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THE ADVISORY COMMITTEE ON
HERITABLE DISORDERS IN NEWBORNS AND CHILDREN

Advisory Committee Meeting - Day 2
November 4, 2022
9:30 A.M. to 1:00 P.M.

HRSA Headquarters
5600 Fishers Lane
Rockville, Maryland 20857

In-person and via Webinar
Attended via Zoom Webinar

C O M M I T T E E M E M B E R S

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Kyle Brothers, MD, PhD

Endowed Chair of Pediatric Clinical and
Translational Research
Associate Professor of Pediatrics
University of Louisville School of Medicine

Ned Calonge, MD, MPH (Chairperson)

Associate Professor of Family Medicine
University of Colorado School of Medicine

Jannine D. Cody, PhD

Professor, Department of Pediatrics
Director, Chromosome 18 Clinical Research Center
Founder and President
The Chromosome 18 Registry & Research Society

Jane M. DeLuca, PhD, RN

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Clemson University School of Nursing
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C O M M I T T E E M E M B E R S

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Professor of Clinical Pediatrics

University of California San Francisco (UCSF) School
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Head, Section of Genetics and Metabolism

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C O M M I T T E E M E M B E R S

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Professor of Pediatrics and Pathology and

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1 **E X - O F F I C I O M E M B E R S**

2 **Agency for Health care Research & Quality**

3 *Kamila B. Mistry, PhD, MPH*

4 Senior Advisor

5 Child Health and Quality Improvement

6

7 **Centers for Disease Control & Prevention**

8 *Carla Cuthbert, PhD*

9 Chief, Newborn Screening and Molecular Biology Branch

10 Division of Laboratory Sciences

11 National Center for Environmental Health

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13 **Food & Drug Administration**

14 *Kellie B. Kelm, PhD*

15 Director, Division of Chemistry and Toxicology

16 Devices, Office of In Vitro

17 Diagnostics and Radiological Health

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19 **Health Resources & Services Administration**

20 *Michael Warren, MD, MPH, FAAP*

21 Associate Administrator

22 Maternal and Child Health Bureau

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E X - O F F I C I O M E M B E R S

(continued)

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ACTING DESIGNATED FEDERAL OFFICIAL

Soohyun Kim, MPH

Health Resources and Services Administration

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Maternal and Child Health Bureau

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ORGANIZATIONAL REPRESENTATIVES

American Academy of Family Physicians

Robert Ostrander, MD
Valley View Family Practice

American Academy of Pediatrics

Debra Freedenberg, MD, PhD
Medical Director, Newborn Screening and
Genetics, Community Health Improvement
Texas Department of State Health Services

American College of Medical Genetics & Genomics

Marc Williams, MD, FAAP, FACMG
Director, Genomic Medicine Institute
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American College of Obstetricians & Gynecologists

Steven J. Ralston, MD, MPH
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1 **ORGANIZATIONAL REPRESENTATIVES** (continued)

2 **Association of Maternal & Child Health Programs**

3 Karin Downs, RN, MPH

4 MCH Director

5 Massachusetts Department of Public Health

6

7 **Association of Public Health Laboratories**

8 Susan M. Tanksley, PhD

9 Manager, Laboratory Operations Unit

10 Texas Department of State Health Services

11

12 **Association of State & Territorial Health Officials**

13 Scott M. Shone, Ph.D., HCLD (ABB)

14 Director

15 North Carolina State Laboratory of Public Health

16

17 **Association of Women's Health, Obstetric and Neonatal**
18 **Nurses**

19 Shakira Henderson, PhD, DNP, MS, MPH, RNCNIC, IBCLC

20 Board Director

21 Vice President, Research Officer

22 University of North Carolina Health

1 **ORGANIZATIONAL REPRESENTATIVES** (continued)

2 **Child Neurology Society**

3 Margie Ream, MD, PhD

4 Associate Professor

5 Director, Leukodystrophy Care Clinic

6 Director, Child Neurology Residency Program

7 Nationwide Children's Hospital, Division of Neurology

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9 **Department of Defense**

10 Jacob Hogue, MD

11 Lieutenant Colonel, Medical Corps, US Army

12 Chief, Genetics, Madigan Army Medical Center

13

14 **Genetic Alliance**

15 Natasha F. Bonhomme

16 Vice President of Strategic Development

17

18 **March of Dimes**

19 Siobhan Dolan, MD, MPH

20 Professor and Vice-Chair for Research

21 Department of Obstetrics & Gynecology and Women's

22 Health, Albert Einstein College of Medicine

1 **ORGANIZATIONAL REPRESENTATIVES** (continued)

2 **National Society of Genetic Counselors**

3 Cate Walsh Vockley, MS, LCGC

4 Senior Genetic Counselor

5 Division of Medical Genetics

6 UPMC Children's Hospital of Pittsburgh

7

8 **Society for Inherited Metabolic Disorders**

9 Gerard T. Berry, M.D.

10 Harvey Levy Chair in Metabolism

11 Director, Metabolism Program,

12 Division of Genetics and Genomics

13 Boston Children's Hospital

14 Director, Harvard Medical School

15 Biomedical Genetics Training Program

16 Professor of Pediatrics, Harvard Medical School

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P R O C E E D I N G S

Welcome and Roll Call

SOOHYUN KIM: Welcome back everyone. I will go ahead and start calling. From Agency for Healthcare Research and Quality, Kamila Mistry. If you don't mind speaking into the microphone.

KAMILA MISTRY: Here.

SOOHYUN KIM: Thank you. Kyle Brothers.

KYLE BROTHERS: Here.

SOOHYUN KIM: Ned Calonge.

NED CALONGE: I'm here.

SOOHYUN KIM: From Centers for Disease Control and Prevention, Carla Cuthbert.

CARLA CUTHBERT: I'm here.

SOOHYUN KIM: Jannine Cody. Jane DeLuca.

JANE DELUCA: Here.

SOOHYUN KIM: From Food and Drug Administration, Kellie Kelm.

KELLIE KELM: Here.

SOOHYUN KIM: From Health Resources and

1 Services Administration, Michael Warren. I know
2 he's online, okay. Jennifer Kwon.

3 JENNIFER KWON: Here.

4 SOOHYUN KIM: Ash Lal.

5 ASHTOUSH LAL: Here.

6 SOOHYUN KIM: Shawn McCandless.

7 SHAWN MCCANDLESS: Here.

8 SOOHYUN KIM: From National Institute of
9 Health, Melissa Parisi, who stepped out
10 momentarily. Chanika Phornphutkul.

11 CHANIKA PHORNPHTKUL: Here.

12 SOOHYUN KIM: Thank you. Now, I'll call
13 on our organizational reps.

14 JANNINE CODY: I am here, but I wasn't
15 allowed to turn on my mic when you called my name.
16 Sure. We can hear you now, thank you, Jannine.

17 MICHAEL WARREN: And same thing for me.
18 This is Michael Warren.

19 SOOHYUN KIM: All right. From American
20 Academy of Family Physicians, Robert Ostrander.

21 ROBERT OSTRANDER: Here.

22 SOOHYUN KIM: From American Academy of

1 Pediatrics, Debra Freedenberg.

2 DEBRA FREEDENBERG: Here.

3 SOOHYUN KIM: From American College of
4 Medical Genetics, Marc Williams.

5 MARC WILLIAMS: Here.

6 SOOHYUN KIM: From Association of
7 Maternal and Child Health Programs, Karen Downs.
8 From Association of Public Health Laboratories,
9 Susan Tanksley.

10 KAREN DOWNS: Here. Sorry, it took me a
11 while to unmute.

12 SOOHYUN KIM: Thank you, Karen.

13 SUSAN TANKSLEY: I'm here.

14 SOOHYUN KIM: Thank you, Susan. From
15 Association of State and Territorial Health
16 Officials, Scott Shone.

17 SCOTT SHONE: Here.

18 SOOHYUN KIM: From Association of
19 Women's Health and Obstetric and Neonatal Nurses,
20 Shakira Henderson. Okay. Child Neurology
21 Society, Margie Ream.

22 MARGIE REAM: Here.

1 SOOHYUN KIM: Thank you. And
2 representing the Department of Defense, Jacob
3 Hogue.

4 JACOB HOGUE: Here.

5 SOOHYUN KIM: From Genetic Alliance,
6 Natasha Bonhomme.

7 NATASHA BONHOMME: Here.

8 SOOHYUN KIM: March of Dimes, Siobhan
9 Dolan.

10 SIOBHAN DOLAN: Here.

11 SOOHYUN KIM: National Society of
12 Genetic Counselors, Cate Walsh Vockley.

13 CATE WALSH VOCKLEY: I'm here.

14 SOOHYUN KIM: Thank you. And from
15 Society of Inherited Metabolic Disorders, Gerard
16 Berry.

17 GERARD BERRY: Here.

18 SOOHYUN KIM: Thank you. And I will
19 just give a quick reminder for our organizational
20 representatives and Committee members, please do
21 not use the chat feature in the Zoom, and for
22 those who are in the meeting, please make sure

1 that your computer speakers are off. Thank you.

2 NED CALONGE: Thanks, Soohyun.

3 Earlier this year, MCHB released the
4 Blueprint for Change, a National Framework for a
5 System of Services for Children and Youth with
6 Special Health Care Needs. This was a culmination
7 of nearly two and a half years of effort,
8 collaboration with people and organizations across
9 the country, including CYSHCN and their families,
10 consumers, health care professionals, public
11 health leaders, researchers, and academic
12 institutions.

13 The blueprint serves as the national
14 framework to improve the lives of children who
15 have special health care needs and impacts nearly
16 one out of all five children, including newborns
17 and children impacted by heritable disorders.

18 Committee members and organizational
19 representatives all received a copy of the
20 pediatric supplement articles introducing and
21 describing the blueprint and more information on
22 the blueprint and links to the articles can be

1 found on the MCHB website.

2 I'm really pleased that as we start the
3 second day of our meeting, which just has, you
4 know, a couple of agenda items in terms of talking
5 about workgroups and solutions and moving forward,
6 we also have the privilege of hearing from Dr.
7 Dennis Kuo, who served on the steering Committee
8 for this work and is the lead author on this
9 critical area of access to care.

10 Dr. Dennis Kuo is a Professor of
11 Pediatrics and Chief of Developmental and
12 Behavioral Pediatrics at the University of
13 Rochester Medical Center and the Golisano
14 Children's Hospital. He received his medical
15 degree at the University of Pennsylvania and he
16 completed his pediatric residency at the
17 University of North Carolina Hospital and
18 fellowship in general academic pediatrics at the
19 Johns Hopkins University.

20 Dr. Kuo has a longstanding interest in
21 the care of children with disabilities and medical
22 complexity, including systems of care, early

1 childhood, and health equity. Dr. Kuo is the
2 immediate past Chair of the Council on Children
3 with Disabilities for the American Academy of
4 Pediatrics, and I'm really pleased that you're
5 here to talk about the blueprint. Thank you.

6 **Blueprint For Change:**

7 **Access to Care For Children and Youth With Special**
8 **Health Care Needs and Their Families**

9 DENNIS KUO: Good morning, everyone.
10 Thank you. This is a really incredible treat for
11 me to be here today. Hang on, I don't want to get
12 ahead of myself here. What did I do? Okay, okay.
13 While we're waiting for the slides, let me give
14 you a little bit of background of the way I've
15 been thinking about the area of the blueprint and
16 systems.

17 My career is really -- I mean, if you
18 follow my CV and my career, it's really kind of
19 gone like this. And there actually is a common
20 theme to everything I do, which is the children
21 and the families and the communities where we
22 serve. And I think when I came out of residency,

1 I started out in several years of private practice
2 and those years, I remember looking at what I was
3 doing and thinking, you know, I could, for
4 example, do something as simple as prescribing a
5 medication, like, let's say an antibiotic for an
6 ear infection, and I have no guarantee that that
7 antibiotic would make it's way into the child.
8 And, of course, it would encompass everything from
9 transportation to health literacy, to whether it
10 was even the right decision at all, because a lot
11 of ear infections just go away by themselves. And
12 when we think about our children who have
13 disabilities and medical complexity, the system
14 just gets much more complicated and there's so
15 many twists and turns and context that we have to
16 think about, and that really led me on my journey
17 to where I am today, and every now and then I
18 pinch myself to think I'm part of this discussion.
19 So, this really is a privilege and thank you for
20 allowing me to be here today.

21 We have objectives, of course. We'll
22 talk about the system of care for children with

1 special health care needs, something I've been
2 looking at academically and in partnership with
3 many colleagues for years, and how that relates to
4 the context of newborn screening. We'll introduce
5 the Blueprint for Children and Youth with Special
6 Health Care Needs, the implication of the
7 blueprint on the care system, and the potential
8 implications for newborn screening and Recommended
9 Uniform Universal Screening Panel.

10 Now, when we talk about system of care,
11 I think it's important to understand, like, what a
12 system really is. It's not just the components
13 that make up what the system is. You know, it's
14 also the philosophy that underlines the system and
15 the journey and the pathways through the system.
16 So, we have to think about the system as a journey
17 in a longitudinal pathway through how you get from
18 here to there -- when you get to here to health
19 and wellness. And that's important because that's
20 really the context of framing. When we talk about
21 the blueprint, there are principles that underlie
22 everything that we do.

1 I want to give credit to Treeby Brown
2 and Sarah Beth McLellan from HRSA, you know, for
3 their partnership, for their leadership, and also
4 to HRSA for a number of the slides that you'll be
5 seeing today.

6 We also have to start with the Maternal
7 and Child Health Bureau Strategic Plan. MCHB's
8 mission is to improve the health and well-being of
9 America's mothers, children, and families, and
10 their vision is an American where all mothers,
11 children, and families thrive and reach their full
12 potential. And I think it's important to think
13 about what those words specifically refer to.

14 Full potential is not, say, an absence of disease,
15 you know, and full potential also recognizes that
16 children and health and wellness and, you know,
17 maternal child health is a journey of health,
18 growth, and development. And so, it's about how
19 do we achieve that maximal potential, not just how
20 do we get rid of disease or ameliorate disease.

21 The goals are access, equity, capacity,
22 and impact. The access is to have access to high-

1 quality and equitable health services to optimize
2 health and well-being for all MCH populations.
3 Equity is to achieve health equity for MCH
4 populations. Capacity is to strengthen public
5 health capacity and workforce for MCH. And the
6 impact is to maximize impact through leadership,
7 partnership, and stewardship.

8 And one thing I also want to note in the
9 goals is how the goals all interrelate with each
10 other, and that's also a principle that we adhered
11 to when we developed the blueprint, is just how
12 all these pieces do fit with each other.

13 So, the definition of children and youth
14 with special health care needs. They are defined
15 as children or youth who have or are at increased
16 risk for chronic physical, developmental,
17 behavioral, or emotional conditions, and who also
18 require health and related services of a type or
19 amount beyond that required for children
20 generally. So, note that this definition
21 encompasses need, it encompasses services, it does
22 not encompass specifically a diagnosis or a

1 specific condition. And that is for two reasons -
2 - two primary reasons. One is that there are
3 children who don't have a specific diagnosis and
4 yet they have special health care needs.

5 The second is recognizing that across
6 different needs and diagnosed conditions that
7 families and communities encounter many similar
8 issues related to navigation, related to service
9 type that they need, related to the stress that
10 families and communities feel when they encounter
11 the service need trying to get to the point of
12 maximum health and wellness.

13 The definition of children and youth
14 with special health care needs does encompass a
15 very wide range of conditions and needs. So,
16 likely the more milder service need, might be the
17 child with relatively uncomplicated asthma, and
18 that child would do well with a controller
19 medication, the occasional scheduled visit with
20 the primary care doctor, and adhering to NHLBA
21 guidelines.

22 On the more complex end, you might have

1 kids who have spina bifida, who require
2 multispecialty care, more of a complex care
3 approach, and also a set of related services
4 through the education, financial, and community
5 support system.

6 It's also important to recognize the
7 definition encompasses a number of behavioral and
8 developmental diagnoses. ADHD and cerebral palsy
9 are within there. Genetic diagnosis including
10 Down Syndrome, which can result in a number of
11 complex care needs.

12 Under the Recommended Uniform Screening
13 Panel, many of the conditions that we screen for
14 and have added to the recommended panel over the
15 years would fall into this category. So,
16 metabolic disorders, endocrine disorders,
17 including hypothyroid and congenital adrenal
18 hyperplasia, sickle cell disease, critical
19 congenital heart disease, cystic fibrosis, hearing
20 loss, and severe combined immunodeficiency.
21 Again, this is certainly not an exhaustive list of
22 everything that's recommended or screened for, but

1 we can see how these particular conditions do
2 result into the care needs that would fall onto
3 the system of care for children and youth with
4 special health care needs.

5 Now, when referring to the charters and
6 the principles that we operate under for this
7 particular group, the Recommended Uniform
8 Screening Panel does -- we're asked to look at
9 conditions that are chosen based on the potential
10 net benefit of screening, the ability of states to
11 screen for the disorder, and the availability of
12 affected treatments. And there are testing goals
13 that when you look at what it could result in, if
14 you can get the testing done very early on within
15 the first forty-eight hours of life and then
16 report it to the newborn's health care provider
17 within five to seven days of life, the thinking or
18 the impact would be that by proper diagnosis and
19 treatment under the life course model, that you
20 can have a much -- a very long-term impact on the
21 child's health and wellness.

22 But it is important to also recognize

1 that the charter does also state that follow-up
2 activities, including those necessary to achieve
3 best practices and rapid diagnosis and appropriate
4 treatment in the short-term and for us to consider
5 those that ascertain long-term case management
6 outcomes and appropriate access to related
7 services.

8 So, that part, long-term case management
9 outcomes and appropriate access to related
10 services, that is a world that I live and practice
11 in, and this is why I appreciate the opportunity
12 to come and discuss the blueprint.

13 And I really maintain that almost all of
14 the conditions that we screen for result in
15 special health care needs because it does not --
16 the journey -- and I use the word journey
17 deliberately -- does not end with the diagnosis.

18 With many of the conditions, there are
19 chronic care and ongoing specialty care management
20 needs. There may be medications. There may be
21 formulas, special diets. There may be therapies
22 necessary. Even with early diagnosis, we may be

1 looking at physical, occupational, and speech
2 therapy, for example, to be able to ameliorate or
3 not just to reduce the risk of a disease
4 condition, but also to make sure the child reaches
5 their maximum health potential.

6 There is also the need for early and
7 continuous screening for co-morbidities, including
8 learning difficulties. And as we enter the world
9 of critical congenital cyanotic heart disease,
10 there is more and more literature about the
11 learning difficulties that many children that we
12 encounter as they start to go through the
13 education system.

14 And because of this, we maintain that
15 children with special health care needs are best
16 served by a comprehensive system of care, and I've
17 mentioned that system is not just the components,
18 like your specialists and your primary care and
19 your schools and your financing system, but it's
20 also how kids get through the system, the journey
21 of the system, and the philosophy of care that
22 underpins the system.

1 And I'm also positive that we need to be
2 looking at the needs proactively and holistically,
3 proactive meaning that when you get realization of
4 a specific diagnosed condition, what is the path
5 forward. You know, for kids who don't have
6 special health care needs, who maybe neurotypical,
7 who are typically healthy, the journey seems like
8 it's fairly straightforward in a sense that when
9 the child turns five, they would go to
10 kindergarten. There's an expectation that when
11 the child finishes 12th grade, that there's a
12 pathway of independence ahead. When you have some
13 sort of a special health care need, the pathway
14 starts to go this way, and that's what we're
15 trying to address.

16 The Maternal and Child Health Bureau has
17 been conceptualizing and looking at the system of
18 care for children with special health care needs,
19 really for many decades. You know, and this, it
20 really comes through the long history of the
21 Maternal and Child Health Bureau, coming through
22 the Civil Rights era, and then look at the

1 involvement of children's families and family
2 advocates who really advocated for the health and
3 wellness for all children with special health care
4 needs.

5 The six indicators of a well-
6 functioning system that's been used for really
7 several decades at this point, and we are still
8 using this system for measurable outcomes, is
9 presented here with the underpinning and
10 foundation of family centered care, and cultural
11 linguistic competence. And we place individuals
12 and families in the middle because they are the
13 center of the system. And you can see the six
14 components, which again, there are metrics that we
15 look at that often we take these metrics from the
16 National Children's -- National Survey of
17 Children's Health. Starting from the top and
18 going clockwise, families as partners, the medical
19 home, adequate insurance, early and continuous
20 screening, community-based services, and
21 transition to adulthood.

22 And on this slide, we'll go through just

1 what did these components mean. So, families as
2 partners means that our system encourages and
3 builds in that families are partners in decision
4 making at all levels, and all levels means at the
5 individual level but partners also at the system
6 level, and that includes organizational and policy
7 levels just to give you a few levels.

8 The medical home. The medical home
9 meaning comprehensive, coordinated, continuous
10 care that is also comprehensive. It should be
11 culturally responsive care. Just comprehensive
12 medical care that's provided to the child with
13 special needs.

14 Adequate insurance. Adequate insurance
15 that is able to cover and pay for the necessary
16 services to achieve health and wellness and
17 potential also in a way that is that the family
18 can afford.

19 Early and continuous screening. And we
20 talk about early continuous screening for special
21 health care needs. I will also add that when a
22 child has special health care needs, the early and

1 continuous screening does not end. You know,
2 there's more screening that needs to be done for
3 things like depression, anxiety, other mental
4 health conditions, or comorbidities that may
5 arise.

6 Community based services that are
7 organized so families can use them easily and I
8 would also say proactively. So, like when we
9 refer to early intervention, special education, we
10 refer to care coordination, that we make sure that
11 the families get the help that they need as
12 opposed to, you know, here's your -- here's a
13 phone number to call and then the family reaches a
14 dead end there because that does happen.

15 And transitions to all aspects of adult
16 life, including health care, work, and
17 independence, so that when our children reach the
18 ages of eighteen to twenty-one, that they
19 transition seamlessly and effectively into the
20 adult health care system and the adult legal
21 system.

22 The context of this that relates to the

1 newborn screening system is that when we screen,
2 and we identify that the system starts to -- the
3 special health care needs really starts to kick
4 in. And I think it's a good opportunity to
5 review what we call the life course approach. And
6 I find often that the life course approach, I
7 think folks heard about it, they know about it,
8 but there's a lot more than saying that, you know,
9 when something impacts a child's life over here
10 that there's an impact down the line. The life
11 course is really a complex adaptive system and
12 that things that happen at a certain child's age,
13 that, yes, it does have impact down the line.
14 It's not necessarily a linear process, the timing
15 makes a big difference. The -- some impacts have
16 larger results down the line than others, but it's
17 also recognizing the impacts of structural and
18 social determinants of health because when you
19 have, let's say, you identify a condition at
20 birth, the system that the child enters will also
21 make a big difference in how the child's health
22 and potential results.

1 So, yes, early diagnosis and
2 intervention does impact the life course,
3 including health development, wellness, and
4 achievement of potential. But after the
5 diagnosis, we have family education and
6 empowerment. We have the medical home and
7 specialty care that come in to be able to address
8 and treat the condition medically. But there's so
9 many other considerations such as the communities
10 where the child and family reside, the education,
11 because the therapies are often handled in the
12 education system, and the financing for service
13 access. So, there's a lot of these considerations
14 that we have to look at.

15 In the next several slides, I'm going to
16 present just a few case examples of how the system
17 begins to look for children with special health
18 care needs. So, in the case of a child with
19 sickle cell disease, kids with sickle cell disease
20 are asymptomatic when they're diagnosed at birth
21 and that's because at the time of birth, they
22 generally have fetal hemoglobin and not the adult

1 hemoglobin that contains the sickle cells, when,
2 you know, that starts to kind of kick in, sometime
3 in the middle of the first year of life. So,
4 while they're asymptomatic, you set up the
5 comprehensive system of care. They all should
6 have that medical home. Many children will get
7 referred to ideally a specialty center run by a
8 hematology service that specializes in a
9 comprehensive management of sickle cell disease.
10 The goal is to maximize health, growth, and
11 potential. You have to make sure that they
12 prevent infection, that we prevent vaso-occlusive
13 events as much as possible, we optimized
14 nutrition, we put in plans to care for acute event
15 management, and we screen and ameliorate
16 psychological co-morbidities because things like
17 learning difficulties and mental health comorbid
18 diagnoses present at a higher rate when you have a
19 sickle cell disease.

20 Of course, you have to have financing
21 for service access, especially since many of these
22 services do add up in costs. And then when the

1 youth turns eighteen, that there is a coordinated
2 and seamless transition to adult health care
3 system and supports.

4 Hearing screening. Now, hearing
5 screening came in when -- after I finished
6 residency and so, I saw this system come in while
7 I was a practicing physician. And that is in part
8 because the technology got better, the research
9 got better, and the recommendations came in, and
10 there is, I think we all know, there is the Early
11 Hearing Detection Intervention system that's
12 through HRSA, which supports the development of
13 state and territory programs and systems of care
14 to ensure that children who are deaf or hard of
15 hearing are identified through newborn infant and
16 early childhood hearing screening, and that they
17 receive diagnosis and early intervention to
18 optimize language, literacy, cognitive, social,
19 and emotional development. Put simply the earlier
20 we identify and address hearing loss, the better
21 the outcomes in terms of language development and
22 social emotional outcomes. So, if you get a child

1 where you identify hearing loss, especially within
2 the first month of life, or ideally less than
3 three to six months of age, you have your medical
4 home, you have your follow-up timely testing, you
5 get your specialty diagnosis and management, and
6 this is all taking place in the first three to six
7 months. Your routine screening and follow-up for
8 developmental delays, plugging the kids in into
9 the education system, making sure they have
10 everything from their treatment of their medical
11 condition to acquisition of hearing aids,
12 financing because some of this care gets very
13 expensive, and then transitioning through the
14 early intervention, to the special education
15 system, to the eventually the adult health care
16 systems and supports.

17 Spinal muscular atrophy screening. SMA
18 frequently results in a more complex care need
19 meaning multiple specialists, technology
20 dependence in many cases, the need for not just a
21 medical home, but having, for example, pulmonary
22 orthopedics, physical medicine, rehabilitation,

1 GI, nutrition, access to disease-modifying
2 therapy, the need for genetic counseling, the need
3 for educational evaluation services and
4 accommodations, and to be able to, again, set all
5 that up while the child is very young, and to be
6 able to not just prevent infections and
7 hospitalizations, but to make sure the child
8 reaches their potential as much as we can. That
9 is the goal of our system of care.

10 So why the blueprint? There's been a
11 lot of really, really incredible work that has
12 been done by the system, by HRSA, by MCHB, and
13 yet, the system hasn't moved enough, and by the
14 numbers, you know, when we look at the National
15 Survey of Children's Health Metrics, eighty-six
16 percent of families of children with special
17 health care needs, are still reporting that the
18 system is not well functioning, and a lot of this
19 is still because the system is pretty fragmented.
20 You know, we've got a lot of our components, and
21 we've got our mechanisms, we've got -- we've made
22 so much progress with payments and insurance, and

1 yet, the services remain fragmented.

2 Two of the areas where we are still
3 seeing deficits in the National Survey for
4 Children's Health, are the medical home, which is
5 a comprehensive coordinated care, and also the
6 transitions from pediatric to adult health care
7 systems.

8 And in addition, we are continuing to
9 see inequities in access, particularly in
10 communities that are under resourced. And so,
11 when we look at this, we also need to acknowledge
12 the foundation and the critical role of families
13 because, you know, when we talk about children
14 with special health care needs, we also need to
15 acknowledge that the health care needs are also
16 accompanied, and really are intertwined with many
17 different service and holistic needs, and that our
18 families are the ones that are able to help
19 visualize and determine what those visions and
20 those goals are.

21 We also have a much more progressive
22 dialogue about the roles of structural racism,

1 ableism, and social/emotional factors that are
2 impacting health and well-being, including the
3 number of physician papers, recognizing the
4 research and experience that have come out over
5 the last several years, along with many events,
6 including George Floyd that has impacted our media
7 discourse in the last in the last several years.

8 So, the blueprint, back in fall of 2019,
9 a steering Committee was convened of numerous
10 experts convened by MCHP, and this started before
11 COVID happened. And, you know, I remember the
12 conversation where COVID started, and we all went
13 to Zoom very quickly and we said, you know, this
14 National Summit, what can we do, and we decided
15 that it was no better time than during a pandemic
16 and a crisis to plow ahead, because we knew that
17 the pandemic was going to really hit our system
18 hard. So, we continued to plow ahead. We had the
19 National Summit in the fall of 2020, where there
20 were over 150 invited participants who attended,
21 and we'll talk about the focus areas that we
22 started to develop in the coming slides. And in

1 addition to our Summit, we also had a public
2 request for information where we received over
3 seventy responses from a variety of stakeholders.
4 And by 2021, we had really division of the content
5 and we convened numerous authoring groups, and
6 we'll talk about those four authoring groups, you
7 know, in those four areas.

8 And that culminated in June of 2022,
9 where we released in a pediatric supplement, a
10 blueprint for change. So, now that the blueprint
11 is out, we're now talking about with all of our
12 partners what the blueprint means. I'm glad to
13 hear that folks got the copy of the pediatric
14 supplement. I definitely invite folks to take a
15 look at it. And we have events like the one that
16 we're that we're here at today, where we're
17 talking about the blueprint.

18 What's new in the blueprint is -- let's
19 start with in the middle top row, that since we
20 recognize the system needs to continue to move,
21 and we're still keeping the system. Like the
22 system, the six focus areas of the system are

1 still there. They're good markers. We know we
2 have work to do. We had discussions as to how
3 much of the system that we're still trying to
4 connect pieces together versus how much of this is
5 that the system and the needs of children have
6 moved. Like are children, like, since in the last
7 thirty to forty years, more and more children are
8 surviving previously lethal conditions. Children
9 demographically have become increasingly diverse
10 in terms of race, ethnicity, immigration, and
11 also, as I mentioned, special health care needs
12 and complexity in needs.

13 So, in order to really take all of that
14 and push the system forward, we came with four
15 independent focus areas that center around the
16 issues that families consider most important to
17 the strength of system of care. And, for me
18 personally, this comes back full circle to just
19 why I went down this pathway in my career, because
20 families see the system, and families are the ones
21 that make the system work, because families are
22 the ones living the system.

1 So, in the lower -- in the upper left-
2 hand corner, the blueprint is a call for health
3 systems to measure outcomes that are meaningful to
4 children to families. Like, for example, their
5 meaning is not necessarily how many doctor visits
6 they have, but whether the child is able to go to
7 school and is able to enjoy the things that
8 children typically enjoy.

9 The lower left-hand corner, a call to
10 design a system that is built around the needs of
11 children and families, not just a diagnosis or
12 treatment protocol. Again, it's centered around
13 the child and the family's needs, not whether they
14 have a diagnosis.

15 In the middle lower, a call to support a
16 service system that supports access, equity, and
17 integration and eases the financial burden on
18 families because special health care needs cost a
19 lot of money.

20 A call to address the upstream and
21 downstream factors that prevent children and youth
22 with special health care needs, from a fair and

1 just opportunity to be healthy. They're all kids.
2 Some kids have increased needs than others, but
3 all kids deserve a fair and just opportunity to be
4 healthy.

5 And in the lower right-hand corner, one
6 of our bottom lines, understanding that if we
7 improve the system of care for children and youth
8 with special health care needs, all would benefit.
9 Because we're talking about structural factors
10 that impact all kids, even if they don't quite
11 meet the definition of children and youth with
12 special health care needs. We have children who
13 are at risk. We have children who go in and out
14 of this special health care needs classification
15 because they might have something that lasts about
16 five years, and they outgrow it, or we have
17 children that enter it because they're diagnosed
18 with lupus when they're fourteen years old -- when
19 they're fourteen years old. But all children will
20 benefit if we look at the system of children and
21 youth with special health care needs.

22 So, the blueprint focus areas envision

1 is that children and youth with special health
2 care needs enjoy full lives and thrive in their
3 communities, from children -- from childhood
4 through adulthood. And the purpose of this -- the
5 purpose of this image is to make sure that we
6 recognize children and youth with special health
7 care needs with a full life in a community in the
8 center, but we had the four focus areas and
9 they're all intertwined with each other.

10 So, we'll talk about the quality of
11 life, well-being, health equity, access to
12 services, and financing of services is really the
13 focus here, as we want to push our policies
14 discussion for children and youth with special
15 health care needs, but they're all intertwined.

16 Okay. So, under financing of services,
17 as a reminder, health care and other related
18 services are accessible, affordable,
19 comprehensive, continuous, and they prioritize the
20 well-being of children and families.

21 Under health equity, all children and
22 youth with special health care needs have a fair

1 and just opportunity to be as healthy as possible
2 and thrive throughout their lives without
3 discrimination and regardless of the circumstances
4 in which they were born, or live.

5 Under quality of life and well-being,
6 the service system prioritizes quality of life,
7 well-being, and supports flourishing for children
8 and youth with special health care needs and their
9 families.

10 Under access to services, children and
11 youth with special health care needs and their
12 families have timely access to the integrated,
13 easy to navigate, high-quality health care and
14 supports that they need, including but not limited
15 to physical, oral, behavioral health providers,
16 home and community-based supports, and care
17 coordination through the life course.

18 Over the next few slides, we're going to
19 go even more into the four focus areas and after
20 this, we'll start to talk about how it relates to
21 the system of newborn screening.

22 The vision for health equity again is

1 fair and just opportunity to be as healthy as
2 possible and thrive throughout their lives without
3 discrimination. The principles for health equity
4 are that there are structural and systemic causal
5 barriers to health equity, and that we eliminate
6 them including discrimination, poverty, and other
7 social risk factors. And that sectors, systems,
8 and supports that fund, deliver, and monitor
9 services and supports for children and youth with
10 special health care needs, are designed and
11 implemented to reduce health disparities and
12 improve health outcomes for all children and youth
13 with special health care needs.

14 My comment on -- my additional comment
15 health equity is that having special health care
16 needs, having disabilities, having medical
17 complexity by itself puts a child into the
18 increased risk for a year for not achieving the
19 health and potential and the intersectionality of
20 racism, ableism, poverty, of all the social risk
21 factors also interplay into this. It's unpacking
22 all this is where we're really discussing with the

1 -- with the blueprint.

2 Quality of life and wellbeing. The
3 service system prioritizes quality of life, well-
4 being, and supports flourishing. So, note that
5 here that we're not saying that the health care
6 access or the absence of disease is the goal. The
7 goal is that families under the principles,
8 regardless of circumstances, can afford -- can
9 access, high-quality, affordable, community-based
10 services that support the medical, behavioral,
11 social, and emotional well-being of the child or
12 youth or the whole family.

13 You know, when we talk about children
14 flourishing and well-being, we talk about are
15 children able to do the things that children
16 typically will do. Will they go to school, can
17 they go outside and play, I mean, these are the
18 things that are important to families -- that
19 families tell us are important for metrics and for
20 principles.

21 Health Systems place value in a
22 measurement and use of both child and family well-

1 being and quality of life outcomes and health
2 outcomes. So, it's not -- when we talk about
3 system care, it's not necessarily about can we
4 reduce hospital costs. It's about did we make
5 sure that our children are flourishing, and our
6 families are flourishing.

7 Access to services. That families,
8 children and youth with special health care needs
9 and their families have timely access to the
10 integrated, easy to navigate, high-quality health
11 care and support that they need. But it's not
12 just limited to health care services. It's also
13 physical, oral and behavioral health providers,
14 home and community-based supports, and care
15 coordination through the life course. And that
16 under principles, that are easy for families and
17 professionals to navigate, when, where, and how
18 they need them, that the workforce is trained to
19 meet their needs, reflects the families and
20 communities they serve, and is culturally
21 responsive, and that service sectors increase the
22 ability of children and their families to access

1 services by addressing administrative and other
2 processes that hinder access.

3 You know, like, even if we take
4 something as straightforward as health care or
5 school, they're governed by different laws,
6 different training, different providers, different
7 places, and even with a system, you're going, you
8 know, even with the education system, even just
9 something as seemingly straightforward as going
10 from early intervention to special education is a
11 transition where kids get lost. And this system,
12 these accesses to services, making it easier and
13 reducing administrative burdens, these are the
14 things that we're talking about.

15 Financing for services. That health
16 care and other services are accessible,
17 affordable, comprehensive, and continuous, and
18 they prioritize the well-being of children and
19 youth with special health care needs and their
20 families.

21 And under the principles, that the
22 health care and related services are financed and

1 paid for in ways that support and maximize the
2 individual's values and choices and meeting needs.
3 And so, here we're starting to talk about, like,
4 should we be paying for other different kinds of
5 services such as telehealth that we started to
6 maximize more and more during the pandemic.

7 Health and Social Service sector investments
8 address social determinants of health to increase
9 family well-being and flourishing. So, you know,
10 it's not just about hey, did you like pay the
11 physician's visit, it's about, you know, are we
12 paying for other things that ameliorate social
13 determinants of health such as transportation.

14 Payers and service sectors adopt value-
15 based payment strategies that support families,
16 advance equity, and incorporate continuous
17 improvement by integrating team-based integrated
18 care. And the of system of finance right now,
19 because it's so split into different sectors, you
20 know, we're asking when we're visioning what the
21 system looks like, how do we make sure that our
22 payment sectors are aligned or even braided so

1 that we can look at health and wellness as the
2 outcome regardless of what sector or training that
3 the child services may be in -- may be located in.

4 So, in summary, the blueprint and the
5 four focus areas inform research policy and
6 programs for systems of care at the federal,
7 state, and community levels. We emphasize care
8 integration, we emphasize health equity, we
9 emphasize family defined outcomes, and I'm using
10 the term human-centered design because we did
11 discuss something called human-centered design and
12 the access paper. That is placing the family, the
13 human, the family, the child and family needs at
14 the center and designing and meeting their needs.
15 But it also encompasses the journey and the
16 pathway and making it easy or when I was learning
17 about human-centered design, we called it
18 pleasurable. One of our family partners at a
19 conference I was in who works in industry now, but
20 it's also a family advocate, said that in their
21 field, they call it a delightful experience. I
22 thought, okay, this is, yeah, I mean, when was the

1 last time you thought about having a child with
2 special health care needs and thinking about the
3 experience of going through the system as
4 delightful? But this is where other industries
5 are taking it, and this is what we need to be
6 aspiring to.

7 Messaging across our bureaus, our
8 divisions, and our systems, and this is what we're
9 doing right now, is saying, you know, we are
10 talking about journeys, we're talking about lived
11 experiences, we're talking about systems. And so,
12 I ask you, how do we develop this? How can we
13 facilitate this discussion? What can we do? What
14 can you do as a family, you know, with these four
15 focus areas? What can you do as a provider? What
16 can do as a state program? And what can you do as
17 a health care research institution?

18 And in the next several slides, I'm
19 going to give some thoughts for discussion for the
20 individual workgroups for the Committee, and these
21 are just my thoughts when just reflecting on the
22 four focus areas.

1 So, for the Education and Training
2 Workgroup, could the blueprints for focus areas
3 influence discussion on the broad system to
4 service partners that we need to be accessing when
5 we're talking about the impact of newborn
6 screening? Can it influence the discussion of
7 health equity and address the systemic barriers to
8 services that exist not just at the point of
9 screening and testing but also the follow-up? Can
10 it influence a community and family partners for
11 collaboration, as we think about the follow-up
12 system for newborn screening, including family-to-
13 family health information centers, Department of
14 Education, Department of Health, many of the
15 system partners that work in the world with
16 children and youth with special health care needs?

17 The Follow-up and Treatment Workgroup,
18 to think about the comorbidities and continuous
19 screening needs that happen when we diagnose a
20 certain condition. I mentioned about cyanotic
21 congenital heart disease, and the literature that
22 really discusses the need for continuous screening

1 for learning disabilities as the child gets older.
2 So, developmental delay, mental health, I should
3 also mention things like structural determinants
4 of health screening, screening for food
5 insecurity. I think we found that many of our
6 families, during the recent formula shortage, that
7 was a huge area of stress. And it was -- it was
8 wild, because we were just trying to pull out,
9 okay, try this formula, try this formula. I mean,
10 that's the sort of thing that families are
11 encountering.

12 Address systemic barriers to service
13 access, you know, access to the medical home. We
14 know that there are distribution issues for, like,
15 for example, not just the rural -- not just the
16 rural urban areas, but even within urban areas,
17 that there are distribution issues for providers
18 who are comfortable taking care of the specific
19 conditions.

20 Health equity and systemic barriers,
21 acknowledging the roles of structural racism,
22 acknowledging the roles of poverty, acknowledging

1 the roles of rural urban divides, and to be able
2 to address those systemic barriers as we're
3 planning follow up and treatment.

4 The role of telehealth, you know, the
5 unwinding of number of the number of the rules and
6 regulations that allow the spread of telehealth
7 and that many of us continue to use in practice.
8 And the importance of care navigation, care
9 integration, and family support.

10 So, when I was preparing this
11 presentation, I hadn't yet heard the word
12 delightful used in here in navigation. I like it.
13 I think I'm going to start continuing use that.

14 But I challenged us, you know, how do we
15 make our system easier to get through, you know,
16 easier to get through, not just, you know, like, I
17 have this phone number, and I'm trying to figure
18 out how to get somebody on the phone to be able to
19 address that issue. We have to make it easy, and
20 we have to make it delightful.

21 Laboratory Standards and Procedures
22 Workgroup, Finance and Payment. Finance and

1 payment not just for the testing, but what about
2 any follow-up and the burden that it may be
3 incurring on the family.

4 System access for false positive and
5 negatives, including what about the training and
6 resources for the hospitals, what about the
7 learning collaboratives and data driven outcomes
8 when you have something like, okay, if you have a
9 diagnosis that requires comprehensive follow-up,
10 and I think hearing screening is something that I
11 have been living through as a provider with
12 children who test positive and require a
13 comprehensive follow-up, and how do we make sure
14 our systems where the data is in different places
15 from hospital to primary care to the state, and
16 how do we make sure they're all aligned so that it
17 is seamless for the family to navigate through?

18 And that's where I also mentioned the
19 regional oversight, including the hospitals and
20 outpatient providers, and examine service access
21 for follow-up. Because we have -- we continue to
22 have large issues with children and families with

1 health equity and equity in access in follow-up,
2 and we have to make sure that when we do our
3 planning, that we address the structural issues.

4 I also mentioned here family support and
5 partners, because when we're talking about
6 navigation, the families are the ones who really
7 understand what that navigation looks like. And
8 so, partnering at all levels is how we begin to
9 solve the issues.

10 I want to wrap this up by talking about
11 some personal experiences, and I chose 22q11.2
12 deletion, which is not on the recommended panel
13 right now. And on the next slide, I do
14 acknowledge that it was looked at about ten years
15 ago, and part of the issue, or a big part of the
16 issue was that the research and the understanding
17 and the follow-up was not there at the time. And
18 so, I present this as a question of, can the
19 blueprint influence the direction so that there is
20 better information to make these decisions on.

21 But I chose this because as a practicing
22 physician in private practice fifteen to twenty

1 years ago, when I was practicing a number of
2 newborn screening conditions, both on the panel
3 and in some cases, not on the panel came up and
4 I've had the privilege of seeing what happens
5 fifteen to twenty years down the line, because in
6 some cases, I kept in touch with these parents.
7 In some cases, they, they found me and just said
8 my child just turned eighteen, and this mother
9 filming when her daughter turned eighteen.

10 So, this child was diagnosed. We
11 diagnosed the child at five weeks of age when she
12 presented with seizures, due to hypocalcemia. I
13 think her calcium was like 5.1, which is really,
14 really low. We did not find a cardiac defect
15 identified when she was hospitalized. We did find
16 immune deficiencies. So, she got placed on
17 prophylactic antibiotics and I became her
18 pediatrician. I was in a small group practice,
19 but, you know, families prefer to try to follow up
20 with one person. And I had a lot of discussions
21 regarding specialty care, feeding management, I
22 remember, you know, instances -- I remember just

1 one instance where the kid -- child came in,
2 barely breathing, choking, and we called an
3 ambulance, and I rode with her to the tertiary
4 care hospital because even the EMS folks weren't
5 comfortable with the way she looked. I remember
6 sitting there when she was eighteen months old,
7 and not saying anything, not saying any words and
8 we were talking about speech therapy and talking
9 about the system. And this was before, you know,
10 the American Academy of Pediatrics' recommendation
11 for universal surveillance and screening for
12 developmental delays came out. I mean, this was
13 2000 and this was like 2001, 2002, or so.

14 And the idea here was, let's walk
15 together, let's plan out, let's be prepared as
16 much as possible, let's stay ahead of the
17 anticipated needs, and this is what we're trying
18 to build towards is to make sure that we not only
19 minimize illness, but that we're proactive, that
20 we're accessing services to maximize health and
21 wellness.

22 So, a couple of years ago, when this

1 child turned eighteen, the mother just E-mailed me
2 out of the blue, and she said that she was
3 following up with all the doctors that had taken
4 care of her child over the years, and I share the
5 quote, "I want to thank you. You didn't sugarcoat
6 what was happening and assured me you'd be there."
7 And she told me that her daughter was preparing
8 for college, and she said she does not let a
9 little missing piece of the twenty-two chromosomes
10 get in her way. Now, I'll tell you, this made my
11 year when I saw this. This made my year because
12 like when you're going through it, you know,
13 you're just trying to do your best as this is, you
14 know, we're just trying to stay ahead of things
15 and I don't want to sugarcoat things because what
16 I've learned is that families want to hear from
17 their physician, from their provider, what the
18 actual truth is.

19 So, going back to 22q11, it is the most
20 prevalent microdeletion syndrome, at least 1 in
21 3,000. I've seen some various estimates, but I
22 think that's -- that's one of the better ones I

1 found. And in 2012, the decision said no
2 published studies are available to show the
3 benefits are effective to early treatment of mild
4 cases, or in cases without life-threatening
5 manifestations if diagnosed early in life.
6 There's a need for pilot studies to propose
7 newborn screening tests algorithm or treatment
8 protocols to provide the data necessary to inform
9 evidence review.

10 So, I look at this as a practicing
11 physician as one who -- and I've taken care of
12 numerous kids with 22q11 deletion -- and my
13 feeling is, yeah, we need to do the studies. We
14 need the framework. We need to understand the
15 system. And we need to understand what will
16 happen if you maximize the system and address the
17 four focus areas. And what can you do -- and what
18 can we achieve for health and wellness when the
19 system works the way it should.

20 So, I feel like this is the blueprint
21 for children and youth with special health care
22 needs to be able to frame system and research

1 initiatives to make the journey more predictable
2 and improve outcomes, health, wellness, and
3 potential. I think that's it. Thank you.

4 NED CALONGE: That was super. I'm
5 hoping you're -- I'm hoping you're willing to
6 stand up there and join in the discussion as we
7 ask questions and continue to contribute. And
8 with that, I'll turn first to the Committee
9 members for questions and comments. And, Kyle,
10 you're up first.

11 KYLE BROTHERS: Great, thank you. That
12 was an extremely helpful talk. I really
13 appreciate it. I know this might be putting you
14 on the spot just a little bit, but I was just
15 wondering if you could, taking the sort of
16 aspirational framework that you just talked about,
17 and think about where our system is currently. Do
18 you have like a wish list of a top three concrete
19 steps that can be taken to move towards a more
20 delightful system? Like what -- what do we need
21 to do?

22 DENNIS KUO: Yeah, I don't mind. If I

1 don't talk in the microphone, they can't hear me
2 online, correct? Okay, there we go. Okay.

3 So, I actually don't mind being put in a
4 spot, it's totally fine. The number one thing I
5 would say is the family partners. Like, I feel
6 like, to make the system designed and I'm using
7 the word design intentionally because there's like
8 a whole world of design literature and principles
9 and such, and the idea behind design is that you
10 make the system work, and you make it pleasurable,
11 and you make it delightful, and to be able to do
12 that you have to have all the right stakeholders
13 at the table, and you have to be journeying
14 together. And even now, you know, I still find
15 workgroups and cultures and organizations where
16 there's still questions about not just whether to
17 include the right partners to the table -- in this
18 case, I'm talking about family partners -- but
19 also to embrace and include them at all different
20 levels.

21 So here's like, for example, yes,
22 there's community advisory groups, there's, you

1 know, there's specific workers that may be at the
2 hospital level, there's, you know, there's any
3 workgroups that may be happening in community
4 around initiatives for like, say, early childhood.
5 But it has to be done in a way that is partnering,
6 and not the kind of, okay, let's just have a
7 family partner sit with a couple of chairs on the
8 side and listen. There's got to be a certain
9 amount of training and support and compensation
10 for the time and, you know, and I think we are at
11 a point where the literature is pointing us in
12 that direction, that there's been more and more
13 experiences, particularly where there are family
14 partners. Like for the grants that we're putting
15 in with my group, one of the things I'm saying is,
16 you know, we have moved past one family partner,
17 you need to have at least two or three, you know,
18 and they have to be reflective, and I think that
19 is -- that's one thing right there.

20 Number two is the need for addressing,
21 you know, equity, diversity, equity inclusion, and
22 I want to be careful about making sure that we do

1 this with the right approaches and intent because
2 I find that there are a lot of organizations now
3 that appropriately have embraced the EI but has
4 still not quite opened up the spaces because it
5 can be an extremely vulnerable conversation. It's
6 got to go past conversations, right? You know,
7 that has to go into the areas of data. It has to
8 go -- that help us achieve from here to there.
9 There are best practices to address diversity,
10 equity, and inclusion. You know, there's -- like
11 you look at -- you look at your own makeup, are
12 your reflective of the conversation, you know, can
13 we do blinded reviews for, you know, when you're
14 doing targeted recruitment? Can you expand your
15 networks? And I think those practices need to be
16 standard to be able to address the structural
17 issues, rather than, you know, just simply
18 convening a group and appointing somebody and
19 that's a really big issue.

20 The third, aspirational, and again, yes,
21 the blueprint is meant to be aspirational, right?
22 It's totally meant to be aspirational. It's

1 totally meant to be aspirational. The other
2 aspirational is to make sure that there's no
3 penalty in our payment and insurance plans that
4 put it on the backs on family.

5 So, I'm going to put my personal
6 experience actually out there as a parent of a
7 child with special health care needs, who's now
8 graduated college. So, imagine being my daughter
9 and hearing health care transition from me, right
10 as a dad, so. But we realized fairly early the
11 financial penalty, and then I would go into talks
12 where they start talking about the benefits of
13 high deductible health plans, and how it was such
14 a benefit and a cost saving and I'm thinking high
15 deductible health plans don't work when you're
16 paying -- when your medication costs \$60,000 a
17 year. I mean, no insurance company wants to
18 insure me or my daughter. And so, the only reason
19 why my daughter has insurance right now is because
20 of the Affordable Care Act. And I think just
21 mandating that we have to have this principle that
22 when you have special health care needs that

1 you're not simply penalized financially for it. I
2 mean, that's my other financial goal. And I think
3 that's a that's a challenging discussion when
4 there is, you know, a thought that if you have
5 patients and families share in the buy in, that
6 you can control health care utilization. I
7 personally don't believe that. I don't think that
8 the research is very good in that area. And I
9 think when you talk about families, and you hear
10 about all the families that have the financial
11 burden, you begin to think, you know, maybe it
12 isn't such a good idea. So those are my three.

13 NED CALONGE: Melissa.

14 MELISSA PARISI: Hi, Melissa Parisi,
15 NIH. Thank you very much for that presentation.
16 I have a question and a couple comments.

17 So, my first question is one is one that
18 really came out of your slide where you said that
19 the process only begins when the blood spot is
20 taken. And I was thinking about a lot of genetic
21 conditions, particularly recessive conditions, or
22 X-linked conditions that run in families, where

1 you may actually know the diagnosis prior to
2 birth, and may want to prepare for the birth of
3 that child, and be ready to go with therapies that
4 may start within the first week, two weeks or, you
5 know, first month of life. And there are quite a
6 few conditions on the RUSP including one that's
7 under consideration right now, in which you really
8 need to get that expensive therapy started,
9 sometimes a gene therapy or a bone marrow
10 transplant within the first few weeks of life.
11 And I'm wondering whether this system and this new
12 blueprint can accommodate earlier and earlier
13 diagnosis and the need for expensive treatments
14 that need to start so soon after birth?

15 DENNIS KUO: Yeah. No, I appreciate --
16 I very much appreciate that observation and I'm
17 thinking I should probably change that slide
18 slightly. There's definitely room because, of
19 course, in maternal and child health care there's
20 vision, it's about the health, it's focusing on
21 mothers and children. And so, that absolutely
22 includes the maternal health.

1 I would also push further and say that
2 the life course is all about, you know, throughout
3 the entire lifespan, and that includes prenatal or
4 in even the term before a child is born because of
5 the conditions -- the structural conditions that
6 may lead towards the pregnancy, and then influence
7 the prenatal environment.

8 One thing that I've personally been
9 involved in -- this is not related to the
10 screening panel, but this is related to maternal
11 child health -- is, let's say, Down Syndrome, and,
12 you know, American Academy of Pediatrics released
13 updated Down Syndrome guidelines, and one of the
14 areas that we focused on when that was being
15 developed was the prenatal diagnosis and reframing
16 -- making sure that we reframe the discussion to
17 something that sounds straightforward, but it's
18 not, it's congratulations on your baby, you know,
19 and to be able to use that as a discussion to set
20 up the system, you know, rather than looking at it
21 as like, oh, it's too bad, you think about this or
22 that, and that's -- that's, that's where that

1 discussion is going. Is there room in a system?
2 Absolutely. You know, I think it absolutely is
3 part of it, especially since we're talking about
4 the life course.

5 MELISSA PARISI: Thank you.

6 NED CALONGE: Ash.

7 ASHTOUSH LAL: Hello, I'm Ash Lal. I
8 wanted to support what was said earlier. I think
9 it's -- the therapies currently are, we looked at
10 them after birth. But I think the future is that
11 many of the therapies will become prenatal and
12 intrauterine. So, that's just a comment to kind
13 of support that idea.

14 My question was that the mention of
15 eighty-five percent of children with special
16 health care needs are not in well-functioning
17 programs and fifteen percent or fourteen percent
18 are, and in a way, that doesn't surprise me
19 because I'm also engaged in similar clinical
20 activities as you are.

21 Is there something to be learned from
22 that data? What is your view on the fifteen

1 percent, are they different in terms of diagnosis?
2 Are certain diagnoses better -- does the system
3 care for them better, or is it a regional thing,
4 or is it rural urban? What are your thoughts
5 about that?

6 DENNIS KUO: Now, that's a really good
7 question because it is striking. But when you
8 delve into it, there were even further
9 differences. So, the biggest drivers -- so, the
10 system and services question in the National
11 Survey of Children's Health is a composite measure
12 and the areas that tend to get the least positive
13 responses are medical home and transition to adult
14 care. So, we could start there. But even from
15 there, there are further differences. There's
16 difference by condition like developmental,
17 behavioral, mental health disorders tend to rank
18 lower. You know, children who are from immigrant
19 families tend to be lower. Children, you know,
20 there was racial and ethnic disparities in these
21 metrics. And so, it's a combination of the system
22 is fragmented and there's differences within them.

1 And I think that reflects -- I think when we talk
2 to folks, it doesn't surprise folks, but I think
3 that it's not a simple solution.

4 You know, I think that when it comes to
5 medical home, for example, there's -- there's
6 issues related to scope of practice for the
7 medical home because, you know, where in primary
8 care the providers are asked to do a lot, and
9 they're asked to do it with a financing system
10 that does not necessarily value counseling, and
11 it's necessarily provided the resources that are
12 necessary to be able to provide that comprehensive
13 care to the extent that's really needed.

14 But you also have, when the areas of
15 health care transition, you know, there's learning
16 collaboratives, there's needs for awareness, and
17 there's needs to be able to partner with the adult
18 health care systems so that there is a place to be
19 able to do a warm handoff when they're going from
20 one to the other.

21 And then when it comes to some of the
22 areas of like, say, children and youth who are

1 from -- who are from immigrant families, you know,
2 now you're talking about a system where you have
3 to understand the service access, the language
4 access, the navigational aspects, and the partner
5 with community services.

6 So, I don't think there's really an easy
7 answer to that. We have made progress in a lot of
8 areas like, you know, you look at the insurance
9 coverage, and insurance coverage for children has
10 gotten a lot better in the last thirty years, like
11 much, much better.

12 But I would also raise something I
13 mentioned earlier, which is that the landscape of
14 children's health has changed, you know, like a
15 lot of our conditions that we formerly treated
16 that resulted in kids not surviving past
17 childhood, the kids are living today and the
18 demographics have changed.

19 So, it's really a combination,
20 understanding that if we have these metrics that
21 we know we need to reach for we have to have those
22 conversations to say, you know, we need this many

1 stakeholders at the table, and I do come back to
2 the ones who understand are the ones on the
3 ground, are the families.

4 NED CALONGE: On that phone, we have
5 Jannine Cody.

6 JANNINE CODY: Thank you for that
7 fascinating presentation. I was concerned about
8 whether you've taken into consideration when you
9 talk about handoff to adult care, what about
10 training of the adult physicians who have no idea
11 how to take care of an adult with growth hormone
12 deficiency that's typically only been treated by a
13 pediatric endocrinologist or congenital heart
14 disease, or so, is there considerations not just
15 for the handoff to adult care, but for training
16 the adult providers need in order to take care of
17 the survivors?

18 DENNIS KUO: That's a great question,
19 and I can tell you from being on the ground with
20 that and being involved with some of the local
21 initiatives that that's a very, very -- that's
22 very high on everyone's radar. You know, so

1 everything from say, congenital heart --
2 congenital heart disease, to rheumatologic
3 conditions that are childhood onset, to the growth
4 hormone deficiencies, as you've mentioned, and
5 there's even some debate about how long that these
6 young adults will stay in a pediatric system. And
7 yet, at some point, even if you go past say
8 twenty-five or thirty, then you begin to get into
9 things that the adults, you know, that really,
10 that the pediatric providers don't know.

11 And another example, which is again, not
12 on the panel, but Down Syndrome, you know, as the
13 life expectancy of an individual with Down
14 Syndrome gets longer, we're finding the same
15 issues along with new onset conditions and adults
16 that were not necessarily understood or seen
17 before.

18 I haven't seen yet any systemic
19 initiatives to just, you know, but on the local
20 levels and with individual learning
21 collaboratives, there's a lot of discussion to
22 that.

1 Our med peds colleagues are particularly
2 good at that. Our family medicine colleagues are
3 also very good at that because there is no switch
4 of locus of care. They continue to take care of
5 the young adults as they go through.

6 And these are the -- again, I do think
7 that working with family partners and thinking
8 about the continuum of care of health and wellness
9 as opposed to the here's the system, let's hand
10 you off, here's the system, let's hand you off,
11 you have to really start with the framework of
12 what's best for the child, young adult, and
13 family. That is when you begin to have that
14 discussion that we need to be working together
15 across systems.

16 NED CALONGE: Jennifer.

17 JENNIFER KWON: So, I really appreciate
18 Jannine bringing up this very specific example
19 because I think I too, I think this is a beautiful
20 framework for how we all want our children, our
21 patients with chronic care to be cared for.

22 I just struggle with how to like, what -

1 - what I might want to do with this blueprint,
2 like, I think that many disease-specific advocacy
3 groups take blueprints very similar to this or
4 have ideas similar to this or could use the
5 blueprint as a way of creating standards of care,
6 guidelines of care that they hope providers for
7 their patients will -- for these children will
8 adhere to.

9 But I was curious how -- so, I'm already
10 sort of formulating ways to try to think about
11 this without being consumed by the fact that the
12 deficiencies that are highlighted by this
13 aspirational document are so numerous, right,
14 they're just, they're overwhelming to think of a
15 system, a financial system, for example, that
16 really gives children with chronic disease or
17 disabilities the care they need seems -- that
18 seems really pie in the sky, and that's just a
19 small part of what you're talking about. So, I
20 was curious how you see this document being used.

21 DENNIS KUO: Yeah. Thanks, that's -- it
22 can seem daunting, you know, and I think that when

1 we put the blueprint together, we were asked to be
2 aspirational, knowing that we weren't going to
3 come up with all the solutions from the very
4 beginning.

5 I will contribute a few thoughts. The
6 first is that there are -- there have been
7 numerous examples of policy and financial
8 initiatives that we know help and do work. And,
9 you know, when we talk about the system, we have
10 to, you know, support nutrition, we have to
11 support coverage, and we have made substantial
12 advances in that understanding and the programs
13 over the last several decades. You know, I go
14 back to when I was in medical school, and I look
15 at the insurance rate coverage for children, and I
16 look at it today, and I look at the changes in
17 Medicaid, and it's huge.

18 Another area, I would add, you know, so
19 we have to look at those policies to be able to
20 strengthen just this, you know, just the supports
21 for kids' well-being, coverage, food security, and
22 access to care. That's one.

1 Another area where I advocate is that
2 we're really pushing folks to think in a way
3 that's holistic and systems based because, you
4 know, as a physician, I came through a medical --
5 a medical training system, where I'll go back to
6 my own training, where it was, okay, if you see a
7 red eardrum, and at those days, it wasn't even,
8 you know, it had to be red, bulging, and, you
9 know, pus-filled. It was if you see a red
10 eardrum, give the kid ten days of amoxicillin and
11 then somewhere along the line, I also realized
12 that while these kids are coming back to me, and
13 they weren't necessarily taking a medication for
14 all sorts of reasons.

15 And I think that training and that
16 understanding of how to think differently and
17 holistically involves several things. Once we
18 have the principles that we have to think this
19 way, it involves a stakeholders that you bring to
20 the table, it involves, you know, the questions
21 that are asked, it involves imagining in ways that
22 we don't necessarily know or understand.

1 I will come back to -- I give the Down
2 Syndrome example, because for me, personally, that
3 was quite impactful in that I had numerous
4 partners for me, family partners, who work in the,
5 you know, who have kids with Down Syndrome, who
6 were very, very specific about that. And to see
7 that in the, you know, in that the prenatal
8 discussion, to see it and writing, what I'm told
9 it was, it was incredibly well received by the
10 colleagues I have in the Down Syndrome Community.

11 And that started because we allowed
12 ourselves to come to the table and have these
13 discussions with the principals that families and
14 communities have to center, and it's about the
15 health and wellness of the child and the family.

16 And I think these little discussions
17 little by little, that's just one example. But
18 these discussions little by little start to make
19 that difference.

20 I think we were we were asked to put the
21 blueprint together with like a fifteen-year time
22 window. So, this is where we need to go. But I

1 do think that there are steps and strategies and
2 some of those principles, you know, they don't
3 come necessarily from the health care field. I
4 mean, to think of a delightful experience, I've
5 never heard that in health care training. But
6 that is what the IT sector is using, and I think
7 we should draw on those lessons.

8 NED CALONGE: Chanika.

9 CHANIKA PHORNPHUTKUL: Chanika
10 Phornphutkul, Committee member. Thank you very
11 much for your talk. What struck me was the
12 transition of care, which seems like sort of, you
13 know, we've been able to keep our children alive
14 and healthy, and transitioning them out. I think
15 Down Syndrome is a great example of the natural
16 history that continues to evolve.

17 And I am interested in hearing your
18 thoughts about, you know, how can we help children
19 who have, you know, specific medical diagnosis,
20 which I think the pathway is actually pretty --
21 it's actually more straightforward, like asthma,
22 diabetes, children with intellectual disability,

1 chromosome disorders, Down Syndrome being one, but
2 all the microdeletion syndromes, and how can we
3 help them and the family, get to that point, not
4 just working with the primary care, but all the
5 subspecialty that may be involved in taking care
6 of these adult in the future?

7 DENNIS KUO: Yeah. No, thank you for
8 highlighting. So, we're talking about
9 specifically our children and youth with
10 intellectual and developmental disabilities and
11 the systems that the children and their families
12 reside in, which I purposely highlighted the part
13 in the definition of children and youth with
14 special health care needs, that it does include
15 the group with an intellectual developmental
16 disability, so kids with autism, for example, you
17 know, the kids with genetic syndrome, diagnoses
18 that also are associated with intellectual
19 developmental disabilities. That's -- it's a
20 complex system, and I think the pandemic, in
21 particular, highlighted that if one system falls
22 apart, like we close the schools to in-person

1 learning, it just has the cascading effects in so
2 many other areas.

3 I know of initiatives, and one
4 initiative -- I'll just give one example -- is in
5 New York State, we have the First 1000 Days
6 Initiative, which purposely strategically brought
7 together the education and the health sectors to
8 be able to have this conversation so, if you
9 didn't know, those kids are going back and forth
10 through them.

11 There's also, to give another example,
12 when we're looking at the child and family as a
13 center and framing this as a just and fair
14 opportunity. So, this actually is framed in a
15 civil rights -- in a civil rights framework that
16 you begin to get into aspects of guardianship and
17 supported decision making, and some of the
18 research, which is still fairly new. But it shows
19 that if you empower and you recognize the inherent
20 rights of the child and the young adult, that the
21 health care outcomes, and the functioning
22 outcomes, the educational outcomes as a whole,

1 just tend to be better.

2 And I think that having -- starting -- a
3 big part of what we're doing is framing this as it
4 is equity, it is fairness, it is potential, it is
5 recognizing and affirming the rights of the child
6 and the family. And when you start with that
7 framework, and you start with discussion at
8 framework, and there is some literature in that
9 area, and it continues to grow, then that sparks
10 the right conversations.

11 With regards to intellectual and
12 developmental disabilities, navigation is a huge
13 issue, you know, and I continue to do this in my
14 own personal practice. Navigation, especially
15 going between not just the school and the medical
16 system, but like within the medical system, you
17 know, between the hospital and mental health and
18 developmental behavioral pediatrics, that's --
19 it's an issue.

20 And so, we're down to things like
21 recognizing that the journey and the navigation is
22 the issue -- is one of the primary issues. Like

1 when they tell us that care coordination -- that a
2 lot of families are telling us that they're not
3 receiving care in a well-coordinated system, then
4 the conversation goes to, we need to buy care
5 coordination, but we also need to recognize it's
6 not enough to just say, here's your care
7 coordinator, they need to be versed in the right
8 system, they need to be versed in the journey,
9 they need to be versed in empathy, they need to be
10 versed in cultural humility and responsiveness,
11 and you build those relationships, and then you
12 see how you're doing and you use those metrics of
13 did you achieve family health and wellness.

14 So, I think the blueprint does frame the
15 discussion by saying it's about experience, it's
16 about lived experience, it's about equity, it's
17 about being just and fair, and if we take that as
18 a starting foundational point, it'll lead to those
19 questions of things like navigation, shared
20 decision-making, training, and allocation of
21 resources, to legal questions such as supported
22 decision-making, and it's in guardianship. It's

1 complex issue. But that's the way I see it
2 framing. You've got to start with the areas of
3 equity and fairness.

4 NED CALONGE: Dennis, this is Ned
5 Calonge, Committee member, and I was thinking kind
6 of along the lines of Jennifer. So, I know you
7 say it's aspirational, and I also know you want it
8 to be impactful and not just aspirational. So, I
9 do find myself thinking about the diverse
10 stakeholders and the resource -- the diverse
11 fabric of resources that come into play and think
12 about how -- what are your plans for
13 dissemination? So, understanding that you need
14 the impact, MCH and MCH block grants and funding
15 and special needs programs, CDC from EPI, AHRQ
16 from Systems Research, NIH from effective
17 interventions, and then Medicaid is a shared
18 program with states, so state legislators and
19 state Medicaid programs and public health. So,
20 and then providers, pediatricians, family
21 physicians, and subspecialists.

22 So, what are the dissemination ideas,

1 and how do you see the blueprint starting to
2 impact those resource centers that come together
3 to provide -- actually funding that flows towards
4 supporting the implementation of the blueprint?

5 DENNIS KUO: Yeah. Because the
6 blueprint is in print now, it's really the -- just
7 the beginning of saying, you know, we have a
8 product here that we can refer to and when we
9 release a fairly large product like that, it also
10 catalyzes everything from our social media
11 messaging, to our class or presentations, to the
12 decisions that go into policies, to the decisions
13 that are going to funding opportunities.

14 I will speak as an individual, and not
15 on behalf of MCHB on this, but I have been in
16 conversation with partners at MCHB about how we're
17 working together on all of this. Talks and grand
18 rounds, now writings, publications, interviews,
19 podcasts, those have started to all go out. Grant
20 funding opportunities, programs, policies, that
21 started to go out in New York State because in my
22 day job, you know, at Rochester, we have funding -

1 - we have funded projects through the state, and
2 the blueprint is being looked at at the Department
3 of Health and saying, you know, we need to move
4 away from, you know, here, plug your, you know,
5 like, refer to here, refer to here, from here to
6 here to how can we walk through this journey
7 together? That's a big change. But because we
8 have the blueprints, we can point towards this and
9 say, this is how we want you to think.

10 Now the interesting part in my personal
11 experience is that when I talk with my colleagues
12 who are on the ground, who are right now, still,
13 in some cases, feeling very frustrated in their
14 position, because they just think that they're
15 trying to plug holes into this, the Blueprint is a
16 game changer, because it points to a framework
17 that we need to reset that discussion.

18 So yeah, it's -- there's -- it's little
19 by little, but we definitely asked that question
20 and that's where we're going.

21 NED CALONGE: I appreciate the answer.

22 Michael Warren wanted to make a comment.

1 MICHAEL WARREN: Sure. Thank you so
2 much, Dr. Kuo. Thank you first of all for that
3 amazing presentation, and for your leadership
4 throughout the development of the blueprint. We
5 really appreciate your partnership here.

6 I wanted to touch on a couple of things
7 that relate to this notion of dissemination. So,
8 one is we're in the process of updating the MCH
9 block grant guidance that guides the guides the
10 work of the State Title V Programs in the fifty-
11 nine states and jurisdictions. That happens every
12 three years, and so, we're incorporating the work
13 of the blueprint there to make sure that's
14 reflected in the children and youth with special
15 health care needs work that the states will do.
16 So, that's one way that we're really going to push
17 dissemination.

18 We're also weaving this into our grant
19 making opportunities that are happening in the
20 bureau. So, we've got the Children and Youth with
21 Special Health Care Needs Research Network that's
22 looking at quality of life measures to get at this

1 issue of quality and life and well-being. And
2 we've also got a funding opportunity that's on the
3 streets right now, to support a national center on
4 systems of services. This gets back to this issue
5 that Dr. Kuo talked about, about generally, we
6 haven't met the mark for children being cared for
7 in a well-functioning system. And so, the
8 principles from the blueprint are reflected in
9 that as well. So, we're trying to put our money
10 where our mouth is here.

11 DENNIS KUO: Dr. Warren, thank you.
12 Thank you for your vision and leadership. Yeah,
13 from the ground, I definitely see those changes,
14 but I'm also very, very glad that you were able to
15 be specific on behalf of the bureau.

16 NED CALONGE: Yes, Michael, I'll echo
17 that was the right answer. I appreciate it.

18 If I could turn to our organizational
19 reps for comments or questions, starting with
20 Natasha.

21 NATASHA BONHOMME: Hi, Natasha Bonhomme,
22 Genetic Alliance. First and foremost, thank you

1 for such a great presentation. I know many people
2 have said that. I have to say I've been really
3 excited to see the blueprint and to see all the
4 efforts. I loved how many times you said families
5 in your discussion, I should have kept count. And
6 so, I'm really excited. So, I don't want my
7 follow up comments to be interpreted as though I'm
8 not excited, I am.

9 You know, I, one, you mentioned kind of
10 this focus on DEI, which is critical, and, you
11 know, how those can be really hard conversations
12 and people and different stakeholders can feel
13 very vulnerable. I want to -- I just want to
14 remind us, we ask families to be vulnerable all
15 the time, as was exhibited yesterday with them
16 sharing their stories about both some highlights,
17 but many times sharing the worst days of their
18 lives. So just really thinking about that, that
19 we're all coming to this with vulnerability.

20 I appreciate what was just said about
21 funding opportunities, and I think when you look
22 at HRSA funding overall and CSHYN funding, it's

1 been really great to see all of the -- the
2 integration of family engagement in that. I'd
3 like to kind of take a moment to look at that
4 through the lens of newborn screening work, where
5 I do think we can have some -- this blueprint can
6 give some guidance around that. And what I mean
7 is that when you look at kind of the funding
8 opportunities and initiatives broadly, they've
9 really been focused oftentimes on lab and state
10 program initiatives, which obviously is very
11 important, right? I'm not trying to pretend like
12 that isn't; that is critical, that can be the
13 kickstart to so much. But when you see such
14 discrepancies, what, like millions of dollars
15 annually going into one slice of the system, and
16 then maybe not even twenty percent of that going
17 towards more some of the things you were talking
18 about around family engagement, public education,
19 like, where does that -- where do these stories
20 start to link up? And that may not be a question
21 for you and that may be more of a question for
22 others. But I think it's really hard to

1 constantly hear about family engagement, and we
2 want families involved, and they need to be
3 leaders, and all of that, and sometimes the
4 financial component of that still needs to be
5 caught up.

6 And I think that's particularly an issue
7 when we see kind of outside of federally supported
8 efforts more on the, what you could say the
9 privatization of health care. We really see those
10 companies making those investments. They see
11 where, you know, what human-centered design looks
12 like. It goes into their marketing, it goes into
13 their education, it goes -- it looks almost
14 opposite.

15 And so, again, though, I think the
16 blueprint, as you said, is aspirational, I think
17 it's -- I'm excited because it doesn't feel
18 completely out of touch. It feels right in line
19 with what we've been talking about. But there are
20 these components that, you know, we really have to
21 line up, especially when the groups taking the
22 brunt are the families, the very ones we say are

1 at the center.

2 So sorry, that was really a comment, and
3 I hate it when people say they're going to ask a
4 question but give a comment. But I just think
5 that's a really important perspective in all of
6 this.

7 DENNIS KUO: Yeah. First, thank you.
8 They're honest comments, and I think they're
9 absolutely right on. You know, I see this as a --
10 this is also a -- all of this as a journey, and in
11 one part, acknowledging that to have -- to be a
12 part of this conversation, to have this
13 conversation is a large advance in and of itself,
14 that we're here to talk about integration and
15 collaboration, and that there are specific things
16 and expectations such as family partners -- and to
17 go back to family partnership and collaboration,
18 just the fact that we're talking about specific
19 standards for payment and compensation
20 representation and DEI at the center in a
21 framework is -- I'm hearing it so much more
22 strongly than we did say fifteen to twenty years

1 ago. And I think those are important. Yes, we
2 have a long way to go.

3 And I think your comment also on, like
4 is the funding, you know, is it properly being --
5 is it being directed properly, does it match, you
6 know, well to where they really need to go, those
7 are right on. And I think that by having families
8 at the center of that discussion, those are the
9 questions that need to be raised when we make
10 these -- when these decisions are made.

11 I think we absolutely have a long way to
12 go. But I am glad that we're at a point where we
13 can have these discussions, and they are hard they
14 are hard discussions. And, as I, you know, I
15 think I told my family years ago when I started to
16 go down this path as a career, you know, this is
17 years and years and years, and if we don't
18 succeed, I at least have to -- we have to try.

19 NED CALONGE: Thanks. Robert.

20 ROBERT OSTRANDER: Thank you. Robert
21 Ostrander, AAFP. First of all, I am very
22 disappointed I didn't know you were up the road

1 for me, because you and I should have had a
2 conversation a long, long time ago. I'm just
3 outside of Canandaigua. So, that's really too
4 bad. I've been working mostly with Steve in your
5 group.

6 DENNIS KUO: Yes.

7 ROBERT OSTRANDER: So, I hate to put a
8 more pessimistic spin on all this, but the way I
9 got into this genetics world was through the
10 Children and Youth with Special Health Care Needs
11 World twenty-two years ago, when our practice was
12 chosen to be part of the NICHQ Learning
13 Collaborative on Medical Home, and this is the
14 same story, right? I mean, the -- other than the,
15 you know, the new -- the more heavier focus on
16 DEI, this sort of aspirational model was what we
17 were working with. And so, I don't know if
18 there's lessons to be learned as to why that
19 didn't take off like it should have. I'd be
20 interested to hear your thoughts on that.

21 The second question is, and again, I
22 don't know how many people are familiar with that

1 learning collaborative, but it was eye opening,
2 because they insisted right off the bat that we
3 have a physician, a staff member that was involved
4 in the sort of outreach part, and a parent
5 partner, and that was just terrific, because it
6 really focused all of our discussions, as you
7 pointed out, on what's important.

8 So, one question is exactly or do you
9 have specific notions of how the agenda is going
10 to be set by the parent partners? I mean, and we
11 did -- I just was on a project with the SCID
12 group, and we did some journey mapping, which was
13 tremendously helpful in focusing our work product
14 and, of course, parent partners need to be on the
15 decision-making end of that. So, I think that's
16 important.

17 And the last two things that I want to
18 hear about, and I think dissemination was one.
19 One of our visions back then was that we were
20 going to get the parents, not just the advocacy
21 groups, but the parents themselves versed in this,
22 so they could go to their medical homes and say,

1 hey, we expect this from you, and that's a
2 dissemination technique that I think, you know,
3 we'd like to hear your thoughts on.

4 And then the last thing, I think one of
5 the reasons actually, that it's fizzled out is
6 that the insurance companies and the government
7 coopted medical home, horribly and, you know, we
8 had a patient and a family-centered medical home,
9 and now we have a payer-centered medical home,
10 private and public payer-centered medical home,
11 and all of our colleagues, that's what they think
12 medical home is, and they think they're providing
13 a medical home when it has nothing, no resemblance
14 at all to the vision that we had during those
15 learning collaborative years. So, that was kind
16 of a speech and kind of some questions.

17 DENNIS KUO: This is -- this is a
18 conversation we should have over like drinks. But
19 I actually do have -- but no, thank you, and
20 twenty-two years ago, I was I was in private
21 practice. And I think that, you know, we've had a
22 lot of journeys, and I've -- and so, I have

1 perspective as well. I've also been involved in a
2 number of learning collaboratives on both ends,
3 both internal and external, and I hear you, and I
4 think, in part, the field has changed. I think
5 that, as you pointed out, that the medical home,
6 like if we look at the 2002 report for the
7 American Academy of Pediatrics, and it's since
8 then, you know, it's been operationalized in many
9 different ways and there's the joint principles
10 statements, and we're here and we're there, and
11 somehow, what I -- my experience living in that
12 world also is that the pieces are just not
13 connecting with each other. It's like okay, you
14 know, there's just a lot of checkboxes that that
15 happened. And then you mentioned the finances,
16 and you mentioned the financing piece, and you
17 mentioned, you know, the partners.

18 There's not any easy answers to it
19 because I think what also changes like as our care
20 and, you know, for example, in the financing
21 world, long-term care expenses just keep going up
22 and are straining so many of our federal state

1 government budgets, along with the other
2 demographic shift that we should mention is that -
3 - is, you know is that the population and the
4 share of Medicare and the dollars that are
5 available for children's health are a smaller
6 percentage of the pie.

7 Let me come back to the family partners,
8 and you had asked, you know, what's -- what's the
9 vision there. I think the thing that I would
10 posit is that I'm one person, and I think that
11 part of what we do is that as we look at our -- at
12 our steps for that we are humbled and responsive
13 too when we bring the right team together under
14 the right principles, and say, it's about equity
15 and fairness and the lived experiences, then you
16 let that come out and you see where you go,
17 because there were so many questions that, you
18 know, I know answers to some of them. But then
19 there's so many that I just haven't even thought
20 of personally, and I think all of us can identify
21 being in that position.

22 You know, one example is that when I was

1 doing early childhood work, one thing that wasn't
2 totally on my radar until I had two family
3 partners as part of that group is that they talked
4 about the transition between early intervention
5 and special education as being one of the hardest
6 things that they had to go through. You know, and
7 that's not something I learned in medical school.

8 So, while acknowledging through
9 observation and experience on there, there's a
10 tremendous amount of advocacy that has to happen
11 and sometimes we feel like we're going, you know,
12 there's like a bit of a two steps forward, one
13 step back, and sometimes it's three steps back.

14 You know, I will go back to in the last
15 twenty years, insurance coverage has changed quite
16 a bit and, you know, that has given us a certain
17 amount of tools that we have that we didn't have
18 before.

19 But I do think the conversation needs to
20 lead with -- and this is a game changer for what
21 we're seeing as a game changer -- the conversation
22 needs to start with the family and communities,

1 and as you bring it down, and you start to see,
2 okay, these are the questions we really, really
3 need to be answering.

4 NED CALONGE: Thanks. We are over time
5 now. But there are two people that have been
6 patiently waiting in the room and other people
7 like Karen Downs on the phone. You can always E-
8 mail but let me just see if we can be quick and
9 parsimonious starting with Margie.

10 MARGIE REAM: Margie Ream, Child
11 Neurology Society. I was wondering your thoughts
12 on hospital children who are identified at risk of
13 newborn screening conditions that may be of late
14 onset, they don't have the benefit of a specific
15 diagnosis that may gain them access to care. But
16 how do those children at risk, but otherwise
17 healthy, fit into the system?

18 And also, I guess maybe more of a
19 comment, the idea of family centeredness, when we
20 talk about diagnosing a heritable disorder, is a
21 family diagnosis, and is there a way that family
22 centeredness could facilitate access to care for,

1 you know, mothers that may be carriers for X-
2 linked conditions or other family members that may
3 need to be screened now that we have the child
4 identified?

5 DENNIS KUO: Thank you. Very brief
6 answer is medical home, continuous screening,
7 surveillance, but also making sure that there's
8 team-based care, and it has to look different
9 because -- and it will look different in different
10 places, because, you know, look different in a
11 sole practice versus a group practice versus a
12 hospital-based practice. But when a system is
13 there to not only identify, but also to be able to
14 screen continuously and collaborate with the
15 schools, that's how, you know, the system is
16 designed to be able to work to get to be able to
17 catch those issues.

18 But I think the other thing is, under
19 the life course, and under, you know, the, like,
20 say, the Bright Futures guidelines, we have to
21 talk about development promotion, and health
22 promotion, and there are some -- there's probably

1 more and more work that really needs to be done to
2 think about how do we promote the kids at risk,
3 because I, you know, I think that you've got to be
4 much more intentional with those kids.

5 NED CALONGE: Siobhan, you have the last
6 question, and Karen, we'll get yours via E-mail, I
7 hope.

8 SIOBHAN DOLAN: Thank you so much.
9 Siobhan Dolan. I am going to make my comment just
10 as an obstetrician and geneticists and not really
11 an organizational comment, if I may, which is I
12 appreciate all the conversation today, and I
13 absolutely support the idea that we have to be
14 thinking about transition from childhood to
15 adulthood in managing these conditions. But I'd
16 also recommend and bring up that when we think
17 about fragmentation, and we think about patient
18 experience, everything that's gone on prenatally
19 and, you know, I admit, that's my lens, but it's
20 enormous and there's enormous pressure in there.
21 There's a lot of industry investment and
22 diagnostic testing. It all, you know, sort of

1 escalates to twenty weeks and then it's like,
2 okay, just tread water, hold on, we'll get back to
3 you at newborn screening, and actually, there's an
4 enormous window there. There's lack of data,
5 right? Actually, medical records have worsened
6 the situation of data because the mother's record
7 with all the prenatal diagnostic testing sits
8 here, may not get to the baby's newborn record, if
9 you have an electronic system, and most certainly
10 won't get out to their community physician.

11 So, I just want to ask, just sort of
12 comment and bring this perspective to this
13 Committee that the sort of fragmentation, which is
14 at largely the heart of a lot of inequities in our
15 health system, are already being deeply
16 exaggerated by what we aren't doing. And I say,
17 we vary generally, as a health care system between
18 prenatal and newborn, and actually also harnessing
19 the data that's collected in that period. So,
20 that would be a question I would have, as I close
21 here. With the group blueprint, could that be
22 used as a sort of framework for data collection,

1 because again, there's going to be investment in
2 the prenatal area around gene therapy and around
3 treatment and outcomes, and could the blueprint be
4 put forward to say, look, this is what you collect
5 according to so we would have good data, and not
6 just one off treatments that we really can't learn
7 from as a system?

8 DENNIS KUO: Thank you. I have two
9 quick comments to that. One is I absolutely,
10 absolutely agree about the data. And having been
11 to different health care systems with different
12 data and EHR systems of varying qualities, it's
13 huge, and I don't think that we've realized the
14 potential, but the potential requires a certain
15 amount of advancements that and also, frankly,
16 things like human-centered design interfaces and
17 thinking to make it actually useful as opposed to
18 like, okay, you know, let's just, you know, click
19 a box here, and you'll get paid more for by saying
20 that's, that's what's going on.

21 The other thing I would come back to is
22 actually relationships. So, one thing -- so, when

1 I was in private practice, we routinely visited
2 our OB colleagues, and I assume that my practice
3 that I started out with still does that, because
4 we would have that interface, because that really
5 did make a difference in that after that twenty
6 weeks where we could have that conversation. And,
7 you know, and overseeing the newborn group in one
8 of my previous positions, we started to do the
9 same thing. And it was just interesting that we
10 just started to reopen that window, and I would
11 advocate that, you know, we're all part of a
12 system, and if we center it on the journey of the
13 parent from prenatal all the way through adulthood
14 and then back to prenatal, then we can see that
15 we're a part of that continuum and sometimes it's
16 just a matter of getting out of our offices for
17 screens and going in and saying let's just chat
18 and see how we can work together.

19 NED CALONGE: Well, Dennis, clearly you
20 captured our attention and interest and did a
21 wonderful job. I hope everyone will join me in
22 thanking you for a great presentation.

1 DENNIS KUO: Thank you very much.

2 NED CALONGE: And Kyle, I wonder if
3 you'll come up and get us started on our next
4 agenda item. You'll remember that we asked the
5 workgroups to think about their last meetings and
6 the solutions they identified, and hopefully come
7 back to us with some priorities that the Committee
8 might have a hand in pushing forward and we're
9 going to with Follow-up and Treatment.

10 **Roundtable Discussion: State Follow-Up and**
11 **Treatment Workgroup Update**

12 KYLE BROTHERS: Great, thank you so
13 much. We have a really great group. We had a
14 very active conversation yesterday, and it felt
15 like we're sort of making headway. So go ahead
16 and to the next slide, if you don't mind.

17 The last time we met, we came up -- we
18 kind of brainstormed like what are some ideas that
19 might help us move along the implementation of new
20 conditions at the state level from the perspective
21 of follow-up and treatment, and I must say that,
22 just making that connection took a little bit of

1 work to think about follow-up, apart from the
2 bigger picture of, you know, this whole spectrum
3 of care, continuum of care, and focusing in on
4 what are the pieces of the follow-up and treatment
5 pie that really affect how states implement new
6 conditions when they're added to the RUSP.

7 So, these were sort of the three big
8 ideas that we came up with last time, and then
9 this time, we tried to focus in on which of these
10 do we think is the most important, the most
11 practical, the one that we really want to focus
12 on, and what are the concrete steps we can take
13 towards making that a reality. So go ahead to the
14 next slide.

15 Great. So, we really reached consensus
16 yesterday on the idea that we'd like to request a
17 blueprint, which ties in nicely with a nice talk
18 for follow-up and treatment as a part of the RUSP
19 nomination, and one of the points that the
20 Committee made repeatedly was that this is not
21 just a task for nominators; it's also a task for
22 the Committee, both to give guidance to nominators

1 about what it is that we're looking for here, but
2 also for the Committee to utilize that
3 information, to hopefully get it out to the states
4 to provide guidance on this is the follow-up
5 strategy that, you know, you need to look at in
6 order to get this, you know, this particular
7 condition out and ready to go.

8 So, we really settled in on that piece
9 of the nomination, but with an element for the
10 Committee to really consider. Okay, next slide.

11 Okay. So, what does this mean to have a
12 blueprint for follow-up as a part of the
13 Nomination Committee, and I just want to say, we
14 got to this piece of our discussion very late in
15 our time. So, this was really more sort of a
16 brainstorming, throwing out ideas, conversation.
17 And so, I really want to highlight this is
18 preliminary. I think this is sort of like the
19 straw man that will start our next conversation
20 about what do we really need to focus in on in
21 this idea?

22 So, I think this is kind of what the

1 Committee came to yesterday. Basically, the
2 blueprint that the nominators would include in the
3 nomination for a new condition that hopefully the
4 Committee would then leverage for guidance would
5 include a breakdown of the subgroups of screened
6 individuals who will be identified by newborn
7 screening. This is different for every condition,
8 as you all know. There are pseudo-deficiencies,
9 there are patients who are asymptomatic early in
10 life, but then later become symptomatic. For
11 certain conditions, we're actually screening for,
12 you know, markers for a condition that some
13 children already have symptoms of birth. So,
14 there's really a broad spectrum of different kinds
15 of subgroups that we might need to worry about
16 here. But by breaking it down, that really helps
17 to get the states moving on thinking about whether
18 the different follow-up pieces that are needed for
19 these different subgroups.

20 And then, you know, we would want to
21 identify those groups, however, that are specific
22 to that condition. So, symptomatic versus

1 asymptomatic what, you know, maybe the various
2 levels of relevant biomarkers, as we discussed
3 yesterday with psychosine and Krabbe disease.
4 Yeah, and they're different for every condition.
5 Go on to the next slide, please.

6 Okay. So, for each subgroup, we would
7 be asking the nominators to propose standardized
8 terminology. This is really key both in
9 implementation and communication about
10 implementation, but also as a starting point for
11 gathering data in the follow-up stage for, you
12 know, for the different groups, what are the
13 outcomes that we're observing in terms of short-
14 term follow-up, and then maybe, you know,
15 eventually long-term follow-up?

16 And then we would -- we would be looking
17 for guidance on the follow-up needs specific to
18 each subgroup. So, which professionals would be
19 needed? Which types of evaluations, laboratory
20 exams, radiography, etcetera? Where are those
21 located? So, for some of these conditions, as you
22 all know, the short-term follow-up plan, pieces of

1 that might be specific to regional centers that
2 are not available in every state. There may only,
3 for certain conditions, may only be a few centers
4 in the whole country. So, it's really important
5 to be aware of that. And then what are the
6 resources that the state would want to sort of
7 check off as they're working on getting a
8 condition implemented? What are those resources
9 that they sort of need to identify and figure out?
10 Okay, do we have access to this? How would our
11 families get access to these resources? Next
12 slide.

13 Okay. And then, it would -- the
14 blueprint would focus on the follow-up needed to
15 identify whether a screened individual has the
16 newborn screened primary condition. So, we're not
17 really talking about the follow-up needed in the
18 long term about, you know, if a patient who's
19 asymptomatic at birth, but identified to be at
20 risk for a condition does get follow-up treatment,
21 what are the long-term outcomes, right? That's --
22 that's sort of a different question, and although

1 the states care about this question, it's not
2 really within their purview in the short term when
3 they're implementing a condition. They're really
4 being asked this initial process, which for some
5 children is days, for some children is years
6 depending on the condition to identify, does this
7 child have the condition that we're screening for?
8 And once the state is aware of whether or not that
9 child meets those criteria, then, you know, then
10 that's moving into a different system of
11 evaluation and care.

12 And yeah, the reason and that we really
13 wanted to focus in on this particular issue about
14 identifying which of these children actually have
15 the condition being screened for is that this is
16 really the component that for the states when
17 they're implementing a new condition, that's the
18 top priority and thinking about what follow-up
19 pieces they need to have in place. I think that
20 might be it. Next slide. Yeah, okay. Yeah, do
21 we have -- are we doing questions now, or?

22 NED CALONGE: I think what I'd -- what

1 I'd like to do in the interest of time, because we
2 have like a full hour, I think, to try to this is
3 ask people to write down their thoughts and
4 questions as we go along, and then we'll have a
5 break, and you can solidify those. But that was
6 great. Thanks, Kyle.

7 I'd like to have Kellie come up to the
8 podium for Laboratory.

9 **Laboratory Standards and Procedures Workgroup**

10 **Update**

11 KELLIE KELM: All right. We had a -- it
12 was great to see everybody yesterday. We had a
13 fantastic session. And I think ours is a little
14 bit more immature than what Kyle provided, but we
15 can give you some of the, you know, brainstorming
16 that we took from the last meeting, and at least
17 tried to whittle it down to things to put out
18 there in terms of some possibilities. Next slide,
19 or do I do it?

20 Anyway, the group we had, almost
21 everybody participated, which was great. Next
22 slide. And next slide.

1 So, the brainstorm list that we had of
2 ideas from the last meeting, most of them fell
3 into two flavors of things and then we had some
4 other outliers. One of the things that we heard
5 from the programs was a lot of ideas on how to
6 help program development around a new condition,
7 you know, things that people had seen help them
8 succeed or where they found challenges. And that,
9 you know, we can help by giving some attention to
10 program development. And I would say most of
11 those things are sort of, you know, where we felt
12 that our workgroup could help give a lot of help.

13 The other flavor of things was, for
14 example, improvement in technology. You know, we
15 had talked about things like other specimen types,
16 or, you know, improving sensitivity and things
17 like that. And, whether I think that that would
18 be, you know, still something that needs a lot of
19 attention, I'm not sure. You know, our workgroup
20 could obviously hear about that from partners, but
21 obviously, was a little bit out of our wheelhouse.

22 So, the things that we have that we

1 heard from the programs that we could, in some
2 ways build on things that are already there, and
3 again, I guess more centralize it as a product
4 that the Committee could help with is both a, what
5 we call a quick start guide, and a project plan
6 worksheet for implementation of a condition added
7 to the RUSP.

8 So, when the Public Health Assessment of
9 a potential condition is being completed by APHL
10 as part of evidence review, they're already
11 putting together what they call a fact sheet.
12 And, you know, one of the things that we heard was
13 that there actually, you know, could be expansion
14 of that to add additional information, that would
15 be helpful, because those fact sheets, for
16 example, could then be in the expansion of the
17 information. There is APHL and NewSTEPS takes
18 that, and when a condition actually is added to
19 the RUSP, there is a toolkit that is developed for
20 states to use, and one of the comments that we
21 heard was, well, it's like a, you know, thirty-
22 nine-page report, and when I want to give it to,

1 for example, my Advisory Board, it's -- it's too
2 much.

3 And so, a, you know, a shorter
4 QuickStart Guide, which we would build off that
5 Public Health Assessment fact sheet with a little
6 bit more detail would be really helpful is what we
7 heard. So, that's the first thing. So, there
8 already are some resources. But we heard that,
9 you know, where perhaps the Committee could help
10 was looking at that and seeing where could be
11 expansion or more detail added that the state
12 programs think would be helpful.

13 The other thing that had been -- had
14 been brought up was that states found that having
15 a champion or project manager when they were
16 starting from something added to the RUSP to
17 screening in their program was really helpful to
18 drive -- to drive getting all the pieces together.
19 So, some states have started looking into having
20 that type of project manager or champion but some
21 states don't really have that resource. Is there
22 some way that the Committee could have like a what

1 we considered a project plan, sort of a shell or
2 worksheet, that would include, you know, what, you
3 know, these states that have a project manager
4 might, you know, have from, you know, when you've
5 got to sit down and think from day one, and then
6 check the boxes, and the idea would be that this
7 obviously, you know, a state, we would have to
8 consider that states have different ways that
9 things are done, different groups, boards, you
10 know, legislation, you know. As we talked about
11 yesterday, you know, the states have different
12 things, steps that they have to go through. It's
13 not all one size fits all. But the idea would be
14 to have that all in the shell, and that states
15 would obviously use it and format it to what their
16 program needs.

17 But then you would include, obviously,
18 you know, if you actually have to bring in, you
19 know, build up a new room, equipment, FTE, you
20 know, there would be this part of the shell. You
21 would start and you would go that direction. But
22 if were building off a, you know, method that you

1 already have, then you would go here.

2 So, it would basically be a project
3 manager worksheet that states could hopefully use
4 and build off of that tool if that's something
5 they don't already have.

6 So, they -- they're different. So, one
7 of them is more about the content of the, you
8 know, what we look at in terms of reviewing the
9 RUSP, and the other one then is actually the
10 implementation. But states said that they really
11 need both when they're going to implement
12 something added to the RUSP.

13 The other thing that -- that we've
14 obviously heard a lot of discussion about, in
15 general, at this Committee, or even in our
16 workgroup over time, is, you know, second-tier
17 testing, and a lot of sharing of information about
18 second-tier testing. And we know that, you know,
19 different ways that states consider these things,
20 and we know, you know, there's been a lot of
21 discussion about regionalization and specialized
22 testing, etcetera.

1 We really, and it doesn't necessarily
2 just apply to new conditions. Obviously, we've
3 had a lot of discussion about improving things
4 that are already on the RUSP, where we know about
5 people developing second-tier testing or using
6 that to improve.

7 So, although this is, you know, we
8 thought about this in terms of implementing, you
9 know, new conditions on the RUSP, it wouldn't be
10 limited to that at all. But again, this is --
11 this is a document that's not for a specific
12 condition or specific test, but would be a best
13 practices document for states to use when
14 considering the utilization or addition of second-
15 tier testing, including regionalization.

16 So, and, as I said, it can be
17 prospective or retrospective, and what we heard
18 was that this would be really helpful for states
19 to be able to use both to, you know, to assess
20 their current performance and think about how they
21 can improve what their screening now, how they
22 could do better, and then it would be

1 aspirational. They could take it and hopefully
2 use this when they're, you know, telling people
3 why they need a second-tier test and show them and
4 use this resource in order to do that.

5 So, and there's a lot of interesting
6 discussion, I think, you know, we heard a lot that
7 CDC does a lot of work in general on looking and
8 assessing second-tier testing and their lab. I
9 mean, all those things, I think we can pull from,
10 you know, a lot of our partners in putting
11 together this type of best practices document.

12 And the last thing is a little bit -- we
13 got a little off and had a passionate conversation
14 that's a little off the chair's assignment. So, I
15 apologize in advance, although this is something
16 that has come up in the past from advocates about
17 whether or not we're doing an effective job of
18 screening for homocystinuria. But I wanted to put
19 it here just because it was another place where we
20 had a real, you know, interesting discussion from
21 several partners and whether it doesn't fit in
22 this, I also think it's something that we'll be

1 hearing about in the future and maybe something of
2 interest to the Committee, sort of like our work
3 in the past on succinyl acetone.

4 But we know that current methodology for
5 screening for homocystinuria is not effective and
6 that there is, you know, a false negative rate
7 that is, you know, that we heard from the
8 advocates is a problem. And we've heard that CDC
9 has been working on this, and I think, you know,
10 we're interested in the potential of gathering
11 that information, and seeing whether or not it is
12 something to bring to the Committee that, you
13 know, something to come back with that may or may
14 not be similar to the succinyl acetone story, but
15 we figured that was -- that was number three, but
16 it's not really part of the assignment. So, we
17 apologize, but we, we wanted to bring it forward.
18 So anyway, that's -- that's it. Thank you.

19 NED CALONGE: Thanks, Kellie.

20 And Jane is making her way and you are
21 last but not least.

22 **Education and Training Workgroup Update**

1 JANE DELUCA: Hi, that's a tall order
2 there. Okay, thank you. Next slide, please.

3 Our workgroup, Education and Training,
4 met yesterday, and we had several lively
5 discussions. Next slide.

6 I just wanted to thank the Committee for
7 all their input yesterday and how we worked on our
8 different questions.

9 So, we had -- we were charged with three
10 top priority solutions the Committee can consider
11 acting on to support state implementation of
12 conditions added to the RUSP.

13 So, this was the outcome of our last
14 meeting in terms of these different solutions that
15 were generated by the workgroup. So, we came up
16 with a little bit more than three, but some of
17 them actually folded on each other, you know,
18 particularly around developing goals for education
19 and training and considering basic genetic and
20 newborn screening education.

21 So, some of the things that we thought
22 were probably not feasible, although were really

1 important, was developing evaluation methods for
2 measurement. So, that is still sort of in our
3 catchment, if you will.

4 So, we discussed support of existing
5 good training and materials, assuring diversity
6 and culturally tailored materials available for
7 families, partnering with governmental agencies,
8 working in similar spaces, taskforce, for example,
9 then again, something that's more germane to
10 education, training, developing those goals, and
11 considering basic genetic and newborn screening
12 education. So, a rich discussion ensued.

13 Okay, so what is the focus? We spent
14 some time talking about who is the education for
15 and who's being trained. So, education and
16 training needs are different for different
17 categories of people, and we already have a really
18 good document that was created several years ago
19 in terms of education, Educational Planning Guide.
20 So, what that consists of is it consists of all
21 the stakeholders, and then of these different
22 topics that will run across the top of this

1 matrix, and we can see how some of these topics
2 are important to different types of stakeholders.

3 So, we have patients, clinicians, the
4 public and more. So, patients really are the
5 priority, but education needs to exist throughout
6 the system. So, if you look at the matrix, we
7 have thirty-one distinct audiences or
8 stakeholders, if you will, and then we know we
9 have twenty-eight distinct topics. So, we're
10 lucky; we got to jump on that because we have this
11 existing document.

12 So how -- where is the information and
13 training located? There's a lot of existing
14 educational materials and training centers, if you
15 will, that already exist. So, I think that what
16 it boils down to is how can we gather this in a
17 way that this could be utilized? Is there like a
18 central way that we can deposit this or a
19 repository, if you will, and there are centralized
20 resources already, that we can look to. So, we
21 spent some time talking about how we might be able
22 to do this so that people can get to this great

1 stuff.

2 So, gathering, organizing, creating, use
3 of templates on these existing places for
4 education materials, and then money has been spent
5 on really good training programs. Let's access
6 that. Let's use that.

7 So, the core question for us and I think
8 it's for other workgroups as well, are we speaking
9 about the newest disorders, or do we want to go
10 back to some of the older conditions where
11 education is still needed?

12 So, and then, we talked about websites
13 are good, but there's even more ways to reach out
14 to people in terms of getting messages across in
15 terms of social media. So, screening is getting
16 bigger and not just newborn screening. This was a
17 really important discussion we had about prenatal
18 screening. Yes, we are newborn screening, but
19 prenatal screening is getting bigger. There's
20 more tests. There's a huge influential industry
21 there, and there's often misunderstanding on the
22 part of providers, as well as patients who utilize

1 those systems. So, you -- oftentimes you don't
2 get to newborn screening without passing through
3 prenatal screening.

4 So, parents can come to us already
5 understanding or misunderstanding aspects of
6 screening that could be really important, and they
7 carry that into our area. So, is more screening
8 better? That's something we ask all the time is
9 if the number of tests that are unscreened for,
10 does that really make a better system? Not
11 always. And we don't speak consistently about
12 these concerns.

13 And it was brought up that The New York
14 Times ran a really important article in the
15 beginning of the year in January about the uses of
16 prenatal screening, and how it's really quite
17 concerning to families that get caught up in this.
18 There's information that's put out there, it's not
19 interpretable. And then in the spring, the FDA
20 actually had issued an advisory in terms of using
21 prenatal tests.

22 So, there's potential for more

1 confusion, not less, and maybe we want to think
2 about prenatal screening in the context of newborn
3 screening.

4 So, to come to our issue of partnering
5 with government agencies, we can identify
6 strategies to partner with these different
7 departments and agencies, because we may have
8 things in common and there's potential
9 collaborations that we can engage in. There was
10 an article published this year in terms of newborn
11 screening research sponsored by the NIH and there
12 was a wonderful diagram, The Road to the RUSP,
13 which showed the sort of interlocking of different
14 governmental agencies and how they are
15 contributing to when particularly disorders get
16 placed on the RUSP. So, we thought this might be
17 something that we could utilize.

18 Federal agencies have different
19 missions. So, we want to be able to identify
20 people and approach them when we're ready to talk
21 about doing a collaborative effort.

22 Now, the other thing that came of this

1 was also connecting with professional
2 organizations because they're a great resource in
3 terms of getting information out. They have
4 educational endeavors that they're engaged in.
5 So, it's not just government. We can be talking
6 about organizations like the ACMG, ISONG, et
7 cetera, or APHL.

8 So, we are prioritizing culturally
9 appropriate information education and training.
10 This is very, very important to our group. We
11 live in a diverse culture that's becoming
12 extremely more diverse. So, do we have
13 appropriate materials that are culturally
14 appropriate, or can we create materials beyond
15 just using language? But how can we create
16 materials that have the look and feel for
17 something that's culturally appropriate for
18 different groups? Newborn screening programs may
19 differentially affect people from diverse
20 cultures, and we need to understand people's
21 experiences of health care because when you come
22 from another culture, you may see health care in a

1 very different way than the dominant culture sees
2 it, and we need to understand people's experiences
3 so that we can address inequities as well.

4 Education and training is everyone's
5 responsibility. We are the workgroup, but it is
6 everyone's responsibility along the continuum of
7 newborn screening. It's the responsibility of
8 every stakeholder. Everyone needs to continue
9 learning and being building their skills. We can
10 find out what is being done and what exists to be
11 able to create a blueprint for us in terms of
12 education and training.

13 So, our three top priority solutions
14 that we considered actually has come about as a
15 statement. So, priority focus and our solutions.
16 It's partnering with governmental agencies and
17 professional groups working in similar spaces. We
18 will support development, distribution, and
19 awareness of diverse and culturally focused new
20 and existing newborn screening education programs
21 and materials, ensuring the coverage of basic
22 genetics and newborn screening for all so

1 hopefully, that'll be something that we can engage
2 with the Committee. And that's it.

3 **Break**

4 NED CALONGE: Wow, those were three
5 fantastic summary presentations and a lot to think
6 about and I would like to challenge folks to think
7 about questions and the discussion which will
8 start around noon, in about twenty-five minutes or
9 so. We will spend the rest of the meeting and
10 kind of talking through these and thinking about
11 how they might translate to action items for the
12 Committee, the workgroups, and others, and that's
13 going to kind of take us to the end of the day.
14 So. I'll see you back in your seats in about
15 twenty-five minutes or so. Thanks.

16 (THEREUPON, A BREAK WAS TAKEN.)

17 **Committee Discussion on Action Items on Advancing**
18 **Newborn Screening System**

19 NED CALONGE: Oh, the miracle of the
20 Friday afternoon meeting in DC. So, I appreciate
21 those of you who were able to stick with us
22 through the end of the meeting, and I hope as

1 people start making their way to respective
2 airports and metro stations, that your travels are
3 safe, going forward.

4 So, we're going to try to reconvene and
5 kind of finish up today with what I know will be a
6 lively discussion on advanced newborn screening
7 systems. And I would like to start with just
8 specific community, I'm sorry, Committee and
9 organizational representative questions about --
10 and comments about the three presentations. And
11 so, if you remember, we started with Kyle and your
12 three issues were -- I'm trying to -- you had
13 them.

14 KYLE BROTHERS: Yeah. Our three
15 starting points, one was having the Committee,
16 when it does recommend adding a condition, to also
17 recommend a follow-up plan. The second one was
18 asking professional societies to put out guidance
19 specific to the newborn screening context for how
20 to follow up and treat the various categories of
21 conditions. And then the third was asking
22 nominators to lay out a follow-up blueprint. And

1 so, we focused on the third, but hopefully, the
2 third would inform the Committee being able to put
3 out a follow-up plan when it recommended adding a
4 disease to the RUSP.

5 NED CALONGE: So, let me start with
6 Committee members and questions or comments or
7 suggestions for this specific issue. Marc
8 Williams. Oh, I'm sorry, Marc, if you wait until
9 we get through the Committee, which will take
10 another ten seconds. Jane, thank you.

11 JANE DELUCA: Kyle, thank you for your
12 presentation. So, my question is, this blueprint,
13 because the states are so different, you know, is
14 the blueprint going to look different from state
15 to state? I like the idea of a blueprint, though.

16 KYLE BROTHERS: Yeah. I think the idea
17 that -- I'm speaking on behalf of others here, so
18 I might get this wrong -- but my understanding of
19 the blueprint is the features of the condition and
20 what follow-up is required for the different
21 subgroups, which would not necessarily be specific
22 to a state's infrastructure, but would really be

1 more about the disease, and then the states have
2 the task of filling in the blanks about how would
3 we manage or how would we offer follow-up for this
4 subcategory. So, just thinking about, you know, a
5 condition that requires ongoing hearing screening
6 for the first couple of years of life, you know,
7 how are we going to make that particular kind of
8 resource available to the patient?

9 JANE DELUCA: And I just had a follow up
10 comment. So, in the process of a disorder, who is
11 being evaluated for the RUSP, how early would your
12 group want to be in there? Would you want to be
13 in that earlier piece where you could see how, if
14 we're talking about different disorders, what the
15 expectation is, because it sounds like if
16 something is approved, then you're coming in, you
17 know what I mean, almost behind or after the fact.

18 KYLE BROTHERS: Yeah. The idea is that
19 would actually be part of the nomination package.
20 So, we would ask the community of folks who are
21 putting in the nomination package to really lay
22 out, you know, what are the subgroups here and

1 what's the follow-up plan for the different
2 subgroups as part of the nomination package, which
3 actually, I think is kind of a brilliant move that
4 the Committee is making there because I think it
5 is sometimes difficult in nomination packages to
6 really sort out who are the subgroups here and who
7 are the groups that are being proposed to benefit
8 from newborn screening. So, I think even that
9 task alone is probably valuable for the overall
10 question of how we, you know, sort of processing
11 and thinking through those nominations, but also
12 it would be a valuable resource then for the
13 states afterwards.

14 NED CALONGE: Melissa.

15 MELISSA PARISI: Melissa Parisi, NIH.

16 So, as you were describing this, Kyle, I kept
17 thinking about natural history, which I don't
18 think you used that term specifically, but so many
19 of these conditions, we have limited information
20 about the natural history and that includes
21 information about the penetrance of having a given
22 condition, and the variability in the expression

1 of a given condition. And so, my hope, I guess,
2 is that, if such a blueprint for follow-up could
3 be developed, that the data that would be gathered
4 from following these individuals longitudinally
5 could help inform our understanding of these
6 conditions and in some ways, that sort of blurs
7 the line between research and practice. But I
8 think that, you know, our goal and our hopes,
9 certainly with the Newborn Screening Translational
10 Research Network and some of our follow-up
11 activities and our longitudinal data collection,
12 is that there would be a mechanism whereby we
13 could learn from babies who have these conditions
14 so that we would understand the natural history so
15 much better in the long term.

16 KYLE BROTHERS: Yeah, I think you're
17 exactly right. I think that's -- we need the
18 information desperately. I think one of the key
19 questions here is about when we transition, the
20 terms long-term follow-up and short-term follow-up
21 are frequently used. I think we need to be more
22 specific than that, because I think, you know, the

1 states, when they're implementing new conditions,
2 they -- it's really within their purview, and they
3 really need to worry about the initial part of
4 that natural history about an individual has
5 screened positive, at what point do we know
6 whether they have that condition or not? That's
7 really, we kind of use the term short-term, and in
8 some cases, that's not very short, that actually
9 takes weeks to months to years. So, I think
10 that's sort of within the state's area of
11 responsibility to understand, are we coming up
12 with false positives? What about false negatives?
13 Is this process working? Then the issues you're
14 raising, which are really longer term that sort of
15 like, okay, we know, this child now has this
16 condition, what happens in the process after that?
17 You know, what is the outcome of treatment for
18 children who are just being followed without
19 treatment? What's the natural history of that --
20 of that course? I think that we could sort of use
21 the broad term of long-term follow-up, and that's
22 a space that we are not necessarily putting into

1 this recommendation for what we should do next.
2 But I think we do need to be thinking about how we
3 interdigitate those two things, because it really
4 is critically important that we understand that
5 long-term piece. It just may not be the within
6 the state's purview in the implementation process.
7 So, yeah, I think it would be wonderful if we
8 could figure out a way to really make one lead
9 into the other successfully. And I'm just not
10 going to hide this message. I think the NIH can
11 play a critical role in that particular stage.

12 NED CALONGE: Shawn.

13 SHAWN MCCANDLESS: Thanks, Kyle. Two
14 questions. Who are you -- who is the target
15 audience for the blueprint, is the first question.
16 And the second one is, how is this different from
17 developing guidelines for management and treatment
18 of diseases and if it is, is the nominating group
19 really the right group to take that on, or are you
20 proposing that we ask that there be some sort of
21 consensus treatment published prior to a
22 nomination being submitted? I'm not sure where

1 we're going with this.

2 KYLE BROTHERS: I'll tell you what I
3 think, but I also believe this is probably still a
4 point of discussion that the group needs to have,
5 and we would welcome feedback from the broader
6 community.

7 I don't think we're focused on treatment
8 in that way. I don't think we're focused on we
9 now know this child has a condition, what's the
10 treatment plan, and how does that follow? I think
11 we're really -- what we're focused on ends at that
12 point. The states need to figure out can we get
13 the child identified to have a condition and in
14 contact with the services that they need in order
15 to get appropriate treatment after that? Then, it
16 moves out of the state's purview into sort of the
17 health care system at large, right? So, I don't
18 think we're focused on that piece.

19 We did have quite a bit of discussion in
20 it, and I do think there's still an open question
21 about, do we need sort of clinical practice
22 guidelines in order to inform that initial step

1 because, you know, you could imagine a group like
2 ACMG having treatment guidelines for children with
3 PKU. That doesn't mean they're actually providing
4 guidance for what happens when a child screens
5 positive for PKU. Those are two different things,
6 right? And in some of the conditions we've been
7 considering recently, there's a huge difference
8 between the people who screen positive and the
9 people who actually have that condition. And so,
10 I do think there is a -- there is room for working
11 with those societies to really give us that
12 guidance on the first step. This is not a
13 guidance for treating the disease, it's guidance
14 for a positive state on a newborn screen.

15 But I do think, if we are going to add a
16 condition to the RUSP, it's extremely helpful to
17 understand what are the different situations that
18 will arise through that. That's just helpful to
19 us in making the decision and sometimes it's hard
20 to identify that in the nomination package. So, I
21 think it's critical. So, I think it is very
22 useful for that.

1 And then the second target, and really
2 their primary target, is that if a condition does
3 actually get added, that there is a starting point
4 for the states and understanding who are the
5 different groups that we need to think about?
6 What's the standard terminology we're going to use
7 so that when we are working together to report
8 that, we are using the same terms, and we know
9 what their definition is. And then hopefully,
10 have the states be able to quickly identify what
11 are the resources they're going to need to bring
12 to bear to make sure that the newborn screening
13 process is getting started, you know, correctly?

14 SHAWN MCCANDLESS: And would that
15 include providing them case definitions to the
16 states rather than the current system where every
17 state figures out for themselves how to define a
18 case?

19 KYLE BROTHERS: I think that's critical,
20 yes.

21 NED CALONGE: Yes, and I think it really
22 is, I would say a responsibility of the Committee

1 in making a recommendation of an addition that, I
2 mean, I think we talked about this a lot in the
3 back and forth on nomination packages, so what is
4 the case? and so, it's not what is a positive
5 test, that's another issue. But then, what's the
6 case? So, it came up with Krabbe about, you know,
7 those high-risk kids in New York and only five had
8 the condition. So, what was the condition that
9 was actually specified and what were the other
10 four? I think those are really important things
11 to really have. And I've seen you do this in your
12 reviews, to zone in on commenting about what are
13 we talking about, what's the condition, and that's
14 a nomination issue. Recognize that the Committee
15 needs to do its work and the Evidence Review Group
16 has to do its work based on the clearest and most
17 specific definition of the condition we're trying
18 to find and treat possible. So, it's like a key
19 part. Yeah, Kyle.

20 KYLE BROTHERS: I think this ties in
21 with your comment yesterday about the secondary
22 conditions, because I think we don't just need a

1 case definition for a specific condition where we
2 think there is a benefit from newborn screening.
3 We actually need separate case definitions and
4 standardized terminology for each of the sub-
5 situations that occur when a patient screens
6 positive. So, you know, what -- what do we call
7 these children who are born symptomatic and are
8 screened positive? That's sort of its own thing.
9 What about children who have, you know, this
10 particular biomarker is low, so, there's a
11 question about whether there might be a pseudo
12 deficiency or whatever. We really need those to
13 be broken down and named in a very specific way.
14 The states need that and we need that in assessing
15 the nomination, not just the, what is, for
16 example, what do we mean by when we say Krabbe
17 disease. It's actually the whole set of the
18 different situations that turn up when we start
19 screening.

20 NED CALONGE: Right. And I guess the
21 only thing that, you know, a small group has
22 talked about during the break is, it could be that

1 a lot of the information that you're talking about
2 would come out of the Evidence Review Group
3 because they talk a lot about treatment. And so,
4 thinking about those issues, and that might be an
5 additional source of filling in that blueprint for
6 short term, and I'm going to say it, not long-term
7 treatment. So, whatever that is, right, there's
8 diagnosis and then what do you need to do in
9 thirty days, for example, for rapid treatment?
10 And then, I think, we do need to have a good sense
11 of where do you get that? So, that was -- that
12 was so important in SCID to say, okay, we
13 identified all these kids, are there enough
14 centers that do transplants and routes of
15 transportation and coordination of care to make
16 sure that once we identify you, you actually get
17 the therapy that will save your life? So those
18 are -- I think those are important things to keep
19 in mind that can be part of the blueprint.

20 Jennifer, you put your card back down.

21 JENNIFER KWON: I'm going to just make a
22 very quick comment. I think that one of the

1 things that came up yesterday, is that we do want
2 to help states implement these programs. But I
3 also feel like we put these imaginary boundaries
4 about what is the state's purview, and how do we
5 negotiate between what different states want
6 versus what -- and I guess I want to go back to
7 this idea that Dr. Kuo brought up, which is, we're
8 here to take care of a child identified with a
9 serious and chronic disorder and when we talk
10 about short-term guidelines, long-term guidelines,
11 all of these -- all of these other issues of
12 implementation, we really need to keep all of
13 these things in mind. And the fact that we're
14 worrying about if it's going to interfere with
15 implementation, I think, raises a bigger concern
16 about what we think of with newborn screening and
17 what we think we're trying to do in newborn
18 screening. I think that we're all here to take
19 care of the child overall and we do want to
20 implement these new disorders, and in order to do
21 that, we have to integrate long-term
22 considerations into our conversations about the

1 implementation.

2 NED CALONGE: Thank you. All right, I'm
3 going to turn to our organizational reps starting
4 with Gerry.

5 GERARD BERRY: I think Kyle ought to
6 really be congratulated for handling this very
7 difficult problem and discussion yesterday. When
8 I first saw what the charge might be, in other
9 words, what we should focus on and those three
10 things, it struck me that they really all ought to
11 be implemented right away. In other words, we
12 have the American College of Medical Genetics.
13 They've had experts in the field that have looked
14 at certain diseases. I don't see why that can't
15 be in place for the Committee at the time when the
16 recommendation is being made and not as something
17 that would happen at a later point.

18 And one of the things that struck me and
19 is the main thing I wanted to discuss is it seemed
20 like there was short shrift that was really being
21 given to long-term follow-up, and I think it's
22 something that the Committee really needs to go

1 after. Even though it's not the purview of that
2 Committee for doing this, it is important in terms
3 of the patient and what to do, and I think we need
4 some more help with trying to get other agencies
5 such as the NIH, to help us with this problem of
6 how should the workup be done properly, especially
7 for the patients that don't have classic disease,
8 but probably have a problem that can surface later
9 in life? And we don't really have the wherewithal
10 to take care of this properly right now, you know,
11 from manpower point of view, and also with
12 finances, and I think we need -- we need the
13 Committee to try to help us engage NIH, et cetera
14 to be able to do this properly.

15 NED CALONGE: Thanks, Gerry. Marc.

16 MARC WILLIAMS: Yeah, thank you. And
17 thanks to Kyle for mentioning the American College
18 of Medical Genetics and Genomics. I want to make
19 sure we're using our actual correct name here.

20 Three quick comments about some of the
21 points that were made. First of all, regarding
22 what do we do with positive screening, I would

1 just remind everybody that the ACMG ACT Sheets,
2 which are produced in conjunction with and through
3 funding provided by the Health Resources Services
4 Administration, do in fact address exactly what
5 should be done in the case of a positive screen,
6 and also addresses the issues that come up with
7 phenotypes that are identified from screening that
8 may not have medical consequences like pseudo-
9 deficiency and that sort of thing. So, there is
10 the attempt, at least, to define some of the
11 phenotypes that are not specifically actionable in
12 terms of the disorder that's being identified, or
13 the purpose for the disorder that is the most
14 severe form to be identified.

15 Now, those are all available and
16 reviewable, and we certainly would appreciate any
17 gaps that are in those ACT Sheets be presented to
18 us because we revise those on a regular basis and
19 we want to make sure that they reflect adequately
20 the best practices, and if we've missed something,
21 then we want to be aware of that.

22 The second thing is standardization,

1 which is critically important. It's something
2 that we are investing more resources in as part of
3 the Newborn Screening Translational Research
4 Network. We're trying to use standardized
5 terminologies and ontologies. We've been actively
6 engaged with the human phenotype ontology, for
7 example, to make sure that that includes all of
8 the phenotypic terms that are directly relevant to
9 newborn screening, so that that can be more widely
10 utilized.

11 Mention was also made about the need for
12 longitudinal follow-up, which is critically
13 important, and is being done with funding from the
14 NICHD, thank you, Melissa, to the Newborn
15 Screening Translational Research Network. But
16 clearly, the current resources that we have
17 devoted to that are not adequate to provide long-
18 term follow up for every disorder, and I think we
19 also need to recognize that there are problems
20 with data access. It's all well and good to be
21 able to get health care-related data, which is
22 relatively easy to come across, but a lot of the

1 things that we're really interested in reside in
2 different places like school systems and that, and
3 so, how we get at those data to really inform the
4 long-term follow-up question more broadly, is
5 really important.

6 And I think it's also important, as we
7 talked about standardization of case definitions
8 and this sort of thing, that it's ultimately the
9 states that make the final decision. So, even
10 though we can provide guidance, it's up to the
11 state to decide what they're going to do. And so,
12 we need to understand that there is explained
13 clinical variation, which is states have different
14 populations, which means that they may be -- they
15 may need to do things differently compared to
16 other states to reflect their population. But
17 probably most of what we're dealing with is
18 unexplained clinical variation, which we
19 ultimately need to reduce.

20 And then the last comment just relates
21 to the work of the Laboratory Quality Assurance
22 Committee of the American College of Medical

1 Genetics and Genomics, which, in conjunction with
2 sister organizations, creates standards and
3 guidelines for testing that should include newborn
4 screening-related tests as well. These are also
5 constantly being reviewed and revised. So, for
6 those of you that are familiar with them, if you
7 see that there are areas that need revision that
8 are not really responsive to the newborn screening
9 area specifically, that's something we need to
10 know about so that we can revise those and keep
11 them up to date. And for those of you that are
12 ACMG members, remember that all of those documents
13 go through a public review and comment, and so, if
14 you see that notification coming out to say we
15 want comments, please look at them with the lens
16 of newborn screening so that we don't again, miss
17 the boat on that. Thank you.

18 NED CALONGE: Thanks, Marc. Natasha.

19 NATASHA BONHOMME: Hi, Natasha Bonhomme,
20 Genetic Alliance. I'm trying to pare down my
21 thoughts. The blueprint is a really great idea in
22 terms of thinking about follow-up. We spent so

1 much time talking about the implementation, and
2 then say newborn screening is a system. So, I
3 really appreciate that this is moving that to
4 really align with that language and the reality
5 that newborn screening is a system.

6 Did you talk at all about how that
7 effort to collect that information would be
8 supported? We've already talked a bit about today
9 the work that NBSTRN does through NIH funding on
10 the pilot side of things, whether that's very
11 formal or informal, I don't know. But we know
12 that that is happening and that is such a big
13 infrastructure. Just, was there conversation
14 about how you would get to that, because that is
15 again, another really big task to put on the
16 nominators, often times who are coordinated by the
17 family organizations, and I think that is right.
18 I'm also concerned from an equity perspective.
19 There are groups that do this amazingly, you know,
20 we know CF has these great, coordinated centers,
21 the work that the MPS society does in terms of
22 short- and long-term follow-up is beautiful. But

1 it takes a lot and not -- I won't even say not
2 every group, most groups are nowhere near that
3 right now. So, I'm just wondering how that came
4 up in the conversation.

5 KYLE BROTHERS: Yeah, this is Kyle
6 Brothers. It did come up repeatedly. I think
7 it's a huge issue. There were several ideas that
8 were generated. I will say I intentionally
9 excluded that part of the conversation for my
10 presentation, just because I was trying to focus
11 on what was doable within the context of like, the
12 charge that we were given, and like what falls
13 into the Committee's purview, you know, the
14 narrower purview, not the bigger purview, which I
15 think, you know, still, there's a lot we could do
16 there.

17 But, so I think the one piece that I
18 proposed that touch on that is just trying to get
19 very specific about standard terminology, which is
20 the step one in any effort to collect data. You
21 really have to have standard terminology.

22 But I think we have a lot of work to do

1 on the issue that you're raising, and I think
2 there probably needs to be multiple players, you
3 know, in that very short-term follow-up stage.
4 The states are playing a role, a very active role,
5 because they're really trying to document false
6 positives, false negatives, etcetera, like really
7 trying to just clarify the testing and its
8 quality. But then that longer-term issue that
9 would help identify disparities and needs and also
10 just whether newborn screening does, in fact,
11 provide the benefits that were proposed for it
12 when it was nominated are giant issues that I
13 think there's a couple of different possible
14 solutions. But, you know, there's all those
15 issues that I think we really need to probably
16 focus on. So, maybe I would say to Ned, let's do
17 this thing, and then let's spend a whole round
18 focused on just that mid- to long-term follow-up
19 and what do we think is the plan. We need a plan
20 that includes a plan for funding about how we're
21 going to replicate what the CF group has done for
22 conditions that don't have the kind of resources

1 that that community has. So anyway, that's just
2 my thoughts.

3 NED CALONGE: Thanks. Siobhan.

4 SIOBHAN DOLAN: Thank you, Siobhan
5 Dolan, March of Dimes. I think that these efforts
6 around the blueprint and, you know, once you get
7 into trying to understand rare disease diagnostic
8 paradigms, treatment regimens is amazing. And so,
9 the comment I'm going to make is not at all to
10 take away from that but to also suggest that
11 there's like some really simple messages of what
12 screening is in health care that are really lost
13 in translation amongst providers and amongst the
14 public. And I say this with ultimate respect for
15 the fact that the pediatric and newborn world have
16 something called recommended and uniform, right,
17 because in the prenatal world, nothing is uniform.
18 Nothing is -- there's no benchmark for
19 recommended. It's absolutely the Wild West.

20 But I think that education to the simple
21 concepts like a screening test is different than a
22 diagnostic test and what a false positive and

1 negative is. I just want to suggest to this
2 Committee where it's just like -- it's, you know,
3 it's like in the air. We don't even think twice
4 about it. It's us such a given to us. But, you
5 know, when you look at that New York Times piece
6 that was written in January of 2022, after this
7 like very bright reporters spent months studying,
8 the way it got translated was you have the
9 screening test and most of the time, it's wrong,
10 and you kind of tap into, you know, mistrust,
11 right, and mistakes and that whole world that goes
12 on in health care, and I don't want any of our
13 work for, you know, in support of children with
14 heritable diseases to be misconstrued. So, I just
15 wanted to point out the idea that in our
16 educational messages, the simple messages around
17 what screening is, you're not done there, it's
18 just the tip of the iceberg. There's steps to
19 take, there's follow-up that's needed, it could
20 help us with some follow-up, it could help the
21 providers understand what they're dealing with as
22 well, because I think there's a lot -- there's a

1 lot of, you know, we understand sort of that the
2 public doesn't understand, but a lot of providers,
3 I don't think they understand either. So, I just
4 wanted to suggest that we add, you know, like,
5 what we don't even notice, but we add that to a
6 lot of our messaging and the blueprint in
7 laboratories, and then in professional provider
8 education. Thank you.

9 NED CALONGE: Thanks, Siobhan.

10 So, I'd like to move on to any
11 additional questions or comments about laboratory
12 where we talked about the quick start guide and
13 the template workplan that was modifiable by
14 states. And then, I would say on a more generic
15 level, how do we take new information about
16 screening technology and implement it through our
17 recommendations, for example, homocystinuria. So,
18 comments on those sets of priorities? See, you
19 did a great job, Kellie. We'll talk more.

20 How about education -- oh, Siobhan, I'm
21 sorry. So, the way I looked at education may be
22 slightly differently than the summary statement,

1 which was great, was that one, how do we use the
2 stuff that's already there? So, that was -- and
3 let me just acknowledge the hard work of that
4 group in creating standardized education materials
5 and recognize it must be frustrating to be asked
6 to create great educational training materials,
7 because we think the job that has been done has
8 been great. And so, I think it's more about
9 distribution, uptake, utilization, and then I
10 didn't miss that piece about measurement and
11 accountability. So, that was kind of on use of
12 things that were already here.

13 Then, there was something new about
14 culturally relevant and tailored educational
15 materials. And so, I appreciated the
16 acknowledgement that that's not just translation,
17 but it actually requires meeting with community
18 members to find out in in the specific culture,
19 what's important, how concepts like screening or
20 identification or heritable disorders play out in
21 terms of different cultures and different peoples.
22 So, I felt that was an important piece.

1 And then I guess the last one for me was
2 getting back to how can we measure that we're
3 having the impact that we want to have?

4 So, that was a quick summary. That was
5 a little off from exactly what you presented. But
6 that's the way I've kind of distilled it and
7 wondered if there were questions or comments
8 there. Yes, Ash.

9 ASHTOUSH LAL: It took me a minute to
10 think about it. So, I'm going to go back to the
11 Laboratory Standards, if you're allowed to. So, I
12 was wondering, as we go along with collecting more
13 and more genetic data on the conditions that are
14 diagnosed, and that may come from second-tier
15 testing or subsequent testing. So, how do we, in
16 the future, use the information from that, as well
17 as from advances in understanding, say, protein
18 structure and so on, to then come back to the
19 first-tier testing and use it in a way to further
20 strengthen the initial testing or shorten the time
21 it takes to make a definitive diagnosis?

22 NED CALONGE: Well, great, great

1 question, and I think, oh, I'm sorry, Shawn.

2 SHAWN MCCANDLESS: I guess I just would
3 like to ask you for some clarification, Ash. Are
4 you asking is there a mechanism for sort of
5 revisiting conditions that are on the RUSP to say,
6 are we doing, you know, is it -- should this still
7 be on the RUSP, or, more importantly, is there a
8 better way to do it, is there new testing that we
9 could -- that we should be recommending that would
10 make it more specific and reduce false positives?
11 Is that the question?

12 ASHTOUSH LAL: Right. So, using the --
13 I think it's primarily the genetic information
14 from the polymorphisms, or the BUS, and all the
15 other information from that, as well as combining
16 that with, I think, with the protein structure
17 information to see whether that information is
18 being used to go back and evolve the initial
19 testing in some way. Is there a way to utilize
20 the information that they're collecting eventually
21 with second-tier testing?

22 SHAWN MCCANDLESS: I may be speaking

1 entirely out of turn here. I don't -- I don't
2 think there's a -- I don't think that we have a
3 specific -- I don't think that there's anything
4 that will prevent this Committee from going back
5 and asking those questions and looking at new
6 data. But I also don't think that there's sort of
7 been a systematic -- and correct me if I'm wrong,
8 anyone -- but I don't think there's a systematic
9 sort of policy or even tradition in place of doing
10 that. It's certainly something that's been
11 discussed in the past, and I think it's come up
12 again in this meeting, you know, should we be --
13 should we like have program reviews of conditions
14 that are currently on the RUSP? The Evidence
15 Review Group is groaning when I even mention that
16 idea. Just for the record, Alex, Alex Kemper is
17 indicating bring it on, I believe is. So, yeah,
18 that's -- maybe that's something that we should be
19 thinking about doing sooner rather than later.
20 Dr. Warren, how much funding can we have to do
21 that?

22 MICHAEL WARREN: The staff are furiously

1 taking notes, as am I, and we will continue to
2 think about how we can make resources available.
3 I appreciate that.

4 NED CALONGE: Karen. That was a good
5 answer, by the way. Karen, can you unmute?

6 KAREN DOWNS: Sure and thank you. I was
7 not quite sure where to add this comment. It
8 really applies to all the different groups. But
9 it also links in with the excellent presentation
10 by Dr. Kuo.

11 So, what I want to bring up is that
12 we've talked about, you know, talked about equity
13 and looking at health care systems and looking at
14 systemic racism and structural racism, and I think
15 we have to be a little bit more explicit across
16 all domains. You know, DDIJ needs to be the lens
17 with which we look at things.

18 And one thing I found missing in the
19 excellent discussion around family centered care,
20 is really a little bit more self-examination of we
21 as health care providers, how is our implicit bias
22 affecting our interaction with families, for

1 example? You know, are we aware of our own
2 implicit bias? Are families still feeling
3 stigmatized by the care that they receive in
4 health care systems? So, that's one point.

5 The other is structural and systemic
6 racism by definition, is somewhat invisible, and
7 how can we be -- how can we make the implicit
8 explicit? You know, how can we look at, you know,
9 historical approaches to addressing some of these
10 genetic disorders, and how can we really think
11 about how is structural systemic racism explicitly
12 playing a role in the field today, and not just
13 within the newborn screening, but across all
14 services for children and youth with special
15 health needs?

16 So, I think that really applies to each
17 of the subcommittees, and I know that it really
18 came up in our -- the subcommittee I was I was
19 listening in on, the Education and Training. But
20 I also think it's very important in the Follow-up
21 and Treatment Workgroup as well.

22 So, I hope we can take the blueprint

1 that was presented this morning and take it just
2 one step further to be a little bit more explicit
3 about what we mean by centering families, and I
4 know following on what Natasha said earlier,
5 families have been very vulnerable. I think we,
6 as providers, or as state employees, or as
7 professionals need to be very vulnerable as well
8 and look at our own biases and how we may
9 inadvertently contribute to some of the -- some of
10 the less-than-ideal experiences that families may
11 be experiencing.

12 NED CALONGE: Thanks, Karen. Marc.

13 MARC WILLIAMS: Yeah, I want to really
14 endorse what Karen just said and reflect on
15 something that we heard yesterday about how
16 newborn screening really provides the opportunity
17 to objectively identify individuals, irrespective
18 of preexisting bias. I think the severe combined
19 immune deficiency is a really phenomenal example
20 of how instituting a screening program really
21 changes what we thought about a disorder that was
22 really considered to be primarily a disorder of

1 Northern Europeans, until we initiated screening
2 and then found that eighty percent of the cases
3 actually occurred in individuals of non-Northern
4 European descent. But the thing that then needs
5 to follow on that Karen has appropriately
6 highlighted is, but now that we've identified
7 this, and we've identified that this is really a
8 pan-Ethnic condition, is the access to services
9 that are needed to appropriately treat those
10 individuals being provided in an equitable way, or
11 are we now again seeing inherent bias and systemic
12 racism interfering with the appropriate treatment?
13 So, that's the next piece that needs to follow on.

14 NED CALONGE: Thanks, Marc. So, I
15 appreciate the rich discussion, and I think as I
16 met with folks during our break, we decided our
17 next step moving forward is to come up with a
18 priority for the workgroups to work on for the
19 next year. So, this is our last meeting of the
20 year, and our hope is to take the work you've done
21 now in the workgroups over the last two meetings,
22 and let's move forward into some very specific

1 issues.

2 So, in the education and training issue,
3 we did learn that there will -- there will likely
4 be resources available for additional
5 dissemination and awareness building around
6 materials that already exist. So, we kind of drop
7 down to the next one and think about how the
8 workgroup could think about who to engage in the
9 creation or the modification of the -- of the
10 training and education we currently have to bring
11 in that issue of diverse and cultural awareness
12 and how to make the training in the specific
13 subgroups of our population who are traditionally
14 overlooked or marginalized more effective, and
15 that information distribution be more equitable.
16 So, that was our charge, if you're willing to
17 accept it to education and training.

18 For Follow-up and Treatment, I really
19 like the secondary condition, and I thought the
20 best place to start though, would be this
21 blueprint for follow-up and treatment. I'm sorry,
22 let me let me go to laboratory standards, really

1 going down to creating this guide and project plan
2 for implementation. So, the Quick Guide and the
3 modifiable, I like the way you said shell. So,
4 the elements. So, the elements are so diverse,
5 but helping a state laboratory think about, can I
6 use the machines I have, or do I need a new
7 machine? If I need a new machine, what kind of
8 footprint does it need? What kind of staff and
9 expertise does it need to run it? If I'm going to
10 add molecular testing, who's going to interpret
11 those tests? And if it's not us, who are we going
12 to send it to and develop those relationships
13 with? So, actually thinking about building out
14 both what would need to be in the Quick Guide and
15 what would need to be wrapped around in the shell
16 is the kind of one-year challenge and charge I
17 would like to give to Laboratory Standards and
18 Procedures.

19 And then, finally for Follow-up and
20 Treatment, we love this idea of the blueprint.
21 And so, the charge would be -- and you actually
22 think about what elements need to be in there. I

1 think, Natasha, I wanted you to know, for what
2 it's worth, I had real worries about saying let's
3 have the nomination folks do it. It's -- it's a
4 complex issue already, and now that I've reviewed
5 a couple of nominations, I realize the challenge
6 that we've given the nominating groups to do, and
7 the dialogue and so, thinking about, are there
8 things that we're already doing that can help feed
9 that.

10 So, then, Alex, I thought about you,
11 because you are bringing experts in treatment and
12 follow up together to talk about evidence review.
13 And so, if we could at least, and maybe working
14 with our colleagues in the nomination space, think
15 about is there any expansion we could add to a
16 very small section in Treatment and Follow-up, but
17 really make that part of the ERG, because you're
18 finding it out anyway, and could we kind of think
19 about taking that treatment information and the
20 secondary testing and all that out and helping
21 flesh out that piece through the Treatment and
22 Follow-up Workgroup, and we thought you could even

1 start with building the methodology with something
2 existing like SMA, where we, you know, states had
3 to go through all that process. So, that was my
4 challenge to your group, and it felt discrete and
5 actually doable.

6 And I had one other point, and I'm
7 trying to remember what it was about -- oh, and so
8 yeah. So, then the last thing Kellie, around
9 implementation was timing and we wondered if, as
10 the information from ERG about the tests and the
11 secondary testing, and how you go for a screen to
12 a diagnosis, as that comes out of the ERG, could
13 we start working with CDC and other partners to
14 already start devising the Laboratory Quick Guide
15 and Worksheet for implementation of the test
16 itself? And the idea would be that we would send
17 the recommendation to the Secretary and have
18 enough developed so that, assuming the secretary
19 approved the condition, that the guidance for how
20 to do it could come out at the same time. So, now
21 you have this coordinated -- oh, you have to add
22 this, and this is how you might do it, or the

1 considerations. And I think that's true for
2 treatment as well.

3 We heard some group that the state says
4 we have to start working on it as soon as the
5 Committee approves it, and that's the wrong
6 decision point, right, because it's the Secretary
7 who adds it to the RUSP. We just make a
8 recommendation.

9 And so, if there could be a coordinated
10 approach of we're adding it, and here's some
11 guidance on how to do it, that, I think, would
12 make the burden on the states maybe a little more
13 palatable, and maybe decrease concerns that the
14 Secretary's office might have on the burden that
15 we're putting on states in terms of
16 implementation.

17 So, that's what we came up with for
18 three challenges, one to each workgroup to work on
19 for a year. And I would open it up to thoughts.
20 Scott. I see Scott has raised his hand. Oh, I'm
21 sorry, Shawn.

22 SHAWN MCCANDLESS: I've already got my

1 card. I never turned my card down. I guess I was
2 talking too much. Could you just remind us of the
3 resources that are available to the workgroups to
4 support this effort?

5 NED CALONGE: Well, yes. What we have
6 for you is staff that will help find the time that
7 everyone can join and then Zoom resources
8 available for you to get together to use.

9 I do want to tell you that I think
10 information flow from the ERG is another thing
11 that you can have to work from, but I am hoping
12 that creating at least the shell or the overall
13 framework, weaving it from your own expertise and
14 from whole cloth is a challenge that would be
15 reasonable to give workgroups over a certain
16 number of meetings between now and this time next
17 year.

18 SHAWN MCCANDLESS: This feels a lot like
19 when the Dean tells me that my salary for teaching
20 in the school of medicine is the honor of putting
21 that on my CV. So, thank you for that.

22 NED CALONGE: Well, you know, what I'm

1 going to say is the overall contribution to
2 population health and your work.

3 I guess the other thing I do want us to
4 think purposefully about is a resource issue, and
5 recommend that our Committee charge is a bit
6 broader than make recommendations about the RUSP.
7 I think if we have concrete suggestions around
8 budget to support state implementation of new
9 conditions -- first of all, let me tell you, I
10 really am so thankful to Michael, and to the
11 Bureau for what they've already contributed and
12 brought to the table, and I don't think that keeps
13 us from asking for more. And I think, thinking
14 about how to do that in a specific structured
15 logical way is something I would like to discuss
16 with the members moving forward, because I don't
17 think there's anything in our in our charter,
18 which will get renewed, or the legislation that
19 created the Advisory Committee, that would keep us
20 from saying, we have a specific recommendation
21 about resources to help improve implementation of
22 our recommendations. So, does that help a little

1 bit to answer yours?

2 SHAWN MCCANDLESS: It does, thank you,
3 and I think -- I think just recognizing that
4 there's, you know, that it's okay to call on the
5 supports -- the administrative support staff and
6 ask questions to the ERG, as the process is
7 happening probably does take a little bit of
8 burden off of the of the workgroups. I don't know
9 if any other workgroups have thought about that.
10 I think some of these things are very -- it's easy
11 to invest a lot of time in some of these
12 activities and just -- we just have to be
13 cognizant of that.

14 NED CALONGE: You know, and I recognize
15 that, Shawn. I would just say a couple things.
16 We're always very enthusiastic about what we can
17 do when we're sitting here in Washington, away
18 from the requests -- other requests for our time.
19 And then the recognition that all of you do this
20 within the margins of what I would call your
21 discretionary time, which is split between
22 professional and family. And for what it's worth,

1 I just really thank you for doing that. And if
2 there are ways we can support you and make it more
3 manageable, and we -- I'm using that global we,
4 that's not me -- the Bureau and other folks, you
5 just need to ask, and we'll see what we can do.
6 Does that make sense?

7 So, I -- yeah, thanks for that. So,
8 this is that wonderful five minutes that I
9 actually can tell you, I don't quite understand,
10 which is, is there any new business for the
11 Committee? Oh, and I'm sorry, Melissa.

12 **New Business**

13 MELISSA PARISI: I just wanted to make
14 an announcement to everyone with an interest in
15 newborn screening, and that's that the NIH has an
16 open request for information for feedback about
17 future research needs and infrastructure support
18 for newborn screening research. It's technically
19 open until midnight tonight, but we will be kind,
20 and leave it open for a few extra days, and if you
21 have some burning feedback that you'd like to give
22 to us, we would be very interested in hearing it.

1 So, if you want information about this, all you
2 have to do is go to Google and type in not-hd-22
3 (for fiscal year 22) -042. So, one more time,
4 that's not-hd-22-042, and we'd love to get your
5 feedback on research and the infrastructure, the
6 Newborn Screening Translational Research Network,
7 and ways in which we can support research in
8 newborn screening. Thank you all very much.

9 UNIDENTIFIED MALE SPEAKER: I pasted it
10 in the chat.

11 MELISSA PARISI: Thank you.

12 NED CALONGE: Scott Shone, I'm sorry, I
13 didn't mean to not call on you. I admit I was
14 staring at the clock and not at my screen. So,
15 Scott.

16 SCOTT SHONE: That's fine. I appreciate
17 it. Scott Shone here. So, I just appreciate a
18 second. I would just ask, Ned, that as the
19 workgroups work on their charges to, one, be very
20 cognizant that some of this work is done by
21 partners and to look into that to not have to
22 reduplicate efforts, especially with the resource

1 discussion that Shawn just brought up. And I will
2 say, Shawn, I was once told that there are
3 intangible benefits of the job.

4 And so, I would also ask the members of
5 the workgroup to look back at the presentations
6 over the last two meetings, because I feel there
7 are some things missed from presentations,
8 particularly some great discussions yesterday from
9 my colleagues around the country, and I want to
10 highlight Dr. Zori's comments about looking at are
11 we doing -- I think we talked about this a lot --
12 but are we doing the best with what we're doing,
13 and just continuing to push forward without
14 reflecting on the past is going to continue to put
15 us down a path of not learning anything, except
16 how to build more challenges for us.

17 And so, I would ask that, in addition to
18 all the challenges that the chair just shared, is
19 that a review of the presentations and the minutes
20 from the last two meetings, and all the
21 thoughtfulness that went into those presentations
22 on the challenges of the system, and the overlap

1 of Public Health Medicine and that intersection of
2 newborn screening are going to be very necessary
3 to address the challenges that were just laid out
4 for the workgroups, and I appreciate the moment,
5 Ned. Thank you.

6 NED CALONGE: And I appreciate your
7 comment and the work you've put into those
8 presentations and before.

9 So, is there any new business before the
10 Committee today? Seeing none -- oh, Natasha.

11 NATASHA BONHOMME: Sorry. One thing
12 that's come up that that I don't think this
13 Committee has discussed recently, are the lawsuits
14 that have come up in newborn screening, and that
15 just may be something to get on the agenda for
16 2023. There have been a couple of really great
17 presentations, many of them including Dr. Aaron
18 Goldenberg, that I think could be really
19 informative to this group, just to make sure we're
20 thinking about what the public is also hearing
21 about newborn screening, which unfortunately,
22 tends to be those topics that hit the headlines

1 like lawsuits. Thanks.

2 NED CALONGE: Thank you.

3 SHAWN MCCANDLESS: can I just add a
4 comment to that? You know that I get -- I'm very
5 concerned about potential harms of newborn
6 screening, that we don't have any way to -- that
7 we really don't have a way to measure and I've
8 said several times before that we don't -- nobody
9 speaks for people that are experiencing the
10 potential harms of this population-based
11 compulsory newborn screening program, and I think
12 -- I do think that those families that Natasha is
13 referring to are those people. That's -- those
14 are the voices that we need to hear. So, I just
15 want to second her request to put that on the
16 agenda for future discussion, because I think
17 those are voices that we need to hear, and I wish
18 they would come to us instead of going to the
19 courts. But maybe that's -- we're just not on
20 people's radar in that way.

21 **Adjournment**

22 NED CALONGE: Thanks, Shawn, and thanks,

1 Natasha.

2 So, our next meeting will be virtual,
3 February 9 and 10th of next year, which is right
4 around the corner. You can look at our other
5 meeting dates on the website. They're available
6 through 2025. And with that, I adjourn our
7 November meeting and thanks to everyone for
8 participating. I thought we had a had a good
9 time. It was so nice to be in person. We'll see
10 you next time.

11 (THEREUPON, DAY 2 OF THE MEETING
12 CONCLUDED AT 1:00 P.M.)