PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

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Baltimore, MD

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AGENDA

1. Welcome, Approval of January Board Meeting
   Minutes, and Executive Director’s Report 6/11
   Growing the PCORI Staff 13
   New PCORI Office Space 20
   Looking Ahead - The Next Six Months 23
   National Priorities & Research Agenda 26
   Funding Announcements/Funding Cycles 32
   Patient and Stakeholder Engagement 41

2. Program Development Committee Report 46
   PCORI Pilot Projects Grants Program Update 47
   Update on Plans for Analysis of Public
   Comments Received on Draft National
   Priorities for Research and Research Agenda 89
   Developing PCORI Funding Announcements 106

3. Public Comment Period 133

4. Break 166
AGENDA [Continued]

5. Finance, Audit and Administration Committee Report 166
   Standing Committee on Conflict of Interest
     (SCCOI) Appointments 167
   GAO Oversight and Compliance 182
   2011 Financial Statement Audit 182
   Managing Cash Flow 192

6. Lunch 210

7. Methodology Committee Report 211
   Finalizing the Methodology Report 213
   Board-Methodology Committee Engagement 238
   Beyond the Methodology Report 241
   Revising the Working PCOR Definition 256

8. Public Comment Period 287

9. Break 293

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AGENDA [Continued]

10. Communications, Outreach and Engagement

Committee Report 293

Update on Public Feedback Received on Draft National Priorities for Research and Research Agenda 296

Report on National Patient and Stakeholder Dialogue 297

Report on Clinician Focus Groups 304

Update on Stakeholder and Community Engagement Events at Board Meetings 311

11. Wrap up and Adjournment 337
CHAIRMAN WASHINGTON: Good morning and welcome. This is the Ninth Board Meeting of the Meeting of the Board of Governors of the Patient-Centered Outcomes Research Institute. Today’s meeting is available via a live webcast on our website at www.PCORI.org and webcasts will also be archived for those of you who won't be able to stay tuned the entire day on our website after this meeting.

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

In thinking about the meeting today, it dawned on me that this month will mark actually the second anniversary of the Patient Protection and Affordable Care Act. March 23rd is when the statute was signed into law for the nation and it was that statute that I think stipulated that
within six months, this GAO was to appoint the
Board of Governors for PCORI, and so, it’s actually
been less than two years; to be exact, it’s been a
little over 17 months since we as a group have gone
on working together in collaboration with many,
many others to form what is now the Patient-
Centered Outcomes Research Institute.

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

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

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

What we’re going to be talking about this morning relates to the other two areas where I think that we have also made significant progress as we look ahead and look at where we are now. One is that we really have advanced our mission. We have established a mission statement and I’m just going to reiterate it for those of you who have not heard it. This is not for the Board, but for others. PCORI mission, the Patient-Centered Outcomes Research Institute helps people make informed health care decisions and improves health care delivery and outcomes by producing and promoting high integrity, evidence-based
information that comes from research guided by patients, caregivers, and the broader health care community. And, indeed, we have been working and making progress in advancing each of our mission areas, and to reiterate, they are engaging patients and other stakeholders, providers, caregivers, clinicians, researchers, policymakers to conducting PCORI patient-centered outcomes research we’ve been doing. Disseminating research finding, we’ve been organizing ourselves so that we’re in a position to have impact through dissemination and communication of the research that’s conducted. We similarly have been working on how do we lay the foundation and strengthen the infrastructure for not only conducting PCOR, but also for more effectively meaningfully engaging patients as well as infrastructure for more effective dissemination.

And then, finally, underpinning everything that we undertake across our mission areas. We have an outstanding group that’s been spearheading our activities to advance rigorous methods, again, in all of our mission areas. And so, our
discussions today just continue our efforts to fine-tune what we’re doing in these respective mission areas and then, secondly, our discussions also continue to focus on our desire to strengthen our governance and improve the excellence of our operations looking across the Board at how we do business to ensure that we are, in fact, incorporating best practices and optimizing the opportunities we have to work with many across the nation and to use the resources that’s been entrusted to us.

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

And so, I want to open the meeting by
thanking all, particularly my colleagues on the Board of Governors, but everyone that has participated with us up until this point and we look forward to continuing to work with you in a collaborative way to be more effective going into the future.

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

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

But, first, I want to start as I usually do by acknowledging the Board of Governors and the Methodology Committee for the help and support that you all provide. I think I’m finding that you are providing this help and support in new ways as our staff increases in addition to the work that gets done through committees and working groups and we
even form new ones as time goes by. Increasingly, the Board is lending their assistance in the form of one-on-one discussions, conversations, and advice not only to me, but to a number of our staff. So, we’re continuing to be grateful. I talk everywhere I go about how exceptional the -- [off microphone] -- let you know that we’re aware at least of some of the honors that come your way and here are three that we just became aware of in the last couple weeks.

Dr. Debra Barksdale received an award from the Delta Sigma Theta Sorority. They have an annual Queen of Hearts Gala, and Hearts refers to cardiovascular disease and she was given an award for outstanding research contribution on cardiovascular disease in African Americans. Dr. Christine Goertz is this year’s Chiropractor of the Year, Outstanding Chiropractor of the Year in the U.S. named by the American Chiropractic Association. And Dr. Freda Lewis-Hall, who will this Saturday receive the 2012 Alumni Award for Distinguished Post-Graduate Achievement in the
fields in medicine and health care leadership from Howard University’s Board of Trustees.

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

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

   We have added a number of key staff and I can say that while for the last eight months I’ve been celebrating the extraordinary Board and the Extraordinary Methodology Committee, I can now say that we have a sizable extraordinary staff. These folks have come very excited about PCORI’s mission, very competent, very accomplished. It’s a pleasure
and a privilege to go to work every day, and I’ll start at the top.

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

Susan Hildebrandt is here. Susan? There's a hand raised. Susan, we’re delighted to have and Susan will be PCORI’s director of Stakeholder Engagement. Susan comes to us after 19-plus years at the American Academy of Family Physicians, where she has represented clinicians and interacted with other groups of clinicians and I think just makes a perfect person to engage
clinicians and other stakeholders in the work of PCORI in making sure that their voice is heard as we put research together and conduct it.

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

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

And next is Sue Sheridan. There's Sue. Sue comes to us from Boise, Idaho, and, in fact, the plan is for Sue to continue coming to us from Boise, Idaho. Sue’s position will be deputy director of Patient Engagement. So, we have two people, two high-level leadership team individuals managing patient engagement, and we see Sue’s role as somewhat complementary to Judy’s in that Sue has been for many years linking patients together across the world, internationally, using a lot of virtual methods, as well as a lot of travel and she’ll continue to do that with PCORI. And if
Judy’s role is substantially to be at the Center, and to be able to relate and engage to organizations that represent patients, Sue’s is to connect us to the patients well out beyond the Beltway, across the country.

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

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

She also does a whole lot staffing the Methodology Committee.

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

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

So, here is our ever-changing organizational chart. Just the notation that there are a couple slots still open; the Chief Science Officer and the Director of Information Technology are positions that are posted and we’re not quite
to the stage of interviews yet, but those are two positions we have our eye on. Human resources is another area that are determining whether to add an individual on staff or to continue contracting and the rest of it is as you see.

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

The scientists need to be engaged and it’s the engagement folks that make sure that they are. The process of engagement needs to be studied, and so, part of us being a learning organization is, in
fact, figuring out whether what we’re doing in the name of engagement is actually effective. So, the scientists support engagement and engagement supports science and that is one of the ways that we will distinguish ourselves and our research and it’s one of the ways in which we intend to be a learning organization.

So, just the next steps in hiring, I’ve already mentioned the Chief Science Officer, scientist interviews underway. Research associates, I think we will have a number of research associates added to PCORI’s staff to support Board activities, Methodology Committee activities, and staff activities by May. The same on the engagement side. We’ve told folks who came to join the Engagement Team that now they need to turn around and recruit staff to do the work to expand our digital engagement with patients and stakeholders to build up the communications and to begin convening meetings of these folks. So, they will need help. And in Operations, I’ve told you we’re looking for Director of Information.
Technology, and I expect Martin and Pam Goodnow to build up the finances in Grants Management staff.

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

DR. DOUMA: Can I --

DR. SELBY: Yes.

DR. DOUMA: A question. I just wanted to ask a question. The Director of Information Technology, will the roles and responsibilities include both internal and external Information Technology or is this focus on the internal?
DR. SELBY: No, to the extent I understand exactly what you mean, I think this is going to be a very high-level person who knows the entire field and will help us make decisions, critical, as you know, decisions and adheres always whether to hire staff to do a particular task or whether to engage through contracts so that you can get a broader level of expertise for the amount of time and that you need. So --

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

DR. SELBY: It would fall under this person.

DR. DOUMA: Yes.

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

DR. DOUMA: Right.

DR. SELBY: Harlan?

DR. WEISMAN: Harlan Weisman. I had a similar question. So, what people call health
informatics, health information databases,
analytics, data analytics and so forth, is that
what we’re talking about or are we talking about
somebody who helps us run our internal IT
infrastructure, which are two different types of
roles, I guess?

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

DR. WEISMAN: What I meant Joe, was not so
much do we construct our own databases, but that’s
particularly in outcomes research an important part
what outcomes will be and the construction or
advocacy of construction of interoperable databases
that can be utilized for PCOR as something having somebody who can inform us, I guess similar to what some of the other roles are. It would be important, but the kind of individual who specializes in that wouldn’t be a classic IT infrastructure person, I guess is what I’m saying. So, they're almost different descriptors, job descriptions. By the nature of my asking the question, I think that’s an important thing, for us to build expertise in, so that’s why I’m asking the question.

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

DR. BEAL: Yes. Hi, Harlan. Yes, so, we have someone who we’re thinking about from an IT perspective who’s dealing with data, data infrastructure; also, our infrastructure internally with regard to Finance, Communications, as well as Grants Management. What our thinking is, is that
this is a high-level person who’s able to address
just the issues that you’re talking about because
some of the other things in terms of just our IT
inside the building, that we can easily purchase.
That’s sort of capacity. So, we’re really thinking
about this as being the high-level person who can
help from a strategic perspective, really
addressing what the IT needs are for PCORI.

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

So, that’s a topic that will be one of our
eyearly advisory groups, and in July 2nd and 3rd, the
Methodology Committee, the PDC, anyone who’s
interested will be invited to a workshop where we
kick that off, beginning to understand what role
PCORI can play in advancing the nation’s ability to
do Patient-Centered Outcomes Research.

Steve?

VICE CHAIRMAN LIPSTEIN: Steve Lipstein.

Joe, I think we’ll have an opportunity later in the
agenda because when the Methodology Committee does
the report, Chapter 4, my favorite chapter of the
Methodology Committee Report, really gets at this
whole issue of patient-centered datasets and the
kinds of data, Harlan, that you were talking about.

So, Sherine, when we get to Chapter 4 in the
discussion later today, let’s bring this subject
back up for Board discussion because I think it’ll
be an opportunity also to get these two subject
issues, okay? So, that way we can keep pushing on
with this, but this is a great topic for Board
discussion.

DR. GABRIEL: So, I can certainly comment
on it. Just as a reminder, that’s Chapter 4 to
question mark, because the chapters haven’t been
built out yet.

VICE CHAIRMAN LIPSTEIN: Right.

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

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

The public comment that we’ve received from all sources, including from the National Dialogue, including from our website, will be
analyzed by a committee of the PDC and reported
back along with suggestions for revisions to the
Priorities and Research Agenda to the Board at a
meeting. We have not identified a date for it yet,
but it will be likely a public webcast meeting, a
virtual meeting, but webcast, and the Board will
hear the report and hopefully adopt the Priorities
Research Agenda.

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

We anticipate that 2012 will be a year of
engagement with patients, patient groups,
clinicians, and other stakeholders, and they will
be in the form of conferences on specific topics,
they’ll be in the form, as for example, the EHR workshop in July, brainstorming sessions where we begin deliberating on whether there are specific areas that may deserve special emphasis from PCORI that PCORI may want to focus on and advisory groups. Some are named in the statute and others may evolve as our discussions advance. And we anticipate that at some point, hopefully late in this year, PCORI will identify one or more areas where we would release a funding announcement for specific type of research that was deemed by stakeholders to be of particular importance and relevance to PCORI.

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

And last, but by no means least, the Methodology Report is due to the Board and I have
every confidence will be delivered to the Board on May 10th. Public comment period will ensue 45 to 60 days and beginning in mid-July then, the input will be analyzed and the Methodology Report revised and the revised report will be submitted for adoption to the Board by August. So, we will have version one of the Methodology Report by mid-August.

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

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

CHAIRMAN WASHINGTON: Okay, Steve has a question.
VICE CHAIRMAN LIPSTEIN: So, Gene, there were a couple of things we were thinking about as a board. One was that once we receive it from the Methodology Committee, we don’t have to approve it at that point. What we want to approve is approved to send it out for public comment. Then when we get it back, it will probably flow back to the Methodology Committee with all that input and they’ll probably make recommendations for revisions or changes and then we’ll have a second take at it as a board before it receives final approval. So, it’ll probably play out across the summer. Is that what you’re thinking, Joe?

DR. SELBY: Yes.

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

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

VICE CHAIRMAN LIPSTEIN: The 20th. That
weekend of the 20th.

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

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

MR. BARNETT: Perfect.

DR. SELBY: Yeah.

VICE CHAIRMAN LIPSTEIN: And given the iterative nature of what the Methodology Committee has laid out, we’re going to get an opportunity to really participate with them in a very organized and I hope very participative way between now and then via workshops, phone calls, and I think they have laid out an outline for the report. Like when I said Chapter 4 through question mark, and that was my favorite part, that’s the part that deals with robust datasets for clinical research, and so,
we’ll all have an opportunity as Board members to participate in that area of support development that we think is really kind of important to us.

DR. NORQUIST: Greg Norquist. I just had a comment, Joe. One of the things we talked about is learning from what we’ve done in evaluation.

So, we spent a lot of time getting public comment on our priorities and stuff. I hope we don’t just put this Methodology Report out to public comment without learning maybe there’s a different way we want to do it to get our input. So, I hope we’re learning from what we’re doing right now, but when we put this out, we don’t just issue it, that we rethink how we get public comment.

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

So, funding announcements, and as I
alluded to before. We see the first four
priorities so this is assessing options for
prevention screening and treatment, improving
health care systems, communication and
dissemination research, and research on fairness
and addressing disparities. Those will be
released, that’s the yellow box, in mid-May and
applications are due in July. We also though,
anticipate, that for the fifth announcement, we
will see -- the fifth announcement is an
infrastructure priority and it has two broad
components that we’re thinking of now.

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

The issue of research infrastructure is
particularly complex. There are a lot of efforts already in the field and we need to make some sense about what those efforts are and how PCORI funding could augment support, catalyze the next step in those efforts.

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

DR. DOUMA: Joe?

DR. SELBY: Yes.

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

DR. SELBY: Yes.

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

DR. SELBY: Well, the way that the PDC has seen it thus far, those will be the equivalent of standing announcements with submission dates every
four months. So, you could apply under this standing announcement. These announcements will be quite inviting in terms of the kinds of studies that we’d consider. You could apply in November. If you don’t apply in November, I mean, you could apply in July, you could apply in November, you could apply the next March.

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

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

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

DR. SELBY: That’s a good point.
CHAIRMAN WASHINGTON: Francis? Yes, Francis?

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

DR. SELBY: It has gotten a little tight, Francis. At first, it looked like the workshop was going to take place in June, but I think schedules conspired to push it to early July, and so, that makes it very tight. And as you’ll hear, there’s a lot of discussion and work that we can do preparatory to that workshop particularly in collaboration with colleagues at NIH and AHRQ and others to get our arms and our minds around this vast field. I mean, I know you know this. I’d just emphasis though that there’s a lot going on in this area, it’s an area where we all have great hopes that electronic health record data and other data can be harnessed and linked and we can deal with the privacy issues involved, we can find ways
to add patient-reported outcomes to these research networks or databases and really, as has been said here, have a reusable resource for efficiently conducting important studies. But they’re costly, not all of them work out, and there are a lot of players in the field. PCORI couldn’t really by itself fund a national infrastructure if it had its heart set on it, so, I think there’s a lot of strategizing and just a lot of getting this full appreciation of what’s going on that can happen even before the workshop.

DR. CLANCY: Joe?

DR. SELBY: Yes, Carolyn?

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

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

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

DR. SELBY: Thanks, Carolyn.

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

And this infrastructure development could
become the foundational framework for a lot of what we want to accomplish over the next seven years, but, Carolyn, I think it’s really important that what the research community may already know, and I appreciate the concern about rehashing old work, the provider community is just learning, and if we really want to have credibility for our work and dissemination of what we find as a result of that work, creating these foundational frameworks in cooperation with the provider community is very, very important and what I mean by that is that the research community for a long time has been using datasets to do comparative effectiveness or outcomes research that the provider community has found suspect. And so, if we can build these frameworks together so that we agree from the outset that they have credibility, that they really are patient-centered datasets, then I think the research we do using that research will have far greater credibility.

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

DR. SELBY: Steve, thanks. I appreciate your saying that, and I’d just like to go on record as saying that if the providers, the ultimate owners, if you will, of the data don’t get involved and motivate collaboration, it probably won’t happen just with the researchers. So, I’m glad you said that.
My time is just about up, but I don't want to shortchange the notion of patient and stakeholder engagement. So, you’ve met our engagement team and this is our plan. Step one is to begin building communities of patients and stakeholders, and these are very large numbers of both, of patients and also stakeholders, clinicians, and others through a variety of means, including our website, social media, face-to-face meetings, so that we can have ongoing dialogues, bidirectional dialogues so that we can ask questions of the community so that the community has ways of getting to PCORI with their questions. We want to strengthen ties with advocacy associations, professional clinical organizations, purchaser organizations, and the research community, and that is some of the early work of our engagement team.

Refining the PCORI Research Agenda means getting stakeholders to the table to talk with PCORI about what is important to study. We’ve defined patient engagement from the point of view
of setting the agenda, prioritizing questions as a hallmark of PCORI, and 2012 is the year when we being doing that, Multi-Stakeholder Workshops focused on the National Priorities, Multi-Stakeholder Advisory Panels, and again, the use of social media and surveys are some of the ways that we will obtain that input in 2012.

DR. WEISMAN: Hey, Joe?

DR. SELBY: Yes?

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

DR. SELBY: I certainly can’t give you dates yet. I will say one thing: I think it’s our
strong feeling that out of this July 2nd and 3rd workshop will come the origins of an advisory committee on research networks, and that has a lot of aspects that we’ll need advice on, both on just strategies for building a comprehensive network, but also strategies of engaging patients, strategies for engaging systems for dealing with issues such as privacy, for protecting privacy, but enabling research, and for questions like how do we use these networks then to heighten patient engagement in the research process?

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

Another area where we’re mandated to have an advisory committee is in clinical trials, and I think we’ve modified that to say clinical trials...
and observational studies because oftentimes, the question is: What is the proper role of one versus the other? So, that’s the second advisory committee.

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

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

DR. SELBY: I certainly hope so.

DR. GABRIEL: Another one worth mentioning that came up in last night’s discussion actually is on dissemination and implementation and we’ve got an effort that Methodology Committee and COEC, collaborative effort to move that forward, and I’m
pretty confident that we’ll be proposing an
advisory committee on that topic, as well.

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

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

DR. SELBY: Oh, sorry.

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

DR. SELBY: Thanks.

CHAIRMAN WASHINGTON: Thank you, Joe.
Next on the agenda we have a report from the Program Development Committee, the committee that’s chaired by Dr. Richard Kuntz. For those of you who new out our ongoing proceedings, again, just to give you a little context, this is the committee that in particular is focused on conducting Patient-Centered Outcomes Research, so, despite its name, the principal focus of this group is how do we, in fact, advance our Research Agenda?

Dr. Kuntz?

DR. KUNTZ: Thanks, Dr. Washington. Good morning, everyone. On behalf of the Program Development Committee, I’d like to spend the next hour-and-a-half reviewing updates in our PDC Report. The agenda will be fourfold. We will review the PCORI project grants initially with Dr. Goertz and Ms. Hunt. We will then review the analysis of public comment, specifically about where we stand with the National Priorities in Research Agenda. We’ll then go over a little bit about the processing for the PFAs, the PCORI Funding Announcements. That, again, will be done
by Christine and Gail. And then at the end, we’ll
review the Dissemination Workshop and Workgroup
with Dr. Clancy.

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

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

DR. GOERTZ: Great, thank you. Just a
reminder of our deliberation process from this
point forward, what we have been working on over
the last couple of months is basically to come up
with some specific criteria to be considered by the
PCORI Selection Committee when we’re determining
what might be an appropriately balanced slate of awards, and now that we’ve come up with that information, PCORI staff is working to look at the applications, looking at the scores, and our other criteria and looking at different ways where we might want to consider the applications based on some of the criteria that are important to us, and I’ll be showing that criteria in the next slide.

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

The next slide.

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

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

CHAIRMAN WASHINGTON: Yes, we’ll keep you
all after school one day.

[Laughter.]
CHAIRMAN WASHINGTON: We’ll cover it.

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

CHAIRMAN WASHINGTON: I think that’s an excellent idea, Steve.

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

The other criteria that we thought might be important, that the working groups thought were important were area of interest, population, methods, geography, discipline of the PI, seniority of the PI, condition, and then stakeholder and patient involvement. Some of those criteria are a little bit easier to operationalize than others, not surprisingly, but we are working to find a way to operationalize each of those criteria in a meaningful way and these are the things that the
Selection Committee will be considering as we move forward.

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

DR. GOERTZ: Absolutely.

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

DR. GOERTZ: We’re absolutely not planning to redo the scoring and our metrics did go into the review criteria that NIH used when evaluating the applications, the training that the reviewers received were based on our review criteria, which some of those criteria were similar to the things that NIH uses and some of them were quite different. For instance, we added a whole entire criteria on patient engagement, stakeholder engagement, which is not part of the normal
criteria. So, many of those things are, in fact, included. So, all of those levels, when it comes to environment and expertise of the PI and the novelty and the soundness of the approach, the significance, all of those things are built into the review process.

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

DR. GOERTZ: Yes, Francis?

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

DR. DOUMA: It seems like it’s really important that we do research across the care continuum from primary care through end-of-life...
care, and I’m not sure, I don’t know, and this is a question part: Is that being taken into consideration in our scoring? And, if not, I don’t know what “area of interest means”. Would that be included under that bullet?

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

DR. DOUMA: Then what does “area of interest” mean?

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

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

DR. GOERTZ: Thank you.

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

[Laughter.]

DR. WEISMAN: No, I’m skilled at this.
[Laughter.]

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

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

DR. WEISMAN: Before or after the fact?

DR. GOERTZ: Before, during, and after.

DR. WEISMAN: Good.
CHAIRMAN WASHINGTON: Dr. Collins then Dr. Selby.

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

For the PCORI reviews, however, this was not the case because these are special panels. So, every panel was just percentiled against itself. So, that means if an application was ranked number three in terms of priority scores out of 100, it would have been ranked at the third percentile. So, very direct assessment that should be pretty
transparent when you see the PCORI reviews that CSR puts forward.

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

Certainly, when one jumps in and begins to rearrange the decisions about what’s getting funded, it will have to be done transparently and with very clear justification. I would just flag one of these elements, and I’ve said this before in a phone call, but I’ll say it again, as being particularly troubling, and that’s the one of
geography. If an investigator has a special population that is geographically important, that ought to be covered in other ways, but we at PCORI ought to represent the fact that we’re a meritocracy and the geography, while it may in fact be important politically in certain circumstances, I think it should not be something that we pay a lot of attention to in terms of figuring out how to fund the best research.

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

[Laughter.]

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

DR. SELBY: Right. Just kind of a fundamental point, I think, about the notion of seeking balance. When a study section is reviewing, when a reviewer is reviewing a particular proposal, they have no clue what else is being reviewed by others and other study sections, they have no clue how the final distribution is going to play out. And so, there is no way in
which they can be expected to create balance on their own.

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

DR. KUNTZ: Sharon-Lise?

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

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

But I think more important than that, I just thought it would be important just to give you the thick of the scope of the problem you’re trying to deal with, we call big piece, small end problem. But from a more practical standpoint, I think I have trouble with this balancing issue from the perspective of somebody who has served on study sections. Like almost everybody in this room, you look at these things, and, again, it’s in your head when you’re clicking off the box. So, the discipline, the seniority, the conditions, all of that is integrated in the reviewer’s head when
they're scoring and it is true, as Dr. Selby says, that other study sections aren't seeing what other people are doing, so, they can't balance, but why should we balance is the question I have. And someone cares about this, but the fact if the top 40 or 50 studies didn’t have anything to do on the aging, they will next time. So, I guess I’m sort of looking at this thinking why do we need to go through this phase?

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

DR. SIGAL: Ellen Sigal. So, I, too, have very huge concerns about this and I would have hoped that our metrics for establishing these grants or these procedures would have incorporated a lot of these issues prior to this, but I served on NCAB, the National Cancer Advisory Board, for years and it’s the only advisory board, I think, by statute that basically has to review all the grants and has the authority to say yes or no. And when there was disagreement with the grants, we did this in public session and it was very open. So, even
though we have our criteria which may be open and
we will explain if the discussions will be closed,
and I’m concerned about this. It doesn’t feel
right to me and I would hope that next time when we
do this, that our grants will be or our review
process will incorporate all of these metrics for
distribution all these priorities that we think are
important, but this should be by merit. So, I am
very worried about transparency.

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

DR. GOERTZ: The priority scores are
absolutely the most important criteria. Just to
give you a sense, for instance, with the
stakeholder and patient involvement criteria, that
was one of the our review criteria, and so, the way
that they were operationalizing that is to look at
the score, the NIH score for that particular
criteria because we didn’t want, for instance, in
the top 40 was to have everybody have a very poor
stakeholder criteria and the reason we wanted to
look at that is because this was a new criteria, we
didn’t know how that would work.

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

It is not intended in any way to
invalidate or to trivialize the priority score,
which was absolutely our top criteria when we’re
looking at these applications, but more to say here
are some things that we have said are important to
us and we’re interested in looking at, how the
natural process worked when it comes to some of
these things and as we move forward.

CHAIRMAN WASHINGTON: Dr. Levine?

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

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

DR. LEVINE: Balancing.

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

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

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

DR. LEVINE: Oh, okay.

DR. GOERTZ: -- that were selected by
DR. LEVINE: Okay. Thank you.

DR. COLLINS: But they are not NIH staff.

DR. GOERTZ: Right.

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

DR. LEVINE: So, staffs it.

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

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

DR. COLLINS: Yes.

DR. LEVINE: Study section.

DR. GOERTZ: Yes.

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

DR. KUNTZ: I just wanted to accelerate the discussion and maybe we can take this offline a little bit, but we did discuss before a method to reduce the impact of this balancing part and that was that we were always looking for exceptions to
the rules to why we would be out of order, why we would award a grant out of order, and one of the options was to potentially identify a priori all these areas, what would identify unusual clusters of grants in certain areas, and that would be a binary rule that would make someone look at this. So, if we saw, for example, 70 percent of grants coming from California, we’d say there’s a problem there and then that might compel us to go down to the next order, but rather than to develop an equation that solves for balance, which would then be something competitive with our part.

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

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

[Laughter.]

MR. BECKER: That’s the expected.

CHAIRMAN WASHINGTON: Dr. Becker?

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

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

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

DR. GOERTZ: Well, it very well may be yes, go ahead. In the end, somebody has to make a decision, the ultimate decision about what’s going to be funded or not, the official decision, and we made the decision at other Board meetings that it would be the Board that made that official decision about what we’re going to be funding. So, what you’ll get is a recommendation from the Selection
Committee on what to fund that the Board can either vote yes or no to.

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

Dr. Weisman?

DR. WEISMAN: Harlan Weisman, member of the Board. I have a couple of points I wanted to make, but one of them just real briefly is I agree with what Sharon-Lise says. This is over-parameterized. This is too many things to really do other than qualitatively, which I think is probably what you were saying, Rick.
The other thing, I recall, Carolyn, you saying that in reviewing priority scores, the precision, although we aren't measuring caps or anything that a score plus or minus 5 or 10, they're actually not going to be that different from each other in terms of the view of the peer review process. So, there's some looseness there, and we have an arbitrary cut point of 40, is that correct?

And one of the things that I was wondering, Christine, or maybe just saying it overtly is this doesn't have to be a subtraction process, this can be an addition process for rebalancing and that what would be bought in are not things from the bottom of the priority scores, but things right on the edge of the 40 that would have been within the range of precision of the scores anyway and that would allow this more qualitative type of ranking that would respect what was done when the priority scores were done and maybe adding several just below the line, which is an arbitrary line anyway and would allow to us to
achieve both sets of goals. One is to recognize
the process that was followed in giving the
priority scores, but also recognize that perhaps
there could be from the reasons that, Joe, you
said, that unawareness on the part of people in
terms of balance across the groups, something
egregious may have occurred, as Rick said, that
could be rebalanced and while maintaining the
integrity of the process.

DR. GOERTZ: Go ahead.

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

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

DR. WEISMAN: No, I didn’t suggest that.

I actually meant what you just said.

DR. CLANCY: Okay.

DR. WEISMAN: Just for clarity.
DR. CLANCY: All right.

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

DR. CLANCY: Yes. Yes.

DR. WEISMAN: Okay, that’s what I meant.

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

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

DR. WEISMAN: I had one more --

CHAIRMAN WASHINGTON: Harlan, we’re going
to need to rotate around.

DR. WEISMAN: Okay.

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

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

DR. GOERTZ: Absolutely, and just to
quickly answer your second question about can we
reach down and fund more than 40? I think at the
last at least two Board meetings, we have discussed
the possibility that the Selection or Balancing
Committee may come back to the Board with a
recommendation that would have more or less than
40, but we were thinking it might be more than 40
based on the fact that we had so many applications
submitted. And so, that’s always been something that we hope -- I don't think we’ve ever had a vote, but nobody ever said no when that concept was presented, and so, I think we’re moving forward with the belief that that would be acceptable to the Board if we ended up with more than 40 applications or less than 40 applications for that matter based on priority scores and other considerations, but mostly priority scores.

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

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

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

DR. GOERTZ: No, I think it was actually more in the other direction that we were interested in, in new investigators and considering who might be new investigators or -- again, we really -- when we put out this program announcement, we were very
interested in attracting non-traditional investigators, and so, if we were looking at that, it would be looking at more, and the way that we’re operationally defining seniority of the PIs whether somebody has been the principal investigator of a federal grant or not. And, again, I don’t see this so much as divvying it up, but, perhaps if we’re trying to make a decision between two applications where all the other criteria are the same; we might consider someone who is more of a junior investigator.

CHAIRMAN WASHINGTON: Okay, Norquist. I’m just going to start calling last names. Then Krumholtz.

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

[Laughter.]

DR. NORQUIST: But let me just say you’re kidding yourself if you don’t think this goes on all the time at NIH. I spent 15 years at NIH and
what happens is you get the scores in from the review groups, the divisions sit there and they go over all this and they have project officers how help them try to figure out what the balance is and what to do and then they go to the council, which is like this Board, and they say here are the scores, here’s what we’ve done, we’ve looked at this, this one is way out of line, but it’s so interesting, we really want to pick this up. And then, you have council members kind of divvy around and say oh, no, you shouldn’t fund this, we want you to fund that, this kind of thing, and that’s all done closed because you cannot expose these individual grantees and the issues about their grants and other stuff to the public, and everybody understands that.

Then it comes back, the director makes the final decision after Dr. Collins or the Congress gives them money enough to do it and then they make certain decisions about what to fund and then later, they’ll say there was a lot of good stuff that we missed, let’s come out with a targeted
announcement in this area and pick this up.

So, what I think this group is going to do is basically we’re going to look at this. We’re not going to go out of control and say, oh, we don’t think anything that these review groups did is any good and we’re going to pick this. We’re going to look for the things that are way out there. We should learn. I absolutely agree with Carolyn, one of the things we should learn if you believe that review processes are prefect, no offense, Dr. Collins, but it’s human behavior, they just don’t actually work -- I mean, always well. I’ve sat in on many of these and things happen and groups get a little out of control and stuff, and, so, you have to be prepared for that and you have to look across. In general, they do a very good job as best they can because when people complain about them, I always say they are us, because we’re the ones sitting there and doing it. So, it’s us at fault sometimes.

So, I think what we will do, I hope, the committee actually hasn’t met as a group yet, which
we’re going to do tonight actually after the talk to start talking about this is we will come up with in some sense about how to look at these applications, we will present them to you the ones with some evidence of where we think we would go down to a funding line, it’ll make your job a lot easier than looking at the 400 applications that were actually scored.

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

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

DR. KRUMHOLTZ: Thanks, Harlan Krumholz.

To me, I think it’s important to think about what this means in terms of our strategy and if we are emphasizing this transparency, to the degree to which you can pre-specify what it is you’re doing and how you’re waiting, I think, will
go a long way because what you really want to do is promote the idea of fairness.

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

The second thing is that if we’re true to what we’re about, then we really need to be giving disproportionate credit to those who have truly
engaged patients and caregivers in their conception
and in operations of their proposals.

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

It is a pilot grant, after all, we’re
going to learn a lot, it’s going to help us in the
next step and we’re going to have confidence in
what you do because we know how seriously you’re
taking it, but these are just some of the potential
issues, I think.

DR. GOERTZ: Thank you.

CHAIRMAN WASHINGTON: Thank you,

Krumholtz.

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

DR. GOERTZ: Absolutely. Next slide.

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

Then, if I could turn this over to Gail,
to just really briefly to talk about some of the
ways that we’re reviewing our peer review
experience because this is our first time out of
the box, we wanted to make sure that we were
capturing some information about it in a number of
different ways.

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

We also had 10 randomly-selected reviews
where we had people from PCORI go in as observers
and essentially observe the process of the NIH
review to get an idea of how, for example, the
patient and stakeholder person was a part of that
actual review. And now we’ve gotten the data on
preliminary and final scores for the applications,
including information on the six PCORI review
criteria, and as we’ve just spent an inordinate amount of time talking about it, we will use that as the primary cut point for our decisions based on the Selection Committee.

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

CHAIRMAN WASHINGTON: Sigal has a comment or question.

DR. SIGAL: Ellen Sigal. Gail, I’d be
specifically interested in the survey and whether you targeted a separate survey for the patient groups that were involved and the patient reviewers because, often, they can be marginalized and whether this was just sent out to all the reviewers or whether you targeted the patient reviewers.

MS. HUNT: Christine, will --

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

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

MS. HOLE-CURRY: Leah Hole-Curry, Board
Thanks, this is great. So, an observation and a question. My observation is it’s very hard for organizations to be learning organizations if someone isn't operationalizing that component. So, looking at Joe, I would ask that we consider a staff member that specific responsibility is continuous quality improvement, learning organization, whatever it is. I know just in terms of the PDC meetings and listening to you all and how hard it was to incorporate this evaluation in, even though we have said at each Board meeting how important this is to learn from, how hard that has been to do. So, if this is important to us, I sincerely think that we have to consider making that an operational responsibility somewhere.

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

DR. GOERTZ: There will definitely be an
evaluation reported. When we first started talking about the Pilot Projects Program, we said that one way that it was going to be a pilot project was to find out what all the learning experiences were going to be along the way and there have been very many, and so, we have been compiling those, and so, part of that will be the data that we get from the surveys and from the observational studies that we did during the review process. So, absolutely, that will be coming back to the Board.

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

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

MS. HOLE-CURRY: Right.
DR. GOERTZ: That we’ll want to make sure that we consider as we’re moving forward.

MS. HOLE-CURRY: Great, thank you.

CHAIRMAN WASHINGTON: Douma and then Normand.

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

MS. HUNT: Yes, I think that we’ll definitely have those things, we’ll want that to get out the staff, for example, who are in the process of developing what the review process will be for these grants, the RFPs that are going out in mid-May.
DR. DOUMA: Yes, just again reinforce it by getting some dates on it. Dates are magical when it comes to getting things done.

DR. GOERTZ: We will do that.

CHAIRMAN WASHINGTON: Normand?

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

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

And so, I don't know if there's a process in place to select who’s going to serve a two-year term on the PCORI, this, that, and the other thing. And just like we talked about PCORI scholars, I
think it’s also good to get in place some committees that are the PCORI committees.

CHAIRMAN WASHINGTON: Okay, that’s an excellent thought. Okay, Selby.

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

Your idea though is a brilliant one. The notion of a standing study section, I think there has been some question about whether we would continue working with the Center for Scientific Review over time and sort of establishing a standing study section if we do it with the CSR next time, would kind of imply that we were going to continue with them. But I think we really need to get moving on that quickly. I love the idea because it’s going to be critical to introduce
PCORI’s unique review criteria and they're going to be more of them next time than there were this last time, to all reviewers and then we can evaluate whether they are able to apply those criteria.

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

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

DR. GOERTZ: Yes, thank you.

CHAIRMAN WASHINGTON: Okay, thank you.

Great work.
Rick, just a time check, we’ve got a little under 40 minutes. I know you have two topics, so, keep that in mind.

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

[Laughter.]

DR. GOERTZ: I did not.

[Laughter.]

DR. KUNTZ: So, we’re moving on now to the public comment process and timeline for what we’re doing for the National Priorities in Research Agenda, and I want to bifurcate the two discussions. The discussion we’ll have here is about what the PDC is doing about the process for incorporating comments, and we want to make sure that everybody is aware, the public, that we take all of the comments that are solicited through a variety of different vehicles very, very seriously and we want to outline some of the processes that
we’re doing to demonstrate our accountability in processing these comments into the final shape of the NP and the RA going forward.

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

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

We will then move on to number two, which is the suitability of the themes to determine whether the themes really fit PCORI’s mission and also our evolving vision statement. That will have
a deadline of March 27th.

Number three will be --

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

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

DR. WEISMAN: And so, what you’re calling outliers, those would be publicly open, not
identifying the individual, but identifying the --

DR. KUNTZ: That’s correct.

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

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

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

DR. KUNTZ: Then moving on to the third component, which will be performed by the staff and I’ll talk about how this is done and how all members of the Board can engage in these processes.
Will be to conduct the initial evaluations of these processes and evaluate the impact of the changes based on the themes that we are developing for the National Priorities and Research Agenda and for the overall PCORI mission. So, this will be the processing component.

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

We will then have a voting conference to reach consensus on recommendations. This will be a separate meeting two days later at the PDC on a face-to-face meeting that we have scheduled April 11th to drive the kind of language we want to put
in for the recommendations overall and then on
April 17th, we will solicit the recommendations to
the Board in an open meeting being planning on the
17th.

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

VICE CHAIRMAN LIPSTEIN: Yes, I would, and
just one comment. The asterisks here are really
important because one of the things we’ve been
trying to do is when we get into Board meetings not
rehash what the committees have already done, and
one of the best ways to do that is to allow Board
members and Methodology Committee members to participate in each of these steps so that you feel like your voice was heard before we get to the next Board meeting.

Harlan, did you want to weigh in now? The other Harlan. I didn’t mean that. Harlan Krumholz.

DR. KRUMHOLZ: Thanks, Harlan Krumholz.

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

What is important, I think for those who are thinking about commenting in the last 10 days
is that we’re not looking so much for individuals
to come forth and to promote their own singular
cause as we are trying to get them to reflect back
on the general overall themes and importance of the
kind of work that PCORI’s capable of doing and
helping inform us with respect to those activities
that we may pursue. So, as we look through and
distill the comments that we’ve gotten, we’re not
looking to actually tabulate votes around whether
or not one cause got more votes than another, but
we’re looking to try to understand how are people
trying to help us position ourselves in the best
way possible that will allow us to support
activities that will produce knowledge that will
have meaningful importance to patients.

And so, there are some important decisions
that the PCORI Board has to make in putting forth
agenda and priorities that are very germane to
that, how we should be spending our time, how we
should be devoting our money so that we can ensure
that we are being positively and constructively
disruptive to the current research architecture and
that we are generating a way of doing work and a
way of incorporating input and a way of producing
knowledge that’s different than what has been
traditionally done.

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

DR. GABRIEL: Sherine Gabriel, Methodology Committee.

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

Likewise, as we’re moving forward our recommendations, we’ve developed a preliminary voting process of voting, a process to reach consensus regarding our recommendation for methodologic standards and then, of course, the public comment period for the Methodology Report. So, I’m just making a suggestion that we kind of connect the dots and particularly get the staff working on all of these processes, talking to one
another so that we’re not reinventing the wheel internally and unnecessarily.

CHAIRMAN WASHINGTON: Weisman.

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

Harlan, pretend for a second -- I don't think this would happen, but pretend for a second that people said you know what, we’ve heard your vision of the future, we’ve heard your new way of doing research, but, actually, we’d like the approach that’s been standard in the past and what we’re really hoping is that PCORI would pick up from what the IOM left off with their specified 100. Pick the top five that decide on and run with it. And let’s say that that was if not a vast majority, a large plurality, what would we do with
DR. KRUMHOLZ: Oh, I think we’d listen very carefully to what people are saying, we’d try to understand the perspective that they’re bringing to it. It would be up to us, I think, to reflect on where we can make our greatest impact and to understand whether we, even in the course of soliciting input for our priorities and agenda, have been able to frame the possibility that wisdom resides outside of the Institute of Medicine. That, in fact, throughout the entire country, there may be people facing challenges that were unable to sort of bubble up to that esteemed group that met that set those priorities and that what might be most important is that we construct teams where patients and caregivers have a fundamental, important, substantive role in influencing the design, implementation, and dissemination of research.

And that, those teams are also including researchers and clinicians and others who might be involved and that we at least are given a chance,
and I’m just promoting this as my view, that we’re at least given a chance to say that we could construct a world in which that becomes standard operating procedure. I believe the IOM put together their report thinking about conventional research, in thinking about the usual way that things are done.

Now, they did point to important content areas, and I very much hope that when we open applications that people will pay attention to those content areas and if they can pull together the right teams and if they can ask the right questions and if they can show us that within three to five years, they can produce important knowledge, I guarantee that we will pay a lot of attention to those content areas, but that that’s only facet of what we’re trying to do and what I’ve reflected on in the pilot grants is by opening it up to a broader range rather than just circumscribing it, people reflected back to us that the process of applying changed their view about how research might be done and brought together
people who wouldn’t otherwise be talking to each other and I’m worried if we circumscribe too much or if we kowtow too much to prior efforts that may not have had this in their mind when they developed their priorities, then we will be losing an opportunity to help set a new approach to the way in which knowledge is generated.

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

Again, I’m playing devil’s advocate.

DR. KRUMHOLZ: I think it’s up to the Board to reflect.

CHAIRMAN WASHINGTON: Steve.

VICE CHAIRMAN LIPSTEIN: I want to answer that one for you, Harlan. I think, Harlan, your construct is a little bit incomplete in that what likely happens, what, in fact, does happen is you will have a group of people who will say we should pick up where the IOM left off and follow their guidance and you will have an equal number of
people who will say just the opposite, who will say
we should start fresh, we should take into account
what they did, but we should also solicit
perspectives that go well beyond the Institute of
Medicine.

The same exact thing actually happened
when we issued our National Priorities. Some
people said that they weren't specific enough and
some people thought they were perfectly on target
or too general or appropriately general, and so,
what I think our Board is going to need to do isn't
to accept or reject, but it’s going to be to listen
to all the input we get, and so, if somebody, for
example, said our National Priorities weren't
specific enough, what we say to that person is
we’re also listening to that other voice which says
that they were appropriately broad and general so
as to incorporate lots of input and lots of ideas
and lots of perspectives. Not that we’re ignoring
or discarding the people who wanted us to be more
specific, but that we were also listening to other
people.
I think in your example, yes, we would listen to the people who would advocate for our following on with the IOM, but we are going to hear other voices, too, and then the role of our Board of Governors is to hear all of those voices and to use our best judgment.

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

So, Rick?

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

I just want to show you two slides of these kind of scorecards, which we will all be looking at, at both it’s a complete view of the comments, as well as a summary of where those
categories are to address these issues we just talked about how we can be aligned on them. And so, a scorecard like this will indicate what themes are rising from the stakeholder groups, which stakeholder groups, whether or not they occurred in time, following a specific event, for example. Did they originate in certain parts of the country, and we’ll start to get more of the dimensions and metrics associated with where these comments come from, the magnitude of the comments, the magnitude of the themes, and so on.

The next one is a dashboard which can be drilled down to show the individual comments that are made that contribute to the overall themes seen in the summary comments going forward. I think we want to let the staff with their expertise have a lot of latitude to develop the scorecards. These are experts in the areas in processing this information. I think it’ll be very, very valuable for us as we go through the process of understanding what is a public comment and how are
we going to process it? But I also just want to
reiterate the theme that PCORI takes very seriously
all the public comment we’re eliciting and we will
try to process it to the best of our ability in a
transparent way, but also meets our timelines.
It’s really critical that we get these timelines
out, that we process our National Priorities and
Research Agendas so that we can process a PCORI
funding announcement by mid-May.

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

So, like I said, we are still geared for a
mid-May release. The PFAs will definitely solicit,
the solicitations will be based on the response
about the National Priorities and Research Agenda, as I said, it was baked in, and I had to just step back a second and say that this is a very exciting moment for us. We have really been evolving over the last year-and-a-half, we have established our first set of National Priorities and Research Agendas, we are getting enthusiastic response back from the public about these comments, we have actual timelines and processes to process these programs, and we are still on track to send out our first PFAs, which is really the first publicly-processed PFAs going forward in addition to the accomplishments we’ve made in the PCORI Pilot Project Grants.

This is just a high-level overview of the Gantt chart associated with how the staff will help us drive the processes to get these announcements out by mid-May. We reviewed earlier in Joe’s presentation the five priorities that we’ve aligned on for National Priorities to link up with PFAs with. The first four priorities will be focused on PFAs that will be generated by May 15th and the
fifth priority, which deals more about the infrastructure research and the definitions of PCOR, which has a heavy component of the Methodology Committee, will come out a month or two after that going forward.

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

A little bit more detail about the plans for priorities one through four and this shows that we are still in the process of hiring our research
scientists. I’ll show you a little bit more detail in the next slide. We are going to use CROs and we’re in the process of getting a few on board. We have an open competition that’s very transparent and our applications are leaning towards using the Center for Scientific Review. We had a very, very good experience, I think, in general with the PCORI Pilot Project Grants and at this stage, this seems to be how we will be leading in the first round of our PFAs to use CSR for the review process. And, again, all of these applications will be branded and really administered by PCORI, by both the staff and also the Board of Governors and Methodology Committee.

Here’s an overview of the engagement of the Board and the staff with the priorities and you can see the principal Board and the Methodology Committee members who are associated with each of the five priorities. We do have a lot of opportunity for more Board members here to help participate, especially in the areas of the first, third, and fourth National Priorities. So, I would
encourage individuals if you have time and have an interest to sign-up and to start to get engaged in the process of developing these PFAs going forward. And, with that, I think we want to expand a little bit more on priority number five. Again, this is bifurcated into -- we initially called this Accelerating PCOR and Methodological Research. It really is about the Methodology Committee and their efforts to really establish CER and PCOR methods, and we’ll hear more about that as the report comes out over the next month or so. And, in addition, this subsumes the data infrastructure that we had talked about earlier, that is the IT issues are linked with existing and new databases and the potentials for developing network systems going forward.

So, with that, I’ll turn it over to Dr. Goertz.

DR. GOERTZ: Thank you, Christine Goertz.

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

DR. DOUMA: Yes, Allen Douma, Board
member. Just it may be a semantic issue, but we’re always in such a hurry that I want to make sure we didn’t miss it, and it may be semantic in the sense that you have a draft Board PFAs and the Gantt chart, end of April, they’re done. You also have finalized PFAs, end of April, they’re done. Is that simply the finalized PFA as part of the drafting process?

DR. KUNTZ: Yes.

DR. DOUMA: Okay, so, it’s at some point –

DR. KUNTZ: Absolutely, yes.

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

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

DR. DOUMA: Okay.

DR. KUNTZ: Thanks for pointing that out.

CHAIRMAN WASHINGTON: Lipstein.

Joe Selby, can you go back a slide? Whoever had the slide, clicker. That one.
If you want to be on one of those groups that Rick just invited us, who do you call? I mean, do I call Mike Lauer or Carolyn or Gray or Arnie or Harlan or who do I call?

DR. EPSTEIN: Can’t you just call everybody?

[Laughter.]

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

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

VICE CHAIRMAN LIPSTEIN: Melissa Stern, thank you.

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

CHAIRMAN WASHINGTON: Okay, Christine and we have public comment in 45 minutes, so, this is points of clarification before we move on. In 15 minutes, that’s right. Okay, so -- [off microphone] -- Barksdale.

DR. NORMAND: Sharon-Lise Normand,
Methodology Committee.

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

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

DR. NORMAND: Yes.

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

DR. NORMAND: Okay.

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

CHAIRMAN WASHINGTON: Weisman.

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

And I think there's substantive issues in
some of this and I’m uncomfortable with some of it
and we don’t have time now to discuss it, so --

CHAIRMAN WASHINGTON: Okay.

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

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

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

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

CHAIRMAN WASHINGTON: Okay, Goertz.

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

So, as Rick had said, that priority number
five is we’re really envisioning it as being divided into two separate areas. One is the CSR methods and the other is something that we’re calling Clinical Research Data Infrastructure. And since we’re calling this out because the process that we’re proposing for this one is just a little different than the process for the others and that the program announcement would be written by PCORI’s staff and assisted by AHRQ, NIH staff, and the Methodology Committee. And this would be a separate funding announcement from that, from the analytic method. So, I think with the other priorities, we’re looking at one funding announcement, at least in this initial round. With this one, there would actually be two funding announcements.

And the solicitation and review process for this particular effort would be managed by both AHRQ and NIH through contracts from PCORI to both of those organizations. We are looking at this more of a focused competition with clear data and governance requirements, including engagement of
relevant stakeholders. So, as we know with the Pilot Projects Program, that was a rather general announcement; we anticipate that this to be a much more specific type of announcement and that the funding would be through a cooperative agreement mechanism which means that PCORI’s staff and AHRQ and NIH staff would have substantial involvement in the research as it moved forward, as is normal with cooperative agreements.

Can I have the next slide, please?

The rationale for contracting with these federal agencies for this particular initiative is really a multi-folded. First of all, they have years of experience in this particular area that we feel will be really invaluable when it comes to writing this particular funding announcement. They also have a much better idea of the gaps and opportunities in this particular area of science which allows our program announcement to really be specifically targeted towards those gaps and opportunities. We also have a current knowledge of the state of the science based on work that they
have funded and are continuing to fund in this particular area so that we are making sure that the work that we do here really does fill a gap that exists.

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

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

Next slide. Then the second RFA for this, again, would be in close collaboration with the Methodology Committee. We still see AHRQ and NIH
having substantial involvement in this particular initiative. We see this one as being more targeted than priorities one and four, but probably not quite as targeted as that for the research data infrastructure and it's not as clear that this would be a cooperative agreement though, again, depending on how it finally gets conceptualized, it certainly could be.

I’d be happy to answer any questions.

CHAIRMAN WASHINGTON: I have Weisman first and then Lipstein.

DR. WEISMAN: There's another federal agency that's involved in this and that's the Food and Drug Administration, and they also have efforts in this regard of databases, data analytics, comparative effectiveness, and I'm not suggesting that we complicate things with cooperative agreements, but I've been asked the question and I don't really know the answer about how do we formally engage FDA in thinking about this because they certainly, not sponsor, but encourage this kind of research and are highly influential in this
regard and it would be nice to think that we could get aligned with them, as well.

VICE CHAIRMAN LIPSTEIN: Steve Lipstein.

I want to first make a comment as Vice Chair and then make a comment as my stakeholder representative, representing hospitals and health systems.

As Vice Chair, I think it’s really important as we go into this next stage of work that since a lot of the work that we’re describing has been assigned to the Program Development Committee and the Methodology Committee that so we don’t get to May with the Board being uncomfortable with the process or the opportunities for input. We really have to figure out a way for those that are on the other committees, either the Finance and Administration Committee or on the Communications Outreach and Engagement Committee, to participate in this process before the next Board meeting. In other words, we otherwise will just rehash a lot of work that’s taken place, a lot of important works. So, we have to incorporate that involvement between
now and then. So, that’s my vice chair comment.

My stakeholder comment is --

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

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

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

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

CHAIRMAN WASHINGTON: [Off microphone.]

VICE CHAIRMAN LIPSTEIN: Never mind.

Never mind.

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

Okay.

DR. DOUMA: Yes, I just want to comment based on two colleagues who are, your organizations AHRQ and NIH are just tremendous and your abilities are tremendous, but I think it’s important that we don’t sort of go down the slippery slope in which we lose our identity because of the work we do with you guys and building on what Harlan Krumholz has
been saying, we need to figure out how we are
different, even when we’re doing cooperative
agreements, and it’s easy not to do that
particularly in the timeframe that we’re in.

CHAIRMAN WASHINGTON: So noted. Okay.

DR. ZWOLAK: Bob Zwolak, Board member.

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

DR. SELBY: A couple of things. First, I
think the FAC is keeping up with us on this. Some
of this is fluid; some of this it has to be said
awaits the comments on the National Priorities and
the Research Agenda itself. So, that’s why we’re
anxious to get those comments analyzed and have
that input by April 15th. If we say we’re issuing
funding announcements in mid-May, they need to be
based on the revised agenda and priorities, no
doubt. But I think, as you’ll hear shortly, the
FAC is doing some heavy lifting on thinking about
spending.

CHAIRMANK WASHINGTON: Okay.

DR. COLLINS: Francis Collins, Board
member.

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

And with regard to Allen Douma, I totally
agree with you that while I think NIH and AHRQ can
bring some capabilities to these different RFAs or
PFAs for the fifth priority here, we very much want
to incorporate into that the PCORI view of patient-
centeredness. That’ll be good experience for
everybody. I think it is true that the statute
encourages this kind of collaboration and I think
we can through the process of that collaboration
actually get more done than any of the three
organizations could do by themselves, and in a way,
that’s really a good thing for the taxpayers to
see, that we are willing to roll up our sleeves and
work together. And, certainly, speaking for NIH,
and I’m sure Carolyn would say the same for AHRQ,
that’s entirely our intention.

DR. CLANCY: Ditto.

CHAIRMAN WASHINGTON: Thank you. So,

we’re going to move to wrap-up.

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

DR. CLANCY: Great. So, you’ll recall the
Dissemination Workgroup actually made its initial
kind of stage setting presentation at the last
Board meeting in Jacksonville. The members of the
committee, a really fantastic group, I just have to
say, are shown on this slide, and you may recall that one of the proposals we made at the last Board meeting was that starting with the initial funding announcements, that we would include some dissemination accelerating components. I will be totally honest and say when I did my part, we had no idea what that meant. So, what we are showing you today for the first time is version 1.0. This will not be your last time to comment on it, but I just wanted to show you we started down the path of developing a checklist. This has not even been extensively vetted within the workgroup just because of the timeframe coming up to this Board meeting, but we do have a particular sense of urgency about it.

The other thing I will just make a comment on, which is separate; is that a number of you had comments about how AHRQ makes investments and I was trying to explain that we have an approval process that we need to go through with the administration and so forth. And so, on April 13th -- I just confirmed this with Sharon, at the next meeting of
AHRQ’s National Advisory Council, in the afternoon, and you’ll all get information about it and the meetings are webcast, so you can tune in if you’re interested, we will be presenting in a public session all about the investments that AHRQ is making thus far with our 16 percent that comes directly to AHRQ.

So, next slide, please.

UNIDENTIFIED SPEAKER: [Off microphone.]

Everybody is asking me who Howard Holland is.

DR. CLANCY: Who is Howard Holland?

Howard Holland directs the Office of Communication and Knowledge Transfer at AHRQ and you may recall that that office is explicitly mentioned in the legislation, however, dissemination is not just limited to his office, but if you ever meet him, you won't want to deal with Gene or me again. He's a wonderful, wonderful guy.

UNIDENTIFIED SPEAKER: [Off microphone.]

Speak for yourself.

[Laughter.]

DR. CLANCY: Well, I will speak for
myself.

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

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

So, here are the specific ideas that we
thought would be included. The first is to identify the stakeholders: patients, caregivers, clinicians, communities, policymakers, and institutions relevant to your proposed study. A second relates to engagement. Describe at which points in your proposed study stakeholders will be engaged. Some people think engagement is a once-a-year meeting, other people think it’s weekly calls or meetings. It’s kind of important to know what people have in mind.

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

And the fourth area here talks about a governance plan. How will you develop a plan for
the project that articulates specific role and responsibilities for the research team, stakeholder groups, and defines rules for decision-making, especially in the context of different opinions.

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

I can know I need to take an inhaler. If I don’t know how to use an inhaler, I don’t get the benefit. Similarly, if we’re funding studies that would require fairly complicated changes in
practice or how health care is delivered, we think it’s very important that the team is thinking about that from day one, when they get their check. So, again, this will not be your last opportunity to comment, but we wanted to get this in front of you because we feel pretty urgent about getting something like this, more specificity into these initial announcements.

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

CHAIRMAN WASHINGTON: Anything to add?

DR. LEVINE: No, I don’t. I think she did a great job.

CHAIRMAN WASHINGTON: Okay.

DR. LEVINE: Thank you.

CHAIRMAN WASHINGTON: Please move to wrap-up.

DR. KUNTZ: Sure. That’s our last slide,
and, again, in respect of time here, I’ll be very brief.

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

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

And I just think, final comment, I know there are concerns about going through some of
these slides very quickly and I think we had to have a process to get everybody’s views on this. But, in general, I think we have to start to let go of some of the operations associated with what we’re doing and get more trust into the staff who are actually trying to deal with the processes going forward.

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

CHAIRMAN WASHINGTON: Thank you, Rick, and to other members of the committee who presented and thanks to the entire group for just a Herculean effort. It’s a quite a bit here, which is one of
the reasons where is such stimulating discussion  
and we didn’t get to complete the discussion.  

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

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

   MR. SCHMITZ: Thank you, Dr. Washington.  
I want to start by reminding those participating by  
webcast that there's a teleconference number that
you can dial into if you would like to provide comment and that is provided on the website. We will hear first today from individuals who are in-person and then we will check to see if there is anyone by teleconference who wants to provide comment. I want to remind everyone that individuals are asked to limit their remarks to three minutes. We’ll use the standing microphone for the public comments. If there’s anyone that has a disability that would like to provide comment where they’re sitting, we will bring a handheld mike to you upon request. Any written testimony should be submitted to PCORI by e-mail at info@PCORI.org.

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

MR. KIMMEL: Good morning.

CHAIRMAN WASHINGTON: Good morning.

MR. KIMMEL: I’m Larry Kimmel and I’m here on behalf of Hopewell Cancer Support, a Baltimore-based non-profit, whose mission is to create a community for all people with cancer, their
families, friends, that encourages an exchange of information, the development of support systems, and hopefully in a setting of hope.

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

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

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

Since 1993, more than 9,000 individuals
have accounted for more than 90,000 visits to Hopewell, where through varied programs, lead all by certified social workers, people with cancer in their families learn about excess treatment for, cope with, recover from, and live with cancer. Though people who have cancer have opportunities every time they visit Hopewell to learn from each other, there is a program there called House Call Educational Series, and this is when health care professionals, largely oncology physicians, will come and interface with patients, participants at Hopewell over a period of time, and since January of 2010, we’ve had well over 100 professionals participate in this program. And the long and the short of it is that this changes the whole character of decision-making for participants and also for the professionals who come and participate in Hopewell. It’s a wonderful collegial kind of experience and it really does for Hopewell patients, if you want to call them that, they become participants in the process of making decisions and knowing where it is that they would
like to go and be.

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

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

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

MR. COELHO: Hi, I’m Tony Coelho and the chairman of the Partnership to Improve Patient Care, also known as PIPC. I’m pleased to hear today that PCORI is striving to identify a transparent, open process. What is most important to us is that PCORI is responsive to the stakeholder input you receive particularly from
patients. We are hopeful that the process you are articulating today will meet that goal. I think you all know that PIPC has concerns with the Board’s draft Priorities and Research Agenda, which I’ll touch on in my comments.

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

The statute envisioned a process that is guided by and responsive to stakeholders with you as a stakeholder Board bringing the views and concerns of your representative group. The statute specifically authorized additional resources to support the patient representatives on the Board as well as the expert advisory panels to assist in identifying research priorities and the Research Agenda. These elements make PCORI fundamentally different because the priorities and subsequent agenda are to be developed in this stakeholder
dialogue. On that note, PIPC appreciated that the Board held its recent stakeholder dialogue in Washington, a process we hope you will continue in the future.

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

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

PIPC stands ready to assist you in any way we can, and our members look forward to participating in the process articulated by PCORI to identify research priorities and a Research Agenda. I want to congratulate your new staff and let them know that we look forward to looking
closely with them in this endeavor, and, as always, I thank you for your important work.

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

MR. SCHMITZ: Yes, our third public comment is Paul Zimmet of Parkinson’s Disease Foundation.

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

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

Last Monday, I had the opportunity to attend the all-day national meeting in Washington, D.C. Prior to attending the meeting, I studied the
mission of this organization and reviewed the Draft National Research Priorities, and after doing this, I’d like to offer two points of commentary, both of which center on the issue of clarity.

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

Second, it’s been made clear to me that PCORI will remain patient-centered. The organization has been struggling since its inception on how to both defines, as well as, plans to lead in the area of patient involvement. A good first step is to be sure the differences between
patient-centered and patient involvement is clearly understood and articulated and incorporated in all of PCORI’s work.

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

A central piece of the program is multi-
day learning institute and I’m sure a PCORI representative would be welcome to attend one of these trainings, one of which starts Wednesday in Atlanta.

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

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

MR. SCHMITZ: Brian Lyles, People’s
MR. LYLES: Good morning. I’d like to join all of the other Baltimore-based organizations in welcoming you to Baltimore. I represent People’s Community Health Centers, which is based here in Baltimore.

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

In fact, we provide more uninsured patients with primary health care than any other
institution in the State of Maryland. We’d like you to know that community-based organizations like ours represent an opportunity to interact with professionals who work with special populations and real-life concerns on a daily basis. We know our community of patients, dedicated staff, institutional partners combined with our years of hands-on experience and people-centered health care could play in a valuable role in PCORI-sponsored research projects and we look forward to the opportunity to work with you not only to find solutions, but to help in this early stage in generating the questions that need answers regarding the delivery of services, workforce development issues, reimbursements, and cost management that, again, we deal with on a daily basis. Thank you.

CHAIRMAN WASHINGTON: Thank you, Mr. Lyles.

MR. SCHMITZ: That’s all of the preregistered commenters for the 11:00 a.m. period. So, I wanted to check with the teleconference
operator, Debbie, to see if there's anyone on the phone who wants to provide comment.

OPERATOR: There are no comments in the cue.

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

CHAIRMAN WASHINGTON: Yes. Yes, please.

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

But I wanted to talk a little bit about the clinical research infrastructure, which I know you must have thought of this, but nobody mentioned it, so, I’ll mention it. The Office of the National Coordinator for Health Information Technology is doing a lot of work in that area. So, interoperable data exchange standards and the like and including -- but these are mostly organized on a regional basis with a major medical center as a core. And I would like to put in a
pitch for also considering the patient and
scientific point of view which would organize the
whole data system, the whole national data system
along a specialty disease-oriented focus, which has
a lot of advantages. Not only does all the science
and the professions organize that way already, we
also have the patient advocacy groups and you need
the specialization to use the specialization for
developing new treatments and scientific
innovation.

So, Carolyn Clancy asked me to write up
some of the comments that I gave on Monday, which I
will do, and I wanted to add one more point, and
that is on the grant announcements that you
considered, on review, the pilot grants, have you
considered if you have a lot of meritorious
proposals, which I expect you will have out of 800
that have been submitted, maybe more than 40, if
it’s an area of strategic importance that you could
add money to the pot to pick up those strategic --
so we don’t have to wait for another grant process
and take into consideration the people who are
writing these grants. It’s not easy.

So, that’s my comment. Thank you.

CHAIRMAN WASHINGTON: Thank you, Mr. Cohen.

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

I spent 30 years in the federal government in health policy and health services research, including a few years at AHRQ. In August of 2008, I had a sudden onset of flu-like symptoms that never went away. After seven frustrating months of having doctors telling me they didn’t know what wrong with me or I wasn’t tired enough to have CFS, I finally found a physician with expertise in CFS, who determined that I had seven of the eight symptoms that is established by the CDC. My illness significantly affected my personal and
professional lives. I was no longer able to travel for business, needed to work at home on a regular basis, and really had no ability to do after-work activities. I was relieved to be able to retire from the government in June of 2011.

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

The CFIDS Association is focused on research and has established a bio bank and research institute Without Walls, a virtual network of CFS researchers, some funded through our organization.
We are working to find a biomarker and effective treatments for this debilitating illness. Yet, there is much more that needs to be done. We believe that PCORI can make an important investment in two of our National Priorities by working with the CFS patient and provider communities.

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

Second, communications and dissemination. These patients and families want to and must be part of their own treatment plans if they're going to improve. Working with CFS patients and families could serve as a model for engagement with other patients with chronic illnesses.
In both of these areas, lessons learned with the CFS patient and provider communities can be applied to other chronically ill patient populations. Thank you and we look forward to working with you.

CHAIRMAN WASHINGTON: Thank you, Ms. Williams.

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

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

It’s now 11:30 and I realized that we’ve had a long morning with no break, and so, we are scheduled right now for a 15-minute break. I don’t
see where we’re going to have another time to come back to this on the agenda, but what I want to ask, are there other Board members besides Harlan who at this point have concerns because I take a presentation like that to mean this is the direction that the group is proposing to go and our general protocol has been it’s a general green light, proceed, and we’ll incorporate suggestions, comments, and we’ll address concerns, and that’s the way I’ve interpreted this discussion, that there is general agreement. But I want to be responsive to Dr. Weisman’s concerns and I want to arrange for those to be heard, one being a public setting, given the rest of the agenda, particularly to the leadership with Rick and Joe and with me. Unless we have some time later on today, I just know that there are a host of really tough issues that we’re going to be dealing with, and I don’t see -- I thought maybe we’d have some time here. So, are there others? And I’m not putting you on the spot, Harlan, but I’m trying to identify. Okay, so. Okay.
MS. HOLE-CURRY: Leah Hole-Curry, Board member.

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

CHAIRMAN WASHINGTON: Yes, okay.

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

I have tremendous trust and respect, admiration, and I genuinely like everyone on the
Board and on the Methodology Committee and the staff and it’s not a question of that, it’s a question of if we’re being asked to consider and vote or approve of something, I think me, as a board member, I feel an obligation to the people I represent, which is the American public, that I understand enough of the issue at hand that I can provide a vote or give a vote that has adequate thought given to it, and it’s not a reaction or it’s not just because I like somebody, I want to vote for their ideas, it’s because it requires consideration.

I absolutely agree with Rick that we have to delegate operational responsibilities to our staff and to our working groups and to our committees certainly on the tactical issues, but we talked about some things today that are fundamentally about who we are or how we’re going to project who we are going to be and visibly, publicly, and those are things around how we respond to feedback and how we incorporate feedback and, you know, the openness by which we operate.
When it involves that kind of setting strategic direction or it involves philosophical stances, my own view is that that isn't something that the Board delegates, but that's something that the Board considers and in considering it, it has to go beyond the 12 point PowerPoint.

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

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

Well, we have a process has been working.
The aberration here is that we don’t have enough time on this particular topic. So, we have a process. The process has worked up until this moment.

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

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

CHAIRMAN WASHINGTON: Okay. Okay, so, just by process, I’m saying we don’t need a new process, we need a modification that says in situations where there seems to be overwhelming
support for a proposal to move forward, but we haven't allowed sufficient time for a discussion from the perspective of a board member or multiple Board members, what should that next step be?

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

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

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

DR. WEISMAN: I think we’re abrogating some of our responsibility as Board members. The PFA -- the National Priorities and the Research Agenda are the two biggest things right in front of us and there is no thing in May for that, that’s a done deal, and if I’m being asked to approve it, I just feel like I don’t have -- and I’m not saying
it has to be a board discussion, but maybe there has to be more meat or material that if I have specific questions, I can e-mail it to Rick or somebody else, but I just feel like the PowerPoints and the speed by which we went through it and it’s of some importance, this is going to say who we are. I don’t see how my working on a committee solves that problem. Personal opinion again.

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

DR. WEISMAN: Thank you.

CHAIRMAN WASHINGTON: So, I’d like some comments on that as a process proposal.
DR. DOUMA: I always like it when you open up to us being able to call and talk to you. It’s always been elucidating. I would suggest though that minimize or decreasing the amount of phone calls that we could look at two things that are just process variables, that is, perhaps, have more information prior to a board meeting. The decks are really talking points versus explanations and with those explanations, if a committee could add what are you actually looking for the Board to do? Is there a vote? Is there an agreement? What is it you’re looking for us to do?

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

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

DR. SELBY: A couple of things. I just want to say that this process of repairing the funding announcements is going to be a very
concentrated process and I think we will, as we
sink our teeth into it, have and find opportunities
to go buy it with Board members, but one thing, and
you’ll also recall that these funding announcements
are likely to like fairly broad because they’ll be
roughly consistent with our Research Agenda.

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

So, I think that in particular as a multi-
stakeholder Board, you getting to the folks that
are putting these PFAs together, your ideas were
dexample questions. No special considerations, just
they would be in the PFA and they would remind reviewers of the kinds of things under each priority that would be of interest. So, that’s one very specific way, Harlan, for Board members to have input.

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

That’ll minimize my efforts along with Joe
and the particular programmatic leader. And I 
don't think we need to write that, Mr. Barnett, 
anywhere, but that’s what we’re agreeing on as 
procedure.

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

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

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

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

MS. HOLE-CURRY: Please.

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

DR. KUNTZ: Well, first of all, I’m very 
sensitive to all the comments that were made here,
and I think it is a time issue. I think we’re moving at breakneck speed, a lot of decisions being made, and we’re constrained by the time we meet together.

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

CHAIRMAN WASHINGTON: Okay, last word from Douma.

DR. DOUMA: Yes, a quick follow-up on requests. It would be really nice to have a simple place that we could all go to find out where, when, and how to contact or call into the meetings, whether it’s PDC or otherwise. And, also, it’d be great, sometime soon, to have a list of staff and perhaps some of the questions would be addressed to a staff person, but, at this point, other than
sending an e-mail that I guess what it is. I don't have like a staff directory and that would be helpful, as well.

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

[Recess.]

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

MR. BARNETT: Mr. Chair, the best thing about this committee report is that it is going to be an easy one for me, because I don’t have to do any of the heavy lifting. I’m going to turn to Larry Becker and he’s going to present some
information and an action item relating to the Standing Committee on Conflicts of Interests, that he’s been working with very closely and will come up to the table and talk a little bit about the current audit process. Just give the Board a quick update as well as the substance of some conversations with the GAO and their oversight activities. And then, it will be back to Larry to talk, to sort of kick-off that discussion about kind of, big picture cash flow issues and exactly how we are going to approach that, which is particularly important given all of the activity that we’ve just been hearing about, because very, very soon we’re going to have to attach it in time for those funding announcements -- we’re going to have to begin to attach specific dollar amounts to them. And we just want to make sure that we have a pretty clear understanding of what our cash flow strategy is in that regard.

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

MR. BECKER: Thank you very much. This is
Larry Becker, a member of the Board.

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

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

Bernie Lo, from UCSF, has very graciously agreed. Joe had a long conversation with him. I
did as well. He’s agreed to participate and I remember in our very first meeting when we set up the ad hoc committee, his name came up from multiple people around the table as a potential participant. So he’s very graciously agreed to participate. In your package, by the way, you’ve got his CV and I stopped counting at 200 publications. So he has done a fair amount of work in this area.

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

The third person who has agreed to participate is Annette Bar-Cohen. She is in the
Washington, D.C. area. She’s helped, as I understand, has been very gracious with her help around getting some of the members for the -- Christine’s gone, but members for the groups that looked at the grants themselves, to get patient consumers that would participate on those groups. And, she was very thankful to be asked. She was very cautious, very careful about thinking about in terms of time commitment, because she’s got a fair number of things on her plate. But, again, an individual that we think can represent the consumer population. And, again, I don’t think it’s in your package, her CV, but we will get that to you. That came in, I think, Friday night.

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

We’ve asked several people, and in fact, to do this and we’ve been turned down, I believe
three times now. And so, I’ll give you an example. Many of you might know Milt Freudenheim, was somebody that we talked to. He’s retired, except that he’s on contract for the New York Times to right some pieces and he felt that would be a conflict of interest, and so, it’s sort of -- it’s been particularly difficult and what I’m hoping is that by the time we get to our first meeting we would, in fact, be able to find an individual and we have to figure out a way to get this Board to approve that seventh member once we have identified them.

Yes, go ahead.

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

MR. BECKER: So, I went to the staff to get names and maybe I should have gone out to everybody with a letter to say, “Give me whatever
names you can come up with.” I didn’t do that, so that’s on me. But, I guess, from my perspective, we put this out there and I would have hoped people, if they had thoughts they would have come after the last meeting.

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

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

UNIDENTIFIED SPEAKER: At the last Board meeting?

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

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

We went out and we looked for law firms. We looked for university lawyers, we looked at Washington lawyers. We got turned down by Covington, for example, and I asked Covington if they could come up with another Washington law firm
and they looked around and felt that there were all kinds of conflicts, so we did come up with Harris Beach and the individual Karl Sleight. Whose part of that counseled the New York State Ethics Commission, and he’s been involved with various private sectors, as well as, public sector counseling in the area of ethics both legislative and non-legislative in this State of New York.

MR. BARNETT: Just to clarify on that Larry.

MR. BECKER: Yes.

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

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

Yes. Francis.

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

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

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

So, we went through that and that’s in the
guidelines for the committee.

DR. COLLINS: And would this also apply to
when the Board is in conflict in making decisions,
because we are talking about an opportunity in the
not too distant future where the Board is going to
be asked to sign off on the first set of pilot
Projects. How will that play out in terms of
whether or not there are conflicts that need to be acknowledged and disclosed and potentially result in people leaving the room during various conversations? Is that all part of this committee’s role? How are going to handle that question?

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

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

VICE CHAIRMAN LIPSTEIN: But -- Gene, I think Francis is raising a point here, that we need
to come back to and I’ll tell you what it is, is that for example, in the final 40, we haven’t scrubbed those 40 for how many that I submitted personally. And so, we haven’t a process in place that says we’re going to scrub the current Pilot Projects process for conflict of interest, so if there are any that are identified, they get referred to the proper committee.

MR. BECKER: Right.

VICE CHAIRMAN LIPSTEIN: Or included in the proper process. So, I think what Francis is saying, we have to do some of this in real-time. Is that what you were suggesting?

DR. COLLINS: You got it.

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

CHAIRMAN WASHINGTON: Okay. But let’s also keep in mind that first of all, as Board members we are prohibited from applying, one. Two, we were also prohibited from providing any consultation or advice in any form to any member in
your institution. Now, I know Francis asked a
slightly different question, but let’s keep in mind
that we have honored some process up until now and
the implicit assumption Francis, at least, I’m glad
you’re raising it, was that when we got to that
point where you felt it was more of an honor system
that there was a conflict of interest and you
needed to be recused, then you would do that.

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

MR. BARNETT: And Gene, I think
immediately prior to that Board discussion, where
we start to make some of these decisions, we’ll
spend some time reviewing what those conflict of
interest requirements are, so if people need to
make declarations of conflict of recuse themselves
CHAIRMAN WASHINGTON: And going back to your original question Francis, I would see that we could consult this group about their opinions, about this kind of question and issue, given that there’s some real expertise on it.

MR. BECKER: Right.

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

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

So, with that I would -- Allen.

DR. DOUMA: Just to follow-up. I think I understand pretty well when we’re recusing ourselves, when we have some direct relationship to
a research project and funding. My question is, if for example, I’m in the infrastructure building business, which I’m not. But if I were, should I recuse myself when we’re voting on the percentage of our funds that go to infrastructure building?

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

DR. DOUMA: That’s fine with me.

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

VICE CHAIRMAN LIPSTEIN: Oh, I’m sorry.

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

DR. CLANCY: So moved.

MS. HUNT: Second.

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

[No response.]

CHAIRMAN WASHINGTON: All in favor?

[Chorus of ayes.]

CHAIRMAN WASHINGTON: All opposed?

[No response.]

CHAIRMAN WASHINGTON: Okay, so the motion carries.

MR. BECKER: Thank you very much.

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

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

MR. BECKER: Thank you.

CHAIRMAN WASHINGTON: That’s great.

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

CHAIRMAN WASHINGTON: Please carry on, Kerry, Larry.

MR. BARNETT: If I may just make one closing comment. The biggest challenge that we’re going to have with this committee and Larry and I have already talked about this, is it is a committee and it takes time to get people together and so, the biggest concern is that it’s going to be difficult for this committee to be able to very quickly spit out answers to specific questions. Instead, I think there’s going to have to be a more thoughtful iterative process, but over time it will result in sort of case law if you want to think of it that way where we have a greater and developing, and even, evolving understanding of how we’re going
to operate. And I think this committee is just going to play a critical role in that regard.

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

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

And so, as part of that process we have engaged an external auditing firm and sat down and spoke with them, as well as, with GAO. And so, what GAO is going to do is actually review the process of the audit and not necessarily do a direct audit of us. The other to note is that since we really came into creation in September of 2010, what this means is the financial audit
process is going to cover all of 2011 plus that
little tail end of 2010 and then going forward it
will be on an annual basis.

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

What we have decided internally, as an
organization because the early indications are, in
fact, that we will probably not have to adhere to
some of these reporting requirements, is that we
would still have in terms of our own processes and
reporting, essentially adopt the most stringent
criteria that are available, because there is a
little bit of ambiguity around that. But as I said, the preliminary reports that we’re getting from some of our discussions with staff at the OMB is that we probably will not have to adhere to some of these, but it is still, I think internally, we’ve made the decision that we will probably go for the most conservative and stringent approach in terms of our own accounting.

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

And I think that is it.
CHAIRMAN WASHINGTON: Thank you Dr. Beal.

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

DR. DOUMA: I have a question.

CHAIRMAN WASHINGTON: Yes.

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

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

DR. DOUMA: Do you think it is acceptable for us to give the GAO the information we have on March 12th with the provision that we haven’t approved it yet, but it will give them a little
jump on getting their evaluation done? Or do we have to wait until we’ve actually finally approved by the Board?

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

MR. BECKER: Well, I respectfully disagree. And I believe that we have to approve it, because once we approve it, it closes the audit. And therefore, any events of materiality that occur after that closing, goes to the next audit cycle. Until we approve it and close it, other things could enter into there and that could create a problem for GAO or Carolyn’s not sitting here, because I know with NQF, we had exactly that
problem and we ended up with someone from the
government --

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

MR. BECKER: Correct.

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

We’re just talking about an endpoint to
the audit protocol.

MR. BECKER: Yes.

VICE CHAIRMAN LIPSTEIN: I understand.

MR. BARNETT: I think the word is “accept
the audit” as opposed to “approve the audit.”

VICE CHAIRMAN LIPSTEIN: That’s right.

DR. WEISMAN: You know, I’ve served on
boards before and boards do review the audits and
do vote to accept it or not. I mean, there are
things that can come up during an audit, and we,
the Board is responsible for the organization from
that formal sense and whether there are questions
that we have back to the auditors or other things, 
those are things that happen. We want it to be an 
independent process, but also something that we 
accept.

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

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

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

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

DR. BEAL: Mm-hmm.

MR. BARNETT: That’s the magic date.

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

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

DR. WEISMAN: Right.
CHAIRMAN WASHINGTON: Okay, there are two questions. One is what our general policy might be and we can always modify that in terms of delegating the authority in this particular case versus what it would be in this specific case and you’re proposing that in this specific case we delegate the decision-making, officially, to the FAC to essentially approve the audit.

VICE CHAIRMAN LIPSTEIN: Accept the audit.

CHAIRMAN WASHINGTON: Accept the audit, right.

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

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

DR. DOUMA: And let’s just check with the
GAO, that it’s okay with them.

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

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

VICE CHAIRMAN LIPSTEIN: [Off microphone.]

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

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

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

MR. BARNETT: Okay. So then Mr. Chair,
we’ll go back to Larry on a completely different subject relating to our kind of broad strategy around cash flow, given the grant cycles coming up.

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

And so, considering those strategies and how that cycle works, funding those multiyear grants there are varies cash flow that occur in those grants. Now, let me just say that the numbers you see on this slide are purely hypothetical for the purposes of teeing up the
conversation that we want to have. And that is, that some grants might pay 50 percent up front, 25 percent in the second year, and 25 percent in the third year. It might be 25 percent up front, 40 percent and 40 percent on the back two years or over five years. And so, with those kinds of variables in the discussion and we look at our funding, the money that we get from the Affordable Care Act,

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

So the question becomes, do we as an organization, take a process that enables us to spend $90 million on just the grants that we grant
in the first year or do we take $90 million and
grant twice as many. So in the 50 percent model,
right, you could have $45 million of grants and you
could hold the $45 million for those grants that
get paid in the next year, or the alternative is to
say as this example, where you could put out $90
million of grants knowing that you would then fund
the balance of those grants with dollars that came
in future years.

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

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

CHAIRMAN WASHINGTON: Could you go back
two slides? Please.

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

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

MR. BECKER: Right.

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

MR. BECKER: Right.

CHAIRMAN WASHINGTON: So, we’re talking Option A versus Option B for the discussion purposes.

MR. BECKER: Right. Thank you.

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

DR. CLANCY: So, as Larry knows from another conversation, I’m a huge fan of Option A. We’ve got incredible opportunities ahead of us. We’ve got a mandatory funding stream. We have some people asking questions about why, perhaps, we haven’t funded more now. So I would be a huge fan of that.
I would also point out that there is potentially an unintended consequence of Option B, which is that if I were a grantee under that option I might actually try to frontload year one even if I knew there was not an ice cube’s chance -- I’ll stop there, of actually being able to spend all the money in that year.

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

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

DR. KUNTZ: Well, Rick Kuntz here, member of the Board. I’m glad we’re bringing this up and trying to understand what the parameters are for us to be able to predict and I suggested earlier that we start to have a communication, at least between the PDC and the Finance Committee so that you can ask what parameters we need to have in order to be
able to understand the grant parameters and try to find this understanding. It may include things like, what is the gating process going to be for grants. I guess we assume it’s going to be three times per year. The other is going to be the award sizes, are we going to prescribe them up front or ask them in an RO-1 type scenario. And then, all of those parameters we talked about.

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

DR. COLLINS: So this is very much, oh
yeah. Francis Collins, Board member.

This is relevant to something that Rick just said. If you are going to go with Option A and I agree with Carolyn, that makes a lot of sense in terms of trying to get our Research Agenda up and going as vigorously as possible. I think one consequence of that is then when you make a grant award, you’re probably making it year-by-year, because otherwise you are potentially at-risk of making a commitment that you don’t have. But that’s okay, because don’t we also expect our awardees to provide something in the way of an Annual Report of Progress and they should not assume that just because you got a three-year award, you’re actually going to get all three years if it turns out that you don’t do any work. So this would pretty much then, put you into a scenario where you give a grant award that says, “Predicated upon the availability of funds, here is what you will get on year one, two, and three. But we will expect to see a progress report from you before we make that second and third year.”
And again, it’s based on the availability of funds because we can’t entirely predict the future.

CHAIRMAN WASHINGTON: Norquist and then Krumholz and Zwolak.

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

But the other good thing about it, is it really puts the grantee on the spot because it makes them do something at the end of their first year because if you frontload and you kind of guarantee them, then we’re going to have all of this, kind of, you know, stick approach with them and I think it’s very easy to say, “After the first
year availability of funds and progress and what you’ve told us what you were going to do at this point.” Because often when I was at NIH, we would have these large clinical trials and we’d get stuck at the second year and we’d go, “Dang. Nothing’s happened. Do we keep putting money into this or do we stop and cut bait at this point?”

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

CHAIRMAN WASHINGTON: Okay, Krumholz and then Zwolak.

DR. KRUMHOLZ: Okay, I just want to make the point that even if we had the funds in the bank, that doesn’t mean that we would necessarily give it the next year without satisfactory progress, and so, I don’t think it precludes that. I do think by the way of the satisfactory progress,
again, we should build in that we should be
interviewing the patients at an annual basis to see
about how they understand and are participating
actively in the research itself and that should be
part of the evaluation. Not just a report that is
submitted, but actually talking to the people who
in the application were intended to be part of that
process to guarantee that.

I just want to strongly come out with
everyone else in saying I think we should go with
the first, and in part, I think, because we keep
hearing about the possibility that people may want
to undermine our funding. Our funding is fairly
firmly embedded, but there’s not guarantee for it
going forward. The best guarantee that we can have
is to fund a large number of important
consequential research projects that people are
excited about and that if we stop early, will lead
to the nonperformance of that production of
knowledge, which people are actually anticipating.
So if we’ve done a really great job funding the
right projects and getting people to anticipate
their results, and that money is predicated on our continued existence rather than money we had in the bank that we can just dispense with, it will ensure our continued -- it puts pressure on us. I just wanted to say that.

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

CHAIRMAN WASHINGTON: Zwolak.

DR. ZWOLAK: Bob Zwolak, Board member.

I’m also a very strong supporter of Option A for all the reasons stated, but in addition when you think about the timeline of doing the research, even with Option A, the dollars aren’t really going to start to flow out the door very much until 2013, 2014. A year or two to do the research, analyze it, and get it published, we’re looking way down the road at 2015, 2016 before our most impactful studies are published. And if we go in slow mode
it’s going to be 2017 or 2018 before we get much important out there. So, I think it’s almost imperative to do Option A.

CHAIRMAN WASHINGTON: Mr. Becker.

MR. BECKER: I think we got our answer.

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

MS. HUNT: So moved.

DR. CLANCY: Second.

MR. BECKER: All in favor of Option A?

CHAIRMAN WASHINGTON: Any further discussion? All in favor?

[Chorus of ayes.]

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

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

MR. BECKER: Yes, that’s a topic for discussion.
DR. COLLINS: Okay, good.

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

MR. BECKER: Right.

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

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

CHAIRMAN WASHINGTON: Douma and then Gray.

DR. DOUMA: This is really a question because of my ignorance in this field, but it’s also important that we have very well-defined processes that when somebody reports and what they report in the first year before they get the second year. Clearly, we don’t want to have a break in funding and so, I don’t know what the standard protocol is so we need to have -- particularly there are going to be a lot of people, perhaps like me who don’t know what the standard protocol is and we need to be very precise so we don’t have somebody whose funding breaks down for 90 days and
the research project goes away because they had to fire everybody.

CHAIRMAN WASHINGTON: Got you. Gray.

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

[Off microphone discussion.]

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

MR. BECKER: We’ve got the motion on the floor, I think.

CHAIRMAN WASHINGTON: Okay.

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

CHAIRMAN WASHINGTON: Are you commenting
on Option A versus Option B or are you moving onto something else?

    MS. HUNT: No.

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

    [Chorus of ayes.]

    CHAIRMAN WASHINGTON: Okay. All opposed?

    [No response.]

    CHAIRMAN WASHINGTON: okay, you have your answer.

    MR. BECKER: Okay, thank you very much.

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

    CHAIRMAN WASHINGTON: Hunt and then we’re
going to ask you, Barnett, to wrap up the report.

MS. HUNT: I just --

CHAIRMAN WASHINGTON: Go for it.

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

DR. KRUMHOLZ: Well, of course, this is something that will be considered and Judy is going to, I think, play an important role in leading. But it would have to be a standardized assessment that we felt was reproducible. It would have to be authentic and genuine with respect to trying to ensure that we are reaching out. It should not be considered, like don’t tell on your investigators or anything.
It would need to be welcoming and collegial and in a way just to try to learn from the experience that they’ve had, but also inform us about whether they’re authentically involved in the research and can they discuss fluently what their talking about in language that they can use, but really is someone gets on the phone and clearly doesn’t even really understand what’s going on or -- we’ve got -- probably not that you’re going to say, “Okay, we’re not funding you.” It will elicit another call and a discussion and some assessment. This is part of what’s new about us, I think, if we’re going to try and pursue this kind of work. We’re going to have to develop these kinds of methods, as well. And maybe, Sherine and your group can think about, how do we do this in a reliable, reproducible way and how can it inform us going forward?

So, Gail, I really don’t have the answers about it except that I want to cite it as an aspiration, that if this is what we want to do, then we want to make it clear this is another facet
and people will be evaluated on the substance and content and progress traditionally, but also on their success on incorporating the various members of the team in the work that they are doing.

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

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

[Laughter.]

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

MR. BECKER: Thank you.

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

So, we’re going to take a break and we will return at 1:45, and we will start precisely at
1:45 where in the afternoon we will hear the report from the Methodology Committee and we’ll hear a report from what we call COEC, Communications, Outreach and Engagement Committee, and we’ll also have another public session this afternoon.

Enjoy lunch. See you at 1:45.

[Whereupon, a luncheon recess was taken.]
AFTERNOON SESSION

[1:45 PM]

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

CHAIRMAN WASHINGTON: That sounds great. Please continue.

VICE CHAIRMAN LIPSTEIN: Sherine, you’re on.

DR. GABRIEL: Okay, I don’t have the slide changer, but -- if somebody has it, pass it down. Okay, well thank you very much Steve and Gene. I’m happy to present an overview of the activities of the Methodology Committee. Some of my colleagues are just coming in from lunch here,
but Jean is here as always and that’s great and David’s here.

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

Just with respect to that, you’ll all recall -- I don’t remember how many months ago when we first put forward the initial PCOR definition, we asked for a vote of this Board to endorse it as
a working definition pending the public comment period and the edits we anticipated making and follow up of that. All of that’s now complete, so we will be looking for a vote of this Board to endorse the PCOR definition, now with the public comments all in place.

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

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

But this is what the report will look
like. Chapter 1 will be an introduction. There will be, “What is PCOR?” And that will be based on our definition. We’ll hear a little bit more about that later. Why do we need to do this and obviously talk about responsiveness to the statute. Who is the audience for the report? What are the goals? What is the report trying to do? What it cannot do in this first version of the report?

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

All of Chapter 3 is really dedicated to patient-centeredness. How does it apply in research prioritization? Identifying questions, design of studies. The whole PICOTS set of categories: population, intervention, comparator, outcome, timeframe, setting. So, we’re talking about instilling the patient viewpoint in patient-centeredness in every stage of the process and what
do we really mean by that and then, dissemination/implementation. This is something that a fair bit yesterday evening. We have begun to work on that really, under Brian’s leadership and collaboration with Sharon Levine’s team and the Communication Dissemination Group headed by Carolyn, and we have a plan for how dissemination/implementation is going to roll out following the report and you will hear more about that in subsequent meetings. What methods make research more patient-centered and how is patient-centeredness balanced? How do we balance the whole notion of patient-centeredness with feasibility and other stakeholder concerns? So a lot of that will be in Chapter 3. Some of it has already been written.

Chapters 4 to I don’t know how many we’ll end up having in here. We’re waiting -- of course, we have 15 contractors that are busily working on their research product and we’ll be getting those in a matter of weeks. You will be seeing some of the early results of that if you stay on for our
workshops, the results of some of it anyway. And, that’s really what those chapters will contain; the standards for selecting, designing, and conducting research. And then we’ll have a final chapter just talking about future plans. What the public comment period will be like. Again, this is really where the dissemination and implementation plans will be outlined. And then, our plans for updating the report, we’ve got -- we’ve tried -- I’m not sure we’ve done a terribly great job of expectation management. This is really the first -- this is really version one. We’re going to have, I think, a great version one, but all of the answers to all of the questions regarding methodologic standards for PCOR will not be answered in this first report. And so, our plans for updating will be a key part.

So, that’s basically what it will look like. Again, for those of you who participated in the last call, you’ve got to a sense of this, but just to give you a visual of what a section might look like, and again, we don’t have a lot of the
content. The content that we can write we’re well on our way to writing it, but the pieces that are being written by our contractors are still pending, so none of this has been populated yet.

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

And then, some recommended action. So, you know, we might encourage training in a certain area or we might encourage dissemination of certain
software and so on. So, again, we’re kind of making this up, but just to give a sense of what the chapter sections will look like.

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

UNIDENTIFIED SPEAKER: Audio.

DR. GABRIEL: Audio. So at least everything will be captured and we will provide a summary, so for those of you who aren’t able to attend, you’ll be able to take a look at a summary of what went on and what the initial contractor reports look. We will review a draft or summary of these draft recommended standards. We’ll begin to do that in April and then we’ll be looking for
input from the Board shortly after that on this initial drafted report and then, of course, May 10th you will receive the final report and look for input and approval for public comment by our Board meeting May 22nd or something like that. I got that right.

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

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

And so, they’ve been working very hard to keep that on track.

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

And they will screen the recommendations that are coming from the contractors and really have a deep discussion and reach internal consensus on which recommendation coming from those reports they’re going to put forward as recommendations that are sort of ready for prime time. These are ready to be included in the May report. And we’ve agreed to set a pretty high bar for those, so it really has to meet all of our criteria to be
included. If it’s incomplete in some way or
another, if more research needs to be done, or if
there are some questions about what has been done,
we will reserve those, we’ll put those aside and
look at revamping them for version two.

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

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

Where we agree, those will go in the
report, where we don’t agree, they will be put
aside for a discussion, and then we’re going to have a face-to-face meeting on April 3rd where those recommendations from the working groups, from the contractors, where there has been disagreement, will be put to discussion, almost like a study section format. We’ll have maybe 15, 20 minutes per standard. We’ll review them and after that discussion we’ll come to consensus on what standards are to be included in the first report that you all will eventually see.

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

DR. GABRIEL: Right. So, that’s a good point. So, the first step is internal consensus within the workgroup. So, that’s essentially unanimous. We want to be sure that everybody in the workgroup agrees that these four or six or
eleven standards are ready to be moved forward.

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

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

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

DR. GABRIEL: Absolutely. You’ll see it
all.

CHAIRMAN WASHINGTON: Douma?

DR. DOUMA: Just a little variation on
that. I was going to ask that, but also, will we
be seeing any recording of the deliberations, what the concerns are, so we can look at those moving forward? Not just us, but -- is that going to be made public?

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

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

We have four experienced report writers that have really been brought on Board to help us get the words together and develop the report, and
so once we’re in agreement on what needs to be there with respect to recommendations, they will help us do that and this group has been meeting already with us and with our Deloitte staff, so they’re pretty much up to speed.

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

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

CHAIRMAN WASHINGTON: It’s a good place to pause. Collins?

DR. COLLINS: So, thanks. That’s very helpful. Sherine, can you just remind us in terms of the audience, for the recommendations about standards, what is the expectation about what the investigator community will do once these have been
produced? And what are the expectations about how PCORI will use those standards in terms of reviewing grants or making other decisions about how to spend our resources?

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

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

So, in terms of what we’re going to do with them as an institute, that’s one of the key intersections between developing the standards and
then funding PCOR research, so that’s one step.

And, you know, as I’ll mention in the

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

DR. COLLINS: Can I quickly follow up?

So, in circumstances where you have a grant application that actually is proposing a new approach to developing standards for something like, say, missing data, which was one of the examples you used --

DR. GABRIEL: Right.

DR. COLLINS: -- if you’ve already established, well, here is the standard, does that mean that grantee is no longer welcome?
DR. GABRIEL: No. That’s why we’ve got a priority five, and I think actually Joe mentioned this this morning, one of the goals of the Methodology Report is to understand what’s known with respect to PCOR methodology and understand where there are gaps and where new research is needed, and that gaps piece is going to drive what we will propose for a methodologic Research Agenda under your priority number five. So, yeah, we’ve got to marry those two.

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

DR. SIGAL: So, Sherine, thank you very much. It’s a thoughtful presentation. So, my question is a follow up on Francis’ comment. So, because we don’t know exactly what we’re going to be studying and because we have complex work and complex patient populations, is there enough flexibility in these guidelines. So, as an example, in our outreach last week we heard a lot about mental illness, we heard a lot about adherence, comorbid conditions, underserved
patients, rare disease. So, is there enough
flexibility built into this for the kind of studies
that we ultimately may do?

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

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

CHAIRMAN WASHINGTON: Lipstein.

VICE CHAIRMAN LIPSTEIN: Sherine, I guess
I have two questions. The first one is, when I
look at the outline that you presented earlier and
it talks about how you develop the standards,
patient-centeredness, standards for selecting, designing and conducting research, future plans and directions, and then I kind of ping that up against our National Priorities. So, I’m wondering, for example, would the Methodology Committee, either in this first report or in subsequent reports, need to identify, here are the standards that applied at, say, comparative clinical effectiveness research, priority number one? Priority number two is patient-centered outcomes research -- different set of standards, different set of guidelines. Number three, dissemination research, different set of guidelines. Number four, serving vulnerable populations, eliminating disparities. And then, ultimately, number five, you know, creating a robust data infrastructure or developing PCOR infrastructure.

So, question number one is, do the standards go specific with the priorities? And I guess -- and then coming back to a related question is, when the Methodology Committee basically opines and says, yes, there’s missing data in every kind
of analysis we might do, but if you’re missing data
elements A, B, and C, it’s not going to be credible
outcomes research unless it’s a complete data set.

So, those are my two questions.

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

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

We mentioned this morning the work that’s
underway to help understand the EHR issues and how
do we use EHR data more effectively for CER work,
and, you know, we’re putting together this workshop
in July to understand what’s been done, what’s not
been done, and what makes sense, how would we move
forward in this area to build networks, what kind
of infrastructure makes sense given everything
that’s already been done, what training might make
sense, what standards are needed.

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

CHAIRMAN WASHINGTON:  Douma?

DR. DOUMA:  Freda’s ahead of me, by the
way.

CHAIRMAN WASHINGTON:  Okay, Lewis-Hall.

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

I just have one quick question, which is, in
noticing the public comment period that follows all
of this hard work, I was thinking, you know, this
report is inherently very technical and the
question is, what, if anything, do you think we
could do or what’s planned for us to do that might
make it easier for, I guess, less technical people
to understand this and to be able to respond to it?

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

Now, we haven’t done that work, but that’s
still in the plans. I mean, it’s technical but not
every consumer of the report needs to see all the
technical pieces. Every single one of our
recommendations is going to have relevance to
people, but it will have to be presented in a
different way.
Now, we haven’t done the work yet of sort of redefining the report based on the audience, but we hope to be doing that.

DR. DOUMA: Gene?

CHAIRMAN WASHINGTON: Douma.

DR. DOUMA: Yeah, my comment statement is actually from the same number four that Freda was talking about. If you read it, it says that the Methodology Report will be posted for public comment. It sounds really passive to me. It sounds not very -- perhaps not very effective regardless of which audience we’re trying to reach. And what I would like to see here at some time this written to say, “At this point we will implement our distribution and dissemination plan for the Methodology Report in order to get 10,000 comments from various audiences” and really actually have some goals, objectives, things we can strive for, and if we’re not reaching them, because it would be some time period, that we have the ability to crank up our marketing plan, so to speak, in order to reach some significant goals.
Because if we only get feedback from 50 people or 100 people, then we have to call into question the selectivity of those people makes it invalid, almost, what they’re saying because we can’t sum them up.

Anyway --

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

CHAIRMAN WASHINGTON: Weisman had a comment related?

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

DR. GABRIEL: Well, that’s a good question. I’m not sure if we’ve actually talked about that at length. I mean, we’ve obviously talked about, you know, publishing bits and pieces...
of it, but I can’t tell you that we have a real plan.

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

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

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

CHAIRMAN WASHINGTON: Normand.

DR. NORMAND: Sharon-Lise Normand, Methodology Committee member. So, just to follow
up on that, I think the other thing, I know the other aspect that we’re working on is this translation tool, which is different from a publication, but something that we are thinking a lot about so that it reaches many different users, and rather than thinking of the usual publication type of article, not that we’ve ruled that out, but we certainly have been thinking more about a translation tool using very different formats and getting it to people who would be unlikely to go and read a book on standards or methodology, so that’s the one item I would --

DR. GABRIEL: Yes, thank you for bringing that up. So, maybe if I could just invite other members of the Methodology Committee to comment and add to what we just said. Is that all right?

CHAIRMAN WASHINGTON: Sure.

DR. GABRIEL: Brian?

MR. MITTMAN: Just one quick comment in response to Allen’s note about comments. One of the key strategies for the outreach in receiving comments is to work with some of the professional
associations and in some ways delegate at least some of the responsibility to them to reach out to their members and perhaps collate comments, so I think we’ve been in the process of actively identifying the key stakeholder groups and the representative groups so that we ensure that we’re in touch with them and that they’re on Board and will help us with that review process.

CHAIRMAN WASHINGTON: Okay? Please continue.

DR. GABRIEL: So, the next couple of slides really just speak to Board engagement. I’m sorry this is such a messy slide. Next time we’ll have to think of something a little bit different, because I’m sure there will be things added to it.

So, our goals with respect to engaging with this group are to be as transparent as we possibly can, to collaborate and to coordinate our activities, and the stuff in the green boxes are the new engagement activities since the last Board meeting and the stuff not in the green boxes is what I shared with you last time.
So, since we met last, we’ve also gained the support of two committee members in kind of framing the PFA, so I’m talking about things that we’re doing together. Gail, actually, prepares these wonderful weekly status reports that she shares with Joe and Anne, and it’s really been a nice way to sort of give the staff at the leadership level an update of, here are the things that we’ve been working on this week and it’s really been a good way to sort of keep tabs. And all of this information, by the way, once evidence is up, will be in a board site where you can go and kind of check on, okay, what’s the Methodology Committee been doing this last week or the week before that. We’re, of course, participating in the pilot selection process and other activities. These teleconference calls that we’ve had with Mark, under Mark Helfand’s leadership in his role as the Assimilation Group chair, I think, have really helped by sharing with the Board our interim thoughts on how the report’s coming together, what the outline looks like, and
as Sharon-Lise reminded me, this translation tool, the statute requires us to produce a translation table and we kind of see it as a translation tool where an individual -- it could be an investigator, it could be a patient -- at some point can look at this tool and look at the kind of research that they have a question about and then match that to the kinds of methods and approaches that might be advisable or less advisable and why, and that’s basically what the translation tool will look like. And there are some in the literature, some examples already in the literature.

And we’re collaborating, as I’ve mentioned a couple of times, and this is something Brian is leading from the Methodology Committee, working with Board members to develop a dissemination plan, and he’s mentioned a little bit about that.

So, we’re continuing to do more and more to ensure engagement and I think there’s a box that’s hidden there that just talks about our participation in a scientific publications committee.
So, more and more we’re doing more things together, which I think is a really good thing.

So, next steps with respect to engagement, the case study teleconference, that already happened in follow up to the January Jacksonville meeting. The green things are the Board engagement steps. We will either have you at the workshop, if you’re able to make it, or share executive summaries of the workshop and contractor reports shortly after the workshop so you’ll see those preliminary reports, have a sense of what’s happening there, and then hopefully we will get input from you as we’re revising our report, and then May 10th we’re submitting it to the Board and, again, we’ll be hopefully posting it for public comment or maybe, I take your point, change that language as the first step in our dissemination process, and then we will discuss and approve a more detailed dissemination plan shortly after that.

So, the last couple of slides before I turn it over to David to talk about the definition
just gives you an idea of what discussions we’ve had within the Methodology Committee regarding, you know, what happens after the report. You know, I’m not great at visuals, but it was the best I could do.

So, following the release of this first report, our goals will be to enhance adoption of the recommended standards, a push for research, methodologic research to fill the gaps that will become even more clear after we put together this report, and really have the Methodology Committee act as a convener, that is, bringing together others around the country that have thought about these things to help us improve the report and improve the recommendations going forward as a communicator, to share what we’ve learned, whether it’s in the scientific literature, in the lay literature, through a translation tool, you know, through novel means of communications.

I think Robin was sharing some ideas about some novel communication approaches that she became familiar with at another meeting through -- it was
a fellow who was actually a poet, right? And actually the same individual was -- it just so happened when she shared it, I learned the same individual was brought on at Mayo as kind of an innovative, out of the box approach to sharing difficult concepts in an unusually way. People have suggested video games, obviously social media, so what are the ways we can imagine to communicate what we’re developing as effectively and efficiently and maybe using novel approaches going forward, and as a catalyst, so can we serve as a catalyst to ensure that these practices and standards that we’re putting forward are because of their scientific integrity, because of the effective way we’re communicating them, are really catalyzing more research in this area and just being very widely adopted.

So, obviously, you’re our first audience. Beyond that, it’s the wider stakeholder community, really, across the country. And so, how are we doing that? The committee member feedback sessions, I’ll just share with you, Sharon-Lise and
I have started -- we thought we’d be done by now, but we’re only halfway through -- meeting with our committee members one-on-one, or I guess it’s two-on-one, to really get a sense, individually, how they think the process has worked over the last year, what we can do differently, what we can do better as we go forward.

We’ll also be asking them to complete a survey tool, an anonymous survey tool to, again, understand from the perspective of each and every one of our Methodology Committee members, get feedback as to what we can do to improve our process going forward.

I’ve mentioned the dissemination implementation plan that we’ll be developing going forward along with Carolyn’s group and the COEC. We’ll bring all of the feedback from these committee member feedback sessions and the surveys and some of our initial discussions. After the May report is out for public comment we’re going to plan kind of a mini retreat where we take the feedback that we’ve heard from our members and
really use it to drive our plans going forward. We’ve already produced, as you all know, kind of a blueprint for the next couple of years and we’ll be revising that based on the input that we get from our Methodology Committee members. And we’re planning to engage, I think as Brian mentioned just a bit ago, professional societies and other stakeholders using advisory groups and other sorts of activities to look at areas that are particularly challenging and, obviously, the one that we’ve talked a lot about is electronic data systems, implementation, dissemination is another one, novel delivery tools, how are we going to get this somewhat technical information and really assemble it in ways that a variety of different audiences can understand it and consume it and use it. And then on the health systems standpoint, are there systems, engineering principles, or experts that can help us drive some of these standards into our health systems? And these are just ideas, but they’re the kinds of things we are starting to think about in terms of
serving as a convener, communicator, and catalyst to push our standards forward and improve -- know what to do so that version two is even better.

And then the last one I’ll mention is the first annual PCOR conference. I think all of us on the Methodology Committee, and this came up again last night around the Board, see the importance of really sort of stepping up and kind of taking the podium, if you will, and saying, we are the PCOR leaders, and one way to do that is to really hold the first annual conference and serve as the convener for those around the country.

Some of these conferences are popping up already and I’d rather we’re at the helm rather than invited to speak or even worse, sometimes not even invited. So, you know, we’d like permission from the Board to start thinking about this, at least from a methodology point of view and, you know, just start with the easy stuff, you know, let’s get a date in place, let’s get a simple agenda in place, let’s get a venue in place and really plan for this. It won’t happen in the fall
if we don’t get moving.

CHAIRMAN WASHINGTON: Could we pause for a minute?

DR. GABRIEL: Yeah, I think --

CHAIRMAN WASHINGTON: We have Collins and then Lipstein and then Douma.

DR. COLLINS: So, just a process question. I appreciate your putting forward these ideas about advisory groups and its potential considerations. It would help me, I think, to know what exactly is the process by which the Board decides on advisory groups? And have we decided on some already? Could you just give us a quick snapshot on what that process could look like? Because this is a mechanism that could potentially be valuable in quite a number of places and we want to be very thoughtful about how we set these up so that they actually fill the gaps that most need filling and don’t end up conflicting with each other.

CHAIRMAN WASHINGTON: Okay, I was just confirming with Joe that to date we do not have a clear process for setting these up across the
organization. We’ve expressed intent, and that is the plan.

VICE CHAIRMAN LIPSTEIN: We don’t have a clear process, I remember because I led this panel. Early on we developed a panel of guidelines for advisory panels so that whenever we did want to begin to establish them we had some general ground rules to follow. So, there is a document somewhere in -- Joe, you’re looking at --

DR. COLLINS: Archives.

VICE CHAIRMAN LIPSTEIN: There’s a document somewhere in PCORI land with guidelines for the creation of advisory panels. We ought to dust it off, Francis, and bring it back.

DR. COLLINS: Yeah.

CHAIRMAN WASHINGTON: Okay. Good point. I have Lipstein and then Douma.

VICE CHAIRMAN LIPSTEIN: So, breaking with a little bit of our tradition, Sherine or Sharon-Lise, I want to think out loud for a second. So, Joe and I are going -- I invited Joe or I asked Joe to come meet with a group of stakeholders from
health systems in May, I think it is, April or May, and these are 30 really large health systems and so imagine that Joe was very, very effective at saying, we want to create these robust, PCOR networks for both data or investigation or research or however we want to do it, and imagine that in this room, I’m just going to cite five that I can think off the top of my head -- Kate Walsh will be there from the Boston Medical Group and Steve Safyer from Montefiore in the Bronx and Kevin Lofton from Catholic Healthcare Initiatives in Denver, and you’ve got Charles Sorenson from Intermountain and you’ve got Tom Priselac from Southern California. So, I picked five disparate geographies. If we wanted to get those five organizations to work together to develop a network of either investigators or to put research or data together for the purposes of achieving our five priorities and I said something like, well, I have 17 new best friends on the Methodology Committee who want to work with you to figure out how to do this.
I don’t know how that works. I mean, I don’t know how we get the expertise that they might need to develop something that’s truly novel and innovative in the way of a network to do research, and unless it results in a grant application, how it would ever come to our attention. And since I’m not allowed to help them develop a grant because that would run afoul of the conflict of interest rules, how would we take an idea like that and do something with it? And so that’s what I wanted to just think out loud briefly about, Gene, if we could.

CHAIRMAN WASHINGTON: Sure. I take that question as a question to the Board, not just to Sherine. So, those of you who don’t currently have your thinking caps on, please pull them out and put them on.

DR. GABRIEL: I mean, I would just suggest that we need to understand from leaders such as the ones you mentioned exactly what their needs are and what the barriers are, and I think that’s one of the goals of these advisory groups. We need to
listen, probably, more than anything else as a
first step.

VICE CHAIRMAN LIPSTEIN: Harlan, to add to
that, I think this group of five might know what
the goal is, but they certainly wouldn’t know what
their needs were and that’s what, Harlan, maybe you
can help us with that.

DR. KRUMHOLZ: Well, I think there’s two
distinct issues here. One is where we target a
specific kind of network or group that we’re trying
to foster where we, as a group, have come together
and said, for example, we want to emphasize
longitudinal prospective collection of data that
brings forth the voice of the patient, that’s going
to ensure that we’re doing that. Another might be
that we say we want to leverage, like you showed a
long time ago in St. Louis, the FRED database where
we say we want to create a series of resources from
existing data that might be leveraged for wider use
that might build beyond the traditional use of
claims data and might overcome some of those
limitations and have outcomes.
We would target that. To me, that’s some of the targeted opportunities that we might have and we might want to put together an advisory group, we might want to be very agile in trying to move rapidly in trying to develop that and see if we can seek people to make applications.

Another way, again, is in the broad-based portfolio of the infrastructure where people might coalesce and say they might pitch to us an idea where we’re ready to catch it and we want to encourage that group to work.

Now, the Methodology Committee is so busy, I wouldn’t want to promise their ability to work closely with any single group in the country. On the other hand, I think there are people like the Methodology Committee members around the country and if a group coalesced that had the reach of the one that you just described, they could bring together that kind of expertise, bring together patients, bring together the people within those organizations, and we ought to be prepared to be able to support proposals that are -- maybe even
formative, pilot proposals, I’d like us to think about planning grants for opportunities like that, where we can fund those groups to make the next steps together that might then lead to an ultimate proposals.

Then, Joe, you know, you and I have talked about how with a pilot proposal then someone might petition to put in a large grant and then the group could continue. NIH does this all the time, go above a certain amount, somebody can pitch it, but they’re not going to go through the regular mechanism because it’s such an audacious goal that we have the opportunity to -- you petition it, it’s bigger than usual, and we have a chance to vet it through some mechanism that Joe would set up internally.

So, I think there are different kinds, ones that might emanate from us where we’re particularly looking for that and we’re saying, who can do it, and another might be where we are looking for new and novel ideas we couldn’t even envision, we’re ready to catch it, and the catch
might be petition for doing it or a planning grant that lets you get started and pull together the expertise that you need in order to get to the next step.

CHAIRMAN WASHINGTON: Douma?

DR. DOUMA: I just want to say that seeing systems engineering up on your list is just so wonderful. I think that’s going to be key to a lot of the -- we were talking about it yesterday, it’s going to be key to a lot of different -- of the various challenges we’ve been facing and as an old engineer who went to medical school not understanding why medicine was 50 years behind everybody else, it’s great.

I also, with regard to the PCOR conference, and I’m not in the middle of this, I am seeing stuff popping up all over the place. My e-mail is filled with workshops, conferences, et cetera, et cetera, and I think the earlier the better. And I would like us to give a great sense to our communications people and our meeting management people that at least by the next meeting
we’ve got something fleshed out pretty thoroughly across the Board with regard to PCORI.

DR. GABRIEL: I couldn’t agree more.

CHAIRMAN WASHINGTON: Could I just pick up on that point since that was a question to you --

DR. GABRIEL: Yes.

CHAIRMAN WASHINGTON: I am -- we’re going to commit that by the next meeting, Joe, right, that we will have fleshed out plans. We will have even, by then, surveyed for possible dates and sites for a PCORI first annual meeting.

DR. SELBY: Yes.

CHAIRMAN WASHINGTON: Okay.

DR. GABRIEL: Yes, and I would say if Board members have ideas about a luminary or two or three that could serve as a keynote, we need to identify those folks early because their schedules really get filled up.

So, I’m now going to turn it over to Dave, if you want to come over here and talk about the definition work, and we’ll be looking for a vote of the Board.
I guess there are only two slides, so I could even do it for you if you want.

DR. FLUM: That sounds great. So, Dave Flum, Methodology Committee. Thank you very much for giving me the opportunity to share this work. This work started a year ago, so we’re -- this is now a year-long process that’s been really inclusive to help do one of the formative activities for PCORI, which is to really define something that had yet to be defined at the time of the creation of the institute.

I’ve had the opportunity to shepherd this group that’s involved, both Methodology Committee members and also some members of the Board. You see the Board members and the workgroup members that are listed there.

This has really been an iterative process that took the thoughts of the group a year ago and then refined them through a process of public input, very formalized public input, with opportunity for the public to respond both to questions we posed to them about the degree to
which they understood what we were trying to get
at, and also public comments.

We received 568 non-duplicated comments
that were collated by the NORC group and then
turned into about 12 distinct themes that emerged
that we were able to sub-classify all the comments
back and then consider them in definition revision.

NORC also conducted six focus groups
nationwide that involved a diverse group of
patients. Those focus groups identified themes,
many of them that were different from the themes
that emerged from the public comment period. All
of that was assimilated into a refinement process
by this group.

This was genuinely a consensus activity,
so there was no voting that took place, by the end
everybody agreed that the definition and then the
revision of the definition met their needs and met
the institute’s needs. And so what we’re preparing
to show today is the last step in that process of
creating a draft definition that we’re hoping moves
from a draft or a working definition, to the
definition, acknowledging that definitions can be considered for change over time as the needs meet.

But I want to just describe the very last step to you, which was from an update from the last time we got together, the product of several more consensus calls where, based on the NORC comments and the public comments, there were several changes that were made to the definition.

The next slide, actually, is the definition and because I don’t like PowerPoint very much, this is the only other slide you see. But I suggest we all take a moment and read this definition, because this is the current definition of patient-centered outcomes research. And for those who are viewing this on the web or on the phone, I’ll just read it, if you can indulge me in that.

“Patient-centered outcomes research helps people and their caregivers communicate and make informed healthcare decisions allowing their voices to be heard and assessing the value of healthcare options. This research answers patient-centered
questions such as: given my personal characteristics, conditions, and preferences, what should I expect will happen to me? Two, what are my options and what are the potential benefits and harms of those options? Three, what can I do to improve the outcomes that are most important to me? Four, how can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"

“To answer these questions, PCOR assesses the benefits and harms of preventative, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision-making, highlighting comparisons and outcomes that matter to people; is inclusive of an individual’s preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health related quality of life; incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and, lastly,
investigates or may investigate optimizing outcomes while addressing to burden to individuals, resource availability, and other stakeholder perspectives.”

The definition has two parts, the first part is really considered for the public, if you will, the second part is intended to clarify for investigators and other stakeholders who need more details and not the how-to of PCORI, if you will, the how-to of PCOR, I should say.

The highlighted components of this definition in yellow are the things that really changed substantively from the first set of definitions, and I’d like to just highlight those changes so that you understand what the public process involved.

The first change, we’ll start with the first sentence, many of the themes that emerged from the focus groups and the public comment emphasized that for the public that was at least involved in this process, one of the major shortcomings of the way investigators or research, I should say, is used or intended, misses the boat.
in terms of communication, either because it fails
to adequately deliver the information in a way that
people can understand health literacy, numeracy,
but also that the goal from a patient’s perspective
is not just have a data dump of research or sheaf
of papers, but information that they can
incorporate into the decisions that they need to
make.

Communication was as important as
healthcare decisions and that aspect of adding
communication into the first line of the definition
was felt to be important by many stakeholders.

The word potential, added to benefits and
harms -- benefits and harms were words that, this
is in the second question, benefits and harms were
words that lots of folks had trouble with. Harms,
risks, were, by some, viewed interchangeably but
others viewed as having different meaning, adding
potential signal that there’s a lot of uncertainty
in every healthcare decisions, both on the benefit
side and the harm side, and that seemed to be
responsive to the public comments that made the
information sound a little more doom-ful.

Question four has been totally changed. There was lots of concern about what we meant when we talked about the healthcare system. A healthcare delivery system was not something that was understood by many of the people who responded in the public comments and during the focus groups.

By changing it to “clinicians and the cared delivery systems they work in” we were hoping to signal that we weren’t talking about necessarily what some people first viewed that term, health system, were responding to. Many felt that when you add the words “health system,” it just meant the insurance company.

The second part of that sentence also refines the idea that the information is intended to help people make the best decisions about their health and their healthcare.

The last two comments are on the second half of the definition. There was considerable interest in including the word palliative or palliative interventions as a distinct form of
interventions that were neither preventative, diagnostic, or necessarily therapeutic. It’s a subtle point, but palliative is considered by many to be in a separate category.

And, lastly, the last bullet under the how-to of PCOR was the word “availability” after “resources.” Actually, regrettably, this was part of the initial definition to have the words “resource availability” included, and it was simply a matter of editing that it was not included in the definition that went to the public, but the take home message about the last bullet is that by including the issue of resource availability as one of the many issues that patient-centered outcomes research includes, specifically by including it in the context of the way in which it becomes a barrier or a means to achieving successful patient-centered outcomes, many felt that this was something that PCOR should be inclusive of.

The last question that came up repeatedly was the extent to which PCOR and CER are synonymous. I think all the members of this
workgroup have felt that this definition of PCOR is certainly inclusive of traditional comparative effectiveness research, but also allows for a lot more room for a lot of other areas that may not traditionally fall under comparative effectiveness research definitions that have been offered in the past.

Now, I suspect many of you have words that you see here that you disagree with or you’d like changed or maybe that you’re not 100 percent on Board with. I’ll reflect what I started with, which is this was a consensus process by which the main concepts, if not the specific words, by many, many different individuals, including the voices of hundreds of people from the public have been included, so I’d encourage you to, as you consider this definition as your moving-forward definition, reflect that and respect that process which has been genuinely the first time that PCORI has exploited the use of the public’s perspective in creating its work, and I think it’s important that we take advantage of that opportunity here.
Thank you very much.

CHAIRMAN WASHINGTON: Okay, David. Before we open it up for Dr. Flum to questions and comments, I take this as a recommendation from the working group at this point.

DR. FLUM: That’s correct.


Okay, first Sigal and then Epstein and Collins and Douma and I’ll work my way to this side.

DR. SIGAL: So, this is the first time I’m seeing question four. I guess I just missed it. I don’t understand it. It’s complicated and I don’t understand what it really means. The first three questions are good, I’ve seen them before, they’re tangible. This, to me, is very convoluted. Patients go to physicians, the healthcare system, we know, has issues, but this is just -- doesn’t seem to be something primary for a patient. They’d want the best answers for them, but fixing the healthcare system -- needs to be fixed for them,
but I just have a hard time with this. I don’t
know what it means and it’s very complicated to me.

DR. FLUM: So, this is Dave Flum again.
Let me offer a point of clarification then. This
question, and its modification, came from a set of
public comments that we heard about things that the
patients would like to know about where to go to
get their healthcare. This often comes up as,
should I go to the big university hospital or can I
go to my local -- is this something I can go to the
local clinic for. Is it better to be in an HMO or
an integrated care delivery system? Or should I go
to my doc who I’ve been seeing who works out of his
office? Questions that often come to bear by --
when patients are trying to figure out what is the
way to navigate their course in the healthcare
system, and it reflects the fact that people, I
suspect, think that there’s a role that the
healthcare system and their doctors play and their
clinicians, I should say, play in helping them make
the best decisions and getting them the best
outcomes. It’s the only question that refers to
the system.

DR. SIGAL: Look, I live in the world of cancer and where 85 percent of the people are treated in a community setting and if there were one recommendation I would make is get a second opinion at an academic center. But, having said that, this doesn’t say that to me. This is -- I don’t know what it says, but maybe it’s a question we have to answer, and I think it’s a legitimate question for PCORI, but for me on these very basic questions that are really important, I just -- I find it just convoluted. I’m sorry.

CHAIRMAN WASHINGTON: Okay. Epstein and then Collins.

DR. EPSTEIN: Hi, Arnie Epstein, BOG. I’m going to follow up Ellen’s. I’m really respectful of the process. It sounds like it was careful and deliberative and sought outside opinion. I certainly like those first few questions, Harlan mentioned them, I think one of our first meetings, and I found them engaging then and I find them engaging today.
I’m really troubled by the fourth question and the top, which is focused, and the issue for me is not whether decision making is important, it’s central, that really ought to be there. The issue for me is that I think that there’s a lot to do with patient-centered outcomes, which does not mediate through direct patient decision making, and to lose that emphasis as part of our research, I think, would be a mistake, and I’m thinking of the many, I’ll name some studies of nurse extenders who can help patients with chronic disease after they leave the hospital, IT aids to help patients, you know, keep track of their medications and other aspects that are important, the whole service of health services. And to not see that included as part of patient-centered outcomes research to me seems like we’re going to be losing too many valuable things.

DR. FLUM: I would just offer you to consider the first bullet under PCOR really writ large talks about assessing the benefits and harms of everything from health system interventions of
the very type you just described. This is in the first bullet of the operationalized component, the definition.

This definition can hold an awful lot underneath it and although we might make other questions, including the types of questions you just asked, we thought that we were covering that in bullet one.

DR. EPSTEIN: Since I didn’t get it and I don’t get it now, maybe we could cover it a little differently. It says “interventions to inform decision-making.” This is not about decision-making. Decision-making is really important, so don’t hear that I wouldn’t say it’s first and second, I’m saying, we don’t want to lose things that are really very important predictors or remedies for patient outcome merely because they’re not mediated through conscious decisions.

CHAIRMAN WASHINGTON: Joe has a comment relating to this specifically.

DR. SELBY: Yeah, I just -- a couple things. First of all, with respect to your most
recent comment, Arnie, I don’t think that that bullet that starts “assesses the benefits and harms of preventive,” et cetera, speaks only about interventions meant to inform decision-making. So, I think you’re just reading that wrong.

It assesses the benefits and harms of health delivery system interventions in order to inform decision-making, but it’s not interventions to inform decision-making, it’s assessing interventions so that decisions can be made.

So, you know, I do take your point that sometimes even patient-centered research might not be about informing decision-makings, but that’s not what this first bullet says. It doesn’t go to the extreme that you suggest it does.

CHAIRMAN WASHINGTON: David, and then we’ve got to move on to the --

DR. FLUM: And because we’re not obviously going to sort of have a debate about each word, I would just say that there was a considerable discussion, Dr. Epstein, about your point. One of the considerations was actually that really
everything is a decision made, and it may not be by
the patient, it’s true, but it may be made by the
system, about whether or not to pay for those
nurse, whether or not the healthcare system will
include health extension at home or any of the
things actually mentioned, but implicitly there is
a decision being made between the alternative
status quo and any of the components that may be
important that may be not mediated by the patient
making the decision, but certainly somebody is
making the decisions.

CHAIRMAN WASHINGTON: So, Collins and then
Barksdale.

DR. COLLINS: So, as one who’s, I guess, advocated that we just need to come up with a
decision and move this forward or face
embarrassment after all these months of trying to
decide on the decision, I’m loathe to weigh in, but
I will anyway. I’m just a little troubled by that
very first sentence in bold because that’s the
thing that people will look at and perhaps won’t
dig any deeper down into the document.
“PCOR helps people and their caregivers communicate and make informed healthcare decisions allowing their voices to be heard and assessing the value of healthcare options.” If you just read that, I think you’d be wondering, is this a platform that’s focused primarily on communication or is it focused on research? And I think you might think it was the former.

So, I get it about why communication is important, but if that sentence is really encapsulating the main idea of what PCOR is, I think it is skewed very heavily in the direction of the communication function and it doesn’t emphasize the primary function, which is to do research.

CHAIRMAN WASHINGTON: Okay, Barksdale?

DR. BARKSDALE: My comment was related to the word caregiver and I know that we’ve spent a lot of time on the call discussing what we meant by caregivers, and it’s my recollection that we went with the broader notion of a caregiver, not as the member of the family, for example, but caregivers including clinicians? Am I confused?
DR. FLUM: You’re not confused. There’s a rationale document that accompanies this that can help sort of translate some of the words by the intended meeting. It may be, by the way, a wonderful opportunity to have lots of these points of clarification further made.

You made the point, I believe, that it was your desire that caregiver reflected anybody who helps care for you, including your doctors, but also family members and other clinicians and other non-clinicians necessarily. By keeping the language broad here we have the opportunity to define that -- to further refine that, define that, and clarify that in any way we want.

I think the rationale document is a great opportunity to cover a lot of these issues, though.

CHAIRMAN WASHINGTON: We have Douma then we have Hole-Curry, Becker, Weisman. So, Douma.

DR. DOUMA: Yeah, I just want to report that, what, ten days ago when we had the committee meeting I was given permission to actually vet this at a presentation, which was about, I don’t know,
six, seven days ago, and it went off very well. There were several hundred people and they were all in the population health arena, so they’re geared toward thinking this way in the first place, so some of the nuances that are being brought up by the more clinical folks were not addressed there, but I do want to do number four, particularly because there’s a lot of push back on that.

I think that is one of the most significantly different phrases that we’re seeing in our definition versus what we’re used to. What we’re used to is we’re trying to collect, gather good research information that could be used by clinicians and the delivery system to really make great choices for me, I’ll just personalize this, versus what we’re trying to say is that, yes, that’s true, but I am, in the final analysis, as Joe was talking about, I’m the decision maker whether or not that particular piece of information actually applies to me.

And so, we turn it around a little bit to say, the system needs to engage me in making that
decision, although we realize that in many circumstances it’s a piece of information clinicians use and they make decisions and it’s by default it’s accepted.

And it’s maybe unconscious that I’m making the decision, but by me not saying no, I’m saying, yes.

CHAIRMAN WASHINGTON: Okay, Hole-Curry and then Becker, Weisman, Clancy.

MS. HOLE-CURRY: Leah Hole-Curry, Board member. Thank you to everyone on the committee, I saw it was a big committee, for doing this work.

So, what I brought with me in prep for this Board meeting was the July 15, 2011 announcement that we put out about our working definition and then I compared it against this document and I did read the rationale or discussion document that went with it.

So, my first question is just an easy one. Is it our intent if this passes to include the discussion or rationale document of the final -- when we publish? I think it includes a lot of
valuable information and I would suggest that that
be on the table as well.

DR. FLUM: So, that was the intention of
the group. Yeah.

MS. HOLE-CURRY: Okay, great. And then
the second one is, I guess I just want to stress
from a process point how much work went into the
first one and then all of the iterations, so I
really would look to either the group or the chair
and vice chair to help us figure out, process wise,
how to vote this through or not vote it, because I
get that there’s -- that words mean something, but
we’ve also been at this a really long time and I
think that we should be able to vote on this as a
whole. That would be my proposal.

CHAIRMAN WASHINGTON: That is the intent.
I framed this discussion by saying that there was a
proposal on it. What I didn’t say, more
explicitly, I will say now. We’re going to vote at
the end of this discussion.

Becker, Weisman, Clancy.

DR. FLUM: Sherine, did you want to --
DR. GABRIEL: I was just going to suggest at some point to just summarize quickly the work that has gone on in case people don’t really recall, you know, the NORC step and the focus group step, just to ensure that everybody around the Board table hears that again.

MR. BECKER: So, I wanted to comment, too, on number four. I’m a lot where Allen and Arnie are. I read the NORC work. I recollect the comment about people misinterpreting it and thinking about it in terms of health plan. I get that. But what is, to me, significantly changed in number four is outcomes.

In parallel with number three -- number three talks about, how can I improve the outcomes, my outcomes? Number four, in its earlier stage, was, how can the health system -- I understand the misinterpretation maybe of those words -- help me get to the outcomes. And here it is simply about the decision and it takes the system off the hook for the outcomes.

And so, I have trouble with number four,
because now the outcomes are totally on me and not in concert with my clinicians, providers, et cetera.

CHAIRMAN WASHINGTON: Okay, Weisman and then Clancy.

DR. WEISMAN: Well, I’ve been part of this as part of the working group and, you know, number four is problematic only because it takes a lot of work to talk about what we mean, but this thing has been wordsmithed. I think this thing has been written forwards and backwards and sideways, seriously, in all different ways. It usually ends up about where it is with some wordsmithing.

Some of the things we’re going to have to explain to some people some of the time, you know, some people are going to get some parts and not others, but I think it does -- my own feeling is that it does the job that we intend it to do within the limits of people arguing about words.

Larry, I really like what you said, I like what some of the other comments were, but I can’t even think about the idea that this thing goes back
to the working group and we rework it. Maybe we evolve it over time.

You said something really crucial, you said you compared it to a document of last July, July 2011, and it’s now 2012 and we’re moving closer to July of 2012 than we are distance from 2011. And a lot of people are wondering what are we doing with all the information we’re gathering. It’s been quite extensive, as Sherine said. That was just a comment.

The other comment I wanted to make is, I think you have another document that’s really nice, which is that you outlined the comments, summarized the comments that we received from the various stakeholders, wrote — there’s then a statement about how we’re either making the decision to incorporate or not incorporate that feedback, and then there’s further elaboration on what we’re doing with that feedback, either to accept it and incorporate it and make changes or to not accept it, which I think is an absolutely wonderful model for what we were talking about earlier in the day.
about how we take in stakeholder feedback.

And I was just wondering whether you could comment on that process? It’s short and to the point, but it’s very effective.

DR. FLUM: So, we -- if I can, this is Dave Flum, we modeled that response off of CMS’s response system, so every comment, every theme, I should say, from the comments in the NORC process was distilled into a sort of recommendation by the public and we responded to whether or not that was going to reflect into a change in the definition and the rationale for either including it or not including it. They’re about a paragraph long, they’re written in as close to lay language as we can get with this stuff, and it’s intended to be posted on the web.

The rationale is intended to be posted on the web as well and the whole process can result in a publication and scientific journal as well, but our primary response to the public that reflects the degree to which the public’s voice has been integrated into this definition would be the web
response, I think.

   DR. WEISMAN: Thanks.

   DR. CLANCY: David, I want to actually join with everyone who saluted the process. The scheduling challenges alone for this rather large group are close to giving me a headache. And I want to say, bravo. I think it’s wonderful. I speak from the perspective of someone who’s spoken to a lot of different audiences, not just my large extended family, although I’ve mentioned them, but very diverse audiences in terms of their understanding about what this means, that it’s about end results that matter to me, and so forth, and I think this works.

   And, Arnie, I actually say that there is a distinction between number four and that first bullet. I think the first bullet does encompass some of the issues that you were identifying.

   I read number four as being, A, more understandable, and B, something about what is the obligation of clinicians and the systems or organizations in which they work to make something
like, I’ll put this in quotes “shared decision making” actually possible, right? We talk about that a lot in almost musical tones. We’re almost on our feet. You know, we get very, very excited.

In real life, it doesn’t happen. In fact, people, you know, often get out the door and aren’t clear where in god’s name their parking ticket is much less what is going to be coming next and so forth. We haven’t done such a great job.

So, I’m incredibly enthusiastic about this and plan to use it early and often.

CHAIRMAN WASHINGTON: Okay, Norquist are you up or down? Norquist will be the last comment and then we’re going to call the question.

DR. NORQUIST: Yeah, so this is Gray Norquist. I can’t help but having acted like a psychiatrist all day, so I have to say something about them. So, it’s okay to have --

[Laughter.]

DR. NORQUIST: No, no, I was going to say, you know, the sense is that I have -- actually, Sherine and I were kind of talking -- it’s okay to
have disagreement, you know, and I think we need to stop worrying that everybody’s going to agree.

I’m okay. I was on the committee so I’m okay with it, but I think, I get the sense that people want to have us all agree, but that’s okay. I think that’s the spirit of what we are. So, I hope people understand that.

CHAIRMAN WASHINGTON: Krumholz?

DR. KRUMHOLZ: As somebody who has been involved from the very beginning, I do want to say this is extraordinarily difficult. I want to commend David. I want to say that, Arnie, you know, the thing is, it is hard, but these are questions such as, so it’s not exhaustive with respect to the scope and so it provides some examples that do focus on the decision-making.

I’m not saying you’re wrong, I’m just saying where we are now I don’t think excludes the point you made. If it had been incorporated earlier, we might have been able to act on it a little bit better, but it’s been through so many different iterations.
And I think the part that Francis said does, if anything that I’ve heard, did give me a little pause, David, I don’t know, just to make sure that we are talking about this through scholarship, I mean, that it is research. And maybe it’s obvious enough, but of everything I heard, that’s what I thought, um, you know, maybe. Because there are a lot of things that can help people communicate and make informed decisions, but it is really through research.

The only thing is, it does say patient-centered outcomes research and if people don’t just see that as a name but actually see that it says research, it may be the one thing that signals to them.

But I am very loathe to think that we would bounce it back rather than say this -- this isn’t something necessarily any one of us would write but we could all live with given that that’s sort of what we’ve got as a group and the need to move forward.

But that was the one thing that I was a
little bit thinking about.

DR. LEVINE: I promise it will be brief. I think one of the -- what’s not written, but I think intended, is that the first -- what bridges the first sentence and the second are the words “by doing,” so that we communicate or, it helps people communicate in making informed health decisions and allows their voices to be heard in assessing the value of options by doing research that answers patient-centered questions such as -- and maybe that could be put into the document that goes along with it, if we don’t, I mean, I -- by the way, I agree with Carolyn, that this -- you know, David has essentially done a Talmudic scholar’s worth of work in terms of how many angels can fit on the head of a pin, but I think that clearly was the intention, is that the vehicle to do that is research that answers patient-centered questions. It’s just missing those two words.

CHAIRMAN WASHINGTON: Thanks.

DR. CLANCY: We are not going to step away. People are confused about patient-centered
care versus patient-centered outcomes. That will persist for the life of this institute even if it’s eternal, I guaranty it.

CHAIRMAN WASHINGTON: Well, this represents an extraordinary amount of work and I actually also think it represents a culmination of a remarkable process, and so I want to commend David, the working group, but I also want to commend all the various stakeholders that have provided us with input over the last, almost, nine months. And so, the question on the table is, all those in favor of approving this definition as it is, raise your hands.

[Show of hands.]

CHAIRMAN WASHINGTON: Okay. It’s going to be easy for me to count those opposed. Okay. All those opposed?

CHAIRMAN WASHINGTON: One, two, okay. Three, okay. And abstaining.

DR. SIGAL: Can we abstain?

CHAIRMAN WASHINGTON: Okay, I mean, I don’t know if we need to get this official, but I
think we should. Do you want to be abstained?
Because we’re don’t have a category of abstain.

DR. SIGAL: For some reason, this is the first time I saw this and I’m not comfortable with it, but, again, I was so -- yeah, abstain.

CHAIRMAN WASHINGTON: So, we have two opposed, one abstention, the motion carries. Thank you, again, to everyone involved including the Board.

DR. GABRIEL: That’s the end of my report.

Thank you.

CHAIRMAN WASHINGTON: Okay.

[Off microphone discussion.]

CHAIRMAN WASHINGTON: For the next public comment period.

[Off microphone discussion.]

[Applause.]

MR. SCHMITZ: All right, thank you, Dr. Washington. We now have a 30-minute public comment period scheduled. Just as a reminder, we’ll hear first from those in the room who are pre-registered, then we will check the teleconference
to see if anyone participating by phone wants to provide comment. Individuals are asked to limit their comments to three minutes and written testimony should be submitted to PCORI by e-mail at info@pcori.org.

The first commenter is Ellen MacKenzie at John Hopkins School of Public Health.

DR. MACKENZIE: Thank you very much for this opportunity to make a few comments. I’m Ellen MacKenzie, I’m a professor and chair of the Department of Health Policy and Management at Johns Hopkins Bloomberg School of Public Health right here in Baltimore. I’m also a former Board member of the National Trauma Institute and it is that institution that I’m representing here today.

I’m a health services research who has spent the past 30 years working with trauma providers to improve our understanding of trauma outcomes with an emphasis on developing programs and policies that make a difference in these outcomes.

As you move forward with the work of
PCORI, I ask that you remember that trauma is the leading cause of death among our children and young adults and requires your serious attention.

Overall, injury is the fourth leading cause of death -- the fourth leading cause of death over all ages and the leading cause of death among children and young adults. And data from AHRQ has shown that trauma-related disorders are consistently among the five most costly conditions for our country.

In 2008, direct healthcare expenditures for trauma -- related to trauma were outranked only by heart disease, and by a slim margin, by cancer.

Attention to the priorities on comparative clinical effectiveness that PCORI has proposed are critical to reducing this burden. As with most other areas of medicine and surgery, direct head-to-head comparisons of specific acute care treatment options are sorely needed to improve our understanding of which treatment works best for which person under what conditions. Often these comparisons are challenging in trauma specifically...
as they require comparing different surgical approaches or very often surgical versus non-surgical approaches.

And all of this must be done within the context of a very challenging patient as well as a challenging treatment environment. Decisions in trauma are often needed quickly and there is little time to consider alternatives. The need for good evidence is sorely needed.

But we know that even with optimal acute care that long-term outcomes are not often good. Our own work, for example, has shown that only a little over 50 percent of individuals who’ve suffered a bad leg injury are back to work in two years. Rates of return to work are even lower for those suffering traumatic brain and traumatic spinal cord injuries.

These outcomes are complicated not only by the physical impairment associated with the injury, but by the psychological consequences including high rates of anxiety, depression, and poorly managed pain.
Identifying these individuals who are at risk of poor outcomes early in the recovery process is critical and is the critical first step, and we really don’t know how to do this.

Coordinating a wide range of post-acute care services and ensuring that patients have access to these services and are motivated to use these services is the next critical step.

Collaborative care models that foster interaction between informed activated patients with prepared, proactive practice teams, have been shown to be effective in managing complex medical conditions. These types of models must be developed and evaluated specifically for younger trauma population if we are to have a chance of improving recovery.

We request that PCORI recognize that trauma is a huge problem facing our country and ensure that you will include it among your priorities. It has been shown over and over again that funding for trauma research and trauma outcomes research is nowhere near commensurate with
And from a personal standpoint I can’t tell you how frustrating it is for me as a health services researcher and health outcomes researcher to work with young, very motivated, bright clinicians who are working in trauma and have a great research idea and then we sit down and say, all right, who’s going to fund this. The funding opportunities for trauma outcomes research have always been very limited and hopefully this will change. Thank you.

VICE CHAIRMAN LIPSTEIN: That’s Professor MacKenzie from Johns Hopkins, my alma mater. Thank you.

CHAIRMAN WASHINGTON: Thank you, Dr. MacKenzie.

DR. DOUMA: And my alma mater too.

MR. SCHMITZ: That concludes the number of individuals registered to comment on site, so we will turn to the teleconference to see if there’s anyone on the phone who wishes to provide comment.

OPERATOR: There are no comments in queue.
CHAIRMAN WASHINGTON: I also think that with two alums from Hopkins that Hopkins should be disqualified from applying for any PCORI money.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: There’s more than two.

CHAIRMAN WASHINGTON: Oh, there’s more than two? Oh, for sure.

Okay, anyone else? I mean, that didn’t register that would like to comment?

Okay, because we have agreed that we do not want a break during a period when there’s a public comment, in case someone wants to present, I’m going to ask Dr. Levine, if you are ready to move on? Okay.

And, again, if we identify someone, Richard, in the time allowed, we will stop.

[Pause.]

DR. LEVINE: Thanks. And this is the report from the COEC and I think I have to apologize to the committee members and acknowledge that given how fast things have been moving, there
are things in this report that have occurred since
our last committee meeting two weeks ago, and so,
some of my colleagues will be seeing this for the
first time also, though many of them have
participated in this work along with me.

And just, again, a reminder of the heroes
of the COEC, and we always put Gail Hunt’s name in
italics because in spite of her non-voting status,
she’s been one of the most loyal attendees at our
committee meetings and a tremendously valuable
contributor.

So, I’m going to briefly cover, today,
public feedback on the Draft National Priorities to
remind folks about that process, again, not the
content, to give you some additional opportunity to
see what actually happened at the February 27th
meeting, for those of you who weren’t able to do
it.

I want to briefly report on the clinician
focus group that took place in February. This will
just be highlights of this and the full report will
be provided to the Board, and these are clinician
focus groups on the Priorities and Research Agenda,
process for incorporating input into the revisions
of the Priorities and Research Agenda and, again in
the spirit of continuous quality improvement and
being a learning organization, the committee’s
thoughts about evaluating what we have done in
terms of stakeholder and community engagement
events associated with Board meetings, collecting
feedback, not just from Board members, but from
others, and then bringing forward some
recommendations about thinking about this going
forward, which will, I think and hope, have some
opportunity to inform our conversations about our
Board meetings in 2013 and going forward.

And finally, just a reminder to everyone
in the room about connecting with PCORI.

CHAIRMAN WASHINGTON: Just a process
question. We were scheduled to break at 3:45.
Now, we can plan to take two of these, if we want,
and have our break and reconvene, or we can work
through them and have you step out as needed.
What’s your preference, break?
UNIDENTIFIED SPEAKER: [Off microphone.]

CHAIRMAN WASHINGTON: Okay.

DR. LEVINE: Okay? So, all in favor?

CHAIRMAN WASHINGTON: [Off microphone] -- hear from the others, yours count for more this time. I was counting nods of heads too though.

DR. LEVINE: So, as I think was previously mentioned today, we have ten days left from today -- from tomorrow in the public comment period. The primary modality for submitting responses or reactions and thoughts about the Priorities and Research Agenda is through the website though we are providing opportunity for feedback by mail and we distributed it at the stakeholder event. We distributed the information with a mail address and the website is there, the website address with /prioritiesagenda.

To date, we have received, actually, I think it’s 115 comments through March 1st -- or through yesterday, sorry, and I’m going to show you just a quick summary of where the comments are coming from, both in terms of stakeholder group and
geography. And this is a bar graph on stakeholder
type. You can see that the largest number of
comments, 36 or 37, have come in research
community, 27 from physicians, and I’m guessing at
where those bars stand between numbers looks like
about 23 from patient advocates, and 14 from
patients themselves, individual patients.

I would say also that people had the
opportunity to identify themselves or to mark off
more than one category, so these numbers don’t
necessarily add up to the whole.

And this is a geographic representation of
where the comments came from. As you can see, they
tend to add, congregate, aggregate in large
population centers and our hope is that by --
through contact, and we know that generally in the
last ten days of an open comment period we get -- a
lot of people wait until the very end to submit
comments, so we’re hoping that actually this
pattern will shift as we’ve worked with national
organizations with local affiliates to try and get
feedback from less than the most concentrated

B&B REPORTERS
701 Copley Lane
Silver Spring, MD  20904
[301] 384-2005
population geographies.

The stakeholder event, the patient and stakeholder dialogue on February 27th, which, just to remind the Board, this was Gene’s idea when we first began to get a sense of the variety and diversity of feedback we were getting about the approach taken on the Priorities and Research Agenda and I believe this was in December, Gene said, we need to open this up.

We clearly need to really put on steroids the opportunity for people to engage with us around this and for us to explain the rationale and to get feedback on this. And in an almost amazingly short period of time, staff and -- PCORI full time staff and Board members put together an event, which attracted 900 individuals who preregistered, 400 in person, 530 by webcast or phone, and the actual participation had a much smaller fall off than is usually the case.

Usually when you put on a large meeting you expect 15 to 20 percent no shows, 850 people actually participated. The archived webcast is on
PCORI.org under the Past Meetings and Events page.

And the day -- I think you’ve all seen the agenda, Joe led it off, Harlan Krumholz spoke to the National Priorities and set a context for why the Board -- or the PDC and those involved actually went down the pathway of this approach to the Priorities and Research Agenda.

And a couple of statements that Harlan made, which were resonated with the patients and patient advocates were, one, our true north is our patient, and one of the patients who was blogging while the day went on made the comment that Harlan’s comments represented a pledge of allegiance to patients the likes of which this individual had never heard, and I just thought that was a very touching comment and a way of encapsulating the passion that Harlan unleashed on that audience.

Also, we had two panels. The first was a Patient and Caregiver Advocates Panel. These were really representatives of large patient and caregiver advocacy organizations. As you can see:

Those organizations represent more than 130 million individuals who are affected by the conditions the organizations represent, which they made the point several times.

The second panel of clinicians and payers, clinicians: American Academy of Family Physicians, the AMA, American Nurses Association, and payers -- AETNA and the National Business Group on Health, and industry, a spokesperson representing pharma.

And I’m going to just take two minutes for you to be able to see:

[Video shown.]

DR. KRUMHOLZ: I want to welcome you — the notion that we’ve got is that we are problem solvers together. Our accountability is to patients. Ultimately we’re going to be listening to a lot of stakeholders, but our true north is going to be patients, patients and their caregivers, and in this conception, I think maybe
we have a chance to turn the world upside down just a bit.

UNIDENTIFIED SPEAKER: It also provides an opportunity for the patient and consumer communities to collaborate with the scientific community in really designing robust and responsive research projects that will result in answers to the pressing questions we have.

UNIDENTIFIED SPEAKER: Congress envisioned that PCORI would carry out its mission in a unique way. At its core, PCORI is an agenda setting body. Patients have a different view of what the priorities would be from researchers and that they should be involved in the very initial stages of setting the Research Agenda.

UNIDENTIFIED SPEAKER: As one of our patients so eloquently stated, an outcome is how I end up. That’s what they care about.

UNIDENTIFIED SPEAKER: In the past ten years I’ve seen increasing awareness of the value of patient input to policy and regulatory decisions and what I see is a major paradigm shift from an
expert-dominated medical decision-making where the patient’s role is a passive recipient of the treatment to a truly patient-centered healthcare.

UNIDENTIFIED SPEAKER: Members of the public, patients and consumers, can be a force that can make these reforms succeed if they are utilized. And the time is now to begin that communication.

UNIDENTIFIED SPEAKER: I hope that there is rigorous enforcement of meaningful patient involvement in leadership teams receiving the grant funding.

UNIDENTIFIED SPEAKER: We need to move away from token patientism and while the diseases that we all represent are critical, we need to find ways to really represent patient -- not centered research, its patient-driven research.

DR. KRUMHOLZ: This is going to be research done differently. How? Because in the governance, design, implementation, dissemination and application of this research, patients are going to be involved at every step. And in order
to get funded by us, on your team you’re going to need patients, clinicians, and researchers, authentically and genuinely working together.

[End of video.]

[Applause.]

VICE CHAIRMAN LIPSTEIN: Hey, Gene, seeing Harlan Krumholz wrapped in the American flag.

Harlan --

CHAIRMAN WASHINGTON: I’m going to start recognizing him as Mr. President.

DR. LEVINE: The impact, as you can tell, was quite powerful. The morning was a combination of PCORI Board members, Harlan, in particular, and the two panels, and the afternoon was three hours of public comments. We had 46 individuals, in person, who made statements. For those of you who didn’t -- we didn’t -- this is hot off the press. They’ve been editing up through lunchtime to get you brief clips, but Lisa Simpson was one of -- the President of Academy Health, Shawn Bishop, one of the staff folks in Congress who helped to write -- had a substantial hand in writing the
legislation, and, of course, Perry Cohen who is well known to all of us and to whom many people in the audience actually expressed a debt of gratitude to Perry for his comments that day.

We had eight individuals making comments on the phone. Ninety percent of people who filled out the evaluations felt the event was informative, which I think is quite stunning. And 85 percent -- just below 85 percent felt the panel discussions helped provide context for the Priorities and Research Agenda.

In addition to the website and the stakeholder dialogue, we reviewed in Jacksonville the results of the patient and caregiver focus groups, which were not specifically focused on the Priorities and Research Agenda, though the conversation in those focus groups actually had elements of what had already been formulated inserted into it.

And then in February, there were nine clinician focus groups in four cities with 58 participants to get -- and this is really the first
detailed feedback from clinicians around the
Priorities and Research Agenda. And to look at the
Priorities from the clinicians perspective, their
understanding and reaction to PCORI’s proposed
priorities, as well as their general opinions about
PCORI’s work and whether they actually understood
who we were and how we were relevant to their
lives, and ultimately to try and better understand
the practice needs, clinical issues, and how this
research is going to -- could be helpful to them in
their pursuit of their mission as practitioners.

This is, again, a geography -- San
Francisco, Chicago, Philadelphia, and Birmingham,
Alabama. Advanced practice nurses, cardiologists,
integrative healthcare practitioners, PAs, RNs,
primary care physicians, a mix of nurses,
psychiatrists, and orthopedists. And for many
reasons, we kept the specialists separated so that
we could get some sense of whether there were
differences among the specialties in terms of how
patient-centered outcomes research, what their
attitudes were and how much utility they saw in it
for their clinical practice.

And when you all get -- and this report will be posted on the website, but you’ll see that, in fact, there were substantial differences among the specialties in terms of avidity for patient-centered outcomes research and their sense of utility in their practice.

And these are just some of the findings from the clinician focus group. Again, these are very high level and quick and dirty, assembled in the week prior to our Board meeting.

Clinicians have mixed feelings about the research. They use and appreciate research, but have concerns about corporate agendas, about the issue of FDA approval times, they are split on whether it’s too fast or too slow, and feel several steps removed in clinical practice from actual research activity.

They voluntarily articulated the need for many of the concepts behind comparative effectiveness research and patient-centered outcomes, but this is not the language they use and
the language required some explanation.

In terms of impressions of PCORI, one of the biggest stumbling blocks is the perception that PCORI is broad, overreaching, too idealistic to have a meaningful impact. And, again, this is a theme we heard from some of the patient focus groups also.

Another communication challenge is, coming from the clinicians interestingly, that how can we ignore costs, the issues of access and payer decisions that they feel overshadow discussions about clinical outcomes. Again, split on whether PCORI ought to be addressing them but articulating that they become the 800 pound gorilla in the room, unspoken and unaddressed.

Clinicians, similar to patients and caregivers in the earlier focus groups, agree that assessing options and communications are key priority areas for PCORI. Clinicians also prioritize improving healthcare systems, which really means improving the conditions in their working environment in terms of their ability to
achieve their own personal mission around
supporting patients and providing optimal patient
care.

In terms of advice for engagement, strong
preference for professional organizations,
professional societies as the preferred channel for
information. They trust their specialty societies
and believe information that comes from them.
They’re willing to engage with PCORI if the
opportunities are convenient and very specific to
their practice setting in the patient populations
they’re caring for.

They also like the idea of surveys,
you’re easy, they’re fast, they don’t require them
to leave the office, but are willing to participate
in focus groups, again, if they have a sense that
the information is going to be used in a way that
ultimately is useful to them. And many underscored
the fact that ongoing communication is going to be
necessary, will take diligence on PCORI’s part, but
without it, they’re going to forget about us pretty
quickly.
This was the exercise of allocating funding, you know, if you were running PCORI and you were going to make funding decisions among these priorities, the averages here really mask the range of opinions. While the average of 17 percent of funds would have been allocated to the disparities, many individuals said it ought to be part of everything else we do in addition to having its own separate funding allocation. If we get all the other stuff right, we will be addressing the issue of eliminating disparities.

And, again, there was tremendous range from the cardiologist who thought 75 percent of the funding ought to go into assessment of prevention, diagnosis and treatment options, to the psychiatrist who thought that 80 percent ought to go to addressing disparities.

And just one other point is, these allocations were very similar to the patient and caregiver focus group in terms of over -- again, on average, representing funding.

And so, just once again, and I think we
talked about this earlier, the process of revising
the Priorities and Research Agenda, the PDC and
PCORI, and the PCORI Board, will review input from
the website, from the stakeholder dialogue, from
the focus groups, and from formal and informal
feedback that is being received by Board members
and staff at PCORI related events. There’s a lot
of conversation going and many people have asked
for a mechanism to communicate that to staff so
that it can be incorporated into the work that
Deloitte will be doing on behalf of the PDC to
organize the feedback and put together the work
that will make the -- that will enable people to
understand what happened with their feedback and
how the feedback influenced the revised Priorities
and Research Agenda.

The report will be published on the
website, again, explaining how input led to changes
in the Priorities and then there will be a meeting
of the PCORI Board, a public meeting of the Board,
in April during which the revised Priorities and
Research Agenda will be presented.
April feels like it’s tomorrow, but the intent is they will be adopted in mid-April so that they can, in time for the funding announcement in May.

And, again, as I said earlier, in the spirit of continual improvement, subsequent to this Board meeting, Board members will receive a survey, which I would -- we would really appreciate it if 100 percent of people filled out, on -- and this is relating to our stakeholder and community engagement events associated with Board meetings. And these are the Board meetings we’ve held, really, from the beginning through this Board meeting.

We have -- we’ll also be surveying participants from our March 2011 through January 2012 stakeholder engagement events. We have feedback from New York and St. Louis already. We will be reaching out and surveying those who presented to us and those who Board members met with at the other Board meetings, to enable us, again, to come back to the Board. We had hoped to
do this in May, I’m not sure that will be feasible, hopefully we can, and to feed this into our planning for the remainder of -- stakeholder events for the remainder of 2012 as well as how we plan -- what we think we ought to be doing and can we be doing creative things going forward, both in 2012, second half, and 2013.

And, again, just a reminder about the website address, the mailing list, just for people to sign up on the mailing list. We have a Twitter account for those of you who Tweet or follow Tweets, and there is a separate portal for providing feedback at any time, unrelated to the Priorities and Research Agenda, and, again, a web address for requesting speaker from PCORI for an event in the community or for a professional meeting.

And I will ask if any of the committee members have any comments.

CHAIRMAN WASHINGTON: Okay. Start with Sigal and then Hunt.

DR. SIGAL: Well, first of all, thank you
for your hard work and it’s a good report and it’s interesting. I just have a specific question on the patient and the patient advocates that responded. So, I assume you mean patient -- individual patients? Okay, and in terms of the advocacy organizations, do you have a breakdown of whether they were disease specific or whether there were big omissions? Because, you know, I know I’ve been trying to get people to respond to this and it’s been a big task.

DR. LEVINE: We do have the information. I don’t have it here with me, but we do have the names of all the organizations.

DR. SIGAL: Okay, and you did say you proactively went out and tried to get more response from groups too? Great.

DR. LEVINE: We’re still doing that.

DR. SIGAL: Yeah, I know. Thank you.

CHAIRMAN WASHINGTON: Okay, Hunt and then --

MS. HUNT: Yeah, Gail Hunt, Board of Governors. Sharon, I know that we’re just seeing
some of these numbers, you know, just literally now and they’re being updated. I’m concerned about how few people have responded on the public feedback on the draft Priorities and Agenda. One hundred and one --

    DR. LEVINE: It’s 115, but, yeah.

    MS. HUNT: Even if it’s 150, it’s -- and I know that you say right before the 15th a bunch of people will probably reply, and that’s probably true, but it’s kind of -- the numbers are so small and I’m concerned that the -- it’s going to be the big organizations that they’ll will probably have their letters in because I know that some people are actually out there at the moment, organizations, soliciting, let’s get our letter in to PCORI.

    So, I’m concerned about it being a small number and about they’re just the big voices. And, you know, I know that we can’t, I guess -- we’ve got these other things to rely on, the focus groups and all, and we can go ahead, but I guess the sense is that we need to, when we write this up, we need
to say that we understand that these are -- that we’re basing this, basically, on smaller numbers and that we’re not necessarily getting the voice of the patient and caregiver in what we’ve got.

DR. LEVINE: It’s a really good point and I think the other point that will be made is, this is the first iteration of National Priorities and Research Agenda, and I think as we move forward and our reach into the broader community over time gets deeper and broader, hopefully that will result in more familiarity, more interest in responding, and I think how we behave in relationship to the feedback we do get, will help to generate trust and hopefully more interest in providing information.

CHAIRMAN WASHINGTON: Douma and then Weisman and Clancy. Oh, Leah --

MS. HOLE-CURRY: Just for context, too, I would say that the great thing about the presentation, thank you, is also that it’s not just the online comments that we’d be referring to, but the focus groups which did include actual patients and the 800 or 900 folks that were at the
stakeholder focus event, which included, I think, some patients. So, I think that’s a good thing, don’t you?

MS. HUNT: Yeah, it’s good that we had those 800 or 900, but we didn’t hear from 800 or 900 voices at that meeting saying, this is what we think about the National Priorities and Research Agenda. That’s all I’m talking about is the input to that.

CHAIRMAN WASHINGTON: Douma.

DR. DOUMA: Couple of responses. Ellen, first of all, you can go online and see who’s actually signed up. I did that less than a week ago and the vast majority of people are not identifying with organizations, they’re individuals, so it’s hard to tell.

Anybody? Anybody?

DR. SIGAL: Oh, so how do we classify them?

DR. DOUMA: Oh, no, there’s a separate classification scheme and I didn’t add those up. There’s just a list, you can see how they
identified themselves.

I am also very concerned about the small number. I mean, hate to get too hyperbolic, but with 200 million patients and 5 to 10 million other stakeholders, we’ve got to figure a way, because this is our third effort, really, and if we’re only getting a couple hundred people -- we’ve got to have, and I’m not sure we did have, a communication strategy or plan with regard to how to market this. And we’ve got to learn from this experience -- and decide, what are we going to be content with? Are we going to be happy with 200 or is it 2,000? What do we shoot for?

Because unless we’ve got something to shoot for, we’re not going to be able to measure whether we’re doing the right things or not. And, so, I think we need to get more proscriptive, we need to -- we just really need to have a communication plan, measure against communication plan, and every time we do it, adapt some of the stuff we learned from the previous experience.

CHAIRMAN WASHINGTON: Is it related to
that?  Krumholz, please.

**DR. KRUMHOLZ:** I just want to follow up with Allen because I think that you’re speaking of the method, which is important, are we getting to people in a way that they can contribute, but I think the one thing that we may not have reflected well enough with regard to the Priorities and Agenda was laying out it conceptually, like, what exactly would you say to it, because in deciding to go in this direction, it may confuse people a little bit because it’s not saying, okay, there’s atrial fibrillation and cancer and this and that, and maybe it was our fault, but we can work on the methods, there’s no question. Because I told Carolyn, if I were to sit a family member in front of a computer on the webpage and say, please comment on this, they wouldn’t know what to say, I mean, you just wouldn’t know how to manage it. And there’s the piece about how do we get them to the computer to read -- to do that, but then there’s also the part about, when we went in this direction, did we frame well enough what we were
looking for and how people might contribute to our own evolution of thinking about this.

And I think our own thinking has continued to evolve over time and the one thing that we could do better going forward is that framing for people about what kind of input might you give to this. I mean, some people can give whatever they want, but if someone who’s a Tabula rasa is sitting down and doesn’t really have an idea about PCORI, it’s hard for them to engage in it the way we presented it and that’s what, I think, we need to work on.

CHAIRMAN WASHINGTON: Yeah, I think this is an important point, and it’s not just PCORI. Remember, again, we’re conducting this research for the nation and I think this is a fundamental question that all organizations are going to encounter, and that is, again, it’s basic: what is the best, most effective way, in this case, to get feedback? And that hasn’t been defined. We don’t know even the basics about that, so that becomes a research question.

I also think the point that Allen made is
one that at least I don’t remember us discussing is, what’s our target? You know, we need to be thinking about what makes sort of us feel that we have in fact reached some penetration that satisfies that we feel like we really do have feedback.

DR. DOUMA: Can I quickly respond. I agree totally with what both of you just said and I think we just need to be much more proscriptive and I just want to add a little nitpicky because I’ve been involved with surveys for 35 years, the survey, we’ve got to be careful about our survey instruments themselves. This particular instrument asks people whether -- it was basically a five-point scale, three of those points were positive, two were negative, that’s not the way to ask a survey.

We’ve got to be a little bit more rigorous in the type of survey we do.

CHAIRMAN WASHINGTON: Next time all five should be positive, right?

[Laughter.]
DR. DOUMA: Absolutely. If you’re going to do it, be blatant.

CHAIRMAN WASHINGTON: Okay, so we have Weisman and then Clancy and Selby.

DR. WEISMAN: Yeah, I hate to disappoint the Board, but this is not the most exciting thing in peoples’ lives although it is for us. So, I mean, the fact that you’re not having overwhelming crowds in the streets, you know, cheering us on, you know, there’s a lot of other things going on. There’s the economy, there’s elections, there’s all kinds of Academy Awards, there’s lots of things going on in peoples’ lives, and this is important, but I would say that we have had a fairly effective way of getting feedback, particularly from patients. You know, we’ve done focus groups. Could they be done better? Yes. You know, I’ve advocated for some quantitative market kind of research kind of stuff that we can do, but, boy, Joe’s been on a road show forever. You know, the only breaks you get off the road show are when you come to a board meeting, right? And, you know,
other Board members have too. We’ve met with patient groups.

You know, the heterogeneity among patients is more narrow than I think it is among other stakeholders in that they universally say that, you know, they’re not happy with -- by and large, they’re not happy with healthcare as it relates to the information available to them that they don’t feel that people communicate with them effectively. I mean, that’s resoundingly what we hear over and over again at the town halls that we had in New York and St. Louis.

And I think the idea now, asking for them to translate that into, how do you come up with National Priorities, maybe we could do that better. I’m not sure what else we could be doing, to be honest with you, because we haven’t done stuff yet that shows them the value of what we can do for them, and I think as we do that, as that momentum builds, you know, maybe we will get more engagement, but I do think we’ve done a reasonably good job at hearing what’s on the minds of patients
and I think a lot of what Harlan was addressing in his inaugural speech then -- or, state of the union, was addressing that for them.

    DR. LEVINE: Right. And I think one of the things that was very illustrative for me was I talk to lots of folks in breaks in the morning and it took most of the morning for people to actually understand -- and these are people who are very sophisticated and for whom this is their life, for the most part, to really get what we were asking and get what -- why the framework and how we actually thought we might get from where we’re starting to actual answers to questions.

    And I think the same thing was true in the focus groups with the clinicians. Again, it took a while for them to actually be able to engage and answer the questions, and so imagine, you know, people sitting down getting a note from a consumer advocacy organization and saying, you know, go to the website and let PCORI hear from you about what you think, I think it’s a tall order because we were asking for a lot in terms of the feedback for
Now, so what I take away from that is the more targeted and specific the questions we want feedback on, and the more relevant they are to peoples’ lives, the more likely we are to get a more robust response. And I do think that our ability to disseminate the request for help through trusted organizations and building a network of organizations who trust us enough to do this on our behalf with their constituents, again, will help us achieve what we really want, which is deeper and broader understanding.

CHAIRMAN WASHINGTON: Okay. Clancy? And then Lipstein, Norquist and --

DR. CLANCY: So, first I wanted to thank Sharon and the committee for a terrific presentation.

I will tell you, and as your own Sue Sheridan, part of the wonderful engagement team knows very, very well, in many areas, whether it’s quality, safety, a variety of things, all of which are a little bit more proximal to peoples’
experience, it is hard to get people involved.

In general, they tend to be a narrow, tight group of folks who are wonderful, but Sue will tell you, this is why we call her a lot -- we have in her prior life anyway -- it is difficult and it’s pretty abstract stuff and in addition to that, I think it’s fair to say that there’s been an unprecedented number of opportunities, I’m thinking about proposed rules related to the Affordable Care Act, for people to weigh in about stuff that’s going to affect them next year, okay.

So, I think that bandwidth issue is all part of what we’re doing. That said, I think from what I understand, there were a lot of patient groups who wanted this legislation to happen. We have an incredible opportunity to reach out directly, not just come to our website, that is fairly passive, I mean, great if they do, but it is abstract stuff. On some level there’s a whole lot of people, I think, want to hear what are the priorities going to be and do they care about it. To tell them that they get to do more work for free
to be engaged in potentially writing proposals, I mean, this is all very, very downstream kinds of stuff at a moment in time when there’s a lot of challenging issues right now today.

The other thing I wanted to just underline in Sharon’s presentation, in case it was too subtle, was the word diligence. I think this comment came from a focus group participant or I can’t remember if they said it or if that was your interpretation.

I heard a lot of kudos for the meeting last Monday, well-deserved kudos, but I also heard people say, “show me.” I’m thrilled to be here today, but I want to be involved with you all moving forward.

So, I think the stakeholder engagement team here at PCORI will have their hands full and I think that as a board we’re going to have to figure out how do we allocate resources, because the one thing PCORI can uniquely do, and probably needs to do uniquely, is to engage that. A lot of the other functions, it’s a little bit easier to outsource,
but if we’re not doing that, then people are not going to care.

CHAIRMAN WASHINGTON: Let’s go to Selby first because I skipped him.

DR. SELBY: Thanks, Gail. Yes, and those people who said, “Show me,” were all from Missouri. So, I’ve also been watching the numbers accumulate slowly and been -- I’m in full agreement with all the people who’ve offered explanations for why the numbers are low, and the question I’ve had -- and so I’ve had a little bit of mixed feelings, is whether efforts to gin up the response rate more would wind up giving us a more or less balanced -- biased -- more or less biased sample in the end, and so I’ve been wanting to be careful about those efforts.

But back at PCORI, others have also been watching and we do have, I think, some strategies in place, and I’d like to ask Bill Silberg, our Director of Communications, to just speak briefly on some efforts we’re going to undertake in these last ten days to see if we can’t get the rates up
MR. SILBERG: Great. Thanks, Joe.

And we also share the concern that the numbers have been smaller than we might like and are growing slowly, and I think all of the issues that have been raised and the points that have been made are part of that whole question.

That having been said, we are working full tilt to do what we can in the next ten days to accomplish, really, two things. One is to try to, as broadly as we can, both on the professional and the consumer side, do as much outreach as is reasonable given the time we have so that we are able to defensibly say, we made every reasonable effort to get the word out.

If that didn’t directly result in the kind of numbers we would all like to see, you know, there’s only so much we can do about that, but we don’t want to be caught with anyone saying, how come I didn’t know, because I think that is a big perceptual issue and we owe it to our various audiences to do that. So, we are doing that in a
number of ways.

We now have all of our engagement team engaged fully in a full court press to contact all of the folks that they know with an eye not just toward would you please individually send us a comment, but to mobilize all of their communications capacity to get the word out to their constituencies because obviously we could hire a thousand folks to make phone calls and we wouldn’t reach as many folks as if we could mobilize all of our partners.

So, that’s one piece. We’re doing a lot of this. We’re also doing a series of targeted online ads and alerts to both professional and consumer media trying to get the biggest bang for the buck. So, on the professional side, trying to go out through places like Modern Healthcare, American Medical News. We’re working with the Health Affairs listserv and blog on the consumer side, WebMD, the AARP website.

We’re really trying to get the word in front of as many folks who will see it and try to
get back to us as possible.

In addition, we’re trying to work with what’s called in the business, earned media, but it’s basically trying to get to folks who reach these audiences, not through paid advertising or just through personal calls, but really trying to get our message in front of them through their various communications vehicles, which are expected by those audiences, so they have some resonance.

So, we really are trying to do everything we can, but we hear you, we hear you totally, and I think one of the important points to kind of leave you with is just as much of the rest of what we’re doing is a piece along a road, it’s a start or maybe step two in a start, we see what we learn here, as several have said, to contribute to an ongoing conversation. Our real opportunities are not just, we think, to try to do the best we can to get as much comment and synthesize it based on this one piece of PCORI’s work, but to begin to set the stage to do this over and over and over again in a consistent and iterative process to build these
partnerships so that the next time we have something important we want our communities to talk about, we hopefully will not be having the same conversation.

CHAIRMAN WASHINGTON: Lipstein and then right next to him, Lewis-Hall, and then --

VICE CHAIRMAN LIPSTEIN: So, there are two points, one that Gail made and one that Carolyn made and I know we don’t want to repeat, but there are things that I think are worth emphasizing.

We do know now after two years of experience with PCORI that there are organizations that send a representative to every single one of our meetings, so they have a voice which will be heard loud and clear because they have a paid professional on their staff whose 100 percent role is to track PCORI.

And so we will hear from them. So, I think we need to be sure that that voice doesn’t get magnified to the exclusion of other voices that we want to hear from. And that was a key point.

Two was, Carolyn brought up a key point
too, which is, for the last two months, the medical
establishment has been really focused on what was
going to happen with the SGR, sustainable growth
rate fix, and then the offsets affected every other
aspect of our industry, and so we were all consumed
with writing testimony or feedback or opinions on
things that actually had significant dollar
consequences for the healthcare sector of the
American economy, which means we weren’t focused on
PCORI, and so I think we need to keep that in mind
too, that the timing here is not great for getting
feedback.

But the third was, is that as Joe has made
his presentations and I’ve made three and, Allen,
you commented that you -- it’s been very well
received. The National Priorities and the Research
Agenda have been very well received. The number
one criticism being that, you know, maybe we
weren’t specific enough, which could also be
interpreted as we didn’t give people enough to
shoot at.

And if you didn’t give people enough to
shoot at, then maybe that explains a little bit of
the de minimis return in terms of feedback, but I
think we need to -- you know, when I saw this, I
didn’t necessarily think it was an inadequacy of
interest or concern, it just meant there were a lot
of other priorities going, or, alternatively, that
people were very much -- people don’t tend to write
in comments or provide feedback if they’re in
agreement with you.

CHAIRMAN WASHINGTON: Okay. Lewis-Hall.
Then Norquist.

DR. LEWIS-HALL: Freda Lewis-Hall, Board.
Actually, I was going in a little bit of a
different direction, which is, I’m not sure people
know what to say along the lines of what Harlan
said, you know, I don’t recognize this, I’m not
quite sure what this means to me, and I’m not sure
what to say even if I had something to say.

So, I think the reframing is really
important, one. The second thing is, we continue
to ask people to come to us to make the comments,
and we may want to -- you know, the reach is great,
but we’re still saying, now that I’ve reached you, please come to us, to our website, to our meeting, you know, to our focus groups, or whatever. There may be an opportunity for us to shift a little bit and to literally go where people are and ask them their questions there, and I think, Steve, you had given the comment once, you know, why aren’t we roaming the halls of a hospital or a clinic or where people are receiving care or in a drug store or a mall, or wherever it is people are congregating and ask them the questions if you really want people who, you know, don’t have a bias or some acute interest in this.

So, I think we do have an opportunity to evolve and grow in the way in which we do outreach, both in simplifying our message, framing specific questions that people can respond to that would, you know, give them a way to give us feedback, and then to go where they are and not to ask them to do any more work than they are likely to be inclined to do.

CHAIRMAN WASHINGTON: Norquist.
DR. NORQUIST: So, Gray Norquist, member of the Board. So, I’ll follow on with Freda because one of the -- I didn’t make it to the February 27th but I got to watch it and keep the recording of Harlan and everything on my personal -- but the one comment that actually struck me the most out of all the people who testify was a woman, and I can’t remember what organization she was with, but stood up and said, this is all well and good, I like this, but I hope one day we have a meeting in which people are unlike us are here.

And so, I just want -- it’s very hard. I agree with Carolyn, it’s very hard to get input and I agree with Freda, you can’t, you know, build a place and assume that people are going to come because they’re not. I mean, they’ve got -- trust me, they’re not worried about the healthcare, they’re just worried about just surviving day to day many of these groups.

So, I hope -- we now have an engagement group and I hope we can work with them to really get out of our little tower or whatever and get out
there and really try to figure out how we can get them, but it’s not going to happen this year, but that could be something really different that no other group has ever done to really try to reach these people who underrepresented, who are suffering with chronic medical conditions, who really have something it input. Now, they may not say it the way you want them to say it, but they know what the problems are and they’ll say it.

So, I hope we put some strong effort in that and really try to reach the groups who are suffering the most and, it’s hard, but I think it’s worth it.

CHAIRMAN WASHINGTON: Dr. Levine, you want to wrap up your report?

DR. LEVINE: I want to thank everyone for their comments. I mean, this is really -- we are at the beginning of a process and I’m the number one fan of our new engagement team and I think the capability and potential they bring to us in terms of putting on steroids what our -- you know, what we have been trying to do for the last year and a
half. And, again, to continue to learn from what we’re doing.

So, my ask of you is to fill out the survey and be free. You all know exactly what those questions are about, so there shouldn’t be any issue of framing or reframing, but give us your thoughts about how we can actually make these engagements in relationship to our Board meetings meaningful. And to Freda’s point, perhaps turn our approach 90 or 180 degrees.

CHAIRMAN WASHINGTON: Okay, just in wrapping up this session, again, I want to acknowledge that this represents an amazing amount of work on the part of not just those involved in the communications and outreach and engagement committee, but also other Board members and the many stakeholders who, in fact, showed up for the conference and are responding online.

And, importantly, last Monday was a big success, I would say principally because in addition to the Mr. President’s speech, the staff, and I really want to compliment the staff for a
phenomenal job in putting this together in a very short period of time and I think that they, from everything that I have heard, really reflects the best of what PCORI is offering now and what we are going to offer in the future as it relates to patient and stakeholder engagement.

So, it feels good.

DR. CLANCY: Are you going to post the video on the website? I mean, that would actually, I think, capture peoples’ attention. The video from last Monday? I know there’s a video of Joe, but -- great. Great.

UNIDENTIFIED SPEAKER: Do you have a screensaver?

CHAIRMAN WASHINGTON: Of Harlan? Okay. We’re going to pass that around.

We’ve come to the conclusion of the day and I think every Board member would agree that this has been an intense but highly productive meeting today and so, again, I want to thank everyone who came to join us and participate in person as well as those on the line, and thank the
Board for your ongoing deep involvement day to day in the life of PCORI and in ensuring that we realize the promise that’s inherent in our charge.

So, thanks, everyone, for your participation. That concludes the meeting.

[Whereupon, the PCORI Board of Governors meeting was concluded.]