PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

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Park Hyatt Hotel,
1201 24th Street, NW,
Washington, DC

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Harlan Weisman, MD
Robert Zwolak, MD, PhD

A G E N D A

A G E N D A [Continued]

P R O C E E D I N G S

[8:34 AM]

CHAIRMAN WASHINGTON: Good morning, everyone.

SPEAKERS: Good morning.

CHAIRMAN WASHINGTON: And given that we're the future of comparative effectiveness research and patient-centered outcomes research, I expect a more robust response. I'm going to try this again. Good morning, everyone.

[Laughter.]

SPEAKERS: Good morning, Gene.

CHAIRMAN WASHINGTON: That's more like, good morning, Principal Washington. But, no, to everyone in the room this morning, welcome, and thank you for participating in this board meeting of the Board of Governors for the Patient-Centered Outcomes Research Institute, which we call PCORI, and I also want to welcome our audience which is joining us via webcast.

For those of you who are joining us from afar, as well as those of you here in the room, if

you have questions or information that you want to pass onto us, please do so at our website at info@pcori.org.

First, I want to remind everyone that this is actually our second anniversary, that we were officially appointed by GAO yesterday, September 23, 2010, and here we are 18 -- I mean, two years later, fully established institute with just an outstanding, I would say, exceptional staff with superb leadership, and over the course of this time we have benefitted greatly from the support of many across the country.

And so, on behalf of the Board, I want to thank all of you who've helped us arrive at the point where we are now, where we're actually supporting patient-centered outcomes research.

And so, I want to move to the official part of -- and before I end I also want to just say thanks to my Board members. Your contributions have been enormous and I think that just about everyone at this table has committed probably, at least five if not ten times more time than they

expected when they received that call from GAO.

UNIDENTIFIED SPEAKER: Here, here.

CHAIRMAN WASHINGTON: Here, here. Of course, over the last two years, on every occasion that I have -- and/or Steve, have asked one of you to take on a task, you've done it, and more often than not, you contacted me before hand to say, this is something that I could help with and I'd be glad to. So, thank you.

Moving to official business, we want to approve the minutes. Now, these are minutes from January, you would note. For those of you who are joining PCORI for the first time, it's not typical that we approve minutes eight months after, this is an aberration here. We looked at the minutes and we wanted some corrections made and I understand from Joe we still have a couple of minor ones that we want to make as we look to approve these, so with those edits Joe.

DR. SELBY: That's right. I'll just mention that one of our staff, Gail Shearer, was left off the attendance for the closed session in

January when she was mentioned in the open session minutes she was misidentified as a TMC employee and Judy Glanz was identified once as the Director of Patient Engagement when she was the Director of Stakeholder Engagement at the time, so those three very minor corrections --

CHAIRMAN WASHINGTON: Okay.

DR, SELBY: I think the minutes are finally ready for consideration of a vote.

CHAIRMAN WASHINGTON: Bob.

DR. ZWOLAK: Bob Zwolak, Board member. I was listed as being both present and absent at that meeting.

[Laughter.]

DR. SELBY: That's you Bob.

[Laughter.]

CHAIRMAN WASHINGTON: Harlan asked you a question. Harlan said do you have a preference? He was happy to be here. Any other comments?

[No response.]

CHAIRMAN WASHINGTON: Is there a motion?

UNIDENTIFIED BOARD MEMBER: So moved.

UNIDENTIFIED BOARD MEMBER: Second.

CHAIRMAN WASHINGTON: Okay. It's been moved and second. Further comments?

[No response.]

CHAIRMAN WASHINGTON: All in favor?

[Chorus of ayes.]

CHAIRMAN WASHINGTON: Okay. Any opposed.

[No response.]

CHAIRMAN WASHINGTON: So the motion is carried and the minutes are approved.

As you know, we still have the minutes from May, but we're going to approve those at the November meeting.

Later in the Board meeting, Joe is going to give us an update on our plans for how we go about both taking minutes as well as subsequently reporting them. Okay?

And with that as my welcome and introduction, I'd like to turn it over to esteemed Executive Director, Dr. Selby.

DR. SELBY: Thanks, Gene. Hello, everyone. It's really nice to see you all gathered

together again. It's been a long time. It's been four months, that's the longest we've been away from each other and we -- it's not that we haven't been talking a lot in committee meetings and face-to-face in Palo Alto or the workshop in Palo Alto for a number of you, and one-on-one conversations, but great to see the entire Board assembled again.

Much has happened and today we're going to update you with some -- a lot of new news, a lot of the results of a lot of hard work over the last four months, and some decisions to be made.

First piece of news is that we have grown. The growth trajectory has definitely steepened in the last three to four months. Here are pictures of nine new employees. We no longer, I think, have time to kind of call out each one, but you will meet them through the course of the day and hopefully this evening.

In addition to the nine that are shown, there are five shy ones listed below who didn't want their pictures up on the screen. We have scientists, we have project and research

associates, we have deputy directors, we have assistants, we have a communications director, people in contracts, so I'd like to -- because we were in Washington, D.C., we asked as many of the staff as could to attend the meeting just to watch this Board in action, so I'd like to ask at this time if the staff members present would just stand for a moment.

UNIDENTIFIED SPEAKER: Big group.

DR. SELBY: Such a handsome lot as well, and I think, you know, we can note today that the staff now outnumber the Board, and that's the first meeting at which that's been the case.

Thanks, everybody.

[Applause.]

DR. SELBY: And you will hear from several of these folks in the course of the next two days.

At the last Board meeting we celebrated several major milestones, as you recall. We adopted the revised National Priorities and Research Agenda, we received from the Methodology Committee their version one of the Methodology

Report along with 60 standards and recommendations for future research, and we announced the release of the first four PCORI Funding Announcements that matched up to the first four Priorities. And we said, at that time, that we would begin being PCORI, and indeed, that's what we've been doing, working to fulfill PCORI's mission over these last four months.

I want to just tell you just a little bit of what that feels like. As we go to work every day, we increasingly appreciate that we are building a research enterprise that does research differently, and we feel very fortunate to be involved in that activity.

We hear repeatedly from patients and patient organizations that we are distinct and an improvement on what's going on in the research enterprise up to this point. We hear from researchers both that this is new and refreshing and exciting, and also from some researchers we hear that it's worrisome and that it's so different, it's difficult to change, and we agree,

it is going to be difficult to change in some of the ways that our Funding Announcements require that changes be made. But we're happy that researchers have noticed us and we are very anxious to be supportive as we move toward this new way of doing the business of research.

We realize that we're blazing a new trail and we often say to ourselves as we sit down to a meeting that this is a historic meeting, and we're often right.

I also want to just say, in light of the staff, that these people work harder than any group I've ever seen. They work -- they're short-handed, not quite all the infrastructure is in place from day-to-day, and yet they go forward passionately and we -- I've never worked with a group as supportive, so it's a pleasure. I think Anne and I both just thoroughly enjoy coming to work and working with this group.

And lastly, I just -- I'd be more than remiss if I didn't say that we are grateful and we know that we are immensely fortunate to have the

Board of Governors and the Methodology Committee as partners in all that we do. Your involvement on the teleconferences, face-to-face committee meetings, at the Palo Alto workshop, ongoing one-on-one communications, we have no doubt that you're with us and you're in this with us for the long haul, and we really appreciate it.

So, last Board meeting we talked a lot about research funding and planning, both the Pilots and the first Funding Announcements. This meeting, maybe more than any meeting that this Board ever has, we are going to talk about engagement. We're going to talk about what we're planning to do by way of engaging with our patients and other stakeholders, we're going to talk about why we're planning to do it. We've been working very hard on this.

We don't want you to think that research is not our primary business, but in order to do research the way that the Board has instructed us, that needs to be done, we feel that engagement and what comes from engagement is very crucial.

So, the whole morning is going to be essentially dedicated to talking about our plans for engaging with patients, for engaging with other stakeholders, and for beginning to work with patients and stakeholders toward a more specific research -- for research and then considering them in multi-stakeholder sessions. We do them by forming advisory panels, multi-stakeholder advisory panels.

So, that's a lot of what our morning is going to be like, but I want to just give you a reminder that indeed research is underway. By October 1st we will have begun signing the contracts with our 50 pilot awards. We're in intense communication with them and ironing out the wrinkles in this first set of research contracts issued by PCORI.

Just to remind you, we approved 50 projects; they're all in line to be funded. Most of them are two years in length, total of $31 million in funding, and they have a rather uniform size. I mean, there's a little bit of variation,

but they tend to be about $500,000 in direct costs for most of these 50 awards, and so that -- and then adding on in-directs, it brings it to $31 million in funding.

There is a pretty nice distribution across the country of these projects, but, you know, we are aware that there are some areas of the country that are not represented yet in this first round of PCORI research. We're looking at that and what we see is not so much that one area of the country did better in terms of getting its research applications funded. The distribution of funded research is pretty reflective of who submitted research. So, if we divide the country into four quadrants, we find that the hit rate, the funding rate, was very similar across the four areas, but there's just a real deficit of applications from the West, to some extent, the South, and we hope to work with you to continue looking at this to try to understand this, to try to get the word out about PCORI and the PCORI opportunities so that we can populate the whole map a little better as we go

forward.

It's a nice distribution across the areas of interest, although there are a couple areas that really stand out as having a large number of projects, so you can see in the middle column how many were submitted and in the right column how many were funded, and your eyes may be drawn to the 19 or the 11, so that's 19 projects where patients are engaged in translating evidence into healthcare practice. This might be by the development of decision support tools, it might be by working with a system to implement a new program of care, but it's not the program itself that's being evaluated, it's how patients are integrated into that planning of the system or the development of the decision support tool.

Eleven projects looked toward developing patient-centered outcomes instruments and, again, these were awarded because they specifically engaged patients in the development of the outcomes measure.

Couple gaps too, and we're going to have

to decide what we want to do about that. The most prominent one is the one where there are zero funded applications in the topic area of collecting and assessing patient and provider perceived gaps in evidence, and I would just say that there are a lot of ways to find gaps in evidence and it's not been historically a busy area of research up to this point like some of these others are, and so that may explain it.

We didn't get a large number of applications and none of them succeeded in getting funded.

This slide shows essentially who got funded, and the news here really is that among the -- first of all, there were a lot of applications that had subs, and if you look at the pie charts on the left, the primes were predominantly came from academic centers, probably about -- looks like about 65 to 70 percent came from academic centers, but if you look at the bottom pie, a large majority of the subcontractors in these projects were indeed non-academic centers, and the table on the right,

you'll see that the majority of the primes under the funded column did go to academic centers, even those four hospitals are -- I believe they're all four links to academic centers. A small representation from non-academic settings -- health systems, research organizations, patient associations, and nonprofit foundations, but just a very small representation, so this is something we -- and it should also be said that this was methodologic research, but this is something we really aim to change through our engagement activities.

We were concerned that these applications should include underserved populations and specific priority populations, and you'll see that, if you just look down the column of funded, or you look at the bar graphs, either one, substantial representation of various priority populations.

And this is a piece of completely new news, I think, to many of you. We competed a contract about two months ago and the winner, out of nine applications, was Academy Health, and the

contract was to work closely with PCORI to track the Pilot Projects. So, Academy Health will help us monitor the Pilot Projects for the overall achievement of specific aims, but also specifically to assess the learnings on patient engagement and to identify at least five sub-groups of these projects who are linked by common themes to develop joint projects within those thematic areas.

So, the notion here is that PCORI wants to get as much as possible out of these methodologic projects that aim at understanding how we engage patients in research.

I want to say a little bit, what we know so far preliminarily about the applications to our PCORI Funding Announcements. So, these came in July 31st. We received 483 applications. This was fewer than we anticipated. We had 1,300 letters of intent. We did a quick online survey of all of those respondents to the letter of intent who did not submit applications and overwhelmingly they told us that they intended to submit the next round, that the two-month -- two and a half months

that they had when we announced them was just not enough -- perhaps it was not enough to really go out and make sure that they were engaged with patients or the community or other stakeholder groups.

So, the big news was that those who declined to submit intended to submit in the future.

Again, the states applying looks a fair amount like the pilot project distribution. And the funding in the pie chart is pretty much proportional to the funds available, so almost to a T. There's somewhat more money available for assessing, prevention, diagnosis, treatment options, and that's where the largest number of applications was. Improving systems is second, and the purple portion of the pie, and that's what we saw.

And then the other two, communication and dissemination research and addressing disparities, have proportionally about the same proportions as the amount of funding that we had announced.

So, it just seems to say to me that people were listening and reading.

Very nice to see the distribution of topics, and these are the topics that the applicants told us in specific questions they were considering, so chronic conditions was the largest single one, multiple chronic conditions, but cancer, diabetes, cardiovascular disease, mental health, acute care, pain, vascular health, rare diseases, all of these get some mention. So, it shows you on the one hand that we would expect to have a nice portfolio across a wide range of conditions. It also shows you some of the challenge that the review committees are going to have, that we're going to need to have experts and we've spent time recruiting experts for these.

Also, a very nice mix of stated methods. A lot of these studies use more than one -- may use mixed methods, but they may use some qualitative research as well as then a randomized trial. But I will point out that, to the far right, under randomized control trials, there are 80

applications and this is just in the one priority for which there were 211 overall applications. So, we see randomized trials, we see a lot of perspective observational studies, and then smaller numbers of qualitative studies, secondary data analyses, some modeling studies, and a small number of evidence synthesis study.

So, the wide range is what we expected based on our Funding Announcement.

And, again, looking at priority populations, this is out of -- this is, again, just for priority number one, I will say that the four priorities, quite similar patterns across the four, but, again, priority populations, pretty well represented -- the elderly, racial and ethnic groups, urban and rural. So, we were pleased that vulnerable populations were quite well represented in these applications. And, again, this is just what applicants told us.

And then I want to say a word of thanks to the remarkable number of people both technical reviewers and patients and stakeholders who

volunteered online to review for us. So, we had, in response to our online solicitation for technical reviewers, more than 800 individuals volunteered, patients and stakeholders, these are approximate numbers, but approximately 225 of each, and these patients and stakeholders, when we looked, a large proportion of them had a lot of prior experience either reviewing research or being involved in research.

So, out of those, you know that we have -- the review will go forward in two rounds. The first round will be done by mail, will not be a face-to-face, and those are the technical reviews. They'll review all of our research -- review and score on all of our review criteria. That 483 comes not only from the 800 but also from a search that was conducted by Martin and his staff to find reviewers with expertise in these areas.

So, the 800 didn't give us enough expertise to cover that broad range, so the 483 comes out of the 800 but also comes from a larger pool that we used an electronic search to identify.

And in the first round this time, there are only technical reviewers. That will change in the future. The second round is face-to-face, those are your traditional study sections. There will be about 75 to 100 technical reviewers and then 15 percent of each review panel will be patients and 15 percent stakeholders.

We solicited and recruited specifically committee chairs, and I didn't think it was quite proper to put the list up, but I will tell you that the roster of chairs, the folks who are going to chair these committees, are truly impressive. It's just real all-stars in clinical and outcomes research, so we're convening for a special half-day session to talk about how we go through the review criteria because the review criteria differ, and I want to just put these up here so you get a -- we'll talk a lot about PCORI's review criteria. I know you've seen these, to some extent, but it takes a while for them to sink in.

They are syncing in with us, and we're getting to love them. They're somewhat different

and they're more numerous than the review criteria that NIH or other federal review panels use. They typically have five. And these speak to some special interests of PCORI.

The first one, the impact of the condition, that is pretty traditionally used, and it has to do with the prevalence of the condition, the frequency, the survival, the complications, the burden of suffering that condition imparts. It can also speak to the burden of cost that it imparts to the country just by virtue of its size or complexity of the condition.

The second one, we call it innovation and potential for improvement. This might be the most complex of the eight criteria, but it speaks to, is this research novel in a way -- does it use a new method, a new way of engaging or reaching patients? Does it use a new analytic method? Does this study a new population that hasn't been studied before in some way that it makes it more likely that the results will impact practice?

In addition, this criterion asks, is there

currently evidence of uncertainty? Is there wide variation in practice across the country? Have systematic reviews called for an answer to this question? Are clinician groups or patient groups asking for this information? And finally, does preliminary evidence suggest that the findings of a larger study could change the way we see this question?

So, that's a crucially important one and its purpose is to lead us toward research that will change practice and improve outcomes.

Impact on healthcare performance just means, does this help us provide higher quality care, more efficient care, more convenient care?

Patient-centeredness, means is this a question of importance to patients? Are these outcomes the right outcomes, the outcomes that are important to patients? And this is one of the criteria that we'll ask patients to weigh in on particularly when they review.

Rigorous research methods points applicants toward our methodology standards and is

obviously essential in reviewing research.

Inclusiveness of different populations means does the research give us a chance to see differences in patient populations, differences in effectiveness across patient populations, or does it give us information about a population that hasn't been studied to date?

The seventh one, team and environment, speaks primarily to, is this research team comprised of people able to do the research, including does it have patients, relevant patients, and other stakeholders on the team?

And the last one, efficient use of resources, speaks to the budget for the piece of research. Is it a reasonable budget?

Yes, Harlan?

DR. WEISMAN: Joe, I have a question on this slide but also on the previous slide. You mentioned, when you got to the -- Harlan Weisman, Board member. You mentioned that the chairs -- you talked about that they were a very impressive group of experienced people in clinical research, maybe

outcomes research. I'm wondering whether you could talk about them a little bit in terms of characterizing who they are. In other words, are they, as you did on some of those pie charts, are they largely of academic or government research background? That's a question.

And then, does that -- while we're so interested in rigorous methods and rigorous research, does that bias, to some extent, given perspective of people with that background, people to maybe really, possibly in this initial screening, overemphasize number five at the expense of maybe some of the -- five being rigorous research methods, which I totally support, does that bias against some of the types of groups that we would like to be applying for these grants? Because it seems to me if you were meeting one through eight, and five were an issue, that might be something that we could bolster or find a way of bolstering.

DR. SELBY: Okay, so these individuals are based in academia. They are individuals who have

led study sections like these before. I mean, I think you're right. First of all, your concern is completely legitimate and we are -- actually, right now, Michael Lauer is analyzing some data for us from the pilots to see whether rigorous research methods drove the scores in those pilots like they have traditionally in study sections.

These, I would say that these individuals, among all individuals, have a capacity to appreciate the meaning of criteria and the fact that we want to weight them somewhat differently. So, yes, they are academic. They are all seasoned review committee chairs. And I think they are the kind of individuals who actually could help -- with consultation with us, could help guide the committee toward a more balanced evaluation, but --

DR. WEISMAN: The other question --

DR. SELBY: -- your concern is something that we're going to have to keep a close eye on over time because I believe we're seeing signals already that methods still do drive scores.

DR. WEISMAN: And with that in mind, it

might be useful, and perhaps you're going to do it, it's often as interesting to find out who was not accepted and characterize them as it is to understand who was accepted and characterize them. And I think that would be extremely valuable for us, because if we find that there might be a bias against, you know, less experienced investigators and more of a bias towards the classic research community that would indicate that we ought to take some actions different than the ones that we're currently taking.

DR. SELBY: Yeah. Thanks. I'm going to just get off of here as quickly as I can because of the time, but I just want to give a quick preview of today.

This morning we are going to start with three presentations in a row. Sue Sheridan and Susan Hildebrandt are going to lead off with a description of our activities and our plans for patient and stakeholder engagement, not only what we're going to do, but a good deal about the why. That's going to be followed by a presentation from

Rachael Fleurence, a PCORI scientist, on our thinking on how we prioritize research, how we generate the topics coming from patients and stakeholders and how we prioritize them. And then Anne Beal will present our thinking on the formation of PCORI's first advisory panels. Among the roles of these advisory panels are to monitor the way that we do engagement over time and to help us in multi-stakeholder fashion, to help us prioritize the research driving toward having a research agenda that has more specificity, that has projects funded that we can say came from listening to the voice of patients and other stakeholders.

So, that's the chunk of this morning. As I said, you'll probably hear more about engagement and prioritization at this meeting than any, but it's crucially important and it's -- we're at that point in our history.

A little bit out of order here -- then you'll hear very briefly about our plans for a Funding Announcement that corresponds to priority number five in methods, and Rachael Fleurence will

present that.

In the afternoon we're going to hear an update from the standing committee on conflict of interest from Larry Becker on our plans. In Denver we approved a policy, a conflict of interest policy, that would allow Methodology Committee members who wanted to, to be eligible to apply for PCORI funding in the future and yet discharge their duties as Methodology Committee members. So, this is a plan to put a firewall in place so that both of those things can obtain at the same time without conflict.

We'll then hear from the Methodology Committee an update on the public comment that we received and on the process that the Methodology Committee is going through to incorporate, to review, consider and incorporate suggestions from the public comment period into revisions to the standards and the recommendations of the methodology report.

And we will then hear presentation from Anne and Pam Goodnow and Kerry Barnett from the

FAAC on the 2012 budget to date and a quick glimpse forward into 2013.

And lastly, we'll have an update on communications, both what we've been doing and beginnings of a vision of communication plan going forward.

So with that, I'll stop. I'll see if there's a question or two and then move onto Rachael.

DR. KRUMHOLZ: Thanks, Joe. That's a great presentation. I just was wondering whether, if you think about the pilot grants that we've put out, whether we're putting enough oomph behind this with regard to dissemination. And I say this because I think we should be partnering with everybody we gave these grants to, creating YouTube videos with the patients telling why they're participating, what's it about, and explain to people why this is important and connecting out with groups around the country that are both in their immediate community, and you did show a broad swath of the U.S., but also broader.

I know people who got pilot grants and they're doing like what they usually do. They're getting the money and they're starting on the project, but they're spending very little time reaching out to the communities explaining what they're doing, and this isn't a criticism, but it's just saying, we need to partner, I believe, with them to create, you know, five YouTube videos from each one, one with the investigator explaining what's going on, one with sitting across from the patient, but particularly with the patients. Because if a patient can't authentically and genuinely sit in front of, and I'm just talking webcast, I'm not talking high-end video production, I'm just saying, sit in front of the webcast and talk for a minute or two about why this is important to you. Why are you involved? What does this matter?

Because also when other people are applying for our future, we can point them to these videos and say, hey, take a look at what's going on. We can point to anyone who wants to see, you

know, what is PCORI doing, but let's speak with the voice of the people that we've given grants to, and particularly the individuals that we were trying to pull into the process. And I'm worried if people can't sit in front of a web cam for, you know, two minutes and explain very well and seem to authentically and genuinely be involved. That's a problem.

And anyway, I just wonder if we can redouble our efforts in a way to kind of leverage, we've now funded all these people. They're part of the PCORI family now, and I don't know that they feel part of that family, and I think part of that family -- let's all hold hands, let's tell people what we're doing, let's explain why it's important, let's talk about what we're trying to deliver as a result of this. And the more they have to defend this publically and say, here's the deliverable for what we're doing -- they can speak more clearly -- here's the product of the work that's going to be coming, the more they're going to be thinking about their own accountability to their communities and

to the country as a result of the investment that's been made.

But that's my thought.

DR. SELBY: Thanks, Harlan. Excellent.

CHAIRMAN WASHINGTON: Joe, I just want to comment on that point. I think it's an excellent suggestion, and it may be, Joe and Harlan, that we not have that as an expectation of each unit, but have that expectation of ourselves where we create some, almost like a core going across these to select a set that might, that we might develop these portfolio stories around that you're talking about.

DR. KRUMHOLZ: But we can -- I think there are two ways. One, we may be able to choose ones we want to particularly highlight, but we can provide the tools and instructions to let people post their own videos.

CHAIRMAN WASHINGTON: Yeah, no, it's more the tools and instructions, not us necessarily choosing. So, I just think it's asking a lot for some of the ones who struggled to even get in the

pilots on their own. So, it's the tools that I was --

DR. KRUMHOLZ: [Off microphone] it's just a -- you know, sit in front of a web cam and talk about what you're doing. If they can't do that, I'm worried.

CHAIRMAN WASHINGTON: Okay, okay. I know we've got a tight schedule, but I think this is a superb suggestion.

DR. LEWIS-HALL: Yeah, I do think that it's important, not just to scattershot information from various sites from their perspective. I think one of the important things for us would be to really focus on the message. What do we want to be understood and when? And then organize the communication around that so that we can be sure that our messaging is clear. I think we want to build, kind of, scientific pursuit across all of these, we want to encourage citizens, scientists to participate in all ways.

So, what is it that we would have to say, from whom, and when, in order to get those points

across? And then I think you're absolutely right, we've got an incredible group of researchers and participants in research that can help us get that message out.

CHAIRMAN WASHINGTON: Last comment from you on this for now.

DR. KRUMHOLZ: Okay, just for us to consider, I think it would be good for us to decide on some message coming from PCORI, but I'm actually more interested in kind of a disruptive approach, I know it would surprise you, that would allow sort of -- you know, encourage people to be Tweeting and sending out through -- I know you're hiring someone, Joe, for social media.

To help these sites keep their community abreast of the progress, try to bring people in so that maybe there's a two-strategy here, one is, what does PCORI really need to get out, how can we help the sites get that out? Another is keeping them connected with their communities, not just the patients working with them, but that entire community, to try to get people excited about the

work that's done and anticipating the results. Again, it will bring some impetus. And let the sites share information too about how they're doing this because we should be trying to create connectivity between the groups that we've funded, even though their topics may be different, their themes may be similar around reaching out and learning things together.

So, can we create a learning community among that entire group that we've funded so we can accelerate the knowledge, not just that we're going to be able to produce, but they'll produce themselves and get back to us?

CHAIRMAN WASHINGTON: Again, excellent point. I skipped Larry, so Larry gets the last word, and would you state your name again? This is being recorded.

DR. BECKER: This is Larry Becker, member of the Board. So, my question is, where are we relative to the Pilot Projects? Are they contracted? Have people begun to work? And what's the process by which we get updates along what

they're doing, how they're progressing? Because it will be two years, I presume, for most of these and I think we don't want them to fall into sort of a hole, and we want to know where we are. So, I was just interested in what the process is.

DR. SELBY: Right. Well, this first round of contracts required both that, as usual, you go through due diligence with each awardee and make certain that a number of things are in order, but it also required that we just develop things as basic as "the contract" and a lot of policy around the contract. So, we are on the brink. Martin tells me that we are on the brink of signing them, that it should be October 1st or that first week in October when we get these contracts signed.

One of the reasons we let the contract and competed the contract and Academy Health won the award, was precisely to help us keep closer track on the progress of these, not only the progress according to specific gains, but also specifically what are they learning about patient engagement, so that we can bring that back to you.

And then the last thing, Larry, is that at our November meeting, we intend to have more of a presentation for you on who applied, who didn't, and how the scoring went from the pilots.

CHAIRMAN WASHINGTON: [Off microphone] -- introduce this next segment of the Board meeting, Harlan W. has reminded me on a couple occasions and so have a couple others of you that best practice dictates that we have breaks, and so we're going to have about four breaks today, even if it means we have to curtail some of the discussion.

Going into this next session, I'm going to ask that you hold questions, unless it's a clarifying question for something that you feel is important for you to understand as the staff and/or another Board member moves forward in providing information.

You're also going to note that for these presentations there's going to be a set of questions that we're being asked to cogitate on and so I'm going to ask that you keep in mind what the questions are that we're going to come back to at

the end of the presentation to address.

So, with that, Joe, would you introduce the next?

DR. SELBY: So, yes. Our first presentation is on patient and stakeholder engagement. Dr. Anne Beal, our PCORI COO, Sue Sheridan, PCORI's acting Director of Patient Engagement, Susan Hildebrandt, PCORI's Director of Stakeholder Engagement, are at the table and I think I'll turn it over to Anne, that's my guess. Yes.

DR. BEAL: Great. Well, good morning. So, as you all know, we spent a good part of this summer really focusing on a lot of the work that we plan to be doing in terms of patient and stakeholder engagement and are very happy to share with you some of the results of the planning that we've been doing and plans for upcoming activities.

One of the things that I wanted to start with as we go through this presentation is that we have a very specific set of questions that we'd like to direct to the Board and are seeking to get

your input on a variety of issues.

So, essentially, one of the big questions, and you heard Joe allude to this a moment ago when he talked about as we're looking at a lot of the work that we're doing, we're particularly interested in outreach to vulnerable patient populations or to those who have traditionally not been very engaged in the research enterprise. So, as you heard Joe talk about it in the research, we're also interested in it, obviously, in our engagement activities.

The other thing that we're asking you to think about is when we think about, a year from now, as we're embarking on these activities on patient engagement, what is it that the Board would like to see in terms of success? How would you all define success? And that would actually give us a lot of guidance in terms of helping us with the activities that we plan to engage in.

We have some thoughts, but we want to make sure that we have a shared plan for success.

And then lastly, we want to get to this

issue that Harlan actually was just talking about in terms of doing research differently for patients, and I think a big part of that really rests with the work that is going on with the engagement team. So, we wanted to make sure that more than just this aspirational idea of how do you do research differently, we want to get some guidance in terms of specific operationalization so that you know it when you see it. And so, we will come back to these questions at the end of the presentation, but really wanted to present these up front so that you can think about it and help frame some of the discussion towards the end.

So, with that said, I will now turn it over to Susan.

MS. HILDEBRANDT: Good morning. I am just delighted to be here to talk about our recent efforts on patient and stakeholder engagement. Before I begin, I just wanted to introduce the remainder of the engagement team, including Greg Martin, the new Deputy Director for Stakeholder Engagement. He has a lot of expertise with state

and local organizations, so that we can get beyond the Beltway, as well as Lorraine Bell, a Senior Project Advisor. And then additionally our invaluable AA, Kim Holloway.

In any event, Sue Sheridan and I will touch on three issues during our presentation, just a quick review of the strategic priorities, which you're familiar with, the engagement touch points as we're describing them in the PCORI process, how we want stakeholders to get involved, and then we'll also talk more specifically about the workshops coming up.

So, this slide obviously looks familiar to you. These are the engagement priorities from PCORI's strategic plan. Won't read them to you, just to reiterate, continue to seek the wisdom of our patients and stakeholders, want to form a community, always be transparent and open, and then continually learn and get feedback, both positive and negative.

Let me just kind of give you a quick example of that in action. Sue, Greg, and I have

been meeting with just scores of stakeholders over the last couple of months, and we do a few things. First of all, obviously, one of our key objectives is to build community. We talk about what we're doing at PCORI and want to get them excited and energized. But then we also really listen. What do they think? What do they think about PCORI and what we are doing? How can we change?

Then we really try to keep listening and talking to them. For example, in planning our workshops, do they think that's a good idea? What topic are they interested in? Are our Funding Announcements user friendly?

And finally, we take their input seriously. We've made a number of changes to things that we have done based on stakeholder input. For example, the workshop that we're holding in December came specifically out of input we got from stakeholders. They said, you know what, we want a workshop that talks about the topics we feel PCORI should study. We want you to be more specific. And so, we did that.

So, in sum, really, our goal is to create an energized community of people around the U.S. who are excited and eager to be part of having us help transform the research system.

MS. SHERIDAN: Like Susan said, we are building the PCORI family. I really want to emphasize the building community priority of ours. We're calling, we're emailing, we're going to presentations, we're giving presentations, we're blogging, we're being blogged about, we're Tweeting, we're reaching out to hundreds of stakeholders and patients about our methodology report, about our Funding Announcements. We're actually building a community based on the principles that we learned about from our Methodology Committee.

We're building energy, we're building awareness, we're building trust, we're building hope, we're building partnerships, and we're building a network that's interested in research done differently. In order to plug them into this virtuous cycle that you see on the screen and the

various touch points of engagement that will ultimately improve patient outcomes.

So, this cycle you're very familiar with, we have kind of de-wonkified some of the language and made it more patient and stakeholder friendly, that answers the question, you know, when we reach out and make presentations and reach out to our communities, we ask -- we're inviting patients and caregivers and stakeholders to advise us as to what PCORI should study, what questions are most important, what outcomes should be studied, this is what we want to hear from our patients and stakeholders.

And then going over to the second touch point, the reviewing of proposals and partnering in research. We're going to take each one of these sections, as we make this presentation, and speak specifically to each section, but the review of proposals -- Joe touched on that earlier. We're really going to focus on some of the key PCORI unique criteria, the patient-centeredness, the impact, and teams. And then in the conduct of the

research, really focus on, you know, what is in our PFAs that's really calling for this patient partnership in the research that we fund, in the conduct of that.

And then help us share the findings, you know, it's really different with patients and stakeholders how we disseminate and how we communicate. So, we're looking at, through our networks and through our workshops, to identify creative and innovative ways to reach the patient population. Typically patients don't read peer-reviewed scientific journals. How do we reach them? Through their church communities, through the print media, through magazines, through blogs, they read different things.

And then, finally, tell us how we're doing, and this is really important. We want to be courageous and reach out to our stakeholders and our community to help evaluate ourselves and to help us become better.

And I'm going to share a patient vision that was captured at our very first stakeholder

event that was her vision about what patients -- how patients could get involved in research.

MS. WILLIAMS [VIA VIDEO]: You have to sort of get patients involved in the entire cycle of research, from the original designing of the studies all the way through to the dissemination and feedback.

UNIDENTIFIED SPEAKER: Who is she?

MS. SHERIDAN: That was Christine from the -- Christine Williams, yeah, from the Chronic Fatigue, yeah, she used to work at AHRQ. She was in healthcare for 30 years and became a patient and has become an advocate for patient engagement in research.

MS. HILDEBRANDT: So, just to move on and quickly go through the remainder of the presentation, since I know we're a little short on time, let me give you a quick update on what we call topic generation or, in simpler terms, what should PCORI study. We've tried to do this in a number of different ways. First of all, we've just launched a website that allows individual to put up

questions about what they think we should look at. We've gotten responses to that already. Prior to that, Sue and I ran the website and a lot of the language by a number of patients and stakeholders and said, what do you think? Does this make sense? Would you use this?

Additionally, we always ask about this question; what should PCORI look at, at our various meetings? And then lastly, the stakeholder workshop, as I indicated on December 4th, is pretty much strictly on topic generation. It's called "What should PCORI study?" and, again, the reason we're doing this workshop is because stakeholders asked us to do so.

MS. SHERIDAN: Okay, in terms of reviewing the proposals and partnering research, Joe touched on the review of proposals and in this cycle we reached out and got feedback on our Pilot Projects and that review process and we revamped the recruiting process and the application process and the training process. So, we created a new, user-friendly application. We had heard that our

original application was somewhat intimidating, a little overwhelming, the process was overwhelming, and so we've revamped that.

We have reached out to extensive lists of patients and stakeholders and caregivers and networks, online and through email.

We have vetted the reviewer applications in-house, this time, so we read the applications and got to know what the characteristics of the reviewers were.

We're currently contracting with key experts in terms of training our reviewers. They'll go through a training in October as well as November in preparation to review on November 15th, so it's really focusing on the unique criteria of PCORI's review on the engagement -- patient-centeredness and the impact.

And then, finally, in this cycle we're going to be working directly with the reviewers on an improvement process that we're going to be speaking with them and working on the application and the review process and the communication

process. We've been working with Martin on this throughout the whole process in terms of constant communication with our reviewers.

CHAIRMAN WASHINGTON: Just a quick pause. We have a clarifying question. State your name.

MS. HUNT: Yeah, Gail Hunt, Board member. Sue, you said somewhere, it was like maybe two bullets ago, that you were having a review -- you were having experts train these reviewers. Could you just say who these experts are that are training the reviewers?

MS. SHERIDAN: Martin, do you want to comment on this?

MR.DUEÑAS: I think that we just engaging them and we're finalizing contracts and we're developing that, so I would rather hold explaining that until that next session.

MS. HUNT: Okay.

CHAIRMAN WASHINGTON: He's saying that he doesn't want to disclose that information, essentially.

MS. HUNT: Oh, okay.

CHAIRMAN WASHINGTON: Okay. Thank you.

MS. SHERIDAN: Yeah. So, on this next slide, we'll just go quickly through it, but we'll show that we got -- we were aiming for 50 reviewers, as Joe mentioned, that we have five study sections and ten stakeholders on each. We got 350 total applicants. We went through a vetting process looking at who had experience in grant reviews and also who had some experience in comparative effectiveness research. We looked at geographic spread, and we ended up with 58 selected in the final vetting.

The goal is to create a PCORI family of reviewers and over to the right hand side, this is the breakdown of those 58 that were selected, and we have patients and caregivers and caregiver organizations in the blue, and you can see the other stakeholders to the left of the blue.

This is just to show our geographic representation. You can see we have eight reviewers in Texas, seven in California, we have some from Louisiana, from St. Louis, from

Washington, D.C., we have one from Hawaii who specializes in Native Hawaiians. We have one from a federally qualified healthcare clinic in St. Louis. We have reviewers from rural Texas. So, we have a really nice geographic spread as well as diverse in disease and background, systems improvement, and so we're very confident -- this is a very energized group of reviewers. We spoke to every one of them that will be here next month.

MS. HILDEBRANDT: Yeah, as Sue said, we did call every single stakeholder reviewer on the telephone, got some terrific quotes. For example, "This is exciting and will lead to positive outcomes." Comments like, "This is really the first time the patient's voice is being formalized."

MS. SHERIDAN: We heard that, "We want to give back expertise," and "this is a great learning opportunity." And finally, "I want to do my part as a patient and I'll be honored with this opportunity."

MS. HILDEBRANDT: So, the next point I

just want to talk about quickly is dissemination and really helping us to spread the word. Clearly, that means initially developing the communities, engaging them in a meaningful fashion, and then hoping that they will share and adopt the latest information. Clearly, we're still developing best practices in this area, but we do realize that we need to get information to stakeholders directly, and ultimately we want this PCORI community to help us spread the word in a way that works for them.

Here's, I think, a terrific view of a stakeholder's view on dissemination.

DR. HOVEN [VIA VIDEO]: PCORI should develop the infrastructure that delivers information in a learning loop, a real-time learning loop for all of us. That includes physicians, other clinicians, patients, and caregivers.

MS. HILDEBRANDT: I think that what this speaker said was helpful in terms of information coming from PCORI but then really using a learning loop so that we are continually getting information

and learning from each other.

MS. SHERIDAN: And so moving along the virtuous cycle --

CHAIRMAN WASHINGTON: We have a question. State your name, please.

MS. SIGAL: Ellen Sigal, Board. Just -- it would be really better for the patients and for us if we knew who was making these comments. There should always be an identifier of their name and --

UNIDENTIFIED SPEAKER: It was on the last slide --

MS. SIGAL: It was on the last -- I didn't see it.

UNIDENTIFIED SPEAKER: You missed it.

MS. SIGAL: You know what, it's cut off. It really helps. Who was this one?

MS. HILDEBRANDT: That was Ardis Hoven from the American Medical Association.

MS. SIGAL: So, again, not really a representative of a real patient.

MS. HILDEBRANDT: Right. And that was to, essentially, show you what some stakeholders are

thinking about in terms of dissemination.

MS. SHERIDAN: Okay, going on to evaluation, telling us how we're doing. In a book written by Atul Gawande that probably many of you know, he wrote a book quite a while ago called Better, and he said, "Better is possible. It does not take genius." He said, "Above all it takes the willingness to try."

So, the engagement team has the willingness to try to always do better and always reach out into the patient and stakeholder population to get that feedback on every step of the way of what we're doing. And so right now, we're planning on getting feedback from a disabilities roundtable we just hosted, get feedback on the workshops that we'll be doing, working with our scientists at PCORI to make sure we're evaluating this, to get feedback on our reviewers, how did this review cycle go. Eventually we want to get to, did patient engagement make a difference?

And that is our goal, and so, Gene, we'll

be able to address the three success metrics that you've shard with us, and that is creating an international network of PCOR advocates, becoming the gold standard in the science of patient engagement, and then to be the trusted source of information. So, we will have this continuous learning and continuous reaching out so we can be better.

Next we're going to talk about our various workshops. The first workshop is coming up on October 27th and 28th, that you've all received an invitation to, and I hope you'll consider coming. This is "Transforming Patient-Centered Research: Building Partnerships and Promising Models". Our objectives are, number one, to create community, once again, that PCORI family.

The second objective is to work with the patient population -- we're inviting 150 patients and stakeholders with at least 75 percent being patients, and to invite them to a workshop to help us identify and develop best practices in all of those touch points that you see on the virtuous

cycle. So, how can we best do topic generation with the patient-stakeholder population? What are the modalities? What are the questions we have to ask? How do we engage with them to help them generate research topics and along the research cycle?

So, we want to develop all of those touch points. How do we bring researchers and patients together? How can they help us develop that infrastructure to do so?

And then also, with this workshop, we'll actually be informing our Methodology Committee. We have two of our Methodology Committee on our working group as well as Gail Hunt, who is our Board member on our working committee, and we will be informing the Pilot Projects. We see a great opportunity for a lot of cross-fertilization within PCORI with this workshop. So, this workshop is really the beginning of a whole strategy of other events after that, which this workshop will feed into the workshop that Susan's going to talk about.

But something that I wanted to share --

this shares a little bit of some general criteria, but on Thursday, we got a report that GolinHarris created for us, and like I mentioned, we're going to have 150 participants to -- as of Thursday, we've received 308 applications.

This is a demonstration of a very energized, very excited patient population. They're ready for us and I think we're ready for them.

We have, of the areas of interest, 35 interested in the elderly, 60 in children, 25 in disabled, 18 in African-American, 12 in Hispanic, and on, and we have right now representation in the applications from all but seven states and our goal was to have all of the United States represented.

It ranges from cancer to neurological conditions to mental health, cardiovascular, diabetes -- it really mirrors very much what you saw earlier on the Pilot Projects in terms of themes that we're seeing.

We also see systems improvement, patient safety, prevention of hospital-acquired infection,

which is amazing to see in this pool -- we asked questions about their research and health systems experience. Of the 308, 115 have been involved in some way in clinical trials. They have -- 120 have grant or research application experience, 170 have been on advisory committees, 134 have been involved in translating or disseminating research and information.

So, we see this as a really rich group of patients and stakeholders. We see a really rich opportunity for us to learn from them and incorporate that into our next steps for 2013.

MS. HILDEBRANDT: So, I'll just talk quickly about the stakeholder workshop on December 4th. It's called "What should PCORI study?" Again, the goal is to get topics for research. We'll give them an opportunity in small breakout sessions to talk about our four key areas, CER, health systems, disparities, and communication, give them kind of what I'm calling a sneak peek about our draft prioritization process, and you'll be hearing from Rachael shortly on that.

And then also get their thoughts on how we are engaging people and stakeholders and allow them to look at what we learned in October and move on from there.

I'll just quickly go through our other, the criteria that we are seeking in terms of individuals, you know, leadership and key priority areas, but also say responsibility for healthcare delivery. For example, it would be terrific to get somebody who has been involved in a Medicaid program at the state level.

So, what's next? And I guess, really, more importantly, why? First of all, advisory panels, two, as you know, are required by the law; Rare Diseases, Randomized Clinical Trials.

We also want to do more events around the country, and these certainly will be informed by what stakeholders tell us. We want this to be done in a way that works for them. For example, we may wish to reach medical students by going to a medical school to have a learning session or even do a webinar that could be up on the web that they

could look at their convenience.

You know, most importantly, just to sum up, we want all of our activities to be done with -- and have them answer the question, so what? Why are we doing this? What is really the goal here for PCORI?

So, in conclusion, I just want to finish up this section of our presentation and we'd be delighted to answer any questions, and Anne will lead that session.

CHAIRMAN WASHINGTON: Okay, I'm going to ask you to put your cards up, if you don't mind, and also when I call on you, to please state your name again. And just on the last topic, or next to the last topic, that Susan mentioned, the PCORI advisory panels, no questions on that now, please, because we have an entire session in a few minutes on that topic.

So, with that, I'm going to start with Larry Becker.

MR. BECKER: So, that's great work. I mean, that's really hard. It's really hard to get

really good people.

I would make one recommendation and one thought about this. As you showed a couple of people, as you talked about the kind of people that you were bringing, you referenced that they had research background, et cetera, in the field, and all I would say is, just remember that every patient is not a researcher, doesn't have exposure to these things, and so there's another spectrum of people that we need to reach out to, the ones that have no experience and are grappling with this system to be able to use it and answer questions and they have no background.

MS. SHERIDAN: Do you want us to answer these?

CHAIRMAN WASHINGTON: Please.

MS. SHERIDAN: Larry, just along that point, we had a working group meeting last Friday with who's planning this -- the patient workshop, and we addressed that. And fortunately, in our expression of interest forum, we did ask an open narrative and why were people interested in coming

to this.

So, we're capturing people who may not have experience in research or advisory committees, but they've got the vision, they've got the passion, they've got some kind of personal experience, and so we are really looking for them as we vet these applications.

So, we definitely want the new and emerging champions in this area.

CHAIRMAN WASHINGTON: We'll stay on this side. [Off microphone.]

DR. DOUMA: Two things. To follow up to what --

CHAIRMAN WASHINGTON: Name, please.

DR. DOUMA: Oh, I'm sorry, Allen Douma, Board member. Follow up to what Larry's bringing up. One of the things we need to be guarded against is by training people so well they cease to be patients. We can professionalize this group of people very quickly, so we need to refresh it over and over to make sure it's fresh. It's kind of like the corollary to Eisenberg Uncertainty

Principle, if you measure something, you will change it. If you train somebody, you will change them, so be careful about that.

In the appendix, in the material appendices, the material you gave us, for each of the workshops you have a very nice write-up and a summary. On the stakeholder workshop, you have some outcomes or variables you're looking for. In my mind, they're more process oriented than they are outcomes oriented, but for the patient workshop I didn't see any defined -- specifically defined outcomes that you're trying to achieve. Could you talk about that?

MS. SHERIDAN: Sure. The outcomes that we're hoping to achieve from the patient engagement workshop is -- well, there's a couple of different -- we're going to be doing a pre and post expectation survey and then also our biggest outcomes will be the recommendations that the patients will form on each of our -- the engagement touch points. So, they will develop a consensus, recommendations on best practices for PCORI in

patient engagement and research, as well as principles.

So, we'll end up with final recommendations.

DR. DOUMA: And then that you'll bring back to the Board so we can be smarter about all of that?

MS. SHERIDAN: Absolutely. Well, I hope the Board is there because part of the agenda is that the patients will report to the Board members who are accepting the invitations and that there will be a dialogue at the end to refine them and then this will be reported to the full Board.

CHAIRMAN WASHINGTON: Clancy and then Krumholz and Norquist.

DR. CLANCY: Carolyn Clancy, Board member. I'm looking forward to this workshop, so thank you for the presentation. I had two questions. I presume that we're paying for travel for these people. Are we paying these people for their time? I know this is an interesting issue. We are. Okay, great.

I worry a lot about volunteer fatigue and many professionals are effectively subsidized by their day jobs and that opportunity is not there for many patients.

DR. BEAL: Just to make sure that it's recorded, since the audio may not see head nodding, the answers to your questions were yes.

DR. CLANCY: Thanks.

CHAIRMAN WASHINGTON: Krumholz.

DR. KRUMHOLZ: Harlan Krumholz. Briefly to say some of the most exciting information I've received at a Board meeting and the idea that there's so many eager and excited groups is both a tribute to you, but also, I think, should be heard very clearly by the Board about the interest that people have in the work that's being done here and the possibilities that exist for it. So, just wanted to thank you all for that.

CHAIRMAN WASHINGTON: Norquist.

DR. NORQUIST: Gray Norquist, member of the Board. So, in answer to your first question, I think the other problem is -- and I appreciate that

you can pay people to come to meetings but, you know, if you have a family and you have jobs and you have other things, you just can't do it, and so I think if you really want to reach people who do not normally come -- they're not going to come to a meeting, you've got to go to them. And so we've got to figure out a way to get two people and stuff, and so I think it's -- I agree, I'll be at the meeting, and I think it's going to be very important. It's the beginning of a process. But the hard thing is really number one, and I will tell you that trying to reach populations like this is not easy.

And this is just not a part of what they find exciting, to come to a meeting in Washington, quite honestly, they've got a lot of other things to deal with day-to-day, so, for those of you who live in Washington, I'm sorry to tell you that.

UNIDENTIFIED SPEAKER: Get a life?

DR. NORQUIST: Yeah, get a life. Yeah, talk to some of these folks and they'll tell you [off microphone], so I think that's going to be the

hard work about getting it.

MS. HILDEBRANDT: Absolutely, and we agree with you completely. Part of our plan is to get outside of Washington and the so-called beyond the Beltway. We have a series of workshops and events we'd like to hold around the country for that very reason. We don't expect people strictly to come to Washington. We want to go to them, to where they are living.

DR. NORQUIST: Can I just -- one thing I want to follow up on, because we're doing this on something else, even in my own area, and one of the things when you have a meeting is that people want to know, why am I wasting my time to come here today because I've got to do all these other things? What's the end point of this for me personally and what am I going to get out of this? So, we really need to think about that. So, the fact that a group is coming to town to have a meeting is not going to be very exciting, so, we have to think about what's going to be in it for them and the follow up after that. And I think

I've said this before that we had a lot of meetings in the first couple years and I'm not sure we've gotten back to even some of those people, and I think we need to keep that kind of process going because we're going to quickly lose interest if we don't keep people engaged.

MS. SHERIDAN: Can I make a quick comment about the patient population and reaching into those underserved and hard-to-reach areas? One of our strategies is when we bring in patients, now we have almost all the states coming to this workshop, and we also -- our reviewers are geographically very wide spread, so we want to use some of those champions coming from those states to help us identify where geographically we need to go and what are their priorities and how do we best deliver what's best for them.

DR. NORQUIST: I'm sorry. I have to add one other thing and that is that sometimes people who identify themselves as champions are not champions for the community, and so it's going to be -- that's going to be another hard part is

really finding out from a community perspective who really represents them.

DR. BEAL: So, Gene, I'd like to then ask the Board, as we think about, then, 12 months from now, what might be our measures of success. So, to spend some time thinking about, particularly this second question, because what we're interested in is thinking about what is the future state, and what would make the Board say, we are really meeting the needs, meeting the vision, and really executing on what it is that we think we should be doing in terms of engagement?

CHAIRMAN WASHINGTON: Okay, just for recording purposes, that was Dr. Anne Beal, COO. And Sharon, who is the Board member working with this team, along with her committee, would like to comment, and then I'll recognize some others.

DR. LEVINE: Thanks, Gene. Sharon Levine, Board member. I just want to thank, on behalf of the COEC, thank the staff for an incredible amount of work in a very short time. As Joe has pointed out multiple times, none of us are really experts

on patient engagement, so we are learning as we go, and unlike some of the scientists who are leading our science and research efforts. And I think, on behalf of the COEC, we really appreciate the spirit with which you have entered this work, your openness to suggestions and advice and last minute changes, and really appreciate the work you've done to help us actually change the world.

CHAIRMAN WASHINGTON: Gene Washington, Board member. I'm going to recognize the three remaining individuals who would like to comment, then I'd like for us to really spend a few minutes focusing on the question that Anne just raised for us. And so I'm going to go next to Hunt, Zwolak, Lewis-Hall, and then specific comments on the question.

MS. HUNT: Gail Hunt, Board member, and I was planning to comment on the question, question number two, as it turns out. I think that because of the nature of the discussion that we've had so far, it's going to be really important for us as a measure of success, being able to look at whether

we succeeded in engaging hard to reach populations, so not are we getting 380 people who are just really excited -- not that that's bad -- but we really need to be able to say, we've reached groups that -- or/and individuals who, for example, maybe represent the mental health issues in a community.

So, we have people like that, not just people at the national level or even the state level, but we've been able to engage people who are at the local level, who may be the, you now, the person that stands out as a person in the community who would be really outstanding. So, that was for number two.

CHAIRMAN WASHINGTON: Zwolak.

DR. ZWOLAK: Bob Zwolak, Board member. I really want to applaud you as well and I think these meetings are fantastic, but of course the meetings, by their nature, have to be sporadic and I wonder, with regard to number two, about building an army of grassroots supporters at the patient level and in addition to the meetings and everything, are we exploring other -- every other

possible way.

For instance, on Twitter, I'm fascinated by Twitter over the last two or three months. Are we on Twitter? Are we building an army of patient supporters on Twitter?

MS. SHERIDAN: Well, to answer your question, absolutely, and this is -- we are building an army and, honestly, in the last three months -- and I've had the privilege of witnessing the creation of patient networks over the past decade, and PCORI is doing it. You're onto something right. And so the Twittering and Tweeting and the blogging is happening and it's been positive, it's been -- there's curiosity, there's enthusiasm, and so that's something, you know, working with communications, with Bill and Marla, that we're creating a strategy to ramp that up. But that is definitely something we want to do is create this army of patients and stakeholders and caregivers.

CHAIRMAN WASHINGTON: Okay. Just in case we have some others listening from other branches

of the armed services, we're not going to limit this to just creating an army, we're going to have a Navy, an Air Force, and Marines, and Coast Guard and -- of course all of you serving in the public health service, we're also going to have you, even though you can't wear an arm, so we're going to have literally a phalanx of individuals from different backgrounds working on this. Yes, Sue?

MS. SHERIDAN: Gene, could I just make one more comment? Sharon, to your point about changing the world, I want to share that in this workshop -- communicating this workshop and inviting applications of interest, we've received interest from around the world, and so we are being watched, and it's great to see that kind of enthusiasm.

CHAIRMAN WASHINGTON: Great. Lewis-Hall and then Weisman.

DR. LEWIS-HALL: I had a question and a comment. Freda Lewis-Hall, member of the Board. The first is I want to underscore Gray's point about holding meetings, if you would, even if they're geographically distributed. I think that

engagement sometimes actually means you have to go to where they are -- church basements, you know, at clinics, in hospitals, wherever people rest or don't, as patients, caregivers, and other stakeholders.

So, I just want to underscore the fact that I don't think Gray means, and I certainly wouldn't mean -- it means that you held it in Far City, Arkansas. It meant that you actually went to where they were at the meetings, at the homes, to get that kind of feedback, because sometimes that's what it takes to reach hard to reach people.

MS. SHERIDAN: And we totally agree with you, and actually inpatient surveys, that's exactly what they've said, is they say, come to us. And that's exactly what we want to do.

DR. LEWIS-HALL: That's perfect. Then the second thing was, on question two, around the measures of success, and I think it would be interesting if there was a way to do it to evolve some quantitative measures of success. I understand that we're getting, you know, good

feedback and we're incorporating that, but is there a way to take a look at, I'll call them typical levels of engagement in research and to exceed that, both quantitatively and in -- quantitatively in, say, the general population? So, if 3 percent of the population has actively participated in research, can we identify two or three populations that we want to push that number to something different and then qualitatively measure the experience that they've had? I'm a little -- so, I'm a little bit nervous about not having -- I'm going to call it -- a hard measure, kind of a quantitative measure, and I know that's kind of typically where we want to go in science, but I think in this case it will be important to demonstrate a lift, if you would, numerically.

CHAIRMAN WASHINGTON: Okay. Last comment in this session by Weisman.

DR. WEISMAN: Harlan Weisman, member of the Board. I'm also a member of the COEC and I would echo what Sharon has said. There's just been a tremendous amount of work by the staff working in

engagement to come up with these ideas and drive the -- you know, simultaneously drive a number of ideas, such as the workshops and other engagement activities.

In terms of the questions, I am a firm believer that engagement is a good idea. I also totally support the idea and am a strong advocate for doing research done differently, but those, I think, we need to remember whether it's engagement or research done differently, are a means to an end and they are -- the end is the vision mission, whatever it is that we say PCORI wants to achieve, and what we want to achieve is providing, you know, information that can be relied on, the best available information that can be relied on, that helps patients, caregivers, physicians, other clinicians, understand the options available so they can make high quality decisions in a way that's as applicable as possible to them as individuals.

So that's, you know, an overall goal. We also say we want to be a trusted source of

information. A couple things, while some of this isn't going to happen right away. We're not going to get research we're funding results within the next year, but I do think we've got to think about what does it look like if PCORI is a trusted source of information for patients and other stakeholders? What would that look like? And what does it look like when we're doing research differently in the service of achieving that? And also what does it look like when we're a trusted source of information?

I think some of it is the research we're funding, but there must be other things along the way that help us achieve that. You know, if we say we want to be a trusted source of information, does that mean we should also be spending time looking at available information and packaging it in a way that's available to patients and their caregivers and clinicians?

I don't know the answer to that, but I think we should -- it would be a mistake to confuse the means to an end with the end that we're trying

to achieve, and it's a great means, believe me, and I totally believe that we ought to be doing them, but we also ought to be keeping the end in mind, and somehow, just to Freda's point, we ought to think about our progress in achieving that.

When I look at all the things we're doing, I'd like to know in a year, year and a half, two years, six months, hopefully, what have we done to move the ball closer to that endpoint, you know, to that mission/vision? Not easy to do it, but I think that starts to frame our priorities and frame the kinds of things we ought to be doing.

CHAIRMAN WASHINGTON: Important points were made and I want to thank the Board members for their input and I want to reiterate one that Harlan Weisman made earlier regarding it being just as important to analyze the 158 or so of the 308 that are not going to be included to see who, in fact, exhibited this enthusiasm but was not able to participate after we've selected the 150, because I think that they tell us a great deal also about who else is out there and what a different segment

might look like.

It also tells us something about ourselves in terms of our biases and values when we compare these two groups to each other, so it's a very important point that was made that we should be applying here and probably in other areas as well.

So, with that, Joe, introduce the next session, please.

DR. SELBY: You bet. So, to Harlan's point, in a way, toward what end are we doing this work of engaging with the patient and stakeholder communities? As the first slide that Sue and Susan showed pointed out, one of the first touch points is in the area of generating research ideas, finding -- obtaining research ideas, soliciting them from these communities, and then together with these communities, prioritizing them.

I'm very happy to present Dr. Rachael Fleurence. I think this is the first time Rachael's presented at the Board meeting, but she's been working -- diligently is an understatement -- on developing this thinking. We look forward to

your comments today, and she'll tell you about a workshop that's coming up in December to refine the thinking how we do this.

DR. KRUMHOLZ: Can I just ask one question? Because it seemed to me that Anne asked a very critical question about this measurement and I just wasn't sure -- there were a few comments going back and forth, but I just didn't -- wasn't sure where it ended up and to me it's the critical nature of this. I mean, and Harlan Weisman, Harlan Krumholz, Harlan Weisman said, let's not confuse the means with the ends, which is a very important notion, because the question is, is our means, is our trying to invert the typical research paradigm an intervention in itself? But even more, what are those ends? And that's where the measurement's going to come in.

So, I wasn't sure if Anne felt satisfied with -- or got guidance out of that. I know we need to keep on the schedule, but it does seem to me that this issue of, what is the end, and it's one we've talked about earlier, which is, if we're

successful, what does success look like? And I don't know, maybe -- is there another time we're going to come back to that? Or did you feel that you got enough guidance? Because as a Board, I think our job is to provide some strategic oomph to, you know, give you support, and your staff, so you don't come back to us and we say, well, you know, you're going in the wrong direction. Well, we didn't give any clarity around that.

I'm just a little worried because it seems like such an important question was posed to us, there were a few comments, but I don't know how we can best help. Maybe in other ways?

CHAIRMAN WASHINGTON: Before you respond. Harlan, I suspect that in every topic today we're going to want to go deeper and we could spend a half day on just one of these sessions. That's not going to be possible. So, I sort of get a cue from Joe as to whether or not we've got enough at this point now.

The idea is that we've introduced it. If you've got some ideas, put them out on the table.

Now. But we're all going to be reflecting on this, and I don't think we fully answered the question, but, you know, we have ongoing discussions.

Please follow up with additional comments in response to all of the questions, so to get to your concern, Harlan. I would say this also to anyone that's joining us via webcast, you can offer your input, as I said earlier, by just going to info@pcori.org, or you can also join us this afternoon for the public comment period via teleconference, just let the operator know, so you'll be able to provide us with some live input today.

So, Harlan, please, I'm urging Board members to follow up. That's not the end of the discussion, but you're going to see that there are some other burning topics. And I would be remiss, as I was thanking the Board for their comments, if I didn't also really thank the staff, Sue and Susan, for -- along with all the other colleagues that are involved, as well as the committee members, for some terrific work.

We really do feel like we are moving forward and what we're talking about right now is how do we create that context and how do we create those longer-term, clearly identified goals with progress measures to ensure that we are moving in the right direction and in a timely manner. But thank you, very much, both of you.

Okay, with that, Rachael?

DR. FLEURENCE: Thank you. Can I get a quick time check to see how long I have since we're a little off the agenda?

CHAIRMAN WASHINGTON: [Off microphone.]

[Laughter.]

CHAIRMAN WASHINGTON: Okay we're at 10:05 [Off microphone.] Let's go to 10:30. [Inaudible.] So, 25 minutes.

DR. FLEURENCE: Thank you. So, Dr. Rachael Fleurence. I'm delighted to be here this morning to talk to you about topic generation and research prioritization, which, in other words, is really asking the wider community what research topics they think PCORI should be funding and then

how, among these questions, do we select the ones that will actually go for funding.

So, like my engagement colleagues, we have some questions for you to consider as I present and we'll go back to these questions at the end of the presentation. So, the first question we're asking you to consider is whether the process that we are proposing for research prioritization engages the patients and stakeholders at the appropriate level and whether this process is transparent and rigorous.

The second question we're asking you to consider is whether the process itself will enable PCORI to develop a balanced portfolio, which is in line with its mission.

And then, finally, the third question is whether this process will enable the optimal level of engagement between the Board of Governors and the future advisory panels, which Anne will talk to you about a little bit later.

So, to give you the context on this initiative around topic generation and research

prioritization, PCORI's Board approved in May 2012 our National Priorities for research and the Research Agenda. These are the five priorities that you'll recognize: addressing disparities, communication and dissemination, assessment of different options for prevention, diagnosis, and treatment, improving healthcare systems, and infrastructure and methods.

Under this remit, PCORI has embarked on two complementary approaches to developing its research portfolio, so under these National Priorities. The first way is the more traditional way, which is the investigator-led research and under this approach, PCORI issues broad Funding Announcements like the ones that were issued in May. Researchers partner with stakeholders and patients to generate questions of interest. Researchers and stakeholders then apply the PCORI criteria to developing their proposals, which then get submitted to PCORI. And then a peer review process prioritizes the applications and ensures that they're aligned with the PCORI criteria.

So, this is the first approach that allows us to develop a diverse research portfolio and answering key questions for patients and clinicians.

This is just one way to do this and a second way that PCORI is proposing and which is unique to PCORI is a patient and stakeholder-led approach. In this process, PCORI and stakeholders and patients generate and then prioritize questions based on review criteria. PCORI then issues specific Funding Announcements for the highest priority topics. And then similar to the other process, researchers, patients, and stakeholders develop responsive proposals that will then go through the peer review process.

And, again, this is a process that will also allow us to continue building the diverse research portfolio and answering key questions.

So, PCORI is developing its process based on an existing scientific base and also prior experience from other organizations. There is a scientific literature on research prioritization.

We've been using this literature. We've also been working with our Methodology Committee members and the Methodology Committee report, which has a chapter on research prioritization, and we're also building on the experience of other organizations that have been here before us, NIH, AHRQ, and places like the World Health Organization.

So, on this slide, I show you an overview of the four big phases that go into this process. I'll be diving into these phases in a little bit more detail over the next few slides, but essentially the first step is called topic generation, and this is essentially asking people to generate questions that are of interest to them. We are using several ways to approach this.

The first is reaching out to patients and stakeholders, and my engagement colleagues talked to you about this at length.

We launched a webpage on Friday that allows patients and stakeholders and the wider community to send questions to us.

We're working on social media outreach

opportunities and we're also holding these workshops that Sue and Susan discussed. However, I just want to mention other ways that PCORI will also be identifying really important gaps. So, one is through a continuous review of our own research portfolio as it develops to ensure that we are identifying major gaps there, and then working with other agencies such as AHRQ and NIH and tapping into their expertise about big research gaps in various areas of interest.

And so then just quickly, the next few phases of this overall process are a gap confirmation process whereby the research questions will be vetted by a team of scientists to ensure that existing research isn't currently underway and that we're not duplicating any research efforts.

In a third phase called research prioritization, we'll be engaging our future advisory panels made up of patients and stakeholders in prioritizing these questions for funding. And then in a final phase, these selected lists will be presented to the Board of Governors

for final choice of the topics that will then go for a Funding Announcement.

CHAIRMAN WASHINGTON: Rachael, would you pause for a minute. This is a key slide and I see a few cards. Starting with Ellen. Name please?

DR. SIGAL: So, Rachael, I'm very pleased we're doing this -- I'm sorry, Ellen Sigal, Board member.

So, I'm really happy we're doing this. One threat or one problem is, and I know from the community that I work with, is that a lot of people don't feel we really listen, so if we are going to do this and we're going to reach out to various stakeholders, how do we know -- how do they know that not everything they want will be studied, but at least some of it or a process -- because often it's a dark hole. It goes in and it doesn't come back out, and that is, you know, if people are really going to generate topics and they're going to work hard to give you something really important, they're going to want to know that at least we have some criteria for paying attention to

it and we at least, if it doesn't make it, we get back to them and let them know why it didn't make it or what the issues are.

DR. FLEURENCE: That's an excellent point. So, there's several touch points along the process where we do get back to people. So, we do plan to get back to everyone who submits a topic to us with a topic disposition explaining whether current research is underway or why this didn't meet PCORI criteria.

And the other thing is our process is going to be utterly transparent and the criteria by which we make decisions will be publically available, but I think, you're right, that there is a reality that PCORI will not be able to fund every research question that gets submitted to us.

So, the more transparent we are about the process, the better served we'll be.

CHAIRMAN WASHINGTON: Rachael, what I heard is, transparency, objectivity, but also follow up, and follow up keeps coming back as a recurring theme that we need to keep in mind on all

of our activities. Douma, please.

DR. DOUMA: Allen Douma, Board. I think it's really important that we don't forget that we're asking people to submit their questions, and they're very personal, they're very specific. And then we automatically begin, in our flow diagrams in our presentation at least, talk about topics. And a question is not a topic. A key issue is, how do we do that translation to create a topic out of a question, and are there multiple questions that turn into a bigger topic? And that's a process that I don't see us addressing quite yet. Well, it will happen, I mean, once we get enmeshed in the process itself, it will be naturally demanded of us to make that kind of link between A, patient's question, and what we consider a topic.

It might be good to prepare a little bit more for that.

DR. FLEURENCE: Yes, agreed.

CHAIRMAN WASHINGTON: For those of you who are listening, there are heads nodding in agreement. So, Norquist, please, and then

Rachael's going to continue.

DR. NORQUIST: Yeah, kind of following up on what Allen said -- Gray Norquist, member of the Board -- is that I think what's key here is that, you know, one of the things I've said in the past is that PCORI has to take the leadership in this field. We're not going to fund everything, but there are others who can fund, including NIH, who has a lot of money, and so I think we need to set the agenda and say, these are our key priority areas, here's where our money can fit in this or we can co-fund with others and leverage, so that people aren't necessarily disappointed in the fact that PCORI itself did not do it, but that the field starts to address it, and I think that's one of the issues that we have to get that message across too is that it's not only us, but we're trying to drive the field in a certain direction and that we use it in that way, so we may want to think strategically about how we do that also.

CHAIRMAN WASHINGTON: Thank you.

DR. FLEURENCE: Thank you for that

comment.

Okay, so, I'm going to talk a little bit more about each phase with a little bit more detail. So, our topic generation phase, which is reaching out to the wider community to ask them to send questions into us, so we have several ways that we're envisaging to reach out to the wider community, my engagement colleagues talked about it in some detail. I just want to highlight that the process always begins with patients and stakeholders. We have the webpage. I'm going to show you a snapshot of it in the next slide and also be able to share with you some of the questions that have already been transmitted to us.

We'll be using social media outreach ways, the in-person workshops, and there will be some topic generation sessions at the workshops that my engagement colleagues are preparing for in the fall.

There are, however, some other ways that we'll be looking to use. AHRQ has funded a number of future research needs report where they have

done systematic reviews in a number of disease areas and conditions. We will be looking at the gaps in research that were identified in these reports.

We're also, as I mentioned earlier, going to be looking at gaps identified by AHRQ and NIH is really critical questions in certain fields.

And so, once all these topics have been or will be sent to us, we're going to be using just a basic filter to ensure that it falls under the remit of PCORI's mission, that it's answering a clinical question around a healthcare decision, that it's not a cost or cost effectiveness question. And then these topics will be sent over for the next phase, which is the gap confirmation phase.

This is a snapshot of our webpage.

DR. WEISMAN: Can I ask you a question? On the previous slide -- Harlan Weisman -- just for clarification -- it would seem that you could, out of the big list of things that are coming in and nominated, that the filter may not allow you to

reduce it to a small enough number to get it done because there could be a lot of very worthy topics there that would be generated by us that would meet our criteria.

DR. FLEURENCE: Yeah, so this filter is really a very basic filter and it's not intended to really reduce the number of questions, it's really intended to just ensure that they broadly fall under the remit.

DR. WEISMAN: Okay.

DR. FLEURENCE: The prioritization is going to happen later and I'll talk about that.

DR. WEISMAN: Okay. Thank you.

CHAIRMAN WASHINGTON: Douma, is that a clarifying question?

DR. DOUMA: Yeah, quickly clarifying. When we use, in that last slide, as well as it's in this slide -- we use the term healthcare decision -- do we mean health decision? So, we can include prevention and self-care and things like that as well?

DR. FLEURENCE: Absolutely, yes. Yes.

DR. DOUMA: Okay.

CHAIRMAN WASHINGTON: Sigal, clarifying question?

DR. SIGAL: Ellen Sigal, Board. Clarifying question. So, there's a lot that has already been submitted that I don't see up here from IOM and other sources. How are you going to handle that because the communities, where many have put a fair amount of work in terms of topic generation, and I would hope that we're not going to go de novo on this.

DR. FLEURENCE: We're not going to go de novo. The IOM is actually -- I didn't mention it out loud -- it's actually on this slide and we'll be using a number of the topics that were sent for our fast track Funding Announcement that will be talked about tomorrow.

DR. SIGAL: Okay, but that's not my point. My point is, there are others that have submitted, others -- and others that come to talk to you about that. How does that fit in? There's a world outside of IOM and NIH and people that have

submitted and will submit. So, what are you going to do with what has come from other sources?

DR. FLEURENCE: So, these topics will be considered and go through our next phase of gap confirmation process.

DR. SIGAL: The ones that have [off microphone].

DR. FLEURENCE: Yes.

CHAIRMAN WASHINGTON: Okay.

DR. FLEURENCE: I wanted to just share with you -- this is a snapshot of our webpage, our topic generation webpage, so I invite you to go and look at it on the web. We went live on Friday and a number of topics came through. I just wanted to mention some of the questions that came up somewhere on progression of chronic kidney disease, coordination of care with patients with heart failure, the use of MRI versus mammography for breast cancer, asthma management in children, so we had a few more but I just wanted to give you a flavor of what came in over the weekend.

Our phase two of this process is what

we're calling gap confirmation. We are working with AHRQ to work with their scientists in order to proceed with this gap confirmation and what we're calling also a topic disposition process whereby people who send questions in will get a response to their question and will be told what the determination of the question was.

So, we see three potential determinations. So, one is that there are a number of existing studies but they need to be synthesized so the outcome would be an evidence synthesis project. The second disposition would be that new primary research is needed. In both these first cases the topic would go to our research prioritization process and to the future advisory panels.

A third case is that the answer is already known or research is currently underway. And then there will need to be a dissemination effort for the results of that research.

DR. WEISMAN: Just a quick question. Are you envisioning that last thing? That's something that we view as PCORI will be active in doing that.

DR. FLEURENCE: That's correct. Yes.

Phase three is our actual research prioritization process and this slide outlines the various steps that will take place in this process. The research questions will go to the future advisory panels, and here I have some examples of what these panels might look like. We're envisaging that we would have at least one panel per research priority, but as you know, rare diseases is also one of our mandated advisory panels. And these will be discussed a little later in the next presentation.

The advisory panels will use PCORI-specific criteria that I will describe to you on the next slide in order to come up with prioritized lists, and then these lists will come to you, to the Board of Governors, for a final selection of the topics that you feel are of highest priority for PCORI staff to issue Funding Announcements.

This slide shows you the PCORI criteria that we are proposing to use in this research prioritization process. They're built upon the

existing PCORI criteria that you will be familiar with from our Funding Announcements, but they also include some of the methodology from the Methodology Committee report that has -- that was worked upon in order to propose some research prioritization processes.

So, the criteria are, starting with patient-centeredness, then the impact of the condition on the health of individuals and population, the third criteria here is what we're calling potential for improvement, but it contains a number of really important aspects to consider when doing the prioritization process. It includes thinking about the differences in benefits that the interventions may show the reduction in uncertainty, the likelihood that the findings will change clinical practice, and then how long the information will be valid.

The last two criteria refer to the potential for the impact on healthcare performance and the potential for inclusiveness of different populations.

CHAIRMAN WASHINGTON: We have a clarifying question.

DR. DOUMA: Allen Douma, Board. On the last slide, the number three, it seems like pretty much all of those four bullets you wouldn't know until after the research has been done. How are you going to answer those questions a priori and how are you going to answer those questions a priori for hundreds of questions that are coming at it?

DR. FLEURENCE: So, that's a great question. We believe that it's possible to provide some evidence in order to help people think about these criteria in this way and some of them will be assumptions. For example, how long will the information be valid will come down to using some assumptions. We, on the next slide, actually, I show what we're calling a sample PCORI topic brief where we will be providing the folks engaged in the research prioritization with as much information as we can around these different criteria to help them make decisions.

I think, again, the idea is that asking people to think explicitly about criteria is a step forward from just having people talk about things in general terms, so that's sort of where we're going with this.

DR. DOUMA: Okay. I think I'm going to be frustrated a lot, in particular --

CHAIRMAN WASHINGTON: Allen, I'm sorry to do this, but a clarifying question --

DR. DOUMA: Yeah. Gotcha.

CHAIRMAN WASHINGTON: We're going to go a little deeper into this. We're right near the presentation, so if it's -- you raised a good point. We're going to be discussing it in a minute, but we're not ready to discuss it yet.

Ernie is down. Debra, do you have a question -- a clarifying question?

DR. BARKSDALE: I'm back at page nine where the -- on the web where you're soliciting the questions. Did I hear you say that you will be getting back to each person that submits a question?

DR. FLEURENCE: You did. Yes.

DR. BARKSDALE: So, if a person submits -- what kind of information will you be getting back to them with? For example, if a person submits a question like, what's the best treatment for my father's hypertension? How -- I mean, what would they get?

DR. FLEURENCE: What would -- so, I can't tell you that in exact detail what they would get back, but they would certainly -- we will be determining whether information exists in order to be able to answer that question. There will be some opportunity to transform these questions, I think, into -- you know, from the research question into a sort of actual research topic, and providing the person back with information on, actually there is good evidence right now on what the different treatments are for hypertension, or if there were not, saying that this is something that PCORI might consider funding in the future.

CHAIRMAN WASHINGTON: Epstein is really struggling with his card over there, so I'm going

to help him out by calling.

DR. EPSTEIN: Are you asking just for clarifying questions?

CHAIRMAN WASHINGTON: Just clarifying, because she's near the end of the presentation.

DR. EPSTEIN: Then let me pass.

CHAIRMAN WASHINGTON: Please, Rachael, continue.

DR. FLEURENCE: Okay. And I'll try and wrap up fairly quickly.

We've developed a first draft of a process for research prioritization. We've invited patients and stakeholders to apply to become members of a pilot that will take place in October and November of this year. The application process opened last Monday and we have approximately 64 people who have applied to become part of this pilot group.

In this pilot, we will ask people to prioritize ten research topics that we chose randomly from the future research needs reports from AHRQ. These topics will not be then submitted

to you for any Funding Announcement, this is really for the purposes of piloting the process.

This pilot group is going to meet three times by teleconference, discuss the questions, discuss the process, and provide feedback to us on how the process is working for them.

The revised process will be presented at the December 5th workshop on research prioritization. We will also gather feedback on that day about our process and a revised process will then be used in the winter when the future advisory panels will start doing actual research prioritization with topics submitted to PCORI.

So, quickly, this is our timeline from August to March of next year. We are on track for the pilot in October and November, as you see on this slide, and December 5th is our research prioritization methods workshop and people will be trained in January and February on the methods in order to be able to conduct actual exercises in the winter.

This slide simply lists our team. We have

Board members, included Gail Hunt, Arnie Epstein, we have members of the Methodology Committee helping us with this. We also have a patient representative, Linda Morgan, and a stakeholder representative, Neal Kirschner from the American College of Physicians helping us work on this, and as I mentioned previously, we have a pilot that will be up to 30 people that we'll be starting in a couple of weeks.

So, just to summarize really quickly, since I'm running out of time. We are engaging patients and stakeholders at each step of the way. We're developing criteria that are transparent. There will be challenges along the way. I think you've pointed out some of them already to us, but we're very keen to proceed in this way using objective criteria as much as we can, and really having -- developing a transparent and visible process that's going to be shared with the public, that's going to be open, and allow us to do the best job that we can in this endeavor.

Okay, so my last slide is just revisiting

the questions that I asked at the beginning of the presentation about whether the level of engagement of patients and stakeholders is appropriate, whether you feel this process will enable us to develop a balanced portfolio, which is in line with our mission, and then finally, whether you think that there's an optimal level of engagement between the Board of Governors and these future advisory panels.

And I'll stop there.

CHAIRMAN WASHINGTON: Okay, thank you, Rachael, for the presentation and thanks to others working with you on it who you've acknowledged, and particularly Rick in his role as Chair.

Could you go back to the last slide? Then I'm going to open it up for questions. Epstein's going to be first.

You know, as far as this summarizing, the key point about follow up is not explicitly stated here, and so that may be the fourth leg of this structure here, because otherwise, we keep coming back to it in whatever form it takes. That would

be unique too, as a PCORI sort of signature, because we don't tend to follow up when we get feedback in general across the research enterprise.

DR. FLEURENCE: Okay, so just to -- we are -- we're definitely planning on that, but I need to highlight it on the slide, so thank you for making the point.

CHAIRMAN WASHINGTON: Epstein and then Becker.

DR. EPSTEIN: Can we put back the slides with the -- Arnie Epstein, Board. Can we put back the slides with the questions for the Board?

So, first, Rachael, let me just say, I thought that was really lucid and I think you've take this as far as certainly I could. I really appreciate the work you've done. And I want to say some things which sound like they're going to reinforce what Allen was really heading for.

I'm not sure that those questions get to the nub of what we're about. I think the nub of what we're about is, can we establish priorities in our different areas, can we target specific areas,

which are likely to be verdant, which are likely to enable us to turn over new information that's going to effect the healthcare and health of people all over the country? And that's not there.

And that is what's hard here. I want to think for a second, there are a lot of people on the Board who do research for a living or have done it during parts of their career and know it intimately. So, I want to reflect a little bit on how I think of -- how I figure out research questions, which is that I start with topics that are important, they're all around us, but then I'm looking for an opportunity to do what 350 million people in our country haven't already done, turn over some new information, which is going to make a change.

That's key, and my ability to do that and guess right is what it's all about. And I want to just say on a macro level, our ability as an organization to do that and guess right about the areas we're going to target is going to be key to our success. And there are a couple hints that I

have when I do that at a micro level. I look for places where there's been an exogenous change to the system, for me it's health services, so it might be the establishment of legislation on ACOs or readmissions, but in the clinical world it might be new drugs that come on or things of that nature.

I look for those changes exogenously, or I look where new data are available or new methods are available or there's a new technology that lets me get to a question that I haven't gotten to before.

I think we have to do the same thing right here, nothing less than that. We are, essentially, making ourselves the researchers. If we target an area, pharmacotherapy for diabetes, we're inherently saying, we think it's ripe right now that we can make real changes in that area and go forward, and I think Allen talked about the formidable nature of that. I do see it as formidable. I don't know that I have the answers for how to do it, but I think that's the central challenge for us here. It's not this stuff.

CHAIRMAN WASHINGTON: Okay, Joe wants to just comment on that, then we'll go to Becker and Hunt.

DR. SELBY: Yeah. Arnie, thanks, that's much appreciated. You're absolutely right, you and Allen are absolutely right, though because we have such a broad mandate, in a way, that has not been narrowed by anything we've done at this point in terms of what we might fund, our priorities are broad and within them we haven't specified particular conditions or anything like that, so we are starting by prioritizing from across the vast realm of healthcare and health services questions that could come up.

One of the reasons we're doing this is precisely because we're concerned and we have heard that many stakeholders have felt that there's not a chance in the process to get their question looked at or vetted, and this is that process. This is -- it's quite a democratic process, actually, to get these questions looked at and vetted.

And the vetting actually speaks directly

to what you just suggested as criteria, that notion of, is there a new intervention on the street, has some new technology come up -- it might be a technology for reaching patients, it might be a drug, it might be a new analytic method, a way to reach a patient population that wasn't reached before. That is that central innovation and potential for improvement criterion and that will be a central part of what the prioritization advisory panels work on.

Now, how we operationalize that, how we take that information, how we quantify that information, from question to question, is the grist of the December 5th meeting and it's the core of whether we succeed or not. If there is a stakeholder out there who has a burning question, our process has to be able to spot that question.

The last thing I'll say is that a lot of this will come back to the Board. The Board will take a look at the prioritized list and the reasons why, and the Board may decide to coalesce questions along the lines that Allen suggested, and the Board

may say, this is a compelling question, but it's not one that makes sense on its face to name as a specific Funding Announcement, but we'll put it into the broader Funding Announcements as a reminder we would be interested in research like this.

So, there are ways we can take those prioritized questions and put them in front of the research community, short of --

SPEAKER: I agree with what you said, I was just focusing us on the central task is, how do we make the decisions that this is an area in which we can turnover new knowledge which has not heretofore been here, that can have an important impact? That's all. But I agree with everything you said, Joe.

CHAIRMAN WASHINGTON: Becker?

MR. BECKER: So, I readily -- this is Larry Becker, I'm a member of the Board, and I readily admit, I'm not a researcher, I come from industry and I'm coming from a very different paradigm on this.

I've heard Carolyn and many other people over the years quote literature that says it takes 17 years to implement something. And I also know that hospitals, physicians, medical centers grapple with questions from patients every day and they find best practices that work in their institutions or their practice.

And it seems to me that we're looking for research done differently, new and untraditional ways, continuous learning, we're looking for benchmarks, and it dawns on me that maybe one of the things we ought to think about is a registry. Try to accumulate all the stuff that we've done, spent fill in the number trillion dollars over fill in the number of years, and put it out there and learn also about how to disseminate it. And how will patients, physicians, providers pick up that information while we're priming the research part of this?

Because that's the next step, right, after the research comes, how are we actually going to get it? We know it doesn't get picked up very

well, so why don't we try and figure out what we've already done, put that in some kind of registry, and then figure out how does that get taken up by people.

So, that's my nontraditional thought.

CHAIRMAN WASHINGTON: It's 10:38. I've already allowed us to go over eight minutes. What I'd like to do is recognize the remaining Board members, so that would be Hunt and --

MS. HUNT: I'll pass.

CHAIRMAN WASHINGTON: -- Weisman, and then we're going to break, and we're going to take our full 15 minutes and then we'll adjust the agenda accordingly. And Hunt is going to take a pass, and so, Weisman, you get the last comment on this topic, but I'm going to reiterate, emphasize the point that I made in response to Harlan's comment earlier, Harlan K., and that is, we're going to continue this dialogue because this is a critical topic. Please provide comments to Joe and to Rachael and others on the staff, and I would emphasize the same message to those in the audience

as well as those who are listening via the webcast.

So, with that, Harlan, you get the last comment and then we're going to wrap.

DR. WEISMAN: Harlan Weisman, Board member, and my comment is very complementary to what Larry said. I think one of the strategic issues for us is how much do we, in trying to achieve our end, if we can agree what our end is, which is helping patients answer the four questions, and being a trusted source of information, if that's what we are, in the end, how much of what we do needs to be original, new research that we fund, encouraging others to do research to answer some of those questions? And third, taking what we know, this is Larry's point, taking what we know and figuring out how it can be effectively disseminated and taken up in the community so that it's useful.

In other words, there's probably a lot of things today that if only it could get to the end user, it would really help people understand what options are available to them in a way that's

meaningful for them that would enable them to make higher quality decisions.

Personally, as somebody who, besides being a doctor and a Board member, I have been a patient and I have family and friends who have been patients, and I find it awfully hard, with all the knowledge I have and all the connections I have, sometimes to answer those questions. But I also have the means of going after it in a way that most people don't have, and if we could only achieve a way to let people easily get that information, whether it's the patient or the doctor, based on what we already know, we would achieve a whole lot and it would help set the stage for doing what we want to do with the original research that we're already sponsoring or that we plan to sponsor.

CHAIRMAN WASHINGTON: Okay. Thank you, Harlan. Again, encourage everyone, continue to dialogue, follow up at an appropriate time. We're going to take a break now, but Rachael, terrific presentation, superb discussion, and on a critical topic, we will certainly be hearing more. But

thank you.

It is now 10:42. Colleagues, we're going to start -- rather than a 15 minute break, you're actually going to get an 18 minute break, so that's the reward for your patience. But we're going to start at precisely 11:00 o'clock. Please, be back and in your seat.

[Recess.]

CHAIRMAN WASHINGTON: We're live. Welcome back to everyone to this meeting of the Board of Governors of the Patient-Centered Outcomes Research Institute.

In this next session we're going to discuss this important topic of PCORI advisory panels. For the Board, you've heard this topic discussed before, and there are two broad questions that are going to be on the table for us during this session. One has to do with the principles, the policies, and the procedures for how we establish these advisory panels. And the other one relates to which of the advisory panels would be approved at this point in the development of this

entire area.

And so, keep in mind, certainly -- am I giving your introductory comments, Anne? Okay, keep in mind that while there are multiple that are going to be proposed, at a minimum, I think, that I've heard we want to seek approval to at least two of these, but I'll allow Anne and Joe to clarify exactly what the expected outcome is. And so with that, Anne, would you introduce yourself?

DR. BEAL: Hello, Anne Beal, COO of PCORI.

So, as you heard earlier, Joe said that this is really the meeting that's focused on engagement and you've heard other speakers allude to our plans around the advisory panels and most currently you heard Rachael talk about our thinking about utilization of advisory panels for helping to refine in terms of our research agenda.

One of the things that you heard Gene talk about is some of the questions that we will be presenting to the Board in terms of this discussion around advisory panels, and specifically our questions are: is this the right scope for the

advisory panel activities that we will be proposing? And also we're looking specifically for information in terms of the proposed number and type of advisory panels.

So, you heard Rachael talk about her intention for utilization of those advisory panels in terms of each of the priority areas that we have as part of our research agenda, and so we would like to hear some of your thoughts about it.

The other thing that I'd like to point out is at the end of this conversation, we will actually have a formal vote that will reflect some of the discussions and decisions that are being made in terms of the number and type of advisory panels.

So, what I'd like to do is just start in with a reminder of what was said in the law in terms of the role of advisory panels for the work of PCORI, and so what you'll see here is that essentially they reminded us that we should develop advisory panels to really help us with developing research priorities and to help us with

establishing the research agenda.

And as you heard from Rachael's presentation, that is part of our thinking as to the role of them.

In addition, the legislation is quite clear that they say that if we were to carry on work around randomized clinical trials, RCTs, that we may want to appoint advisory panels of experts in those areas to really help inform some of the work that we would be doing.

In addition, the legislation also talks about the need for us to focus on rare diseases and makes recommendations that if we are going to pursue in that area, that we should also have advisory panels in that regard.

And so, this is what the legislation tells us, but as we were thinking about it we said that we're also thinking about the role of advisory panels in other ways.

So, first and foremost is that we need to walk the walk if we're going to talk the talk, so if we're going to ask our investigators, if we're

going to ask others to really think about getting input from broad stakeholder audiences, then we need to demonstrate that in terms of what it is that we do as well.

And so, as we've thought about the advisory panels, we think that it's very important for us to really think about them as a way to model patient and stakeholder engagement in PCORI's efforts to do significant research.

As you heard Rachael say that we're also interested in having the advisory panels help us with the process of refinement and prioritization of specific research questions that we would pursue, and in addition, what we're interested in is really having people and experts available to us who can provide scientific and other types of technical expertise. So, it may not necessarily just be limited to the prioritization questions, but there may be other questions that we have, whether they're methodologic questions or policy questions, but that it would be very helpful to have an extended -- expanded panel of experts who

can provide us with input.

And this really gets to the fourth area that is listed here, which is really just addressing other questions that may arise. Again, we have an amazing staff, as Joe has pointed out, but really the more heads, the more smart people that you have who are helping to think about a particular issue, then, the better for our work.

So, as we've thought about it, each panel will have a unique charter and duration, and really the thinking behind that is that what the needs might be, say, for a patient engagement panel might be very different from, say, a communication panel. Also, we wanted to make sure that we are building in flexibility for us to think about developing panels that really are meeting our needs now, but our needs now may not be the same as our needs in, say, two or three years.

And so we wanted to be very clear in making sure that we understand, as we appoint each panel, what their input is, what is it that we want them to do, and how long they will essentially be

working with us. And we want to be very clear in terms of setting expectations for anyone who participates in any of these advisory panels exactly what is their defined scope of work.

One of the other things that we've been discussing is what might be the compensation plan for members and participants in these panels, and one of the things that you'll hear about in a moment is that we're very clear that we do want broad-based input and we do not want financial barriers to really prevent people from working with us.

So, similar to the workshops where we're talking about being able to provide support to people to come and engage with us and to give us their information and knowledge, we're also working on this similar principles for the advisory panels in that we just want to recognize the expertise of people who will come and participate.

And so, our thinking is it's similar to how you might be willing to pay for the expertise of a biostatistician or at least give them some

sort of payment to recognize their contribution. We need to recognize the validity and the expertise that patients would bring. And so, we're actually working very actively with the FAAC to think about what are some of the principles behind the compensation policy that would be applied to these advisory panels.

So, as we've thought about it, this is what we're proposing would be the set of advisory panels that we would start with. At the top of our list is thinking that we would want to have an advisory panel which is made up of patients to really help guide our work, both in terms of research, and in terms of engagement, but at the top of our list is really this type of opportunity for there to be really broad-based and substantive input from the patient population.

The other thing that you'll see is that we then have thought about developing advisory panels that align with the five priority areas that are part of the National Priorities and Research Agenda, so as you'll see, we had the assessment and

prevention, diagnostic and treatment options, our program in health disparities, our program in health systems, communication and dissemination.

In addition, what we've listed here is infrastructure, which we'll be talking about today as our fifth priority area, and also randomized clinical trials, which as I mentioned, is really highlighted in the legislation as an area of focus for us.

The asterisks there that we have for both infrastructure and RCTs actually represents the fact that we are very interested in working very closely with the Methodology Committee in terms of populating that advisory panel or hearing nominations from them because we know that they are spending a lot of time working in this area, and so we think that particularly this will be an area or an opportunity for significant collaboration, although in our view, for any of the advisory panels, we're more than interested in having MC involvement in helping to formulate those.

And then lastly, the other advisory panel

that we're thinking about forming would be one in rare diseases, which, again, really aligns with what is mapped out in the legislation.

So, as we've thought about it, we've said that we would want to roll this out in essentially two phases where we would have the first set of advisory panels be the ones that focus on patient engagement, assessment and prevention, treatment and diagnostic options, health disparities and improving healthcare systems. And essentially our rationale for this is a combination of strategic priorities and, frankly, feasibility.

As we think about patient engagement, we think that this is the number one area for us and so it's one of the reasons why we want to start with this as one of our first areas.

In terms of the assessment of prevention, diagnostic, and treatment options, we felt that this type of advisory panel would be very helpful, particularly for the work that Dr. Fleurence just mapped out in terms of our topic generation and research prioritization process, and so thought

that an advisory panel would be very useful for them.

And then in terms of health disparities and improving healthcare systems, we actually, as you know, are in the throes of hiring all of our senior scientists for all of the areas, and so some of our first hires were actually in health disparities and in improving healthcare systems.

And so, one of the first things that we're going to -- or first tasks that we're going to give to these senior scientists is to really help thinking about the further refinement of our funding in those respective areas, and so our thinking is that it would be very useful for them to have advisory panels to help them with the tasks that they have at hand.

Then as we've thought about it for the second half of 2013, that's when we would then roll out then the advisory panels on communication and dissemination, infrastructure, RCTs and rare disease. And, again, part of our thinking, also, is that we wanted to do this in somewhat of a

stepwise fashion so that if there are any learnings, if there are opportunities for improvement in terms of our processes, nomination, execution, that we're able to give ourselves an opportunity to learn from our initial efforts as we then go through in terms of our subsequent efforts around these advisory panels.

So, what this is, is really just the language from the legislation and what I'd like us now is to turn our attention to the question of who would actually sit on the advisory panels and what is it that we're trying to achieve by the different people who we would have come and participate? And so, what's important to remember from the legislation is that the language is quite clear that we shall include representatives from a variety of different perspectives.

So, what's mapped out here is that we should look at research clinicians, patients, experts in scientific and health services research, health services delivery and evidence-based medicine, and essentially, as we think about it,

each of the different advisory panels would obviously include people with these different types of expertise, but we would also look for people who might have different types of expertise from a methodologic perspective, obviously from a content perspective, potentially from a dissemination perspective, so there are a lot of different types of characteristics that we're thinking about.

But I think what's important to understand is that what we're looking for is broad-based and diverse input as we're developing each of these advisory panels.

In addition, as we are developing each one, we're very specific and targeted in terms of what it is that we want them to do, which would be mapped out in each charter, and that helps, then, to inform who are the people that we would invite to participate in each of these panels.

So, as we're thinking about it, each panel would be comprised of 10 to 21 people, and it somewhat depends upon what the purpose is of the panel. Membership on the panel will be based upon

the scope of work, which is established in the charter, and essentially mapping their skills and expertise to what we have in the charter.

In addition, as we've thought about it, we would be very interested in having members of the Board participate on these advisory panels and to serve as a non-voting liaison from the Board of Governors.

In addition, we're very interested in having members from the Methodology Committee serve a similar role, but part of our thinking is really around the consistency in terms of priorities, and so making sure that there's opportunities, frankly, for cross-pollination across various parts of our organization.

In addition, as we think about each advisory panel, there will be one person who would be selected as chairperson and that person would be selected by you all as our Board of Governors, and that members will be appointed for one-year terms with an opportunity for reappointment. And so, quite conceivably, we could have advisory panels

that are one to three years, but then within each one, we might have every person has an appointment for a year at a time. And so our thinking is, is that gives us some flexibility to adjust the composition of the advisory panels as needed.

So, one of the other things that we're paying very, very close attention to is the considerations around conflict of interest and currently our thinking is, first of all, that the advisory panels will be, as they're labeled, giving us advice. And so we would need to be clear, as people are appointed to these advisory panels, exactly what their role is and that as advisory, they will be giving us information, but we will make sure that there are appropriate firewalls in place to make sure that any information that they receive as a result of their participation in the advisory panels is, in fact, public information, such that it does not preclude them from being eligible to apply for funding from PCORI.

And essentially, if these represent the leading thinkers around a number of different

topics in the field, we wanted to make sure that we would be able to include them potentially as recipients of awards from us in the future.

And so, as we're going through and thinking about what would be the proceedings and what we put into places for each of these advisory panels, we would make sure that we're keeping the issues around conflict of interest top of mind.

One of the things that we're currently discussing is different options to ensure transparency of the proceedings of these meetings, and so one of the easiest ways to address this may simply be to have all of the meetings of our advisory panels webcast so that they are available for everyone who wants to observe, participate, and then gain access to any of the knowledge, which is transmitted within the conversations that occur within each advisory panel.

But, again, one of the things that we're making absolutely clear is that these advisory panels really are designed to provide input to both the Board and to staff, not to make decisions, and

so that they are not in a decision making position, but they are, in fact, in an advisory position.

So, as we've thought about the process, this is very much a process that we think about would really be a partnership between staff and the Board, and so we will be asking you to be very actively engaged in establishing the different advisory panels.

So, one of the first things that we would do is think about having, first, the staff draft and submit charters for the different advisory panels to the Board. And so then this gives you all an opportunity to help shape it from the beginning, but essentially the request for specific advisory panels would come from staff and it would be incumbent upon us to develop then the draft charters.

Next, then you all would review these proposed charters and then determine if they should be expanded, if they should be contracted, if there are any adjustments that need to be made, and then we would essentially work in an iterative process

until we have the appropriate charter that really reflects what it is that we're trying to accomplish with each of the charters.

Then once you all approve the charter, then we would then, as staff, take the guidance that was established in each of the charter and then activate the nomination and selection process for the different panel participants. And, again, one of the themes that you're hearing consistently is that we're very interested in making sure that we're open, that we're transparent, that we get a broad-based representation, that every organization or group of organizations that we're creating are very diverse in terms of the perspectives that they offer to us, and so those same principles obviously would apply in terms of our process for nomination and selection of participants in the advisory panels.

And then lastly, once we have selected those individuals, then we would present them as a slate to the Board for approval and then that would then allow us to move ahead with the work that's

established in the advisory panels.

So, I think, the big take home message, though, is that as we're moving ahead with this, this is a process whereby we're going to be asking a lot from our Board members in terms of really helping to drive and shape the charters for each of these advisory panels.

So, as I mentioned, we are thinking that for the first half of 2013, we would like to launch first with the patient engagement, and then with assessment of prevention, diagnostic, and treatment options, and then health disparities and improving healthcare systems. So, I just want to take a moment to just walk us through what we're thinking, for example, with the patient engagement advisory panel, which, as I've stated, is the first one that we would like to actually be able to launch.

CHAIRMAN WASHINGTON: Anne, could you pause for just a minute. I see three cards and clarifying questions, or are you just getting ready for the discussion? Okay, same with you, Epstein? And Kuntz? Okay, please continue.

DR. BEAL: Okay. Thank you.

So, as we've thought about taking the patient engagement advisory panel as an example, essentially our thinking is that we would like to hear from patients about all aspects of our work. And, again, as I said, we want to walk the walk while we're talking the talk. And so when we think about the purpose, it really is very overarching that we say that we want to ensure the highest patient engagement standards and patient-centeredness in all aspects of PCORI's work. And so having that opportunity for having that patient panel available to us to provide us with feedback and advice is something that we're actually very keen to have available to us.

As we've thought about it, the term would be one-year. The membership would be between 10 and 21 members, and our thinking is that we wanted to have a 75 percent patients and caregivers and advocacy organizations, and 25 percent researchers and other stakeholders so that it helps with the dialogue and the discourse, so although this is a

patient engagement advisory panel, that we would have people who really represent the diversity perspectives that we are discussing.

And essentially this panel would provide advice and make recommendations to us as PCORI, but also would help inform decisions of the Board, the MC and just the staff in general on any number of issues that we may have.

Part of our other thinking is that to ensure that there's, again, cross pollination across our different groups is that as we rolled out the different advisory panels on health disparities and prevention and treatment, in communications, then in each of those advisory panels we may also have, then, patient representatives on each of those and that those patient representatives would then also serve as the patient engagement people who we have serving on this patient engagement panel.

So, again, that helps to make sure that the information that we're developing in all of the other areas then also then comes to this patient

engagement panel as well.

And so, as we've thought about it, and what are the type of criteria that we would look for the people who we would want to appoint, is that we really want patients and caregivers who can really represent the collective voice of their communities and networks, and so we've heard a lot today around making sure that you can get out to people where they eat, work, play, and pray, and so we're very interested in is making sure that we have representatives who are really able to get us that information and bring it back to us.

In addition, we're very interested, and I think this was something that Bob raised earlier, in reaching out to people who have access to online communities and organizations particularly with extensive reach into the priority populations and hard to reach populations that we've talked about.

We're very interested in some of the priority groups that we've talked about, so we talk about populations that experience disparities, those who are underserved, those who experience

rare conditions, again, thinking about the diversity of different types of perspectives that we would want to engage.

And then obviously those who may have some experience, previous experience, with having either supported or participated in or reviewed research. In addition, we're very interested in those who are involved in systems improvement and part of our thinking behind that is that there is a huge patient safety world, there's a huge quality improvement world that has engaged a lot of patients in the dialogue about how do you improve health systems, and those people tend to be very activated patients, but they also tend to not be very disease specific, and so what we didn't want to do is get into a dialogue of only this condition and not that condition, what we want is people who really can think broadly.

And the reality is, is even when we do bring people who might have started in the world as a patient advocate for a particular condition, we wouldn't preclude them from being involved, but

what we would really want them to think about is essentially thinking about issues that affect all patients and not just necessarily those for a particular condition that initially got them engaged in patient advocacy.

So, I'll go back, then, to the questions that Dr. Washington teed up, which are really the questions about, is this the right scope of activities for the advisory panels? And then, as we've mentioned, we are really thinking about eight different advisory panels, and so are these the right number and types of advisory panels?

So, with that, I'll close and take your questions.

CHAIRMAN WASHINGTON: I have Sigal first, then Epstein, then Kuntz, and Becker, Lewis-Hall.

DR. SIGAL: Ellen Sigal, Board. So, Anne, thank you, and I think this is really important and we need to do this, there's no doubt about it.

A few questions about process and then about priorities. So, I would agree the patient advisory panel should be first and it's very, very,

very important. My concern is that we are simultaneously going to do a lot and the process is going to be difficult and consuming for staff. I mean, I would assume we will probably, for all the panels, have way over 1,000 applicants, and to distill it down, so I'm a little concerned about if we have the bandwidth to really do that and do that efficiently and set them up and then just staff that. So, I don't know what the answer is, but we need to be thinking about that.

That's one issue. The other issue is a little bit -- and not so much for the patient panel -- is as you start to get very specific expertise on these other panels, it's going to be hard, even though it's transparent, not to have some conflict of interest because they are going to -- they may not advise you on what to study, but they're going to have a lot of influence on what we do study, so we do have to think about how that works and whether, in fact, we can keep it that open that they're not going to have an unfair advantage. So, I don't know the answer to that.

Also, the only other thing, it's just a question, I know why we're not doing it, but the two that are really mandated we're doing the last, which are the rare disease and clinical trials. I understand why, but it may create a bit of a problem. But essentially what I'm saying is this is important, we need to do it, but think about how we're going to get it done efficiently in a timely way and get it up and running, because I think it's going to be daunting.

DR. BEAL: Anne Beal. We very much share your concern and it's one of the reasons why we're thinking that we would first like to do the patient engagement one and then get an understanding of what is the volume, what is the interest, and then once we have experience from that, then we can start to roll out the others. I don't have a better answer for you than that because we do share your concern as we think about -- I do think there's going to be significant interest in this.

CHAIRMAN WASHINGTON: Okay, Kuntz and then Becker.

DR. KUNTZ: Rick Kuntz, Board member. Thanks, Anne, I thought it was a great presentation and I think the topics are spot on. It would be great to understand a little bit more about your thinking is, in my mind advisory panels stand between what I would classically call an advisor panel and a consultant, and it looks like you have a mix in there, like the randomized control trials, it sounds like you may want some consulting.

In the management aspect of these advisory panels, and I think it's going to be a lot for the staff, my suggestion would be to use them as what I would call advisory panels, that is to have meetings that are scheduled where you want to have a lot of people show up on staff and Board and have them witness open discussions about topics that are important to you and not have them perform consulting activities. And that's the best way for us to both get integration of the concerns we have and to bounce it and use them as a sounding board more than anything else.

I think if you structure the advisory

panels that way, and maybe some of them can't be, maybe the randomized clinical trials one is more consulting, you might be able to free up some of the conflict of interest issues so that one could say that, you know, we're not going to bar you from actually applying. We really want to get your feedback on some activities we have. And if you take the advisory board out of the decision making process, keep that within the Board of Directors and the staff, and use them as a sounding board, I think we can bypass some of the COI issues and also manage this to be more of a time and place and event where we get advice with a lot of witnesses from the staff and even the Board of Directors.

DR. BEAL: Thank you.

CHAIRMAN WASHINGTON: Good point. Becker. Lewis-Hall. Zwolak.

MR. BECKER: So, this is Larry Becker, member of the Board. I think this is great work and in developing the charters I would strongly suggest that we're very pragmatic about developing the problem statement or the questions to be

addressed up front, because it seems to me that with one-year terms, we want people to be able to work through a process and develop the answers to whatever those questions are so that they feel like they've made a contribution and seen the beginning, the middle, and the end, of those processes, because otherwise I fear that, you know, if it's a two-year thing, it takes two years to do, and someone rolls off after a year, they're really not going to feel like they had the kind of import that they had hoped to have.

CHAIRMAN WASHINGTON: Lewis-Hall and then Zwolak.

DR. LEWIS-HALL: Freda Lewis-Hall, member of the Board. This is actually really great work and I complement the team for having addressed it in such a thorough way.

I have several concerns. The first is, this is a lot of advisory boards. I know it's been said before, but I need to put an exclamation point, underline, bold, and it may be that the topics are, in fact, so broad that it will be

challenging to funnel some of the feedback, even in the environment that Rick described as kind of an open advisory board where we're listening and then trying to synthesize these.

So, one is I would recommend that we think very carefully about paring back the number. Two, to Ellen's great point, I would think about moving the mandated one up as a priority. If we field rare diseases towards the end of the year, next year, that means three years will have lapsed before we actively pay attention in the space that we were mandated to do so, that gives me some concern. And the third would be, for those that we've chosen to actively in panel, what you did around patient engagement and being very specific about what questions you want to ask and how you want to ask them and to have some outcomes, measurements for the input of the Board, I think are going to be very important.

CHAIRMAN WASHINGTON: [Off microphone.]

DR. ZWOLAK: Bob Zwolak, Board. I certainly support the initial creation of the

patient engagement panel, but I -- I guess I'm the third voice now, as I read through today's agenda, one of the specific questions I came to ask is why we would defer the two mandated panels and what the thought process was and whether we should potentially just approve creation of the mandated ones and get that off the Board's list of things to do.

CHAIRMAN WASHINGTON: Okay. Clancy.

DR. CLANCY: So, I appreciate the presentation and actually other comments that folks have made. The one comment I'd make is agreeing with the exclamation point, so I'll add one or a like or something to Freda's comment. I wonder if to some extent this might be a menu of options. Obviously, rare diseases is one that I think is a must, but for other areas, particularly if we're trying to drive people to the website and, you know, get them engaged with a lot of what PCORI's doing, if we wouldn't be preceding any advisory panel in all of the work of convening with some sort of request for information and, you know,

broad public input to figure out is this topic ready.

DR. BEAL: Could you elaborate a little bit on that?

DR. CLANCY: Well, you've got a whole lot of topics there and on some level I think we're giving you a Rorschach reaction to the titles -- patient engagement, we're all for it. You knew that. It didn't even have to be on a slide. You knew that before we got here. And a few other disparities, all for it -- I mean, all for getting rid of them.

But the question is, how is it that you frame the specific scope. Having sat through a number of meetings on disparities where at the end of like one or two days what you've learned is that people are talking past each other or looking at different sides of the elephant. I would think that we would want to minimize that if we could.

CHAIRMAN WASHINGTON: Okay. Levine, please.

DR. LEVINE: Sharon Levine, Board member.

And I think this is consistent with what Carolyn's suggesting. The actual language in the statute is, "in the case of a research study for rare diseases, the Institute shall appoint an expert panel." And so I think we need to be sure that the sequencing of the panels and, as Carolyn said, sort of getting enough information so that it's clear to those who are interested how the panels work will be relevant to what PCORI is doing rather than just a title and a group of people who say, yeah, I'm interested in rare disease or I have a child with a rare disease.

CHAIRMAN WASHINGTON: Right. Okay. I want to summarize some of what I'm hearing and while I summarize it I'm going to ask Joe and Anne to be prepared, in a couple of minutes, now ask -- or really tell us what you would like from us at this point, because I'm hearing a couple things.

One, strong broad support, for proceeding with the development of the appropriate panel and/or numbers. Two, we didn't have much, in fact, we had almost no further commentary right now on the guiding principles, policies, and procedures,

so I would tell Board members, please look at them, you've seen them. They weren't in your book, but they were passed out. But there are two key questions that are on the table now. One is, what seems like a logical number to sort of handle at any one time? And my sense is, is that there's discomfort with the idea that we would take on more than two at any time, and probably more than two in the next year. There was at least a hint that we should do one, sort of, pilot it even before we get to a second one that we've decided upon before we launched it.

And then the second has to do with which two. There seems to be, again, unanimity about engagement, but if it's really the second one, and what I'm hearing is, maybe there is real reason for us to be guided by what's in the statute, in which case it would be one of the two mandated ones, and given what we're doing in other areas in terms of prioritization, maybe now would be the time for rare diseases.

So, you know, at this point -- and before

I turn to you, any other -- just to add to that for Joe and Anne to respond to? Rick?

DR. KUNTZ: I just wanted to raise that issue about the conflict of interest again. I think that it restricts the optimum Board composition if we're going to restrict them from grants, and I think if we structure it in the right way, we can hear their voice and not make them be decision makers.

DR. SELBY: Well, first, thanks very much for your thinking and we really appreciate the fact that you're enthusiastic about getting on with the process of creating advisory panels.

Real quickly, to Rick's comment, I think we meant to say in the slides -- and I think the slides said -- that, in fact, we do consider these -- membership on an advisory panel as being the provision of input or advice, not consultation and not any kind of activity that would lead directly to a PFA except to the extent that we heed the advice and in the fullness of time and without the involvement of those folks we move ahead.

So, we distinguish between giving input and being involved in the preparation of PFAs, and so we really -- we really consider membership on these advisory panels to be in the form of giving input. And we back that up by making the advisory panel discussions completely open and transparent, so there's not an advantage that obtains from attending a meeting.

The second thing is I'm really delighted that the suggestion that we need to move ahead with a patient engagement panel should come first. I think it should, given who we are. I think if we want to continue to be in the vanguard of patient-centered outcomes research, we need a panel like this to consult with.

The only reason that I know of that we did not put the rare diseases and the clinical trials panels in the first four, so we noticed we proposed them for the second half of 2013, was in the case of each of them, they are complex and we need a lot of consultation, in the case of the rare diseases panel, with the rare diseases community, in the

case of the clinical trials panel, particularly with the Methodology Committee, which is otherwise occupied right now responding to the 120 some lengthy public comments on the methodology report, and we'll hear about that this afternoon.

So, on the other hand, we've just spoken about prioritization and if we don't create an advisory panel related to some of the priorities, the prioritization process just doesn't happen. So, we've gone on record as favoring prioritization, but not authorized the next steps in getting ready to do it.

And among the four priorities, we anticipate that the vast bulk of the questions will fall into priority number one. In other words, most of the questions will be about a treatment decision that I need to make.

So, we would respectfully submit that probably the two highest priority ones, the most urgent are, patient engagement and the advisory panel that would consider the questions that fall into priority one.

We would -- I think we would be delighted to take on preparing the charter for rare diseases and preparing the charter for clinical trials now in lieu of those other two, and we would then put them just slightly on the back burner just until the second half of 2012.

But the advisory panel that is related to priority number one seems, to us, very urgent.

CHAIRMAN WASHINGTON: Okay. Other comments? Feedback?

I must confess, for whatever reason, it never dawned on me until now that when you say priority one, although we know what you're talking about, it almost implies as though that really is the number one priority, and we need to maybe think about how we reframe these in terms -- because we thought of them as pillars, and they are priorities, but, you know -- but I've never thought of them as being priority number one and I don't think that was intended. I'm looking at other Board members, so it may be subtle. I mean, if we say -- okay. Enough said on that.

Just to comment on -- Joe's asking for some more direction because based on the comment, he's saying that this is the way that they would plan to proceed.

So, Lewis-Hall, and then Weisman.

DR. LEWIS-HALL: Actually, mine is a follow on to the comment that you just -- Freda Lewis-Hall, member of the Board -- and that is, if the intent of the prevention, treatment, blah, blah, blah, advisory board is really one around prioritization, perhaps we should articulate it in that way unless we really have agreed that that is priority number one.

So, from what you just said, maybe this is a clarifying question, did you mean that this board would be -- advisory panel would be intended to help prioritize in that amongst our priorities with the, I guess, a lane drawn around these topics, or -- what would they do?

DR. SELBY: So, as questions come in, they will naturally drift toward one of the priorities. Remember, we might be confusing a little bit here

priorities with the pillars of our preliminary Strategic Plan, but the priority number one is this comparison of prevention, diagnostic, and treatment options that patients face. That is what the legislation called on us most primarily to do, that's where we put 40 percent of the funding as opposed to 20 or 10, and that's where, I think, the vast bulk of the questions will come in that we'll have to prioritize.

Those are the reasons that -- and, yes, this advisory panel would be comprised as a multi-stakeholder panel. It's -- one of its main activities would be to join us in the prioritization work.

CHAIRMAN WASHINGTON: Weisman.

DR. WEISMAN: Harlan Weisman, Board member. I'm going to go back to the refrain of earlier when we were talking about the workshops, and I've said it also at the COEC meetings. Again, these are activities that are designed to help us achieve our strategic objectives, and for the advisory panel, whichever one we do, and engaging

being -- if that's the first one, then we've got to be really clear because your time is valuable plus the advisory committee's time is valuable, is that this is in the service of helping us achieve X, and I'm not sure myself yet what X is. This panel will have -- is essential, is critical, it's mission critical, to have this panel because by virtue of having this panel and having the questions and the discussions, perhaps recommendations from the panel, it will facilitate and accelerate our ability to achieve what -- you know, and so, that has to be really clearly stated because that really helps me understand whether we should -- what we should do and which panels get impaneled.

And I have to admit that until you answered Freda's question, I thought the panel was about something else. Freda's question was about, is this about having this advisory panel, stakeholders and how to engage them, about helping us prioritize? I thought it was about helping us understand how to engage people effectively and --

DR. SELBY: There are two panels we're

proposing.

DR. WEISMAN: Okay, so you were talking about --

DR. SELBY: The first one is on patient engagement and it's about making PCORI be as good as it can be at engaging patients and other stakeholders --

DR. WEISMAN: Okay.

DR. SELBY: -- particularly patients, and about making -- about developing the field of patient-centered outcomes research. It actually won't be prioritizing research questions.

DR. WEISMAN: Okay. Very good. Thanks.

DR. SELBY: And the second one would prioritize research questions in that bucket that I called priority one, the first of our five national priorities.

DR. WEISMAN: But, you know, one of the things, Joe, and thank you for that, and I was just being -- hopefully most of our stakeholders get it better than I do, but I think the reason I keep hammering this is that it should be, you know,

almost automatic and like a mantra or a refrain that we all know, you know, it just -- this is what we're doing, this is where we're going, and, you know what, this is why we're doing this. And that even people like me who have these lapses of attention, just go: "Harlan, remember, we're doing this because we all said this is where we're going." And that's what's missing for me.

And we've got to be clear to ourselves as a Board, we've got to be clear to the Institute, all of you, we've got to be clear to the public and we've got to be clear to advisory panels and everyone else who's working with us because time is valuable, time is limited, it's crucial that we achieve whatever it is we say we're going within a finite time period, and I need to have that.

So, you know, my recommendation is on all these presentations, you know, we just nail that, here is what we are doing and why we are doing it and this is why the Institute staff believes this is essential to why -- you know, for us to achieve what we want to achieve.

And then I can react in a way that is less vague and ambiguous and less drifting, I think, as some of our conversations go. Just advice, but you've heard it from me before.

CHAIRMAN WASHINGTON: Point well made. Just to take it a step further, Harlan's suggestion that we find a way structurally to have this embedded into -- and that can be done. I've seen it done. So, you can follow up on that.

But going back to the second panel, there seems to be some confusion as to what the objective here is, and so, Joe, just playing this out, we've now got a panel on assessment of prevention, diagnosis, and treatment that helps us to prioritize questions related to that priority area, but we don't have a panel that's helping us to prioritize all the other questions.

That seems sort of problematic and if I'm not represented in this group, then I'm somewhat concerned about what are the implications for the rest of the projects. So, I'm just playing it out. Yeah.

DR. SELBY: You know, I don't think we -- first of all, we proposed that we have panels in three of the four, that's the proposal on the table is that you authorize us to create charters for three out of the four research priorities as well as the patient engagement panel. And the only one that's not on there right now is the communication and dissemination research, and that would come shortly.

The way that we're proposing it is we do those four panels at the beginning -- patient engagement and three out of the four research priorities. For other panels, on rare diseases, on clinical trials, on the fourth research priority, which is communication and dissemination, and on the fifth research priority, which is infrastructure, that we do those in the second half of 2013.

So, I'm with you, I'm just saying that if you want to advise us to only do two, we would choose patient engagement and the assessment of prevention, diagnosis, and treatment options, but

we'd prefer to do four, that included two of the other three research priorities.

CHAIRMAN WASHINGTON: I now have it. Hunt and then Douma.

MS. HUNT: Gail Hunt, Board. I'd like to sort of line up with the people who are saying we really should have rare diseases or rare disorders as a part of what we are doing in this initial round because otherwise we're establishing advisory panels, patient engagement, I think, is not a problem, but I do think that putting assessment, diagnosis, and treatment ahead of rare diseases or rare disorders is politically not going to be viewed correct, it's not going to be viewed, it's like, Congress said, you do this, and they didn't mention that many that we actually had to do, and that's one of them.

So, I think we should definitely include patient engagement and rare diseases if we can only do two. I don't -- thanks.

CHAIRMAN WASHINGTON: I hear you, Gail. Douma.

DR. DOUMA: Allen Douma, Board member. In looking at the value of the panels to us, and let me just use the example of panel number two, the prevention, diagnosis, and treatment panel, are we looking at them to give advice of what's the process we should use to prioritize topics? Or are we looking at them to choose topics?

DR. SELBY: They are the venues wherein the process that Rachael presented earlier this morning plays out. They are the multi-stakeholder groups that take the questions that have been confirmed to be gaps and applied prioritization criteria.

They generate a list of prioritized topics that come back to the Board.

DR. DOUMA: But will they also be vetting our prioritization criteria?

DR. SELBY: I think, in an ongoing way, they certainly could, but I think so could -- I mean, the patient engagement panel could weigh in on that as well, any panel could, but I think if you are a panel that's engaged in the

prioritization process, you'll have your moments to vet and comment on the process you're being put through.

CHAIRMAN WASHINGTON: Krumholz and then Kuntz.

DR. KRUMHOLZ: Harlan Krumholz. I just wanted to make a couple quick comments. Again, I think it's very important for the Board to focus on the what and leave the how and the operational and tactical parts to the staff, and so the guidance around saying that maybe one to two -- I think that's a great suggestion, and the notion that we should be leveraging on rare disorders and rare diseases, I think, is a great suggestion, but we need, I just think, to be careful, because we have a lot to talk about on the what side.

And Harlan, I just want to say that for the last two years I think we have actually come together on a lot of common principles about what it is we're trying to accomplish. This is a bit of an experiment and part of it is the idea that can we get ordinary people, including the people around

the table, that can help direct a research program that is more responsive to patient needs, wants, desires, than has ever been done before by fundamentally integrating the patients into the process, not treating them as subjects, but as partners, and helping putting them in leadership and sharing the power so that we're really fundamentally inverting that process with the notion that that will produce research that's more relevant, more efficiently accomplished, and more actionable and adopted more rapidly than any of the research that you've seen before because we're holding hands with the people that we're trying to help.

And I think that we have come together on that what, and a lot of what is being talked around on the edges is the how. How are we best going to get there? How can we be most efficient? How can we accelerate the process while still being attentive to the need to listen? Because we have these competing tensions about trying to move quickly, but not because we think we're smarter

than anybody else, but ways in which we can funnel in the kind of input that we need to do well.

And I think that that's what really, Joe, we need to be able to sort of charge, and as you think about these panels or question how they're going to help you get input in different, new, novel ways, this isn't going to be exclusive, but it's an option and a means, and I think the idea of the one to two, to me is, trying to figure out what the best way to run these are so you don't have to devote so much resources to kind of, you know, if you learn best practice for PCORI around this, which we think will have maybe a little bit of a special approach to this, you want to sort of pilot it on two groups so that then you can apply it more broadly.

But I just want to come in and say, for anyone listening, I don't think there's any ambiguity about what we're doing. We've been doing this for two years. We've honed down on this. We've listened carefully. We are the ultimate group that's advocating for the needs and interests

of the patients to integrate into a research program that's going to produce knowledge that will be meaningful to them. And our challenge is to figure out just how we can truly work with communities and bringing them in and share power with them, and I think that's the fundamental thing, that we can't be afraid of failure, we can't be afraid of that risk, we have to boldly push forward and posit a vision by saying we can hold hands with the people who traditionally we've been telling, hey, you know, this is the research project, do you mind signing up? And, by the way, you'll probably never hear the result of this, but maybe it will filter down to the people caring for you -- that's just off the table for us, that's not what we're doing.

And it is a bit of an experiment. I think the process by which we go -- because, Harlan, you're talking about means and ends -- I consider this an intervention in itself because if we're successful, we will have changed the way that people think about research from here on, and we

are given that gift.

But I just wanted to make that point, and I think for -- I'm just worried, also, about getting too deep in the weeds and telling you, Joe, how to do this. I think we need to be kind of globally, hear some feedback, here's our gut about it, and this isn't a criticism of any of the comments, but just saying we need to be careful about backing staff, backing the team, but giving that clear strategic vision of where we want to go. I think it's totally legit to ask about what the ends are, but anyway, that's a few comments.

DR. WEISMAN: Can I just -- I don't -- I want to make sure though that, I mean, you seem utterly convinced that that tie between what you say we agree on and these is there, and I guess the only difference is, Harlan, I'm asking for explicit connection point, because of the -- if we want to get to wherever it is we all agree -- I'm not disagreeing with you -- then we've got to make sure that where we spend the money, where we spend the time, is in the service of that which is most

effective -- it's not that any of these are bad, I'm not arguing that --

DR. KRUMHOLZ: But it's just one tool that Joe has.

CHAIRMAN WASHINGTON: I'm going to take the Chair's prerogative. I hear what you're saying as complimentary and so I'll just say [off microphone]. Kuntz, please.

DR. KUNTZ: Yeah, I just wanted to make a comment, similar to what Harlan said about the operational part, this is in your domain, Joe, and I think that I'm not so concerned about four of these advisory panels in the first year because they've already got these as work streams within the staff, and I think that it's not, to my view, an extra burden to do four advisory panels. As a matter of fact, it helps to demonstrate more engagement if we get them involved.

So, I just wanted to just make one comment that I don't think it's overly burdensome to have four advisory councils if they're already matching the existing work streams that the staff is working

on.

CHAIRMAN WASHINGTON: Okay, Hunt.

MS. HUNT: Yeah, Gail Hunt, Board. I just wanted to go back to this question that Joe raised that the patient engagement advisory panel is not going to be involved in prioritizing research topics. I thought they were and I'm sure that they are going to think that they are.

If you've got other panels that are actually coming up with lists of potential projects to be decided on, but this group, the patient engagement group, they don't have -- they're not doing that? I think that could be potentially a problem.

DR. BEAL: So, I think it's fair to say it is not off the table and what I'll remind us is that -- so, the request that we're having for the vote is for us to actually draft up the charters for you all to review, and so if your recommendation is that we make sure, as part of the patient engagement panel, that we include their participation in those sorts of activities, we

would certainly include it within the charters.

CHAIRMAN WASHINGTON: Okay. I'm going to propose that we just give some indication of what a Board is so we can give the staff, responding to Harlan K.s' comments earlier, clear feedback regarding our thoughts about a question. And what I hear is a range of opinions about what might be included, but also about what we might take on. And so, why don't I frame it so -- this is a straw vote just to get some sense of how we feel about taking on one, which the Board is saying, go grab one, which would be grab instead of [inaudible], which would be patient engagement, I think we all agree with that. So, that's option A, is one, which assuming option B would be two, without saying what the second one would be -- my own preference would be, again, following Harlan K., we'd leave that to the staff to sort of look at and decide. This is a question of your feeling now about load and bandwidth and timing.

And then option C is go over what the staff has proposed here, which would be four,

that's been approved, obviously with patient engagement being the highest priority in terms of time and laying it out.

Is that clear? So, we're voting on whether or not --

DR. KRUMHOLZ: The three might be the staff suggestion after they've reflected on the conversation and decided what -- I mean, we're not actually going to weigh in on a strong yes/no, but we're basically saying, we've hope you've listened to us and reflect on what we said -- so, three is, not set in stone what you've done, but that plus your reflection in the future, god speed, but you know, reflect on what we've said.

DR. SELBY: It's really authorized but not required; I think is what people were saying.

CHAIRMAN WASHINGTON: [Off microphone.]

DR. DOUMA: Microphone.

CHAIRMAN WASHIGNTON: -- three options. That would be four?

DR. KRUMHOLZ: Well, you said three is what they've got up here, and I'm saying, with the

ability for the staff to be flexible to sort of refine it based on what they've heard, but we don't tell them how to refine it.

CHAIRMAN WASHINGTON: I get it now. Right. Okay. Is that clear now? Okay --

DR. DOUMA: No.

DR. LEWIS-HALL: So, this is Freda. One of the questions that I had is the recommendation, I thought, was actually eight, which was four in the first half of the year and four in the second half of the year. So, are we agreeing to the four in the first half of the year or -- right, so the recommendation was eight, four in the first half, four in the second half. So, are we just kind of providing a recommendation on the first half of the year or are we taking a step back and doing the whole year?

CHAIRMAN WASHINGTON: It's sort of between -- voting on three -- if we're voting on three, it sort of gets factored into that that they would take that under consideration, because -- I understand the difference, but I mean, I was

thinking first half, but it could be the year, and that we expect the staff to make that judgment and work through it.

Okay, C. Right. That's what I -- C. He changed it to three. Okay, so -- and since Francis is -- has joined us, he's probably got the clearest view of all of us.

[Laughter.]

CHAIRMAN WASHINGTON: But let me repeat it again. Option A would be that we are favoring, meaning, we're just -- this is not a decision making recorded vote, but you favor that the staff would proceed with one, which we assume is patient engagement, but option B, you favor that the staff would proceed with only two, and option C is that you favor allowing the staff, knowing that the baseline is this is what they've proposed, to revise it in the context of these comments and move forward. Obviously, we'd get updated and we'd know, but -- yeah.

DR. BEAL: May I ask just that the language be modified slightly to say "up to four".

CHAIRMAN WASHINGTON: Okay. Up to four. So, all in favor of option A, which is one?

[Show of hands.]

CHAIRMAN WASHINGTON: All in favor of option two --

MS. HUNT: B.

CHAIRMAN WASHINGTON: B. Thank you -- which is two? Okay. All in favor of option C, which is up to four?

[Show of hands.]

CHAIRMAN WASHINGTON: Okay, so, again, this is not a vote, but we've gotten the feedback. [Off microphone.]

DR. SELBY: [Off microphone] -- incorporating your comment to decide what number three and number four particularly are.

CHAIRMAN WASHINGTON: Great. And as I've emphasized earlier, on multiple occasions, if you've got additional thoughts, please pass them on to Joe and Anne.

Okay, and don't forget to review the current version of the guiding principles,

policies, and procedures as it relates to the panels.

Okay, with that I want to thank you, Anne, for the terrific work and we're moving forward on this again, important topic.

Okay, Joe, we have -- let's do a time check here. It is now 12:05. And next, let me see, we are scheduled to start back up at --

DR. SELBY: 12:30.

CHAIRMAN WASHINGTON: -- at 12:30, so we're obviously going to have to make some adjustments in the afternoon somewhat. I think you told me we could wrap this up in about five minutes?

DR. SELBY: Rachael, I think we could just -- this is an informational item on some work that's going on.

CHAIRMAN WASHINGTON: Okay. Let's keep it at that level, Rachael, please.

DR. SELBY: I would just skip the slides altogether and just say what's happening.

DR. FLEURENCE: Okay, so I -- so the purpose of this presentation is to inform you about

the development of the Funding Announcement with respect to methods, which is the fifth priority, so I'm going to focus on the process of the development rather than on the contents. Since this is not being released to the public, we want to stay at a fairly high level.

So, it's to let you know that we have a subcommittee composed of members of the Board, Rick Kuntz, and members of the Methodology Committee, who are firewalled and who are helping us develop this Funding Announcement, that we have used documents in the public domain to develop this method's Funding Announcement, so the Methodology Committee report itself, summaries from the Baltimore workshops that took place in March, and other documents in the public domain.

We have crafted a Funding Announcement. It's in fairly final stages now of development. It's already been through one round of review with our subcommittee and it's scheduled for release on November 15th.

CHAIRMAN WASHINGTON: Anything to add?

DR. SELBY: I'd only add that before it's released it will be circulated. In fact, I think we could circulate it soon to the Board. And the second thing, when Rachael says the subcommittee is firewalled, the actual members of the Methodology Committee who are working with us on developing this Funding Announcement are those members who are not considered eligible by their own choice or by their site of employment to apply.

So, the other Methodology Committee members can give input, but they are firewalled from participating in the development of the Funding Announcement.

CHAIRMAN WASHINGTON: Okay. Well, that concludes our morning session. It's 12:08 now and so if we reconvene at 12:45, that will give us about 37 minutes.

Okay, so for those of you who are listening via the webcast, we will reconvene at 12:45. Thank you.

[Whereupon, at 12:08 p.m., a luncheon recess was taken.]

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

[12:50 PM]

CHAIRMAN WASHINGTON: Welcome back to this afternoon's session of the meeting of the Board of Governors of the Patient-Centered Outcomes Research Institute.

I want to remind everyone who is participating via webcast that we encourage you to provide us with comments and that today you can do it by either calling in or attempting to call in during the public session this afternoon, and so you do so by teleconference and just let the operator know. And then longer-term, we'd ask that you send any suggestions or any questions you have to info@pcori.org.

Okay, I understand that we also need to make a correction to a statement that we made this morning regarding reimbursement for the workshops that are going to be held next month.

DR. SELBY: Thanks, Gene. Yes, this morning during the discussion about the patient and stakeholder workshops, Carolyn Clancy asked if we

were, in addition to covering -- first she asked if we were covering travel expenses and lodging, and we answered yes, and she asked if we were also -- if there was also a reimbursement in the form of a stipend and we had said yes, but that's -- we misspoke there. We, very clearly intend to have stipends as we form advisory panels, and those will be panels of, as we said, between 10 and 20, 21 persons.

With meetings of 150 people, our judgment was that we could not provide stipends to 150 people and then think about continuing to have such meetings. So, travel and lodging expenses will definitely be covered, but not a stipend for attendance at these large meetings.

CHAIRMAN WASHINGTON: Okay. First, our apologies for communicating that incorrect information this morning and thank you for that clarification, Joe.

The next topic is going to be one that we have discussed on a few occasions and it continues to be one that I expect we're going to be grappling

with for weeks, months ahead, and so I'm going to turn it over to Mr. Larry Becker, who's been chair of the standing committee on conflict of interest.

MR. BECKER: Thank you very much, Gene. So, today I'm going to just briefly go back to remind you where we've been in the past. And then spend the bulk of the time on the things that we have done to operationalize the conflict of interest rules based on your direction at the last Board meeting, and then we'll talk a little bit about where we go from there, and then I invite comments, questions, and other discussion.

So, just to remind you, at our last Board meeting, we put together some framing principles and concepts around conflict of interest, primarily focused on the Methodology Committee, so that those that wanted to, could participate in an appropriate way with Funding Announcements from PCORI.

So, after a series of call after the meeting last time, the committee got together. We also had a series of calls with Steve and Gene and discussions with the Methodology Committee to get

input. We also got the assistance of Deloitte. Our legal counsel was also involved. And we agreed on a few fundamental infrastructural, sort of, underpinnings with the help of the staff and most specifically Gail Shearer was instrumental in helping us pull all this together.

And so a couple of those things included confidentiality agreements, separating voluntarily the Methodology Committee into two different groupings, and we'll talk about that in a minute, so that we could preserve PFA confidentiality for the group that wanted to be involved.

And so, in fact, we created what we call the Methodology PFA Development Subcommittee to work with the Board and the staff on the development, and that was on a voluntary basis. And what's important about this group is that this group would not otherwise be eligible to apply for PFA funding. In fact, a couple of the people are ineligible already, but anybody on the Methodology Committee that wanted to be part of this committee, or subcommittee, could, in fact, do that.

And here you see the folks who agreed to be part of that, and you'll see there are six, Naomi, and Al, and Sherine, and Mike, and Gene, and Clyde. And so, they will work with the staff in the development of PFAs.

So, it's also very important to understand that even though we've created these two groupings, the Methodology Committee remains united in its mission to provide scientific guidance to PCORI. The new operating model doesn't change that, so they've got their continuing responsibilities around helping guide the Institute.

So, we created three basic principles, if you will, or constructs. We continue to make sure that appropriate recusal and disclosure take place. We're trying to protect against conflicts of interest occurring and somebody having an unfair advantage in knowledge as those happen. We worked on a nondisclosure agreement, which we've asked all of the Methodology Committee members, all the Board members to sign. By the way, the Board members already have a responsibility, irrespective of that

nondisclosure, duty of loyalty, for example, to the Institute.

And the point there is that people keep confidential information that's not public yet and understanding, when it is public, talk about it then, but we also created that, in a way, so that people could perform their roles as mentors to their -- in their universities or institutions.

We also are in the process of creating firewalls so that when we do have, in this case the Methodology Committee members who do want to compete, we have effective firewalls to operationalize the retention of non-public information, so that there's a level playing field for those people who are competing for funding.

So, we're putting these firewalls in place, as I said, to make sure that there isn't unfair advantage, and to control access so that we know who's got access to which piece of information. And there really are four pieces around which these strategies revolve. First, the IT governance, so that we know who has access to

what; mitigating -- we said time would mitigate some of the advantage, maybe not entirely, but it makes -- it puts in place lead times for various pieces of the process; distribution controls, understanding who can and can't have access to the information until it's public; and then meeting controls, understanding, for example, who is in what discussions, whether it's a physical meeting, a virtual meeting, a telephone meeting, and the like.

So, the committee clearly asked us to organize and implement a robust set of policies and practices, and so we've put some IT solutions to maintain the firewalls in place, putting together policy and training for Board, Methodology, and staff, and encouragement of preparation of public facing documents that reinforce the significance of what we're doing so that both the committee, the Board, the staff, and the public, knows how we're going to operate in this domain.

So, where do we go from here? So, there's certainly more to be done, to continue, as Gene

said a minute ago, to develop. And earlier you heard about advisory panels, again, this notion of advice, unidirectional input, but not decision making, so, again, appropriately firewalling off the advisory panels, implementing firewalls for the Methodology Committee, and there will be -- these will also be pertinent to the staff and the Board in respective roles, and then monitoring regularly to make sure that we have a closed loop process so we understand what's going on and improve these practices and policies if, in fact, we feel that we need to do that.

And I think that's all I have in this presentation, so I'll invite questions and thoughts and comments.

CHAIRMAN WASHINGTON: Okay. Weisman first?

DR. WEISMAN: The last slide, Harlan Weisman, the last slide triggered a question and it's not, maybe, appropriate for you, but I don't know if there's another place to ask it, is that one of the concerns I personally had when we did

this with the Methodology Committee was not so much the firewalls, because I was confident, although I know it wasn't an easy task, that you and your committee would be able to come up with something that was viable and would work, but was whether in creating these two types, this split within the Methodology Committee, whether the Methodology Committee functioning or PCORI functioning would have any limitations in terms of the diversity of views and perspectives that were on the big Methodology Committee when it came down to discussing certain matters that might be involved in PFAs or other issues, and that truly, our Methodology Committee, in my opinion, is a truly impressive group, but part of that is driven by the diverse talent we have on it, and now we've segregated off some of the individuals. And I don't know whether we've come up with a way of, in addition to monitoring COI compliance, we're able to see how we're doing and whether there are ways that we need to address that in some fashion.

MR. BECKER: Well, I'll start, and I would

say that the larger committee is still about inputting and providing information and their expertise, but clearly, the people who are not in that group of six, aren't involved in writing the PFAs themselves, so, in a way, it's a bit unidirectional, but Joe or maybe Jean, who's involved in that group?

DR. SELBY: Yes, I'll just say that -- and then ask Gene or Michael to comment -- the Methodology Committee is so busy as a whole responding to the public input and revising the standards and recommendations that were a part of the report, that I think, to the average Methodology Committee member, this is not noticeable. Those on the smaller group contribute extra time, but it looks to me to be pretty separate time helping us on the Funding Announcements.

And we're blessed that there are actually six that are on this side of the firewall, so we do have a range, and then we felt that there's a variety of ways to get "input" that does not

"involve" them in preparing the PFAs, so there's a way to get this unidirectional input when we need it.

So, Jean or Mike, if you want to --

MS. SLUTSKY: I actually think it really doesn't diminish the main focus of the Methodology Committee, which is to advise the Board on the best methods for patient-centered outcomes research, and many of the PFAs that will be written will develop off of the work of the Methodology Committee in their public reports.

CHAIRMAN WASHINGTON: Rick -- and I will remind everyone on the Board that we will treat this policy like we treat others in that we will revise them as appropriate based on experience. So, Harlan, the value of raising it is that it's on our radar screen and it is a concern that's been broached by some others. So, Joe, we know that you will alert us if we see it as in any way diminishing the efficacy overall of the Methodology Committee.

MR. BECKER: Okay. Any other comments?

Questions?

CHAIRMAN WASHINGTON: See, Larry, this is either --

MR. BECKER: It's either good or bad?

CHAIRMAN WASHINGTON: No, it's either hypothesis A or B. Now, hypothesis A is that you have been so thorough and so superb in this that you just left us speechless --

[Overlapping speakers.]

[Laughter.]

CHAIRMAN WASHINGTON: Option B --

MR. BECKER: Is that one or two?

CHAIRMAN WASHINGTON: Option B is that this is all post-prandial rush with the last minute --

MR. BECKER: Yeah, right.

CHAIRMAN WASHINGTON: But it's option A, really. I want to publically acknowledge the work that you yourself have done in bringing us to this point, so -- your colleagues feel the same way.

[Applause.]

CHAIRMAN WASHINGTON: You've got to remind

me, I need to do something?

DR. SELBY: No, no, I was just going to make a comment that if you go back several months, we were in a very difficult tangle on this issue and I just want to underscore, this committee has just done an excellent job of really finding a very reasonable and rational middle ground that I think is going to be very administratively doable. And so it leaves us all, I think, in a great spot. So, thanks.

CHAIRMAN WASHINGTON: And for those of you who are listening in, and present, who don't know, the person who just confirmed that we have a reasonable conflict of interest policy is an attorney, so that means that we're in great shape.

Okay. Next session please.

DR. SELBY: So, we are going to get a report now on the public comment period, the yield from the public comment period, and how the Methodology Committee, along with staff, are handling those public comments and what you can expect. And I'm very happy to introduce Dr. Lori

Frank, who is a PCORI scientist. She's actually the first PCORI scientist that Anne and I successfully recruited, and I think this is the first time you've presented to the full Board, Lori, so welcome, and Bill Silberg, who, by this time, needs no introduction, but has been handling, along with Golan Harris, the receipt and management of the public comments. Lori, I should say, works very closely with the Methodology Committee supporting them.

And we had planned to have a Methodology Committee presenter alongside, but illness kept her away. Or perhaps we do have -- should we coax her up or --

DR. FRANK: We should.

DR. SELBY: Okay. Jean Slutsky has graciously agreed to sit in in Sharon-Lise's absence.

DR. FRANK: Okay, thank you, Joe. I'm Lori Frank, director of engagement research with PCORI. And over the next 20 minutes we're going to share with you information on the Methodology

Committee report public comment period, we'll provide an update on related outreach efforts, and then conclude with a summary of the Methodology Committee plan for the coming year, which will be presented by Jean Slutsky, a member of the Methodology Committee.

As you know, the Methodology Committee delivered its legislatively mandated standards to the Board of Governors on May 10th of this year. The public comment period opened on July 23rd and just closed on September 14th. And the committee is now actively revising the standards in response to the public comment received as well as in response to the comment from the Board. And they'll deliver a revised set of standards to the Board later this fall.

Now I'd like to turn it over to Bill Silberg, our director of communications, to discuss some ongoing outreach efforts.

MR. SILBERG: Thanks, Lori, and good afternoon, everybody. I'm going to give you a brief overview and be happy to answer any questions

you might have about how we sought to take this extraordinarily important resource and initiative and try to cast as wide a net as possible to get public comment.

As you know, the report deals with very important methodological standards for doing the kind of research that we will be engaging in, and it was very clear from the committee from the very start that they and we did not want this to be something that only would draw comment from a narrow, research-oriented community, as important as the research community is and their comments are.

So, Sherine Gabriel, the chair of the committee, really set the tone early on for the theme, which you see here in the middle, there's Sherine from a little video we did. The theme was "Why Methods Matter". We really tried to dig in on that and come up with an integrated approach working with our colleagues at Golan Harris and members of the committee and others on the PCORI staff and the Board to try to figure out a number

of different ways that we could, as widely as possible, seek public input on the report by trying to explain why we thought methods matter to multiple audiences.

So, we did this through the channels that you see here. We did focus on the professional journal community, mostly with digital ads, which we found from our priorities and agenda public comment period efforts were a good way to provide some general visibility. We also did some targeted outreach through some of the various e-alerts at major journals that we though the research of the professional community we'd be interested in would follow.

We did a series of videos and columns that we put on our blog on the website and pushed out, through a series of targeted emails and general emails, to multiple stakeholders urging them to not only pay attention to this work that we had done, but to pass that on to their own audiences, and we believe we got a bit of pickup there.

We thought that it would make sense to try

to focus in on a couple of particularly important aspects of the standards with two webinars, and we also did a fairly active social media campaign, additional targeted outreach through email, and issued a news release and did some -- attempted to place some stories in various media.

These are the three columns that we did that I mentioned and for each one we had a very specific purpose here. In the interest of time, I won't play you the little clip from Sherine, but I really urge you to, if you've not already, take a look at these clips on the website. They remain there.

We thought it was important to try to customize the why methods matter theme to several key stakeholders, so we asked Sherine and Sharon-Lise Normand, the vice-chair, to write a column on why methods matter for the professional community. Harlan Weisman was kind enough to do a similar column focused on industry. And Ellen Sigal was gracious enough to do a piece that tried to put into real terms for the patient and caregiver

community why this report and its standard and the work it was trying to do is important.

We did associated videos with each and this is a technique that we hope to use more in the future.

Here's just a very quick look at some of the journals in which we put digital ads as well as some email outreach and in a very happy -- I won't call it a coincidence, because it was planned, Sherine and Sharon-Lise had a piece in The New England Journal right around the time that the public comment period opened and the NEJ was good enough to link into -- directly into our public comment survey tool. So, the stars really aligned in that instance.

So, here's a few numbers on how we did, and these are really gross measures, but they are, for the moment, I thought, a fairly good indication of the reach that we tried to achieve through these processes.

The pages associated with the report itself on our website, about 6,500 page views, the

report itself downloaded 1,600 times -- at least 1,600 times because we put some new software in place after the report was available, to track downloads more accurately, so it was probably well over 2,000, I would guess.

And you can see in each of the six areas that I referenced what some of the associated numbers were. A couple of things to call out, under social media, when you add up all of the followers of all of the Tweets and re-Tweets that we had on the Methodology Committee report and associated PCORI mentions that were talking about methods, the number of impressions, it's similar to ad impressions, 7.4 million, which really is just a very gross measure of broad awareness.

I'd also draw your attention to the targeted outreach box, which has a couple very interesting numbers about our email alerts. The two alerts -- the three alerts that we sent, all had open rates, what percentage of folks who got the alert actually looked at it, and click-thru rates, what percentage of people who looked at it,

clicked on the link to go to the website, that are dramatically above industry standards, so we felt very good about that.

Industry standard is somewhere around 15, 18 percent, so we have an audience of folks who expect to see our stuff and are interested in what we're doing.

And with that, I will turn it back over to Lori.

DR. FRANK: Thanks, Bill. The Methodology Committee hosted two webinars in August to help bring the standards and the process the committee used to generate those standards to life for a range of stakeholders. The other purposes of those webinars was to help encourage public comment submission through the PCORI website.

The first webinar focused on research methods and was presented by Drs. Robin Newhouse and Steven Goodman. The second webinar focused on patient-centeredness and research prioritization and was presented by Drs. Ethan Basch and David Meltzer.

Half of the one-hour time for each of those webinars was reserved for a question and answer period in which the participants were encouraged to submit their questions via email and the Methodology Committee members could respond to those questions immediately in real time.

We also took advantage of the webinars to briefly poll the participants on a few questions, and so that bar chart on the right shows one of our poll questions, which we used as a pre-test, post-test, with blue as pre-test, red as post-test. We asked participants to rate their understanding of the process the Methodology Committee used to generate standards with three categories of response -- I do not understand, I understand somewhat, or I have good understanding.

Prior to the start of the presentation, about 30 percent of participants said that they did not understand the process and after the presentation about 2 percent responded, so we were down -- that they did not understand, so we improved understanding through the course of the

webinar, which we were pleased to see.

This next slide is a screenshot from the PCORI webpage showing the actual public comment input form. We supplied free text fields to encourage public comment in addition to some closed-ended questions, and we also encouraged commenters to upload documents, which about half of the commenters chose to do.

We selected the American Institutes of Research, based on competitive bid, to assist with evaluation of the comments received. There are two main goals for this work, first is to provide thematically organized analysis of comments to assist the Methodology Committee in their revision work, and the second is to create a comment disposition table to ensure that PCORI continues to be transparent about comments received and the disposition of comments. Their winning proposal involved inclusion of a patient panel for input on the qualitative analysis and thematic groupings.

We received 124 sets of comments from a range of stakeholders. The line graph on the left

shows the pace at which the comments came in, not surprisingly, the last week was very active and the last 24 hours was particularly active.

On the right, we have a pie chart to show the type of stakeholders that provided comment. One-third self-identified as researchers and just over 10 percent identified as patients or caregivers or representatives of patient or caregiver advocacy organizations.

The 124 public comment sets varied in level of depth of the comments. Some commenters made only one discrete comment in their submission, others completed all fields in the input tool and had several specific points to make, so the bar chart here shows the number of discrete specific comments by stakeholder category, so you can take this as an index of comment density, essentially, so those self-identifying as researchers or from industry had a lot of discrete comments included within their submissions.

The pie chart shows the type of comments. About half of all the comments related to specific

standards or to specific content from the methodology report chapters, and about a third related generally to the report, and the rest were related to PCORI policies.

A qualitative review of the comments has yielded five broad themes, noted here on the slide. First is the role of standards in the conduct of patient-centered outcomes research. Second is the group of comments relating to feasibility of implementing the standards. Third relates to the accessibility of the document, with many commenters noting that the document was long and making some suggestions for optimizing accessibility. Fourth is the commenters expression of interest in accessing support for their patient-centered outcomes research and support in implementing the standards. And fifth is the group of comments expressing interest in further specifics on research methods discussed in the report, so essentially, requesting that the Methodology Committee go into greater detail on specific research methods.

The results of the analyses are being shared with the Methodology Committee now and there are several meetings, upcoming, and they'll be discussing the public comments to determine the direction for their revisions.

So, now I would like to turn it over to Jean Slutsky.

CHAIRMAN WASHINGTON: Okay, before we shift, Lori, to Jean, Sharon has a question.

DR. LEVINE: Just a clarifying question. There were 25 policymakers in that, are those folks who just self-identified as policymakers --

DR. FRANK: That's correct, self-identification.

DR. LEVINE: So, we don't really know anything about them.

DR. FRANK: Yeah, that's right.

CHAIRMAN WASHINGTON: Jean, please.

MS. SLUTSKY: Yeah, so, first of all, you can tell that I'm not Sherine and I'm not Sharon-Lise and I'm not Naomi Aronson or anyone else who's come down with an upper respiratory infection,

which one would wonder, like, why did I survive?

[Laughter.]

MS. SLUTSKY: Which is unfortunate for you all because I am part of the Methodology Committee, I have my piece of it that I'm active in, but the one thing I'm not active in is the overarching -- how the results are going to be worked on grossly across the report and standards, so --

CHAIRMAN WASHINGTON: Joe says we can fix that, Jean.

MS. SLUTSKY: Yeah, so all your questions should be directed to the ether.

Anyway, this is -- it is my pleasure to figure out how to do this -- so, the Methodology Committee will provide revisions to the standards and recommended actions.

So, what's important about this chart is that I'm here to thank you for, first of all, the Board's comments and all of the individuals and organizations that made comments to this report. My day job is actually similar to this, and I know how challenging it is to meet deadlines and to

actually provide comments to a very dense document.

So, we are now analyzing the comments. In fact, there are conference calls going on today as well, and it will really help us revise these proposed standards. And the revision process is being organized by standard categories, which you see on the slide, and the Methodology Committee is organizing this with a chair and co-chair in the lead along with Al Berg and Mark Helfand directing this process.

And some domains have been added in response to the comments and to further our discussion. So, notably you'll see that there are two domains that weren't here the last time you saw this slide, and that's dissemination and systematic reviews.

So, our next really audacious task is by the end of October, to deliver the revised standards and recommendations to the Board for consideration, and in doing so, we'll provide information on changes to recommended standards and recommendations based on this feedback that we

received, and our continuing deliberations on how we're analyzing this.

So, this is an algorithm that we're using as a Methodology Committee for how to assess how we might revise the draft standards. So, I won't walk through this, but you can see that there are key decision points that are guiding our actions as the standards and recommendations are revised, and you all have that in your packet.

So, the translation table, which is, in and of itself, quite a task, the activities will include to review and propose responses and revisions to the comments we've received, both from the Board and from the public comment period. And, again, including justification for not making a response, why we're not making a response, and no change is recommended, so this will all be a very transparent process and comments will be addressed as received.

So, the next steps for the translation table provide options, and two of which are here, no further changes, and we'll just leave it as it

stands in the draft report, or propose a request for proposals to develop version two of the translation table, which both expands it and creates additional versions for different audiences, so, researchers, students, general public, policymakers, et cetera.

So, this is the overall timeline, which is why I wanted to say that, you know, all joking aside, even though there are not a lot of Methodology Committee members here, even at lunch there was a conference call between committee members to discuss the comments, which we've only received a few days ago.

So, this overall timeline shows you where we are in the revision process. So, we're right there. The public comment period ends November 14th, AIR aggregated the comments, and so in addition to updating the standards, we'll also take the next several months to update the entire report, which includes narratives that explain the broader health and healthcare community, the rationale and context for which the report exists

by section.

And see that star that you see, that sort of like you are here when you're lost in a city? That's actually when we will bring the revised report to the board for a vote to accept it as a final document. And so, we are very confident that the report will be vastly improved through its standards and recommendations based on the comments that we've received.

So, for future directions, and this is obviously a challenge when you're down in the weeds and you're doing a very accelerated activity, but most likely what we'll be doing is a deep dive and reflecting on our experience over the last, I guess, year and a half and understanding where we are and where we need to go for 2013, because the Methodology Committee has always thought of this as a dynamic process, and to develop a very detailed standards implementation and dissemination plan along with the PCORI staff.

PCORI staff will likely be incorporating the standards into PFAs and incorporating

principles of research prioritizations into evaluation and the impact of standards on improving research quality and advancing the PCORI mission. And one of the priorities, obviously, is for any document that comes out of Methodology Committee is to enhance the methods that we use for patient-reported outcomes and to create training programs for people who will use and be affected by this methodology report.

So, finally, I want to just close with, I guess it's almost a follow on to Larry's discussion about what happens to the PCORI Methodology Committee based on conflict of interest, and we firmly believe that the committee, as a whole, will contribute to the PCORI patient engagement research, upcoming methods workshop, and the subset will participate in the PFA development, which we've talked about, and, again, the subset will advise on methods relevant to dissemination, and as Joe has said, we're lucky to have six, and I'm taking -- Mike and I can take -- we'll just do everything that doesn't involve conflict of

interest, but there are individuals who have said, we want to be taken out of the mix of being competitive. And so, we're very grateful for their participation that they've chosen to join that subset of Methodology Committee members.

And then moving towards standards 2.0, I take that with kind of a gulp because going through this, again, sounds really fun, but, seriously, ongoing outreach to talk about what we want to do in the follow on to this report and further standards development to be evaluated based on our being able to take a deep breath. As the Methodology Committee has said to you in the past, we couldn't cover the entire universe in this first report because of timelines, but it's important that what we can do now is step back and look at where we are and where we think we need to go as a committee.

So, finally, from all of us on the Methodology Committee, and I think I speak for PCORI staff as well, thank you so much for providing input. It's hard to provide input and

it's even harder to provide input that's meaningful. And then for my colleagues on the Methodology Committee, this has been quite a challenge, so that's it.

CHAIRMAN WASHINGTON: Clarifying question, but before we're going to actually -- discussion. I think we're ready, right, for a discussion? But I want to say in response to you saying thank you from the Methodology Committee, thank you from the entire Board. This is just a tremendous amount of work, as we all know, and the product is one, even at this stage, and we haven't gotten to the final, that we all are proud of and I think we see as enormously promising as it relates to, not just enhancing methods and also ultimately improving the quality of the research, I mean, the endpoint in this case, Harlan W., is that through improved methods we're going to improve healthcare and improve health.

So, we see the link. It starts with rigorous methods and where we are right now is quite encouraging, so kudos to all involved for

both the effort and the outcome. So, with that, Kerry?

MR. BARNETT: Kerry Barnett. So, what's the impact of us adopting the final report, particularly with respect to research that's in flight and PFAs that are in flight and future PFAs? What's really the point of intersection between these standards and the people out there who will be working on PCORI research?

CHAIRMAN WASHINGTON: Jean, Mike has his hand up. So, while you all are thinking about it, we're going to ask Mike to come in.

DR. LAUER: So, that's a great question, Kerry, and this is a question that we have directly --

CHAIRMAN WASHINGTON: Identify yourself.

DR. LAUER: Oh, I'm sorry. Mike Lauer from the Methodology Committee. So, this is a great question and it's a question that we have directly addressed in the course of our internal deliberations.

What we would like to measure and then

actually see is that the publication of these standards will lead to concrete changes in the way proposals and RFPs are written and evaluated and how decisions are actually made about where to go forward. And we are already starting to think prospectively about how we're going to evaluate that.

This is potentially a tremendous opportunity, because we're making a deliberate attempt to improve the level of methodology for research applications, research considerations, and then ultimately, funded research. And because we're doing this in a deliberate and prospective way, we're actually in a position to evaluate it correctly, and so we're thinking very hard about ways in which we can do that now.

And what we would like to be able to see is that we can document that PCORI research was proposed, evaluated, funded, and ultimately, executed and implemented on a higher methodological level.

MR. BARNETT: Well, as this comes up in

November, and there will be a motion on the table to adopt the report, we would look to you to suggest, call that a companion motion, that might require all future PFAs to stipulate that there has to be the kind of tie-in with these methodological standards that you're talking about. So, we'd make a very clear statement that says, you know, this is what we expect people to be living by, abiding by, who are conducting PCORI-related research.

CHAIRMAN WASHINGTON: Okay. It's a key point. At the same time, I want us all to remember that we are expecting that these become national standards that not only guide PCORI research, but guide research across the spectrum in industry as well as in government at NIH, at VA, at AHRQ, so, I see the impact here as being potentially quite broad and deep as it relates to the spectrum of research.

But, you're right, we control it within PCORI and it should be linked there as a start.

Okay. I have Levine and then Kuntz and Douma and, okay, Sharon. Oh, cover it. Okay,

Kuntz and then Douma and Epstein.

DR. KUNTZ: A little bit of follow up on that question, maybe for Jean or Mike. Do you view yourself as summarizing the best of methods or actually pioneering new methodology? And if you do, are you going to start entering into the academic literature and engage that as a vehicle for dissemination?

MS. SLUTSKY: I didn't hear the last thing you said, the last --

DR. KUNTZ: If you -- are we going to learn something new and develop new methodologies from this experience? Was that the charge? And if we do that, should we have a publication strategy that's more along the academic literature leveraging people on the MCC? Or is it going to be in the more public domain dissemination?

MS. SLUTSKY: I mean, I think we see it as both. You know, there are parts of the standards that are probably leading edge, and there are parts that reflect best standards that already exist. So, you know, I think any time that you engage on

methods, standards, and recommendations, this is a debate and a public process, even after the report is finalized, that's the beauty of the peer-reviewed literature among researchers and scientists from all sectors.

DR. KUNTZ: What I was thinking of is, are we going to have an authorship as PCORI or is it going to be --

MS. SLUTSKY: Oh, I see what you're saying. Yeah, the report is authored by the Methodology Committee under support of PCORI. I can't really speak to that. I think that's a publication issue that I don't really have the authority to speak on.

CHAIRMAN WASHINGTON: Okay, let's see it for now as a suggestion or recommendation that's on the table for us to consider how we might address it. Okay, Joe?

I have Douma then Epstein, Barksdale, Weisman, and Becker.

DR. DOUMA: Allen Douma, the Board. My comment really addresses or tries to get at the

issue of how are we going to disseminate this in order for it to become a national standard? And also I want to really -- kudos to you guys for tracking, as you did, in the communication process, in getting the feedback. But, having said that, we had hundreds of thousands of impressions, 6,500 page views, 2,000 downloads, and 200 comments. That's -- I'm sort of adding at the comments. That's not precise, but it's close. With that kind of fall off, what have we learned so that we don't get that kind of fall off in the dissemination side?

MR. SILBERG: Well, subject to digging in more on the issues you raise more broadly, there's a couple of different questions. I'm not sure we know quite yet what the relationship between casting a very wide net and getting a relatively small number of very specific responses is, to be perfectly honest.

I think we were trying our best to tell a very broad story about a very complicated subject, and so I guess I'm not really surprised that the

numbers were what they were, although I don't think there's any question we would have loved for it to have been -- we would have loved for our story to have been heard and acted on by many more folks. But I think that's a subject for further review because it does lead to the second part, which is, once the pieces are in place, at a point at which they need to be pushed out and eventually used, hopefully followed and then refined and improved over time, I think that leads to a much different and complex set of activities that have not nearly as much to do with broadly -- broadcasting that we have this thing, but really working very, very closely with our colleagues on the Methodology Committee, the dissemination workgroup, the COEC, other members of the Board, to really figure out what are the key drivers of behavior change, of adoption of new professional standards and practices? How does that work best? How can we figure out how to tap into existing systems, existing bases of knowledge to try to get done what we want to get done? And if we find that certain

things maybe don't work so well, maybe that's an area where we try to blaze some new paths.

But that is going to be, I think, a long haul. I don't think there's any question that one of the things we're very clear on is the need to be as inclusive and as embracing as possible of all of the potential channels, not just for dissemination, but for activation, for use, for engagement, for impact, uptake, and so that -- this is something the committee has said over and over again -- so that this is seen as a resource for the profession and beyond just healthcare professionals and researchers. This is seen as a resource for communities broadly. And if we can get that sense of ownership right, then I think the sorts of questions you raise -- we'll find a better way to try to answer those questions.

So, we're just getting started. I will say that fortunately on the Methodology Committee and input we've had from members of the Board and the COEC, we have a multi-page spreadsheet of all of the organizations we should be targeting and who

our contacts are and just a tremendous amount of thinking has already gone into this. Now we have to operationalize.

CHAIRMAN WASHINGTON: Sharon would like to make a comment.

DR. LEVINE: I don't know if my institution is representative, but I do know that the comment letter that was -- oh, sorry, Kaiser Permanente -- is representative, but the comment letter that was submitted probably reflects the input of about 60 or 70 people. It was -- the report was disseminated widely to the research community, the policy leadership, and clinicians in the organization. And the letter, which, anyone who read it would see, actually reflects a large amount of input.

So, I don't know whether that -- and that may be true of others also.

MS. SLUTSKY: It most definitely is true of many other --

MR. SILBERG: The same is true for BlueCross/BlueShield Association.

CHAIRMAN WASHINGTON: Okay. It's a good point. Okay, I have next, Epstein, then Barksdale, Weisman, Becker.

DR. EPSTEIN: I'm not sure how the report looks, so I'd be interested maybe as appropriate for Jean, Mike, or others to give me a read on what I'm about to say.

I think the purpose here is really laudatory. It's laudatory. Yeah, this should really help the field. I think the idea that whoever had the foresight to think clearly that methods are a key part of what we do, and that part of our contribution can be in advancing the methods across the whole field was right, and the process here has been exactly what I would have defined in terms of pulling together a group of experts who represent different intellectual constituencies, engendering a process whereby they work together, coming up with a report, getting multiple comment, and reproving it.

So far, so good. I also see us, if I look ahead, I think what will happen in November, left

alone, is there will be a report presented that we'll hear about and we'll then approve, and that seems like it's okay. And I was just trying to reflect on another process that goes on every day, which is the process that a number of us have lived, either by submitting articles to a journal or by being an editor, and that's a little bit of a different process, and what happens is that people submit articles and they go out for external review, and a reviewer often has useful things to say, sometimes because people have made a mistake, sometimes because they just didn't explain it well enough, but the reviewer does, and the editor makes a decision, when the article sender responds to the reviewer, the editor makes a decision about the integrity and comprehensiveness and success of that response.

And it is often the case that a person who writes an article blows off the reviewer and it's for the editor to say, I don't think so, you really didn't address it, or in some cases to go to the reviewer and say, I hear that you had this concern,

but they don't really seem very important to me for A or B. And that's a part of the process.

And I don't think we got that part of the process in this, and I'm just wondering how we could do that. What it really involves is, how do we get a process by which the places where there was controversy, that may or may not be addressed as a, yes, you're right, I did it, were alerted to and judge? I try to think of a couple ideas. One is, maybe type one and type two recommendations. A type one recommendation was the experts all recommended this and there was no dissent or the dissent was really minimal. Type two is, our experts thought this was an appropriate way to go, but we recognize we got five comments from people, which we think represents a group out there who don't agree and so we think they're -- we can apply them less forcefully or with less -- there may be other ways to do it, but I'm wondering -- what I'm really suggesting is, I see the ball going for a process that I'm not sure is the best one for us, and I want to just open that up and ask about that.

MS. SLUTSKY: Yeah, so, are you talking about the deliberation to the Methodology Committee with regard to the comments they've received? Or when someone actually submits a research application and someone throws out the recommended actions and standards?

So, if you're talking about the deliberations of the Methodology Committee and how they're adjudicating the comments, it is a very interactive process. I mean, it's --

DR. EPSTEIN: Amongst themselves?

MS. SLUTSKY: Well, I'm not sure what you mean by amongst themselves?

DR. FRANK: I would just want to add that we have the disposition table, so that's -- there's a lot of effort being put into collecting the deliberations that the Methodology Committee is going through right now in response specifically --

DR. EPSTEIN: I hear that. The issue is, imagine that the Methodology Committee all believes A, because they've built up consensus and they've got this bias, and B is held by three or five or

seven people elsewhere. We, as a Board, are never going to know that, left alone, because there's no independent process and I'm just wondering whether -- and I'm not even sure we're the right people to make that judgment. But what seems to be is in places where there is not clear consensus, I don't know how strong an opinion -- who strong a position we want to take as a Board as PCORI.

CHAIRMAN WASHINGTON: Could we get Mike to come in?

DR. LAUER: Mike Lauer, Methodology Committee. I think, Arnie, what you're saying, which makes a lot of sense, is that in our final report we should indicate whether or not a particular standard or recommendation is very strong. Like, for example, we might say, it is unacceptable to totally ignore the issue of missing data. I think most of us would agree -- almost all of us would agree on that one.

On the other hand, there might be disagreements about if data are missing at random in 5 percent of cases, then you must use XYZ

approach of imputation. That is probably an area where there would be a fair amount of debate.

And what we should do is we should explicitly say that and then that way when applicants and reviewers are struggling over particular approaches, we are able to provide them with that kind of guidance. I think that's what you're saying.

DR. EPSTEIN: I think that would be certainly one-way to effectively address it, Mike.

DR. LAUER: Thank you. I mean, that's a great recommendation.

MS. SLUTSKY: So, I think that both Mike and I agree with that. I also think that the disposition table is also a way to exercise the veracity of comments in a particular area, you know, to give a measure of how tightly debated they were, both in the external reviews and internally, because you're quite right, even internally, there are different views --

DR. EPSTEIN: Yeah, I like Mike's better because I think what we're talking about is taking

these recommendations and making them required standards for PCORI, and that's -- that won't show up in the disposition table, it's going to be a binary.

MS. SLUTSKY: I guess I think -- the way I see it is both, that not only do you want a discussion in the methodology report about it, but you also want to be able to go back to the disposition table and actually see what happened.

DR. EPSTEIN: Both would be better.

CHAIRMAN WASHINGTON: Okay. We're not trying to solve it right now, Jean, Mike, and Arnie, but your point is well made and we're going to refer it to the Methodology Committee.

But the Board has also been put on notice that, you know, we need to be thinking about whether or not there are at least two types of potential recommendations. So, a very timely and well-made point. Up next is Barksdale, then Weisman, and then Becker.

DR. BARKSDALE: Debra Barksdale, member of the Board. I have a question about the committee

goals on slide 16. In goal number three it says that you will offer additional suggestions for methodological research gaps gleaned from the public and Board comments. I think I miss exactly what that means. Are you planning to add additional sections or is this a list that goes for future reports or --

MS. SLUTSKY: Yeah, so, many commenters and peer reviewers of the report actually made suggestions about where further methodological research could be done, and we don't want to lose that, and we want to be able to capture that --

MS. BARKSDALE: For future --

MS. SLUTSKY: For both future reports and also future investments.

MS. BARKSDALE: Thank you.

CHAIRMAN WASHINGTON: Weisman, please.

DR. WEISMAN: Yes, Harlan Weisman, member of the Board. I have a question that really goes all the way back to the conversation that Kerry started about what we're doing in November when we approved the report. And this is something I've

wondered about since I read the report.

The report recommends not only specific methodology for research, which guides the research, and I understand we'll be accepting that, but the report also makes specific recommendations to the Board and to the Institute about things that we ought to be doing. And I'll just give you an example.

I went to the first one, but it's sprinkled throughout the report, recommended actions for transparency. The Methodology Committee recommends that PCORI develop policies to encourage public registration of all PCORI studies, ensuring study protocol, statistical code, and data.

Now, we've talked about that a bit. Form a standing committee within PCORI to recommend appropriate methods for data sharing and to ensure that proper scientific credit is given to those sharing protocols, code, and data.

I won't go on, but what you can see there is that they are making a recommendation to us, and

so when we approve the report, are we also approving all the recommendations and are we prepared to implement all the recommendations? And, by the way, the ones I just read, I'm totally fine with. I could support them. I just want to make sure that we are, as a Board, you know, taking seriously what we're doing. It's not just we're telling the research community what to do, we're telling the Institute what to do as well in several of these examples.

CHAIRMAN WASHINGTON: Harlan, we're not going to answer that question today. I mean, it's an important question. I think we might end up with, if not 21 points of view on it, we end up with a collection of three or four or -- 23, he said 23.

DR. WEISMAN: You'll make an executive -- I'm fine with however we resolve it, I just want to know what the answer is when we vote.

CHAIRMAN WASHINGTON: Right. Okay. Well, it will be in consultation, start with committee chairs and with others. But, no, it's an important

question.

Okay, Becker and then Hunt.

MR. BECKER: Larry Becker, member of the Board. I want to go back to Arnie's comments for a minute. So, as I recollect, there's really no authority in the law to require the use of the methods that we come up with. But I want to point us back to the purpose for all this; it seems to me, is about integrity and trust in the data that is ultimately put out there, for the patient, for the provider.

And while there are no perfect ways to do this, one of the things -- I belong to the NQF and so one of the things is voluntarily, a lot of organizations belong, and a lot of organizations agree to abide by the measures that NQF develops, and I wonder if it's not worth, once we get through and we, as a Board, approve whatever it is, that we also have a process by which we go to other organizations, whether it's publications or universities or other people that will use these standards, to get them to voluntarily sign on to

agree to use these standards so that people know at the end of the day that these things are being used and applied by these -- I'll make it up -- 400 organizations as they do their work.

So, just a thought for consideration.

CHAIRMAN WASHINGTON: Okay. And I think the question, Larry, becomes, to what degree do we want to promote these? Because I can tell you, there's some other areas where standards are developed and different, particular professional societies, they will make a statement, we have adopted the standards of XY&Z, and more often than not, that's sort of, again, what you're suggesting, that is a question is, you know, do we want to aggressively promote this such that we actually accelerate the process of those that are adapting it and officially recognizing them as their standards? It's a very good question.

Okay, Hunt and then Sigal.

MS. HUNT: Oh. Gail Hunt, member of the Board. I'm just throwing this out also as a thought for consideration. When Jean was going

through the -- I guess it was two pages of bullets about future direction and talked about the process the Methodology Committee is going to be taken post-November -- post-November -- I would wonder if after it's come up with its idea, what it wants to do in the future? If that's something that the Board should be able to weigh in on since the Methodology Committee are -- it's an advisory body to the Board?

CHAIRMAN WASHINGTON: Okay.

MS. SLUTSKY: Just to comment on that. I think the Methodology Committee would be delighted to hear if there are areas that you would like us to undertake.

CHAIRMAN WASHINGTON: Okay. We'll take it under advisement from the Board perspective. Thank you, Gail.

Sigal, can you put those two cards down, Barksdale and Becker, if you're finished? Yeah. Sigal.

MS. SIGAL: Ellen Sigal, Board. So, I had not thought a lot about the adjudication, but now

I'm thinking about it a lot. I actually think we do have a little bit of an issue because, based on other things, the research priorities and other comments that have come in before -- I'm not quite sure that we've listened enough and this is technical and complicated, but as the comments came in, one of the comments that was called out to us is that we didn't really have sufficient or really external patient representation in this committee. Although some of us sat through some of it, it was highly technical.

So, I'm wondering when we adjudicate this or when we look to see what we'll accept whether we are going to have a more transparent process and some patient groups or patients, part of it, because this does represent, ultimately, how we do trials and how we do statistical methods, which, for sure for rare diseases and for other diseases, are really important.

So, I'm wondering if we should now think about that. I had, frankly, not thought about that a lot because I think that the report is pretty

good. But now that I am thinking about the comments, I am a little worried and I think we should figure out how to do this and do this in a transparent way and to get more patients involved. That's one thing.

The other thing I want to add to that is the issue of adopting it. If we finally get this and get it right and adjudicate this properly and it's meaningful, it would not be meaningful if this isn't embraced and we don't really try very hard to get people to buy in, but I'm worried about the first part of it, which, frankly, I had not been worried about until now.

CHAIRMAN WASHINGTON: I think we agree with you. So, we're now alerted to this concern and more sensitive as we approach the November meeting. Again, Ellen, I don't see that we're going to resolve that here. It's a very important question that's on the table as to what do we mean by "accept the committee's report". Yeah.

[Off microphone discussion.]

DR. SELBY: No, I don't think so, unless

Lori or Bill have a closing comment?

CHAIRMAN WASHINGTON: Or Jean or Mike who's over at the sign.

DR. FRANK: I would just add that the committee itself has spent a great deal of time thinking about dissemination and implementation, so you will be hearing some more about that.

CHAIRMAN WASHINGTON: Well, again, please convey our thanks, enormous thanks, immense thanks, to all involved in the Methodology Committee and in this effort of the staff as well as on the committee. We regret that neither the chair or the vice-chair could make it, in one case because of illness, and we do want them to know how much we appreciate it. So, thank you.

Next, we're going to move ahead to address the -- a more administrative and operational issue. This relates to our overall emphasis on what we're calling operational excellence as we strengthen the infrastructure for administration of our pillars as well as how we operate from day-to-day.

And so I'm going to turn this next session

over to Kerry Barnett. And Kerry, we're going to go until -- it's right at 2:00. I guess we could go to -- no, we could go to 2:30 and break or we could go -- why don't we go to 2:30 and break? So, we're going to break at 2:30 and you'll have some extra 15 minutes when we come back if necessary.

MR. BARNETT: Yeah, I mean, we'll see if we need it. We may not. I mean, I think a lot of this is pretty straightforward.

Pam and Anne are going to do all the heavy lifting here. I am just going to take a quick minute to tee it up.

We've gone through, I think, a nice transition with respect to the committee and now that we have Pam on board and actively engaged and other staff actively engaged, the FAAC is really playing a little bit more of a more traditional, I think, finance committee board role than we were previously.

We're still working to get some of the reporting models up and running and figure out some of the other important pieces, but we're certainly

looking to staff more and more and more to really be driving this.

You know, historically, our concern has not really been determining whether or not we have enough money in the coffers to do what we want to do. It's really been exactly the opposite, that the struggle has been to sort of rev up our activities and our staffing to begin to accomplish what we want to accomplish and to deploy the funds that we have on hand.

And as you see from all the staff around us and in all the great reports, PFAs that have been launched and other great activities, it's pretty clear that as an organization, we are revving up and the resource spend is revving up appropriately as well, which we see as a very good thing.

As a result, I think the primary issue that we're dealing with right now is more along the lines of cash flow, is being able to predict to what extent we will have resources on hand when the expenditures -- the call for the expenditures

actually occur. And it's not just a matter of determining when we make decisions about grants, because as I'm sure you're all familiar, we make decisions to launch a PFA, but the decision on what actually get funded may not occur for quite a number of months after that.

And then even then it takes a number of months after that for all the contracts to get in place. And then as you saw with the pilot grants, it could be a two-year -- on average, a two-year, and in some cases longer, grant itself. So, the dollars are actually going out the door over an extended period of time.

At the same time, we're trying to track how the dollars come in the door and I really commend Pam for her unbelievable tenacity in trying to wrestle these issues to the ground, because it is far more complex than anybody could have ever dreamed as this all came underway.

We now have a very good sense as to when the Congressional appropriation comes in the door and must be accounted for, but more complex than

that is the issue of when the fees come in the door.

The PCORI fee goes into effect in 2013, but we now know that actually those fees -- well, Pam's going to go into this in some detail, Pam and Anne, but we now know that the fees actually come in on a delayed basis. And so, it's a matter of kind of synchronizing dollars going out with the dollars coming in. And this is going to be a particularly thorny issue as we get to the end of the lifespan of our statute and the fee, because in some cases, we're worried, in some cases it appears that fees may actually be coming in after the trust fund is actually shut off.

And so this is obviously something that we're going to have to deal with in the coming years working with the GAO and working with Treasury and the IRS and maybe even with Congress to address, to make sure that, in fact, the resources that we're looking forward to and we're counting on and that were intended as part of putting PCORI in the act, that those dollars are

deployed for patient-centered outcomes research.

So, with that I'm going to turn it over to Anne and Pam to kind of go through some of the details, and if there are questions, you'll let us know.

DR. BEAL: Thank you very much, Kerry. So, what I first want to point out is that as we thought about presentations for budget for both 2012 and 2013, I want to make clear that today's presentation is really about looking back in terms of what our expenditures have been for 2012, some thinking about what the implications are for 2013, but what you can expect also at the next Board meeting is that we're going to be presenting you with a much more robust plan for what we plan to do in 2013 going forward.

So, this is really just the update and report for this year and then next year will be for -- I'm sorry, next Board meeting will be for next year.

So, if you look at this slide, one of the things that I want to underscore, which Kerry

alluded to, is the massive amount of work that Pam has done in terms of our reporting from a budgetary perspective. As you all may remember from the last time we had a discussion around budget, a lot of the way that we organized our work was really around the committees, but now that we have staff, we need to start thinking about this in a different way, specifically from a programmatic perspective as well as one that aligns with the pillars of the strategic plan that we've been discussing.

In addition, we need to think about it from the perspective of administrative oversight and really to adhere our reporting to really what are some standards in terms of the way that monies are reported.

So, what this represents is really the high level view of our unaudited expenditures through June of this year, of 2012, and so the bottom line is, is that when you look at the way that we've been able to identify programmatic costs around engagement and communication, research, and methods, that our total expenditure in that area

was $6.3 million.

When you look at our total administrative cost, which includes both Board as well as, then, obviously, all of the staff and the activities that we're doing that are staff supported, the expenditures through June of 2012 were $4 million. And so the total amount that we've expended through June of this year was approximately $10.4 million.

So, if you now look at, then, what our projections are for Q3-Q4, let me just take a moment to walk you through this. So, as you can see here, our expected revenue, the $120 million, represents the appropriations that we expect to get later this year, and then what the other numbers represent is our best estimate as to what we expect will be our expenditures for programmatic as well as administrative costs.

As you can see, not surprisingly, there is a significant uptick that is going on in terms of many of these activities, particularly when you look at our research and when you look at activities around our total administrative

expenses. And, again, that represents an expansion of the activities that we're planning to have through the rest of this year.

And so, when you look at them then taken all together, which is the column all the way to the right, then what you'll see is that the totals in terms of a programmatic are expected to be around $21.4 million, the totals around administrative are expected to be $8.7 million.

As I mentioned, we had $120 million that came in, which leaves around $90 million, but we want to remind you that we have these awards, which are now currently under review, that will be finalized within the next two or three months, and so those are going to be about $96 million in new commitments.

So, now I'm going to turn it over to Pam who's going to talk a little bit about some of the challenges that we have in terms of trying to figure out exactly some of the cash flow issues. And so, I'll let Pam take it away.

MS. SIGAL: Ellen Sigal, Board. So, I

don't think we have detail. Is there any way we can see some of the detail of the breakdown because it's hard to see these gross numbers without the detail about how it's broken down?

DR. BEAL: Sure, you should have in the appendix the detailed financials.

MS. SIGAL: I'm just trying -- because I know I looked through this --

DR. BEAL: It should be after the blue tab.

MS. SIGAL: Is it in the appendix of the section or in --

DR. BEAL: In that section after the blue tab there should be detailed financials.

MS. SIGAL: I don't think so. Okay --

UNIDENTIFIED SPEAKER: [Off microphone.]

DR. BEAL: Yes, we can send you as much detail as you want.

MS. SIGAL: Okay.

MS. GOODNOW: Okay, so the issue that has really been the hardest about all of this is figuring out not only when we're going to get the

revenue, but how much it's going to be.

We started out with the figure of $320 million from the Congressional Budget Office, which we've been talking about for the last couple of Board meetings in terms of our expectation for revenue.

What we now know is a couple of details of how those revenue streams are going to come in and the timing of when we receive that money has a large impact on when we can spend it. The first money that we know we get is the direct appropriation, $150 million less the monies for HHS and AHRQ leave $120 and we are showing that in our budget right now today as coming in on October 1st. It won't necessarily make the bank on October 1st. A lot of money changes hands at Treasury right after the new fiscal year, but we do know that sometime in those first couple of months we'll receive that money.

The big question is the other kinds of monies that come into the fund. The first one is the dollars on the health plans and the self-

insured covered heads out there, and initially in this $320 million, what we were given as an expectation for this year, we weren't sure what that timing was going to be, but we do know that that's what the government was expecting to receive in their government fiscal year.

And what we know now is that subsequent to that, the IRS has made some initially proposed regulations and now they've had a comment period and they've accepted them. They're going to collect that tax as an excise tax on the Form 720, which is accounting-speak for an annual return that's going to be filed by plans and self-insured people to self-report these monies, and in some cases they're going to be done manually because the process of getting an electronic filing system into place this quickly has also been a little bit of a difficulty and it will go through a third party.

So, we have been told by Treasury to expect, first of all, if you remember, these monies come in in the first year only on government fiscal year '13, so it's October 1 to December 31 of 2012

is the first reporting period, and whether, in theory, when you think about it, that eliminates the government fiscal year, because those plans close on September 30.

We don't know the breakdown of what plans close during what time of the year, so for purposes right now today in doing our estimates, I've just taken a quarter of those, and assuming that it may be less, it could be nothing, but in the months to come we've been assured by Treasury and others involved that they will get to the bottom of these, establish their procedures, and begin to come forward with some more information for us.

So, instead of looking at probably receiving our $320 million when we were thinking it would come in, October 1st of 2012, we know that we're probably going to get the $120 in appropriation.

The Treasury Department has told us that the first payment will be at estimate for the monies that are being levied against the plans and the self-insured, and they won't come in until --

the reporting date is July 31st for the first annual return, and then subsequent to that, we'll get six installments between August 15th and October 15th of monies at estimate.

Then it takes -- this excise tax return collects monies from almost 19 different excise taxes that are levied in different parts of the government, and somebody has to figure out at Treasury who the money belongs to, so after we've gotten our money, there will be a six to eight month delay and then we'll be told whether they got it right in estimate. We may owe money back, we may have money coming towards us.

There will also be penalties and interest that are assessed against employers that don't pay on time. We are not going to be able to receive those monies at all. Those go to the IRS to defray their cost of collection.

The last --

CHAIRMAN WASHINGTON: Pam, before you move on, Francis seems to have a clarifying point here that might help us with --

DR. COLLINS: And it's actually not about this extremely complicated issue of collecting on excise taxes, it's more about the appropriation. Just a point of clarification, since we do not have an appropriation for FY13, we have a continuing resolution that has been passed for six months, through March. Are you, in fact, confident that that entire $120 million is going to come to PCORI on October 1st?

MS. GOODNOW: What I was told, and this is just from day one stepping in the door, and I know it came in a memo that came from our legal counsel, was that our monies for appropriation had already been appropriated through the life of the project, through 2019, and when we looked at this sequestration report the other day, there is no money that they're holding back from the appropriation.

DR. COLLINS: So, that was the second part of the question. You're immune from the sequesters?

DR. BEAL: Slightly.

MS. GOODNOW: No, not entirely. The fee, and we're not sure how that would have an impact on the general fund, but the fee has been subjected to sequestration, but not the actual --

DR. BEAL: So, just to be clear, the appropriations are not, but the fees are affected.

MS. SIGAL: Ellen Sigal. I was told that the fees are not, maybe a small percentage are, but who knows, but that's what I was told, that we would get our fee but perhaps a little less, but not a lot less.

DR. BEAL: There's -- in the actual report, their number for the fees is much higher than the CBO number that we've been looking at, and, in fact, we only lost 7 percent, so the potential for us actually getting more, even after the sequestration reduction, is there. And we're waiting -- Treasury has promised to bring me up to date as soon as they get any information when they get it.

CHAIRMAN WASHINGTON: Clancy also has a clarifying point.

DR. CLANCY: So, Pam, just a clarifying point -- you can tell where Francis' and my brains are these days. Technically that $120 -- an appropriation here, in government context, refers to discretionary money, which this is not. So, I don't know if allocation is the better word, but just to minimize confusion, I think, because I can't imagine you're showing this or having this conversation anywhere where someone's not going to say, well, wait a minute, the government is not -- you know, et cetera. We haven't done appropriations bills, but that's for like the other side of the House.

So, just a word substitute might be helpful.

MS. GOODNOW: Okay. Good enough. The last one is the monies coming from CMS. They are in the process of developing a draft plan for how they'll treat those monies. They can't tell me when they're going to come to us. As soon as they know, they'll let us know.

The bottom line is that this year in 2012

and 2013, we're expecting in 2012 just our $150 and then in 2013 we're expecting $150 million from the appropriation, the gross appropriation, or my new terminology -- allocation, and $34 million from what essentially is a quarter of the PCORI fees, whether they come in from the trust fund or the fee itself.

DR. BEAL: So, as you can see from this slide here, so then that means that the net revenues that we are thinking about for 2013 are a little over $100 million. And what we've estimated is what the research outflows are based upon our current recommendations for $96 million per cycle. So, this current cycle, which is under review, as well as the next cycle, which we recommend that it also be $96 million.

And so, the outflows, when you look at research outflows, 2012 represents both the combination of the announcements that we're going to make this year as well as the plans for funding the next year.

As you heard from Kerry, one of the issues

from a cash flow perspective is that we may make a commitment in one particular year, but then pay it out over time.

Then as we look at 2013, then our estimate is that if we again continue at the same rate of three cycles per year and then around $96 million per cycle, then those would be the outflows for commitments made in 2013 recognizing that we will then also be making subsequent payments in 2014 and '15 to essentially cover the commitments that we're making in 2013.

So, the bottom line is, is that although we do have a lot of uncertainty in terms of the numbers and the actual dollars that are coming in, from a cash flow perspective, even in what Pam has mapped out as a -- let's not call it a worst case scenario, let's just call it the real likelihood that the dollars will be significantly delayed -- that we would still be able to cover the commitments that we've made, maintaining the current rate of commitments that we have made, and then would, at 2013, have potentially $188 million

at the end of the year.

So, as I said, in the appendices, you have the financial statements, which do have more detail than what we presented here, although for any of the Board members, if they want to go further into detail, we're happy to provide that as well as some of the information that provides details regarding the monies that are coming in through the fees that we can expect.

CHAIRMAN WASHINGTON: Okay, back to you, Kerry? Other comments?

DR. COLLINS: Francis Collins, member of the Board. So, if you try to project forward, because this tells us about 2012, 2013, but clearly you are making commitments that have multi-year consequences, and I think this Board would be very interested in knowing what's going to be available as far as new enterprises in '14 and beyond. So, recognizing that you don't have a clear fix on what income is going to be, you have uncertainties about those, can you try to, at least, give sort of ranges of what uncommitted dollars are going to be

accessible in the out years so that we have some idea of what we have to play with?

MS. GOODNOW: We actually have a model that goes all the way through 2022 in the event that we are not able to get any change to the sunset date and our ability to get those monies out of the fund. But that was one of the big variables involved in deciding how much we could give out because when you are doing it in three-year periods, we actually have to have the cash.

So, we modeled it out and in each year and then had to scale back what we thought we could give out based on the timing of these monies, and we have that detail and can provide it to through 2019 with so many issues on the table now for immediately not getting answers for the real timing of the money, we just thought trying to present all that information today was a little bit of guess work, but we can certainly provide it to you and continue to update it every time we have more information.

DR. COLLINS: I think that's pretty

central to our thinking about the future.

MR. BARNETT: Yeah, and Francis, I can't remember if you were here at the last meeting when we did present this model, and the model, as you can imagine, is always in motion because we learn more and different things happen, but we'll plan o re-presenting that at the November meeting with kind of updated information as we know it then.

And our intent is to do that periodically to give everybody exactly the snapshot that you're talking about.

DR. COLLINS: Good. Thank you.

CHAIRMAN WASHINGTON: Norquist?

DR. NORQUIST: Yeah, Gray Norquist. I just want to follow up on what Francis is saying because it bothers me because, you know, this changing model, it's very hard to make a decision about what we want to fund, we've been talking about being more specific, so we really need to have a little bit more -- or we need to like fix a point and say, okay, we're going to go with this instead of continually changing, because that may

make a big difference in what we do.

MR. BARNETT: It's a critical component to the annual budgeting process where we make exactly those decisions about what we're going to commit in grants in the coming year, and if you remember, going back either one meeting or two meetings, I think it was, when we had that discussion around this cash flow model to ensure that we did, in fact, feel comfortable with the outflow that we were biting off for the PFAs that have now been and are being announced.

But you're absolutely -- on an annual basis, we're going to need to kind of determine how comfortable we are kind of making those commitments in the future.

DR. NORQUIST: Yeah, but I'm afraid this year it may not be on an annual basis. It may have to be soon. I mean, if we have a group -- what is it, four announcements that we're getting and then another, we've already announced for the next round. I mean, it would be very helpful to know what amount of money we should commit to this next

group, because that's going to make a decision on the pay line, if you will, and then for the next group after that, and then what we might do for the next year, to be quite honest.

DR. BEAL: So, for every major outflow that we have, every major announcement that we have, we're actually looking very carefully to make recommendations as to how much money can be committed to each one.

I do think that as Kerry said, that we were very interested in essentially making commitments ahead of the actual dollars that we had because we wanted to try to get monies out on the street and get grants started and work started.

I think we're going to have to step a little bit back from that because I know it was something that we wanted to do in 2013. We may have to change the timeline to 2014 because my expectation is, is by the time we're in 2014, then we've had a full year of then seeing where the revenues are coming, when they're coming, how much is coming in, and so then we'll definitely be in a

much better place and in more of a steady state in 2013 going forward than we anticipate we're going to have in 2013.

DR. NORQUIST: I'm sorry, and just one other thing is do we have a scenario for the worst-case scenario, that we actually -- the reading that you get back, which can happen, as you know, with the federal government and depending on what happens, they could say, well, you are subject to whatever this -- do you have a scenario in case it's at your worst figure, I guess?

MS. GOODNOW: Yeah, and, in fact, right now, here, today, we've been as conservative as we can be and one of the reasons for only going through 2013 in the presentation today is because that's the only revenue stream that I have a lot of confidence that they've actually got a good plan and procedure for.

We're speaking to the Treasury Department, the IRS, legal counsel, and everyone on a regular, daily basis to try to get everyone to get their procedures and policy in place so they can be a

little more specific for us, and the calculations are still ongoing for what they think the tax will be now, but that office expects to be able to give those to me within the next couple of weeks.

DR. BEAL: So, Gray, I just want to point out that as you recall, we have been saying for a while that 2013 would be a year with about $300 million, and so what we're presenting here is $100 million, and so in many ways this does represent the most conservative estimate, but we're still able to maintain our commitments at $96 million per cycle with that.

So, it's a flat line rather than an escalation from where we are.

CHAIRMAN WASHINGTON: Okay. If there are no other comments then, again, Anne and Pam and Kerry, thank you for overseeing this and for the very, very clear presentation.

DR. BEAL: Thank you to Pam, particularly.

CHAIRMAN WASHINGTON: It's no reflection on you at all, Pam. It's a question of understanding exactly how we operate in the context

of resources coming both from inside the government and outside the government.

Okay. Given that we've been such a, as a group, task -- we've been taskmasters this morning, we're actually a little ahead of schedule. Joe and I will work on apportioning the time a little better in the next meeting because I think we're all feeling we could have used a little bit more time on the front end, and so we will work on that.

But to reward you for your focus and great behavior, we're going to have a 30-minute break. So, we're due back at -- but you can't go take naps, you can't leave the premises, but we're going to reconvene at 2:55. See you in a half an hour.

[Recess.]

CHAIRMAN WASHINGTON: Welcome back to this last afternoon session for the Board of Governors of the Patient-Centered Outcomes Research Institute and in this session we are going to receive an update from our communications enterprise.

So, who's going to introduce it? Bill, you're on.

MR. SILBERG: Thank you, Dr. Washington, and thank you. Good afternoon, again. I hope to do three things in this presentation and I'll tell you what I hope to accomplish in a second, but I want to thank -- start by thanking the COEC, whose input and guidance on what you're about to see has been incredibly helpful.

We have, as I'm sure you can imagine, extremely vigorous and robust discussions about how we can all get to where we want to go, and I, for one, know that every time I have one of those discussions, I am smarter and have better things to say than when I started. So, much of what you will -- I'll present to you today was filtered through that lens, although these are my thoughts.

What I hope to do is three things. One, I want to talk a little bit about the framework that drives what we do, and I'll say up front that this is not a communications plan, strategic or even a complete work plan. That doesn't mean that we have not heard the regular concerns raised by members of the Board and others about having such a detailed

document that's fully appropriate and is something that we will be providing, but I did want to give you a sense in the interim of how we have been, as a group, making decisions about what to do, where to go in the communications realm and hopefully show you that it is driven, if not by a very specific detailed plan, by fairly specific and detailed planning that takes its cues from much of the strategic planning work that has been done by the Board and by others in the last six months.

Then I hope to lead you very briefly through what we have done with that sort of planning framework and good communications practice, I hope, in mind. Then talk a little bit about where we hope to go and what we would hope to do, obviously with your input and guidance, and then pose some questions that I don't think we're going to answer today, but I hope they'll be the start of a conversation and a discussion that we'll continue to have over tie about how to do things better, because that's really -- that's always where I start. Much of what I'm going to show you,

I think, we have tried to do our very best at and I think we've had a reasonable amount of success by certain gross measures, but we do want to do a better job and we want your help in doing that.

So, let me pose some of these questions just for you to think about as we go through the discussion, and these are emblematic of a number of discussions that I think we will continue to have, but I thought they would be good things for us to think about. One has to do with the question of our messaging because I think we are in a bit of a transition period moving from some foundational work to really beginning to have some very specific activities and, soon, research results to talk about, and we need to start thinking about how we can tell those stories.

At the same time, I think you've heard a fair amount today about work that has been done to date and how we can begin to analyze that work, again, with extracting stories that we can tell that talk about who PCORI is and what it hopes to achieve.

I would be very interested in your thoughts on how we can make that storytelling process real and meaningful to our multiple stakeholders, because I think at the end of the day, we want to be relevant no matter who the stakeholder is, we want to be speaking to them in a voice that they understand, providing useful, meaningful, trusted information to them, and I certainly value the multi-stakeholder representation on this group to help do that.

And the final point, and we have talked about this many times, but I think we are always -- we always want to talk about it more -- how can we both collaborate with and leveraged the work of others in this space, as well as point to the new and different work that we are doing ourselves to advance our strategic and communications goals and exert a leadership in this area. So, those are a few things to think about.

So, as I mentioned, this is not a detailed communications plan, but I refer to it as a framework, and I consider communications to really

have multiple purposes, but at the end of the day, any good communications plan really is designed to advance organizational goals.

There are relatively few activities in communications that exist, in my view, anyway, for their own sake. We've heard a lot today about reaching the end goal, an end, not a means, and I take that very seriously.

So, a lot of the work I'm going to talk about is really picking up on what, to date, have been the expressed strategic goals, imperatives, and overarching messages that PCORI, as an enterprise, has been talking about.

So, here is kind of the broad framework that any communications professional would likely tell you has resonance, and I got a little bit specific here with regard to the sorts of things that we want to do in particular, again, picking up on our initial strategic planning process, and you will see some of these themes discussed in a little more detail further, but the last point is really one of the guiding principles. I try to tie

everything back that I think about doing to how it will help advance the organization's mission as expressed at any particular point in time.

We have been using a number of our key messages, if you will, what are our stories, or what is our story. These are three that in various combinations should look reasonably familiar to you. They may not be the exact language we've used in every case, but you'll recognize elements of these themes in our mission statement, in our vision, in a variety of elements through the strategic plan that was reviewed over time and approved earlier this year.

We also spent a fair amount of time, I think, refining the notion of who it is we are trying to reach, who our key audiences are. We know we have some substantial challenges here because we are charged both by statute and by mission with working with and reaching multiple audiences, and we have many of them represented right here on the Board. So, I list that in a general sense, but we clearly are giving particular

attention to a subset of our many stakeholders and this is important because the more we are able to reach consensus on how we prioritize these key audiences, the better we will be able to refine our messaging and hopefully reach them to achieve -- to advance our goals.

I also wanted to just, in the same spirit, mention -- list some of our key organizational goals, again taken from a combination of points we have made in the strategic planning process, ongoing conversations we've had, and I think this captures many of the high points, some of which we have talked about today.

They may or may not be listed exactly in the order that everyone would agree they might be, first, second, third, and fourth priority, but the point here was to try to capture, kind of, a locus of critical goals for the organization.

Now, the organization's goals are one set of critical imperatives. The communication's plans goals are to, in effect, take the organization's goals and make them real through communications

platforms, practice, technique, technology, and I'll tell you a little more about that in a second. But these are the sorts of planning guidelines, if you will, that drive much of what we are trying to do.

We are building quite a bit as we go along. The organization, as we heard earlier today, is two years old, but in terms of having detailed operations that try to deliver our messages, reach our audiences, engage our stakeholders to achieve certain ends, that is a more -- a relatively newer phenomenon that has come with the building of staff and the more detailed direction that we've been receiving from the Board and through the discussions we've all been having.

So, I try to list for you here what I think are some of the key issues that I think about as I try to plan -- when I wake up in the morning -- I was going to say when I come in in the morning -- actually, when I wake up in the morning, what are some of the things that I think about that I might try to advance within my control during the

day working with staff in the building and folks that are on the Board, on the Methodology Committee, and others who we work with over time?

This should look fairly familiar. I would draw your attention to the last bullet here as a really critical issue that we've heard about several times today. I am going to show you some metrics, but I'm the first to acknowledge these are fairly gross metrics, and one of the critical elements of strategic planning and strategic communications planning is to be sure that you are identifying the metrics that matter, that have to do with where you want to end up and how you know when you are there or when you're on your way there.

I think we heard earlier today someone refer to, how will we know what success looks like? And I'm spending a lot of time thinking about that, so I do not have those answers for you today, but I can give you a sense of how I think we begin to get to some of those answers.

Here the point I hope to make is that one

of the exciting things about this job and working for this organization is that we have tremendous opportunities to build something new, to change the way research is done, and to bring multiple stakeholders together to pursue a shared agenda.

We also have substantial challenges, which just happen to be exactly the same things as our opportunities, I my view, and I don't show you this to be cute or clever, but to indicate that it's important to think about all of the touch points, all of the opportunities here in their entirety so that we can begin to plan effectively to look at leveraging opportunity, but also being aware that there are challenges inherent in every opportunity and the best communications planning will look at the two sides of that equation.

Now what have we been doing? I've spent a fair amount of my six or so months here working with colleagues at GolinHarris, colleagues at PCORI, and others, to build infrastructure. By infrastructure I don't just mean bricks and mortar, although obviously that's very important. But

because communications is a platform for helping the organization to achieve its goals, because it's a support mechanism and a series of support processes for all of the activities you heard today and what you will hear over time, there have to be pretty robust frameworks in place in order to allow that work to go forward.

So, that involves building, not just a website, which we have and have refined over time, and I hope you spend time on it and will tell me when you think we can do a better job, but the series of related platforms, technologies, and tools that will really allow us to robustly and quickly and in a very agile way, make real some of the plans you heard today.

If the engagement team wants to very quickly -- I'll pick something out of the air -- if the engagement team very quickly wants to do a survey or a webpage that asks for input from their constituencies, and very quickly pulled the results together and turned them into some sort of action for a planning group, you have to have the

mechanisms in place not just to say we now have a webpage, but to reach the folks who you want to contribute. All of that takes platform and infrastructure.

So, we're working on that. As you probably know we are working very hard to build up the staffing and resources that will allow us to carry out our mission effectively. We spend a fair amount of time, and I probably will be spending even more time in the next few months, working on process and procedures, because all of the work we are doing involves some sort of workflow, some sort of process, some sort of quality review, and I don't think there's any question that we are not only hoping to do that work better and better all the time, but we are beginning to prepare for when we have a whole lot more material to work through our workflow and our processes and procedures. And we want to be sure that we can very quickly and adequately serve all of our constituencies, internal and external, who might want to count on us for helping them with the process of producing

the research and the information that results from that that we are charged with giving out.

We're also spending a great deal of time looking at opportunities to build and leverage partnerships and relationships, some are in a more traditional communications sort of way. The theory here is that you can never do a good enough job on your own, and especially with a multi-stakeholder mission like we have. I'm a firm believer in working with many, many others to extend our reach and extend our impact. They have audiences that we don't and they have expertise that we don't, and we really need to be working with them to try to get the message across and close the loop with feedback from their constituencies so we can do a better job.

As you might imagine, with any new organization, we have spent a fair amount of time building awareness. The stories that we have been telling to date have largely been aspirational, organizational, stage setting. We have been spending a lot of time talking about the work we

are doing to lead to the actual development -- the production of primary research. But we've done a lot in the meantime. And so it's been very important to me to be able to try to make as real as possible the work that we have done, focusing in on the milestones that we've achieved, many of which have been dictated by statute, but others have not, others have been a consequence of other work that we've done.

You see just a couple of examples here, there are many others, but I wanted you to be sure that I'm aware that there's a tremendous amount of material that we have already been generating within the organization. You heard about some of it today. We will continue to generate even more, even before we get to the primary research stage where we have actual studies and actual results to talk about, and one of my jobs is to try to figure out how we can make that information as emblematic of what PCORI means, of what PCORI is, and what PCORI is hoping to achieve as I can.

And included within this is building these

relationships that will not just help get the story out in the near-term, but will set the stage for one of our ultimate goals, which is to see that the research and the information we produce is disseminated widely, used widely, and has impact over time.

I'll very quickly just remind you of some of the many things we've done in the last six to nine months. There's a few numbers in here that I won't go through, I invite you to take a look at your leisure and tell me what you think, but you'll recall the priorities for research, research agenda, our Pilot Projects, the PCORI Funding Announcements, which will, of course, be ongoing. You heard earlier today about the draft methodology report, so no need to go into that. But just to let you know that we are using all of these milestones, all of these actions as touch points, as communications and engagement opportunities in the broadest sense, not just holding workshops to engage patients and other stakeholders to help guide and refine the research agenda, but using

that as a way to help tell our story more broadly, that we are an organization that listens, that is serious about asking our stakeholders to help us refine where we're going, that we are open and transparent in this regard.

Each of those pieces of this overall puzzle is a communications and engagement opportunity, and my challenge is to try to make these stories as compelling and as real as I possibly can and move them out as quickly as I possibly can, because we want to move on to the next opportunity.

Some very quick metrics, because I wanted to do a couple of things here, one, I wanted you to be assured that we follow this stuff, we pay attention to this stuff, and the individual numbers are not as important here, the data points are not quite as important as the goal of having an upward trend over time.

You will notice a certain -- and these are visits to our website, the number of visits to the website, track the number of pages that are viewed,

track the number of individuals who come to the website, but I just wanted to give you a very gross sense of a couple of things. One, if you drew a trend line you would get some upward movement. The point after each peak is to come back to a point that was above the previous valley, so we hope to be moving in that direction.

There is a definite seasonality to this. There is also a clear relationship to our announcing things, so the quickest way that I can get that 50,000 to go to 65,000 is to make news and hopefully we will make a lot more news in the coming months and years. But where you --

CHAIRMAN WASHINGTON: We -- I was going to say --

MR. SILBERG: Good news. Good news. No news is good news.

CHAIRMAN WASHINGTON: Thank you.

MR. SILBER: Yes, make --

CHAIRMAN WASHINGTON: We want the numbers up. Sometimes negative news will get us higher numbers.

MR. SILBERG: No, but I wanted to make another point, and you see some call outs of the numbers below, just to give you a sense of what's called in the business stickiness. One figure that's not here is the majority of our visits or returning visitors, not new visitors. That's an extremely important measure. What that tells me is that we have an audience that counts on us and comes back to us.

Returning visitors generally is defined as more than one visit per month, so it's not like people are on the site six times a day, I don't want to paint a phony picture, but that is one of the metrics we look for. Another is how much time is spent on the site, and you can interpret this in one of two ways. The average visitor spends four minutes per visit, that either means they are just so engrossed in what they're finding that they can't tear themselves away, or it means they are hopelessly and totally lost and can't figure it out.

I prefer the former, not the latter, but

we need to dig in a little further to find out exactly what people are looking at and do surveys to try to find out, are we serving their needs.

The website is extremely important, but as I often tell people, you can have the best website in the world and if people don't get to it, you've spent a lot of time not really doing very much. So, the opportunities we have to reach out and grab our audiences and create that pull, that demand, that desire for what it is we offer are extremely important. Email is one clear way that we do this. I wanted you to be aware that -- this is our opt-in list. We follow best practice in our email communications. People have to tell us that it's okay with them for us to communicate with them on a regular basis.

So, that number has been growing pretty nicely, but we want it to double by the end of the year and I don't think that's very difficult, to be honest. We have a number of techniques we can pursue to try to grow this to 10,000 by the end of the year. We've already started.

But I also wanted to draw your attention -- and I mentioned this with the Methodology Committee report -- we have an audience that, at least so far, is pretty interested in what we have to say, so the rates at which they open our emails, the opt-in list, are relatively high, actually they're quite high. I said 15 percent earlier today is the industry standard, it's really 19 percent, but 15 or 19, we're double that.

We need to be careful that we don't over-communicate to folks because we don't want email fatigue, but I'm very confident that as we grow the list and have good news and important news and compelling news to deliver to folks, it doesn't hurt that we're giving away a lot of money, we will have very loyal users.

The 4,800 number is a little bit deceiving because between our easy grants list of our applicants and multiple other stakeholder lists we probably have another 10- to 15,000 names that we can communicate with on a very careful and selective basis.

So, if we want to really reach a large group, we have a fairly nice list already, but I would like that opt-in list to be the big number.

CHAIRMAN WASHINGTON: Question.

MR. BARNETT: Kerry Barnett. Do we have an ability to stratify those contact lists so that we know, you know, who's just interested in money and who's, you know, just miscellaneous stakeholder group or, you know, who's really part and parcel of trying to drive towards accomplishing our mission?

MR. SILBERG: Absolutely, and I didn't get into that simply for matter of time, but the opt-in list is stratified and segmented by the self-identified stakeholder groups that we ask folks to pick from a drop-down menu when they sign up. We also, through the easy grants process, we know that those are folks who are interested in Funding Announcements.

One of our big tasks coming up is through a new contacts relationship management system to put all of that information in a single database, scrub the list of duplicates, and begin to build

segmented lists, not just for the sake of knowing who's out there, but for the sake of growing those lists and communicating in a more targeted way with each of those lists.

So, you could easily imagine that there will be people who only want to hear from us when we're offering them money. That's fine. There will be others who will want to know when we're doing patient engagement workshops. That's fine. We're not there yet. We're doing a lot of that work by hand, but that should be in place before very long.

We have spent a fair amount of time looking at -- and you heard some of this today -- convening is a tremendously important tool for PCORI, strategically, programmatically and from a communications point of view. For a variety of reasons, but the way that I like to think about it is, when we use our convening function, we are bringing folks together to help continue to build, refine, and implement our shared agenda, but we're also engaging these folks in conversation with each

other.

One of the best examples of this was at the dialogue event that we did back in February. Joe likes to point out that one of the most interesting and exciting things to him, and I would agree, that came out of that was not that we had 500 people in the room and 500 people online, although that was very nice, and not that we had 50, 60 people who walked up to the microphone and delivered specific comments, although that was very nice, it was that for the first time, in a PCORI context, everyone in that room was hearing from each other, talking to each other and to us, all at the same -- well, not all at the same time, but over the course of the day, and that was the kind of multi-stakeholder conversation that we really thought was a powerful example of why we're here and what we can do.

We need to turn those conversations into action and those actions into outcomes, but just knowing that the power of our convening function, I think, is what it is, is going to be tremendously

helpful.

We're spending a fair amount of time using new technology. Here's a quick look at our YouTube video channel. That number of videos is up since this slide was created. We hope to do much more of this over time because we want to show as well as tell and having personal messages not just from our own Board and staff, but from stakeholders, patients, those who we hope to help and work with, is very powerful and important.

Quick look at some of the media coverage we've received here. I'm focusing on mostly professional and trade media, but we are also getting an increasing number of stories in the consumer media. Those of you who know anything about this know that it's a different sort of process to try to engender consumer coverage versus professional and trade coverage, but we're very serious about doing a better job here.

There was a question earlier today about how we're doing on social media. A quick look at our growth of Twitter, we're pushing 800 followers.

It's probably more now. The 7.6 million impressions, that's similar to ad impressions, that's an updated number from what I told you earlier today.

So, we are active in the social media space, but we also need to figure out how to use social media more effectively to advance our goals. There's no point in doing social media just for the sake of social media, as there's no point in doing anything just for its own sake.

So, here's some future opportunities that hopefully will lead into a bit of discussion. I think we want to spend some time refining our messaging as we continue to build our research portfolio and our activities grow. We are beginning to have discussions with our partners at AHRQ about long-term research dissemination efforts.

We really want to spend a lot of time mining the work that has been done programmatically to begin to pull out interesting, useful, and important data that will help to tell the story of

what PCORI is learning in the work that it's done so far and make those stories real.

We need to make a pretty substantial ongoing investment in our infrastructure so that we can do all of the work that you heard about today.

We want to do some landscape reviews so that we know where we stand in relationship to our peer organizations and institutions that are in this space so that we can assess a couple of things. One would be, over time, our impact as measured by metrics that we would agree on, but also to see that we are not duplicating or reinventing the wheel, which is extremely important. We want to be viewed as an organization that adds value, that doesn't just do what other people are doing, but learns from what others are doing.

And finally, and you'll hear a little bit more about this when Debra and I talk after this presentation, we want to take an even more strategic approach to our publishing opportunities, and from a communications point of view, our

speaking opportunities.

So, with that I come back to the questions that I posed, and again, I hope this will be the start of a conversation and discussion, and not the end. Thanks.

CHAIRMAN WASHINGTON: Okay. Thank you for the comprehensive overview. We're going to start with Ellen. Name please.

MS. SIGAL: So, Ellen Sigal, PCORI Board. Thank you, Bill, for that good presentation and all your work.

A few things. The idea of consumer media or patient media or popular media seems to be an area that we're -- you mentioned we need to grow on. So, two specific things. How do we become a source? And how nimble can we be?

So, as an example, The Washingtonian, this week -- and it turns out that Joe tells me and I didn't even know this, The Washingtonian is in our building on L Street, but they had an article on what to do if you have a diagnosis of cancer. In my opinion it was an okay article, not great. We

could have done a much better job on it.

But there is data that comes out every day that is very confusing for patients. So, I guess two prongs to this question, number one is, how nimble can we be? And can we be a resource? And how do we outreach for at least what we know? Because, ultimately, if we're going to help patients, it's not going to happen through The New England Journal.

MR. SILBERG: I think we do it a couple of different ways. This sort of thing, building a presence where you become a go-to resource if not the go-to resource, takes time and it takes a lot of elbow grease, but I think we do it in a few ways. One is to really begin to have a good sense of what areas of expertise we can put our hands on quickly so that when the questions come, we have resources, not just a resource, but multiple resources. Anyone who's been in this business at any institution organization, really anywhere, knows you have an experts list, you know how to reach them, you know who the second expert is, you

know who the third expert is. So, we're not there yet, but I think between the expertise we have on the Board, on the Methodology Committee, on staff, as well as increasingly through our research -- our growing community of researchers, we will have the tools to begin to do that.

So, one is assessing what you have, which is a fairly routine approach. It takes work, but it's not that complicated.

The much more complicated process is to begin to build awareness among key media contacts that, one, you're in this business, two, you're open to commenting, and three, you have areas of expertise that are both PCORI-centric, in other words, what is PCORI, what is it about, and why should you be interested if you are serving a consumer market in telling those stories. And secondly, if you are working in an area where that sort of approach could be useful to explain a clinical decision making dilemma or explain issues related to how research is done and why that's important for methods to be trusted so that the

information can be trusted, that we become more and more one of the places that's on the short list of folks to go to.

That takes a concerted effort over time, it takes building personal relationships, it also takes, I think, being very responsive when we do get queries and being increasingly proactive with the work we have as we gin it up.

So, I don't think we could create a comprehensive experts compendium in a week and immediately expect people to pay attention, but I do think with a number of the milestones we've achieved and a lot of the work that's coming out, the more we can make it plain that this is the business that we're in and the implications of this specific work are far broader than the fact that we're working, for example, in the methodology area, that is one way that you begin to build this awareness and these relationships.

So, we have our work cut out for us. The one thing I would point out is that it is a very different set of levers than the PROFASIN [ph.] you

obviously know, than the professional or the trade side, but it's high on the agenda, it's just going to take some time and some heavy lifting.

CHAIRMAN WASHINGTON: Okay. Weisman.

DR. WEISMAN: I had two things. The first one, and I really think it's not for discuss now, but, you know, a parking lot item that the Board and Institute staff have to come to is the one that Ellen raised, Bill, and the one that you just -- and how you addressed her, because to the extent that we are going to be a trusted source of information and could provide cancer patients, just as an example, with important information, we can't do that today because we don't have any infrastructure for doing that.

We are gearing up a lot around how we are going to fund research. We are not, to the best of my knowledge, gearing up as much or, I think only very little, on how we create the infrastructure and what is needed to become a trusted source of information and method of dissemination, whether it's the research that we sponsor, which we have

some time on because it's not happening yet, or it's any information related to a particular health problem.

Now, we can't boil the ocean and we can't do everything, but I think it's worth a discussion about how do we begin approaching it. And, again, you can answer if you want, but let me go to the second thing real quickly.

Again, I think we can do it at another time, have that discussion -- was that you said that we convene people, and you're right, the February meeting was like so much energy and I think all of us that were there, you know, both PCORI people and our guests, felt very energized by it, and a lot of that had to do with Harlan K.'s video, but even beyond that it was a very energized meeting.

But I think we convened, I don't think we really had -- I think you used the word discussion or we didn't really create a discussion in a meaningful way that would allow people to really connect and discuss. We created contact.

You know, I think what we heard in the engagement presentation this morning, we're going through the workshops and maybe even the advisory committees begin to create those more real conversations, but what are your -- I think, again, going back to Harlan K., I think this morning when you threw out some things about creating either online or Twitter conversations -- a real community out there that's interacting with us, I would be interested in your thoughts on that, the kind of thing that Harlan was talking about earlier.

MR. SILBERG: Sure, and just very briefly on your first one, I agree it's worth a conversation. I think there's some strategic questions that we really want to consider as a group to figure out, one, where do we go in that space, and two, how do we get there.

On the second point, I'm very pleased to tell you that we are talking about those very issues now. I think you address the question of community building in a couple of different ways. You really need to know why you're building a

community in the first place.

Secondly, I think you'd need to figure out the best ways to tap into what those communities already do that you could leverage, I'm talking strictly from a practical point of view, but Sue, Susan, Greg, and I, our partners at Golan Harris, and others, have spent a fair amount of time talking about how, beginning with the workshops, this is really -- we've talked about it before, but this is really one of the jumping off points for this very activity.

And there's a couple of ways to do it. One could be a PCORI-centered community that follows up in a very specific way on the activities that we talk about and engage in at the workshops and additional workshops, but I think one of the other things we need to explore is, what communities are already there that we might partner with to reach folks who are already engaged in this sort of activity? What gaps might there be? In other words, are there populations who are not online who we need to reach, and if so -- I mean,

we know the answer, of course, is yes, but we need to figure out, how do we make the assessment of how we can reach those folks.

But I think it's a combination of figuring out what we can do that PCORI builds that meets -- that advances our goals, but also to look at how we might tap into partnerships so that we don't have to reinvent the wheel.

If, let's take diabetes as an example, and I know this is a real example, there are a number of very active, if you're talking online diabetes communities, we might want to partner with them if it's appropriate rather than build our own.

DR. WEISMAN: One thing, just to follow on. One thing that was discussed early on, and I think it actually happened in either the St. Louis meeting, no, I think it was the New York meeting, when we first started having the town halls, where there were a lot of the people participating in our breakout groups who were advocating that into our website -- to the point you were making that we don't have to do it all -- is that if there are

existing good sources of information, we could incorporate links to them on our site to let people know where else they can go to get some good information that we believe is a good source of it, whether it's, you know, a government agency or it's a nonprofit organization.

And I don't know whether that's worthwhile or not, but there seemed to be a real desire expressed by the people participating in the town halls for something like that.

MR. SILBERG: Yeah, it's just a question of what you do yourself as opposed to working with others who already do good work.

CHAIRMAN WASHINGTON: Okay. Collins?

DR. COLLINS: Francis Collins, Board. I just want to press you a little bit more about what the plans would be in terms of what you're calling mining the programmatic efforts in order to identify stories, because clearly the question I think people will ask is, if PCORI had not existed, what would we have missed? There's a lot of other activities going on in this space, including

communication about health information, which many organizations are trying to do. What has PCORI contributed that is unique and meaningful and significant? And I think a lot of that will be those stories.

So, how exactly, with now grants beginning to get supported, presumably reports coming in from those grantees about their progress, publications starting to appear -- how do you cast that net in a fashion that's credible? You don't want to sort of jump on the very first thing that comes out, which is rather sort of incremental and imply that that has changed the world if it hasn't. But at the same time, you do want to be very thoughtful and scrutinize carefully what the outputs are going to be.

Because that really is, I think, ultimately, how the public will judge whether PCORI has made a contribution or not.

MR. SILBERG: Right. I couldn't agree with you more, and I'll give you three very brief examples of how we're starting to do that. Our

science team is culling through the work that the methodology contractors did to try to come up with a series of learnings, if you will, about patient-centered research, patient engagement research, and I haven't seen the results yet, but we'll be working very closely with the team to see what sorts of stories come out of that that would be information that could be emblematic of the work we're trying to do why if PCORI didn't exist this work, perhaps, would not have been done, and turn that into a message, if you will.

Second example, we are beginning to assess the plans for the Pilot Projects to, again, look at how might these be examples, even though they are not primary research -- how might these be examples of work that is going on in the field to try to more meaningfully and fully engage patients in the research process to try to change practice? And we've already started assessing those, and one way you could do that is to tell those stories from both the researcher and the patient point of view, to show that there really are patient-researcher

partnerships and they really can work.

So, that's -- I'll leave it to two because I know we're tight for time, but it's that sort of work to try to figure out what are we contributing already in the preliminary work we've done that will, again, not be looked at as, well, I know that from the good work that these folks have already done. Why are you different?

That will, in fact, be the measure. One of the measures.

CHAIRMAN WASHINGTON: Lewis-Hall and then Douma.

DR. LEWIS-HALL: Hi, Freda Lewis-Hall, on the Board. You may have partially answered this, but maybe it can rephrase it, and that is in a previous slide you said that we were going to be more strategic in the way in which we deployed our communications. What will be the heart of that strategy, the what we are trying to get done? And then what form ought we expect to see that strategy to come back to the Board? And then the second part of that is, I guess the fourth bullet you have

on the current slide, which his really around collaboration. I guess Francis alluded to it earlier as did Allen, which is there's a lot going on in this space, so how will the strategy define how we're differentiated, but also how we are collaborating or cooperating with the other folks in the landscape?

MR. SILBERG: So, to the first point I think that being more strategic in communications really is driven by what the organization's end goals are. When I say being more strategic in communications I guess the best way to think of it is being less reactive and routine and really sitting down with multiple folks within the organization and saying, these are the organizations we wish to reach for the following purpose -- dissemination and uptake of the Methodology Committee final report, for example. That is a very specific task. It involves very specific sorts of activities. It's a big challenge, but it's pretty clear that if you want to try to get into the sphere of changing

professional practice, there are certain things that you should be looking at, and I would apply that same sort of end goal, although it's not a particular point in time, it just keeps on going, right, but I would apply those same sorts of filters, if you will, to how that then rolls down to what I would try to do with my team.

I think on the question of collaboration and leverage and differentiation, this is a very important point from a variety of points of view, but I think at the end of the day it involves really being very clear on what your work -- what we, as PCORI, are producing, that that is in line with our mission and our organizational strategic plan, and to be very clear how that does or does not look and work differently from what others are doing, and to the degree that it is different, work with as many partners as we can to try to get that word out.

And in the case of where we may be interested in something that others are doing well, figure out ways to have them give more visibility

to their work, not an endorsement, if you will. But, again, it's not reinventing the wheel. If we decide to get into the consumer health information business in a big way, we could either figure out a plan for creating all that stuff, or we could figure out a way to look at what kind of information we want, see if others are doing it well according to very rigorous standards we would set, and perhaps partner with them to point to them or actually provide it through us as an organization.

So, it really is very much knowing what environment you're working within and where it is as an organization you want to go.

CHAIRMAN WASHINGTON: Douma.

DR. DOUMA: Allen Douma on the Board. Let me just say from the scratch that everyone probably knows my bias. I think how well we communicate is going to be determinate of our success, period. Not only our success in achieving our goals, but our success as being a viable institution.

So, I think we need to focus on this a

lot. I think it's particularly difficult for us because we have multiple layers of messages that we want to communicate, all the way from communicating to a person or a physician how to better treat somebody, to communicating that PCORI is really cool.

It's also we have multiple audiences, and the difficulty there is not that we can't identify them, the difficulty is, how do we prioritize them. And that leads me to, perhaps -- one comment here and then in sort of a global question -- on the questions to consider, I would suggest that we focus on leveraging the work of others, period, that we don't concentrate on the CER, PCOR space. There's a lot of people who are not in that space. Now, perhaps we want to engage them to come into the space to get them to recognize how important it is, but they're not there now and particularly if you're talking about going through a lot of sort of non-disease specific organizations or institutions.

And finally, one of the things I think is really important is that we support communications

at an adequate level, and with the budget considerations coming up in a month, my question is, what is your timeline really to have a work plan so that we can see that we need to spend the $50 million next year?

MR. SILBERG: That would be nice.

DR. DOUMA: Obviously --

MR. SILBERG: Wasn't quite that high, but now that you've suggested it I'll go back.

CHAIRMAN WASHINGTON: Now you're really stating your bias.

MR. SILBERG: Now I'm really going to have a work plan.

Anne and I were just talking about this the other day. We are deep in the middle of beginning to put some real flesh on both the wish list, the work plan that flows from the wish list, and the numbers that are associated with that. And I believe the plan is to have something internally that we will beat on in the next few weeks, next month and a half, so that there's a very clear set of plans for the Board to consider in November.

DR. DOUMA: And other thing, just to focus, is I know you won't get it all done in the next six weeks, but to have a timeline when it will be done so we can use metrics to measure whether we're successful or not.

MR. SILBERG: Agreed, and one of the key points of the first round is, I think, to throw a lot of things on the table and to begin to whittle down what's most achievable and over what period of time, based in part on we can throw a lot of good ideas out and look smart, or we can pick a smaller number and look successful.

CHAIRMAN WASHINGTON: Zwolak, and then we're going to wrap this part of the discussion up because we have a second item that we want to cover as well on communication.

DR. ZWOLAK: Bob Zwolak, Board. This is a very nice presentation. I had one comment and one question. The comment, I think, has been alluded to a bit by Francis a few minutes ago. It seems like when I look at our story, first it's infrastructure building and hopefully in a year and

a half or two years it will be the results of our research, and then the gap, it seems to me one of the exciting things to put down is to figure out why the people who won the pilot project grants won the pilot project grants. What was different about their submission? And how is it more patient-centered than other things?

And I think that pushing the concept of research done differently -- it's not quite done yet, but certainly it was done -- the applications were done well enough that we chose those.

The question I have is about the website and where you set the thermostat between the website is for the researchers and the website is for the people of the United States. If I look at maybe the two ends of the football field, the NIH.gov website and the AHRQ.gov website, NIH is advertising National Cell Day coming up on November 2nd, that's pretty scientific, but if you look at the AHRQ website, right on the splash screen, as you open it up, it has questions about me, the patient, and it has -- if you look at the AHRQ

website I think it almost looks more patient oriented than PCORI's website.

So, I wonder about the set point of our website.

MR. SILBERG: Well, it's an important question because all the website is, is a reflection of where we, as an organization, are trying to go. So, at the moment, I think it's a bit of a hybrid. I think the general look and feel is more consumer focused and the language tries to be more friendly than if it were a wonkier site. But we don't always succeed once you get under the skin, and I think that's partly because we're still feeling our way as to who we are trying, primarily, to get to do what.

I think we'll have a lot more clarity on this in the next few months as the engagement team really digs in with their constituencies, comes up with very specific programming and very specific opportunities that clearly will need to be phrased and framed and presented, the outreach the same, to appeal to those consumer and other stakeholder

audiences.

I think it will have to be a balance for a while yet because we are appealing to the research community from a -- largely -- from a funding point of view, and from an information point of view we will be producing a lot of research that also then has to be translated for the general public.

So, I think we're going to be feeling our way for a little bit. I hope that what we can begin to do before very long is figure out, what are the areas where we absolutely from the get go have to say we are really friendly to the layperson? What's the language we use? What's the graphic approach? Is it a series of separate entry points? Is it a series of websites? I'm not sure yet. But we -- I recognize the issue and I think this is something that many of our peer institutions have tried to work on over the years.

CHAIRMAN WASHINGTON: Clancy.

DR. CLANCY: I'm sorry, I thought you said Francis and I realized you said Clancy.

So, I will take that as a compliment, Bob.

It does seem to me a strategic question for PCORI and not for an answer today, but one that I think the Board would probably have a range of opinions on is, does it make sense to have separate entry points? You know, which some sites do, right, click here if you're a patient, and you go to all these things. Or are we trying to build something that is -- would that be antithetical to this notion of researchers and patients telling stories together?

I don't know the right answer to that and obviously that's not quite where we are at the moment, but I just wanted to flag that as an important issue.

CHAIRMAN WASHINGTON: Okay. And Francis, you're going to get the last word.

DR. COLLINS: Oh, dear. Francis Collins, Board member. Well, just in that regard, of course since there is a synergism between AHRQ's communication efforts, some of which are, in fact, directly connected by statute to PCORI, as you're putting forward this plan about how this is going

forward, I assume there will be lots of thinking going on about how that works so that it is complimentary, synergistic, not duplicative, all of those things that we would assume would be a good outcome.

MR. SILBERG: Just part of the plan to learn from the best and the people who do it well now.

[Laughter.]

CHAIRMAN WASHINGTON: Okay, you're also going to present on this next topic, scientific publications.

DR. BARKSDALE: This is Debra Barksdale. I'm actually going to get us started if that's okay.

CHAIRMAN WASHINGTON: Oh, fantastic, Debra. As chair of the committee.

MS. BARKSDALE: So, I think this is the first official report of the scientific publication subcommittee to the Board. So, what we're going to do today, what mostly Bill is going to do today, we're going to talk about the subcommittee

activities, policies, and procedures today, on tracking the pipeline, some coordination with CEOC and AHRQ, or at least some coordination issues that have come up, strategic publishing, what our next steps will be, and then, of course, we'll have some questions for you to consider.

With that said, these are the members of the subcommittee. There has been one addition, Al Berg, and it's not indicated here, but I'd like to point out that my esteemed colleague Harlan Krumholz is the co-chair of this committee.

So here are some of the questions to consider and you all will see these again at the end of the presentation.

MR. SILBERG: Thanks Debra and I want thank Gail Shearer who was staffing the committee until she very reluctantly turned it over to me a few months ago. But Gail was a tremendous source of help in getting me started.

Let's talk for a couple minutes about the committee's activities, policies and procedures. One of the reasons we wanted to do this

presentation was just to be sure everyone -- we reminded everyone there is a Scientific Publication Subcommittee which has a very specific charge. Oh, I have it here.

[Laughter.]

MR. SILBERG: Redundant systems.

And here is sort of a high level listing of the charge of the subcommittee taken from the establishing policy document that the Board approved some time ago. So I just wanted to remind you of that because the subcommittee, which I think will become very, very much more active in the next six to 12 months, is a real resource and one of the points here, as you will here in a little bit. If we want to be not just facilitative of all of the wonderful publishing opportunities we now have and will have, but strategic about those opportunities, we really do need to be sure that we have a subcommittee and a related set of processes that are agile and really can help support the organization's publishing enterprise and that of the researcher's that we will be working with even

if it is only to give them occasional advice or check in with them.

One of the things that I am charged with doing, which I have just started to do is tracking the papers in the pipeline. It's actually five PCORI-related papers now published and this is since I was handed the spreadsheet, but I think we've had a real spat of high profile publications going back the last few months that I'll show you in a second. We have others that are review or have been cleared for submission and we will soon have a number of additional potential publications that the committee needs to know about thanks to some publishing opportunities that have come our way.

One thing that I would like to think a little bit about with you and with the members of the subcommittee, is how we can do a better job of not just having a spreadsheet that lists everything, but spending a little time thinking about prioritizing papers that may be of particular interest to PCORI at a particular point in time.

Some that may have been in the hopper for awhile, but because of the press of business have not been able to proceed for one reason or another and really see if we can help to move some of these things along to help to raise our profile in the influential professional journals.

We also want to be sure that the subcommittee is not weighed down by a lack of effective and natural process in helping them do their jobs. So, I need to spend a little time thinking about how to do that better. And I also want to be sure that the members of the Board and the Methodology Committee, the staff and others within the PCORI community are aware very quickly of when we have a paper that has been published or is about to be published. Right now we do that a little based on input we receive and I'd really like that to be a resource for everyone in this room. And because we are putting into place a PCORI document delivery system for the scientific literature, we would certainly want to make access with an appropriate intellectual property rules, of

course, access to those published papers as they come online.

Here's three papers and one blog at get to what I what I was talking about. You will recognize them, I'm sure. We had a couple of pieces in the JAMA theme issue on CER, I referenced earlier today the Methodology Committee paper in the *New England Journal*. There was this other paper in the *New England Journal*, paper in *Annals*. And I mentioned the blog, because one of the things that we will be thinking about on the subcommittee with your help is how do we think about opportunities to use other forms of scholarly, scientific and professional communication that are not necessarily the traditional article as a way to inform, message and communicate with our critical stakeholders.

I would simply point out that in the policy sphere, a well-placed and a well-timed blog post can get a whole lot more attention and impact in certain halls of power than an article in *Health Affairs* and *Health Affairs* would be the first folks

to tell you that. So it's a new world in terms of the communications tools that we have and I think as an organization we owe it to ourselves to figure it out.

I wanted to be sure you understood that we are completely aware of the need for the scientific publishing mission to be appropriately coordinated with the broader communications engagement outreach mission of the organization and with the work that we will be coordinating well over time with AHRQ, which of course is charged by statute, with being the primary dissemination organ for our published research. We've already started to have those discussions, the information we've gotten from AHRQ about how they've done this sort of work with their own work over the years has been incredibly helpful. For starters, it has given us some real important things to think about, so I have no doubt that we will continue to work together to figure out how this works appropriately over time.

We have some real challenges. One of the things that we talked about a little bit last night

was this whole notion of the 90 day rule we are charged by statute with, with making the information available upon from 90 days of receipt or completion of the primary research and anyone here who knows what that means please see me after because I'd really like to know. But these are some of the challenges that we will work through in an effective way because we have a statutory requirement, we have a real mission that we believe in to get this worked out as quickly as we can at a high level of quality so that it can be used by the various communities.

When I talk about a strategic publishing plan, what I'm interested in think about with you is how can we get ahead of the curve, if you will, in terms of the source of opportunities we have to publish, plus those that come our way and those that we suggest to various journals and other scholarly communication outlets. What might be the topics that we would think about? Both those that come in the door and those we come up with. Who might the appropriate authors be? What might be

the processes for pulling those papers together so that they are of high quality and we have a good shot at getting them in the literature for very specific purposes.

These are all questions that are part and parcel of broader strategic communications, but in a scholarly publishing sense they're particularly important because many of our critical stakeholders will be looking to the literature that we will be producing to show some of the measures of value that our research entails. So we want to be sure that we are thinking about how we can be as effective as possible, proactively, to really try to help guide the profession. Both the research community, the clinical community, the scholarly community, the policy community with information that we think will be of use to them.

The last bullet I put up is simply to remind everyone by statute we are charged with having consumer level, lay level, non-technical level summaries of the primary research we do. How that's done, what the metrics are, what the health

literacy levels are, what the form and format are. We intend to, this is another area where we will be consulting quite closely with our friends at AHRQ who do this exceptionally well and there may be any number of ways that we proceed.

So here's some next steps. Some of them are very technical. The second bullet for example we had a couple of questions that had come up on email of our authorship policies, so the whole notion of corporate authorship, a paper written by the Methodology Committee, not all journals will accept that form of authorship so we want to be sure we're clear on what we prefer because as we try to get more material published and more material comes our way, we want to be sure that we're working within the rules, but also have our own preferences to give appropriate credit to the work that's being done.

We also, I think, want to talk a little bit about how the subcommittee, again in consultation with COEC, can help to shape the process by which the various types of professional

material that will be produced by in-house staff: white papers, monographs, commentaries, background pieces. How will that be done to a level of quality that PCORI can feel good about and take ownership of even if it's not the scientific article in the traditional sense. A number of folks need to have a really clear role in this and I don't have an answer yet, but I do think it's a discussion that we do want to have. And you see a couple of other steps that we want to be looking at.

The next to last bullet is one that we talked a little bit about today and the whole notion of where PCORI is going to stand and what activities we're going to undertake in the open access movement, I think is important, and the subcommittee can help inform us along with others who will be helping to set policy in this area.

Let me close with some questions for you to think about that we won't answer all today but I would be very interested in hearing from you over time as we really gin up the activity of this group

to try to be very visible.

CHAIRMAN WASHINGTON: Okay, again, thanks to Debra and members of your committee as well as Bill and other staff members involved in developing this presentation, but also in moving the agenda a long way to publication, particularly scientific publication.

We're five minutes before the public comment period and we're going to stick to that. I have two Board members, three. Sharon you're going to get the last word and then we're going to move to the public comment period and then I would urge others to follow up and provide written comments and/or calls. So Hunt, Douma, and Levine.

MS. HUNT: Gail Hunt, Board member. Bill, I thought when we did the Pilot Projects we required them or we said that they had to, at the end, disseminate their or be prepared to develop some kind of consumer-focused results, findings, out of their studies. So, I guess, you know, I didn't quite understand what you were talking about when you were saying, you know, I mean, I think the

ball is in their court with technical assistance maybe from us.

MR. SILBERG: It's part of broader conversation. The Methodology Committee -- excuse me, the Methodology Contractors' reports had a requirement in their contracts, most of them for a non-technical summary. We provided some guidance. We probably need to do a somewhat better job of the guidance we provide and the process we look at. For the Pilot Projects and the primary research results, the language you refer to is being finalized now in those contracts for exactly what the publishing intellectual property, technical/non-technical summaries, work products, all of that is being worked on. So it's an opportune time to have the conversation and the input about exactly what --

MS. HUNT: Can I just ask, is that -- when you say technical/non-technical, is non-technical something somebody would read in *Health Affairs* or is non-technical something that a consumer, a person that participated from Baltimore in that

research, they would understand? I only say Baltimore because I went to the focus groups there.

MR. SILBERG: We need to do a better job of setting the parameters, but I can tell you in the case of the Methodology Contractors the non-technical work was defined based on an assessment of about half a dozen of these sorts of things done by others and in consultation with three or four health literacy experts, so we talked about a level of understandability, 6th to 8th grade level; we talked about a general format, bullet points/summary points; clear writing, no use of jargon. It's fairly standard stuff.

And I think we want to spend a little more time thinking about how we define that as we go forward.

CHAIRMAN WASHINGTON: Okay. Douma, then Levine.

DR. DOUMA: Thank you. Allen Douma, Board.

I think it's great to be included in one of the bullets, the middle bullet "Consider how it

might apply to consumer media." Clearly, given who we are, we need to be thinking about that but we also may be wanting to put it on the same level as the professional side, because they're totally different audiences, totally different distribution channels, et cetera, et cetera. Just for consideration.

The last bullet "Formalize strategic publishing plan," I think is absolutely critical and I would put it as the number one bullet, meaning it's what you work on next since it incorporated into the master plan anyway.

CHAIRMAN WASHINGTON: Okay, thank you Allen and then Sharon.

DR. LEVINE: Sharon Levine, Board member. Just a quick comment. Debra and I have had this conversation. I think one of the things we need to do for the committee's sake is to define scientific publications or change the name of the committee to ensure, number one we're not duplicating a peer-reviewed publication and a journal, and that in fact, we've covered the water front of what the

original intent was.

CHAIRMAN WASHINGTON: Very good point, and so, we're going to ask the subcommittee to certainly address this question.

Again, thanks to Debra, thanks Bill, and thanks to others involved and the work of this important subcommittee. We're now going to start with the public comment period and I want to again empathize that we in PCORI, that's Board and staff, highly value and strongly encourage public input and so at each of our meetings identify at least a block of time where we can hear from the public.

We have five individuals signed up already. If there are others, either in attendance here, or again, on the line who would like to provide comment. Please let -- who should we have them see in this case? David?

DR. SELBY: Richard or --

CHAIRMAN WASHINGTON: Richard, no.

DR. SELBY: -- Erica?

CHAIRMAN WASHINGTON: Where's Erica? Okay.

DR. SELBY: Is Erica in the room?

CHAIRMAN WASHINGTON: Okay, Richard you're going to be multitasking here then, so if somebody else wants to add, you should let Richard know. So Richard would you introduce the first speaker?

MR. SCHMITZ: All right.

CHAIRMAN WASHINGTON: And I'm going to remind the speakers to please limit your comments to no more than three minutes.

MR. SCHMITZ: All right. Thank you Dr. Washington. In addition to limiting your comments to three minutes, I also want to remind everyone to please submit any written comments to PCORI by email at info@pcori.org.

We do have five individuals signed up to provide comment in person. After they've had a chance to speak, we'll check with the teleconference operator to see if there is anyone who would like to provide comment by phone.

I'm just going to name quickly the five in-person so that you will know when to expect to comment. They are: Lisa Simpson, Carter Beck, Tony

Coelho, Andrew Spiegel, and Perry Cohen. And so, the first public commenter is Lisa Simpson of Academy Health and we're going to have individuals provide comment from the table here today.

DR. SIMPSON: Good afternoon and that you for the opportunity to provide comments today. As you've heard, my name is Lisa Simpson and I'm the President and CEO of Academy Health, which represents the fields of health services research and health policy research and all of the professionals who use this important work, including many of your PCORI partners and stakeholders.

We're taking this opportunity for public comment to reinforce some of the points that we made in our submitted full comments on the Methodology Committee report and really just want to compliment the Methodology Committee for this very thoughtful and very important report.

There are three specific aspects I wanted to underscore in my public remarks today. First, to continue to support the struggle and the

guidance from the Methodology Committee of matching the right question with the right methods, because that clearly is going to be where this whole effort, where our whole field sinks or swims. And so, we continue to encourage PCORI to do as it is doing to solicit and fund research projects that employ a wide range of data and methodologies.

And so, we were pleased to see in the report that there was attention to both experimental and observational designs and how important both of those are to this area.

We also encourage PCORI to go beyond this traditional single site studies and further explore in updates to the report the methodologic issues with multisite studies and particularly the issues around context and really understand what determines the ultimate outcome of which intervention for which patient for which setting and that will, I think, be real valuable.

The second point I want to make is just how welcome your guidance is and the field welcomes your guidance and your deep thinking on these

issues. Some areas that we're particularly interested in seeing, perhaps even more guidance in future reports or updates, is the issue of capacity building and training. And obviously, PCORI working with the Agency for Healthcare Research and Quality will be taking on this issue of training, but really not just training the researchers, but also, the training of the patients and caregivers and those, and clinicians -- everybody who we expect to both contribute to the research production, but then the application of the findings. So capacity building will be critical.

The second area I just want to highlight where we welcome more guidance is the issue of methods around studying health equity and health disparities and how critical that is going to be and we speak to that in our written comments.

And then turning to the balance, is as you think about the Methodology Committee and its work in the future is the balance between innovation and supporting that continual innovation in methods and data, while continuing to demand high data quality

and research methodology quality and how that's going to be important for the field.

And so, we encourage you and encourage the field to test and evaluate new methods particularly around validity, generalizability, other scientific study dimensions as well as going beyond the issue of data quality that's dealt with in the report, because there are many other issues around data that go beyond just data quality. And since obviously data is the backbone of our knowledge, this should be assessed rigorously and continually.

So, with that I would like to thank you in closing for the opportunity to speak today. We, as always, stand ready as a field and as an organization to assist you in this important work and to continue to contribute to support the Methodology Committee in its work.

Thank you.

CHAIRMAN WASHINGTON: Thank you Dr. Simpson.

MR. SCHMITZ: Our second commenter is Dr. Carter Beck of the Montana Neurological Associates.

DR. BECK: Good afternoon.

CHAIRMAN WASHINGTON: Good afternoon.

DR. BECK: Good afternoon Mr. Chairman, members of the Board. I've flown here from Montana for the second time this year to hang out with you guys and I've listened closely --

CHAIRMAN WASHINGTON: Invite us to Montana.

DR. BECK: You're welcome to come anytime, you'd love it. We have forest fires right now unfortunately, so don't come now.

I wanted to bring to you today, a down to earth clinical problem and raise your awareness about how this institute can very much help me help my patients and how it can very much harm me and prevent me from helping my patients. In the course of being a neurosurgeon I do a great deal of complex reconstructive spinal surgery. The most important tool that I have in reconstructive spinal surgery is the lumbar fusion.

Now the lumbar fusion is a very common, a very expensive, widely utilized procedure. It's a

procedure, probably in some cases is over utilized, in some case underutilized, and in many cases is mis-utilized. Without it though, I could not take care of my patients and with Americans living longer and expecting more from their bodies, really out living their lumbar spines, this tool has given me a great deal of ability to help people.

The data is mixed. The literature is a mess. We need your help. We need outcomes research to show what are the best practices, what is working well and resulting in clinical success, and what is harming patients and I think we would find both. That would be something PCORI would very much help me with. It could very much harm me by generating the wrong data, and could very much harm my patients by generating an incomplete dataset and I'd like to give you an example from this afternoon.

If we abstract today's meeting, we say how many slides today were about PCORI truly being patient-centered and engaging. Well, a lot of the slide were about engagement and the PCORI's

interaction with the community. How many slides were about what the community was actually saying? Zero. We went through the whole public comment period, which I listed to intently as a public commenter and there were no mention of what anybody said.

That abstraction I recognize is not fair, because I'm sure that those things are duly considered in other venues, but you would think that the Board of Directors would be interested in what actually people are saying and we didn't talk about it. And so, if we were to take that abstraction and apply it to PCORI's work, it would be unfair and damaging and I'm worried that if we're not careful, particularly with very, very complicated clinical problems like lumbar spinal surgery, it will have the same unfair impact and really do a disservice to our patients.

Thank you.

CHAIRMAN WASHINGTON: Thank you Dr. Beck.

MR. SCHMITZ: Our third public commenter is Tony Coehlo of the Partnership to Improve

Patient Care.

MR. COELHO: Thank you very much. Thank you for having me, again, here today. As indicated I'm Tony Coehlo and I'm Chairman of the Partnership to Improve Patient Care, also known as PIPC.

As you know, PIPC has been a champion for patient-centered comparative effectiveness research since the inception and we applauded the creation of PCORI. Earlier this year we sent a letter to PCORI expressing some significant ongoing concerns related to PCORI. In particular, we called for PCORI to establish a National Priorities for Research that identifies specific research topics through an inclusive transparent process. We also called for progress in creating the Advisory Panel capacity and vision in PCORI's authorizing statute, and creating mechanisms to engage patients and patient advocacy organizations through PCORI's decision-making process. I appreciate the steps, you as a board and Dr. Selby and his team, in particular, have taken in response to these concerns.

While we think more can and should be done, we're pleased with the steps that are being taken to identify National Priorities based on specific research topics, to begin creating advisory panels, and discussing ways to better engage stakeholders; such as patients and people with disabilities.

Our end goal is a PCORI process that one, engages patients, people with disabilities, and caregivers in meaningful ways throughout the process; two, creates advisory panels to obtain expert clinical input; and three, defines National research Priorities that identifies specific study topics to guide PCORI funding decisions.

Patient engagement should start at the stage of identifying potential research topics and continue through the process of study design and results dissemination. Our end goal is communication of research findings that are as stated by statute, comprehensible and useful to patients and providers in making healthcare decisions. To achieve this goal you need to start

with patients at the earliest stages of decision-making and engage them throughout the process. If a study is not asking a question that is relevant to the needs of patients and providers, no amount of effort will enable you to communicate results in a way that is useful.

Advisory panels are needed to enable PCORI to obtain expert clinical input from physicians in a wide range of specialties. Over the past year, we at PIPC, have been conducting roundtable discussions with physicians on the most effective ways physicians can engage most effectively with PCORI. These discussions are yielding consensus recommendations from the participants for PCORI's consideration. These physician organizations have recommended that PCORI support meaningful physician input into by creating expert advisory panels with sufficient representation of clinical experts, caregivers, and patients; and training patients and clinicians to be full participants in priority setting and other PCORI activities. Physicians and other caregivers are key partners in advancing

patient-centered care. Without their input and expertise, we will not get there.

PIPC encourages PCORI to clearly establish a complete formal strategy for engagement and priority setting that is transparent, focused and relies on patient input and clinical expertise. This would allow stakeholders the opportunity to not only participate in one-off requests for input, but would allow interested stakeholders to be resources as projects move forward.

As members of the Board, you have heard me say before, PCORI was set up to conduct CER in a new and different way. One that is focused on the questions identified as most important by physicians and patients. No other CER program has this unique mandate and no other program includes patients that way PCORI does. In this regard, PCORI should clarify the role that recommendations from HHS research agencies will play in defining PCORI research priorities. This is particularly important in light of the influential role these agencies already play in the work of PCORI and the

Methodology Committee.

In closing, I want to acknowledge the great progress PCORI has made in the last few months. We look forward to providing continued support to make your new stakeholder engagement and priority setting efforts a great success.

Thank you.

CHAIRMAN WASHINGTON: Thank you Mr. Coehlo.

MR. SCHMITZ: Our next is Andrew Spiegel of the Colon Cancer Alliance.

MR. SPIEGEL: Good afternoon Board and Panel and thank you for allowing me the opportunity to address you today.

By way of background, my name is Andrew Spiegel and I am the CEO of the Colon Cancer Alliance, which is the oldest and largest national patient advocacy organization dedicated to colorectal cancer.

The issue under discussion today is an important one, and I know firsthand what's at stake for patients and medical practitioners and future

innovation. I personally witnessed the devastating effects of cancer and felt the hope associated with the development of new and innovative technologies and treatments for patients. In 1999, I lost my mother to colon cancer, two days after losing my father to pancreatic cancer. At the time there were limited treatments available to patients to fight against these diseases and these were among the top killers of cancer death for Americans. And shortly after that life altering experience, I decided to get into the advocacy world and leave my real job and I co-founded the Colon Cancer Alliance.

Thankfully today in 2012, we don't have to fight these deadly diseases of cancer with the same treatments that we had back in 1999 when we lost my parents. Since that time, we have come a long way in providing lifesaving treatment options to patients with all types of cancer and specifically in the case of colon cancer, we see the average metastatic patient now living three times longer than we did back in 1999. But there still is work

to be done and concerns to be addressed.

I decided to come here today after recently attending a conference in Montreal where I attended a healthcare technology workshop. During that workshop there was a discussion on the role of healthcare technology assessment and the role it plays in patient access and how that can impact and limit patient access to treatments. Following this three-day conference I had a renewed interest to highlight many patient concerns about government involvement in healthcare decision-making. What I witnessed in Canada and have seen what the reactions of NICE in the UK have given me great concern as a patient advocate.

I specifically watch a video that was played at this conference that somehow somebody obtained of a NICE review of a cancer therapy. We heard patients testify before the NICE panel about how this drug was saving their life or potentially could save their life, and what I heard this panel specifically say was that they had a representative that had to go back to the drug manufacturer and

get the price under roughly $35,000 for a year of the patient's life or they wouldn't cover it and the could be covered in this case, and so, the cancer drug was not recommended and because they put the value of a human life at about $35,000 and that couldn't be met. And I also learned at the conference that things are ever worse in Canada where they are valuing a human life year at about $15-20,000.

And so, I am worried about CER in the US. I'm worried that CER is trending towards a model that injects too many obstacles into the healthcare decision-making process. I am worried that the U.S. will start putting values on our American's lives. We must ensure the integrity of the doctor-patient relationship and while I welcome more data and information being made available to doctors, I cannot possibly support the intrusion of government or any other entity that dictates coverage requirements or limits a patient's access to personal, individualized care.

So, I come here today to urge PCORI to

work to ensure personal medical decisions are left to patients and their doctors without interference from regulators and bureaucrats who often focus their efforts on cutting corners to save costs. Everyone, including advocates, are for lower healthcare costs, but this must not come by sacrificing the doctor-patient relationship.

As technology opens the door to more lifesaving medications and treatments, let us now focus on the main component of this discussion, the patient. Above all other concerns, we must be sure that the patient is the priority as PCORI considers the future of CER. With all that a cancer patient has to worry about, it is imperative that intrusion or interference in treatment decisions does not become one of those worries.

As a patient advocate I cannot emphasize enough the importance that all patients have the assurance that their healthcare decisions will remain intact with their doctor as a trusted medical advisor.

Thank you very much for the opportunity to

have provided comment and provide insight and recommendations on this topic. Thank you.

CHAIRMAN WASHINGTON: Thank you Mr. Spiegel.

MR. SCHMITZ: Our next public commenter is Perry Cohen of the Parkinson Pipeline Project.

DR. COHEN: Thank you for the opportunity to speak with you again.

I've been a patient advocate and an active voice for patient interests ever since I was diagnosed with Parkinson's disease in 1996. Currently I'm working with PCORI staff led by Sue Sheridan on the Planning Committee for the Patient Engagement Workshop next month, but most of what I have to say I've said before, but this paper says it again as a reminder.

Patient-centered health, who decides? I have observed that every constituency claims to represent patient's interest when, in fact, they're mostly representing their own interest that overlap patient's interests but may be contrary to the patient's interests. So it's important to identify

the differing perspectives of major constituencies of medical care on what patient-centered outcomes are and clarify who determines the evaluation of patient-centered outcomes. To me, patient-centered means patient's interests come first over the interest of science and the wider community.

Fundamental paradigm shifts in the U.S.A., patient-centered research not only touches on the core values of scientific knowledge for medical professions, but also medical research and healthcare have in general become big business. Patient-center outcomes and comparative effectiveness research stand as challenges to some of the strongest institutions in our society that have been established to reinforce the dominant professionals and increasingly strong business interests in medicine.

The need for change is dictated by the steady decline of productivity, fewer new theories of medical research since the turn of the millennium. I'm talking about true Keynesian paradigm shift that means fundamental cultural

changes and whole new ways to conceptualize the meaning of medical care and the roles of doctors and patients in evidence-based health information. In a large part, this change is being driven by rapid advances in information and communication technology that empower patients for activation and self-help in collecting aggregated large observational databases both needed for health research and management [inaudible] healthcare system.

My questions for the Board: Does PCORI intend to take a leadership role and become a champion for patient interest and patient-centered healthcare assistance? In the current environment of doctor-centered healthcare system, which is resistant change, does enabling legislation for PCORI to educate other actors in healthcare to take a patient-centered perspective in their policies on clinical research, particularly the FDA who holds trump cards on research -- patients and consumers.

I pointed out in past presentations to this Board, that the difference between consumers

and patients, seriously ill patients have a different risk to medical decision-making than consumers and others. Illustrations of the viewpoints of patients in clinical sciences include three differences. The fundamental differences between patient's views and research scientist views including time delay versus urgency and urgency versus safety or error preferences for false negatives versus false positives. Patients prefer -- would rather have a false positive than a false negative as a scientific model that focuses on false positives; and the view of psychological impact of hope and spirit as therapy versus bias. Those are the issues that I've specified in the past.

Now, this morning's discussion of advisory panels sort of makes my next point moot so I'll skip it. But, basically the idea was that the Methodology Committee needs to be patient-focused.

I'll move onto the next topic. Patient advocacy organizations have an increasingly important role as trusted stewards to ensure

individual privacy standards and for health information and support of self-activated activities such as exercise classes. We need to build the capacity of the advocacy organizations as intermediaries to train and support and represent patient's interests at the table, thus providing counterbalance to the other strong interest groups in medicine. And I have been involved with a group called the Working Group on Evidence-Based Medicine that offered to do that.

Finally, I want to applaud the objective of building communities of patients, finding productive roles for patients that express an interest by responding to the workshop announcement or applying for patient positions in PCORI. For most chronic disease, participation in a research enterprise is not only good for the cause, but it's good for the patient.

Organizational systems, which is where I spent most of my professional career, in my experience the best way to build a health community is to work through national intermediaries, such as

the National Health Council to build on existing national, local networks to reach the ultimate target, which is an individual patient except where there is no local patient organization or the local patient organization is not up to the task.

Notice that these healthcare intermediaries are mainly disease focused and with good reason. Patients are self-organized by disease and the science and medical professions are organized around diseases and body systems. Consideration of information technology and optimal medical care organizations are addressed in the research priorities, but that is too big of a topic to be covered here.

So if you want to hear more about that just ask. Although, I will not give up my interest in accelerated paradigm shift in medicine, the rate of my PD is advancing. This may be the last public comment for the Board, so I'm counting on you, my partners in health, to go out and win one for those patients with serious chronic diseases.

CHAIRMAN WASHINGTON: Thank you Dr. Cohen,

very much.

[Applause.]

CHAIRMAN WASHINGTON: Okay, that was the last of our scheduled speakers, we're now going to open it up. Richard have you heard from anyone?

MR. SCHMITZ: The only other would be to check with the teleconference participants.

OPERATOR: If you would like to make a comment over the phone, please press *1 on your telephone keypad.

[Pause.]

OPERATOR: We have no comments in queue at this time.

CHAIRMAN WASHINGTON: Okay, then we're going to conclude this public session of the meeting today and move now into the last segment of our schedule program which is really just a wrap-up of today and I'm going to take an unusual step, risky too, but just opening it up to the Board members to see if there are any comments that you want to make or suggestions to the staff about follow-up that you particularly want to emphasize

as we are wrapping up today.

[No response.]

CHAIRMAN WASHINGTON: I'm not going to leave that window open too long.

[Laughter.]

CHAIRMAN WASHINGTON: Okay, so I want to, again, say to everyone that's participated today.

DR. SELBY: Can I just say one thing?

CHAIRMAN WASHINGTON: Okay, I'm going to turn it to Joe in a minute, but thank you. I have just observed myself, sort of the growth of our board, and acting more and more like a board and I think that really is just a reflection of the high caliber, highly committed and competent staff that we now have garnered under Joe's and Anne's leadership. And so, besides thanking all of the participants who joined us via webcast and here today, I especially want to thank Joe, Anne, and all of the staff who really just performed in an exemplary manner and I'm going to ask the Board to join me in thanking you.

[Applause.]

CHAIRMAN WASHINGTON: So, Joe.

DR. SELBY: Well, we could do the same in thanking you and I hope Gene is right, that it is the maturation of the staff. I think, obviously, the staff has grown and matured and I hope that's giving you some well-deserved confidence that the way forward will be smooth and we thank you for your forbearance during the early going. Your patience and your support is never forgotten for a moment.

I just wanted to say in closing that you should find in front of you two documents for tomorrow's discussions. Grab them. You received them electronically, but some people prefer looking at hard copy and there they are.

CHAIRMAN WASHINGTON: Okay, with that note, thanks again everyone. This meeting is now concluded.

[Whereupon, at 4:50 PM, the PCORI Board of Governors meeting was concluded.]