PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Tuesday, September 15, 2020

Teleconference/Webinar

[Transcribed from PCORI teleconference.]

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APPEARANCES:

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Kara Ayers, PhD
Lawrence Becker
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Alicia Fernandez, MD
Christopher Friese, PhD, RN, AOCN, FAAN
Christine Goertz, DC, PhD [Chairperson]
Michael Herndon, DO
Russell Howerton, MD
Gail Hunt
Michael Lauer, MD [alternate for Francis Collins, MD, PhD]
Sharon Levine, MD [Vice Chairperson]
Freda Lewis-Hall, MD
Michelle McMurry-Heath, MD, PhD
Barbara J. McNeil, MD, PhD
David Myers, MD [alternate for Gopal Khanna, MBA]
Ellen Sigal, PhD
Kathleen Troeger, MPH
Robert Zwolak, MD, PhD

AGENDA

AGENDA [continued]

P R O C E E D I N G S

[1:01 p.m.]

MS. JACKSTADT: Dr. Goertz, the floor is yours.

CHAIRPERSON GOERTZ: Thank you Kat.

Good afternoon and welcome to the second day of our mid-September 2020 meeting of the PCORI Board of Governors.

I'm Christine Goertz, Chairperson. I want to welcome those of you who are joining us for today's Board meeting by teleconference and webinar. Thank you to everyone who's joined us virtually online and on the phone. We're very pleased to have you here.

A reminder that conflict of interest disclosures of Board members are publicly available on PCORI's website, and that we are required to be updated annually, and if the information changes. If the Board will deliberate or take action on a matter that presents a conflict of interest for you, please recuse yourself or inform me if you have any questions. If you have questions about disclosures

or recusals relating to you or others, contact your staff representative.

All materials presented to the Board for consideration today will be available during the webinar, and then after the webinar will be posted on our website at www.PCORI.org. The webinar is being recorded, and an archive will be posted within a week or so.

Finally, a reminder that we are live Tweeting today's activities on Twitter. Join the conversation with @PCORI.

Kat, could you please call roll?

MS. JACKSTADT: Certainly.

Kara Ayers. Kara Ayers?

DR. AYERS: Present.

MS. JACKSTADT: Thank you. Larry Becker.

MR. BECKER: Here.

MS. JACKSTADT: Michael Lauer, filling in for Francis Collins.

DR. LAUER: Here.

MS. JACKSTADT: Jennifer DeVoe.

[No response.]

MS. JACKSTADT: Alicia Fernandez.

[No response.]

MS. JACKSTADT: Christopher Friese.

DR. FRIESE: Here.

MS. JACKSTADT: Christine Goertz.

CHAIRPERSON GOERTZ: Present.

MS. JACKSTADT: Mike Herndon.

DR. HERNDON: Present.

MS. JACKSTADT: Russell Howerton.

DR. HOWERTON: Present.

MS. JACKSTADT: Gail Hunt.

MS. HUNT: Here.

MS. JACKSTADT: David Myers, filling in for Gopal Khanna.

DR. MYERS: Here.

MS. JACKSTADT: Sharon Levine.

DR. LEVINE: Here.

MS. JACKSTADT: Freda Lewis-Hall.

[No response.]

MS. JACKSTADT: Michelle McMurry-Heath.

[No response.]

MS. JACKSTADT: Barbara McNeil.

DR. McNEIL: Here.

MS. JACKSTADT: Gray Norquist.

DR. NORQUIST: Here.

MS. JACKSTADT: Ellen Sigal.

DR. SIGAL: Here.

MS. JACKSTADT: Kathleen Troeger.

DR. TROEGER: Here.

MS. JACKSTADT: Janet Woodcock.

[No response.]

MS. JACKSTADT: Robert Zwolak.

DR. ZWOLAK: In attendance.

MS. JACKSTADT: Dr. Goertz, we have a quorum.

CHAIRPERSON GOERTZ: Thank you, Kat.

Our agenda this this afternoon includes the PCORnet update where we will consider for approval PCORnet extension funding. We'll also consider for approval a commitment plan model, and our FY2021 expense budget. This will be followed by a Strategic Planning Committee report to the Board, and then we will wrap-up with a panel discussion from outgoing Board members and our public comment

period.

The first item on the agenda is our PCORnet update. I'm going to turn the meeting over to Dr. Briggs to lead us through this presentation.

Hi Josie.

DR. BRIGGS: Hello Christine and thank you, and good afternoon to the Board. I'm pleased to be with you once more in my role as a consultant and advisor to Dr. Cook.

The presentation today has several goals. One year ago, the Board approved $37 million budget for 2020 funding of PCORnet, most of those funds have not yet been committed. At this time, we need your approval to commit $17 million of those funds to an extension phase.

An extension phase will provide research infrastructure support that will allow the maintenance of the network and the coordinating center ongoing activities, particularly support of the common data model and the Front Door activities. This extension proposal has been reviewed and approved by the RTC.

The funding approval a year ago by this Board of $37 million was approved, anticipating some expansions of the network and a solicitation in February for competitive renewal of the network. A number of events have pushed that renewal back. It includes in my period, where I had the honor of serving as the Interim Executive Director, work that was developed largely in cooperation with the SOC for development of PCORnet activities that included the Rare Disease Network, work partnerships, and the development prompted by the DCCO subcommittee of the SOC for the PLACER awards.

But the other event, of course, the big event that slowed the re-solicitation has been the COVID pandemic. So as a consequence of these events, we have not expanded the network in this -- or infrastructure support in this period, and the budget funds will actually cover activities through much of 2020, and -- through the rest of 2020 and 2021.

But most importantly, the extension phase will allow the completion of an ongoing internal and

external evaluation of the network which I will tell you a little about. And I think, should allow this board to develop a strengthened strategic vision for the next phase of PCORnet.

I am well aware that this board with Dr. Cook's spectacular leadership, and that of the Board, has considered many aspects of the strategic vision for the next phase of PCORI, broadly. Now I am interim here as you -- as the Board knows well. But I'm representing a very strong internal team.

Kim Marschhauser and Claudia Grossman will talk to you as part of this presentation today, are two extremely able program leads for PCORnet projects. They know all aspects of this work, they are meticulous in the oversight of the allocation of funds, and can provide a level of detail, well-beyond what I can provide. They've been -- we've added to the team Penny Mohr, also very experienced in clinical research infrastructure with a lot of understanding of economic issues and FDA and industry issues.

And this internal team, research

infrastructure team, and Penny sort of has dual membership in that and the other parts of science, is going to be providing absolutely critical leadership of this evaluation process.

But I've come to believe that we can't just talk to the RTC and SOC, this strategic evaluation process has to be integrated with and mesh with the broader strategic visioning that I know you and the Board are considering.

I hope that the presentation I'm going to give you will help you think through some of the hard priority setting issues that I think will need to come back to this Board for decision this winter and in the spring.

To start, I've asked Kim Marschhauser to provide an update on some of the dashboard metrics we have been using on an ongoing way to evaluate PCORnet's activities. The metrics, I think, will give you a window into the very expanded uptick in PCORnet activities in last few months in response to the pandemic. The metrics, I think, are largely familiar to the RTC, but, and we're only going to

cover some of them that seem of greatest relevance to today's discussion. But I think they will help set the groundwork for the other matters we're going to talk about today.

Could we go ahead to the next slide?

So this is just the introduction, we do need your approval today to commit $17 million to extend the network. These are not new funds; these are funds that have already been approved but are not actually committed to a specific award. PCORI's governance rules do call for award-specific commitments to go through this Board. And these commitments of $17 million will be adequate to cover the funds through this evaluation phase that we are envisioning.

So with that preamble, now I'll turn things over to Kim who will tell you some of the ongoing metrics of PCORnet activities. Kim.

DR. MARSCHHAUSER: Thanks Josie. As she mentioned we wanted to share some of the metrics that we're following that really highlight the activity of PCORnet. So shown here is the number of

publications, each year, and as you can see over the last five years, PCORnet network partners have authored over 300 publications. The total number of publications each year, with Altmetric scores that are greater than 20 can be found at the top of the bars for each year.

As you may recall Altmetric is a tool that tracks a variety of sources to capture attention or activity around a publication. In general, a high score is greater than 20, which is attained by about, five percent of all publications. A very high score is greater than 100, which is attained by about one percent of all publications.

The PCORnet bariatric demonstration study had a publication that received an Altmetrics score of 315 and ADAPTABLE had a publication this year that received in Altmetrics score of 45.

We can move on to the next slide.

So here's a picture of the full PCORnet dashboard. So as Josie mentioned we're going to focus our discussion on dashboard metrics related to the PCORnet Front Door which is these first figures

shown in the top row here.

So we can move to the next slide.

So PCORnet Front Door is an online portal, or gateway, for potential investigators, patient groups, government, industry, and other stakeholders to access the infrastructure. The Front Door team at the Coordinating Center work with Front Door visitors to answer questions, advisor on designs, and work to connect research opportunities to investigators across PCORnet. Over the last two years, there have been 262 visitors to the Front Door. And as you can see the network saw the greatest number of Front Door visitors in Quarter-2 of this year.

We can move on to the next slide.

Who visits the Front Door? Although the most frequent visitors to the Front Door are academic investigators, funders representing federal organizations, industry, and foundations also visit the Front Door. This year so far, there have been 142 visits, of these 96 for academic investigators, seven were federal funders, 10 representing

industry, and 29 represented other stakeholders like foundations, patient groups, and healthcare organizations.

We can move on to the next slide.

So why do they come to the Front Door?

Well, visitors often come to the Front Door consultation to better understand the PCORnet and to learn how to leverage the infrastructure. The Front Door team also supports proposal development, data requests, and network collaboration requests.

So far this year, there have been 106 consultations, which are shown in green for each quarter. There have been 15 proposal development requests which are shown in that dark blue color. Ten data requests which is highlighted there in orange. And then lastly, nine network collaboration requests which are shown in gray. And again, the majority of these requests came in Quarter-2 of this year.

And we can move to the next slide.

So this slide captures information on the types of funding Front Door visitors, either already

have or the type of funders they're developing applications for. So it's important to note that not all Front Door visitors are seeking funding, some simply want to understand PCORnet and may reengage in the future around a targeted funding opportunity.

Now shown here for each quarter, you can see the number of Front Door visitors that came with funding. So this is labeled as a funded visitor on the graph. These funded visitors almost often have industry funding. Also shown for each quarter is the number of visitors that are developing applications for a targeted funding source. Although visitors most often are developing applications to submit to PCORI, as you can see in blue, they're also developing applications for federal funding, as well as foundation and industry.

Now in Quarter-2 of this year, 37 visitors were preparing applications to submit to PCORI and eight were preparing applications to submit for federal funding. Now the Front Door team is tracking the outcomes of these interactions and

we'll report back in the coming months on the number of successful collaborations that result in funded studies.

And so, I will stop here and turn it back to Josie to talk a little bit more about the applications that are being submitted to open PCORI funding opportunities.

DR. BRIGGS: Thank you, Kim.

So the surge in Front Door use does not of course tell us which these applications will be successful, but we track that of course and we'll be able to report back to you. The network has, a year ago, received a very large award from NIH, for the PREVENTABLE Trial of approximately $90 million. And we do track all of the cumulative funding from other funders as well as PCORI, but I want to primarily talk about the way the network is being used for PCORI-funded research.

When I arrived to take over the responsibilities here, I heard two recurrent concerns. One was that PCORI was perhaps not using the network as much as we could to figure out and do

more efficiently large-scale studies that would recruit patients. And I also heard from a very active committee of the SOC, a Direct Comparison of Clinical Outcome Committee, a concern about PCORI might -- should perhaps be doing more studies that directly compared to clinical decision dilemma alternatives.

And so, that was initially in the pre-COVID time which, goodness, feels like a long time ago. Part of what led my conversations with the SOC and RTC about ways to strengthen our use of this infrastructure. And those conversations resulted in three solicitations, which are now in process. The first is for the phased large awards in comparative effectiveness research.

We originally anticipated that we would be inviting those awards to be submitted in June, but recognizing the enormous challenges that the research community was facing, it was decided to push the Letters of Intent back to the end of this month and to allow the investigator community more time for application development, recognizing that

these were complex challenging projects to launch.

We are expecting a robust response, Letters of Intent submissions are not required to use PCORnet but it is encouraged, and a number of PCORnet partners are part of what we anticipate for the response at the end of this month.

The second solicitation has been for the rare disease PFA. This again, was a desire to take advantage of one of the recurrent potential strengths of PCORnet that it might facilitate identification and recruitment of subjects with conditions too rare to be effectively studied at single or small -- two sites, and the broad reach of this network, I'd facilitate broader studies of conditions that are relatively uncommon.

The way this solicitation was developed, again, with advice and input from the Rare Disease Committee and the SOC, was that these applications are to come in as partnerships with an organization or infrastructure that has direct ties to patients, and will propose to answer, an important question of relevance to the care of patients in this rare

disease category.

The Letters of Intent -- the response to this has been very robust, and a good number of proposals were invited to submit, and the applications were submitted the first of this month. They will undergo the Merit Review process this fall, and we'll come back to this Board in in early winter for potential approval.

And the third solicitation that is on the street, is on a long-standing question of which -- which I think this Board is quite familiar. And that is the question of what should be the best second line therapy. Among the new drugs and new and often costly drugs that have been developed and approved for treatment and reduction of cardiovascular events in people with diabetes.

This, again, had a very robust response with several of the applications planning to use a PCORnet data resources.

So these three solicitations and the response, I think, are part of appropriate development of -- for PCORI -- of broad use of this

network. Next slide please.

But these are primarily specific research projects. Another activity that has, I think, developed very quickly, and is in fact a research infrastructure investment, not a specific research project has been the work by the network to develop an enhancement of the common data model that will capture information about COVID-19 positive patients.

And this is involved with the development and curation in a variety of ways to extract from electronic health records variables of importance in study and understanding of this pandemic. This effort attracted interest from the CDC, and currently under consideration, potentially, to be finalized by the end of the month, is a very sizable CDC investment in this work. This is research infrastructure support, assuming this is completed as we now anticipate will be the first large non-PCORI-funded investment in research infrastructure.

What's the CDC? The CDC, of course, has extensive infrastructure investments in surveillance

activities, including the partnerships with state health departments. Some of this has had some changes with changed data collection to the Department of Health and Human Services and the CDC's network of information collection from hospitals.

But what PCORnet has brought to the CDC's -- or the needs that PCORnet is recognized as a able to fill do involve the extensive ability to extract more detailed, more granular information from electronic health records. Particularly electronic health records of hospitalized patients that allow measurement of medication use, laboratory values, and the use of other hospital resources. And this data is at a level of granularity and detail that the other surveillance efforts from the CDC do not support or do not have.

The network has also been partnering, partly prompted and I thank you for this out by Ellen Sigel's efforts, to participate in Evidence Accelerator Initiative of the FDA, and it's been a very effective partnership with Reagan-Udall and

Friends of Cancer Research, and members of the PCORnet team are regular participants in the weekly meetings of that group, and are bringing a variety of kinds of data efforts with the particularly, well-curated electronic health record data of the common data model into these very important deliberations.

FDA Sentinel is also in the process of developing a contract to describe the course of illness among hospitalized patients and evaluate therapies in real world settings.

So these are, I believe, important partnerships in the public health space. That, I think, in part, illustrate some of the strengths that the common data model and this infrastructure has. Next slide please.

We've also had a pretty active portfolio of research project support. The HERO Research Program, Nakela gave you wonderful summary of that yesterday.

Three enhancement awards have been funded that utilize the PCORnet studies and two of the

targeted PFA responses the titles of which are shown here, also are PCORnet-based studies.

Next slide please.

So to stand back a bit. PCORI investment in PCORnet is I think something that needs, and will benefit from ongoing strategic discussions by this Board. And I wanted just to share with you a few thoughts about that. The original vision for creating PCORnet was a broad and highly ambitious, and in fact, quite wonderful vision that we could improve the nation's capacity to conduct Patient-Centered Research, enabling us to learn from the healthcare experience, and to allow large scale research and recruitment with enhanced accuracy and efficiency, very ambitious aims.

There are two big parts to this one is the data structure. Extracting electronic health record data from both ambulatory and inpatient care with all its complexity into a curated data model that would allow standardized capture of a variety of variables in a more efficient way. Part one.

Part two is an infrastructure that connects

people and the people that this broad network is designed to capture are both the healthcare providers, the clinicians who take care of patients, and the patients themselves. During the COVID pandemic our primary emphasis has been to focus on how this infrastructure facilitates PCORI in other public sector-funded work. But there has been interest in use of this infrastructure as part of vaccine development, where we have allowed or facilitated some recruitment through the registry and other places into work funded by the ACTIV and Operation Warp Speed.

But again, these are large resource, heavily resourced ventures, and our major focus has been on the work that PCORI's directly funding. Could I have the next slide please?

So just to stand back on the two big pockets of funding that PCORI has directed to PCORnet. There are two categories of funding. The first is the actual funding of research projects, the total through September is as $130 million approximately. This is work that largely goes

through the oversight of the SOC, and includes such things as the large pragmatic adaptable trial, which is Trial ADAPTABLE, which is nearing completion. The large observational studies, particularly the Bariatric Study, the HERO Research Program, Health System Quality Improvement Rapid Cycle Research and Projects Initiatives are smaller commitments.

This number of $130 million does not include the way in which some of the networks have individually or local funding for a single project within a network, and it does not of course include the large investments being made by the NIH in PCORnet directed funding. This is PCORI funding directly. Next slide please.

And then the other big bucket of funding PCORI has funded provided is the infrastructure funding, and this is largely overseen through the activities of the RTC. That that investment is about $357 million, so far over the last seven years. It has supported the network partners primarily as the biggest investment investments, the CRNs, but also HPRNs and PPRNs as smaller network

investments, the Coordinating Center and during its interim phase, the PCRF Foundation.

Next slide please.

So to place these yearly expenses in context, I think it is very helpful to think of this as having had phases. The first phase of the fiscal year '14 was a planning phase. And this was a period where the actual funds invested in the course of the year were substantially lower. The numbers I'm showing you, with the exception of the last bar, are actual expenses. As I think you all know, PCORI operates with a cost reimbursement budgeting process and committed funds are often more than the actual expensed funds.

So the initial planning phase was about $17 million. The building phase in which the infrastructure tools for the data common model were created, and the personnel support necessary for that to happen was approximately $50 million a year. And that extended over a four-year phase.

In the last couple of years it's been reasonable to think of us moving into more of a

maintenance phase. And, in fact, the expensed costs for '19 were $35 million, and we're anticipating for fiscal year '20, they will be above $32 million.

Our placeholder estimate for maintenance of this infrastructure, as it currently exists is approximately $25 million a year. That is not the costs if this Board elects further expansion to meet unmet needs, but is -- I think, a reasonably well-grounded estimate of what the yearly maintenance costs will be for a network configured as it is currently.

Next slide please.

We are now embarked on a process which has been presented and discussed with both the SOC and RTC to evaluate where we are right now, and it's got two pieces. We are working through all the information that has been provided to us by all the sites to evaluate site performance including data quality linkage performance, population diversity, diversity of care settings, how well sites participate in network management, and how extensively they participate in projects that

recruit patients, and the metrics available there include how rapidly contracts can be put in place, how rapidly IRB approval can be, what the recruitment metrics are, and how effectively the sites retain patients in the network. The Coordinating Center helps enormously in actually measuring some of these metrics, and we work very closely with them.

An area we're engaged in right now, is strengthening the measures of socioeconomic status, economic, and racial diversity of the actual patient populations available.

We believe this assessment will be very valuable in actually getting a clear understanding of metrics that can help in making future funding decisions and anticipate that the metrics developed through this will be part of any future applications, and will inform merit site-specific merit review.

Well, we've also asked RAND to provide the big picture evaluation of the Coordinating Center itself and data networking and how well it is

working.

And how does structure funding and performance compare with the Coordinating center, and other networking functions of other large networks, and in fact we hope out of this will come some advice on how might the structured funding and governance and operations of the Coordinating Center be changed to meet PCORI's goals.

As I think most of you know I came to this project with some background at the NIH from the CTSA program and All of Us, and I think there are valuable lessons to be learned there in what the financial and other expectation should be. And indeed how to best think of the various Coordinating Center functions. Next slide please.

So just a couple examples of some of the numbers that we have. This shows our current patient coverage, and as you can see, we cover in the networks that we have funded -- a large portion of the country, but there are other areas that are much less well-covered by this network. The areas of most dense patient coverage are, in fact, often

close to the health care systems that have been funded through this network.

Next slide please.

I thought it was also of interest to look at what information we have currently about racial diversity of the patients that are being served by the network. And as one window into that, we've used self-identified data, but use utilizing the data collection vehicles that were in place when this work began. And what this tells us is that in these metrics which are actually evolving and committee people who are advising us on this, but if these are the metrics that were used at this time, patients are asked both to identify their race and their ethnicity.

The left-hand panel shows the 700 approximately positive children who were found to be COVID-19 positive and the right panel shows the approximate 21,000 first and positive patients -- adult patients. And as you can see, a reasonably sizable portion of the patients are Hispanic or identify themselves as Hispanic, 26 percent, and

about of 40 percent, identify themselves as not white either -- Black or African, or Asian American.

These are imperfect measures of the diversity of the network, but I still think they're of interest and in one step in learning how effectively this network is able to capture the diversity and ultimately, the special needs of underrepresented populations in the research enterprise.

I think this will be an important strategic question for this Board is, is how strong and important that is an emphasis for PCORI funding generally, but specifically for PCORnet.

So, that's the comments I wanted to provide you as some background. I want to now turn this, the mic over to Claudia. She'll outline some of the next steps and then we will be interested in your comments prior, to a needed vote on extension funding. Thank you.

DR. GROSSMANN: Thank you, Josie. So now as Josie mentioned I will get into some of the details around the timeline and specific activities

that we see as leading up to a Phase 3 of PCORnet infrastructure funding.

So as laid out in this slide, fall of 2020 will include the evaluation activities Josie described in the previous slides in order to inform the development of the strategic vision for Phase 3 of PCORnet. This would culminate in a Board vote at the beginning of 2021, followed quickly thereafter in early Winter of 2021 with solicitations for the PCORnet networks and the Coordinating Center. This would allow for selection, approval, and contracting of those awards by late Summer of 2021.

So, this is in a quick timeframe and an ambitious one, but this extension funding would maintain the PCORnet networks and Coordinating Center while the Board develops its strategic vision for Phase 3. The solicitations can be developed and awards are reviewed and selected.

Next slide please.

So as Josie started off, she reminded everyone that almost exactly a year ago the Board approved PCORI's budget for fiscal year 2020, and

that included $37 million for PCORnet funding. Due to a number of considerations and delays as she laid out, including COVID-19, those Phase 3 solicitations planned for this Spring were not released, and therefore fewer funds were expended that that was anticipated.

We are requesting to approval to commit $17 million of the $37 million previously approved to extend the PCORnet networks and the Coordinating Center. So just to be absolutely clear, no new funds are being requested for this extension.

And as mentioned before, this extension will allow for the development of a strategic vision, the development of solicitations, their release, applications to be received, and then awards to be reviewed and selected.

Next slide.

So just to review the actual numbers for the fiscal year 2020 approved commitment plan. As you can see in the left most numerical column, 37.2 million were approved. In the next middle column only 6.3, of those 37.2 were awarded in 2020,

leaving almost $31 million available for this extension period.

Next slide.

Of the 30.9 million remaining we are proposing to use 17 million of those to extend the PCORnet Clinical Research Networks, Health Plan Research Networks, and the Coordinating Center, as you can see here, leaving almost 14 million that could be carried forward for 2021 and for use in Phase 3.

So I'll stop there and ask for any questions.

CHAIRPERSON GOERTZ: Thank you. Thank you so much, just before we before we get started on our discussion, I wanted to let you know that there are three Board members who have notified us of their intention to recuse themselves from the deliberative discussion and vote on PCORnet extension funding, based on a potential conflict of interest. These include myself, Michelle McMurry-Heath, and Barbara McNeil. If any other Board member believes they should recuse themselves from this deliberative

discussion and vote, please feel free to do so.

All right. Thank you to both of you for this really in-depth presentation regarding PCORnet infrastructure. I'd like to now open it up for Board discussion.

Just a reminder to Board members to please identify yourself and put yourself on webcam when you're speaking.

Bob.

DR. ZWOLAK: Thank you. Hi, it's Bob Zwolak. It was a great overview and I want you to know that in general I certainly endorse the entire concept, but my question has to do with my own unofficial benchmark for PCOR net, which was the ADAPTABLE Trial, it was, it was one of the very original and in fact, large trial of the two doses of aspirin and Kim teased us a little bit earlier in this presentation with a preliminary publication regarding ADAPTABLE. I think it was a publication on the design of the ADAPTABLE Trial, but it was my vague impression that ADAPTABLE should be finished or almost finished, and it would be a wonderful

benchmark if this huge landmark trial which included many innovations and innovative applications of PCORnet would be done or nearly done. So I wonder if we could have an update on that briefly.

DR. BRIGGS: Yeah, thank you. It is almost done. Kim or -- Kim, can you provide an update on where we are with ADAPTABLR.

DR. MARSCHHAUSER: So ADAPTABLE has finished recruiting, and they are doing their analysis so it will be completed in the coming months, in early 2021, and in part of all of our demonstration studies as well is an aim for evaluation and so we should have some really good understandings of what you mentioned Bob, about how they've used the infrastructure to do this large pragmatic trial. So we will be happy to report back soon about all of those results.

DR. BRIGGS: You know the other very large trial that's going on, actually, larger investment than ADAPTABLE. ADAPTABLE, I think it's in the order 25 million, is the large prevention trial that the NIH is funding to look at the benefits of

statins for preventing dementia, and that study was funded about a year ago. They enrolled their first patient earlier this month. It's a public, it's an NIH-funded trial, not a PCORI trial. But I think one trial learns from the other. And it will be both informative to hear all that we learned from ADAPTABLE and it will also informative to look at how those lessons are then applied to this second large phase trial.

One of the hard questions I think that this Board should struggle with in the coming time, is how much optimization of the common data model to serve the needs of studies like that, whether that should be a priority. That would be my advice. But it does help if that is identified as a priority. It helps in making some of the resource allocation decisions in building the common data model.

CHAIRPERSON GOERTZ: Bob, did you have a follow up question or comment?

DR. ZWOLAK: I'm fine, thank you very much.

CHAIRPERSON GOERTZ: Okay, great.

DR. BRIGGS: Thanks for the question Bob.

CHAIRPERSON GOERTZ: Any other comments or discussion points? Questions?

Chris.

DR. FRIESE: Thanks Christine.

Josie, Kim, Claudia, thank you so much for your presentation today and I know I've spoken with many of you on these matters for PCORnet. And again, I remain very supportive of PCORnet to really be the crown jewel of comparative-effectiveness research and see a great deal of promise, and I think the work ahead for the Board is to really help set that strategic vision, so that we can really be very forward thinking with our funding commitments and our budgeting moving forward so that we're aligning our financial resources and our staff resources and our other resources to really meet the shared vision of what we can do.

So I'm very supportive of that.

You know through other communications I have some lingering questions about the current commitment in front of us, so I plan to abstain from

today's vote.

Just two quick comments.

One is, I think we want to go beyond counting the numbers of people who access the PCORnet from the Front Door and really go to end-user satisfaction and the experience and the diversity of entrants, both from an institutional and individual perspective. So I'd encourage us to think about that.

And the second, and this might be a question for Claudia and Kim, quickly is -- again, I will abstain this time because I'm missing some key information for my own decision-making, but is it expected that all the CRNs and HPRNs would be funded if this motion were to pass, or is there some attrition or reduction in the number of networks that will be funded moving forward?

Thanks very much.

DR. BRIGGS: The extension funding is not going to be a competitive one in which the number of networks is changed. We are asking the Coordinating Center for help. There about 70 data-marts, and

some changes in allocation of funds to data-marts may evolve from the work that's ongoing. But this is extension funding. The question of competing and other configuration of the network at the next phase will be a process that will require careful merit review.

CHAIRPERSON GOERTZ: Thank you. Great.

Any other further questions or comments?

[No response.]

CHAIRPERSON GOERTZ: All right, I'm going to ask then for a motion to approve of the $17 million in funding to extend infrastructure project of PCORnet networks, and the PCORnet Coordinating Center.

DR. LEVINE: So moved.

DR. TROEGER: So moved. This is Kathleen with a motion.

DR. SIGAL: Ellen, second.

CHAIRPERSON GOERTZ: Okay, Kathleen, and then, Ellen. Thank you.

Are there any further discussion?

All right, Kat I'm going to ask for a roll

call vote then.

MS. JACKSTADT: Certainly Dr. Goertz.

Kara Ayers.

DR. AYERS: Approve.

MS. JACKSTADT: Larry Becker.

MR. BECKER: Approve.

MS. JACKSTADT: Mike Lauer filling in for Francis Collins.

DR. LAUER: Approve.

MS. JACKSTADT: Jennifer DeVoe.

DR. DeVOE: Recused.

MS. JACKSTADT: Alicia Fernandez.

[No response.]

MS. JACKSTADT: Christopher Friese.

DR. FRIESE: Abstain.

MS. JACKSTADT: Christine Goertz is recused.

Mike Herndon.

DR. HERNDON: Approve.

MS. JACKSTADT: Russell Howerton.

DR. HOWERTON: Approve.

MS. JACKSTADT: Gail Hunt.

MS. HUNT: Approve.

MS. JACKSTADT: David Myers, filling in for Gopal Khanna.

DR. MYERS: Approve.

MS. JACKSTADT: Sharon Levine.

DR. LEVINE: Approve.

MS. JACKSTADT: Freda Lewis-Hall.

DR. LEWIS-HALL: Approve.

MS. JACKSTADT: Michelle McMurry-Heath is recused.

Barbara McNeil is also recused.

Gray Norquist.

DR. NORQUIST: Approve.

MS. JACKSTADT: Ellen Sigal.

DR. SIGAL: Approve, and I want to thank Josie for your really hard work on doing all of this. Thank you.

DR. BRIGGS: Thank you.

MS. JACKSTADT: Kathleen Troeger.

DR. TROEGER: Approve.

MS. JACKSTADT: Janet Woodcock.

[No response.]

MS. JACKSTADT: And Robert Zwolak.

DR. ZWOLAK: Approve.

MS. JACKSTADT: Dr. Goertz, the motion passes.

CHAIRPERSON GOERTZ: Thank you so much, Kat. And thank you, Josie for your leadership and for your hard work as well as all of the other many staff who have worked so hard to help bring PCORnet to this point.

All right. Our next agenda item is commitment planning and Nakela I'd like to turn the meeting over to you to lead this discussion.

DR. COOK: Thank you so much, Christine.

In this next part of the agenda, we're going to begin a multi-part discussion on commitment planning for the future, and the focus today is going to be a big picture focus in terms of the arc of commitments that we'd like to envision for PCORI moving forward.

I'm going to show you a couple of model options to get your input on the opportunities they present as well as some of the implications, and

ultimately ask for the Board, a model that they would prefer that you would prefer to pursue over the next 10 years. Though I recognize that this model may need to be revisited with time.

Next slide.

So the purpose today is to determine the commitment planning model for 2021 through 2030, and we'd like you to consider opportunities and implications and ask ultimately what model you prefer, as well as hear some of your thoughts about advantages and disadvantages that you may see in a preferred model.

Once we have a vote on a preferred model, or even the key elements of a model that may not be necessarily presented here but is desired, then we will then go and develop a three-year commitment plan that we can bring back to the Board for approval at a future meeting.

Next slide.

So this slide displays the four big picture model options and approaches to guide our commitment planning over the period of 2021 to 2030. And on

the left is a depiction of the funding, over the past eight years just as a point of reference. And just to show you how these models are pictured I'll go through what each line represents. The black line on the top of this graph represents all PCORI commitments and the blue line underneath it represents a subset of the overall commitments that are dedicated to research commitments. And then, there's a green line that represents a subset of overall commitments that are dedicated to the dissemination and implementation commitments.

And I'll note the reference model of the past eight years, has an average commitment of about $400 million per year over those last eight years, with a peak of about $554 million total commitments around 2015, which was related to investments and PCORnet.

So on the right side of the slide, I'll walk through each of these different models to consider for the future. And the first of the four different models for the future is the steady state model. And this model essentially assumes that all

PCORI revenue is committed in an even distribution across the years.

The next three models proposed more of a front-loaded approach; the ramp up/ramp down model has a steep peak in research funding commitments in the early years post-reauthorization, and then declined down back to a steady state in just the latter few years. The hybrid model number one is a front-loaded model with an early peek and predominantly research funding commitments and a decline to a steady state average of research funding commitments over the out years. And hybrid model two is also a front-loaded model with an early peak, a little less than hybrid one in research funding commitments and then it declined to a steady state average of research funding commitments that's actually a little higher than what we saw and hybrid number one.

And all of the models have an increase in dissemination and implementation funding, with increasing research results that are anticipated over the years.

Next slide.

I'd like to take a moment to look at each one of these different models in more detail, as well as some of the implications for each model.

Let's start with the steady state model. And while this model provides a predictable commitment level to the research community and an operating model for PCORI that's more predictable. I've heard less resonance for this approach from the Board, it does allow flexibility in the out years to be able to adjust for large commitments related to either unforeseen or emerging priorities, and all the models presented today do not commit ahead of the overall 10-year revenue described in our reauthorization language, but some do borrow from anticipated revenue in the coming years for commitment and this steady state model does not.

And lastly, the steady state model because it's not front-loaded will have the smallest amount of research results as outputs after about five-plus years of investment.

The ramp up/ramp down model. We also heard

that this one may be a little less attractive of a model for the Board, but it's presented for completeness to garner the Board's input. And it's the steep gear up/gear down model, and may require a surge of up to an approximate 30 percent or so of PCORI's staffing and operations to support the awards processes and provides, I would say the least flexibility in the out-years as compared to the other models for large investments that may be needed for emerging priorities or opportunities that come in the out-years.

It does commit ahead of revenue in several years, up to about 300 million per year in total commitments in some of those years, yet it does have the potential for the greatest amount of research results in about five years time, due to the steep investments early on in reauthorization.

The hybrid one model attempts to blend the positives of the steady state and the ramp up/ramp down, and essentially has this early peak for total commitments of around 650 million, and an early peak for research commitments about 550 million per year.

It does require significant gear up and PCORI operations and staffing maybe up to about 20 percent above where we are now, and has some limitations on the flexibility for large commitments in the out years given the expenditures early in the reauthorization period. And the steady state commitment funding in the out years is probably about equal to or a little less at about 250 million per year than what we had done and seen over the past eight years of PCORI commitments. plus, there's some predictability for the research community and thinking about that steady state portion after that early upfront surge.

This model does commit ahead of revenue but to a lesser degree than the steep ramp up/ramp down, and it is anticipated that we would have a significant amount of results available in about five years due to the front-loading.

And the hybrid number two model also attempts to blend some of the positives of the steady state with a front-loading approach and it has a more modest early peak for total commitments

of about 550 million and research commitments of about 450 million. And there's less effect on the year-to-year staffing and operations, it's a little bit more stable there, but we do anticipate that it's so needed a surge in staffing and operations to support the Research Award process.

And there's minimal committing ahead of revenue in this proposed model. And it maintains some flexibility for large commitments, such as the funding of emerging topic areas or even funding large studies or single-large studies that may emerge or even more dissemination and implementation opportunities. The steady state commitment funding in the out years of this model is more per year than what we've seen on average in the prior eight years, so something close to about the 350 million per year for research commitments in steady state.

Plus, there's some predictability for the research community at a higher level or greater level than the way in which we have operated in the past. And many large studies would have been completed in the early ramp up phase, that would

allow time for implementation by the time of our next reauthorization discussions.

Let's go to the next slide and we'll take one of these model options and go into a little bit more detail for greater understanding, and this is specifically taking the hybrid model option number two, and looking at the yearly commitments from the past and projections from the future in this specific approach.

And in the past, you'll see the yearly commitments averaged about 388 million per year. And the projections with this model show a point estimate and the potential variability around the point estimates, that's the gray band around the solid line, the darker solid line.

And this gray band, the potential variability around the point estimates, really represents the fact that we're rarely able to really predict with precision. And so, we want it to represent the range in which the commitments may fall, and beyond the front-loading the steady state period has a range as well which accounts for a low

and a high assumption about PCOR fee which could have some fluctuation over the years.

So this model peaks at about $500 million in commitments and overall, and about 450 million in research commitments specifically.

Let's go to the next slide.

This slide I'll give an example of a three-year commitment plan that could correspond with one of the model approaches and this corresponds with the one seen on the prior slide, hybrid number two, and it shows how we would anticipate developing a commitment plan based upon the Board's decision regarding the overall model approach, and we would envision a three-year rolling commitment plan which we could revisit with the Board as needed.

And this specific commitment plan represents about a 50 percent increase in research funding from the past average, and doing so by offering a full complement of PCORI funding announcements in all three cycles, averaging about 150 million per cycle.

And just as a point of reference,

previously we've typically offered each type of query funding announcement in two of the three cycles.

This commitment plan also represents a doubling of dissemination and implementation funding from past averages and anticipates twice as many dissemination and implementation results or research final results for dissemination and implementation in the next few years from investments, like the pragmatic clinical studies, PFA, and targeted topics.

It also represents a significant decrease in the infrastructure components with the maintenance costs of PCORnet that Dr. Briggs just talked about to be less than half of what we've previously invested in terms of the building costs. It also represents some increase in engagement funding with more engagement awards needed really to support the higher level of research and dissemination and implementation commitments.

And similarly also has an increase in workforce funding. There's also represented in this

model an average of about 50 million per year available for flexibility for new initiatives or unanticipated or emerging opportunities that may come about for PCORI to take advantage of.

Next slide.

We recognize that for most of these models PCORI will need to continue to ramp up post-reauthorization for staffing and operations to really fulfill these new requirements and, as such, we're thinking about a multi-pronged approach that would accompany a three-year commitment plan that would undergird the model approach that the Board would prefer to take.

And this may include re-staffing key functions as well as expanding operations for award support and the oversight of awards. We also recognize we can learn from the past 10 years, and reexamine our processes for opportunities for efficiencies of scale. And we anticipate that we'll need increased engagement with stakeholders and researchers to enhance our pool for robust research applications to fulfill these requirements.

And each model does represent a different staffing and operational implications and some early rough estimates were given that would be refined post-decisions on a model, including some of the following things. In the steady state model we anticipate there probably would be very little change in terms of the need for increased staffing and operations. However, a ramp up/ramp down model may have the steepest implications for expanding PCORI staffing and operations, whereas the hybrid number two model may have the smaller amount of necessary increase for the early peak approach and steady state given it's a more blunted peak as compared to hybrid number one.

Next slide.

We also wanted the Board to consider the other considerations that underlie the model and that we decide upon and want to measure in terms of thinking about success with our selected approach. So in addition to dollars that are committed and ultimately expended, there may be other measures of success that we may want to consider, such as even

offering the full complement of PFAs in all three cycles. And if this makes sense to consider in terms of our success measures as we move forward in thinking about the level of commitments we'd like to make, and this could include having the broad PFA with special areas of emphases, our pragmatic clinical studies, and PLACER awards that Josie just mentioned, including certain priority topics.

We also could and identify the number of targeted announcements per cycle that we're interested in pursuing, as well as if they're novel PCORI funding opportunity announcements to pursue off cycle in terms of thinking about that as a measure of success. I also think there are opportunities to measure increased influx of applications and/or the higher rate of fundable applications. And there may be existing data that can help inform the metrics that we could develop, if such a measure for success were thought to be attractive.

And lastly, the innovations and efficiencies in our funding processes are another

way that we could think about measuring our success and have existing data that we can use to develop such metrics and targets for success measures.

Next slide.

So I just wanted to revisit the model approaches to have them fresh in your mind as we start to have the Board discuss the preferred approach. And following this discussion, we would like to call for a motion to approve the development of a proposed three-year commitment plan.

Next slide.

And we anticipate with this motion that perhaps the proposed three-year commitment plan could be consistent with either the proposed steady state approach, the ramp up/ramp down model, the hybrid one model or the hybrid two model, or perhaps there's another model that would actually be characterized based on the Board's discussion with certain key elements such as whether or not you'd like to see a front-loaded model, and if so, to what degree? The vision, perhaps of what steady state would look like in the out years, or the degree of

that flexibility that's preferred.

So we're really interested in hearing your thoughts about the model.

Next slide.

And essentially, would be asking you to consider the opportunities and implications for the model that may be preferred. The advantages and disadvantages you may see for the preferred option, as well as whether or not you have additional thoughts about the resources needed to accomplish the goals of the preferred option. And lastly, if there are thoughts about how you would measure success, and what metrics or targets resonate with you that you'd like to see us pursue.

So Christine, with that, I'd like to turn it back to you for the Board discussion.

CHAIRPERSON GOERTZ: All right, thank you. Thank you so much, Nakela. So would anyone like to open it up for discussion? Any questions or thoughts? Russ.

DR. HOWERTON: I would like to thank you for an excellent presentation. I would like to

suggest that I think something different than steady state is needed. I favor a ramp up.

I believe there are two variables in play. One is more science, more quickly available. But I also believe the concept of having a highly functioning installed research base in the out years as we approach reauthorization would be reasonable. And to me, option two, ramp up number two seems to balance those and not apply too disruptive of an increase in resources needed at the beginning. So as a starting marker for discussion, I'll come out in support of hybrid model two.

CHAIRPERSON GOERTZ: Thank you, Russ.

I have Mike, then Alicia, then Gail. And then Sharon.

DR. HERNDON: And I kind of have a question Nakela that influences my, maybe bias, towards which model I like.

What degree of confidence --I think, can we and not the Board but we PCORI have that the ramp up could be hit as projected with staffing and with proposals? I'm kind of thinking hybrid model one as

the projected knowing that kind of historically, we've underspent the bit, and then it may end up looking more like hybrid model two, you know, after our intent to make it look maybe more like model one. And that may be bad thinking that, I just -- the ramp up seems pretty steep. But I do -- I agree with a lot of what Russ has said. But can you just talk a little bit about your confidence to hit the ramp up projections as outlined?

DR. COOK: Certainly, Mike. It's a great question. And I think you were asking about the confidence to hit that early peak in hybrid number one, the one that kind of has a steeper peak.

DR. HERNDON: Right.

DR. COOK: And one of the things I would say is that I think it probably means a slight phase shift in where the peak hits, meaning that we probably would need to spend the course of the next year ramping up to be able to start to move to that peak. So as represented on the graphs, we probably would start to hit a peak around FY22 to FY23, as opposed to in the hybrid number one starting to ramp

up toward that peak by FY21.

So that builds in a little bit of that time to actually both recruit, as well as think about the processes and changes in our processes that are going to be required, and engage the research community in the way we think it'll require in order to have the robust applications in.

So those are maybe three spaces we've been focused on in terms of what it's going to take. And I tried to give a little bit of kind of difference between hybrid number one and hybrid number two in terms of what we think the percentage increase of staff would be in terms of a 30 percent -- I'm sorry, 20 percent versus 10 percent, in that type of ramp up, but we do think having a year to, to get us to that point is probably what it's going to take.

DR. HERNDON: Thank you.

CHAIRPERSON GOERTZ: All right, thank you. Anything else, Mike?

DR. HERNDON: No, that's good. Thank you.

CHAIRPERSON GOERTZ: Gail?

MS. HUNT: Yeah, I really appreciate all of

the word that has gone into development and I think that we can draw from just from the development of the four different models. It's great.

I tend to be more interested in hybrid model two, because it looks as if there's the opportunity to get results, maybe a little quicker than some of these others, as you put it for five years, results after five years. Although I'll just say I think we -- this doesn't maybe take it into consideration, but we need to be thinking along the lines, not just have big five-year projects that we can fund, we need to be thinking about short-term projects, like we've just been talking about with COVID-19.

So short-term projects, maybe, you know, finding a topic that would really lend itself to one-year quick return and then a lot of three-year projects rather than going five years like what is more NIH. But that's that we're supposed to be more nimble than that. If you don't mind my saying. I know you're on Mike.

The other thing is, though, in every one of

these, you could -- the D&I is so minimal, even though as you put it, it's doubling their relation to what they've gotten in the past. But if you're actually saying we're now in PCORI 2.0 and we really don't have results that have come out of PCORI 1.0, more results that we can generate this dissemination and implementation from. That we're going to have to wait sort of until there are more results at the end of -- I don't know, five years, I guess is here, where we're really going to have results. And even then, the green line is just minimally raised.

So I would suggest that we say something about we're going to -- we in 2.0, are going to invest PCORI's funds substantially in dissemination and implementation as soon as the results are available. Thanks.

CHAIRPERSON GOERTZ: Thank you. Thank you, Gail. Very important comment.

Sharon?

DR. LEVINE: So thanks. And I agree with the previous comments, this is a terrific presentation, and extremely clear as to what the

choices are.

Looking at the models, it seems to me the, potentially, the major difference between hybrid model one and hybrid model two will be in the execution. And the -- if you will, the structured thinking behind the two is quite similar and whether it looks in the end like model one or model two will depend on the volume and quality of research proposals that come in. And the -- quite honestly, the speed with which you're able to figure out the staffing plan and attract the kind of research proposals that we've been aspiring to.

And I also want to agree with I was -- I was also going to agree with Gail's comment about dissemination and implementation. And looking at both hybrid model one and hybrid model two. The appeal to me of hybrid model two, particularly around this notion of flexibility in later years, I think the implication on the slide was that it was flexibility around research funding, but I suspect it also creates increased flexibility for committing funds to dissemination and implementation.

And particularly, if we are fortunate enough to have a homerun, particularly, potentially, in the public health sphere, where there was real opportunity for implementation in spread to a majority of the 50 states in this country, I would favor a model that creates the flexibility to actually make a sizable investment to try and make that happen. Because I think PCORI has a real role to play going forward in broadening our notion of research to public health. And I think having that kind of flexibility around dissemination and implementation, which hopefully, either of the hybrid models would create -- but particularly hybrid model two is what appeals to me about it.

Thanks.

CHAIRPERSON GOERTZ: Thank you, Sharon.

Bob?

DR. ZWOLAK: First again, I'd also like to compliment Nakela and her team, for providing these models where I think these -- the ability to look at options in a thoughtful way, is a benchmark that we're seeing here at today's meeting. So again,

thank you.

I believe there are external variables, external limiting factors, and internal variables or internal limiting factors. The external variables are -- are there science questions with capable scientists to carry out the research? And we think there is, we hope there is, but we're not 100 percent sure there is.

The internal variable is something that we can have impact over, we can ramp up to meet the demand. And quite honestly, I do believe in more science quicker as Russ said, and to me, that is reflected in hybrid model one, if we can do it, and I think it would be quite reasonable to set the hybrid model one as a target. And then, if there are external limiting factors, that reduce the outcome to hybrid model two, then so be it.

It'll still be quite good, but I do worry if we focus on just setting our internal capacity to hybrid model two that, either due to external limitations or internal limitations, we may not achieve hybrid model two. So my personal sense, is

to shoot for hybrid model one so that our actual outcome is at least hybrid model two.

Thank you.

CHAIRPERSON GOERTZ: Thank you, Bob.

Sharon, did you have another comment?

Sharon, you're on mute.

DR. LEVINE: Is it worth looking at a hybrid model 1(b)? That would be halfway between model one and model two that would, you know, look at a half a billion dollars early peak and sort of divides the distance between those two hybrid models, but retains the benefits of each.

CHAIRPERSON GOERTZ: Thank you Sharon.

Jennifer?

DR. DeVOE: I was going to echo what Sharon just said and make a motion for a hybrid model 1.5. If that's possible.

And I apologize, my webcam seems to have gone dark, which is probably okay, because I've been moved up to my bedroom with all the various rooms in my house being used for classrooms right now. So --

CHAIRPERSON GOERTZ: Yeah. All right.

Thank you. Thank you, Jennifer.

Nakela, do you want to comment on this idea of a model, you know, 1.5, or 1(b)?

DR. COOK: Yes, absolutely. And this actually goes -- is consistent with our thinking that if you would have preferred a different model than what's presented, just understanding the key elements would be critical. So what I'm hearing in the 1.5, or the 1(b) is this idea of having some sort of peak, kind of an early peak, that may be somewhere between the peaks that we were showing of 650 million at a peak for hybrid number one, or in hybrid number two, it's 550. So splitting the difference there may be peaking around 600 million or so.

And also, I think, I heard a desire to retain flexibility in the out-year, similar to what we had before. So the width of that peak may need to be adjusted a little bit in order to think about that.

And I also may have even mentioned on the detailed slide that I showed for hybrid model number

two, and you may remember in the projections, there was that gray range around the projection. And the top of that range is kind of like the 1(b) or the 1.5. So there is a little bit that we've already modeled, that I think fits close to what you're describing.

And certainly one motion could be that you would propose the development of a three-year commitment plan consistent with a model hybrid number 1.5, that peaks at about 600 million for total commitments and preserves out-year flexibility for emerging priorities, including research and dissemination and implementation. And then we can show that to you in a follow-up meeting with the three-year commitment plan that will correspond to that.

CHAIRPERSON GOERTZ: All right, thank you, Nakela. I'm going to ask for -- it sounds like there's some interest in coming up with this this hybrid model.

Mike, did you have a comment or question? You're on mute.

DR. HERNDON: I just wanted to say that I think of all the comments that have been made, that sounds very consistent with kind of what you're hearing from all of us. So sorry, Christine. My timing was bad.

CHAIRPERSON GOERTZ: No, that's good. I appreciate that.

Well, it sounds like there's some momentum then towards this model 1.5. And so, I'm just going to ask for a motion. And then we'll see if there's a little bit further discussion after that.

So can I have a motion for model 1.5?

Bob, is that a motion?

DR. ZWOLAK: It is. I move model 1.5 with approximately 600 million peak target that retains flexibility in the out years.

DR, HERNDON: This is Mike, I'll second.

CHAIRPERSON GOERTZ: Okay, great. Thank you. Thank you, Mike.

All right, why don't we go ahead and see if there's some further discussion. We've got Freda and Alicia. Freda?

You're on mute.

DR. LEWIS-HALL: Sorry, I was just trying to get in to second. I'm not as fast on the draw some others, I guess.

CHAIRPERSON GOERTZ: Okay. All right.

DR. FERNANDEZ: Same here. I think that's an excellent proposal.

CHAIRPERSON GOERTZ: Okay, great. Thanks to you both, Mike.

DR. LAUER: So I agree this is a strong proposal, but I wonder about giving Nakela and her staff the flexibility to work with that because when they dive deeper, they may discover something that that may make more sense. So you might say 1.5 with some flexibility.

DR. FERNANDEZ: I think all of these are all aspirational.

DR. LAUER: Yeah.

CHAIRPERSON GOERTZ: All right. So are -- Bob and Mike, are you willing to take that friendly amendment of with, you know, some flexibility to that motion? Is that okay?

DR. ZWOLAK: Works for me.

DR. HERNDON: Yes --

CHAIRPERSON GOERTZ: All right, thank you.

All right, any further discussion?

[No response.]

CHAIRPERSON GOERTZ: Then I'm going to go ahead and call the question. We can actually have a voice vote for this. So I'm going to -- so all those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[None.]

CHAIRPERSON GOERTZ: Abstentions?

[None.]

CHAIRPERSON GOERTZ: Great. Well, thank you.

Thanks to everyone. It was a great discussion and thanks, Nakela, for just all the thought that went into coming up with these models, and we very much look forward to seeing your implementation plan when you -- as you work through the, the details and figure out how to execute on

this.

DR. COOK: Thank you all.

CHAIRPERSON GOERTZ: All right. We are even though I know we're supposed to have a break soon. I think we're going to plow ahead and go through our budget.

I know, almost all the committee members, if not all the committee members, have already seen this budget in the context of the various strategy committees. So let's turn it over to Larry and Nakela If we can try to move through this as quickly as is feasible. That would be great.

MR. BECKER: Thank you, Christine. So the FAC does recommend for the Board's approval of the fiscal year '21 proposed budget.

It represents a culmination of work by PCORI's departments. Outline the key activities for PCORI will be embarking on in 2021. In support of PCORI's institutional goals and objectives as well as the costs associated with those activities.

PCORI has shared information with each strategy committee, as Christine just mentioned, on

the proposed 2021 key activities in the proposed budget under their oversight, so everybody's had a chance to look at this, as you mentioned.

The FAC looked at this several times over the last several months. And as I mentioned, we do recommend it for Board approval, and so I'm going to ask Nakela to walk us through the budget.

DR COOK: Thanks, Larry, we can go to the next slide.

You're going to see in this budget presentation, just a few key definitions that are included to frame the discussion. But we'll also go over the revenue and expenditures and the projected fund balances and then get to our proposed fiscal year 2021 budget.

As you see on this slide, as we start to review with the budget, I just wanted to make the distinction between the commitments and expenses. And the commitments are what we were talking about in our prior dialog, and now we're turning to think about commitments. And the key thing to think -- to keep in mind is that PCORI's annual budget is really

reflecting these expenses. And the commitments actually refer to the amount of funding that PCORI intends to award or has awarded.

Whereas, if we can go to the next slide, expenses really talk about the predominant part of our award payments, which are expensed on the award commitments that we previously made, as well as the operational expenses for the organization.

Next slide.

So this slide demonstrates our fiscal year '20 projected fund balances, and the fund balance represents the available resources to PCORI taking all the assets and liabilities into account. So on this slide, you'll see at the beginning of fiscal year '20, PCORI had a fund balance of 1.3 billion, we received 455 million in revenues this fiscal year, and we project about 364 million in expenses.

So at the end of the month, we estimate a fund balance of $1.4 billion, and the outstanding award obligation balance is about $1 billion. So these outstanding award obligations will come obligations will come due and payable as the

research and other projects progress over time. So they may not all occur right in the same fiscal year.

Next slide.

And this slide focuses on the FY '21 fund balance. In FY '21, we expect to receive about 525 million in revenue via the PCOR trust fund. And we're anticipating about 399 million in expenses, which is our awards payments from prior commitments as well as our operating costs and we'll go through that in our FY '21 budget.

By the end of FY '21, we actually project a fund balance of $1.5 billion and the outstanding award obligation balance is estimated to be nearly $1.3 billion, and that's as we currently see it. But this could change a little bit as we bring that three-year commitment plan that we just talked about back to the Board for approval based on this model approach that we'll be using going forward in that 1.5 hybrid model, or the 1(b)-hybrid model that we just discussed. So there may be some fluctuation in that amount.

Please note that the outstanding award obligations do include assumptions that could change and we just wanted to flag that, as we know we're having these discussions with the board.

Okay, next slide.

Here's the proposed budget for fiscal year '21. And in the revenue column, you'll see that in FY '21, we're expecting to receive $525 million in revenue via the PCOR trust fund. And you may recall that back in FY '20, there was an approved budget that focused on $21 million in revenue, which was budgeted at that time with -- due to the uncertainty about reauthorization that that existed at the time the budget was approved. And so, it was limited to just the interest on the trust fees. But as you can see in the FY '20 projection, once the funding was reauthorized, we actually received a total of 456 in revenue for FY '20.

If you look at the expense component of the budget, we are proposing a fiscal year '21 budget $399 million, it's nearly flat compared to the approved budget in FY '20. And expenses, again,

remember, mostly represent those award payments, they make up the largest proportion of the budget, about 80 percent of all the budgeted expenses. And these were based off of the commitments that were approved in prior years.

While the budget proposal for FY '21 is really expected to increase over projected expenses for FY '20. The proportion of the costs for all the major budget components is expected to stay more or less the same and these ratios have remained quite stable over several years. The program support and admin services are roughly comparable to what was also projected in prior years.

Given the Board has seen this budget and the FAC has received -- the Board strategy committees have seen this budget and the FAC has recommended approval. I just thought I'd ask if there are any clarifying questions. Otherwise, we can move forward for the motion.

Christine, I'll turn it back to you.

CHAIRPERSON GOERTZ: Okay, thank you, Nakela.

All right. Any questions or comments?

[No response.]

CHAIRPERSON GOERTZ: All right. I'm going to ask for a motion then to approve the proposed 2021 budget.

MR. BECKER: This is Larry, I'll make the motion.

CHAIRPERSON GOERTZ: All right. Thank you, Larry. Mike are you a second?

DR. HERNDON: Second.

MS. HUNT: I'll second it.

CHAIRPERSON GOERTZ: All right. I think I saw Mike first. So we'll go with Larry and Mike.

Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right. Kat, can we have a roll call vote, please?

MS. JACKSTADT: Certainly, Dr. Goertz.

Kara Ayers.

DR. AYERS: Approve.

MS. JACKSTADT: Larry Becker.

MR. BECKER: Approve.

MS. JACKSTADT: Mike Lauer filling in for Francis Collins.

DR. LAUER: Approve.

MS. JACKSTADT: Jennifer DeVoe.

DR. DeVOE: Approve.

MS. JACKSTADT: Alicia Fernandez.

DR. FERNANDEZ: Approve.

MS. JACKSTADT: Christopher Friese.

DR. FRIESE: Approve.

MS. JACKSTADT: Christine Goertz.

CHAIRPERSON GOERTZ: Approve.

MS. JACKSTADT: Mike Herndon.

DR. HERNDON: Approve.

MS. JACKSTADT: I'm sorry, Hike Herndon?

MS. JACKSTADT: Russell Howerton.

DR. HOWERTON: Approve.

MS. JACKSTADT: Gail Hunt.

MS. HUNT: Approve.

MS. JACKSTADT: David Myers, filling in for Gopal Khanna.

DR. MYERS: Approve.

MS. JACKSTADT: Sharon Levine.

DR. LEVINE: Approve.

MS. JACKSTADT: Freda Lewis-Hall.

DR. LEWIS-HALL: Approve.

MS. JACKSTADT: Michelle McMurry-Heath.

[No response.]

MS. JACKSTADT: Barbara McNeil.

DR. McNEIL: Approve.

MS. JACKSTADT: Gray Norquist.

DR. NORQUIST: Approve.

MS. JACKSTADT: Ellen Sigal. Ellen Sigal?

[No response.]

MS. JACKSTADT: Kathleen Troeger.

DR. TROEGER: Approve.

MS. JACKSTADT: Janet Woodcock.

[No response.]

MS. JACKSTADT: Robert Zwolak.

DR. ZWOLAK: Approve.

MS. JACKSTADT: Dr. Goertz, the motion passes.

CHAIRPERSON GOERTZ: Thank you so much. Thanks to everyone.

So we are going to be on a break now until

2:45. So I hope you don't mind if we cut our break for just about five minutes so that we can stay on time and we'll see you at 2:45.

[Recess.]

CHAIRPERSON GOERTZ: All right, next on the agenda is our Strategic Planning Committee report that will be presented by both our co-chairs Sharon and Nakela.

DR. LEVINE: Thanks Christine. And thanks to the Board for this opportunity to give you an update on our, essentially, our launch of our strategic planning process. I particularly want to thank the Board members who have volunteered to take this journey with us. On behalf of the Board: Jennifer DeVoe, Alicia Fernandez, Christine Goertz, Russ Howerton, and Barbara McNeil and Robin Newhouse and Bob Zwolak.

And our intention is to add two new Board members once we have the information from the GAO as to who will be joining us at the end of September, representing both the patient and payer communities.

And again thanks also to the staff: Steve

Clauser, Nakela, Laura Lyman Rodriguez, Michele Orza, and Jean Slutsky who are going to be partnering with us on this journey.

We had our first organizational meeting on August 25th, and the committee members have committed to monthly meeting to get this work done on behalf of the Board and Nakela is going to go through the framework, with which we're going to be using to plan this meeting. But just as a reminder, the strategic planning process will begin with our legislative mandate to renew our national priorities, and the research agenda. And in many ways, I think we are privileged to actually have this opportunity. The 10-year reauthorization is an opportunity to look out ten years and see where the country is today, what the priorities are for the country, and what are the big problems for which PCORI can contribute to finding big solutions, to paraphrase Freda Lewis-Hall.

So with that, Nakela. I'm going to turn this over to you.

DR. COOK: Thank you so much, Sharon and

I'm pleased to provide a little bit of update related to some of the deliberations from the prior Strategic Planning Committee meeting.

Next slide.

So the Strategic Planning Committee discussed a purpose for the committee that's articulated on this slide and it's to work on behalf of the PCORI Board of Governors over the next 18 months to develop and oversee the conduct of a strategic planning process and the development of a strategic plan for approval by the Board of Governors, and as you've seen in prior timeline highlights about the strategic planning process, it's anticipated that the timeframe would take us from now through the Fall of 2021, and if need be, implementation activities could be discussed in terms of how we want to organize related to that at that time.

Next slide.

So this slide represents PCORI's original strategic framework which was developed back in 2013, and it demonstrates that our current national

priorities for research are focused on guiding our research through several strategic imperatives which include engagement methods, research dissemination, and infrastructure that are designed to create a skilled research community, and a methods and patient-centered outcomes research portfolio, communication and dissemination activities as well as a research network.

And all of this was toward the goals of increasing information, speeding implementation and influencing research for an impact that was informed health decisions, better health care, and improved health outcomes.

Next slide.

So as we consider a revised strategic framework for the future the committee discussed our strategic imperatives frame, what we've accomplished in the mid-term and the potential new framing of our long-term goals of shifting our national priorities to priorities for health, rather than just national priorities for research, which could cover this full fan of all the activities that PCORI pursues

inclusive of research engagement and dissemination and implementation, and this framework focuses on what we've heard from the Board as an emphasis on impact for the next phase for PCORI and how we move closer to that as we think about our strategic framework.

Next slide.

So this slide may look very familiar to many of you, it's representing our complex process for strategic planning with the many elements including identifying our national priorities, establishing and updating our research agenda, all through the engagement of stakeholders in the public and focusing on our commitment planning which we've begun today as well as several other related discussions that are going to be important as we move into the next phase for PCORI.

The high-level timeline on the right basically just shows you that we're in the process of engagement around the first component of the strategic planning process, establishing our national priorities and establishing and updating

our research agenda will follow. And that'll be framed by the national priorities that we identify, and we'll bring it all together and finalize the strategic plan hopefully in the Fall of 2021.

Next slide.

So these next set of slides are going to describe the overall sequence of activities in the strategic planning process that the committee discussed and try to break down more clearly what the -- what will happen when in the strategic planning process. And, essentially, we'll also talk about the national priorities in more specificity related to what's happening in that process.

So in general we anticipate that we would be garnering a diverse array of inputs into the strategic planning process. And this could include stakeholder and public input, portfolio analyses that will help us learn from our last 10 years of investment. Our mission and vision are going to be important inputs into this process as well. And we anticipate an external landscape review through either invited panel discussions or reviews of other

seminal materials that could anticipate issues to consider on the healthcare horizon, as well as some panel discussions that you may identify as being important inputs to the process.

And the strategic planning activities that would be conducted by the Strategic Planning Committee and the staff working groups that will undergird this effort, are going to help develop frameworks for the Board discussions and help guide those diverse inputs and to synthesize materials for the Board's input and review, and the Board would then take on strategic planning activities that will involve discussing and reviewing and evaluating and assessing the issues that are presented related to the national priorities, as well as the research agenda.

Some of the issues of short- and long-term research activities as we just were talking about in the prior discussion, as well as scenario planning and thinking about the different scenarios that PCORI will encounter over the near-term and long-term, and reviewing the portfolio in order to help

inform our future directions.

So the Board will also actively engage in the review of the synthesized public comments to inform discussions and the shaping of the strategic planning products.

The outputs that we anticipate will be Board adopted national priorities, and a Board adopted research agenda, and a Board adopted strategic plan, and this will help frame a flexible approach for us to achieve the vision and mission that will provide the room for evolving priorities, but also give us a sense of the implications for some of the tactical and operational planning that are going to be necessary and implications for Board Governance and metrics that we may want to measure our success against.

Next slide.

So if we focus in on what's happening when as it relates to identifying the national priorities given this is the earliest focus in the strategic planning process. We anticipate several inputs similar to what you saw on the prior slide. Our

advisory panels have provided us input already and will continue to provide input through this process, the stakeholders that we traditionally engage as well as the general public will provide input, and we're going to be reviewing the portfolio, and this will occur between the Summer and Fall of 2020 so this is the period we're in right now.

This will flow into the strategic planning discussions where the Strategic Planning Committee will establish the framework for Board discussions, and that will flow into priorities being drafted and posted for public comment, and more planning efforts would allow the Strategic Planning Committee to review the synthesized input from the public, which we anticipate will be late Spring.

And finally, the Board will have the opportunity for that review and discussion and final adoption in terms of the national priorities for the future in the Spring of 2020.

Next slide.

The Strategic Planning Committee also reviewed input that we've received to-date on our

national priorities from the advisory committees, as well as the input from the Board at our July meeting. And this slide just attempts to try to aggregate and provide a high-level summary of what we've heard thus far. And as you may recall four of our five advisory panels have provided input on the national priorities, and the clinical trials the advisory committee still remains for us to get input. And they were asked to what extent are the national priorities still relevant, need to change or add or remove certain elements. And the Board also in its last meeting in July provided thoughts around some of the things that had been heard from the advisory panels on the national priorities.

So some of the comments are the national priorities have served PCORI's mission well. There were some comments around reinforcing the benefit of keeping the national priorities at a high level, in order to allow for the research agenda to really encompass many of the topics that may fall under a priority area. There was an emphasis on disparities as an ongoing national priority and consider the

embedding of that throughout PCORI's work or even a stronger emphasis of moving to elimination versus addressing research.

And we also heard at the Board meeting, as well as with our advisory panel, this opportunity to reflect an intersection with the broader public health ecosystem. There have also been comments synthesized here around the need for clarity and specificity and the definitions of our national priorities, particularly focusing on the language that we want to describe our priorities.

The Board emphasized as well the importance of learning from our existing portfolio and the work done over the past decade when we talked back in July. And this is something that we anticipate being able to bring back to the Board as the Strategic Planning Committee has an opportunity to look at some of the portfolio analyses that may be helpful for the Board.

And we also would like to make sure that we reflect what we heard from the Board related to hearing the perspectives of a broad variety of

stakeholders and the public as we move forward.

We also heard from the Board to think strategically about where we can have the greatest impact. And this was, again, where we heard about that intersection with the public health ecosystem.

So next slide.

The Strategic Planning Committee anticipates that many of the inputs into this process, are the types of things that the Board may have thought were important to hear, but wanted to hear your thoughts and additional inputs that may be important for us to consider.

Some things that we've talked about are the healthcare landscape review, noting any potential shifts that may be important for national priorities We talked about public input that we anticipate even beginning at the annual meeting later this week on the national priorities, so we'll have some input to flow into dialogue very soon from the public. We also anticipate ongoing portfolio analyses, panel discussions that may include health policymakers and thought leaders or congressional leaders, but we're

very interested in other sources of input that may be of interest to you to inform our strategic planning activities.

We can go the next slide and I'd like to turn it back to Sharon to gather any thoughts or considerations that the board may have.

DR. LEVINE: Thanks so much Nakela. And the only the only comment I would add to this is, as you can see from this slide, the national priorities and research agenda, are a big part but not the only elements of the strategic plan. And one of the things that I think the committee, I know the committee talked about and we will need to keep in mind, is that going forward over the next 18 months to two years, could very well be a period of enormous change in this country in terms of healthcare, and PCORI, we need a strategic plan that enables us to be ready to support with solid research the questions that arise out of any changes that we anticipate in the organization and design of healthcare delivery in terms of public health issues that arise.

So, Christine, if you want to moderate questions and thoughts from the Board?

CHAIRPERSON GOERTZ: Sure, happy to do so.

Any comments or questions about a strategic plan that our co-chairs have laid out for us today?

DR. TROEGER: Hi, this is Kathleen. I just want to thank everybody for one, a phenomenal presentation, and two, a tremendous amount of work in a short period of time. I think this represents a tremendous path forward for us and a structure that we haven't seen before.

I like the way it lays out addressing the national priorities and anticipates proposed changes in the way those priorities may evolve and change as our structure grows to include new members of the board.

CHAIRPERSON GOERTZ: Thanks Kathleen. Chris.

DR. FRIESE: Thanks, Sharon and thanks Nakela. This was great, very exciting.

With regard to, I think it was your last slide in your ask and in terms of other groups to,

with whom to engage. I think one group that will be a bit challenging I had some suggestions earlier when -- pre-COVID, is really a listening tour with the professional organizations that support researchers in this area.

My perception is there's a group of folks who see PCORI as a go-to destination for funding and then there's a group of folks who for a variety of reasons, have determined that, at least, based on their history that PCORI was not a place and I think we want to bring them back to us, and get their feedback. So, you know, formally engaging some of these research organizations through their boards and maybe pushing some materials out. Places like Society for Medical Decision-making, Academy Health, APHA.

And then importantly given our newer area of interest for cost in a non-cost-effectiveness, but other costs would be, you know, ISPOR and ASHE, and the health economics groups.

So I think if we do some targeted partnership with those organizations to kind of push

out, you know, let them know about our RFI, et cetera, I think that'll help us a little bit reach some folks that may not be as familiar with our current plans and portfolio. Thanks.

CHAIRPERSON GOERTZ: Great suggestion.

Any other comments or questions?

Bob?

DR. ZWOLAK: Thank you. Sharon and Nakela, that was great. Also, in response to Nakela's question about other groups to query. It's my sense that there's just an enormously wide-dynamic range of the quality of care that we provide in the United States, and we offer some of the best -- of the very best in the world and some of the least good in the world.

And I think that some of the least good is occurs in socioeconomically challenged urban and rural areas. And if we want to improve the healthcare, some research may take place, trying to improve it in those areas so potentially reaching out to the healthcare providers and the academics in those areas in terms of thoughts of not just simply

treatment A versus treatment B for a difficult medical problem, which is certainly our bread and butter but treatment A versus treatment B provided in very challenging circumstances or challenging patient cohorts, might be groups that would allow us to address areas of low-hanging fruit in healthcare disparities.

And so, that would be another -- I don't know exactly who those groups are, but I think you can understand that the types of groups I'm sort of referring to that would help us understand the challenges that we might address in the provision of healthcare with a goal of improving healthcare.

DR. LEVINE: Great.

CHAIRPERSON GOERTZ: Thanks. Thanks, Bob.

Just to follow up on that, I really think this is an opportunity to rethink how we do outreach to people and you know, and Gray reminded us earlier this morning about the work that we did in PCORI's early days in traveling around and making sure that our -- conducting that deep outreach, and I do think that this is potentially an opportunity to engage in

similar exercises. Now we have a whole staff that can help us do that instead of just our Board members.

And also just a reminder that to make sure that we're reaching out to groups of clinicians that that are not always at the table. So, in addition to physicians and nurses, et cetera. There and are just so many health care workers that are really invested in patient-centered care and making sure that we're also reflecting their voices in our work.

DR. LEVINE: One of the ironies of the pandemic is that many of these organizations, these associations that support researchers -- America's Essential Hospitals, for example, are meeting virtually. And so that, in some ways, it may be easier to create a connection while everybody is trapped in a virtual world, rather than having to get on airplanes and begging for time on an agenda. So it's certainly an excellent suggestion, and one that we may be able to actually effectuate more efficiently and effectively than in a prior time.

CHAIRPERSON GOERTZ: I agree.

Any other comments or questions on strategic planning?

[No response.]

CHAIRPERSON GOERTZ: All right. Well, I want to thank this all of the members of the Strategic Planning Committee and all of the staff who are supporting this important work. This truly is the beginning and I look forward to our continued progress on this and ultimately seeing our end result, and also look forward to making sure that this is a living breathing document that continues to guide our actions over the years. Mike?

DR. HERNDON: Sorry, I was a little slow there.

I apologize in advance for kind of the soapbox message. I keep saying that as a payer and a state health administrator, I have to make the comment I think or I couldn’t sleep tonight.

We're just -- our healthcare delivery system is impacting the quality of care. And you know, it's -- I don't think I'm saying anything to anyone on this call doesn't know already, but we are

-- we're living in a system where that, you know, healthcare is driven by procedures and by frequency of care, not by quality of care.

And I just think part of our focus needs to be -- and we need to play a role in getting some evidence out there that quality delivery of care done at a slower and more correct pace is superior to procedure-oriented, fast care delivery. And if we can prove that as PCORI, maybe we could start changing and moving the needle a bit on how providers see patients and literally, literally have an impact on the healthcare of our citizens.

So any research ideas and priorities that could be centered around care delivery reform, and I know we are not talking return on investment, I'm just talking about how we reimburse providers. I think we should not overlook.

CHAIRPERSON GOERTZ: Thank you. Thanks, Mike.

Any other comments before we close off this discussion?

[No response.]

CHAIRPERSON GOERTZ: All right, thanks to both of you.

DR. COOK: Thank you.

CHAIRPERSON GOERTZ: And now we are going to ask four of our board members Larry Becker, Gail Hunt, Freda Lewis-Hall, and Gray Norquist to join us by a video and we're going to have a panel discussion.

These four members of our Board are four of our founding members, they've been with PCORI since the very beginning and they will be retiring from the PCORI Board. This is their last Board meeting and so, we wanted to really have an opportunity to spend some time with each of them and to hear their reflections on 10 years of Board service and their vision for the future.

And why don't we go ahead and what we're going to -- we're going to ask them to make some brief comments and then we will, the Board will ask them some questions. Gain the last bit of wisdom that we can before they before they go off the Board.

So, not to always put you on the spot Larry, but, you know, we'll go in alphabetical order and ask you if you'd be willing to start with your remarks first.

MR. BECKER: So what you asked me is what advice would I would I pass on.

And, you know, thinking back over 10 years some of the things that we're most proud of over the last 10 years is how we engage patients and as Gail will tell you that the caregivers and gave them a real voice. And in the beginning, there were PIs who said, "How are we going to be bleeping be able to do that?"

And we were undeterred and in hindsight, it doesn't look risky. Many might wonder whether it's always been this way. So, the real advice from doing some things like that is to be bold, take risks, it'll pay off in big and important ways. You know, not to shrink from our responsibility and Mike, I think was a harbinger of that, of how do we change some of these things in big ways.

And one former Board member, when we were

doing this, I said, "How we going to do that?" And his comment was, "Well, we're going to fund the research they do. We have the money. And, you know, maybe it's like herding cats and maybe what you have to do is move their food."

So that's one and I'll turn it over to one of my fellow outgoing Board members for another piece of advice and maybe come back later with more.

MS. HUNT: So in alphabetical order that's me.

You know, I think that the biggest thing -- I mean, those of us who were there in the beginning. Everybody remembers Harlan Krumholz, and he always had these great comments about the North Star -- the patient being the North Star, for example, but in one of the early meetings -- actually more than that, he would talk about the fact that, you know, we're going to have like these big boulders, big topics. That we want to take on, big questions. Like the kinds of things that Mike was talking about with health delivery system changes.

But we also need to keep in mind the little

a important pebbles, that are also, we also need to be funding. Things that are short-term but have lots of impact and they have a lot of visibility. And people are interested in the answer to that question.

And one of the things that he always brought up is, you know, what does it mean when Softsoap says that it's antibacterial. Is it really going to get rid of a lot of bacteria or are we just being sold a bill of goods?

So I think that what I take away -- one of the things I take away, is that we need to have some short-term, highly visible things that we fund, and that we get results on, and that we can push out to be sure that people remember that PCORI is actually doing this. They're actually reaching patients and caregivers, but they're actually getting to the bedside, that's the idea that we're getting to the bedside. And that we are excited, always in support of PCORI and talk about PCORI in an exciting way, which I know my next, the person I'm handing it off to, Freda, is a great booster.

You're up.

DR. LEWIS-HALL: Well, and there's lots to boost, certainly.

I'd like to do one thing, looking backwards and one looking forward. The one looking backwards, it has been, I think, one of the amazing successes for PCORI has been its capacity for listening and hearing.

One of my mentors said to me once that unfortunately, we raised leaders to tell but the real sign of a leader is the ability to listen. And so I think that PCORI has led by listening honestly and fully to patients, caregivers, advocates, people in the community. And we've taken what they've said and translated it into important, exciting, and innovative ways to examine the questions that they have.

The second is, I'm kind of looking forward. We have been given an opportunity through COVID, and the light that it has shown on a whole host of opportunities and challenges in our healthcare delivery system and I think we have an opportunity

to listen again.

This time I think we should ask some very important questions and quoting an African proverb, to be sure that we don't look where we fell, but where we slipped.

So there are some things in our system that are very visibly in need of our attention. But we have an opportunity, and I think an obligation, to take the step back and say, Okay, this is the outcome of all of that but what's really the cause of this? Where did we begin to slip? And to decrease the quality, the access, and therefore the outcomes for people who are relying on us.

And Gray I see you're there ready to be handed the baton.

DR. NORQUIST: I'm ready.

Yeah, so I'll split this into two comments one is, I wrote down some things that I thought I've learned over the last 10 years and then kind of what I'd like to see out of that Phase 2 of PCORI.

So what I'd say what I've learned is it's possible to build an organization. I mean, we built

an organization and it's possible to survive. So we, I think our initial 10 years we focused on building, and then, also one surviving and we accomplished that. So I think in these particular times, people should just remember it's possible to build something and survive that.

I think the other thing that I've learned is how important various stakeholders are, and how to balance stakeholder input. I think that's really critical. We often talk about listening to stakeholders but the ultimate real, I think, difficulty is how do you balance input? So that the end, you at least try to -- you know, get to what people want, but understand that we have to live in a world with other people. And so, we do have to balance off sometimes what we want with what others.

And I think particularly now in the kind of environment that we found ourselves, I think two other lessons that I learned is that diverse groups and opinions can work in a collegial manner. I mean I've seen that with the Board and I've seen that with our stakeholders that it is possible to do that

and I hope that the rest of us can learn that given what's going on in the world these days.

And I think the fourth thing I would say about what I've learned, is that there are still people who care and want to do the right thing. Great people can do great things. And I think this is really critical in this particular point when science enterprises are under attack for all the wrong reasons, but that there are people who are devoted to this and want to do the right thing. And I think that is such a critical point to make at this particular point in time.

And then what would I like to see basically for Phase 2? Now that we got through the building the organization, survived, and actually have accomplished some things that I think are really kind of interesting is that, you know, it's a lot of money that PCORI gets and I'd love to have it in my bank account but in the scope of science, it's a small amount. And so, you really have to step back and focus on what the strategic areas are that are not covered by us. And I think that PCORI has a

unique opportunity to do this.

So I'm glad you're looking at a strategic plan, but I think you also have to be nimble for what's going to come to us. I think if we've learned nothing else by this last year is that surprises do happen, although many people had predicted this surprise, that the pandemic might happen. They will happen and you have to be nimble and ready to take on some of the things that federal agencies and others just can't do for a variety of reasons.

I also think you have to think as we have with the infrastructure development of quicker, more efficient ways to get meaningful results on large populations through these infrastructure developments. I mean, I think, that's something that I learned from the pandemic, but one we've learned about other chronic medical illnesses, is that you need large populations to really understand the impact of interventions, and that quicker ways to do that to get answers at a time when people are hungry for answers, even for just what they need to

do tomorrow.

As somebody who practices every day with underserved populations, I'd love to have an answer to a cure or something else but I have to help people today. And so, I think that's another critical issue that PCORI has to address.

And I think the other opportunities that PCORI has, is we have an outstanding group of methodologists which is very unusual to have a group like that come together and PCORI has a real opportunity to have innovations in clinical trials and implementation studies. And so, I can't emphasize enough opportunities that are there for that.

The other two things I would say is that the evidence synthesis activities, what do we know and what do we not know are so hugely critical, particularly for those of us who practice every day and those who have to pay for things. I think that the things that we have been doing around that are just outstanding.

And then I think the fifth thing, and I

think most important to me is implementation. I think if PCORI doesn't get into that space in a big way, and really understand why people use things or don't want to use them. We're going to do a lot of research on what works and it's not going to make a damn bit of difference.

And so, I think this is really critical at a time when our payment system is moving toward a Value-Based Payment System. And when you get into values about what matters to people, you better know what's important to them. And so, I think that's where PCORI has a unique opportunity is to really inform that discussion through leadership in both the science and also what matters to patients and caregivers, for their care.

So I would just end by saying thanks for the opportunity and that I really look forward to what the next 10 years will bring.

CHAIRPERSON GOERTZ: Thank you so much.

Larry, you said you might have another couple of things to say?

MR. BECKER: Well, I just thought that, you

know, the collective knowledge and experience and wisdom of this group is really powerful and, you know, finding ways when we shouldn't harness it and use it. There's so much that we could accomplish together. And you know they say if you want to go fast, go alone, but if you want to go far, go together.

And, you know, everyone together is smarter than anyone. And so, I'd urge people to focus on, you know, a couple of big things. Synthesize that. Own that together and push to get those couple of things done.

CHAIRPERSON GOERTZ: Great. Thank you. Thank you so much.

Now we're, we're going to open it up to questions from the Board. So I'm going to start out with a question.

So all of us, before we were appointed 10 years ago, we had numerous conversations with the GAO or they talked a little bit about, you know, what our role might be on PCORI and why they were particularly interested in each of us as a Board

member. And I'm just curious, you know, what are the qualities that you think you had that made you be the one that the GAO chose? And then, what are the qualities that you think were most -- actually most valuable to be in being on the Board? What is it that and what was your favorite thing that you did?

You know, all of you have had so many roles on the Board. I'm just wondering if there's one thing in particular that that you that you enjoyed the most.

Fred's?

DR. LEWIS-HALL: Well, I'll go for favorite thing. I have to say chairing the Research Transformation Committee.

For me, that was just a spectacular opportunity. I often tell people, I don't know if research was transformed, but I sure was. I learned so much by focusing in the areas that we have focused on in modeling and developing the workforce and thinking about data transparency and sharing, thinking about innovative ways to get answers to

critical questions like pricing and crowdsourcing.

And then of course, last but not least, is PCORnet. Ways to begin to establish a national evidence generation platform for Outcomes Research. Just a thrilling experience.

My father used to say you should seek legacy-worthy things to be involved with. And my mother would say, "Yeah. You also want to make sure it's obituary-worthy." I think I really met both of those marks with the work in PCORI, and in particular with the work with RTC.

CHAIRPERSON GOERTZ: Thank you.

MR. BECKER: I'll take a crack at that.

It may not have been the most favorite thing but I'll tell you it was the most enlightening thing, and that was chairing the first Conflict of Interest Committee and really getting involved and beginning to understand what that really meant, and we're all -- you know, the difference between actual conflicts and perceived conflicts of interest and how important that was just to our very being as an organization in our integrity and, you know, all

that we do in guarding that. You know, almost jealously, so that no one would impugn our integrity so that we could continue to move forward and it gives us license to do a lot of what we did and I thought that was a really amazing experience.

CHAIRPERSON GOERTZ: Thanks Larry, Gail.

MS. HUNT: Yeah, I was thinking about, with the question of what does the GAO look for? I guess for the slot that I'm in for the PCORI Board.

I know that they told me that passion was something that they thought was a, you know, an important component of an understanding in general of the health care system, and some of its limitations and areas that could be addressed. Because PCORI was going to be looking at those kinds of things.

Of course, we did somewhat under the umbrella of healthcare service delivery.

And my own experience over 25 years or whatever, of starting and running a nonprofit organization. So PCORI was going to be sort of like that. A startup that we had to keep, as Gray says,

you know, we had to start it up, but then we had to have it survive.

So that's a huge accomplishment and that something that they at GAO had said they were looking for. Experience in doing that sort of project responsibility and all that. So that's what I think GAO, I mean what they said, anyway, was what they were looking for in me.

And I think that those are -- we don't have to in the new GAO list, we don't have to have so much the experience of a start up and running necessarily, running a nonprofit organization, but certainly passion is something that I think we need to have.

And another thing that I hope they'll pick up on and it's actually been touched on a little bit in what comments were people were making about -- Freda. It's, you're not just there representing your company or your particular subject matter. So it's great that people said that they now understand for the first time that there could be real nice people work for a pharmaceutical company. And

that's because Freda approaches these things, looking for -- in a broader perspective. She doesn't come to them faced with this is the way Pfizer does it or this is the way Lilly did it.

So I think that that's, I hope that that will be the way that GAO looks too. That it's yes, you're representing patients and caregivers. But that's not all. You really have the opportunity to look much more broadly -- much broader at the health care system itself, and help to come up with a research for improving it.

DR. NORQUIST: So Christine, an answer to your question.

You know, my narcissism would like me to believe that the GAO thought I was just a brilliant, wonderful person but I'm sure that's a delusion. I have no real idea why they picked me I'm sure they needed a physician and I had experience at the NIH in leading comparative effectiveness trials, so they probably thought that was a good idea.

I would say, you know, when you ask about the favorite thing there are a lot of favorite

things. It surprised you didn't ask me what I didn't like. I think I have a number of little stories about the things I didn't like.

But I think my favorite thing was just the opportunity to talk to all these different people. I mean, to meet colleagues in different areas, to go out and talk to stakeholders, I think that was one of the most enjoyable things to me about this whole experience and then really getting that input and really having a much broader understanding of what people are looking for. So for me I think that's it.

And I would also say, and I don’t think we've said this enough, is how incredibly exciting it was for me to work with such a gifted staff that we have now, and I think that the opportunities, Jean and I and Andrew and the rest of us had some very interesting experiences on the Hill, some of which we do not want to repeat. But there's some that were really enjoyable and just the opportunity to go with Jean and Andrew and that team, and to go on a number of other site visits with people and

stuff. I mean, that to me was just an incredible experience and one I will miss it.

MR. BECKER: Gray, one of my favorite events was something that you arranged. That was New Orleans.

MS. HUNT: Yes.

MR. BECKER: And not because --

DR. NORQUIST: Gail remembers that --

MS. HUNT: Yes.

MR. BECKER: But, you know, we went to a health clinic in what can only be described as maybe the worst section of town. As we were driving there, there was an area that was chain-link fenced off, had been destroyed by Katrina, I suppose. And we spent the evening talking to, I guess, a patient a doctor, the receptionist who is also the, you know, the finance person, and they talk to us about their challenges.

And at the end of the day, you know, one of us made the comment, because they didn't have health insurance. One of us made the comment that, you know, the Affordable Act is coming and everybody has

healthcare and they looked at us and they said, "It's not going to help us." We said, "Well, why?" and they said because, "Well, these people, they get jobs wherever they can get jobs every day and they're not necessarily here. And even if we can get them here. They don't have the papers, they don't have the bank accounts, they don't have the IDs, to be able to sign up. And oh, by the way, even if we could arrange all of that. We can't do it because many of these people are illiterate, they can't fill out the forms."

And then we talked about the fact that they didn't have any place to live. They were living wherever they could live and food was an issue.

And I walked away from that thinking two things. "Wow, in America. It's really like that." And secondly, you know, we spend a lot of money on healthcare, but maybe we should be thinking about food and housing and education as real issues, but Freda just said, you know, that's where we slipped.

You know, we've fallen into healthcare issues but we've got to fix the things that come

before that.

So that was an amazing eye-opening trip.

And so, as you said this morning, I think we really have to think about continuing to do those kinds of things and get those kinds of experiences, making the work that we do more meaningful and more effective.

DR. LEWIS-HALL: You know, I want to go back, because, first of all, I am remiss to not say how amazing it has been to work with a staff that was courageous enough to come in with, you know, kind of a vision and a stack of paper and some ideas from people they didn't really know, and to turn those into this magnificent reality, and to work with Board members that also didn't know each other. Weren't quite sure what we were supposed to do and how we were supposed to do it, but somehow, we came together from our various perspectives and sometimes opposite sides of a table to make this work because we weren't serving ourselves. We were serving someone else.

And I -- this is how I describe my PCORI

experience. Actually, my husband described it first. He said, "You're about to do something, you're not quite sure what it is with some people you don't know, in a way that you've never worked before." "Yeah, let's do that."

So, if that's how we started, look at where we are a decade later, and I couldn't be more excited for the opportunities that PCORI has ahead.

CHAIRPERSON GOERTZ: Great. Thanks to all of you.

Do any other Board members have -- this is your this is your last chance to officially ask everything you've always wanted to know.

DR. NORQUIST: We're not ready to write our obituaries yet. I mean, you can still contact us on email or something like that.

CHAIRPERSON GOERTZ: Okay, you all heard it here. We've got that recorded, too. We'll definitely be taking you up on that.

We've talked about, you know, whether it would be possible to have some sort of PCORI Board Alumni Association so that we can still continue to

find a way to rely upon your expertise as we as we move forward.

But any other questions for this illustrious panel?

[No response.]

CHAIRPERSON GOERTZ: Well, Gray while we're waiting --

MR. BECKER: We put them to sleep.

CHAIRPERSON GOERTZ: Well, while we're waiting for people to unmute themselves. Gray, maybe you could tell us some of those things that you didn't like so much.

DR. NORQUIST: No, I'm not going to en that way. There's no way -- maybe over a glass of wine, which now you can buy for me because I won't be a PCORI Board member and you can pay for it.

So -- no, I think, Christine, the other thing is I said, you know, this morning I kind of help with wellness. It's that time of the day, people are tired. And, you know, they've heard enough.

So, but I would just say, you know, of

course, I'm still available. I'm not going to speak for other people, but I think PCORI has some wonderful things, I think, to look forward to and I just hope that 10 years from now I'm still around to see what is there and we'll enjoy seeing what is produced in the next 10. And I would just say welcome to whoever these new group of Board members are, because you're coming into an exciting organization and I'm sure the GAO will do as well as they have in the past and pick a good group.

CHAIRPERSON GOERTZ: So what advice would you all have for new -- for our new -- our next new class of Board members?

MR. BECKER: Be present. Be there. Be all in. Go in with both feet both hands and your head.

DR. NORQUIST: Yeah, I would just say, get to know your fellow Board members, and I do agree if you're not in this to serve, then don't stay. Get out. I mean if you can't make the time, then I don't need to be in the position.

MS. HUNT: And I think that it's really important and I hope they'll do this is, is don't

feel that as a Board member, you've got to talk all the time -- that you've got to make your place and show that you're a big important person in your field.

Listen. The act of listening, and really hearing what other people say, and what they're trying to say is, I think, that'd be really important for the Board.

MS. LEWIS-HALL: And I would add bring all of you. Every bit of you. Your experiences, your background, your perspective, not just the expertise or the depth that you've been "selected for," because it's really the all of you, the authentic you, that will make all the difference.

DR. NORQUIST: Yeah, I like Gail's point. I think you have to leave your narcissism at the door and be willing to learn.

CHAIRPERSON GOERTZ: Sharon, did you have a question?

DR. LEVINE: Yes. So for each of you, you're now going to have a big chunk of time that you no longer have committed to PCORI. So I'd love

to know what projects you have and what you're going to be doing with all this free time you've got.

MS. HUNT: Wow.

DR. NORQUIST: I'm not sure what that free time is for me, because I have two other jobs. As I said I have a few hours here, you know, part of that was going to be my plan to spend some time traveling which is kind of off the books now, but you know I travel virtually, I guess. But no, I have other -- unfortunately, they've all been filled up now.

I looked at my schedule and thought, Oh I have this free time and I was like what the hell -- how did this get in my schedule all of a sudden and, and I've got to stop saying, yes to some other people like at the American Psychiatric Association, who I keep getting roped into something.

So I'm hoping to have even more time by this time next year and that we'll be able to travel, so then we'll have those conversations again Sharon.

DR. LEWIS-HALL: Well, I retired but I had a very terrible misunderstanding because I thought

"retired" meant "tired" again.

And so, I have now obligated myself to some amazing and wonderful projects and organizations that are really taking my time, but are exciting me greatly.

And it includes things like health equity, you know, I'm taking my PCORI heart with me. I'm focused on some health equity projects, diversity and clinical trials is still near and dear to my heart. There are some areas for therapeutic development that we just kind of missed out on, things that disproportionately affect some communities over others that we have an opportunity to begin looking closer at.

So I'm excited about a lot of the things that still need to be done. And I'm going to do my best to contribute where I can.

MS. HUNT: I'm on a new committee for the DC Mayor's Task Force on Age Friendly DC, which is really -- looks at all these different areas; transportation, the kinds of things Larry was talking about, you know, shelter nutrition, safety.

All of those kinds of issues that people have as they age, and I'm excited to be working on that.

MR. BECKER: So, I'm as you know helping you know, Nakela and team while Regina gets well.

Then I started to have a one-third, one-third, one-third rule that I developed over the last couple years and that's one-third give back and so I'm on a couple of boards in Rochester. One-third, travel, which is on hiatus -- Gray, obviously. And then one-third, physical activity. So I play a lot of tennis I visit my kids, my grandchild, whatever I want to do with that other third.

So uncommitted time. So that's kind of my prescription.

MS. LEVINE: Well, thank you all.

MR. BECKER: You're welcome. Thank you. Thanks for a great opportunity.

CHAIRPERSON GOERTZ: I'd like to ask if staff has any questions for the four of you.

MS. ORZA: I think we'd like to know what words of wisdom you would like to leave us with.

DR. NORQUIST: Obey Nakela. That's all I

would say.

[Laughter.]

MS. HUNT: You should be mindful always of those -- all the stakeholders the payers, the health systems, all that. It's not -- it's hard to keep those in mind, because we focus on the researchers the physicians, the patients, and the people who are really integral to what we're studying. But we've got to keep those other groups in mind, if we ever want to implement something.

DR. NORQUIST: So I just want to -- all joking aside, Michele, I do want to say to the staff though I think, believe in yourself. Trust yourself. Because you're all doing great things, so I think that's the one serious piece of advice I would say.

MR. BECKER: Yeah, follow your passion because in your passion, you'll find purpose, and that'll get you out of bed every morning.

DR. LEWIS-HALL: And my advice is along the same. Sometimes when you have your head down getting your work done, you don't realize that what

you've done has saved a life or changed a life. Because you don't see them.

And sometimes the harder we work, the less often we find ourselves exposed to people that have had the benefit of the work that we've done.

So just remember that with what you do, you -- downstream, or more directly than you know, changed someone's life. They don't even know who to thank, but you should know that there's a lot of gratitude for the work that you do.

DR. COOK: Christine. This is Nakela, I'd love to ask -- this has just been phenomenal. I'd love to hear your ideas about those big opportunities for PCORI in the future and if there was something that you just really would hope for that we would be able to pursue, what would that be?

DR. NORQUIST: Well, this is Gray. I mean, I think I said it earlier about the things that I would like to see for PCORI -- it's hard for me to pick one, because it's kind of like a lot of things, I hope you can do more than one thing at a time, you know, in parallel. So I hope -- but I guess my big

hope is, you're going to produce some, I hope, very important findings on comparative effectiveness, but I still want to emphasize this importance of implementation and the importance of really being able to ensure that people are, you know, that you figure out how to get people to use what is right for them and understand the factors that really impact that. I mean, I think the things that we're all learning those of us who work every day about how factors like bias and other things, enter into what happens with actually the diagnosis and treatment of people and I think these things are so critical right now as we look at what's going on.

MR. BECKER: So I would say, be the evidence synthesis tool with all the things that Gray just talked about, not only our evidence, but everybody's evidence that you can substantiate. I think of the evidence tool as the corollary to on your phone, the maps or the Waze application.

You know, a patient approaches that app and says, I have this question I have this disease, I have this situation. How do I navigate it and get

the best available advice around my health for me?

You know, with Waze you know you can go lots of different ways to get to your destination. Well, that's true for patients, too. And so, what's the best way for me.

And that evidence synthesis tool, I think, is the igniter switch.

DR. LEWIS-HALL: And I am also excited about the communication switch. Which, one of the challenges in health and wellness in getting evidence to people who need it, to apply it.

We've got some ways of doing that, that maybe we need to innovate some. What we hear people tell us is, "Please come to where we are to tell us. Don't make us come to where you are to hear it."

And so, with COVID in particular where people are listening and looking for information. We have the ability to test how to reach people that previously may have seemed out of reach. So I think there's really an opportunity to both generate and deliver, and I would say, now's the time.

MS. HUNT: When I think of really big

issues that we could take on -- PCORI could take on, not we anymore.

I think of issues around getting people, that's not just the public and not just patients to understand about how -- what the science brings to questions like around COVID-19. I mean, I feel Tony Fauci is the only person that gets quoted repeatedly -- not that that isn't good, but he's the only person that gets credit and he's carrying a pretty heavy load all by himself.

We need to be able to bring visibility to how science can help. And that part of that is evidence, as Larry said. The evidence basis of whatever PCORI finds out, that's something that we should be able to shine a light on to. This is how we got here with these results, these study results.

So, I think that it's actually something that all four of us have said, in talking about implementation and talking about bringing evidence to the results. So I think that's what will be very important.

DR. COOK: Thank you.

CHAIRPERSON GOERTZ: All right, this has just been a fantastic discussion. I really, really appreciate all that you've shared this afternoon.

Are there any other comments or questions before we close out? We do not have anyone registered to give public comment today, so we will be concluding the Board meeting after this session.

All right, well, again thanks to all four of you not only for this this afternoon but for the past 10 years. We will miss you and we will stay in touch. So take care.

MS. HUNT: Thanks.

MR. BECKER: Thank you.

DR. LEWIS-HALL: Thank you.

CHAIRPERSON GOERTZ: All right. I am going to now turn this over to Nakela for any closing remarks that she might have.

DR. COOK: Thanks so much, Christine for a phenomenal two days of discussions and it's really been great.

We've covered a lot of updates on progress on priorities in our reauthorization language, we

even started some of the strategic discussions related to strategic planning and commitment planning and starting to think about how we incorporate the PCORnet into setting a strategic vision for the next phase. It's just -- it has been a great couple of days and I don't think we could have ended on a better note hearing from our outgoing Board members and my hat's really off to all of them for the major accomplishments that allow us to be where we are today and my deepest appreciation for their service.

The only comment I wanted to make before we close is to please ask all of you to tune in for the annual meeting over the next couple of days, and to let you know we have over 3,000 registrants. This is more than we've ever seen for a PCORI annual meeting, so I'm excited to participate in that and there'll be a forum to gather some input on our national priorities, a virtual forum to do that.

And we'll be hearing about our funded projects and several of the emerging priorities of today including COVID-19 related activities, as well

as dealing with the issues of discrimination and bias in healthcare and health equity. And so it should be an exciting couple of days and I look forward to seeing you all there.

Thanks Christine.

CHAIRPERSON GOERTZ: Great, thank you.

Nakela, is it too late to register? If there's someone who is participating in the Board meeting but hasn't yet registered. What do they need to do?

DR. COOK: You can still register and it's very easy to go to our website and register. Just search PCORI annual meeting and we actually are allowing registration, even through the meeting for people that would still like to tune in for other sessions that may be happening later in the day or the next day. So it's not too late as long as the meeting is going on, you can still get our website and register.

CHAIRPERSON GOERTZ: Great, thank you. Thanks a lot.

Well, let me close by thanking those who

have joined us today via webinar and teleconference.

A reminder that all the materials that were presented to the Board will soon be available on our website. And that the webinar today was recorded and that will also be available on our website in a week or so. We always welcome your feedback at info@PCORI.org, or through our website at www.PCORI.org.

Thanks again for joining us and enjoy the rest of your day.

[Whereupon, at 3:54 p.m., the Board of Governors meeting was adjourned.]