

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Tuesday, September 20, 2022

Washington, D.C.

[Transcribed from the PCORI webinar.]

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A P P E A R A N C E S

BOARD OF GOVERNORS PRESENT:

KARA AYERS, PHD
JENNIFER DEVOE, MD, MPHIL, MCR, DPHIL, FAAFP
ALICIA FERNANDEZ, MD
CHRISTINE GOERTZ, DC, PHD [CHAIRPERSON]
MICHAEL HERNDON, DO
RUSSELL M. HOWERTON, MD, FACS
JAMES HUFFMAN, MSC
SHARON LEVINE, MD [VICE CHAIRPERSON]
BARBARA J. MCNEIL, MD, PHD
EBONI PRICE-HAYWOOD, MD, MPH, FACP
JAMES SCHUSTER, MD, MBA
KATHLEEN TROEGER, MPH
ROBERT OTTO VALDEZ, PHD, MHSA
DANNY VAN LEEUWEN, MPH, RN
ROBERT ZWOLAK, MD, PHD

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P R O C E E D I N G S

[9:02 a.m. EST]

1
2
3 MS. THOMPSON: Dr. Goertz, the floor is
4 yours.

5 CHAIRPERSON GOERTZ: Thank you so much,
6 Maureen. Good morning and welcome to the September
7 20, 2022 meeting of the PCORI Board of Governors.
8 I'm Christine Goertz, Chairperson. Welcome to
9 everyone who's joined us for today's Board meeting.
10 We're pleased to have you.

11 Maureen, would you please call roll?

12 MS. THOMPSON: Of course. Thank you. Kara
13 Ayers.

14 DR. AYERS: Present.

15 MS. THOMPSON: Kate Berry.

16 [No response.]

17 MS. THOMPSON: Jennifer DeVoe.

18 DR. DEVOE: Present.

19 MS. THOMPSON: Alicia Fernandez.

20 DR. FERNANDEZ: Present.

21 MS. THOMPSON: Christopher Friese.

22 [No response.]

1 MS. THOMPSON: Christine Goertz.
2 CHAIRPERSON GOERTZ: Present.
3 MS. THOMPSON: Mike Herndon.
4 DR. HERNDON: Present.
5 MS. THOMPSON: Russell Howerton.
6 [No response.]
7 MS. THOMPSON: James Huffman.
8 MR. HUFFMAN: Present.
9 MS. THOMPSON: Connie Hwang.
10 DR. HWANG: Present.
11 MS. THOMPSON: Sharon Levine.
12 DR. LEVINE: Present.
13 MS. THOMPSON: Barbara McNeil.
14 DR. McNEIL: Present.
15 MS. THOMPSON: Eboni Price-Haywood.
16 [No response.]
17 MS. THOMPSON: James Schuster.
18 DR. SCHUSTER: Present.
19 MS. THOMPSON: Ellen Sigal.
20 [No response.]
21 MS. THOMPSON: Larry Tabak, Director of the
22 NIH, or Michael Lauer, designee for the NIH

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1 Director.

2 [No response.]

3 MS. THOMPSON: Kathleen Troeger.

4 MS. TROEGER: Present.

5 MS. THOMPSON: Robert Valdez, Director of
6 AHRQ.

7 DR. VALDEZ: Present.

8 MS. THOMPSON: Daniel van Leeuwen.

9 MR. VAN LEEUWEN: Present.

10 MS. THOMPSON: Janet Woodcock.

11 [No response.]

12 MS. THOMPSON: Robert Zwolak.

13 DR. ZWOLAK: Present.

14 CHAIRPERSON GOERTZ: Thank you, Maureen.

15 As a reminder to everyone, Board members'
16 conflict of interest disclosures are available to
17 the public on PCORI's website. These disclosures
18 are required to be updated annually and when the
19 information changes.

20 As a reminder, if the Board will deliberate
21 or act on a matter that presents a conflict of
22 interest for you, please recuse yourself or inform

1 me if you have any questions. If you have questions
2 about disclosures or recusals relating to you or
3 others, contact your staff representative.

4 Today's meeting is being recorded. Members
5 of the public who have logged onto the webinar will
6 see that the slides that have been prepared for the
7 Board meeting. The agenda for today's meeting,
8 along with the approved minutes from the Board's
9 prior meeting, and an archived webinar will be
10 posted on PCORI's website within a week.

11 Board members participating on-site who
12 wish to speak should turn their tent card up. Board
13 members participating remotely should indicate they
14 wish to speak by raising their hand.

15 All right. I'd like to -- could we have
16 the next slide, please?

17 We have a somewhat of an action-packed
18 agenda today. We will start out with our approval
19 of the minutes from our prior meeting and as well as
20 committee nominations relating to Board transitions
21 that will be followed by the Executive Director's
22 report, and then we will consider for approval our

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1 2023 budget, a proposed governance framework; as
2 well as proposed strategies to leverage PCORnet, to
3 advance PCORI's National Priorities for Health and
4 to evaluate PCORnet's performance. We will then
5 conclude with a farewell for outgoing Board members
6 and then we will wrap-up and adjourn the meeting.

7 We do not have any public comments today.

8 Board members, please remember to keep us
9 informed -- I think we can see you who are here in
10 the room, whether if you leave, but if you are
11 joining us virtually, please let us know if you are
12 going to be leaving the meeting because we have a
13 number of voice votes and want to make sure we're
14 keeping track of attendance.

15 All right. Could I have the next slide?

16 So our first order of business then is to
17 approve the minutes from our July 26, 2022 Board of
18 Governor's meeting. Can I please have a motion to
19 approve?

20 DR. VALDEZ: So moved.

21 DR. McNEIL: So moved.

22 CHAIRPERSON GOERTZ: All right. We'll go

1 with Bob Valdez. I heard him first. And then,
2 Barbara, are you okay with seconding that motion?

3 DR. McNEIL: Of course.

4 CHAIRPERSON GOERTZ: Thank you so much.
5 All right. Any further discussion?

6 [No response.]

7 CHAIRPERSON GOERTZ: All those in favor of
8 approval, please say aye.

9 [Ayes.]

10 CHAIRPERSON GOERTZ: Opposed?

11 [No response.]

12 CHAIRPERSON GOERTZ: Abstentions?

13 [No response.]

14 CHAIRPERSON GOERTZ: Okay, thank you.

15 I would now like to invite Sharon Levine,
16 our Chair of the Governance Committee, to introduce
17 the next agenda item related to board transitions.

18 DR. LEVINE: Thanks so much, Christine.

19 With the upcoming transition in Board
20 membership, the Governance Committee has the
21 responsibility of ensuring that the current Board-
22 related committees are able to fulfill the

1 governance requirements in their charters in the
2 period between the departure of current Board
3 members, which occurs Midnight Thursday night this
4 week, and the appointment of new Board members who
5 are then able to be oriented and named to serve on
6 committees.

7 In order to meet these governance
8 requirements, the Governance Committee is nominating
9 several of our current Board members to support the
10 function of these committees and so that the
11 committees remain in legal compliance. Each of
12 these Board members has previously expressed an
13 interest in serving on these committees, and the
14 Governance Committee is very grateful to each of
15 them for being willing to serve in these roles.

16 Can I get the next slide, please?

17 There are two motions today for you to
18 approve. The Governance Committee is recommending
19 that the Board approve two motions, one to appoint
20 additional members and leadership to the specified
21 committees as reflected on this slide. To the
22 Finance and Administration Committee: James Huffman

1 as Vice Chair of the committee, Kate Berry as a
2 member of the committee, and James Schuster as a
3 member of the committee. And for the EDIC,
4 Engagement, Dissemination, and Implementation
5 Committee, appointing Connie Hwang, Vice Chair of
6 the Committee.

7 The second motion -- actually, why don't we
8 take a vote on this? Can we do that?

9 CHAIRPERSON GOERTZ: All right.

10 I'd like to ask for a --

11 UNIDENTIFIED SPEAKER: [Off microphone.]

12 CHAIRPERSON GOERTZ: Okay.

13 DR. LEVINE: All right.

14 CHAIRPERSON GOERTZ: Let's do them
15 together.

16 DR. LEVINE: We'll do them together.

17 The second -- next slide please.

18 The second motion for the Board. The Board
19 resolves that if the Chair of a Board-related
20 committee resigns or is no longer able or available
21 to fulfill the responsibilities of the Chair
22 position, the Vice Chair of the committee is

1 appointed to the position of Chair of the committee
2 unless otherwise appointed by the Board.

3 And this is so that there is no question
4 about succession, should there be a need for someone
5 to stand in for the Chair of the committee. This
6 does not, of course, require the Vice Chair serve in
7 that role, but it does create a path for succession
8 and to prevent a gap in leadership in the committee.

9 CHAIRPERSON GOERTZ: Great. Thank you,
10 Sharon.

11 DR. ZWOLAK: A point of clarification. On
12 the previous slide, with the appointment of three
13 new members to the Finance and Administration
14 Committee, will Russell Howerton still remain Chair?
15 And does that mean there will now be a total of four
16 Board members on the committee? Because previously,
17 I believe, it was only three.

18 DR. LEVINE: Yes, that's correct. And that
19 small number at times created an issue in terms of
20 quorum. And so, this is an effort to add members to
21 the committee.

22 DR. ZWOLAK: Excellent. As an outgoing

1 number of the FAC, I strongly support the addition
2 of an extra member. Thank you.

3 DR. LEVINE: Okay. Can I get a motion to
4 approve both of these motions.

5 DR. HERNDON: Mike, so second.

6 DR. McNEIL: Second, Barbara.

7 DR. LEVINE: Thanks Barbara. Thanks, Mike.

8 CHAIRPERSON GOERTZ: All right. Is there
9 any further discussion?

10 [No response.]

11 CHAIRPERSON GOERTZ: All those in favor of
12 these two motions, please say aye.

13 [Ayes.]

14 CHAIRPERSON GOERTZ: Opposed?

15 [No response.]

16 CHAIRPERSON GOERTZ: Abstentions?

17 [No response.]

18 CHAIRPERSON GOERTZ: All right, thank you.

19 And thank you to all of you who have agreed
20 to serve in this capacity. I know I speak on behalf
21 of the Governance Committee and the entire board
22 with that appreciation.

1 All right. Next, I would like to invite
2 our Executive Director, Nakela, to give her report.
3 Nakela.

4 DR. COOK: Thank you. Good morning,
5 everyone. It's wonderful to see you here and on the
6 line. I have a few things that I just wanted to
7 update you on in my Executive Director's report
8 today. I wanted to introduce another new member of
9 the PCORI leadership team. Also give you an update
10 on some of the ad hoc working groups and committees
11 relating to the Board and where they currently are
12 in their trajectory of focus. And then, give you a
13 few highlights as we start to close out the fiscal
14 year of 2022 in terms of looking at the year before.

15 Why don't we go ahead to our next slide.

16 So my first order of business is really to
17 welcome Mieka Martinez as our inaugural Chief
18 Financial Officer at PCORI. Mieka's joining us from
19 Howard University and has been on the job for a few
20 months now. And at Howard, she served as the Vice
21 President and Interim Chief Financial Officer, as
22 well, as Assistant Vice President and Deputy

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1 Financial Officer. And prior to that, was at
2 Georgetown University, where she held several
3 different roles including strategic, operational,
4 and financial roles there, and was the Director and
5 Chief -- Director and Chief levels at Georgetown.

6 We have just been thrilled to welcome
7 Mieka. She's really a seasoned Executive with 38
8 years of experience related to strategic financial
9 management and operational leadership and will be
10 overseeing at PCORI, our finance and administration,
11 including procurement activities. And so, we are
12 excited that she has that in her background and was
13 able to bring that experience to us.

14 And as you can see here, she did all of her
15 training at Georgetown University and both her
16 Master of Business Administration and her Bachelor
17 of Science degree in Business Administration.

18 So what a joy to welcome her and to round
19 out our leadership team with Mieka Martinez.

20 We can go ahead to our next slide.

21 I also just wanted to give you a few
22 updates related to the ad hoc committees and work

1 groups relating to the Board. And this slide should
2 look a little familiar to you, in terms of the way
3 in which we tried to chart the ongoing work and
4 demonstrates the most active work groups and
5 committees at a glance. Just to provide you a quick
6 update. So you can see here the charge and
7 composition and timeline of the work, as well as
8 some of the outcomes to-date.

9 And the first order of business here is to
10 thank all of you who've been serving on these work
11 groups and committees. They have been really
12 important opportunities for us to pull together
13 products in a very short period of time for the
14 Board to consider.

15 The reason that I have first on the left,
16 the Strategic Planning Committee, is because the
17 Strategic Planning Committee wrapped up its work in
18 July of this year. And so, I wanted to make sure
19 that the Board had that report that it has completed
20 the task. And as you know, they began working back
21 in August of 2020 on pulling together the strategic
22 plan for the organization and working on behalf of

1 the Board to do that, and delivered the plan in June
2 when it was approved by the Board of Governors.

3 You can see at the next column there, the
4 PCORnet Priority Stage Two Working Group. And
5 you'll hear more about this work later on in the
6 Board meeting today. This work actually began with
7 the Stage 1 group that identified the prioritizing
8 principles for Phase 3 funding for PCORnet. And
9 their work was conducted between November of 2020
10 and January 2021. And then, the Stage Two group,
11 whose report you're going to hear today, has really
12 built upon those strategic prioritizing principles
13 from the Stage 1 group and has pulled together
14 strategies to help inform the evaluation of the
15 PCORnet, as well as to guide the Board's
16 consideration for future investments, as well as to
17 strategies that will facilitate advancing the
18 strategic plan and how the PCORnet can play a role
19 in really advancing the National Priorities for
20 Health and Research Agenda.

21 So this group will recommend their
22 strategies to you today, and their work will then be

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1 concluded as we move on to start to implement -- if
2 those strategies are approved by the Board.

3 In our third column here, you can see the
4 Work Group to Optimize Effective Governance and
5 Board Engagement. And this working group was formed
6 to develop some options for an evolved approach for
7 the Board's strategic oversight of PCORI's work.
8 And you can see here that it also is wrapping up its
9 work and presenting to the Board today a proposed
10 governance framework with a new Strategy Committee
11 that you will be considering shortly.

12 One of the things that I just wanted to
13 mention here, is that there were several desired
14 outcomes of the work here underway. And one was
15 really to evolve the Board's approach and being
16 grounded in the Board's governance vision and
17 priorities and culture statement. And another was
18 to make sure the Board had the opportunity to be
19 flexible in meeting the changing organizational
20 directions and the needs of our evolving external
21 environment, and to maintain our focus at a
22 conceptual and strategic level in order to provide

1 strategy and policy direction, and to make sure that
2 we had effective structures and mechanisms for
3 committees and work groups that report to the Board
4 and overall alignment with the Board's fiduciary
5 duties and legal requirements. So we'll be excited
6 to present that to you a little bit later.

7 And the last column here, I'm going to
8 spend a little bit more time on, and that's the
9 Healthcare Cost and Value Work Group, whose work is
10 still ongoing -- as you can see here. You heard a
11 report from the Healthcare Cost and Value Work Group
12 back in February of this year. And you may recall
13 their charge was to develop a framework for the
14 activities to support PCORI's approach to collecting
15 the full range of outcomes and informing the value
16 conversation and supporting some policy priorities.

17 And the membership here has been across the
18 Board of Governors, the Methodology Committee
19 members that are participating on this work group,
20 as well as staff leadership. And this group has
21 anticipated to continue its work through December of
22 this year, but thus far has produced a framework to

1 approach activities, a landscape review that I'll
2 highlight on the next slide, and several stakeholder
3 listening sessions.

4 So let's go ahead to the next slide.

5 So here I wanted to just mention that when
6 we spoke with you back in February, at that time we
7 indicated that over the summer we would be pursuing
8 two activities to help us and our applicants, as
9 well as our stakeholders, better understand the
10 conversation around value and health and healthcare,
11 and particularly patient-centered value. And these
12 activities are centered on patients and focused on
13 informing the value conversation. And on September
14 2nd, we published on the PCORI website a landscape
15 review of patient and stakeholder perspectives on
16 value in health and healthcare. And this piece
17 really synthesizes and summarizes the perspectives
18 of posted publicly across many stakeholders that are
19 interested in PCORI's work, including patients.

20 And we identified four initial domains and
21 48 broad components of value that are included in
22 this report, and it's going to serve as a foundation

1 for further engagements of patients and stakeholders
2 as we move forward. And so, we kind of adopted an
3 approach that snowballed in terms of building our
4 growing and understanding in this space. And we've
5 listened to and learned from our stakeholders about
6 healthcare cost and value from a patient-centered
7 perspective.

8 And it's culminated in a multistakeholder
9 workshop that was hosted on September 7th. And we
10 were very excited in this workshop to bring together
11 nearly four dozen patients and stakeholder community
12 representatives who participated. And the goal was
13 really to help identify which components of a
14 definition of patient-centered value and healthcare
15 are critical to which stakeholders and why, and how
16 we can consider measuring that.

17 So we believe we're really learning and
18 synthesizing all of this and we'll have another
19 forthcoming report that will be of value to PCORI,
20 and to all you, our applicants, stakeholders, and
21 patients coming the stakeholder workshop. We can go
22 ahead to our next slide.

1 I also just wanted to transition here and
2 just give you a couple of highlights from this past
3 fiscal year and the spirit of the year in review.
4 And we've been doing this for a few years now, just
5 to kind of think about how we're progressing against
6 some of the goals we put forward for the year.

7 We can go the next slide.

8 So one of the big goals for the year has
9 been to recruit and onboard to fill out our
10 leadership team at PCORI. And we are pleased that
11 over the course of the late last fiscal year and
12 this one, that we onboarded seven new leaders at
13 PCORI, you can see them all here. They've been
14 introduced to the Board at varying stages during the
15 year, and we're just excited to bring all of their
16 talents to bear on PCORI's work and bring a
17 compliment of talented staff into PCORI to those
18 that are already here as well. And we're starting
19 to really build that leadership team and the family
20 at PCORI that's ready to execute on all aspects of
21 our work.

22 We can go ahead to the next slide.

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1 Another major accomplishment of this year
2 is where you're all sitting today, in PCORI's new
3 offices, and we couldn't be more excited to move
4 into this consolidated space and for the staff to be
5 able to come together to build that kind of
6 collaboration and community that's necessary in
7 order to support PCORI's work. For the teams here
8 at PCORI, their grand opening will be next week and
9 we're pleased to have our first Board meeting in
10 this space.

11 As you can see that the space also offers
12 that type of convening opportunity for us to bring
13 our stakeholders together here in the organization.

14 We can go to the next slide.

15 As I mentioned earlier, one of the, I
16 think, biggest accomplishments of the year really
17 relates to PCORI's Strategic Plan and all of the
18 work of all of you in helping to pull this plan
19 together which was approved at the June Board
20 meeting. And it really does provide that roadmap
21 for the years ahead. And the plan builds on a lot
22 of our past work, which is really a nice way to

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1 reinforce and promote the use of CER evidence into
2 the future. It also recognizes that need to remain
3 responsive to an ever-changing landscape of
4 healthcare, as well as to approach some of the
5 biggest challenges facing the nation.

6 What I think was really key to this plan is
7 the extensive stakeholder input that was received in
8 order to shape the plan and formulate the plan, and
9 point out some very important things of particular
10 importance for PCORI to think about and emphasize
11 in our work, including that broadening and
12 diversification of the communities that lead and
13 participate in the research that we fund, as well as
14 how we can leverage the research we fund to advance
15 a path towards health equity, generating a lot of
16 that evidence that'll help to improve care and
17 outcomes for patients and others who have been
18 traditionally underserved by the healthcare system.

19 We can go to the next slide.

20 I also really think that one of the great
21 achievements was the core of this plan, the five
22 National Priorities for Health that were identified

1 as those ambitious long-term goals for PCORI. And
2 these are all generated from that extensive
3 stakeholder input and feedback. And together they
4 really work to reinforce each other as well as
5 create interconnections across PCORI's activities
6 and promote both this kind of broad and deep
7 partnerships that we think are going to be necessary
8 to make progress on the plan.

9 As well as, I think, if we're really going
10 to address some of the biggest challenges in the
11 nation, that it's going to require us thinking about
12 how we work across these priorities for patient-
13 centered health.

14 We can go the next slide.

15 And another, I think, major achievement of
16 the plan was the articulation of the fact that
17 there's a holistic approach to generating and
18 promoting the use of evidence that really builds
19 upon the patient-centered CER that we fund, but also
20 the importance of the dissemination and
21 implementation of that work, leveraging
22 infrastructure investments as well as the importance

1 of engagement that works throughout all of these
2 domains.

3 So our core parts of this work really work
4 together, synergistically, to drive toward the
5 achievement of those National Priorities for Health.
6 And the Board really, I think, hit it out of the
7 park in thinking about how these things work
8 together to enable the types of things we want to
9 see for PCORI's future work.

10 Let's go to the next slide.

11 One other accomplishment I just wanted to
12 highlight this year was a major advancement around
13 thinking about the role of the Methodology Committee
14 to advance a vision for its future, aligned with the
15 work in strategic directions that PCORI was pursuing
16 and conceiving of the Strategic Plan for the several
17 years to come. And the vision was presented at the
18 Board meeting in March of this year. And that work
19 actually resulted in several items that the Board
20 approved to set up some of the necessary steps to
21 implement that vision, including amending the
22 Methodology Committee charter, as well as revising

1 the conflict-of-interest statement or policy in
2 order to incorporate Methodology Committee members
3 more fully into PCORI's activities, and an improved
4 framework for nominating and appointing new
5 Methodology Committee members.

6 And excitedly, we actually recently closed
7 our solicitation for nominations to fill seats on
8 the Methodology Committee and had a really robust
9 response from the community and the Board will
10 consider those appointments for nomination at a
11 future meeting.

12 We can go to the next slide.

13 So this past year, we also had an award
14 winning PCORI Annual Report. We are delighted that
15 the annual report was awarded a MarCom Award. And
16 this is the third consecutive year that PCORI's been
17 recognized for the Annual Report. And the MarCom
18 Award program is really one of these international
19 creative competitions that recognizes outstanding
20 achievements by marketing and communication
21 professionals. So it means a lot that we're seeing
22 that kind of recognition of the work at PCORI, in

1 addition to what's entailed in the report, in terms
2 of the content and the progress that has been made.

3 We can go ahead to the next slide.

4 Last year we had our second Virtual Annual
5 Meeting, and now we're approaching our third. But
6 during the fiscal year, last year, was the second
7 one. And you know, what was exciting about this is
8 we had over 3,700 registrants and over 2,100
9 attendees, and the content remained online and
10 people continued to access that content. But as
11 we're gearing up for our Third Annual Meeting, we
12 are already seeing our registration outpacing where
13 we were at this time last year. So that's going to
14 be really exciting to see forthcoming in October.

15 We can go to the next slide.

16 This year we also launched PCORI's new
17 website. Hopefully you've had a chance to kind of
18 peruse the website and take a look at it, but it has
19 an updated look and feel to it. And it's undergone
20 more than just a cosmetic makeover. It really does
21 allow for the groundwork to introduce new features
22 and content, expanded information on our portfolio

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1 with tools and filters that allow people to identify
2 the work that PCORI's funding, as well as fresh
3 layouts for funding opportunity announcements so
4 that people can find the announcement pages and a
5 news hub for PCORI.

6 There's also this kind of one-stop learning
7 resource about what's happening at PCORI, such as
8 the registration for the upcoming Annual Meeting.
9 As you can see featured here by one of our keynote
10 speakers this year, Kirsten Bibbins-Domingo.

11 And the website was really designed to kind
12 of showcase PCORI's work as a source of information,
13 but also demonstrate the impact of our work, engage
14 diverse stakeholders, and really modernize the
15 vehicle that we have to highlight our work for the
16 experience of different visitors that come to our
17 site.

18 We can go to our next slide.

19 And I'll spend just a little bit of time
20 here because one of the things that we were able to
21 achieve last year was really the advancement of
22 several new innovative initiatives that we launched

1 at PCORI. And all of these really build on the
2 strengths that we have and that holistic approach I
3 mentioned in terms of engagement, dissemination and
4 implementation, comparative effectiveness research,
5 as well as iterative learning and partnership
6 building as we really strive to move forward with
7 our National Priorities for Health.

8 And the first one you see mentioned here is
9 the Health Systems Implementation Initiative. Many
10 of you may recall this is a new initiative that was
11 launched in February to broaden our efforts to move
12 findings from PCORI-funded work into practice by
13 really leveraging the ability of health systems to
14 lead implementation efforts within their healthcare
15 delivery settings.

16 And so, the goals here were to leverage the
17 health system's commitments to providing evidence-
18 based care and engage the experience and expertise
19 that many of these organizations have with
20 implementing practice change and prepare for the
21 future scale-up of evidence-based practices by
22 demonstrating some successful approaches that work

1 for a diverse array of health systems.

2 You may recall that there were kind of
3 three steps to this initiative. And the first stage
4 was to select the health systems that were going to
5 be participants in the initiative. And this is the
6 exciting part where we are right now, we've had
7 applications come in here and we were very pleased
8 with the response. We received applications from
9 health systems from every region of the country.
10 And they range from smaller systems to those that
11 serve more than 200,000 patients to large health
12 systems that serve millions. And we also see that
13 many of the health systems that applied are serving
14 underserved communities, one of the goals of this
15 initiatives.

16 So the merit review is underway and we'll
17 be announcing participants in February of 2023.

18 The second step though, is that they then
19 are eligible for the funding opportunities for
20 capacity building funds to help the systems prepare
21 for the conduct of their implementation projects.
22 And in that third stage, then they will be able to

1 then apply for the funding opportunities for the
2 specific implementation projects that are of
3 interest to them. So really an exciting time with
4 that.

5 The next initiative here that was quite
6 different and innovative for us was the Health
7 Equity Initiative, where we're framing up a new
8 approach to thinking about CER studies that we're
9 calling Partnering Research and Community
10 Organizations for Novel Health Equity Research or
11 the Partner Initiative. And it aligns squarely with
12 our National Priority for Health around achieve
13 health equity. And this is one that's focused on a
14 multicomponent and multilevel type of intervention
15 approach that will simultaneously address health
16 conditions as well as the social determinants of
17 health in order to improve maternal health outcomes,
18 which is one of our priority focus areas for
19 research at PCORI.

20 So we're really excited that there are a
21 couple novel features in this one, which is the
22 requirement of community organizations to be full

1 partners with the research organizations from the
2 application all the way through to the conduct of
3 the work and the dissemination and implementation,
4 and leveraging partnerships that already exist
5 between communities and researchers and research
6 institutions.

7 And another feature is that we'll have
8 flexibilities in terms of the number of rewards that
9 -- I mean number of projects that an awardee can
10 take on in order to really meet the needs identified
11 by the communities.

12 The third one you see here is around
13 Science of Engagement, which many of you remember is
14 a bit novel for us in some ways because it's about
15 building on some of the efforts that we've already
16 learned in the past decade or so about what works in
17 engagement and what doesn't work in engagement. And
18 while we've learned a great deal, we recognized
19 there was still a gap for some of the rigorous
20 evidence to help our understanding of what's most
21 effective in the conduct of engagement. And so,
22 this idea is to help us with understanding through

1 mechanisms and activities and the strengthening and
2 supporting of the infrastructure within PCORI and
3 the broader research community, what really works
4 with the science of engagement.

5 We're trying to generate some actionable
6 evidence here that'll help us with thinking about
7 even how we continue to improve our efforts around
8 engagement in the future.

9 Our Learning Health Systems Initiative is a
10 partnership with AHRQ and was launched this year as
11 well and builds on the first stage of the Learning
12 Health Systems work. And this one was in the first
13 stage was really to support the training of
14 researchers to conduct patient-centered outcomes
15 research in Learning Health Systems.

16 And in the second iteration, it really is
17 building on that to strengthen some embedded
18 research projects for those that are participating
19 in the program, as well as strengthen some
20 partnerships with health systems and think about
21 flexibilities of scholars at different stages in
22 their career. And it's been a strong partnership

1 with AHRQ in advancing priorities that synergistic
2 between AHRQ, PCORI, and HHS. So we're really
3 excited, too. There's an underlying emphasis across
4 everything within the Learning Health Systems
5 Initiative to address inequities healthcare as well.

6 And the Board will remember that earlier
7 this year, you approved a set of eight broad
8 research themes, topic themes, to move forward with
9 -- or converging with alignment with the National
10 Priorities for Health and also represent high burden
11 and high impact conditions and issues for patients
12 and caregivers and others in healthcare systems.
13 And these were all resonant with many stakeholders
14 through the strategic planning process. So we were
15 really excited to be able to move forward quickly on
16 what we heard from strategic planning and to
17 organize these themes to continue the momentum on
18 the Research Project Agenda that systems from the
19 Strategic Plan.

20 These eight themes we think are going to be
21 critical to allow us to remain nimble, continue our
22 funding in areas of importance to those that

1 surround PCORI, and allow for the potential studies
2 that will develop evidence to continue to inform
3 decision-making.

4 And the last thing I wanted to mention is
5 over this past year we released 11 targeted PFAs,
6 which was really our goal to try to release two or
7 three per cycle in order to think about our
8 commitment plan for the next year. Remember, what
9 we release this year actually will be funded next
10 year and would be part of the commitment plan for
11 the following year.

12 So we had eight traditional targeted
13 research PFAs. We had two of those innovative ones
14 that you see above the Health Systems Implementation
15 Initiative and the Science of Engagement. The
16 Learning Health System one was released by AHRQ, so
17 it's not included in that 11, but I did want to
18 highlight that one today, and we will look forward
19 to the release of the Health Equity Initiative one
20 soon.

21 We also had a special Targeted Engagement
22 Awards PFA that targeted smaller or community

1 organizations. And so, that's included there. And
2 so this is a really exciting kind of announcement to
3 make in terms of the progress and moving and ramping
4 up the number of PFAs that we're releasing.

5 Can we go the next slide?

6 And I wanted to round out my report this
7 morning just to let you know about where we are in
8 terms of thinking about our progress on the
9 Commitment Plan of Fiscal Year 2022, a substantial
10 component, really of fulfilling our mission, relates
11 to this Commitment Plan and you may recall when the
12 Board discussed different scenarios and approaches.
13 And that you reached the conclusion that we would
14 have this early upfront funding stage with a ramp up
15 of targets that would be very ambitious in the early
16 years. And the fiscal year 2022 target was \$600
17 million in total commitments and would be up to \$650
18 million if you include that New Initiatives line.

19 And at midyear, we reported to the Board
20 that we projected closing out closer to \$450 million
21 this year, recognizing that our Cycle 3 was our
22 biggest cycle and we were anticipating funds coming

1 in.

2 And so, what you see here is that we're
3 actually estimating ending the year somewhere
4 between about 475, to a little over \$500 million in
5 awards. And there's a range here just because it
6 reflects the fact that there's some ongoing work to
7 the projects that may still be closing out or coming
8 in toward the end of the funding cycle. And so, if
9 those awards are not made until fiscal year 2023,
10 then it may roll over into the next fiscal year's
11 Commitment Plan.

12 But here you can also see the estimates by
13 each of the funding lines within the Commitment
14 Plan. And so, I just wanted to take them one by one
15 and talk about them for a moment.

16 The target for research in the Commitment
17 Plan for fiscal year 2022 is \$500 million. And you
18 can see here that our commitments in this award
19 category for this year will come somewhere between
20 about \$400 to \$425 million there. And while we had
21 11 PFAs that I talked about for fiscal year 2022,
22 what we're really looking at are the awards that are

1 coming in from the funding announcements that were
2 the prior year, in 2021.

3 And so, you know, some of these did produce
4 very significant funding, and some of them we
5 recognized still had more opportunity to fulfill
6 their intent and goal. And so we set up an
7 opportunity where we would re-release those as we
8 wanted to fulfill the full intent of those PFAs and
9 some of those re-releases cross fiscal years. And
10 so, that we'll have to figure out when we talk about
11 the Commitment Plan in more detail later in December
12 how we may want to count for that in some of our
13 modeling.

14 You can see here, the D&I target was \$40
15 million this year in our Commitment Plan, and we
16 anticipate somewhere between \$50 and \$20 million in
17 commitments there.

18 And I mentioned to you the Health Systems
19 Implementation Initiative and other activities,
20 where the commitments for some of those will really
21 show up in a future years' commitment plan. And so,
22 we do anticipate with some of the things we've been

1 working on there that we're expecting to see an
2 increase in Dissemination and Implementation awards
3 over future years.

4 And you can see here for Infrastructure
5 which includes our Engagement awards, PCORnet
6 Infrastructure Workforce, that the target in the
7 plan was \$60 million this year and we achieved about
8 \$38 million. And of note, there's a \$25 million
9 commitment on the New Initiatives line, which
10 relates to the Learning Health Systems Initiative.
11 And so, as a Workforce Initiative, it will be
12 realigned to infrastructure when we close out the
13 fiscal year. And so, that'll bring that line a
14 little closer to target.

15 I wanted to show you one more slide on the
16 Commitment Plan, if we can go to the next slide.

17 And this slide just tries to put into
18 context this year's commitments related to prior
19 years. And as you can see, prior to this planning
20 activity for commitments, our average annual
21 commitment was about \$388 million. And we've been
22 ramping up and in ramp up mode really since 2020

1 with \$313 million in commitments that year. And in
2 2021, about 494. And then you see the range that
3 we're estimating for 2022, and we're about close to
4 where we were in 2021. I think when we land at the
5 end of 2022.

6 Next year's target is also \$600 million in
7 the Commitment Plan, and we're scheduled to have a
8 deeper discussion in December at our Board meeting,
9 to talk about any anticipated needs for adjustment
10 in that plan, revisiting our model, and talking a
11 little bit about what we've learned from the past
12 years that may help us with thinking about
13 projections moving forward.

14 Okay, let's go to our next slide.

15 I'm just going to transition a little bit
16 to mention that one of the other things that has
17 been really exciting about this past fiscal year is
18 really just the number of research results that are
19 coming to fruition and garnering attention.

20 And here you can see some of the highlights
21 of six PCORI-funded CER results publications from
22 this fiscal year that really achieved high levels of

1 attention is measured by Altmetric scores greater
2 than 300. On the left, you can see those scores.
3 And these are considered pretty high scoring. You
4 can see a couple of things that we've highlighted
5 before, including a study that compared spinal
6 anesthesia with general anesthesia for hip surgery,
7 as well as one that looked at comparative
8 effectiveness of reliever-triggered inhaler
9 glucocorticoid in Black and LatinX adults with
10 asthma.

11 And there's also one in here related to the
12 COVID Watch Study, which was around text messaging
13 for monitoring COVID-19 at home and related to our
14 COVID-19 funding. And further down, there's a rapid
15 review on video teleconferencing, which is something
16 that has received a lot of attention related to
17 understanding when and how we use teleconferencing
18 in this kind of telemedicine delivered era.

19 We can go to the next slide.

20 So there's just a couple that I thought you
21 may also want to hear about. And the first one here
22 relates to studies that were conducted utilizing

1 PCORnet, even though funded by others. And the
2 first one had an outstanding Altmetric score, and
3 you can look at that attention score of almost 4,000
4 demonstrating substantial attention.

5 And this was published in the MMWR and
6 funded by the CDC leveraging PCORnet. And you can
7 see the focus here was around cardiac complications
8 after SARS-CoV-2 infection and mRNA COVID-19
9 vaccination, and this was one that I think garnered
10 a lot of attention in terms of understanding some of
11 the effects such as myocarditis and others that
12 follow vaccination or COVID-19 infection.

13 There's a second one on this slide that
14 also used PCORnet, but was externally funded, and
15 this one was funded by the NIH as part of the
16 Recover Initiative, which is focused on the
17 sequelae, the post-acute sequelae of SARS-CoV-2.
18 And here this one was a retrospective study that use
19 some data from nine different hospitals, children's
20 hospitals in the PCORnet network and of children
21 that were tested for COVID-19. And it basically
22 found that there was a low burden of pediatric post-

1 acute sequelae of COVID-19 and presentation to
2 health systems. And that myocarditis was actually
3 the most commonly diagnosed post-acute sequelae
4 associated condition in children and that some of
5 the kind of drivers for that related to acute
6 illness severity in young age and comorbid chronic
7 disease.

8 And so, this was I think another very
9 significant utilization of PCORnet, funded by the
10 NIH and collaboration in terms of thinking about the
11 important questions of the day.

12 And then there's one other one that I
13 highlighted on this slide, which is on the left.
14 It's called the BP Check Study. And this was one
15 that was funded by PCORI, but was a three-arm
16 randomized trial of adults with elevated blood
17 pressure and compared three different ways of
18 monitoring blood pressure; whether in the clinic, at
19 home, or at the kiosk versus the 24-hour ambulatory
20 monitoring for effectiveness of and diagnosing
21 hypertension.

22 And it basically found that monitoring

1 blood pressure at home had better diagnostic
2 performance, adherence, and acceptability than
3 either the clinic or the kiosk for diagnosis of
4 blood pressure. So another important finding of
5 PCORI's work that I think can actually move us
6 forward in terms of thinking about clinical care.

7 You can go to the next slide.

8 So the last slide here is just really to
9 talk about briefly, and we'll come back to this
10 later, one of the major milestones that we're
11 marking this fiscal year, and it's a bittersweet
12 one. It's the celebration of 12 years of service
13 for four of our founding Board members, Christine
14 Goertz, Sharon Levine, Ellen Sigal, and Robert
15 Zwolak. And their efforts really formed the
16 foundation for many of PCORI's successes over the
17 past 12 years, and really all of the highlights we
18 just talked about of this last year. And so we look
19 forward to a very special sendoff for them a little
20 later today to honor their dedication to PCORI. And
21 I look forward to talking more about them at that
22 point in time, but I couldn't end my Director's

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1 report without acknowledging this.

2 So thanks, Christine, for time this
3 morning.

4 CHAIRPERSON GOERTZ: Thank you so much
5 Nakela. All right. I'd like to open up the floor
6 for questions or discussion.

7 All right. Mike. We'll start out with
8 Mike Herndon.

9 DR. HERNDON: Nakela what do you see, you
10 know, as PCORI's role in staying current with the,
11 you know, like just monkeypox and polio resurgence
12 and what -- does PCORI have a role in trying to stay
13 nimble and responsive? You know, and how do we
14 collaborate our efforts with the other public health
15 collaborators and things like that?

16 So could you just kind of explain your
17 perspective on how we address these emerging
18 concerns?

19 DR. COOK: I think that's a fantastic
20 question. And one of the things that we do very
21 regularly as our way of staying in touch with where
22 the landscape is, is staying in touch with the

1 stakeholders. And so, stakeholders include other
2 agencies, federal agencies, as well as patients and
3 others in the healthcare community. And so we are
4 regularly engaged in understanding where the
5 priorities are, what people are seeing on the
6 horizon, and understanding that more fully and being
7 able to capture that input to bring it to the Board
8 for a discussion of potential future activities.

9 The other point I may mention is that in
10 addition to staying connected to the stakeholders,
11 we also want to stay connected to organizations that
12 are really focused on some of the issues on the
13 frontline, some of the professional organizations
14 and things of that nature, that really raised to our
15 forefront, you know, the issues that are facing
16 clinicians and patients and others.

17 And lastly, I may mention that one of the
18 efforts of really remaining nimble is the
19 opportunities that we want to think about as we
20 talked about the research themes in terms of
21 bringing things to the Board where we have that
22 opportunity to discuss more fully together the types

1 of things that even you may be seeing on the horizon
2 that may be important for us to consider as an
3 organization. And because of your connectivity to
4 different stakeholder organizations and groups, I
5 think that's a critical input to that process.

6 So those are some of the things that we
7 certainly can do. And we learned during the
8 pandemic, the COVID-19 pandemic, how quickly we can
9 pivot certain of our mechanisms, the approaches we
10 have, to target things that may be on the horizon.
11 And it's one of the things I love about our
12 Strategic Plan, is that while we have a plan in
13 place, we wanted to make sure we were nimble and
14 flexible for things that emerge. And so, that's
15 really built in terms of thinking about the way in
16 which we assess the landscape routinely and think
17 about what the next opportunities are.

18 CHAIRPERSON GOERTZ: All right. I have Bob
19 Z and then Danny.

20 DR. ZWOLAK: Thank you for that report,
21 Nakela. I'll ask a variation of my standard
22 question. Which is, your thoughts about our

1 assignment of less than half of the dissemination
2 and implementation proposed award roster and how
3 that came to be and how going forward we can improve
4 on our efforts in dissemination and implementation.

5 DR. COOK: Maybe I'll mention just a couple
6 of things. One is that there's a component of our
7 dissemination and implementation activities that
8 really resides on the results that are coming to
9 fruition from prior funding.

10 And so, we are working on with those
11 results in order to think about those that are ripe
12 and ready for some of the dissemination and
13 implementation projects. And that has a bit of
14 variability in terms of when those results come
15 forward for us to be prepared to move them to the
16 next stage of dissemination and implementation. And
17 it's somewhat dependent upon when those come
18 forward.

19 So part of the excitement of what we saw in
20 the last year, in terms of results coming to
21 fruition, would be those opportunities to move those
22 things forward, but it ebbs and flows in terms of

1 the timelines. And so, having a static goal and a
2 commitment plan doesn't necessarily always reflect
3 those ebbs and flows and maybe something that we
4 would want to think about when we look at a
5 multiyear plan.

6 And then the other thing that I briefly
7 mentioned that maybe I'll expound upon just a little
8 bit is that some of the activities that we're
9 gearing up for actually have a multiphase approach
10 that crosses fiscal years. And we really didn't
11 think about that in that way when we were designing
12 the plan. And so, building partnerships, for
13 example, with the health systems. An extremely
14 robust response to that where we think we may have
15 the opportunity to fund that even more than we had
16 initially anticipated. But that's in a stage two or
17 three down the line from the work that we do to set
18 up the PFA and awards.

19 And so, I think we may also have some
20 thinking to do around timing in terms of how we
21 align the timing of our activities with what we want
22 to see in the deliverables of the Commitment Plan.

1 So those are some of the things that we thought we
2 may want to talk about when we come back in December
3 because I think we have a better sense now of kind
4 of the timelines of what it takes for certain things
5 to come to fruition and can model that in more
6 effectively.

7 DR. ZWOLAK: Thank you. As a brief follow
8 up question, do we at PCORI think that our
9 dissemination and implementation effort should be
10 limited to results of studies funded by PCORI?

11 DR. COOK: We certainly focused there with
12 the concept that a lot of the dissemination and
13 implementation activities around the broader
14 aspects, we work through collaborations with other
15 organizations such as AHRQ, et cetera. And so,
16 there are ways that we extend our work in terms of
17 the partnerships and collaborations that we have
18 beyond PCORI-funded activities, but that's where our
19 funding portfolio really emphasizes.

20 CHAIRPERSON GOERTZ: All right, Danny, and
21 then I'm going to check to see if anyone online
22 wants to make a comment or has a question before we

1 turn to James.

2 MR. VAN LEEUWEN: I'm wondering about the
3 scope we have in our definition of workforce, and
4 does workforce include all healthcare personnel?
5 Does it include non-healthcare personnel? Does it
6 include family caregivers and family caregivers that
7 are also employed?

8 Like what do we, when we talk about
9 workforce, what's our scope?

10 DR. COOK: A very broad scope. When we
11 talk about workforce, we talk about all the
12 components that it takes to move forward patient-
13 centered outcomes research, which are all of those
14 that you mentioned in addition to many others.

15 And perhaps one of the things you may be
16 getting at, is that we do have to think about how we
17 tailor activities to different components of that
18 workforce. And some of that work comes through
19 capacity building activities that are done through
20 engagement awards. Some of it comes through
21 partnerships that we have with AHRQ around the
22 training of investigators or researchers that may be

1 sitting within health systems. Some of it may come
2 from the thinking of how we embed kind of a training
3 pathway even in current awards or how we think about
4 the opportunities to link up kind of existing
5 awardees with those that may be thinking forward.

6 And there's a component within the health
7 equity initiative, I mentioned, that has that kind
8 of focus.

9 There are also workforce activities that
10 happen within our infrastructure program related to
11 PCORnet and thinking about the clinical research
12 networks that really have that PCOR focus around
13 them and all those components around workforce that
14 are necessary to make that happen.

15 So it's a broad, broad definition and our
16 activities span many of those spaces.

17 CHAIRPERSON GOERTZ: Well, thank you. Is
18 there anyone online that has a question or comment?

19 DR. McNEIL: Not me. I thought it was a
20 great presentation as usual.

21 CHAIRPERSON GOERTZ: Well, thank you,
22 Barbara. I appreciate that. And I completely

1 concur on that. It was an excellent presentation.
2 James.

3 DR. SCHUSTER: Yeah, thank you. It was a
4 great presentation. Always really helpful.

5 I just wanted to follow up actually on
6 Bob's comment around dissemination and just wanted
7 ask if maybe we could think about some additional
8 discussion in a future meeting, or in a smaller
9 committee or planning group or what have you, about
10 potential dissemination strategies that might go
11 beyond our funding of investigators who are
12 requesting funding specifically for dissemination
13 and what additional strategies PCORI might be able
14 to drive around dissemination.

15 DR. COOK: Certainly. I may have even
16 mentioned that we also have dissemination awards
17 through the Engagement Award program, which kind of
18 takes things a little bit further, too, and an
19 opportunity to move that forward and some of that
20 work gets mapped into our Engagement Awards line of
21 infrastructure.

22 And we also have a lot of dissemination

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1 activities that go through our stakeholder
2 convenings and one-on-one efforts. So we may want
3 to think about that broad scope.

4 And I wanted to mention, as well, that one
5 of the areas that we have established in terms of a
6 kind of collaborative effort and activity for
7 planning how our strategic plan and AHRQ's strategic
8 plan that moves forward, is thinking about things in
9 a collaborative and synergistic way, relates to
10 Dissemination and Implementation.

11 And so, there's some outputs from that work
12 that we had hoped at some point from that work
13 group's effort, we'd have a chance to report back to
14 the Board. And so that may stimulate some fodder
15 for future discussion as well.

16 DR. SCHUSTER: Yeah, I was just struck by
17 the, you know, important findings of a number of
18 studies and whether we as PCORI might want to
19 identify some studies that we think are important to
20 disseminate, that we drive some of that work
21 ourselves --

22 DR. COOK: Yep.

1 DR. SCHUSTER: -- even if the investigator
2 doesn't necessarily want to pursue that track.

3 DR. COOK: Absolutely. That's a great
4 point. And we do some of that already, quite a bit
5 of that already, in terms of when we're reviewing
6 findings internally at PCORI, coming out of our
7 peer-review process, identifying the ones that are
8 right and starting to work on how we actually help
9 the investigator team, which often means thinking
10 about other investigators that are more focused in
11 implementation and dissemination work to pick up
12 that work and help move it forward. And so, we
13 start to tee that up as a place that's important.
14 And we also publish that kind of results findings
15 that are primed for dissemination and implementation
16 in order to open it up for the community.

17 So we'd love to hear if there are other
18 ideas about doing that, but there's a lot we do to
19 kind of push that along.

20 DR. SCHUSTER: Good. Thanks.

21 CHAIRPERSON GOERTZ: All right. I'm not
22 seeing any other requests to speak.

1 And once again, Nakela, thank you so much
2 for that excellent report. I always get excited at
3 the end of the fiscal year to the Executive
4 Director's report. Over the year it's so easy to
5 get caught up in the details of what we're working
6 on, and especially over this past year that there's
7 really been such an intense focus on so many
8 different work streams. And so, it's a lot of fun
9 to see it all pulled together in this, you know,
10 really compelling way.

11 And also, I want to invite everyone who has
12 not yet had an opportunity to read our 2021 PCORI
13 Annual Report, because I had that same reaction to
14 that. It really is an opportunity to see how PCORI
15 has focused over the last year or so in a way, that
16 for me, is incredibly exciting to see.

17 DR. COOK: Thank you.

18 CHAIRPERSON GOERTZ: Thank you. And thank
19 you and thank you to all of -- certainly all the
20 members of the Board, but all the incredible amount
21 of work that this -- that is represented in this
22 report on part of you and your entire staff, is

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1 really something that needs to be noted. So thank
2 you.

3 And for those who are not here, please
4 convey on behalf of the Board, our thanks for
5 everyone's commitment to PCORI and their hard work
6 over the last fiscal year.

7 DR. COOK: Thank you. I'm sure they would
8 love to hear that.

9 CHAIRPERSON GOERTZ: All right, we're going
10 to move on then to the next item. Oh, I'm sorry. I
11 did not see you, Bob V.

12 DR. VALDEZ: Thanks very much. I also just
13 wanted to express my thanks to the PCORI staff who,
14 particularly those who've been working with us at
15 AHRQ, in a very collaborative way to find those
16 synergistic opportunities particularly in the
17 Dissemination and Implementation area.

18 As you know, our agency's focused on
19 Dissemination and Implementation brought across a
20 wide variety of findings and researchers and funding
21 sources.

22 And we, particularly because we're a sister

1 trust fund agency that is specifically focused on
2 training and dissemination and implementation, those
3 are the pieces that we've been asked to focus on
4 using trust fund dollars.

5 It's extraordinarily exciting to be working
6 collaboratively with PCORI and to see our joint work
7 beginning to come to fruition.

8 CHAIRPERSON GOERTZ: Thank you, Bob. All
9 right. We are going to turn then to the next item
10 on the agenda where we will hear a presentation, and
11 then consider for approval the proposed budget for
12 our 2023 fiscal year. And unfortunately, Russ
13 Howerton is our FAC Committee Chair, is not able to
14 join us, so I'm going to ask the Vice Chair, Bob
15 Zwolak, to start with some opening remarks before we
16 turn it over to our Deputy Executive Director for
17 Operations, Brian Trent.

18 DR. ZWOLAK: Thank you Christine. We all
19 miss Russ. I think he's in the air somewhere. So
20 safe travels to Russ.

21 In support of PCORI's mission, the FAC
22 recommends for the Board's approval the FY 2023

1 proposed budget. This proposed budget represents a
2 culmination of the work completed by PCORI's
3 departments to outline the key activities PCORI will
4 be embarking on in fiscal year 2023 in support of
5 PCORI's institutional goals and objectives, as well
6 as the cost associated with these activities.

7 The FAC has had the opportunity to review
8 the proposed FY '23 budget several times now during
9 the last few months, and we recommend it to the
10 Board for approval. I'll now ask Brian to walk us
11 through the budget presentation. Brian.

12 MR. TRENT: Thank you so much, Bob. Next
13 slide please. Thank you.

14 So before getting into the budget, first I
15 want to talk about -- I first want to focus on the
16 fiscal year '23 projected fund balance. The fund
17 balance represents the available resources to PCORI,
18 taking all assets and liabilities into account. The
19 key takeaway here is PCORI has sufficient financial
20 resources to cover our outstanding award obligations
21 and any unobligated cash on hand will be available
22 for new award commitments and operating costs to

1 support the management of PCORI's programs.

2 So on this slide, you'll see that at the
3 beginning of fiscal year '23, we estimate the fund
4 balance of nearly \$1.7 billion. Also in fiscal year
5 '23, we expect to receive \$607 million in revenue
6 via the PCOR Trust Fund, and we are anticipating a
7 budget of about \$451 million, which I will describe
8 later on in the presentation.

9 By the end of fiscal year '23, we project a
10 fund balance of about \$1.8 billion. Of this amount,
11 we estimate about \$1.6 billion in outstanding award
12 obligations. These outstanding award obligations
13 are essentially the amount of contracts awarded for
14 which payment has not yet been made. These amounts
15 will become due and available as research and other
16 projects progress over time, so they may not occur
17 right away in the during this fiscal year.

18 So please note that outstanding award
19 obligations include assumptions about what we will
20 commit in fiscal year '23, so there may be some
21 fluctuations.

22 And finally, the difference between the

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1 projected fund balance at the end of fiscal year '23
2 and outstanding award obligations provides a net
3 funds available of about \$194 million at the end of
4 fiscal year '23.

5 It should be noted that any unobligated
6 cash on hand will be available for new award
7 commitments and operating costs to support the
8 management of PCORI's programs beyond fiscal year
9 '23.

10 If we can move to the next slide, please.
11 Thank you.

12 The FY '23 proposed budget represents a
13 culmination of the work completed by PCORI's
14 departments to outline the key activities we will be
15 embarking on in fiscal year '23 in support of our
16 institutional goals and objectives, as well as the
17 cost associated with these activities.

18 As we start reviewing the proposed budget,
19 I want to make a distinction between commitments and
20 expenses. The key thing to keep in mind is that the
21 proposed PCORI annual budget that I'm about to go
22 over reflects expenses, not commitments, commitments

1 refer to the amounts of funding that PCORI intends
2 to award or has awarded. Once a commitment has been
3 made and a contract has been executed, we will start
4 making award payments to research and other awardees
5 in response to invoices. Additionally, expenses
6 associated with award payments almost always lag
7 behind commitments and are spread over multiple
8 years as research studies and other projects
9 progress over time.

10 In December of this year, we will begin
11 reviewing the Commitment Plan with the FAC and the
12 Board of Governors.

13 Now I want to focus on the fiscal year '23
14 budget.

15 We're proposing a fiscal year '23 budget of
16 \$451 million, which is about \$66 million or a 17
17 percent increase over the \$385 million projected
18 expenses for fiscal year '22. The proposed fiscal
19 year '23 budget reflects estimated expenses planned
20 for fiscal year '23, and are predominantly driven by
21 award payments to our awardees in the following key
22 areas: Research, Infrastructure, and Dissemination

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1 and Implementation.

2 While the overall proposal for fiscal year
3 '23 is expected to increase the proportion of cost
4 for all major budget components is expected to
5 remain approximately the same. Award payments will
6 make up the largest portion of the proposed fiscal
7 year '23 budget, and represent approximately 78
8 percent of all budgeted expenses in fiscal year '23.

9 Program and program support, which provides
10 scientific support and review of award and
11 monitoring of research projects, as well as
12 development of award contracts make up about 14
13 percent of total estimated expenses for fiscal year
14 '23. The \$8.7 billion, or 16 percent, in these
15 programmatic expenses will provide PCORI with
16 additional resources to support new initiatives that
17 are driven by the recently adopted Research Themes
18 and the National Priorities for Health, which were
19 adopted in October of last year.

20 Lastly, administrative support makes up the
21 remaining eight percent of the total budget. The
22 small increase of four percent in administrative

1 support will allow us to enhance PCORI's
2 cybersecurity and data privacy, as well as to
3 provide additional resources related to operational
4 functions.

5 And with that, I will turn it back over to
6 you, Christine, for any discussions and to review
7 the motion.

8 CHAIRPERSON GOERTZ: Thank you. Thank you
9 so much, Brian, I appreciate it.

10 I understand that Russ may have been able
11 to join us.

12 Russ, are you on the line? If so, would
13 you like to make any comments?

14 DR. HOWERTON: No, Bob did an excellent
15 job. Thank you very much.

16 CHAIRPERSON GOERTZ: Thank you. And safe
17 travels. All right, I'm going to open it up for
18 discussion. James.

19 DR. SCHUSTER: I just had a question, and
20 I'm pretty sure I know what the answer is, but I
21 just wanted to confirm it.

22 Are we required to have the funds on hand

1 before we make the commitment, even though the
2 commitment's over many years and we know that
3 there's going to be an ongoing funding stream in
4 those future years?

5 MR. TRENT: In terms of having the entire--

6 DR. SCHUSTER: Yes. I was asking because
7 it was kind of implied by the presentation, right?
8 That we had so much money and funds made these
9 commitments.

10 MR. TRENT: Yes. That's right. The funds
11 will be on hand before we make the commitments, yes.

12 DR. SCHUSTER: Okay, thanks.

13 DR. COOK: Can I make a comment?

14 MR. TRENT: Sure.

15 DR. COOK: I'll just add one thing, James
16 though, is that we're not required to have it on
17 hand to make the commitments because we have a
18 mandated appropriation. But when we went through
19 the Commitment Plan with the Board, there was an
20 approach that the Board wanted to take in terms of
21 making sure that we didn't get too far ahead of what
22 was anticipated.

1 And so, we'll be talking about that more
2 when we come back for the December Commitment Plan
3 discussion.

4 DR. SCHUSTER: Okay.

5 DR. COOK: But our plans right now
6 incorporate that idea that we are within what's
7 coming forward and anticipate they would be on hand
8 before committing, but we follow a philosophy the
9 Board would set that policy and direction on.

10 DR. SCHUSTER: So we could re-look at that
11 at some point.

12 DR. COOK: Mm-hmm.

13 DR. SCHUSTER: Okay. Thank you.

14 CHAIRPERSON GOERTZ: All right. Thank you,
15 James. I've got -- actually I see Barbara's hand up
16 and then Bob and then Mike. Okay. Alicia, too.

17 DR. McNEIL: Should I ask a question now,
18 Christine?

19 CHAIRPERSON GOERTZ: Yes, please Barbara.

20 DR. McNEIL: I have one question that I
21 think the Board members know, but this is a public
22 meeting and it's probably not immediately apparent

1 what the extra \$10 million in infrastructure costs
2 covers. So maybe you could say a word about that.

3 DR. COOK: I'd be happy to, Barbara.

4 So the infrastructure cost are part of the
5 award payments, which means that it's related to
6 what we've already committed and when we anticipate
7 those commitments coming forward for payments
8 against those awards, and infrastructure includes
9 things such as our Engagement Awards, our PCORnet,
10 and funding, as well as things like Workforce
11 Initiatives.

12 And so, we can see a little bump in that
13 related to what we're committing, and we know we've
14 committed some additional funds for the Learning
15 Health Systems. We know that we've increased some
16 of the work with the Engagement Awards, and then
17 we'll have that multiyear plan for paying out the
18 expenses against the PCORnet.

19 And so, those estimates line up year-by-
20 year in that line. So hopefully that helps a little
21 bit in explaining that.

22 DR. McNEIL: Thanks.

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1 CHAIRPERSON GOERTZ: All right. I have
2 Alicia, then Bob, then Mike.

3 DR. FERNANDEZ: Hi, I have two questions
4 and a small one, and maybe a little bit of a larger
5 one. And thank you, Brian, for that very clear
6 presentation.

7 I don't know who my question should
8 properly be addressed to.

9 So the smaller question has to do with
10 actually in inflation. And I am curious whether or
11 not the program officers and others are hearing back
12 from researchers that they are finding it hard to
13 meet their projected expenses or how increased costs
14 and increased salaries are affecting the research,
15 if at all. If we're hearing anything about that.

16 And then my second question has to do, it's
17 sort of a larger question, and it has to do with the
18 amount left over or uncommitted in fiscal year -- at
19 the end of fiscal year '23. And I don't have a
20 handle on whether or not we consider that too large,
21 too small, or just right, and what the Board's roles
22 or opportunities may be related to that.

1 So thank you.

2 MR. TRENT: So are you referencing the \$194
3 million that we are anticipating having at the end
4 of the fiscal year?

5 I mean, I think that that is -- it's an
6 approximation, but I think it's just right because I
7 think that can, you know, there's some fluctuations,
8 it could be a little bit more, a little bit higher,
9 but I think we can also use those funds to add
10 additional awards. So I think that is the
11 appropriate amount.

12 DR. COOK: I was going to add a point that
13 we talked about with the FAC, which is that in the
14 way that we set forward the Commitment Plan, the
15 goal was to kind of, and this was before Brian's
16 time, but to whittle down a bit in terms of what we
17 had in the net funds remaining over the course of a
18 multiyear plan that's in the Commitment Plan. And
19 so this is right on target, as Brian mentioned, with
20 that plan, with the multiyear plan and how that
21 would be kind of ratcheted down with some
22 conservatism of holding onto a little bit for what

1 could be available for additional funds for things.

2 DR. FERNANDEZ: So you, too, would say good
3 amount?

4 DR. COOK: Yes. It's consistent with the
5 plan.

6 DR. FERNANDEZ: Can I ask Bob and the -- or
7 whoever's from the FAC here, whether you also see it
8 as not too big, not too small, good amount?

9 DR. ZWOLAK: Well, I could follow up and of
10 course my question and comment is related exactly to
11 that. So the timing is wonderful, if that's okay.

12 Let me start by saying, I think the very
13 best number on the page we're looking at is the
14 total awards payment proposed budget in FY '23 of
15 \$350 million, which in real hard, already committed
16 dollars, represents a \$55 million increase over
17 fiscal year '22.

18 That proves without dispute that we are
19 ramping up our awards to research. So that's
20 wonderful news.

21 The answer to Alicia's question I think is
22 really important because in the past, in the very

1 recent past, that number of uncommitted funds was
2 potentially as high as \$600 million. And I think
3 all of us would think that number is too high.

4 And so, I see -- two things. First, the
5 number of \$200 million really means that we need to
6 continue ramping up. But it means -- and we fell a
7 little bit short this year, although it did
8 increase, but we fell a little bit short of our goal
9 this year. But it means next year we have to work
10 even harder to find meritorious comparative
11 effectiveness research to invest in.

12 But I do think that 200 seems like a
13 reasonable cushion and that perhaps the first part
14 of your question about inflation, may in fact be an
15 indication for use of those funds for already
16 committed research if inflation continues to be
17 substantial. And so, I'm much more comfortable, I
18 think the discussion we had at the FAC supported
19 that, that we're much more comfortable with a
20 cushion of uncommitted resources in the \$200 million
21 or less category.

22 Certainly much more appropriate than twice

1 or three times that.

2 CHAIRPERSON GOERTZ: All right. Thank you,
3 Bob. Did you have any other comments that you
4 wanted to make Bob? And Nakela, or Brian, did you
5 want to comment a little bit more directly on
6 Alicia's question about whether you're hearing from
7 investigators that there are some impacts of
8 inflation?

9 DR. COOK: I don't have a kind of
10 systematic sense of that right now, Alicia, but you
11 know, I know there has been some discussion about
12 the issue amongst some of the program officers, but
13 don't really know to what extent they're really
14 hearing that as a loud and clear signal.

15 You know, we also have been in many ways
16 finding ways we track what we hear from our research
17 community who have applied and been awarded PCORI
18 funds. And so during those assessments, that can be
19 something we could potentially think about adding in
20 given the unique time that we're living in. But we
21 have those kind of routine assessments that give us
22 that opportunity to do that.

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1 CHAIRPERSON GOERTZ: Thank you. All right,
2 Mike.

3 DR. HERNDON: Brian, a point of
4 clarification. Where do PCORI salaries fall?

5 MR. TRENT: They fall in two places. They
6 fall in the total program and program support and
7 also total administrative support.

8 DR. HERNDON: And how is that determined?
9 Which bucket?

10 MR. TRENT: The total program and program
11 support are those that are directly, individuals who
12 are directly, involved in programmatic activities.
13 The administrative support would be places like my
14 office, Office of the General Counsel, but those are
15 where those salaries occur.

16 So the individuals that are involved in --
17 actually be looking at the awards and those type of
18 things, they're the ones whose salaries are in
19 program and program support.

20 DR. HERNDON: Got it. Thank you very much.

21 And does program support also include
22 experts outside of PCORI that we call on for advice

1 and review? That's also is in program support?

2 MR. TRENT: Yes. Right.

3 DR. HERNDON: Okay. Thank you very.

4 CHAIRPERSON GOERTZ: All right. I believe
5 Russ has a comment. Russ, you still with us?

6 DR. HOWERTON: I just wanted to reply, that
7 I completely agree with Bob as a member of the FAC,
8 the answer to Alicia's question.

9 CHAIRPERSON GOERTZ: Great. Thank you.
10 All right. Bob V.

11 DR. VALDEZ: I just wanted to say that's
12 always the two lines that I always look at, program
13 support and administrative support, for a research
14 institution. And 22 percent falls well in line with
15 an institution of, certainly, this size and the
16 kinds of awards that are given. So keeping track of
17 those two lines is always something that I always
18 like to keep an eye on.

19 And it looks like you're doing a good job
20 of sort of projecting what you need to make the
21 program work.

22 MR. TRENT: Thank you.

1 CHAIRPERSON GOERTZ: All right, thank you.

2 Any other comments or questions?

3 [No response.]

4 CHAIRPERSON GOERTZ: All right. In that
5 case, I'm going to ask for a motion to approve the
6 proposed FY 2023 PCORI budget.

7 DR. LEVINE: So moved.

8 CHAIRPERSON GOERTZ: All right Sharon.

9 DR. FERNANDEZ: Second.

10 CHAIRPERSON GOERTZ: Alicia, as a second.

11 Is there any further discussion?

12 [No response.]

13 CHAIRPERSON GOERTZ: All those in favor,
14 please say aye.

15 [Ayes.]

16 CHAIRPERSON GOERTZ: Opposed?

17 [No response.]

18 CHAIRPERSON GOERTZ: Abstentions.

19 [No response.]

20 CHAIRPERSON GOERTZ: Okay. Thank you.

21 Great job, Brian.

22 MR. TRENT: Thank you.

1 CHAIRPERSON GOERTZ: Thank you so much.

2 All right. We are going to move into our
3 next agenda item then, which is to consider a new
4 proposed governance framework for approval.

5 So we'll be hearing from Kathleen Troeger
6 today, the Chair of our Work Group to Optimize
7 Effective Governance and Board Engagement.

8 This work group, just as a reminder, was
9 developed in March of this year, with the aim to
10 develop an evolved approach for the Board's
11 strategic oversight that advances PCORI's new
12 Strategic Plan and our reauthorization priorities.
13 So I'd like to ask Kathleen to make some brief
14 remarks and then Nakela to present the overall
15 governance framework. And then, I look forward to a
16 robust discussion before we consider a motion to
17 approve.

18 So, Kathleen, I'll turn it over to you.

19 DR. TROEGER: Thank you, Christine. It has
20 been a remarkable opportunity to work over the last
21 six months really with this cross-functional group,
22 including yourself and fellow Board members, Alicia,

1 Russ, Sharon, James, Danny, as well as PCORI staff,
2 Nakela, Harv, Michele, Mary, and Maureen. I see
3 everybody sort of heads down, but thank you very
4 much for really all of your efforts.

5 It's been those sustained efforts, the
6 collaboration, the engagement, and really the act of
7 participation that have advanced this work. Nakela
8 has provided us an overview during her Executive
9 Director report, which address both the purpose and
10 the desired outcomes from the work group, which has
11 really, you know, we firmly believe that they have
12 addressed both the governance challenges and
13 proposed a new governance framework for us to
14 consider and we're bringing to the Board today.

15 So with that, and without any further
16 delay, I want to provide the work group's support
17 and endorsement and the recommendation to be
18 considered by the Board and turn it over to Nakela
19 for the presentation. Thank you.

20 DR. COOK: Thank you so much, Kathleen.

21 I'm excited to present the proposed
22 elements of the governance framework that the Board

1 will be considering for approval. We can move to
2 the next slide.

3 We've outlined here the main elements of
4 the proposed framework, and they're displayed on
5 this slide just for a quick at a glance look, and
6 you can see here that the Board of Governors would
7 continue to operate to provide strategy and policy
8 direction, and have standing committees, including
9 the Selection Committee, the Finance and
10 Administration Committee, the Governance Committee,
11 and the Executive Evaluation and Compensation
12 Subcommittee, as well as a new Strategy Committee
13 and ad hoc working groups formalized into this
14 governance framework.

15 The Board could charge the new Strategy
16 Committee to perform specific and ongoing strategy
17 functions at an early and nascent stage of new and
18 emerging concepts and ideas in this framework. The
19 Board could also task more specific things to an ad
20 hoc work group for short-term, very specific
21 engagement in an activity that's further along in
22 development. And both of these opportunities

1 provide for a mixed perspective from Board members,
2 cross-functional perspectives, to bring to bear on
3 concepts, ideas that may be emerging for important
4 discussion.

5 All of these aspects of the governance
6 framework, the committees and the ad hoc work
7 groups, would then report back their recommendations
8 to the Board in this framework and structure.

9 We can go ahead to the next slide.

10 The quick summary of the proposed framework
11 is outlined here on the slide, and this is what
12 would be considered for approval by the members of
13 the Board of Governors, that we retain the following
14 standing committee structures, including the
15 Governance Committee, Finance and Administration,
16 Executive Evaluation and Compensation, and Executive
17 Committee.

18 That we create a new standing Strategy
19 Committee that can further engage in strategic
20 discussions as tasked by the Board, related to items
21 of ongoing importance, and that we pause the
22 convening of the three current standing strategy

1 committees, including the Engagement, Dissemination
2 and Implementation Committee, the Research
3 Transformation Committee, and the Science Oversight
4 Committee, while the new Strategy Committee is being
5 implemented, and that we expand the Standing
6 Selection Committee to allow it to consider
7 additional types of awards, including comparative
8 effectiveness research awards, dissemination and
9 implementation awards and research infrastructure
10 awards. And that we formally incorporate ad hoc
11 work groups into the governance framework given the
12 success we've seen in piloting some of those work
13 groups over the past year or two.

14 And that we assess the model, the new
15 governance framework, to determine if it's working
16 and if it's achieving the desired outcomes and adapt
17 and adjust as need be through that assessment.

18 So this is the proposed framework that is
19 being put before the Board for any discussion and
20 then consideration for approval. I'll turn it over
21 to you, Christine.

22 CHAIRPERSON GOERTZ: Thank you Nakela and

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1 Kathleen for those remarks and overview. Just as a
2 reminder, even though the working group has been
3 committed diligently to this effort since March,
4 this is actually something that has been evolving
5 over the past two and a half years. Beginning with
6 our work to develop a governance culture and then to
7 begin to look at how implementation of that culture
8 may impact our current governance structure and what
9 changes needed to be made.

10 We first began talking about this proposed
11 governance framework as a board last December with
12 continued discussions at our meetings in March and
13 then again in June. So it has been really exciting
14 to watch this concept evolve over time based on the
15 work, the incredible work of the work group, as well
16 as the input that we've gotten from the Board all
17 along the way. And I'm really excited to have this
18 discussion today and then to bring this to a vote.

19 And I see that Mike has his card up. So
20 why don't we just jump into the discussion, Mike?

21 DR. HERNDON: Thank you, Christine.

22 First of all, much appreciation, Kathleen,

1 to you and the team and the work group for this very
2 important transformational work for the Board.

3 My question, Nakela, I think it's best
4 suited to you and by the way, I fully support this
5 governance framework proposal. The makeup of the
6 Executive Committee currently is based upon existing
7 committees that are no longer going to exist. So
8 what will the makeup of Executive Committee look
9 like in the new governance structure?

10 DR. COOK: One of the key next steps
11 following potential approval of this framework by
12 the Board of Governors, would be that the Governance
13 Committee takes on quite a bit of work in thinking
14 through some of the implications for transition.
15 And this is one of the types of things that the
16 Governance Committee would take on in considering
17 and deliberating what the appropriate next steps
18 would be to propose back to the Board a potential
19 way in which we may fulfill the responsibilities of
20 the Executive Committee with this new framework.

21 And so, it's anticipated that the
22 Governance Committee would focus directly on that

1 point as well as several others. And there are many
2 different options in terms of thinking through what
3 an appropriate kind of appointment for the Executive
4 Committee might look like.

5 Right now, as Mike is referring to, for
6 other Board members, it's ex officio appointments of
7 the Chairs of the current strategy committees. And
8 so there are iterations of that based upon the new
9 framework that the Governance Committee can
10 consider.

11 CHAIRPERSON GOERTZ: Nakela, correct me if
12 I'm wrong, but my understanding is that if in fact
13 the Board does vote to move in this direction, that
14 by pausing the three current standing strategy
15 committees, there would still be a Chair that would
16 be able to serve on the Executive Committee in the
17 interim while these decisions are being made, is
18 that correct? In the interim?

19 DR. COOK: That's right. So there's no --

20 CHAIRPERSON GOERTZ: Gap.

21 DR. COOK: That's right.

22 CHAIRPERSON GOERTZ: Okay. Thank you.

1 Did you have anything else, Mike?

2 DR. HERNDON: I think the last 15 or 20
3 seconds was kind getting it what I was --

4 CHAIRPERSON GOERTZ: Okay.

5 DR. HERNDON: Since we don't have a, you
6 know, governance in this new structure established
7 yet, just what is the -- yes, that answered it.
8 Thank you very much.

9 CHAIRPERSON GOERTZ: Okay, thank you.
10 Kathleen.

11 DR. TROEGER: Just to clarify, and Mary,
12 I'd encourage you to jump in here. I hear some -- I
13 just want to make sure we're not conflating
14 Executive Committee, which as it stands now, with a
15 new Strategy Committee. Okay.

16 Because some of the language in our
17 discussions just leads me to believe that's an
18 important point to clarify.

19 CHAIRPERSON GOERTZ: And just a reminder,
20 while it's incredibly important that we make sure
21 that we have -- that our Executive Committee would
22 be fully operational if indeed it was called to

1 order, it has never yet in PCORI's history been
2 called to order because the entire -- the issues
3 that would -- might normally go to an Executive
4 Committee, in our case, come to the full board.
5 And so, the Executive Committee is really intended
6 to be for PCORI emergencies. We have not, I would
7 say there have been times when perhaps we've come
8 close, but we have not ever had to convene that
9 committee.

10 All right, anyone online -- that's joined
11 us online, who has a question or like to make a
12 comment?

13 [No response.]

14 CHAIRPERSON GOERTZ: Is anyone on mute
15 trying to make a comment?

16 [No response.]

17 CHAIRPERSON GOERTZ: All right. In that
18 case, Maureen, before I call for a motion, I'm going
19 to ask if there are any updates to Board member
20 attendance that we should be aware of.

21 MS. THOMPSON: No changes, other than that
22 Russell Howerton joined us during the Budget item.

1 CHAIRPERSON GOERTZ: Great, thank you. In
2 that case, I am going to ask for a motion to approve
3 the proposed governance framework.

4 DR. SCHUSTER: [Signifies motion.]

5 CHAIRPERSON GOERTZ: James Schuster. Can I
6 get a second?

7 DR. TROEGER: [Signifies second.]

8 CHAIRPERSON GOERTZ: Kathleen. All right.

9 Is there any further discussion?

10 [No response.]

11 CHAIRPERSON GOERTZ: All those in favor,
12 please say aye.

13 [Ayes.]

14 CHAIRPERSON GOERTZ: All right. Opposed?

15 [No response.]

16 CHAIRPERSON GOERTZ: Abstentions?

17 [No response.]

18 CHAIRPERSON GOERTZ: All right. The motion
19 passes. Thank you.

20 A very exciting moment for a process that
21 has been ongoing for quite some time. And so, I'm
22 very excited about this.

1 We are now poised to take a 15-minute
2 break. I think we'll go ahead and do that. I think
3 we probably will -- do we have to wait until 11:10
4 to adjourn or should we, or I mean to come back to
5 order? Should we come back to order in 15 minutes?

6 UNIDENTIFIED SPEAKER: Yes.

7 CHAIRPERSON GOERTZ: In 15 minutes. All
8 right. And because there's no public comment, I
9 think we have a little bit more flexibility, so we
10 will reconvene at 10:45. Thank you.

11 [Recess.]

12 CHAIRPERSON GOERTZ: All right. We're we
13 are going to go ahead and get started again.

14 So what I'd like to do is, actually I'd
15 like to ask Bob to come back.

16 [Laughter.]

17 CHAIRPERSON GOERTZ: Well, when Bob comes
18 back, he as Chair, and Kara Ayers as Vice Chair of
19 the PCORnet Priorities Work Group will introduce our
20 next agenda item, which is to Consider Proposed
21 Strategies to Leverage PCORnet to Advance PCORI's
22 National Priorities for Health and to Evaluate

1 PCORnet Performance. And without further ado, I
2 will ask first, Bob, and then, Kara, to make some
3 comments.

4 DR. ZWOLAK: Well, thank you very much,
5 Christine. This is a very exciting time for me and
6 for Kara and Erin, and I think in the rest of the
7 PCORnet Work Group, to present this information.

8 And the first thing I'd like to do is
9 probably go to the next slide, which identifies the
10 members of our work group. So thank you for all the
11 hard work to Kate Berry, Alicia Fernandez,
12 Christopher Friese, Russell Howerton, Mike Lauer,
13 Barbara McNeil, and Danny van Leeuwen, who helped us
14 immensely through this effort and spent lots and
15 lots of hours, many of them on late Friday
16 afternoons, were extremely challenging to get this
17 work done so Stage Two of this PCORnet Work Group
18 went very well.

19 I'd like, from the hundred-thousand-foot
20 level, to say that our charge was really twofold.
21 One was to consider strategies for evaluation of
22 PCORnet and the other was to consider strategies for

1 moving forward for PCORnet, itself, in terms of
2 research, and we have lots of important information.
3 I think the evaluation piece, we ended up thinking
4 that evaluation needs to be continuous, nonstop, and
5 provided by a combination of internal and external
6 views.

7 I think our take-home from the strategy for
8 research is that there are so many opportunities for
9 what PCORnet can do, that we really have to focus.
10 I mean, if we want this to work and continue working
11 well, it's an amazing tool, but we really do have to
12 decide what we're going to focus on. Because when
13 we started to consider the opportunities for
14 PCORnet, they're just immense. We could look
15 anywhere with it, and we can, but we have limited
16 resources, and so we have to in fact, focus.

17 So those are I think, the two biggest take
18 home points.

19 And since this is my last meeting, I'd like
20 to just make one example. I'm not sure if any of
21 you saw in the last day or two, the JAMA Network
22 identified or published a trial of gabapentin use,

1 perioperatively. So as we all try to get away from
2 opiates, perioperative gabapentin has been very
3 commonly employed to the fact that gabapentin, at
4 least according to this report, is currently the
5 tenth most commonly prescribed medicine in the
6 country. It's amazing.

7 And this report was retrospective. And so
8 even though it was propensity matched, you know, in
9 theory propensity matching is sort of the best
10 retrospective study one can do. It's still
11 retrospective. And so, it's open to those kinds of
12 criticisms.

13 And it was done on the Premier Healthcare
14 Network, which perked up, you know, perked up my
15 mind as being not real competition for PCORnet, but
16 sort of in the same category, hundreds of thousands
17 of patients. And in fact, they found patients who
18 got perioperative gabapentin had higher incidence of
19 postoperative delirium, had a higher incidence of
20 pneumonia, and had a higher incidence of the need
21 for new antipsychotic medications.

22 So not what we would necessarily think is

1 that as the best gift to an alternative to opiates.

2 And we could, PCORnet could look at this,
3 and with our networks, PCORnet could do a
4 prospective study and really get definitive
5 information about this in an area where we really
6 need more information. Alternatives to opiates,
7 perioperatively and postoperative, is a crucial
8 opportunity.

9 We could do this in a few heartbeats and it
10 just seems like that's just one of hundreds of
11 potential comparative effectiveness studies that
12 PCORnet is ideally suited for.

13 So I'm very enthusiastic. I'm anxious to
14 hear this report. The work group put in lots of
15 effort and I think we have some good ideas for you.

16 So Erin, please proceed.

17 Oh, I'm sorry.

18 DR. HOLVE: Kara.

19 DR. ZWOLAK: Kara, I'm sorry. I apologize.

20 DR. AYERS: That's all right. You're so
21 excited.

22 [Laughter.]

1 DR. AYERS: I want to thank Bob for his
2 leadership. I've learned so much, not only about,
3 but also from your leadership style and strategies
4 to move us through some really difficult work. So
5 it was an honor to work with you on what's, I guess,
6 your last work group, officially.

7 I also want to thank the PCORI staff that
8 helped us. We had a lot of hard work going in,
9 between meetings, during meetings. So Erin, thank
10 you, Kim, Claudia, Rachel, Laura, and Nakela. Thank
11 you to those Friday afternoons we were working hard.

12 This group was extremely collaborative and
13 engaging, I think you're going to see that reflected
14 in the priorities. And when I think about what I
15 hope for the future of PCORnet, you know, I hope
16 that it becomes less of this nebulous kind of
17 extraneous thing that is hard for us to wrap our
18 heads around. As we've really grappled with this
19 together, I think what's become clear for me, is
20 that there's real potential for data equity moving
21 us towards having better answers to comparative
22 effectiveness research questions.

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1 And those are really at the heart of what
2 the big questions that we have as, not only
3 patients, but our other stakeholder groups. But
4 patients, particularly, stand in the front of my
5 mind in terms of that PCORnet is hard for us to
6 explain and for different groups to understand but
7 it really, I think, holds the key to answer some of
8 these really important, impactful questions.

9 So thanks to all that have gone into this
10 work and let's hear the plan from Erin.

11 DR. HOLVE: Well, thanks so much again, Bob
12 and Kara, for your tremendous leadership on this
13 work group. And that was really bittersweet Kara,
14 when you said, Bob, this is your last work group.
15 So thank you again. And again, my sincere thanks to
16 the whole work group for their dedication,
17 deliberation, and an impressive final work product,
18 which I'm pleased to present on the work group's
19 behalf.

20 So as Nakela mentioned this morning in a
21 brief reminder, the Stage Two Work Group's
22 activities are grounded in work that was completed

1 by the Board in 2021 to develop a set of
2 prioritizing principles for infrastructure funding
3 relating to PCORnet. These principles really
4 promote PCORI's focus on patient-centeredness, the
5 national scope and comparability of PCORnet data,
6 and its use for studies that are national in scope,
7 as well as governance and partnership of the
8 network.

9 So it's important to remember that these
10 principles were used as the foundation for the
11 current Phase 3 contracts for the Clinical Research
12 Networks, as well as the Coordinating center and
13 guide all the work that the PCORnet does.

14 The focus of the stage two efforts, on the
15 next slide please, was to get more specific and
16 strategic to express the Board's strategic approach
17 to both evaluating the accomplishments as a network
18 that are due to PCORI funding and to inform
19 discussions about future PCORI investments that will
20 maintain and enhance PCORnet, as well as proposing
21 crosscutting strategies to integrate and leverage
22 PCORnet in ways that advance PCORI's National

1 Priorities for Health. Because strategic priorities
2 naturally flow into evaluation strategies, I will
3 discuss the Board work group's recommendations in
4 this order.

5 So on the next slide, please, and then
6 actually we can skip to the one after that.

7 To help frame this discussion it's useful
8 to note that the strategies document presented to
9 the Board for a vote includes four major strategic
10 pillars and three approaches to evaluate PCORnet's
11 performance, and Bob alluded to some of these
12 earlier.

13 So as you can see on the left, consistent
14 with the Board's focus in the prioritizing
15 principles on using PCORnet for research, the first
16 of these strategies as a set of efforts on funding
17 or a set of strategies on funding research. The
18 second focus pillar is on investment strategies for
19 the infrastructure that will both enable PCORnet to
20 be well-maintained and to innovate. The third is
21 addressing strategies to expand uses of PCORnet for
22 research. And the fourth, is increasing the use of

1 PCORnet for PCORI's operational and strategic
2 priorities.

3 The evaluation strategies then flow from
4 these cross-cutting strategies and focus on specific
5 approaches to continuous monitoring, specific
6 priorities and approaches to evaluate performance,
7 and a focus on aligning PCORI's organizational
8 learning strategy and some efforts to assess the
9 maturity of PCORnet.

10 Next slide, please.

11 With respect to the first pillar focused on
12 research funding, the Board work group had extensive
13 discussions about the need to balance PCORnet's
14 intentional design as a disease-agnostic network
15 with the current needs of the organization that is
16 based on the 2019 Authorizing Law. As a result, the
17 work group elected to focus on funding research that
18 uses infrastructure to conduct definitive studies
19 that advance the National Priorities for Health
20 which was part of the prioritizing principles and
21 maintain the broad focus, that disease-agnostic
22 focus, while also calling specific attention to

1 research on intellectual and/or developmental
2 disabilities, maternal morbidity and mortality,
3 health equity, and rare disease research.

4 Next slide, please.

5 With respect to the second pillar, focus on
6 supporting the infrastructure PCORnet that would be
7 both capable of continuously learning and improving
8 while also innovating. The work group emphasized
9 the need to, first of all maintain baseline network
10 functions that enhance data quality and network
11 research capacity to support studies. Again, with
12 that focus back on the research.

13 Second, to accelerate participation of
14 diverse, underrepresented, and underserved
15 populations, both in governance and research. And I
16 think this speaks in part to Kara's comment about
17 data equity earlier.

18 Third, to support PCORnet coverage so that
19 the network is comparable to the general United
20 States population. Maintaining that commitment,
21 again, to data equity.

22 And then fourth, innovating to advance

1 PCORI's National Priorities for Health, including
2 enhancing data capacity in areas such as social
3 determinants and patient reported data, as well as
4 promoting open science approaches that accelerate
5 progress towards an integrated learning health
6 system.

7 Concluding this set activities, the focus
8 was on enhancing an engagement infrastructure that
9 supports meaningful patient and stakeholder
10 partnership in all stages of research.

11 Next slide, please.

12 With respect to expanding the use of
13 PCORnet by enhancing understanding and activities to
14 make full use of the network, there was a discussion
15 and a strategy that focuses on both, improving the
16 visibility and stakeholder understanding of the
17 unique capabilities of the network, really is a
18 transformational resource. This includes PCORnet
19 capabilities supporting the full trajectory of
20 research across a range of studies that may include
21 platform trials, pragmatic trials, and high-quality
22 observational studies, such as the example that Bob

1 mentioned.

2 The second piece here was promoting the
3 access and use of PCORnet by a range of users,
4 including researchers, patients, caregivers,
5 communities, health systems, as well as other health
6 stakeholders. PCORnet, as you all know, is open to
7 all researchers who are pursuing relevant questions
8 in alignment with the National Priorities for Health
9 and the team supporting the front door are ready to
10 answer questions and support via PCORnet.org.

11 The third component here was opportunities
12 for greater partnership with organizations that
13 support research using PCORnet that, again, is
14 aligned with PCORI's strategic priorities. This is
15 part of the initial design of PCORnet and our
16 contribution to the public good. And several of the
17 examples Nakela discussed in her opening remarks
18 this morning illustrate where this type of "powered
19 by PCORnet" research is having a significant impact.

20 The network can and is being used by other
21 funders to support health research such as the CDC's
22 surveillance activities for COVID-19. And there was

1 a strong interest among the work group in seeing
2 this effort continue and expand.

3 Last, but certainly not least, the work
4 group felt that as part of supporting research
5 funding using PCORnet to build awareness of the
6 capabilities in PCORnet, it's also important for
7 PCORI to increase the use of PCORnet for our
8 operational and strategic priorities, such as
9 identifying potential gaps in research or data or
10 knowledge, and to inform the development of our
11 funding announcements.

12 Next slide, please.

13 Turning to the evaluation strategies
14 consistent with best practice, the Board emphasized
15 the need for continuous monitoring and evaluation of
16 the network, both to contribute to network partners
17 capacity to continuously learn and improve. Inform
18 the Board's strategic planning and decision-making
19 about both, baseline network functions and the
20 innovation and expansion efforts, as we've
21 discussed, and to assess the performance both for
22 the network as a whole, as well as all the

1 participating network partnerships acknowledging
2 that dynamic and federated model.

3 Next slide, please.

4 The work group also spent time discussing
5 strategies for evaluating performance, which focused
6 on prioritizing better and faster over simply
7 cheaper research, emphasizing efficiency, but being,
8 again, focused on the better and faster aspects of
9 this transformational network with respect to
10 network capacity.

11 In addition, there was focus on considering
12 the evaluation needs and perspectives of a diverse
13 group of stakeholders in the PCORnet ecosystem.
14 This includes everyone from PCORI staff to the
15 participating CRNs and health systems, and
16 importantly the patients and communities within the
17 PCORnet users, as well as potential users in the
18 future.

19 And lastly, an aim to benchmark PCORnet
20 performance against appropriate comparators wherever
21 possible, which remains an important focus among the
22 Board work group members in their discussions.

1 Of course alignment was also considered
2 important. So on the next slide, please.

3 The work group focused on a strategic
4 approach to evaluation that aligns with PCORI's
5 existing organizational learning strategies and the
6 National Priorities for Health. In addition, the
7 work group agreed that given the complexity of
8 PCORnet, a maturity model would be appropriate for
9 evaluation. In these models, specific domains such
10 as research, data and technology, and engagement are
11 each evaluated independently, though in the context
12 of the whole, to assess the maturity of each domain
13 and assess opportunities for continuous improvement.

14 There are several relevant maturity models
15 in the health research space and the work group
16 agreed that these provided confidence in this
17 approach.

18 So that concludes my remarks, but before I
19 end, I wanted to offer again my great thanks to the
20 PCORI Priorities Stage Two Work Group. It has been
21 such a sincere pleasure to work with the Board on
22 this effort and the PCORI team who, as Kara said,

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1 have been tireless and working collaboratively on
2 this effort. I greatly appreciate all the members
3 thoughtful participation and work to develop the
4 strategies.

5 Again, a special thanks to Bob and Kara for
6 their support and leadership. And Dr. Goertz, I'll
7 turn the item back to you.

8 CHAIRPERSON GOERTZ: Thank you so much,
9 Bob, Kara, and Erin.

10 Before we begin our discussion, are there
11 any Board members who believe they should recuse
12 themselves from this deliberative discussion and
13 vote on PCORnet?

14 DR. TROEGER: Yes, Kathleen Troeger
15 recusing herself.

16 CHAIRPERSON GOERTZ: Okay. Thank you,
17 Kathleen. Duly noted.

18 All right, in that case, I'd like to invite
19 members of the work group to share their thoughts
20 before opening the floor to the full board. Danny.

21 MR. VAN LEEUWEN: Thank you. I want to say
22 something about why I wholeheartedly support this

1 plan. My concern joining this group and thinking
2 about PCORnet is that I was committed to the
3 increase of using an infrastructure, like PCORnet,
4 to further public health research, and that there
5 was considerable, that would require a considerably
6 different approach.

7 So, for example, right now, it, we talk
8 about PCORnet as if it's a monolith, but it isn't.
9 There's PCORI. There's the Duke Coordinating
10 Center. There's the leadership of the Federated
11 Networks. There's the Steering Committee. And I
12 think that we don't talk about, there's the EMR
13 vendors, who have considerable control over clinical
14 data that's available.

15 And that there are initiatives out there
16 working on expanding standardized data sources like
17 HL7's Gravity Project, like the Social Intervention
18 Research and Evaluation Network, the National Birth
19 Equity Collaborative, the Public Health Association,
20 and cybersecurity experts develop a big database.
21 You know, there's cybersecurity.

22 So anyway, I think that we chewed on this

1 stuff and I think to me the Friday evening was the
2 least of it. It was -- these are hard issues and
3 real challenges to think about implementing. And I
4 feel like through discussion and negotiation we came
5 to, and the staff -- you know, every time there was
6 another meeting, there was another iteration
7 bringing in and trying to synthesize, you know, the
8 sometimes awkward conversations or whatever.

9 And that each iteration was more clear and
10 more representative and I think, although I think,
11 this is going to be like a challenge to implement
12 this is a great foundation and I supported
13 wholeheartedly.

14 CHAIRPERSON GOERTZ: Thank you, Danny. Any
15 other work group members? Anyone on the -- who's
16 joining us virtually?

17 [No response.]

18 CHAIRPERSON GOERTZ: Okay. Bob, if there
19 are no other commentors, Sharon, do you want to
20 comment? If there are no other commentors, I'd like
21 to add one piece to this and that's the question
22 about operational excellence and for lack of a

1 better word, productivity and marketing.

2 Because PCORnet is a network of networks
3 and basically everyone involved in PCORnet, to some
4 extent or another, has a different day job. I think
5 if we, PCORI, want PCORnet to succeed, we've got to
6 be the ones to keep the eye on the ball and keep
7 PCORI working and looking for new research, looking
8 for improved methods to determine social
9 determinants. We know -- we've reviewed a nice
10 white paper that suggests it's possible, but it's
11 not going to be easy.

12 And I think we need to be the driver here
13 if we want this to be successful. And it's not just
14 the evaluation strategies. The evaluation
15 strategies are sort of a retrospective look at how
16 well it's done, which is really important, but in
17 terms of making this a longstanding success, I think
18 PCORI needs to provide the energy and the enthusiasm
19 and as well as a direction, I think is much helped
20 by this outline and these goals.

21 But I think this is PCORI's biggest single
22 effort so far, certainly in terms of dollars and

1 magnitude and everything else, creativity. And so,
2 I with the pause of the RTC, which was sort of the
3 committee of record keeping track of PCORnet, I
4 think it's going to be really important that we
5 determine what subgroup, work group, strategy
6 committee pays attention to PCORnet in this new
7 phase. Thank you.

8 CHAIRPERSON GOERTZ: Thank you Bob.
9 Sharon, then Bob V and then James.

10 DR. LEVINE: Bob preempted my part of my
11 comment/question, which was if there is a single
12 thing we've talked about over the last couple of
13 days that deserves a home and a permanent home, it's
14 the PCORnet. And I think, you know, as you all move
15 forward, thinking about where that is, where that
16 lives, is going to be really important.

17 The question I had was, did the work group
18 think about at some point evaluating whether the
19 current governance model of the PCORnet actually is
20 still fit for purpose, or whether there needs to be
21 some reconfiguration or realignment of that?

22 And it goes to your comments, Bob, about

1 marketing, about ownership, about promotion. And to
2 me, I'm channeling Alicia here, ensuring that the
3 values, that PCORI's values, remain embedded in --
4 and the priorities, remain embedded in the approach
5 to who gets to use PCORnet for what.

6 CHAIRPERSON GOERTZ: Thank you, Sharon.
7 Erin or Nakela or Bob?

8 [Off microphone discussion.]

9 DR. HOLVE: Thanks Bob. So Sharon, it's a
10 fantastic question and there certainly was some
11 discussion of that. I gather your question extends
12 beyond sort of PCORI's Board governance to the
13 governance of PCORnet. Is that correct?

14 So we certainly have been looking at those
15 issues in talking with the PCORnet Steering
16 Committee, as you know, in Phase 3, now PCORI staff
17 has a vote on that steering committee. Though,
18 again, it's important to remember that that steering
19 committee is not, you know, binding with respect to
20 decisions that the network makes, so it does not
21 make any financial distinctions because all of the
22 contracts really provide the oversight for

1 activities with PCORI.

2 Where this gets challenging, and I think
3 merits some ongoing discussion, is the partnership
4 model. And we want PCORnet to be used, again as
5 Nakela offered, some very compelling examples this
6 morning by other funders and we want that to be a
7 flexible and living approach. So I think that
8 there's going to be an ongoing evolution there as
9 well and something we're very committed to.

10 And again, that I believe the strategies
11 that are before the Board for consideration to vote
12 will help us work to evolve.

13 I don't know, Nakela, if you want to add
14 anything.

15 DR. COOK The only other thing I may add is
16 that when we were talking about governance with the
17 work group, one of the things that we emphasized is
18 that even the work we're doing in the work group,
19 the work that's happening today as part of the
20 governance in terms of thinking about the strategic
21 direction for PCORnet, and so, it was integrated in
22 the way in which we were thinking about governance,

1 but we also spoke quite a bit about the fact that
2 the way in which PCORI's priorities remain embedded
3 and prioritized for PCORnet really stems from our
4 funding strategy. And so, we fund based on the
5 strategy that's discussed with the Board of
6 Governors and the strategic priorities there, and
7 then we provide the contracts consistent with that
8 strategy and oversee them for execution against that
9 approach.

10 And so, our funding line is really one of
11 the strongest ways that we continue to maintain that
12 PCORI direction in the work of PCORnet.

13 CHAIRPERSON GOERTZ: Bob, did you want to
14 make any comments?

15 DR. ZWOLAK: And if I could add, I agree
16 with absolutely both of those, but I do think that
17 as we talk about evaluation, one of the evaluation
18 issues at a high level may be the governance issue.

19 And while we talked indirectly, many of our
20 discussions were revolved around these issues of
21 governance, none of them were squarely aimed at
22 governance.

1 CHAIRPERSON GOERTZ: Great, thank you. Bob
2 V.

3 DR. VALDEZ: Thanks very much. And Bob,
4 thank you for raising this issue about really having
5 PCORI drive PCORnet if it's going to be successful
6 in the longer run. And Sharon, as usual, you've
7 tapped the main issue, which is how does this
8 partnership actually govern itself and if it's going
9 to carry the "PCOR" part of the name, how it remains
10 true to the PCORI set of values and focus.

11 I don't know enough about it, so I'm glad,
12 I just wanted to say, I'm glad this discussion is
13 taking place because it's one of the things that I
14 was left trying to scratch my head about and trying
15 to understand. And I think it's worth, and as
16 others have said, a longer discussion and more
17 thoughtful consideration.

18 CHAIRPERSON GOERTZ: Thank you. James?

19 DR. SCHUSTER: Yeah. Thank you. I agree.

20 It was definitely a helpful overview and
21 all these discussions are helping me gradually get a
22 better enhanced sense of the PCORnet work. Kind of

1 building on Bob's comment, you know, when we look at
2 the metrics that you've proposed for evaluation, I
3 wondered if one metric really is kind of above the
4 rest, which is funded CER tied to PCORI's priorities
5 and that all the other activities really are -- not
6 entirely, but probably largely in service at that.

7 And so, I wondered if we want to wait and
8 track that explicitly, you know, in the same way
9 that we look at a number of CER studies funded, you
10 know, number of them published in a high impact
11 journal, results published in high impact journals,
12 et cetera. If that's a metric that we really want
13 to highlight in terms of looking at the impact of
14 the funding for PCORnet.

15 DR. COOK: Thanks so much. It's a helpful
16 suggestion. And I'll also note, I think Laura
17 Forsythe, the Director of our E&A Program, is on the
18 line and the Laura's team is really going to be
19 leading the evaluation effort. So I didn't know,
20 Laura, if you are with us, if you wanted to add?

21 DR. FORSYTHE: I am. And I think that's a
22 great comment. I really appreciate it. I think

1 that resonates well with the discussions that the
2 group had over the many meetings with respect to
3 where the focus needed to be and how to prioritize
4 our efforts. So we'll look forward to carrying that
5 through. Thank you.

6 CHAIRPERSON GOERTZ: All right. Thank you.
7 I've got Alicia and then Mike.

8 DR. FERNANDEZ: Thanks, and thank you for
9 this, all the work that went into producing this
10 report. It was well-presented and I, for one, you
11 know, I look at those priorities and I'm like, yep,
12 those all sound -- those all sound right.

13 What they also, however, what I don't have
14 a handle on is that -- is how we're going to not
15 essentially choose among them, but how we're going
16 to invest among them, and how we're going to space
17 that out over time. So, for example making PCORnet
18 more representative of the U.S. population is an
19 important goal. On the other hand, there may need
20 to be -- there definitely needs to be more
21 investment in being able to produce better data or
22 different levels of data.

1 So, I feel that the committee has done
2 great work, but I would like to hear a little bit
3 more on if you could help us move forward in the
4 sense of, I don't know -- I don't have a sense, and
5 of course, it's reasonable that where we're going to
6 have these discussions, how these decisions are
7 going to be made, whether we're talking about a
8 three-year plan or a four-year plan or a two-year
9 plan, you know, and whether or not you considered
10 any recommendations either for governance or for
11 more immediate local target of funding.

12 DR. COOK: I may just open it up for a
13 couple of comments from Erin and then be happy to
14 circle back around.

15 You know, I was thinking about some of the
16 activity that stemmed from the first, Stage One
17 Working Group, that spawned several kinds of
18 convenings with the community around certain areas,
19 including the social determinant space that the
20 white paper stemmed from and how there are efforts
21 that I think the priorities set up for us that then
22 require a little bit more of that kind of further

1 digging and information gathering, et cetera. That
2 what I think was very successful was the ability to
3 then bring that back to the Stage Two Committee,
4 Stage Two Work Group and talk about what we learned
5 and then the next step was a more refined strategy
6 approach.

7 And so, I think that process worked well
8 before and that we may still have the need for that
9 kind of work where we take some of the strategies
10 that are been put forward here and we start to
11 garner the information on what it would take, what
12 would that look like, et cetera, and be able to
13 bring that back to the Board for more discussion and
14 anticipate that's going to be something that's
15 ongoing in discussion. And the Board may want to
16 suggest at that point that perhaps a strategy
17 committee, or something, continue to hear some of
18 that. And so, that would be our first approach
19 would be to bring some things back to the Board
20 following the strategies that have been laid out in
21 order to determine how we move with it next.

22 Did you want to add anything?

1 DR. HOLVE: Thanks so much, Nakela, and
2 again, fantastic question, Alicia. It's something
3 I've spent a lot of time thinking about. I know
4 that Kim Marschhauser and Claudia Grossmann, who are
5 the Associate Directors working with PCORnet, do as
6 well.

7 So I'll just add a couple of quick things
8 for those who have been less involved in the work
9 group, you know, we have about a two-year time
10 horizon with the existing contracts in which we can
11 make some modifications and updates with the current
12 network structure. And so, really there's a good
13 timeframe, I think, in about the next 12 months in
14 which, you know, some of those sort of tweaks and
15 adjustments that the strategies would guide us
16 towards, would address. And then in addition, we'll
17 start to come back and have a conversation about
18 what's the capacity then, potentially for a Phase 4.

19 So again, for those who are not part of the
20 work group, I just want to kind of outline that
21 general timeline.

22 In that context, as Bob alluded to, and I

1 think Nakela just did as well, these reports on the
2 social determinants of health data, alignment and
3 linkage with claims data, as well as patient
4 reported outcomes, and patient-generated data are
5 now really ready for prime time. And so one of the
6 things that we've been working towards, I think
7 we're just about poised to release, is more of a
8 sort of call for comment on some of the
9 recommendations that have been presented in that
10 work. So it's really robust, excellent discussion
11 of the existing data capacity and where we might go
12 next.

13 But to your point, Alicia, I think figuring
14 out from the research community, what do they see a
15 need to be built or enhanced now to, you know,
16 facilitate the research that they most want to do in
17 these spaces is part of the effort that Bob
18 described, I think around selecting, right --
19 prioritizing where we go from here. And as Nakela
20 said, that's feedback we can bring back to either
21 the work group or the Board as the preference of the
22 Board moving forward. So I think are a couple

1 strategies we can take.

2 CHAIRPERSON GOERTZ: Thank you.

3 DR. ZWOLAK: Can I add to that as well?

4 CHAIRPERSON GOERTZ: Yes, please.

5 DR. ZWOLAK: I mean there's some synergies
6 here. So for instance, if we are to scientifically
7 approach maternal mortality, PCORnet has to have a
8 more representative population so we, PCORI, can
9 emphasize by our funding and our bully pulpit, the
10 importance to do that. And likewise, if we're to be
11 successful in assessing maternal mortality, we need
12 to have better tools to measure social determinants
13 of health. And so those things converge and we can
14 drive that with our funding, which is a huge tool,
15 obviously.

16 But I do think that it's got to be, I feel
17 some urgency. I feel, not some urgency, I feel a
18 lot of urgency, that we would stay on top of this
19 and keep this moving. Because again, I don't want
20 to repeat myself, but we, PCORI, are sort of the
21 accelerant here. Without PCORI constantly pushing
22 ahead, I don't think there will be as much

1 timeliness or otherwise, a sense of urgency from
2 others.

3 CHAIRPERSON GOERTZ: Thank you. Mike.

4 DR. HERNDON: Thank you. And again, Bob
5 Kara, and the group, thanks for the tremendous work
6 and great discussion. I couldn't agree more with
7 things that have been discussed, and I do believe
8 this definitely supports our National Priorities,
9 but I just can't help myself in wanting to ask the
10 question and because I truly don't know. But I
11 think maybe there's some low-hanging fruit here, if
12 you will, to use Bob's term.

13 Representing payers, public, you know, and
14 Medicaid especially, I think there's a lot of data
15 in the Medicaid and public-payer space that we could
16 be leveraging. And I know in Oklahoma State, which
17 I live, is standing up a statewide HIE, so hopefully
18 it can be. So, I just want to make the comment that
19 I don't want us to lose sight, and I'm not quite
20 sure how entailing PCORnet is to public-payer data,
21 but I just wonder if there's not a concept to
22 explore there with public-payer data and outcomes.

1 I understand that claims data is limited,
2 but I just wanted to say that.

3 And then the question is, that I can't help
4 myself but ask, is there information within PCORnet
5 that we can leverage to get outcomes data based upon
6 payment methodology and healthcare delivery system
7 design? And can we touch that?

8 You know, we have many physicians that are
9 employed with health systems. We have incentive-
10 based and non-incentive-based contracts with
11 providers and things like that.

12 So, again, getting to this passion that I
13 have, and I think I would have to represent the
14 Medicaid space, is there a way to determine if
15 outcomes are different based upon payer strategies
16 in the healthcare delivery system design?

17 CHAIRPERSON GOERTZ: Thank you. Erin.

18 DR. HOLVE: Well, thanks so much, Mike.
19 Having just come to the PCORI from a Medicaid
20 agency, I can't help but greatly appreciate your
21 comment. And, you know, and really the opportunity
22 to think at the level that you're describing is one

1 of the major reasons I came to PCORI and was excited
2 to re-engage with PCORnet, so I think your questions
3 are really well-suited and fit in with this strategy
4 of the proposed strategy nicely.

5 I can also say from my own experience on
6 the ground, also having just run a network with an
7 HIE, that you know, some of the questions that
8 you're raising -- the data elements you're raising
9 are not easy necessarily to obtain, the structure of
10 the contract shifts and so forth.

11 So I think to Bob's comments, I think this
12 is an area where we would need to decide to invest
13 and prioritize, to look at some of those questions.
14 Again, highly meritorious. I think we just need to
15 engage in some further discussion about the
16 questions that are of most interest to the Board.

17 CHAIRPERSON GOERTZ: Thank you Mike and
18 Erin. Barbara. Barbara, I think you're on mute.

19 DR. McNEIL: Oh, I'm sorry. Sorry.

20 CHAIRPERSON GOERTZ: Okay. We can hear you
21 now.

22 DR. McNEIL: Oh, okay. So I think the

1 whole issue that Barbara raised about the possible
2 difficulties with the current PCORnet members in
3 terms of socioeconomic status and ethnicity in
4 dealing with maternal morbidity and mortality is a
5 real one.

6 And I also think that Russell's comment
7 about Medicaid or other private/public payer options
8 is also a real one. And I'm wondering if we should
9 ask the leaders of PCORnet to actually give us a
10 breakdown for each of their members, what exactly
11 the socioeconomic status, the minority status, and
12 the payer status is as far as they can go, so that
13 we will really know whether we have a good cross-
14 section of this country. And as a really aggressive
15 move, I wonder if we would want to give priority
16 grants to those particular PCORnet groups that
17 actually were high in some of the desirable
18 attributes whose -- that we wanted to reach.

19 I don't know how you feel about that, but
20 it strikes me that we are doing what we've always
21 done. We do men, women, age, old, young, whatever.
22 And we don't preferentially give credit to any group

1 that has brought in minority groups by whether it's
2 payer, racial, ethnicity, whatever.

3 CHAIRPERSON GOERTZ: Thank you Barbara.

4 Erin, did you want to reply?

5 DR. HOLVE: Thanks so much. And Barbara
6 it's a tremendous observation that, you know, again,
7 this is an effort to transform the way we do
8 research, and to get it. You know, both the data
9 equity issues that Kara mentioned, as well as really
10 identifying where there are opportunities to engage
11 particularly underserved patients in the country in
12 this research activity.

13 So I really appreciate those suggestions.
14 You know, we do at the outset at a high level have
15 information by area deprivation index for all of the
16 PCORnet and we can go back and look at those data.
17 They're about 17 percent of participants with 30
18 million participants who we can touch in a year who
19 are in that fourth level, the greatest sort of
20 degree of disadvantage. And we're also taking,
21 again, a closer look as was discussed with the
22 social determinants of health data to try and

1 understand those issues in a more fine-grained way.

2 The other thing your comments highlighted
3 for me that I wanted to make sure the Board knows
4 about, is an ongoing effort to build capacity,
5 particularly within PCORnet, particularly within the
6 areas of MMM and IDD. So there's an active effort
7 across the networks to look at what the capacity of
8 the network is to address many of these questions.
9 And also let us know if they think there are
10 potential challenges with the network structure or
11 data so that we can try to get in a more detailed
12 way at some of the questions, Alicia, that you and
13 Bob were both talking about both MMM and IDD.

14 CHAIRPERSON GOERTZ: Barbara.

15 DR. McNEIL: So can I follow up? I don't
16 want to be too aggressive here, but I think I am
17 going to be.

18 This is a pretty important area and I know
19 we can move on it slowly or fast. We can work on it
20 in a slow fashion or in a fast fashion. And is it
21 possible to get some preliminary information on
22 everything that you've said by, not next meeting,

1 but the meeting after that? So we actually know how
2 the different groups, what the structure of the
3 different groups are in terms of these critical
4 variables and whether or not we could actually do
5 something to improve our success by making awards
6 preferentially to those groups that are more to our
7 liking?

8 I mean, I'm basically asking us to move
9 very fast here because this is an area which we
10 could study to death and get nowhere.

11 DR. HOLVE: I was just going to mention
12 Barbara, that I think the efforts of understanding
13 capacity are just for that intent to inform our
14 funding strategies. And so, that is, I think, kind
15 of the step that we're in now is to understanding
16 that in order to say what is it that we find there
17 is a capacity to go after within PCORnet and what
18 other things might we need to do, thinking about
19 bolstering that for specific studies of interest in
20 this space.

21 And so the research funding would be the
22 kind of parallel corollary once we understand more

1 about what we have in an infrastructure capacity.
2 And so we can drive the research funding in the way
3 that we've driven research funding for other PFAs
4 and other types of things quickly or you know, in a
5 more expedited fashion if we find that there's
6 something we really want to capitalize on.

7 And maybe I'll just add, Barbara, that we
8 are moving with all deliberate speed. I'm not sure
9 I'd promise you a specific date because I know that
10 the Board cares about precision in the data that
11 we're providing as well as speed. So the better,
12 we'll use the better and faster framework again
13 here. But I can guarantee we'll bring back
14 information as rapidly as we can.

15 DR. McNEIL: I don't think this is an area
16 where we need second decimal point accuracy to be
17 honest. So in terms of precision, I think two
18 significant figures is good enough.

19 DR. HOLVE: Very helpful. Thank you.

20 CHAIRPERSON GOERTZ: Thank you, Barbara.

21 All right. I am not seeing any other tent
22 cards up. Is there anyone online that would make

1 like to make -- have the last word?

2 [No response.]

3 CHAIRPERSON GOERTZ: All right. Seeing
4 none, in that case, I would like to ask Maureen if
5 there are any updates to Board member attendance.

6 MS. THOMPSON: There are no changes.

7 CHAIRPERSON GOERTZ: Thank you. Do I have
8 a motion to approve the recommended Strategies to
9 Leverage PCORnet to Advance PCORI's National
10 Priorities for Health and Evaluate PCORnet
11 performance?

12 DR. LEVINE: So moved.

13 DR. HERNDON: Mike.

14 CHAIRPERSON GOERTZ: Okay, thank you. I
15 heard Sharon first and then Mike as a second. All
16 right. Is there any further discussion?

17 [No response.]

18 CHAIRPERSON GOERTZ: All those in favor,
19 please say aye.

20 [Ayes.]

21 CHAIRPERSON GOERTZ: Abstentions?

22 [No response.]

1 CHAIRPERSON GOERTZ: Opposed?

2 [No response.]

3 CHAIRPERSON GOERTZ: All right. The motion
4 carries.

5 Thank you again so much to the members of
6 this work group. I know that this has been a true
7 labor of love over all these many months and I
8 really appreciate your work and be very excited to
9 see how this evolves into action. So thank you
10 Erin.

11 All right. It is quite a bittersweet
12 moment for me then to turn the agenda over to Nakela
13 as we say goodbye to four outgoing Board members who
14 have been with PCORI since the beginning, including
15 myself and our Vice Chair, Sharon.

16 So, Nakela, the floor is yours.

17 DR. COOK: Well, thank you for the
18 opportunity to really have a chance to speak about
19 four of our last founding Board members who are
20 departing the Board. This is their last Board
21 meeting with us today, so it really is a bittersweet
22 moment. While we want to celebrate and recognize an

1 outstanding 12 years of service that each of them
2 have given PCORI, we also recognize as a fond
3 farewell that we'll miss seeing our colleagues that
4 we admire and have enjoyed greatly working with over
5 several years.

6 So today we're celebrating Christine
7 Goertz, Sharon Levine, Ellen Sigal, and Bob Zwolak.
8 And together they've really helped us to oversee an
9 incredible evolution of the organization from a
10 startup with no staff, to a handful of staff, to now
11 a mature and well-established organization with more
12 than 300 staff.

13 And the Board was here even before the
14 organization and they spent time, a great deal of
15 time and energy determining how to interpret and
16 implement our legislative mandate, including even
17 operationalizing the focus on patient-centeredness
18 in some very important ways that have really been
19 making a mark for PCORI moving forward as this is
20 part of our funding criteria and makes PCORI unique
21 in that research funding landscape.

22 They were all, you know, also very deeply

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1 involved in guiding our very first National
2 Priorities for Research, our first research agenda.
3 and PCORI launched its funding opportunities under
4 their oversight. And I've only had the fortune of
5 knowing each of you for a short period of time over
6 your entire tenure on the Board at PCORI, but you've
7 certainly made an impression and none of those
8 accomplishments would've been possible without each
9 of you.

10 They're leaving PCORI incredibly well
11 positioned to build on its unique role in the health
12 research ecosystem. And as we implement the bold
13 and thoughtful strategic plan that they helped to
14 usher through just earlier this year, we'll continue
15 to think of them and remark on their service and
16 contributions to the organization.

17 I just wanted to briefly say a few words
18 about each and then provide them an opportunity to
19 remark on their service as well.

20 Bob, I thought I'd start with you as a
21 physician and surgeon who's represented that
22 constituency for 12 years on the Board. You've

1 served on several committees and just tirelessly
2 given of yourself on the Science Oversight
3 Committee, including chairing that committee for a
4 year and as Vice Chair before that. You also served
5 on our FAC, our Finance and administration
6 Committee, including as Vice Chair on that
7 committee.

8 And in addition to your role on the full
9 board and your big picture thinking, you've also
10 been someone who's been able to help us with the
11 details. From the development of our portfolio to
12 the specifics about individual research questions,
13 the insights that we've gained from you and speaking
14 with you over the years have truly developed
15 important targeted topics that are important for our
16 nation.

17 Your thoughts about our Commitment Plan and
18 our funding profile have led us to be ambitious in
19 the way in which we think about things. And we've
20 also been assessing how we're doing against with our
21 funding, that's really helped to make sure that the
22 right questions are being asked and that we're

1 continuing to push forward with everything we can do
2 for the health of Americans with the funds that
3 really have been entrusted to us and you ensured
4 those principles were embedded in our approaches.

5 So we thank you for that and we fondly
6 remember your years on the Board.

7 Sharon, I also wanted to speak to your
8 service. You've represented the private stakeholder
9 group for 12 years on the Board, or I should say the
10 private-payer stakeholder group for 12 years on the
11 Board and served as the Vice Chairperson of the
12 Board for the past three years and chaired several
13 committees, served on the EDIC for 12 years, and/or
14 its predecessor, I should say.

15 And you have always encouraged us to
16 emphasize impact and to think about the impact of
17 our work for those that we serve. You have
18 articulated for us in the best of fashion, how to be
19 bold and how to think about aspirational goals for
20 PCORI, and you've been passionate about making sure
21 our work delivers what we've said it would to
22 patients, communities, clinicians, policy makers,

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1 and others. And so, we're incredibly grateful for
2 your service as well.

3 I also wanted to mention that in Ellen
4 Sigal's absence today, that she has represented the
5 patient and consumer stakeholder group on the Board
6 for 12 years. She serves with distinction on our
7 Science Oversight Committee, and her creative
8 thinking and ability to push us as an organization
9 to be innovative faster in our approaches and take
10 on some of the challenges that are of most important
11 is really unparalleled and these qualities have
12 served for PCORI well, particularly during the
13 pandemic, when we had to learn how to pivot quickly.

14 And Christine, I certainly would not want
15 to leave this moment for last, but you have served
16 as the integrative healthcare practitioner
17 representative on the Board for the past -- and
18 Chairperson for the past three years, Vice
19 Chairperson before that. And you have led and
20 served on several committees.

21 And one of the things that's been really, I
22 think, advantageous to us for your service on all

1 those committees is that you knew about all the
2 domains across PCORI and it really integrated well
3 in your role as Chairperson. It's opened our eyes
4 to new possibilities on the horizon because you've
5 been able to synthesize all that you've learned
6 across the activities and think more broadly about
7 them.

8 You've always been willing to go the extra
9 mile for PCORI and do whatever is necessary to
10 facilitate our success and PCORI's success and that
11 certainly is just exemplified in these last three
12 years of your role as Chairperson.

13 So to all of our outgoing Board members, we
14 are just really grateful for everything that you've
15 given. We are, I think, in many ways, shocked that
16 today is already here and know that you'll be missed
17 in so many ways and we hope that you stay connected
18 to PCORI.

19 But we did want to give you a moment for
20 some of your words reflecting on any fond memories
21 you may have from your time on the Board, or the
22 PCORI accomplishments you may must be proud of or

1 perhaps your hopes for the future or even what you
2 think some incoming Board members may want to hear
3 about time of service on the Board.

4 So Bob, I was wondering if you kick us off
5 and let us know some of your thoughts.

6 DR. ZWOLAK: Thank you for those kind
7 words. We live in an ever-changing world. And so,
8 it certainly is sometimes a very cruel world, you
9 know, President Putin sees fit to bomb Ukrainians in
10 the homeland of my grandparents. And we live in
11 such a world of hyper-individualism that people get
12 in fist fights at school board meetings and toxic
13 populism is all around us. And in that setting,
14 it's just amazing to me that the PCORI Board could
15 have come together and have been so successful over
16 time.

17 And people, you know, who I represent or
18 who Sharon represents, we sort of all dropped that
19 at the door. Hang up your guns at the door and you
20 know, come in and negotiate and I think we've been
21 very successful in that regard. It's been a great
22 trip.

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1 But my favorite story, or one of my
2 favorite stories forever that I'll never forget is
3 the odd couple of Steve Lipstein and Gene Washington
4 going into a corner Bank of America and saying, you
5 know, they had \$10 million they needed to deposit in
6 a new account and they wanted free checking.

7 [Laughter.]

8 DR. ZWOLAK: And you know, who is this
9 PCORI thing? I mean, that's just a wonderful story.
10 And now we have this just fabulous new location,
11 which I think will bring us together, bring PCORI
12 together more than ever. So I want to congratulate
13 everyone that helped in finding this new home.
14 This is just terrific.

15 I think enough couldn't be said about the
16 staff. I mean the staff has been ever, ever, ever
17 improving and the quality of some of our stalwarts
18 who have been here for many years and the quality of
19 the new additions to the staff, I think are
20 spectacular. And when I look at the changing of the
21 Board, you know, it's six, I think six new members
22 you know, you say, well, this might be a period of

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1 potential speed bumps or even instability. But the
2 fact is that the remaining Board members and the
3 staff are so strong that I think that it won't, you
4 know, there might be a tiny bit of a pause as the
5 new Board members kick in, but the GAO has been very
6 good at picking Board members, at least in my
7 opinion, and so I suspect things will go on and get
8 better and better and better.

9 I want to point out two things that I think
10 going forward are going to make a huge difference.
11 And the first is our just finished discussion about
12 PCORnet, I think that just has enormous potential to
13 answer lots and lots of really important questions.
14 And so, the advice I would give is to really focus
15 on PCORnet and continue to emphasize the need for
16 its development. You have to, you know, we talked
17 about this a lot in the work group, we have to
18 continue to ensure the basic stuff works. Like, you
19 know, the ability to pull labs and really basic
20 things, and the vastly more complex issues of being
21 able to accurately identify social determinants in
22 PCORnet and make sure PCORnet represents the real

1 people in our country.

2 It's very difficult, but I think PCORnet
3 can do it.

4 The other thing I think is that I want to
5 bring up, just again, is the decision we made very
6 recently about the changes on the Methodology
7 Committee. And I do appreciate Robin and the team
8 with the Methodology Committee, but I think that
9 they've been hindered by the firewalls and the
10 makeup of that group. And now I think that they
11 will be released and I'm happy to hear there are
12 potentially lots of good applicants for the
13 Methodology Committee because I think the
14 Methodology Committee has done yeoman's work at
15 their baseline job of making the standards. But I
16 do think that they can help us move forward with
17 lots of research questions if we engage the
18 Methodology group more.

19 So I look forward to a very, very rosy
20 future for PCORI. I think that this is a fantastic
21 combination of staff and Board members that have
22 learned over time and with our new Strategic Plan

1 have the pathway clear to collaborate more and more
2 all the time and make great work of the funds that
3 we've been given.

4 So, thank you.

5 DR. COOK: Thank you so much, Bob. And as
6 always, a wise counselor as when I first met you and
7 you leave us with some wise advice.

8 Sharon, did you want to speak next?

9 DR. LEVINE: So I could just say what he
10 said because much of what I had prepared or thought
11 about saying, Bob has already articulated.

12 Nakela asked us to talk about what our
13 fondest memories were of PCORI and as I thought
14 about it, similar to what Bob said, my fondest
15 memories are every time we've had the privilege of
16 getting together in-person. Healthcare is a
17 relationship business. And you know, as wonderful
18 as technology is, there is no substitute for human
19 relationships and my ability to meet you, each of
20 you, and to even our newest members of the Board in
21 whatever context we've been able to meet it has been
22 an extraordinary privilege and the opportunity to

1 cross paths with people whom I never would've had
2 the opportunity to do so with, other than my service
3 on the PCORI Board. It has just been one of the
4 joys of the last 12 years. Twelve years is a long
5 time.

6 In terms of PCORI's accomplishments, I
7 think for me, from my perspective, the things that I
8 think PCORI should be proudest of is in the
9 beginning, soldiering on, in the face of skeptics.

10 We were surrounded by skeptics from every
11 possible perspective. Those who thought we would do
12 too much and those who thought we would do too
13 little and to the great credit of the Board, it
14 never got in the way of keeping our heads down and
15 focusing on the work and trying to do what Congress
16 asked us to do.

17 The second thing I think PCORI should be
18 incredibly proud of is making good on the promise of
19 keeping patient-centeredness that the core of
20 everything we do. We spent a lot of time in the
21 early days before we had staff debating whether it
22 should be person-centered or patient-centered until

1 our wise council advised us since Congress made that
2 decision for us, we could end that debate.

3 [Laughter.]

4 DR. LEVINE: But I think our recent
5 conversations, and Danny, your contributions to the
6 Board about remembering that this is about people,
7 it's not just about patients, individuals who are
8 ill or dependent on healthcare. And so, I do think
9 the Board gets a lot of credit for keeping that
10 always front of mind, always at the center of what
11 we thought about and did, or think about and do.

12 And as Bob said, as a board intentionally
13 designed to be diverse and balanced and potentially
14 to neutralize one another's perspective, it has been
15 an extraordinary opportunity. And I've sat on a lot
16 of boards, of watching, as Bob said, people leaving
17 their constituency perspective at the door and
18 coming together to do the right thing for patients.
19 And it's been a joy.

20 My hopes for the future, continue to do
21 what Congress intended only faster and better. I'm
22 not going to say cheaper. And address the pain

1 points in the country with great urgency.

2 I saw today that or yesterday, or today, I
3 can't remember, that HHS released some statistics
4 that we currently have like on average 25 maternal
5 deaths per hundred thousand live births. Three
6 times the number of the top five OECD countries.
7 And the range within the country is enormous.

8 And 80 percent of those deaths are
9 preventable, or where HHS is determined, are
10 preventable and preventable means we know what would
11 have prevented it. It's not theoretical, it's real.

12 And to me, this reinforces the need for us
13 to do what we can, for PCORI to do what you can, to
14 address this, as well as the other I'd say public
15 health crises of equity: substance abuse, violence,
16 and the triple threat of anti-science misinformation
17 and distrust, that is a major obstacle to getting
18 the information that we know can help individuals to
19 optimize their health from actually either believing
20 in, trusting, or accessing the services that can be
21 beneficial to them.

22 Advice to new Board members. Show up and

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1 speak up.

2 GAO has done a phenomenal job every time in
3 populating this board with talented, committed,
4 mission-driven individuals and our new Board members
5 should not hesitate to speak up, should not wait a
6 year to offer an opinion. This is an environment;
7 this is an effort that depends upon the
8 contributions of everyone involved.

9 And finally, attend to the Methodology
10 Committee and our partnership with AHRQ. Both of
11 these are critical, haven't had enough presence on
12 the Board's agenda, deserve a lot of investment, and
13 a lot of attention. And among all the partnerships
14 we have, these are two that I think going forward
15 deserve a lot of Board time and investment.

16 Oh, one more thing. One more thing. I
17 realized today as we were going through the Board
18 meeting that there were no public comments. So we,
19 Christine, Bob, and I can, and Ellen, can continue
20 to contribute and just register as members of the
21 public and --

22 [Laughter.]

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1 CHAIRPERSON GOERTZ: I had that same
2 thought.

3 DR. LEVINE: And let you know what we
4 think,

5 DR. COOK: Well, we'd be glad to hear from
6 you in that venue, too. And ,you know, I think that
7 that's a good point for us moving forward too, to
8 think about maintaining a cultivation of the
9 commitment to hearing from our stakeholders in the
10 public.

11 And Christine, I'm interested to hear some
12 of your reflections as well and your thoughts about
13 what you may pass on for us to think about in the
14 future.

15 CHAIRPERSON GOERTZ: Thank you. Nakela.
16 As is frequently the case, if I -- after Sharon
17 speaks, I have very little new to add and she has
18 said it far more eloquently than I ever could, but I
19 still want to take this opportunity to make a few
20 remarks and perhaps even reiterate some of the
21 things that both her and Bob have said.

22 It is been the honor of my professional

1 life to be on this PCORI Board and to serve as the
2 Chairperson. And when Nakela asked us to consider
3 some of our fondest moments. Well, the first thing
4 that popped in my mind is the day that she decided
5 to become our Executive Director. That is
6 definitely up there.

7 But there are literally thousands of those
8 memories and moments and it's like trying to choose
9 who your favorite child is.

10 But when I think about landmarks like
11 getting reauthorized and bringing Nakela on board
12 and some of the decisions that the Board has made.
13 I think those have been incredibly important. But
14 my fondest memories are all about the relationships
15 and the opportunity that I've had to get to know all
16 the PCORI staff and the Board members, all of you
17 that are on the Board now, and those of you who came
18 before this time and left. I just treasure those
19 moments.

20 And in addition, when I think about the
21 ways that PCORI has changed me, and it has in
22 profound ways, much of that change is the way that

1 my worldview was altered by meeting with our
2 stakeholder groups. And so if I have -- and we did
3 that early on in our development, we actually
4 traveled around the country and as a Board met with
5 stakeholder groups and the advice that I would have
6 to you as a board is to find a way to resurrect some
7 of those direct connections with stakeholders,
8 because I truly believe not only will it change you,
9 but it will change the direction of PCORI to have
10 that direct contact in the way that I believe it did
11 in our early years.

12 It helps to keep you focused always on why
13 we're here.

14 And I think that's one of the reasons why
15 we were able to so effectively leave our stakeholder
16 hats at the door and come together in the way that
17 we did as a board because we had this constant
18 reminder that this was not about us. This was real,
19 not even so much about a particular stakeholder
20 group, but really about patients and the whole
21 collective wisdom of all of the stakeholder groups.

22 And I think about what I'm most proud of.

1 Again, there are countless options to choose from
2 and certainly the platform that we've built in order
3 for the next iteration of PCORI to launch from is
4 something that I'm particularly proud of. But the
5 thing that I'm most proud of is that I truly believe
6 that PCORI has changed the conversation, the
7 national conversation when it comes to patient-
8 centeredness. It's put patient-centeredness on the
9 map in a way that really matters, that's really
10 impactful.

11 I see CMMI now talking about being patient-
12 centered and, you know, the DOD and the VA and NIH.
13 I was not hearing any of that and I would've noticed
14 before PCORI began its work. So I'm proud that we
15 have helped to facilitate in a profoundly meaningful
16 way that national conversation and that it is now
17 becoming more and more, not only accepted, but
18 expected for researchers, regardless of who your
19 funding source is to take a patient-centered
20 perspective and to put together multi-stakeholder
21 teams. And, again, I think PCORI deserves a lot of
22 credit for bringing that happen, making that happen.

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1 My hope is that you now take the platform
2 that has been built and you use that to do something
3 that is extraordinary, that is bold and impactful.
4 My day job is primarily focused on conducting
5 research, comparative effectiveness research, and
6 implementing the data that we already know in
7 pursuit of doing a better job of caring for people
8 with low back pain. Low back pain is the number one
9 spend in direct costs in the healthcare delivery
10 system, largely for treatments which largely don't
11 work and can often cause much more harm than benefit
12 to patients.

13 My hope is that you, that PCORI takes on
14 those really difficult tasks, those really difficult
15 issues, like low back pain to the extent that 12
16 years from now when those Board members who are
17 coming on this week are graduating, that what
18 they'll be able to say is their greatest
19 accomplishment is not only that they set up the
20 framework and that they built the platform, but that
21 the entire healthcare system is profoundly changed
22 because of the work that PCORI has done.

1 My advice to new Board members is, as
2 Sharon said, the GAO has done an outstanding job of
3 appointing new Board members just consistently
4 across the board, and I have no doubt that they will
5 do, have done that same excellent job this time.
6 And over the past years as new Board members have
7 come on board, and especially in the last three
8 years as I've been Chair, I've sometimes had new
9 Board members say, well, I was going to bring that
10 up during the meeting, but I didn't know if I
11 should. And what I'll never forget driving to my
12 very first PCORI Board meeting, pretty much
13 frightened to death because thinking about all of
14 the Board members, you know, the Director of NIH and
15 the Director of AHRQ, and people like Harlan
16 Krumholz who makes the stock market drop if he says
17 something negative, and thinking, what do I have to
18 contribute?

19 And what I learned really at that very
20 first meeting is that all of us have something to
21 contribute, and we have been put on this board
22 because we do have a voice. And so, my advice to

1 new Board members would be to use that voice. It is
2 incredibly, from the very beginning, as Sharon said,
3 it's incredibly important that that happens, so that
4 PCORI can be the best organization it can possibly
5 be. And if you do use your voice, I guarantee you
6 that PCORI will listen. Thank you.

7 [Applause.]

8 DR. COOK: Well, thank you for the
9 collective wisdom, even just now, in terms of
10 thinking about the path forward and for everything
11 that you've done for us over the years, there's no
12 way to thank you for your service of the past 12
13 years. It just simply exceeds anything that we can
14 say or do.

15 But I hope you know that you will always be
16 in the hearts of PCORI and we hope that you'll carry
17 PCORI in your hearts moving forward.

18 And to that, we celebrate our fond farewell
19 for the four of you and your service on the Board.

20 CHAIRPERSON GOERTZ: Thank you.

21 DR. COOK: Thank you.

22 [Applause.]

1 CHAIRPERSON GOERTZ: So now, for the final
2 time, let me close by thanking those of you who
3 joined us today. Our meeting agenda approved
4 minutes from the July 26, 2022 meeting. The slides
5 and the archived webinar will be posted to PCORI's
6 website within a week.

7 As always, we recommend -- we welcome your
8 feedback. We recommend your feedback; we beg you
9 for your feedback --

10 [Laughter.]

11 CHAIRPERSON GOERTZ: -- at info@PCORI.org
12 or through our website at www.PCORI.org. Thank you
13 again for joining us. Have a good afternoon.

14 [Whereupon, at 12:05 p.m. EST, the Patient-
15 Centered Outcomes Research Institute's
16 Board of Governors meeting was adjourned.]

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