
funding.

The idea, again, is that the topics that
come out at the top of this list go to the Board.
That’s what we’re doing today. We hope that you
will approve some high priority topics so that we
can move on to the next step, which is to gather
additional expert and stakeholder input in a process that not only helps us make certain that we picked the right topics, but more importantly, helps us zero in on exactly the right questions within a topic.

So, the first filter was looking at the sources of a stakeholder-vetted list, and we started with the IOM 100. This had come out just about a year before PCORI came into existence and is widely recognized and accepted as a good list across the whole range of conditions and treatments and that patients face.

We looked at a range of other topic generation processes, those from AHRQ, those from NIH, and from other organizations. A total of over 300 topics were considered. We looked for overlapping topics and I said -- as I said, there were 40 identified.

So, we then applied this second filter, and these I showed you from the previous slide. So, the first one is salience, and this meant that to the staff person or to the prioritizer, this
topic has some obvious, recognizable importance, that is, the question being addressed is known to represent a fairly common problem. The question sounds like a legitimate question that you'd perhaps recognize that people have -- face. The second is short-term feasibility. We were interested in projects that would have a relatively short turn around, possibly within two to three years, at least for some of the outcomes. The third is that -- and this last one was -- this third one was assessed more in subsequent conversations with other funders, that it was unlikely to be funded without PCORI support. And the fourth was resource constraints, just that moderate investments could suffice or possibly that PCORI could leverage its resources by identifying opportunities to co-fund.

So, that was the second filter these targeted funding factors. And the third is, again, we’ve already gone through this, these are the familiar five.

And this was the process that six staff
reviewers -- four from the science team, two from
the non-science team -- used software to apply
scores on each of these criteria to each of 40
questions.

The rankings were independent, the
criteria were weighted, and we actually looked at
several weights and in the end settled on a
weighting scheme that emphasized, to some extent,
the targeted PFA specific filter.

As I said, 40 were ranked. We took the
top 25 of those 40, so we did not -- it wasn’t that
the filter said absolutely yes or no, it ranked
them, we looked at the distribution and took the
top 25 and discussed that -- those with the PDC.

These are the top 25, I apologize, it’s
going to be pretty tough to read -- yes, it is
going to be pretty tough to read. We will get to
the ten, I guaranty you, you can read the ten
better than these 25, and those of you on the Board
and the Methodology Committee and staff should have
slides that you can look at to see what they all
are.
So, this was discussed with the PDC. It was also discussed with experts in various fields, with funders, and it was also considered in terms of these criteria: we wanted a balance, and whatever we recommended to the Board, we wanted to achieve balance on -- again, this will be familiar to you from our last conversation -- on study population, on the conditions we addressed, and on the potential -- and in addition, we wanted it to have a high potential for impact after all was said and done and after continued consultation.

So, the balance drove us toward a smaller number and these are the ten. So, starting with -- and these are in rank order, I believe, ranked by the scores of the staff.

VICE CHAIRMAN LIPSTEIN: Joe, can you take a pause for one second, because we’re about to go into the recommended topics. I wanted to see if anybody on the Board had any questions or comments about the process, the process that we followed, because it’s a good time to separate the actual output of the process from the process to make sure
you had any questions or concerns. Dr. Zwolak?

DR. ZWOLAK: Zwolak, Board. Just a quick
question, the top 25 were ranked in order? That’s
not a random list that was a scored list from
number 1 to number 25?

DR. SELBY: That’s right.

DR. ZWOLAK: Thank you.

VICE CHAIRMAN LIPSTEIN: Any other
questions or comments about process? Dr. Douma?

DR. DOUMA: Thank you. This is Allen
Douma on the Board. The concern I have about the
process is not the process itself, but it’s that I
can’t understand it because there’s not enough
transparency. It would be really helpful if we had
at each step a list of which diseases or conditions
were in and which came out and the reasons they
came out, and I think that’s important for a number
of reasons, one is that we are a transparent
organization. The second reason I think it’s
important, because 95 percent, at least, 99 percent
of the people who would like us to fund them,
weren’t, and they’d like to understand why not.
But it’s also important that we want to be able to have a dialogue with people in the future who we want them to come forward and we want them to come forward because they understand our process and they have a significant possibility of being funded. So, I would request that we have a greater amount of information, and I’m not saying that we have to have it today, but I would certainly like to see a lot more transparency than we have in our deck.

DR. SELBY: Thanks, Allen. And actually, we do have the individual scores on each criterion and, you know, combined using various weighting approaches that we could prepare into something that was more presentable than it is right now.

DR. DOUMA: And just something as simple as what were the 400 that were in the original list.

VICE CHAIRMAN LIPSTEIN: Any other questions on process or comments on process?

Okay, Joe.

DR. SELBY: Okay. We looked at these 11
and discussed them with the PDC again, and out of this list, we ultimately, taking into account more intensively this notion of balance, we wanted to be balanced across populations and conditions, and the notion of not likely to be funded by others without our participation, and we have come to three that we’re recommending to you and I will move on to those at this point.

The first one is the treatment of uterine fibroids. The second is safety and benefits of treatment options for severe asthma and African-Americans. And the third is the prevention of falls in the elderly. And I’m just going to say a few words about each one.

Uterine fibroids occur appear in at least 70 percent of women by the age of 50. The prevalence is even higher in African-American women. Many have no symptoms, but those who do can suffer months, years of pain and bleeding, interfering with an ability to work, to function in the family, or in other social situations.

Hysterectomy has been the traditional
treatment when symptoms get to a certain point, but there are now both a number of less invasive surgical procedures, including arterial embolization, myomectomy, and high-frequency ultrasound, and there are also a number of pharmacologic treatments that may be suitable for particular women who, on the one hand, may be approaching menopause relatively quickly so that the duration of time they’d need to take the therapy may be short and people who can understand the adverse effects sometimes of these pharmacologic approaches in the name of avoiding hysterectomy.

Avoiding hysterectomy is obviously critical if one still hopes to conceive, but even if a woman is past child bearing age or not interested in conception any longer, still avoiding hysterectomy avoids certain amount of morbidity and risk.

So, this is a topic that in our judgment and in our investigations was unlikely to be funded elsewhere and it’s a topic that has the interesting
aspects of comparing a number of new and more time
honored conditions -- treatments. It’s really
highly relevant to all women of this age range, so
that was why it is among the top three.

Moving on to the second one. Asthma is
one of the most common chronic diseases in the U.S.
It’s increasing in prevalence. It’s much higher in
prevalence in African-Americans. Mortality in
African-Americans given that they have asthma is
much higher.

There’s some evidence that particular,
even guideline recommended therapies, may have more
adverse events including mortality in African-
Americans. There’s some evidence also that genetic
factors may help to identify those who are
susceptible to adverse effects of treatments.

And lastly, there’s a strong sense that
system level interventions to improve the quality
and consistency of care and of support for self-
management may be an important factor.

So, for those reasons, this second topic
is among the top three.
Fall prevention in the elderly. Falls occur in about 30 to 40 percent of people 65 and above per year, obviously not the same rate in a healthy 65 year old as in a frail older person -- frail or older person. Falls are the leading cause of hospitalization and mortality among trauma in the elderly -- among types of trauma. And they often signal an end to the independence -- the ability to live independently among the elderly.

There are a lot of questions these days about the -- and it’s been a recent systematic review which points to the need for more evidence on the effectiveness of particularly multi-factorial screening programs -- screening and intervention programs in the elderly. And the big question is, who among the elderly would this be beneficial for? Obviously, not everybody needs it.

In whom is it beneficial?

DR. WEISMAN: Joe, can we pause there for a second? Harlan. Clarification.

VICE CHAIRMAN LIPSTEIN: Clarification, go.
DR. WEISMAN: On the final point, fall prevention in the elderly, is that including or excluding patients with known high risk factors such as orthostatic hypotension from dysautonomia, you know, from things like Parkinson’s disease and so forth.

DR. SELBY: I think that would likely be a part of the research in those groups -- does screening -- there may be a group that’s so high risk that it’s not even a question, but there are certainly a large number of patients in whom it’s not certain yet whether this would be a reasonable approach.

VICE CHAIRMAN LIPSTEIN: Joe, could we pause for a second? What I’d like to do, since the recommended topics are on the table, is just kind of take them one at a time and ask Board members if they -- as Harlan suggested, if they need any more clarification or comment, I would just highlight that staff did provide for us a reference manual on these targeted funding announcements and Leah and I were commenting that we had a chance to read more
about uterine fibroids than either of us had read before.

And so you do have that as background information at your places, but Ellen, you had a comment? We’re on uterine fibroids right now, is that okay?

MS. SIGAL: Well, it’s just a little bit of a process problem. So, uterine fibroids are good, okay, you should deal with them. Okay, so the issue is, we had talked about the possibility of maybe having five topics that we were going to look at and then honing down to three just in case, for whatever reason this -- you know, there was not consensus on all these three, and I thought we were going to look at five, although the preference was going to be three.

So, are we going to only talk about these three or are we going to go back to the other two? It’s just, again, just a process issue.

VICE CHAIRMAN LIPSTEIN: So, we will come back to that. So, let me just put that question on the parking lot for a second because I think after
we get through with the three we can come back to
the five, but I want to see if there are any
questions about any of the three topics or any
concerns that anybody has about these being areas
of priority emphasis and targeted funding for
PCORI.

Sharon, you gave me my tutorial on uterine
fibroids, so any comments? Good. And Ellen said
good. Any other concerns about the one on uterine
fibroids? Arnie? You’re good. How about on the
second one, on asthma in the African-American
population? Leah.

MS. HOLE-CURRY: So, I have just a slight
process question as well. I think it’s a
clarification question for you, Joe, and that is,
if you were to move forward with these topics, then
you would work with a team, and I’m not trying to
get into all the details of the next step, it’s
just important for me to understand so I know what
we’re voting on, and they would help to refine
questions such as the one that Harlan brought up
about where would you exclude certain high-risk
population groups? That would be their role in general, so we’re really trying to decide on this very high level approach. Is that -- I just want to be --

DR. SELBY: That’s absolutely right. The next step -- for those that you approve, and I will go on record as saying I think we could handle five if the Board wants to expand it to five.

I’ll be interested to see your process for mainly the other two, but we’ll take five -- is to in fact convene an expert-stakeholder panel and in the Methodology Committee meeting yesterday we talked about this some as well, and I think that there is interest in the Methodology Committee in working with us, crafting that meeting, structuring that meeting, asking the questions in the right way is going to be crucial, but it would be great to have the Methodology Committee’s participation in helping us get to the right study and possibly even to the right study design.

I’ll stop there for now.

MS. HOLE-CURRY: So, on the topic of
briefs -- are the topic briefs what you would start
with? Can we separately provide a few comments on
those apart from just the overall general topic
here?

DR. SELBY: Sure.

MS. HOLE-CURRY: Okay.

DR. SELBY: Got it?

MS. HOLE-CURRY: So, now I have a question
on asthma.

VICE CHAIRMAN LIPSTEIN: Okay, we have a
question on asthma, so we’ll still on asthma.

MS. HOLE-CURRY: So, when I was reading
through the background materials related to this,
the systematic review that was conducted also noted
that there was higher prevalence in Puerto Rican
populations, so other ethnic groups, and this topic
says specific to African-Americans. So, I’m
wondering if it would be appropriate to broaden the
topic and then have the sub group -- or the subject
matter expert group go forward in terms of just
African-Americans, or in looking at the systematic
review material, was there a decision already made
that this is the place we should focus?

DR. SELBY: Kara?

MS. ODOM-WALKER: So, to clarify, thank you so much for that question. The initial question that came to us was specific to the African-American population. What we did to work up the topic was to look at the greater body of literature that’s out there, and so you’ll see that other subpopulations have been identified as also high-risk groups.

What we expect in the next steps, and maybe, Joe, you could even advance to our slide on the stakeholder and expert panel process is we would ask those experts with content knowledge and talk about study design and what other subpopulations should be included in a full proposal for funding.

MS. HOLE-CURRY: That would be great. So, then my only other comment at the topic level is I think that when you went back to that safety and benefits of alternatives, I would recommend that all topics where that’s appropriate include safety
and benefit, not just option.

VICE CHAIRMAN LIPSTEIN: Okay. Other comments on asthma? Okay, Joe, can you go to the -

DR. SELBY: Wait, Freda has a comment.

DR. LEWIS-HALL: Mine is also a process clarification and that is, we’re talking about this as a study. Is it possible that at the end of the day it is not one study, but a suite of studies, if you would, that would answer one or two critical questions?

DR. SELBY: That’s what this slide here is meant to portray, Freda, that we convened the stakeholder expert panel and we could come out of that with a recommendation that what you really need is to synthesize the evidence that’s already there. We can’t move forward until you do an evidence synthesis, in which case we’d come to the Board with the proposal that we issue a funding announcement for an evidence synthesis.

They could identify the single study that is needed. You know, maybe it’s a randomized
trial, maybe it’s a huge cohort study. Or they
could, in fact, suggest just what you said, that
you really need a suite of studies, a portfolio of
study, as we called it, perhaps a randomized trial
and a large database study.

DR. FREDA-LEWIS: And just follow up, and
we’re prepared to do any of those, none of those
are stops.

DR. SELBY: That’s right.

VICE CHAIRMAN LIPSTEIN: And the third
topic was preventing falls in the elderly. Any
questions or comments about falls in the elderly?
Yes, Dr. Zwolak?

DR. ZWOLAK: Bob Zwolak, Board. Sorry
about my voice. I think in this one in particular
if the top 25 were ranked in terms of priority,
somehow number 22 hopscotched all the way up to
number 3. So, I think it would be crucially
important for us maybe to hear what it is about
falls in the elderly that made it bypass 18 or 19
other high-priority conditions.

DR. SELBY: We’ll have to get the scores
out to see how much of a hopscotch that was, but you are right, and I think the considerations that got this moved up were, number one, balance, I mean, it was among those that was particularly aimed at the elderly and the other two are not. So, we thought that it was a good idea to have at least one that was aimed at -- that was conducted in that population and addressed a question in that population.

And the other, I think, was the enthusiasm that we ran into in many quarters for that topic. It just seemed like there was an awful lot of enthusiasm for the topic.

VICE CHAIRMAN LIPSTEIN: Harlan?

DR. WEISMAN: In terms --

VICE CHAIRMAN LIPSTEIN: That’s Dr. Harlan Weisman for everybody.

DR. WEISMAN: Harlan Weisman, Board member. I have a question about what this is or what the PFA is -- RFP. This is actually going to be where we specify, after the advisory input, in great detail not only the condition and population,
but also at least the broad strokes of design and that we’re asking people not to offer us ideas of how to approach it as we’ve done before, but in a more specific way.

We’re actually asking for a contract. We are being very detailed on what we’re looking for. Is that the idea?

DR. SELBY: That’s the idea of putting RFP under that single study, yes.

DR. WEISMAN: But not under the other one?

DR. SELBY: But if it were portfolio studies, it would -- you know, I guess it could be a portfolio of two or three very specific studies or it could be within this narrow area, a call for best ideas. So, I think, the portfolio, it’s a little unclear whether it would be an RFP or a PFA type of mechanism.

MR. BECKER: Larry Becker. So, I’m not quite sure if this is an appropriate question or not, so somebody help me. But you’re planning to do some targeted funding of targeted kinds of things as opposed to the more general funding that
we did.

Is someone going to compare these two approaches and at the end determine which ways were more effective and in which ways they weren’t, so, that as we go forward, if we go with this kind of a process, that we sort of have a better idea of how to proceed next time?

DR. SELBY: Well, first of all, I think that we envision probably doing both processes for the duration, so I think we always see some value in having these broad announcements open and an opportunity for people with good ideas to submit even outside of those topics that we’ve labeled as high priority.

But I think the answer is a resounding yes that we, the staff and I, I predict, you, the Board, even more than we, the staff, are going to be watching this process very carefully. I’m sure or I expect that you, like me, are a bit on the edge of your seat right now waiting to see what we in fact do wind up funding through the broad announcement. What does that look like? And that
will be our first glimpse of what a broad solicitation yields. And over time we’ll have a better and better idea of the kind of portfolio we get there.

The idea with this is that it enables you to hone in on a smaller, more focused area, you know, fund one or more studies at the beginning, keep a close eye on them, because you’ve named it a high priority area, consider whether that study answered it, whether there’s a follow on study, that kind of --

VICE CHAIRMAN LIPSTEIN: Dr. Zwolak, are you still asking to speak?

DR. ZWOLAK: Yes, thank you. Bob Zwolak. I don’t mean to push you, but -- so, in response to my question of how number 22 got up to number 3, you said, balance, which is great, and enthusiasm. And so the enthusiasm, that must be internal enthusiasm, right, because we haven’t set this out for public comment or anything?

DR. SELBY: No, it was external because we did tap the expertise of people in other funding
agencies and other experts about this, so we were persuaded that this was an area of great importance.

VICE CHAIRMAN LIPSTEIN: Dr. Kuntz, are you over there?

DR. KUNTZ: Yeah, just a comment on the overall process. I like this process a lot. I think it’s really rigorous and it’s agnostic, and it’s interesting because I would never guess that these are the topics that came through and I think maybe many people around here do.

DR. SELBY: I wouldn’t either.

DR. KUNTZ: One question is, there’s an element there about valuing projects that aren’t being funded and won’t be funded, which is a two-edged sword. I mean, one reason they’re not funded is because they’re really not interesting.

Did we put a lot of emphasis on that or is a moderate amount of emphasis? I mean, how much emphasis did we put on the factor that these are projects that aren’t being funded?

DR. SELBY: I think that helped us in the
end. You know, that wasn’t one of the criteria we scored on, but afterwards -- and this, Bob, might be another partial answer to yours, you know, if we found that something was already substantially funded, that was different than if we found something that had no funding or in one case, I think it was uterine fibroids, I said, this is unlikely to be funded by others.

DR. KUNTZ: Understanding there were two reasons why that wouldn’t be fun -- funded.

DR. SELBY: No, no, no. This is a great idea and it’s unlikely that it would be funded by others.

VICE CHAIRMAN LIPSTEIN: So, I’d like to ask a process question since we have 20 minutes left in this segment of the agenda. Ellen, help me out here a little bit. If we were only going to approve three, would members of the Board, this is going back to what Allen said, would members of the Board want to debate these three more carefully than if they knew we were going to add an additional two and then they wouldn’t feel like we
were needing to substitute? Or would these three
emerge as a consensus group for us to begin with?
And so I’m looking around the room for some input
on the -- does everybody understand my question?

So, if we were only going to approve
three, would we have a lot more debate about these
three, or if you knew we were going to have two
more, would these three be kind of unanimously in
that group of five and you would want to proceed
with approval at this point?

Arnie?

DR. EPSTEIN: I guess my preference would
be to have more than three and as many as the
traffic could bear. I think the key issue is what
Joe can learn from an expert panel about the
likelihood that additional dollars will really pay
off with directive information. And I think that
would guide our discussions much more and any
further information about the potential for averted
morbidity or mortality or numbers. So, I go for
more.

VICE CHAIRMAN LIPSTEIN: So, let me --
Harlan, can you wait? Let me get Larry and then there’s somebody -- Ellen, over there, and then I’ll come back to you, Harlan. Larry?

MR. BECKER: And I said this to Joe when we talked about it, and I support more than three. At the same time, there’s also what I would call the cost of lost opportunity. So, if we do five, there’s something else that we can’t do because we don’t have unlimited resources, unlimited people, money, et cetera. So, what’s the tradeoff that we’re going to make if we decide to go to five versus three?

VICE CHAIRMAN LIPSTEIN: Joe, what’s the tradeoff?

DR. SELBY: You don’t have to fund five because --

DR. EPSTEIN: Five is a way point to get back to three.

DR. SELBY: Yes.

DR. EPSTEIN: Five is, let’s get information from a group of experts and then --

DR. SELBY: Arnie, your microphone.
VICE CHAIRMAN LIPSTEIN: What he’s saying is we’ll pursue five, but then when we get more input and more expert guidance and we put this out for public input, we’ll find our way back to three of the five? Is that what you said Arnie?

DR. EPSTEIN: [Off microphone.]

MR. BECKER: But I thought your question was, do we want to do more than three --

VICE CHAIRMAN LIPSTEIN: Well, but he just clarified my question.

DR. SELBY: We want to process more than three to get to the best three. So, we take the best three out of five.

VICE CHAIRMAN LIPSTEIN: Ellen, it was Ellen and then I had Harlan and then Francis. Are you yielding to Francis?

MS. SIGAL: Yes, I’m yielding, but then I want to go after.

DR. COLLINS: It was relevant to this point. I think the other friendly amendment here is suppose you look at five and you really love all five. Remember, there is a decision we haven’t
talked about, about how much money do you put into each one? So, maybe you do all five, but you don’t fund them quite as liberally as if you were just doing three. That’s the other variable we haven’t talked about.

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

VICE CHAIRMAN LIPSTEIN: Hold on, I’m losing control. Joe, can you sit back? Thank you. Harlan Weisman, Bob -- oh, Ellen. See you made me -- Gene, can you come back please?

MS. SIGAL: I should never have ceded my voice, but it’s okay to do that to Francis, he actually knows more than I do.

So, I think it would be best if we can look at five, if we have the resources, even if we choose three. There may be a few in the top three that are not feasible or we’re having problems with and there may be others that if we do five, may turn out to be more relevant to what we’re trying to do.

So, if we can, even though we may only
fund three, I think it would be best if we can look at five.

VICE CHAIRMAN LIPSTEIN: Can I ask for -- is there a general sense that that’s okay, just looking around the room that what we will do is today we will approve five, realizing that we may end up wanting to fund five at lower levels or we may, through the process, find out that we can’t pursue all five and we would come back to three? Is there anybody that thinks that’s a lousy idea? Harlan, you think that’s a lousy idea?

DR. WEISMAN: The comment I was going to make is I don’t think it’s a lousy idea, but I also -- and I have no idea whether I would have come up with the same three as they did, but when I look at them, they seem like a reasonable three things to do and could there be better ones or could we spend a long time discussing, debating, and coming up with another list of three? Yes. But to me a better question is, is this an okay list? Are these okay? Are these important questions? And should we get on with it? And my vote is, this is
as reasonable three conditions as any and I don’t see a reason not to do them.

And this is a first attempt to get into specificity. We have a whole process designed around getting to specificity over the long-term. So, why should we draw this out? But maybe I’m -- I could go with five if that’s what everybody else wants.

VICE CHAIRMAN LIPSTEIN: I’ve got a lot of people -- Bob Jesse.

DR. JESSE: So, we’ve had a lot of discussion over, I guess, a couple of Board meetings as we moved into this about whether we’re going to fund specific disease-related topics, specific condition-related topics versus on and on and on, and this is kind of our first foray into that very kind of condition-specific issue.

I think that the one comment I would make is that as we do this, they ought to be conditions for which the endpoints are driven by relatively short-term patient-based outcomes, whether it’s pain -- I guess the symptoms of uterine fibroids,
the presence and severity of asthma attacks,
however you do that, but, you know, fundamentally
what we want to do as we move into this is to make
sure that we keep it about very specific about the
patient perceived symptoms or outcomes around these
conditions.

So, you know, falls in the elderly is
actually a really interesting one and probably out
to have very rapid short-term results, likewise
asthma and the others, but just keeping that in
mind because if we can do these in a relatively
short -- quick fashion, with a lot of specificity,
but poignant outcomes, we can actually do a lot
more than dragging things out into long-term
outcomes that are more -- that are less patient-
specific and more actuarial, I guess is the way to
put it.

VICE CHAIRMAN LIPSTEIN: Dr. Selby wants
to respond.

DR. SELBY: Well, first of all, I want to
agree with the second part of what you said
completely that -- and, in fact, part of this
expert stakeholder advisory panel can be to help us explore the -- how attractive it is to focus and how feasible it is to focus on short-term outcomes, and that should be one of the criteria that help us decide which directions to go.

But I want to make a distinction that you blurred a little bit, in my mind, and I think it’s a critical decision. To my mind, no one ever said we were not going to study high-priority, disease-specific questions. People said we were not going to name some diseases as high-priority, that is, we were not going to say that asthma is one of the five diseases we will study.

But to tie our hands and say we’re not going to ask a question in a specific disease cuts out about, you know, 60 to 70 percent of the things we can study and about 90 percent of probably what was intended in the legislation. So, I think the secret is to get to high-priority questions, not high-priority conditions.

DR. JESSE: No, I agree, and I didn’t mean to infer that.
VICE CHAIRMAN LIPSTEIN: Okay, Dr. Goertz.

I’m just going to go around the room one more time and if you’ve already spoken, I’m hoping you’ll let the people who haven’t spoken yet go ahead of you. So, Dr. Goertz.

MS. GOERTZ: Thank you. Christine Goertz. I think it would be helpful to put this in a little bit of a context. I mean, I’m assuming that these are not the only five specific PFAs that we’re going to be issuing. I’m just wondering, what is the timeline and the process? I know that we have a lot of efforts on going to try to figure out how to better prioritize topics, and Joe, what’s the timeline that you see for -- I mean, are we going to do this again as a Board or are we going to wait then after this until we have more information? How does this all fit together?

DR. SELBY: Our thinking is that this is the one and only time that we would use this particular process, that we are working on and testing and refining our long-term -- longer-term prioritization process and the next time we
consider high-priority topics should be after that process is in place. And as I intended to say at the beginning of this, if I didn’t, we think that we could anticipate questions beginning to come to us somewhat after mid-year, 2013.

VICE CHAIRMAN LIPSTEIN: Dr. Levine.

DR. LEVINE: Yeah, and my question was, I mean, I think I agree with Harlan. I worry about this pushing the decision to add to then go back and reprioritize three versus four versus five is going to push out the timeframe and prolong the process, and I think one of the things that drove this was an effort to demonstrate some impact that was valuable and had results that were valuable to patients. So, I worry about the extension of the time before we can actually start and wondered, Joe, what your assessment -- I mean, presumably we would have to do this again in January at our next Board meeting. Is that right?

DR. SELBY: Well, I don’t think we should discard the three that came up in this process lightly, so I don’t think we should sort of throw
it back to 11 or 25. I think we should -- I think these three have sort of made it to the top and we’ve made a good case for each.

If there was a process to add one or two more, that would guard against the possibility that when we really dig down deep with that expert stakeholder advisory panel, we don’t come up with a key question. And so, I don’t think we’re at all adverse to having four to five total, including these three.

DR. LEVINE: That wasn’t the question I heard. I heard --

VICE CHAIRMAN LIPSTEIN: I’m going to try to get us to a summary point in just a minute because as Dr. Washington reminded me, we have public comment in 10 minutes. But let me ask, Debra and then Carolyn and then I’m going to make a suggestion.

MS. BARKSDALE: Debra Barksdale, Board. I actually wanted to support Harlan. I think these three are perfectly fine and that, sure, we could probably come up with some more. I came up with
three more that are my favorites, and if we prolong this too much, because we all have favorites, so I just want to stand in agreement with Harlan.

VICE CHAIRMAN LIPSTEIN: Carolyn.

DR. CLANCY: I, too, want to support Harlan and now Dr. Barksdale. Carolyn Clancy, Board member. We’ve been talking about this and massaging it and debating it for quite some time. I am totally confident that we could perfect anything, but I actually think we need to get moving, so I actually support the staff recommendation.

VICE CHAIRMAN LIPSTEIN: So, I’m going to ask for this motion, and see if we can all support it. The motion would be that we fund up to five targeted areas, that these be three of the five, and that we ask staff to return to us in January with recommendations on the other two. And in the intervening month and a half or two months, that would give them an opportunity to either query individual members of the Board, other stakeholder groups, in order to identify those two. Because I
have a feeling if we were to embark on a discussion now of what those other two should be, it might be a pretty prolonged conversation.

So, the motion I am asking for somebody to make is that we approve up to five of these targeted PFAs, that three of the five will be the conditions that Dr. Selby identified on the slide earlier, and that he and staff will return to us in January to identify the other two targeted conditions. Dr. Weisman.

DR. WEISMAN: So, just for clarity, and I almost would suggest we do it as two separate motions, are we voting in -- what you’re suggesting, we’re voting to give the go ahead to proceed on the three --

VICE CHAIRMAN LIPSTEIN: Yes.

DR. WEISMAN: And in addition, we’re asking them to come back with another two?

VICE CHAIRMAN LIPSTEIN: Correct.

DR. WEISMAN: Okay. That requires -- you could support one part of that and not the other and that’s why I’m suggesting maybe we should
separate them, but it’s up to the group.

VICE CHAIRMAN LIPSTEIN: Dr. Sigal.

MS. SIGAL: So, just a clarification. If we were to decide on five rather than three, wouldn’t it be the other two in the top five? How would we -- or would it just be any other two? How would that work?

VICE CHAIRMAN LIPSTEIN: Well, I think that since I don’t know the answer to that question and it might take us a while to arrive at that process, what I think would be better to do would be to allow staff some time to develop a good process for identifying those two and to come back to us in January.

Can I have a motion to that effect?

MR. BECKER: [Off microphone.]

DR. ZWOLAK: [Off microphone.]

VICE CHAIRMAN LIPSTEIN: So moved by Mr. Becker, second by Dr. Zwolak.

Okay. Any discussion? All those in favor?

[Hands raised.]
VICE CHAIRMAN LIPSTEIN: Any opposed?

[Hands raised.]

VICE CHAIRMAN LIPSTEIN: Dr. Krumholz is opposed. Oh, Dr. Douma’s opposed two. So, we have two opposed, all others were in favor.

Harlan, do you want to speak in terms of your reason for voicing opposition?

DR. KRUMHOLZ: Well, I think there’s room for dissent on a Board. I didn’t do it just for that reason.

Look, this is going to move ahead. I want to just express a minority opinion, that I don’t feel we’re fully leveraging about our vision about where these PFAs should do it and particularly where they fit in the overall strategy and how our approach is going to be to whether we’re focusing on event-driven studies or patient-reported outcome studies, and how the lessons from these are going to then leverage into the next ones, and I just feel that there’s an attempt to say, do something, and so these have come down and I think if you did it again you’d come up with a different list,
probably an equally good list, but I just don’t have a comfort level that this is fully aligned with what we’re trying to accomplish in the bigger picture, with all due respect to the great work that’s been done by staff.

So, I’m just -- I’ve been silent because I just have deep respect for the staff work on this, but it’s just -- I can’t -- I just don’t see it.

VICE CHAIRMAN LIPSTEIN: Dr. Krumholz, thank you for your dissenting view. Dr. Douma?

DR. DOUMA: I sort of presaged this earlier. I don’t think there’s enough -- I don’t have enough understanding of actually what we did, the transparency issue, there’s a lot of stuff that went on that’s unexplained. I’m not saying it’s not right, but another example of that is -- and just looking at the Institute of Medicine’s list, on asthma it says, “Compare the effectiveness of an integrated approach with a non-integrated episodic care model and managing asthma in children.” That’s what they put. Now ours is significantly different than that and I don’t know the process
that we used to get from one to the other.

So, it’s my ignorance that gets in the way of me being able to vote for it.

VICE CHAIRMAN LIPSTEIN: I think those perspectives are useful and we learn from them as we go forward.

Kara, thank you very, very much. I did want to say that in counting the votes I forgot to mention, for the people who are recording the minutes, that Dr. Washington did recuse himself. As an obstetrician/gynecologist he didn’t feel that -- since one of the topic areas had to do with his discipline, that he should participate.

CHAIRMAN WASHINGTON: No.

VICE CHAIRMAN LIPSTEIN: Is that not correct.

CHAIRMAN WASHINGTON: That’s part of my equation. There are other reasons.

VICE CHAIRMAN LIPSTEIN: Okay.

DR. COLLINS: Collins, Board. Point of information. You said that if Board members want to have some input into the consideration of two
more possible projects we should be doing so? By
what path should that information travel?

VICE CHAIRMAN LIPSTEIN: I would think Dr.
Selby has the answer to that question.

DR. SELBY: As Debra said, we all have our
favorites and so as not to be persuaded by the
first or the last person -- differentially by the
first or the last person that calls with their
favorites, it crossed my mind that we actually
ought to poll the Board and I think people could
refrain if they wanted to just stick with the three
or it might be wiser to choose one or two
additional ones.

DR. COLLINS: Great, so that will happen?

DR. SELBY: If it suits the Board, we
could certainly make that happen.

DR. COLLINS: Thank you.

VICE CHAIRMAN LIPSTEIN: Okay, Dr.
Washington, you’re back in charge.

CHAIRMAN WASHINGTON: Okay. Thank you
Vice Chair Lipstein and thanks also, Kara and Joe
and the other staff for superb work.
And we are three minutes away from the public comment period, so I’m going to ask that we all stand and sort of walk and wiggle or stretch your arms in place.

[Pause.]

CHAIRMAN WASHINGTON: Now we’re going to ask our colleague, Ms. Sue Sheridan, to introduce this public comment period.

MS. SHERIDAN: Good afternoon. I’d like to welcome those of you who registered to provide public comment. I am going to just share the process that we’re going to do this afternoon. We’ll take those comments from you, those of you who registered. After everybody has spoken, we’re going to take comments by phone if there are any.

Individuals offering public comment must limit their remarks to no more than three minutes, please. We have several of you, so we want to make sure that everybody has adequate time, and if you have written testimony, we invite you to submit it to PCORI via email to info@pcori.org.

So, I am going to call your name and if
you could just come up to this mic behind me and
share your comments. We’re going to begin with
Aaron Abend [phonetic]? Okay, Aaron, if Aaron
walks in in a little bit we will invite him back.
Next patient or public commenter is Dave
DeBronkhart, who many of us know is e-Patient Dave
on the Internet.

MR. deBRONKHART: I’m going to do the
FedEx commercial. Anybody remember the FedEx
 commercials version of --

MS. SHERIDAN: Mic.

MR. deBRONKHART: Ah. Push the mic
button, folks. All right, the FedEx commercial
version. Thank you for this opportunity. The
Institute of Medicine’s new report, “Best Carrot:
Lower Cost” says that of the four pillars of a
learning healthcare system that we need, one is
engaged, empowered patients. It says, “A learning
healthcare system is anchored on” -- anchored on,
not reflects on -- “patient needs and
perspectives.” I could go on at more length, but I
want to point out -- so, I ask, are we anchoring
our thinking on patient needs and perspectives?

And I say this with the greatest respect and admiration for what this group is doing, but I want to challenge.

This summer at my college reunion I bumped into a classmate who said, oh, what you’re doing in life, you should meet this guy I used to work with, Perry Cohen, who has addressed this group before.

Perry and I have met and we have become instant best friends. Much to our mutual amazement, we were teaching assistants for the same course in managerial psychology at the Sloan School many years ago. We never knew each other. But, you know, our paths diverged. He went on to get a doctorate and to be smart, I went into marketing.

I learned to understand change and give speeches about it, Perry says, let’s collaborate because I’m losing my voice. And he and I would love to engage together in any way we could on this.

Quick examples. Of the three proposed conditions to study, fibroids, I have two relatives
who are significantly affected by fibroids. Do we know if the endpoints researchers are proposing studies on match the endpoints that would be important to those women? We can’t do it by asking surrogates or proxies.

Jack Wennberg’s research in shared decision-making has said for decades that the doctors with the best of intentions are bad at predicting what their own patients would prefer, much less people looking at a patient population in the aggregate.

Asthma, do we know if patients want something different? I understand we’re going to take proposals that researchers have generated and select from them. Do we know if what patients would really like is different from what the researchers have proposed? You’re going to have to interrupt me or knock when my time is almost up.

And on falls, are we considering non-biological interventions like Intel’s smart carpets, things that perhaps would be minimally just minimalist intervention but might cause the
problem to disappear.

In the merit review phase I, phase I as proposed determines the scientific soundness and impact, but to make a long story short, my conversations with Perry make very clear to me that what research savvy patients think is an important impact may be substantially different from what the researchers are thinking, and what I’ve come to see -- and then I’ll wrap up -- from our background at MIT, we taught both engineering and science there. Science is concerned with absolute truth, proposing a hypothesis and testing it. One of the guys I knew in college, a guy named Mike Solomon, is the guy who eventually busted cold fusion. He was such a pure scientist he just -- he dropped a physics lab because he didn’t understand the electronics in the instrument that was measuring the stuff.

Engineering, on the other hand, is concerned with developing something that works in a useful period of time. And in a sense, in addition to all the good things that scientists do to develop and test hypotheses, I urge that we also
think in terms of engineering relief for people for whom time is everything.

Thanks.

MS. SHERIDAN: Thank you, Dave. Our next is Lewis Kazis. No comment. Thank you, Louis.

Our next is Danny Van Leeuwen.

MR. VAN LEEUWEN: Hello. Thank you. I represent a group of e-Patients here in Boston who have collaborated to make three recommendations to this group, and we submitted our recommendations in writing, so they’re either in your packets or they’re available somewhere.

So, three minutes. The first one is to route funding through consumer organizations. The situations that researchers typically struggle to include patients and consumers in their research design, implementation, and dissemination, and the power dynamic favors the researcher, not the patient.

Our recommendation is to route a defined proportion of funding through consumer community organizations with experience recruiting patients
for proposal review and other research tasks, and then allocates that money to researchers and disseminators.

The consumer community organization enlists the researchers to conduct the patient-centered outcomes research and publish in academic journals and allocates a proportion of the funds to dissemination to the relevant community, so a different way of doing it.

The second thing we recommend -- or we’d like to suggest has to do with micro grants. The situation is that patient-driven, patient-centric research opportunities are less likely to be prepared to submit high scoring proposals than traditional research teams. So, our recommendation is to allocate a defined proportion of funding for a larger number of smaller projects in the form of micro grants that either prepare a submitting team for a high scoring, larger grant, or addresses research into partnership innovation, cultural change, social and behavioral determinants, or dissemination.
And the third recommendation that we have has to do with the scope of research questions. The medical model paradigm favored by medical research with its focus on body parts, diagnoses, and disease labels, is insufficient to meet the needs of patients.

So, our recommendation is to expand the scope of fundable research questions to include non-diagnosis related questions, identifying mechanisms and key success factors of patient-professional partnership, patient activation, care coordination and shared decision making, the impact of peer-to-peer, patient-to-patient, and family-to-family relationships, and finally, the impact of social determinants on health.

Thank you.

MS. SHERIDAN: Thank you, Danny. We’d like to invite James Rosensweig [phonetic]. Okay. We’d like to invite Amy Whitcomb-Slemmer.

MS. WHITCOMB-SLEMMER: Good afternoon.

I’m Amy Whitcomb-Slemmer, I’m the Executive Director of Healthcare for All, which is a
nonprofit based here in Massachusetts. We’re 27 years old and our mission is to create a consumer-centered healthcare system that provides culturally competent, high quality, affordable, comprehensive, high quality care for everybody in Massachusetts, and our lens is to look for the needs of the most vulnerable among us.

I’m here with Deb Walkenheim who is one of our policy managers at Healthcare for All, and I know many of you are familiar with the environment you find yourselves in here in Massachusetts, but we take some pride in helping people to understand what is possible with the Affordable Care Act, and I wanted this body to understand and know that we’re in the next phase of health reform in Massachusetts. As we’ve figured out -- were almost ready to declare victory on the coverage issue, we’re now really grappling with cost and quality, and it seems like PCORI has an opportunity to help be a catalyst for the cost issue from a consumer’s perspective.

The foundation that we’ve laid is we’ve
passed something called Chapter 224, which is our
cost savings and quality care bill, that will help
transform our healthcare delivery system, and I’ve
heard some conversations today about the
expectation that we want to really change the
delivery system, but I think it would be incredibly
helpful if, as you look at the funding priority
areas that you’ve laid out, you consider the
opportunities that will come from driving research
from a patient’s perspective.

And you’ve heard the Massachusetts, we are
patient advocates and so we’re excited to be
organized here in Massachusetts, we will push you
all to consider what truly is patient and consumer
representation on some of the research protocols
that you’re supporting.

We think, here in this state, we have set
an expectation for what patient-centeredness means,
for changing the dynamic between patients and
providers. We know there’s shared responsibility
to go around for all areas of the healthcare
community to work on this change, but again, it
feels as though PCORI truly has an opportunity to push us along, and as we are proud of ourselves for having shown how you can cover almost all residents in a state, we’ll be very excited to be able to share the lessons learned that we will figure out about how to address cost and quality simultaneously. Thank you.

MS. SHERIDAN: Thanks, Amy.
CHAIRMAN WASHINGTON: Thank you, Ms. Whitcomb-Slemmer.

MS. SHERIDAN: Okay, we’d like to invite Cristin Lind, please.

MS. LIND: Hi, everybody. Hi, my name is Cristin Lind, and I am a mom, and I am a caregiver, and I am here to just share briefly that -- so, in the course of my son’s care I developed a tool to help to coordinate his care, but I’m not here to talk about care coordination, although I think that’s important.

VICE CHAIRMAN LIPSTEIN: Cristin was one of our guests at the patient-engagement workshop and it was wonderful to meet her and she’s
terrific, so everybody pay really good attention.

    MS. LIND: Uh-oh. Well, I’m still
recovering from that weekend.

    So, the tool that I developed for my son
was identified by a pediatrician here in Boston
who’s working extensively on the work of care
coordination. He even went so far as to talk about
it as the penicillin of care coordination, which is
really exciting, because even I can understand how
significant that is.

    So, we’re collaborating together and I
really just want to share with you sort of tales
from the field of what it’s like to be a patient
doing research about something that we think is
important.

    So, last night he called me at 11:00
o’clock, we were reaching our deadline to submit an
abstract for the Pediatric Academic Society, and
because I was really busy running a Girl Scout
troop meeting yesterday, he offered to submit the
abstract for us.

    Because I’m not affiliated with an
academic institution, the system would not allow
the submission of our abstract to go through, so we
thought about lots of things and eventually I gave
the name of an organization that I’m affiliated
with to sort of get through that obstacle, and then
later that night I received confirmation from the
PAS, and it was addressed to Dr. Lind, which I
thought was a fantastic promotion that I had gotten
over the course of an evening.

So, really what I’m here to tell you -- is
not even to make a recommendation so much as to lay
bare the seismic change of what it is that we’re
talking about doing here, of patients identifying
tools that they think would be useful, of
collaborating together with pediatricians or with
providers who really understand that the tools
won’t only solve an individual problem, but that
could fill a significant need and gap, and that
this culture is so unused to the idea that patients
and providers could collaborate together that the
basic framework could not comprehend that a patient
or caregiver could have something to contribute,
the computer system is just simply not set up that way.

So, I just really -- I’m here to share that experience with you, to say, don’t underestimate how significant this is, don’t underestimate how much support is going to be needed to create this really deep and lasting culture change, to think about how you structure these projects so that what we’re looking for is not only the answer to what some of these research questions are, but how do you structure the work that you’re doing so that you can completely upend a system that doesn’t believe that a patient could have anything significant to say. Thank you.

CHAIRMAN WASHINGTON: Thank you.

MS. SHERIDAN: Thank you, Cristin. And I must add that many of our presenters were also at the workshop that we all got to know and appreciate the comments.

VICE CHAIRMAN LIPSTEIN: I didn’t mean to play favorites, but Cristin and I met at the cash bar, the cash bar, at the workshop and she’s a mom.
CHAIRMAN WASHINGTON: Steve, we are live.

VICE CHAIRMAN LIPSTEIN: I know. She’s a mom with two kids and has just -- with everything that she has going in her life, she took the time to come to our patient workshop and has just committed herself to improving what we do in a very meaningful and inspirational way. So, if she’s back there, she was just one of the highlights of my PCORI experience in telling her story.

MS. SHERIDAN: Great. Thank you. I want to ask our operator if we have anybody on the line that would like to offer public comment.

OPERATOR: If you’d like to make a comment, please press *1 on your telephone keypad. That’s a * and the number 1.

CHAIRMAN WASHINGTON: While we’re waiting on the operator, let’s go back to the first person to see if Mr. Abend [phonetic] is in the room.

MS. SHERIDAN: Like to see if Aaron returned to the room?

CHAIRMAN WASHINGTON: Okay. Operator, anyone on?
OPERATOR: We have no comments in queue.

CHAIRMAN WASHINGTON: Okay, Sue, because we do have a few minutes left, and we just heard some great suggestions from our cohort of speakers, I’m going to ask if there -- if the Board members have a question that you might want to ask, and I know that, in fact, we have one that does.

DR. DOUMA: Allen Douma, Board. It’s not so much of a question but just an amplification. At least two of the presenters today or guests today were from -- identifying themselves as e-Patients. Just to let you know, for you wonks, “e” may have at one time -- having to do with electronic, but now it’s much bigger, broader, and much more important in the work we do, and it stands for empowered, engaged, equipped, and enabled, and all of that works together in those folks being in charge of their own care and also requiring us to be much more engaged and empowering them as we go forward.

CHAIRMAN WASHINGTON: Okay, great. Thank you. Any other comments from Board members?
Others in the audience who have not commented and who did not sign up who would like to make a comment at this point?

Okay. Jesse.

DR. JESSE: This is Bob Jesse, Board. I’m sort of intrigued by that last comment that there may be the expectation from those -- that are engaging us that they’re looking for truly disruptive innovation in the sense of how we’re going to perform our mission. And just out of curiosity, did that sense come through at the engagement meeting in D.C.?

CHAIRMAN WASHINGTON: This is really a question to Board members participating. Why don’t we start with you, Sue? Do you think it came through?

MS. SHERIDAN: You know what, I wasn’t listening to the question because I was speaking with a patient. Can you repeat it?

CHAIRMAN WASHINGTON: Okay.

DR. JESSE: Sue, the question was, there’s a sense that the patients are looking for PCORI to
really be the force of disruptive innovation, and did that sense come through in the engagement forum in D.C.?

MS. SHERIDAN: Oh, absolutely, yes. I mean, patients talked about PCORI being the paradigm shift, being innovative, creative, bold, courageous, and being the agency and entity that they’ve been waiting for.

DR. JESSE: So, that’s not an issue that we’ve actually kind of taken head on yet. We might need to talk about that.

MS. SHERIDAN: I think we have an opportunity. I would like to introduce Sally Okun from Patients Like Me. She’s asked to provide a last minute comment.

MS. OKUN: Thank you so much for this opportunity. I just really want to say, one small thing that we’ve actually thought a lot about at Patients Like Me, and it’s a poem. “To learn, listen well to the impressions voiced by patients first.” I think if you take that and really take that seriously, the comment that you just made, we
will have disruptive innovation and we will make a
difference for patients and their caregivers. So,
thank you very much for the opportunity.

CHAIRMAN WASHINGTON: Thank you, Ms. Okun.

Okay.

MS. SHERIDAN: We just want to check with
the operator one more time to see if anybody has
called in.

OPERATOR: We have no comments in queue.

MS. SHERIDAN: Thank you.

CHAIRMAN WASHINGTON: Okay, we really have
benefitted from, as I said, great insight and some
terrific suggestions in this comment period today,
so I want to thank our presenters for sharing with
us your thoughts and your suggestions. We are
taking them to heart and we are encouraged by your
sense of what it is that we, in fact, can achieve
and what we should be doing in terms of disrupting
the status quo and creating a new paradigm.

MS. SHERIDAN: I think it can be
positively disruptive.

CHAIRMAN WASHINGTON: Positively
disruptive. Okay. So, and keep pushing us, and I heard that terminology used once. We’ll just get better with you pushing us.

MS. SHERIDAN: Yes, we will.

CHAIRMAN WASHINGTON: Okay, so we’re going to move into the last session for today and we’re going to ask our vice chair -- Steve, are you ready?

VICE CHAIRMAN LIPSTEIN: Yup. We’re going to cover the report of the Board Nominating Committee. There’s a tab in your book. I don’t believe we have slides for this presentation, so we’re going to refer to that handout.

Just to remind the members of the Board that the members of the Nominating Committee are Dr. Jesse, Gail Hunt, Freda Lewis-Hall and Robin Newhouse, and Dr. Washington and I sit with that group, and I chair the group.

Under the tab you will see that we have conducted a process where -- as you will remember, when we set up our committees originally, we asked our committee chairs and our committee members to
serve for two years while we were getting started, and I would say that our committee chairs have just done a terrific job. It was way more of a time commitment than any of them could have imagined and we are very grateful for all they did to get us up and running and started.

But as you can see, we’ve asked Dr. Norquist to chair the Communications, Outreach, and Engagement Committee beginning in 2013 -- and, by the way, we are asking that these committee assignments and chair assignments be for two years, and I’ll explain that in a minute why we think that’s important, but as you can imagine, we’ve got good continuity and the only change to the membership of the COEC we are recommending is that Ellen Sigal move to the Program Development Committee, and when we get to that you’ll see her name appear there.

We’re not replacing Ellen on the COEC. We did get future draft considerations --

CHAIRMAN WASHINGTON: We do have Allen Douma there.
VICE CHAIRMAN LIPSTEIN: There is, but I haven’t gotten to that trade yet, okay?

CHAIRMAN WASHINGTON: Okay.

VICE CHAIRMAN LIPSTEIN: But as Dr. Washington pointed out, you can see the addition of Allen Douma to the COEC coming over from the Finance, Administration, and Audit Committee. That was a request as well as -- I’m going to talk a little bit about the FAAC in just a minute. Well, I’ll talk about it right now.

You can see we made the Finance, Administration, and Audit Committee a little smaller asking Kerry Barnett to continue to chair the committee, Larry Becker, Dr. Zwolak, but that Allen, as I mentioned earlier, will be moving over to the COEC and Freda will be moving over to the Program Development Committee.

We think that now that we’ve gotten PCORI up and running and we’ve put in place a lot of our administrative policies and procedures. As I was explaining to Dr. Zwolak earlier, with each successive iteration of the budget, it gets clearer
and clearer what’s in the budget, and while we’re going through some definition and sizing of the budget this year, a year from now we believe we’ll have, you know, budget comparisons that make it really much easier for the Board to do that work, and so we’ve made the FAAC a little smaller, a little bit more nimble.

We’ve asked Kerry to continue chairing that group because, as you know, he was recently appointed for another six-year term to our Board, and so we will have good continuity on that committee for a long, long time.

The Program Development Committee, we’ve asked Dr. Goertz to chair that committee, and as I mentioned earlier, Freda and Ellen will be joining that committee.

We’ve created a committee called the Executive Compensation Committee, which is the committee that will address all issues related to the compensation of our top four officers that Joe has described -- the executive director position, the deputy director, the deputy executive director,
the chief officer for engagement, and the chief
science officer.

We have a Standing Committee on Conflict
of Interest. Larry Becker will continue to chair
that committee. I wanted to ask Larry if he would
briefly mention, since he knows a little bit more
about Silvio than I do, there is one substitution
there related to a new appointment to your
committee.

MR. BECKER: So, this is Larry Becker on
the Board. So, Mark Feldstein was at the
University of Maryland and he joined us in the
beginning. He asked to leave the committee based
on commitments and timing. He recommended Silvio,
again, somebody at the University of Maryland, who
has published extensively on public health. And at
this point, that’s my memory because it’s been
several months since we did that.

VICE CHAIRMAN LIPSTEIN: So, if any of you
need to see a résumé on that, we can certainly
circulate that with the minutes of the meeting.

And then finally, the Methodology
Committee, there are two key changes. We’ve already talked about the outgoing vice chair, Sharon-Lise Normand. The committee is recommending Robin Newhouse as the new vice chair of the Methodology Committee. Rest assured that even though Robin was a member of the Nominating Committee, she was not party to those deliberations or discussions. She was the consensus candidate of the Methodology Committee, so it’s always wonderful when somebody is highly recommended by their peers and certainly we bring her forward for your consideration with enthusiastic endorsement.

I think as either Joe or Gene have shared with you before, upon the occasion of Sharon-Lise’s resignation from the committee, we had a meeting at the General Accounting Office, at the GAO, about her replacement and at that time we had a good discussion with the GAO and they kind of enlightened us as to how labor-intensive and time-intensive it is to appoint a Methodology Committee or a Board of Governors like us, and that doing it one member at a time is not an easy thing or an
efficient thing to do, so they’ve asked that until there are other vacancies on the Methodology Committee, that they not necessarily engage in officially appointing new members of the Methodology Committee, but we came up with a good alternative, which is that as you can see, we’ve created something called the Methodology Committee Board Appointed -- and I think there should be a “c” in that word, I’m not sure -- but I think it’s adjunct members.

And the Methodology Committee has specifically asked that we identify a biostatistician to fill Sharon-Lise’s role, and so Dr. Washington and Dr. Selby are hard at work with input from Sherine Gabriel, and the members of the Methodology Committee on identifying that individual. And once we’ve done so, we’ll bring that forward for your consideration.

So, those are the -- the only other thing I will share with you is that we did not renominate ourselves as a Nominating Committee, but we think that 2013 should be an off year for the nominating
Committee because we shouldn’t have many nominations to make. The committee appointments, the chair appointments are all two-year appointments, and barring any other unforeseen changes, it should be a very, very light year.

So, my recommendation would be, stepping out of the chair for a minute, that we just continue with the current membership of the Nominating Committee as constituted.

So, Mr. Chairman, those would be our recommendations and so as the chair of the Nominating Committee, I would make a motion to the Board to accept the report of the Nominating Committee and these appointments.

CHAIRMAN WASHINGTON: Okay. First, thanks, Steve, for your leadership and collecting all this information and then formulating it and organizing the deliberations of the committee.

But one is, would you comment on the integration of the dissemination into the COE?

VICE CHAIRMAN LIPSTEIN: I will. And Leah pointed out another thing I forgot to do, so those
are two things I meant to mention that I didn’t.

I skipped over, inadvertently at the top of the second page, the Scientific Publications Committee. Debra Barksdale has agreed to continue to chair that committee. She hasn’t yet done her two-year sentence, and so the Scientific Publications Committee remains intact.

The other recommendation that’s coming forth from the Nominating Committee, and it’s actually also coming forward from the dissemination work group, is that we combine the two, that we roll into the charter and the work of the Committee on Outreach and Engagement and Communications, the work that we previously had assigned to the dissemination work group.

And so the COEC, then, would begin to assume that collaborative effort. You’ll remember the dissemination work group was a coordinating group between the Agency for Healthcare Research and Quality and PCORI, in terms of the best way to make sure that we fully align our efforts in disseminating and communicating the work of our
research institute. I think you all are aware that
AHRQ receives 20 percent of the money, I guess it’s
the money, before it goes to the PCORI trust fund, but
20 percent of the proceeds of the revenue
generated by this part of the legislation. And our
Board had asked that we just make sure we are
really well coordinated and integrated with AHRQ so
that we don’t duplicate each other’s efforts, that
we enhance each other’s efforts, and so we think
the time has come, really, to bring that under the
purview of the COEC.

So, that’s another recommendation coming
forth from our committee.

Did I forget anything else? I can ask any
members of the Board, because we’ve had input from
all of you on these nominations and these
assignments. Any other comments from the
committee?

CHAIRMAN WASHINGTON: Just one. There are
a couple of ways to interpret your comment about
the Nominating Committee, but I do think we need in
place over the next year, and at the end your
suggestion was that we just continue the same
group, which I certainly would favor, so that we
are in effect putting forth as part of this slate
the same group that’s on the Nominating Committee,
correct?

VICE CHAIRMAN LIPSTEIN: Correct. And
just so -- for clarity and to -- the members of the
committee in addition to Gene and me would be Bob
Jesse, Gail Hunt, Freda Lewis-Hall, and Robin
Newhouse.

CHAIRMAN WASHINGTON: Okay. Can we have a
motion?

UNIDENTIFIED BOARD MEMBER: [Off
microphone.]

CHAIRMAN WASHINGTON: So moved. Second?

UNIDENTIFIED BOARD MEMBER: [Off
microphone.]

CHAIRMAN WASHINGTON: Further comments?

[No response.]

CHAIRMAN WASHINGTON: All in favor of
accepting this slate, aye.

[Chorus of ayes.]
CHAIRMAN WASHINGTON: All opposed?
[No response.]
CHAIRMAN WASHINGTON: Okay, any abstentions?
[No response.]
CHAIRMAN WASHINGTON: The motion carries unanimously. Thanks again to Steve and the members of the Nominating Committee and thanks to the Board members who are taking on these continued leadership roles. Okay. And to Robin who’s now -- who I thanked again last night and this morning, will be coming up to the table and working even more closely with us and the Board.

VICE CHAIRMAN LIPSTEIN: And just one public comment, since I’ve been on the phone I feel like every week or every other week with Sharon and Rick for the better part of two years, we know where you live -- but in front of the whole Board, I think we need to acknowledge how much time, energy, effort, and commitment you both put into getting us started in your role as committee chairs for PDC and COEC, so we love you.
[Applause.]

CHAIRMAN WASHINGTON: Thank you, Steve.

Thank you. Okay, Francis, you’re talking about efficiency, that was efficient. And, Steve, you’ve used less than your allotted time. You got carbon credits here. You want to sell some of them? Or we’re just going to end early.

VICE CHAIRMAN LIPSTEIN: I’ll take tickets to the cash bar.

CHAIRMAN WASHINGTON: He wants tickets to the cash bar. Okay, Joe, wrap up comments?

DR. SELBY: Good. So, I’m going to go quickly through each of the topics today because each one of them did have some next steps and I want to ask you to please remind us if we don’t have all of them here.

So, we adopted the revised standards of the Methodology Committee today. Checking the legislation, we do not have to adopt the recommendations, so that leads to a lot of exciting next phase work with the Methodology Committee including work, particularly in partnership with
the COEC and staff, on dissemination of the standards.

    We heard loud and clear the MC’s interest and willingness in working with us on both training peer reviewers to incorporate the standards into the review process, also heard loud and clear yesterday and today, an interest on the part of the MC in working with us in helping us to design an overall evaluation plan for both patient-engagement and just for the effectiveness of our research.

    And the last was, I just heard it at the end of the discussion, but it seems like a great idea, which would be to convene the Board, staff, and the Methodology Committee, to carefully go through the recommended actions, of which there are a number, and I think I even heard somebody suggest the word prioritize maybe.

    So, all of that -- anything else as a follow up to the methodology -- that’s a lot -- that’s enough, isn’t it?

    My advancer is not functioning.

    The next topic we heard about was the
advisory panels, and we were instructed by the Board to proceed with soliciting interest and preparing slates to propose to the Board for the three panels that we presented today, that is the Patient Engagement, the -- let’s just -- I hate to do this, but let’s just call it the Comparative-Effectiveness or Priority I panel, and the Addressing Disparities Panels. Heard loud and clear the notion that we need to create a flow diagram that describes the flow of ideas from stakeholders through the staff, through the panels, and ultimately to the Board.

And that’s a great idea, and we will get to work on that.

We need to make sure, as we’re creating these panels, that we build a structure that coordinates their work, enables them to communicate with each other the idea even of their meeting together when they have face-to-faces was a good idea -- suggestion that I think we embraced of changing the composition of the Patient-Engagement Panel to closer to 50-50 than 75-25 that allows
meaningful representation of researchers and other stakeholders on that engagement panel.

The idea that we include a Board member and possibly -- maybe this is my addition -- possibly an MC member as well on each of these committees as ex officio members.

And lastly, that we may proceed to create charters for additional advisory panels if time allows and the need dictates.

Anything else on the advisory panels?

DR. CLANCY: Carolyn Clancy, Board member.

First of all, I love this summary. Secondly, it does seem to me that the flow diagram might at times overlap with some of the Board committees, so I don’t know if that’s a footnote or just an addition to the second bullet.

DR. SELBY: Is the word overlap or it might include -- flow through the committees.

DR. CLANCY: I guess it would include flow through the committees.

CHAIRMAN WASHINGTON: Okay. And Joe, I had one comment. That is, on the 50-50 -- and I
think it’s important that in that other 50, it be
patients, providers, and other stakeholders. I
think that’s a large enough constituency that we’ve
been hearing from that we need to be a little bit
more explicit about in our deliberations.

MS. HUNT: How about caregivers?

DR. SELBY: Yes.

MS. HUNT: Patients and caregivers.

DR. SELBY: It’s the other 50 that doesn’t
have the patients and caregivers in it.

Okay, if there’s nothing else --

CHAIRMAN WASHINGTON: We have Leah right

here.

MS. HOLE-CURRY: As a part of this
process, I heard a lot about evaluation of both
timing and what we’re getting from it and
adjustments, so I’m assuming that’s built in and
does it need a separate bullet? Was that also your
understanding as well?

DR. SELBY: If somebody will please take a
note for me, one of the things I heard was to
change -- reduce the charter of all the committees
from two years to one year, which is a corollary of that, that at one year we have to decide whether we want to continue all the committees, merge committees, depending on our evaluation of their effectiveness.

MS. HOLE-CURRY: Thank you.

DR. SELBY: The next thing we talked about was the 2013 budget, and here are the action items from that. The Board is to communicate as often as need be with PCORI staff, namely Anne, with your ideas and your concerns about the budget as it was presented so that we can incorporate those in the revision.

Staff will continue working with the FAAC, particularly with the Methodology Committee, that we haven’t worked with on the 2013 budget yet, and with the COEC to iron out any remaining concerns and to clarify any still unclear line items from the perspective of Board members.

We will develop an estimate of the proportion of the total budget that is going directly to research, and we will bring a revised
budget back to the Board either on a public phone call, to be scheduled, or at February’s face-to-face meeting in San Francisco.

Anything else on the budget? Any other -- okay. The next presentation was on -- was Martin’s presentation. I wasn’t here, so I didn’t hear next steps on the Pilot Projects. If there are some, Lori will have them, I’m sure, and I can add them or I can be reminded of them now.

On the upcoming work of identifying the awardees for the Cycle I of the broad funding announcements, a Selection Committee will be comprised very quickly and will meet -- will plan to meet twice between now and the December 8th Board meeting. Data on a range of variables will be considered for the top proposals, not only those that are above the pay line, that is, that will get funded, but for those on the other side of the pay line, those just below it, let’s say, that aren’t quite funded, so that we can understand the range of distribution in these variables for those that are funded and what’s in the -- those just below
The Selection Committee will focus primarily -- and actually I’ve got a mistake here -- primarily on the priority score or the overall score from Phase II, and then on two variables -- the conditions studied and the population studied -- and based on that we’ll recommend a slate of proposals in each priority and present that to the Board of Governors at its December 18th meeting, normally a telephone meeting, but for this purpose it will be a public and webcast meeting.

Any other -- I see somebody’s advancing this for me. Any other comments on this?

MS. HUNT: Gail Hunt on the Board. I thought that we also suggested that there might be some additional discussion with the committee co-chairs on the issue of whether the Phase II review, the people get to see the scores from Phase I.

DR. SELBY: Thank you. That’s very good. I think -- we have asked the committee chairs from the Phase II review of this cycle to meet with us by phone to debrief and that’s -- that’s one very
good suggestion that we can bring up with them.

I think, in general, we need to get their
input on how this review went and whether there’s
other modifications we need to make.

DR. BEAL: Joe, over here to your left.
Yeah, just a point of clarification, on the
Patient-Engagement Advisory Panel, I think the
feedback that we received was to expand the number
of researchers, but not necessarily to take it down
to 50 percent because the charter itself says that
there would be a super majority of patients on the
panel. So, just a point of clarification.

We will definitely expand.

DR. SELBY: So, increase the total number then?

DR. BEAL: Increase the total number --

DR. SELBY: Increase the total number on
the committee?

DR. BEAL: Increase the total number of
scientists on the committee, but not undermine the
supermajority of patients on the committee.

DR. SELBY: We also got advised to add
some clinicians to the committee.

DR. BEAL: Exactly.

DR. SELBY: So, we’ll have to do the math and see if we can preserve a super majority, add those people, and not expand the committee.

I don’t know what a super majority is, I’ll admit that.

Anything else -- I think this notion of further evaluation of the review process is a point well taken and will be included. Somebody please note that for me.

Then next, moving on to the targeted PFAs, the staff will move ahead with further evaluation of the three topics we identified and convening of expert stakeholder panels for those topics. Oh, we will present -- this is to Allen Douma’s point -- we will prepare all the data that we’ve got on how the prioritization scoring went and present it to you and make it public as well in the name of transparency recognizing that this was a first time prioritization process using this set of criteria.

DR. DOUMA: Let me just add, I think you
guys did a great job.

DR. SELBY: Thank you, Allen. And the last there is that we will circulate to the entire Board the longer list of 11 topics for the Board members to select up to two additional topics per Board member for our consideration, that’s the idea that we may go to as many as five and then make a decision later how many of those we have funds for and are interested in funding.

So, anything else on the targeted PFAs?

And the next slide, please. Is that it?

That’s it.

CHAIRMAN WASHINGTON: Okay.

DR. SELBY: Thank you very much, Gene.

CHAIRMAN WASHINGTON: Any further comments? Well then I’d like to conclude today by first recognizing our staff, again, for just the phenomenal job that you’ve done in moving along our principle objectives and in positioning us to continue to build on the success to date. So, please join me in a round of applause for all of our staff. Thank you.
[Applause.]

CHAIRMAN WASHINGTON: And, again, I’d like to thank our colleagues on the Methodology Committee for being so actively engaged, and we know, just a tremendous amount of work that you’ve put into developing, first, the draft report, and then through a series of revisions, eventually, a final report, which we believe will truly set a new standard for the nation, in addition to what you do just from day-to-day.

And I think you heard from the discussion that we are going to find new and even more creative ways to tap into your expertise and so I don’t think that you will feel like there’s going to be some let down even though you delivered the report.

This is truly where we behave like the government, more work and no more pay. So, but here’s to the Methodology Committee.

[Applause.]

CHAIRMAN WASHINGTON: Okay, I know, and again, to everyone that participated today, both in
person and online, thank you. And finally to my colleagues sitting around the table, really, we have come a long, long way and this has been a just, I think, astoundingly productive day in terms of moving along a very, very meaty agenda that’s been brought forth by Joe and Anne and the rest of the leadership in our organization. So, thanks to the Board.

[Applause.]

CHAIRMAN WASHINGTON: The meeting is officially adjourned.

[Whereupon, at 5:10 p.m. EST, the PCORI Board of Governors meeting was concluded.]