UNITED STATES OF AMERICA

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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PATIENT ENGAGEMENT ADVISORY COMMITTEE (PEAC)

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September 6, 2023

10:00 a.m. EST

Via Web Conference

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Participants

Chair	Paul T. Conway	Chair, Policy & Global Affairs, American Association of Kidney Patients
Voting Members	Ian D. Burkhart	Vice President, North American Spinal Cord Injury Consortium
	Necie I. Edwards	Patient Advocacy, Fibro Patient Education & Support
	Elizabeth A. Joniak-Grant, Ph.D.	Sociological Qualitative Research Consultant & Patient Experience Collaborator, Injury Prevention Research Center
	Rita T. Roy, M.D.	CEO, National Spine Health Foundation
Consumer Representative	Teresa M. Diaz	Co-Founder, Global Patient Advocacy Coalition
Temporary Non-Voting Members	Gabrielle (Ella) Balasa	Patient Advocacy and Engagement Consultant
	Gwenyth Fischer, M.D.	Associate Director, University of Minnesota Bakken Medical Device Center, University of Minnesota College of Medicine
	Anne Peters, M.D.	Professor of Clinical Medicine, Clinical Scholar, Keck School of Medicine, University of Southern California
	Amy M. Sitapati, M.D.	Clinical Professor; Chief, Division of Biomedical Informatics, University of California San Diego
	David M. White	Proofreader, Healthcare Consultant, Kidney Transplant Recipient
	Michael S. Wolf, Ph.D., M.P.H., M.A.	Professor of Medicine; Director, Center for Applied Health Research on Aging (CAHRA), Feinberg School of Medicine, Northwestern University
	Stephen B. Wilcox, Ph.D., FIDSA	Chairman of the Board, Design Science
	Naveena Yanamala, M.S., Ph.D	Associate Professor of Medicine; Director of Data Science and Machine Learning Research, Rutgers Robert Wood Johnson Medical School
Industry Representative	Jijo James, M.D.	Chief Medical Officer, Johnson & Johnson Medical Devices Companies & Global External Innovation
FDA	Kathryn Capanna, M.B.A.	Associate Office Director (Acting), Office of Strategic Partnerships Technology Innovation (OST), FDA
	Owen Faris, Ph.D.	Principal Deputy Director, Office of Product Evaluation and Quality (OPEQ), FDA
	Michelle Tarver, M.D., Ph.D.	Deputy Center Director, Chief Transformation Officer, FDA
	Alicia Witters	Acting Director/Deputy Director Office of Communication & Education, FDA
Designated Federal Officer	Letise Williams	Office of Strategic Partnership and Technology Innovation, CDRH, FDA

FDA Speakers	Robert M. Califf, M.D.	Commissioner, FDA
	Jeffrey Shuren, M.D., J.D.	Director, CDRH, FDA
Stakeholder Presenters	Patrick O. Gee, Sr., Ph.D.	Former Peritoneal/Hemodialysis Patient, Kidney Transplant Recipient
	Roseanne Gichuru, D.O., M.B.A., FACOOG, CPE	Obstetrics & Gynecology Specialist
	Jennifer Jones-McMeans, Ph.D.	Divisional Vice President of Global Clinical Affairs, Abbott Vascular
	Jennifer Goldsack, M.Chem., M.A., M.B.A., OLY	Chief Executive Officer, Digital Medicine Society (DiMe)
	Tesheia Johnson, M.B.A., M.H.S	Deputy Director and Chief Operating Officer of YCCI and the Director for Clinical Research, Yale School of Medicine
	Behtash Bahador, M.S.	Director of Health Literacy, Center for Information & Study on Clinical Research Participation (CISCRP)
	Karriem S. Watson, D.H.Sc, M.S., M.P.H.	Chief Engagement Officer of All of US Research Program, National Institutes of Health
Open Public Hearing Speakers	Karin Hoelzer, D.V.M., Ph.D	Director, Policy and Regulatory Affairs, National Organization for Rare Disorders (NORD)
	Bibb Allen, Jr., M.D., FACR	Grand View Medical Center, Birmingham, Alabama; Chief Medical Officer, American College of Radiology (ACR), Data Science Institute
	Keith J. Dreyer, D.O., Ph.D., FACR, FSIIM	Chief Science Officer, ACR Data Science Institute; Chief Data Science Officer, Mass General Brigham; Associate Professor, Harvard Medical School
	Ivor Braden Horn, M.D., M.P.H.	Chief Health Equity Officer, Google
	Andrew M. Namen, M.D., FAASM, FCCP	Member, Public Safety Committee, American Academy of Sleep Medicine (AASM)
	Grace Wickerson	Health Equity Policy Manager, Federation of American Scientists (FAS)
	Jennifer Doyle	Vice President of Enterprise Clinical Research and Medical Science, Medtronic

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Call to Order

Mr. Conway: Good morning. I'd like to call this meeting of FDA's patient engagement advisory committee or the PEAC on September 6, 2023 to order. My name is Paul Conway, and I have the honor to serve the FDA as the chair of this committee. Outside of government and outside of this committee, I serve as the Chair of Policy and Global Affairs for the American Association of Kidney Patients, the largest independent kidney patient organization in the nation. I'm also a kidney patient of 46 years. As a patient, I lived for three years on dialysis, and for the past 26 years, I've lived with a kidney transplant from a selfless organ donor. For those who are watching or listening to the proceedings of the PEAC for the first time, it is important to highlight the distinctive nature of this FDA advisory committee. The PEAC is the only FDA advisory committee that is comprised solely of patients, caregivers, and patient advocates. The stated purpose and general function of the committee is to provide advice and recommendations to the agency on complex issues relating to medical devices, the regulation of devices, and their use by patients.

Our first meeting occurred in the fall of 2017. The advisory committee structure and process is the most formal public way that the FDA can receive advice from the American public on scientific matters. The creation of the PEAC by FDA was a significant recognition of the importance of patient, consumer, and caregiver insights on matters that are within the regulatory purview of the FDA. As you will hear shortly, the PEAC is comprised of members with unique lived experiences as patients, caregivers, and patient advocates. Throughout the course of our advisory committee operations, our deliberations have been informed by a wide variety of other expert participants. For example, joining the PEAC today are members with expertise in various disease and condition areas. We have a few additional experts participating with insights on

digital health technologies, user-centered design, underserved population, women's health, pediatrics, and more.

The formal elevation of patient consumers and their unique insights by FDA reflects a far wider and profound evolution over the past decade in how patients and their lived experiences are valued by experts in the medical professions, government and industry, and academia. This evolution has led to a higher acceptance and understanding of patient insight data as evidence to inform and shape decision making. It also represents an important step away from the era of paternalism, when decisions could be made about patients without patient involvement. Over the course of the past five years, the PEAC has had a substantive impact upon FDA deliberations and work. The findings of our 2017 meeting ultimately led to FDA issuing a final guidance document on patient engagement in the design and conduct of medical device clinical studies. The PEAC has provided recommendations on FDA's communications efforts related to medical device recalls and cybersecurity risks and actively contributed to many other efforts, including advice related to patient generated health data, artificial intelligence, and machine-learning enabled devices, and augmented reality, virtual reality medical devices. The PEAC has served as an important model of effective patient engagement for the FDA and FDA has increased the involvement of patients and other agency stakeholder meetings, including those associated with the Medical Device User Fee Amendment Negotiations or MDUFA.

I note for the record that the nonvoting members constitute a quorum as required by 21 CFR Part 14. I would also like to add that the committee members participating in today's meeting have received training in FDA device law and regulations. For today's agenda, the committee will focus and discuss and provide advice on the FDA topic of advancing health equity in medical devices. FDA CDRH is committed to working toward ensuring that all patients have access to high quality, safe, and effective medical devices. This includes ensuring devices

are designed to be safe and effective when used by various populations, are evaluated in the diverse populations for which they are intended, and that patients and consumers have the information they need to make decisions about their healthcare and quality of life.

Technology, including digital health technology, may help bridge gaps in health equity by extending access and bringing healthcare to patients at home, at work, and in their communities. The recommendations provided by the committee will address considerations for FDA and industry on these topics. The committee will consider ways to advance access to devices that allow for care outside of a hospital or clinical care setting. For example, in the home setting, the committee will also discuss considerations for improving reach and comprehension of FDA's patient and caregiver communications across diverse demographic groups. Additionally, the committee will discuss patient-focused considerations for when a device should be evaluated in diverse populations to support marketing authorization.

Now I'd like to set out a few ground rules. If a panelist would like to ask a question, please physically raise your hand and make use of their hand raising function on the platform. I will get to your questions as we proceed throughout the day. We want to avoid multiple persons from speaking over each other since this entire meeting is being transcribed for the official record. Before we begin, I would like to ask our distinguished committee members and FDA experts identified on the meeting roster and attending virtually to introduce themselves. Committee members, please turn on your video, if you haven't already done so in monitors, and unmute your microphones and I will call your name. When I do call your name, please state your area of expertise, your patient and/or caregiver role as it pertains to the PEAC, your position, and professional affiliation. Let's go ahead and start with Mr. Ian Burkhart.

Introductions

Mr. Burkhart: Hi everyone. My name is Ian Burkhart. I'm the vice president of the North American spinal cord injury consortium. I specialize my research in patient engagement and getting those involved in research from a role of not just a participant, but also an advisor. And I myself have been living with a spinal cord injury since 2010.

Mr. Conway: Great. Thank you. Ms. Necie Edwards.

Ms. Edwards: Hi, everyone. My name is Necie Edwards. I'm the founder and organizer of Fibro patient Education and Support, and I represent people with chronic pain, and I myself have fibromyalgia as well as ankylosing spondylitis.

Mr. Conway: Thank you. Dr Rita Roy.

Dr. Roy: Good morning, everyone. I'm Rita Roy. I'm a general surgeon by training and became a patient requiring a spinal fusion about six years ago. I am currently the CEO of the National Spine Health Foundation. We are the nation's only organization dedicated to advocating for patients suffering with the spectrum of spinal conditions and our mission is to provide informed consent and share the good news in evidence around treatment for spine conditions. Thank you.

Mr. Conway: Thank you. Ms. Teresa Diaz.

Ms. Diaz: Good morning, everyone. My name is Teresa Diaz, and I am cofounder of GPAC, which is the Global Patient Advocacy Coalition. I also am a facilitator of the breast implant health summit, and I also run the Breast Implant Illness Florida Support Group. And I am a patient advocate that was harmed by a medical device, and my goal is to give the voice to the voiceless.

Mr. Conway: Thank you, Ms. Gabrielle Balasa.

Ms. Balasa: Hello, everyone. I'm Ella Balasa and I'm a patient advocate living with a rare genetic lung disease called cystic fibrosis. I am an advocate for bringing the voice of the patient early into drug development and empowering individuals to be more active in their care and in treatments. And I'm looking forward to today's discussion. Thank you.

Mr. Conway: Great. Thank you. Dr. Gwyneth Fischer.

Dr. Fischer: Good morning, everyone. I'm Gwen Fisher. I am a pediatric ICU physician at the University of Minnesota. I also run the Pediatric Device Innovation Consortium here at the university, which is part of the FDA's PDC program through the Southwest PDC. Thanks.

Mr. Conway: Great. Thank you. Dr. Anne Peters.

Dr. Peters: Hi, everyone. I'm an endocrinologist and a professor of clinical medicine at the University of Southern California, where I work to reduce healthcare disparities for device use in medically underserved people with diabetes.

Mr. Conway: Thank you. Dr. Amy Sitapati.

Dr. Sitapati: Hi, I'm Dr. Amy Sitapati. I'm chief of the Division of Biomedical Informatics at the University of California, San Diego, a clinical professor of medicine, a primary care provider, a survivor of breast cancer, and I specialize in pop health.

Mr. Conway: Great. Thank you very much. Mr. David White.

Mr. White: Good morning, everyone. My name is David White. I'm a person living with kidney disease. I received a kidney transplant from a deceased donor in 2015 after 6 years of dialysis, including one year of peritoneal dialysis at home. I'm a proofreader for an international law firm, and I'm also a care partner for my mom. I serve on the board of directors of the Patient Advocate Foundation, and my area of expertise is patient engagement.

Mr. Conway: Great. Thank you. Dr. Michael Wolf.

Dr. Wolf: Good morning. My name is Michael Wolf, and I'm a professor in the Department of Medicine at Northwestern University's Feinberg School of Medicine. I also direct Northwestern Center for Applied Health Research on Aging, and I'm a longtime researcher on health literacy and a patient advocate for older individuals living with multiple chronic conditions.

Mr. Conway: Great. Thank you. Dr. Stephen Wilcox.

Dr. Wilcox: Hi, I'm the founder and chairman of the board of Design Science, a consultancy based in Philadelphia that specializes in medical devices. I'm a patient advocate in the sense that I've been working on device development teams for 40 years trying to make products, medical products, easy to use and safe.

Mr. Conway: Great. Thank you. Dr. Naveena Yanamala.

Dr. Yanamala: Good morning, everyone. I'm Naveena Yanamala, an associate professor of Medicine and the director for Data Science and Machine Learning Research at Rutgers Robert Wood Johnson Medical School. Throughout my career, I have been focusing my efforts on safety and health in the context of machine learning and AI applications, preclinical and clinical research, digital technologies, wearable technologies, and data-driven science. And I look forward to contributing to thoughtful discussions today. Thank you.

Mr. Conway: Thank you very much. Dr. Jijo James.

Dr. James: Good morning, everyone. Jijo James. I'm the chief medical officer for MedTech and external innovation at Johnson & Johnson. In this role, I lead an independent internal function that primarily focuses on patient safety. I'm also the current chair of MDIC or the Medical Device Innovation Consortium. That's a public private partnership between government, academia, and industry to advance faster, safer, and most cost effective innovation for patient benefit and advancing health equity is a key area of focus in advancing that mission. Thank you.

Mr. Conway: Thank you. Ms. Kathryn Capanna.

Ms. Capanna: Good morning, everyone. My name is Kathryn Capanna. I'm the Acting Associate Office Director for FDA CDRH's Office of Strategic Partnerships and Technology Innovation, or OST. OST operates the PEAC. We work in partnership with programs across the center to bring topics like advancing health equity and medical devices that are of importance to patients and consumers and essential to FDA's mission to protect and promote public health. Thank you all for joining us today.

Mr. Conway: Great. Thank you. Dr. Owen Faris.

Dr. Faris: Good morning. I'm the principal deputy director and CDRH's office of product evaluation and quality. Which is the office that oversees pre- and post-market decision making for medical devices. I'm also a patient. I've had Type 1 Diabetes for coming up on 40 years. Thank you.

Mr. Conway: Great. Thank you. Dr. Michelle Tarver.

Dr. Tarver: Good morning, everyone. I'm Michelle Tarver. I'm the Deputy Center Director for Transformation. I have also been a caregiver and caring for a person with living with rare diseases. And I'm also a healthcare provider caring for people who are living with ocular inflammation. I'm very excited to hear the feedback from our panel today and look forward to the discussion.

Mr. Conway: Thank you. Miss Alicia Witters.

Ms. Witters: Good morning. I'm Alicia Witters. I'm an Acting Director and permanent Deputy Director for the CDRH Office of Communication and Education. And so, in that role, my office is responsible for developing, disseminating, and monitoring how successful we are with a lot of our public facing communications on behalf of senior age.

Mr. Conway: Thank you. Ms. Letise Williams, good morning.

Ms. Williams: My name is Letise Williams. I am the designated federal official for the PEAC.

Mr. Conway: Great. Thank you very much. I'd like to thank all of our—

Ms. Williams: Paul? Paul, I'm sorry. We have 1 more expert. Dr. Elizabeth Joniak-Grant.

Mr. Conway: My apologies. Go right ahead, Doc.

Dr. Joniak-Grant: Hi, thanks. I'm Elizabeth Joniak-Grant. I'm a sociologist and a patient-lived experience collaborator at the Injury Prevention Research Center at University of North Carolina in Chapel Hill. I am also a patient advocate. I represent those with migraine and chronic pain. And I have personal experience with migraine disease, cervical dystonia, and chronic pain as a consequence of arthritis, myofascial pain syndrome, fibromyalgia and various neuralgias. Thank you.

Mr. Conway: Thank you very much, Doctor. And my apologies.

Dr. Joniak-Grant: That's all right.

Mr. Conway: I'd like to thank all of our panelists. And now what I'd like to do, it's 10:15 A.M. And we'll proceed with welcoming remarks from FDA Commissioner, Dr. Robert Califf. Dr. Califf is the 25th commissioner of the Food and Drug Administration. He also served in 2016 as the 22nd commissioner and immediately prior to that as FDA deputy commissioner for medical products and tobacco, he has spent a good portion of his career affiliated with Duke University, where he served as a professor of medicine and vice chancellor for Clinical and Translational Research, director of the Duke Translational Medicine Institute, and was the founding director of the Duke Clinical Research Institute. He has a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is nationally recognized as an expert in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care. I might also add as a patient community, we

understand Dr. Califf and know him as a strong patient advocate. Dr. Califf, go right ahead. We're honored by your presence.

Welcome from FDA Commissioner — Dr. Robert Califf

Dr. Califf: Thanks so much, and I'm pleased to be with you today to help kick off this meeting, addressing one of the most important areas to us at the FDA, how we incorporate the patient voice in support of the development of new products to treat disease. I did have a chance to look at your agenda for the day and this is like so many meetings that go on now, where I wish I could stay and participate because I think you're in for a really interesting discussion about some very important topics. And I know that throughout the meeting you'll be very engaged. And of course, you'll hear shortly from Jeff Shuren, who I see on the screen, and others at CDRH about their engagement in this area. And some of the important work they're doing related to the issue of health equity. I thought I'd use my time this morning to briefly discuss some of the ways FDA as a whole is committed to better understand and advance diverse patient perspectives, preferences, and unmet needs to inform our work.

One of the most important aspects of our mission to protect and promote public health involves a responsibility to consider, to the extent we can, the needs and characteristics of all people and populations and the policies we advance, the science we support, and the workplace in which we operate. And I used to the extent we can, specifically because the mission is to take into account all populations, but we have to be realistic as we try to overcome our shortcomings, given the complexity just represented on this panel. It's breathtaking the number of different perspectives, even in one panel, and we now have a population of 340 million people that we're concerned with. So, the issue of equity and public health is increasingly relevant. As many of the negative health trends we see today, from shortened life expectancy to increase in chronic

diseases, diabetes and metabolic syndrome, heart, vascular, lung, and kidney disease, mental health issues, as well as depression and suicide, drug use disorder, and gun violence, are all the result in part of social determinants and inequities.

And I want to stress here that, at least as I look at the landscape, there's a lot to be concerned about right now. In this country, we are seeing a decline in life expectancy that's unprecedented really in the past 100 years. I'm getting ready to go to Singapore next week, Singaporean citizens on average are living almost 7 years longer than Americans. And right now, among high income countries, we're essentially in last place in terms of life expectancy. And I know in this discussion, you're going to be talking about the fact that length of life is not the only issue, but it's a pretty good starting marker for where we stand and the need we have to reverse the trends that we're seeing with a lot of these differences expanding. And so, some of this disparity reflects the differences we see in our country as a function of demographics, race, ethnicity, sex, gender, wealth, and education.

One of the biggest impacts involves where we live, as well as to education and access to health and medical expertise are increasingly urbanized people in rural settings, in general, are seeing a dramatic decline in health and life expectancy. And if you just look at some recent pictures, and the pictures are getting better and better, you'll see that people that live in cities and university towns are faring much better over time now than people that live in rural areas. So, it's increasingly important that we study and consider all these factors and prioritize them throughout our scientific work, ranging from access to clinical trials to the availability and consideration of the user interface and the development of medical products and devices.

It's an issue of special resonance as we search for responses to new diseases, like COVID, in which the impact on certain segments of the population, including older adults, pregnant women, children, rural people, and racial and ethnic minorities have been more severe.

Consequently, one especially important area for us has been to work to increase the enrollment of minority women and elderly patients in clinical trials and bring in the voice of underrepresented populations to the world of drug and device development.

Of course, the FDA can't do it alone. That's why we're engaged in multiple collaborative efforts across the healthcare ecosystem. For instance, we issued a call to action for stakeholders that outlines a number of steps. That could be taken to help reduce gaps in health equity. I'm just going to give you a list here. These are fairly broad, but I hope it will provide some perspective as you get into your discussions.

Point one is create a more diverse, equitable and geographically representative system of evidence generation for decision-making.

Point two is revamp the public health information architecture to enable people to see data relevant to their own communities and circumstances.

Point three is to close the gap in knowledge between the evidence requirement for FDA approval, which can involve limited populations chosen, to develop initial evidence of a positive balance of risks and benefits and the appropriate use of products and payments in the real world, where the boundaries and relevant populations, are much less clear. I feel like this is an area where the device world has been in the mainstream for a long time. But as we are dealing now with transformative treatments for large chronic diseases, this issue of the gap between what we know at the time of approval and what we need to know to optimally use medical products is becoming more and more important.

And the next point is, we need to reduce the barriers that prevent aggregation of available information in a way that supports consortia driven by patients as well as their families, caretakers and clinicians while assuring that privacy and confidentiality are maintained. It's pretty well known I'm a big fan of patient-driven research consortia that answer the questions

that are relevant to patients. But it's almost as if our information architecture is built to keep groups from getting the information they really need to be most effective in accomplishing this mission. We need to encourage health entities to consciously create incentives that reduce what's known as suboptimization, a situation in which each segment of our system, hospitals, clinicians, medical products, companies, insurance entities, now even private equity firms, is incentivized to optimize its own well-being without consideration of the joint effect on the system as a whole. Or the overall health of consumers and patients. Or another way to think about this is all these entities, I believe are earnestly trying to be patient centered. But talk to anyone trying to get an appointment in our healthcare system today or navigated and it's hard to see that the whole is greater than the sum of the parts. In fact, the whole is much less than the sum of the parts. Part of this overall effort that's pertinent to FDA is to improve assessment of the impact of subsystems on overall health outcomes for individuals and populations, as medical products have different outcomes in different healthcare ecosystems.

And finally, tackling misinformation and improving education about science, really critical underpinning of everything that we're trying to do. Within the FDA itself, we've been working collaboratively across our medical product centers to implement the diversity action plan for the provisions of FDORA, our most recent user fee agreement. This will help increase participation in clinical trials by diverse populations and allow the FDA to strengthen and expand communications about clinical trial demographics in representative populations so that consumers can make informed decisions that lead to better health outcomes.

Additionally, it's a mission of FDA's Office of Minority Health and Health Equity specifically to promote and protect the health of diverse populations through research and communication of science that addresses health disparities and advances health equity. In 2021, OMHHE established the enhanced equity initiative, which has provided multiple funding

opportunities that have allowed us to engage with diverse researchers and scientists across various organizations and academic institutions. In particular, they focus on supporting activities in three areas. First, increasing equity in clinical trials by continuing our efforts to advance diversity and enrollment. Second, strengthening the application of equitable data by funding research that helps us increase data available on the populations we serve. And third, increasing the equity of voices that focus on continuing to understand diverse patient perspectives, preferences in unmet needs to inform our work.

Not mentioned in my bio, and by the way, I always feel a little self-conscious when it's mentioned that I've done this job before. What resonates in my head is all the questions I get about why on earth would you come back and do this after finding out what it's really like? And the answer, of course, is because of people like you. There's a mission here that's absolutely critical that, as I keep saying, we haven't gotten where we need to be, but we're going to keep trying. By working both inside the FDA and with our external stakeholders across the ecosystem, we're making important strides to expand health equity and better understand and advance diverse patient perspectives, preferences, and unmet needs. I hope that your discussion will be engaging and productive. In fact, I'm sure it will be, after hearing your introductions, and look forward to continuing collaboration. Thanks again, and I hope you have a great meeting. I think you'll have a better time than I'm going to have for the rest of the day, I can tell you. But I won't reveal what it is that I have to do today.

Mr. Conway: Thank you very much, Dr. Califf. We appreciate your leadership and your interest and commitment to these issues and the context that you gave to start the discussions today. So thank you very much. We deeply appreciate it.

Dr. Califf: One thing I forgot to mention, Paul, I really do appreciate it. In the bio, it didn't mention that I did work at Google for five years in between my two stints. And I just want to say

that's another area where a lot of improvement could be made. But what I got to see was the reach of all these different factors that I just described. When applied with over ten products that reach a billion people a month, and when you see the impact of having access to the information on over a billion people at a time, you begin to get a sense for how diverse our world is. But also how much in common we have. So, I'm really hoping that across your different backgrounds, you'll pick out those common factors that will give us the threads that we need to pull on to bring things together. So, sorry to go a little overtime here, but I appreciate the opportunity.

Mr. Conway: No, I thank you very much, Commissioner. As a matter of fact, the staff has put together a set of great questions today. They're designed to get our diverse views and then bring together the common points of interest, I think, for FDA going forward. And each of us are very committed to this issue. So, thank you very much.

Now what I'd like to do is ask Letise Williams, the Designated Federal Officer for the PEAC, the Patient Engagement Advisory Committee, to go ahead and make some introductory remarks.

Conflict of Interest Disclosure Statement & Administrative Remarks

Ms. Williams: Good morning. I will now read FDA's Conflict of Interest Disclosure Statement for the September 6, 2023 Patient Engagement Advisory Committee Particular Matter of General Applicability. The Food and Drug Administration, FDA, is convening today's meeting of the Patient Engagement Advisory Committee under the authority of the Federal Advisory Committee Act, FACA, of 1972. With the exception of the industry representative, all members of this committee serve as special government employees and are subject to federal conflict of interest laws and regulations. The following information on the status of this committee's compliance with federal ethics and conflict of interest laws covered by, but not limited to, those found at 18

USC 208 are being provided to participants in today's meeting and to the public. FDA has determined that members and consultants of this committee are in compliance with federal ethics and conflict of interest laws. Under 18 USC 208, Congress has authorized FDA to grant waivers to special government employees or regular federal employees who have financial conflicts when it is determined that the agency's need for a particular individual service outweighs his or her potential financial conflicts of interest related to the discussions of today's meeting. Members and consultants of this committee who are special government employees or regular federal employees have been screened for potential financial conflicts of interest of their own. As well as those imputed to them, including those of their spouses or minor children, and for purposes of 18 USC 208, their employers. These interests may include investments, consulting, expert, witness testimony, contracts, grants, CRADAS, teaching, speaking, writing, patents and royalties, and primary employment.

For today's agenda, the committee will discuss and make recommendations on the topic advancing health equity and medical devices. FDA CDRH is committed to working towards ensuring that all patients have access to high quality, safe, and effective medical devices. Based on the agenda for today's meeting and all financial interests reported by the committee members and consultants, a conflict of interest waiver has been issued in accordance with 18 USC 208B3 to Mr. Ian Burkhart and Dr. Stephen Wilcox. Mr. Burkhart's waiver addresses his involvement in a leadership position as president of an organization that received funds from a medical device firm. The funds are for general operations and consultant fees paid to Mr. Burkhart via an employment relationship with the organization. The total amount awarded to the organization is between $50,001 and $70,000. And the amount to Mr. Burkhart is between $5,001 and $15,000. Dr Wilcox’s waiver addresses his role as a principal and the founder of an organization, which he serves as chairman of the board. The organization provides consulting contracts, projects with

numerous medical device firms that could be affected by the particular matter. The amount to the organization for services from 2022 through 2024 is between one million dollars and $1,300,000. The waiver allows these individuals to participate fully in the committee deliberations. FDA's reason for issuing the waivers are described in the waiver document, which is posted on FDA's website at http://www.FDA.gov/advisorycommittees/default.htm. Copies of these waivers may also be attained by submitting a written request to the agency's Division of Freedom of Information, 5630 Fishers Lane, room 1035, Rockville, Maryland 20857.

Dr. Jijo James is serving as the industry representative for communication of benefit and risk to patients and is acting on behalf of all related industry. He is employed by Johnson & Johnson. For the record, the agency notes that Mr. Behtash Bahador, who is an invited guest speaker with us today, has acknowledged that his employer provides patient engagement programs, including services to medical products developers, which may include medical products. We would like to remind members and consultants that if the discussions involve any other products or firms not already on the agenda for which an FDA participant has a personal or imputed financial interest, the participant needs to exclude themselves from such involvement, and their exclusion will be noted for the record. FDA encourages all other participants to advise the committee of any financial relationships they may have with any firms at issue. A copy of this statement will be available for review and will be included as part of the official transcript. Thank you.

For the duration of the Patient Engagement Advisory Committee meeting on September 6, 2023, Dr. Gwyneth Fischer has been appointed to serve as a temporary non-voting member. For the record, Dr. Gwyneth Fischer serves as a member of the Pediatrics Advisory Committee in the Office of Pediatric Therapeutics Office of the Commissioner. Dr. Fischer is a special government employee who has undergone the customary conflict of interest review and has

reviewed the material to be considered at this meeting. The appointment was authorized by Russell Fortney, Director, Advisory Committee, Oversight, and Management Staff on August 16, 2023.

Before I turn the meeting back over to Mr. Conway, I'd like to make a few additional general announcements. In order to help the transcriber identify who is speaking, please be sure to identify yourself each and every time that you speak. The press contact for today's meeting is Audra Harrison. For the record, FDA has received two written comments. Thank you very much. I will now turn the meeting over to the chair, Mr. Conway.

Mr. Conway: Thank you very much, Ms. Williams. Before I ask the FDA to begin their remarks, I would like to provide a brief overview of how today's meeting will run. During the morning, we will have presentations from FDA. Afterwards, we will take a short break. And when we return, we will hear perspectives from a patient, a healthcare provider, a representative of the medical device industry, and nonprofit followed by open committee discussions. After open committee discussions, we will break for lunch. We will return from lunch at approximately 12:55 P.M. and we will continue with presentations from a clinical researcher, a health literacy expert, a government researcher with community engagement expertise. This will be followed by open committee discussions. Once the open committee discussions conclude, we will break for approximately ten minutes.

When we return from break, we will proceed to the Open Public Hearing, followed by open committee discussions. During this time, the committee will have an opportunity to discuss the comments shared during the Open Public Hearing. Once the open committee discussion concludes, we will take another ten minute break. When we return from the break, the committee will proceed with committee discussion of FDA questions. Following the discussion of these questions, I will give closing remarks, and we will adjourn for the day. It is now approximately

10:37 A.M., and we'll go ahead and proceed with remarks from Dr. Jeff Shuren, Director of the Center for Devices and Radiological Health at the FDA. Dr. Shuren, you may go ahead and begin your remarks, and thank you.

Opening Remarks — Dr. Jeffrey Shuren

Dr. Shuren: Thank you and good morning, everyone. First, I want to thank the PEAC panel members for your continued service. The advisory committee is unique because its focus is to bring the voice of patients into the work we do at CDRH. As a result, the rich dialogue and feedback from this committee has significantly impacted the thinking direction and deliverables of the Center. So, for example, last year, we heard from the PEAC that we should increase transparency and awareness on medical devices and incorporate augmented reality and virtual reality. In response to that feedback, CDRH has made available a public resource on these devices to better show how AR/VR is being used across medical disciplines.

Last year, during the discussion about informed consent, when a device is used in surgery, we heard from PEAC members that patients want to understand the totality of benefits and risks, a surgeon's expertise with devices, and the surgeon's control over that environment. PEAC members stress that physician and user training needed to be adequate for the intended use, transparent, and based on the levels of risk, and the complexity of the device's use and features. As a resource to aid patients and healthcare providers, last week CDRH released two infographics to support patients and healthcare providers weighing the risks and benefits of medical-extended reality technology to support all users in making informed healthcare decisions. These infographics are available in both digital and print versions to support broad access. Last week's release was in English, and we are planning a future release in Spanish.

Today, we turn our attention to health equity, the advancement of which is a strategic priority for CDRH. The Center has set the following four objectives to advance health equity. To empower people to make informed decisions regarding their healthcare, facilitate availability of and access to medical technologies for all populations, reduce barriers and increase opportunities for participation by diverse populations in evidence generation, and support innovation of emerging and existing technologies that address health equity by changing healthcare delivery to move care and wellness into the home setting.

Putting patients first means all patients, all people should have access to quality healthcare. No one should be left behind. However, historically under-resourced populations have lacked access to quality healthcare. And that gap continues to grow. Lack of access exists for a variety of reasons, including the necessary treatments and diagnostics are not available to the specific demographic groups. Treatments and diagnostics needed by those groups simply do not exist. Sometimes we lack the evidence to know whether an existing product benefits one demographic group similarly to others. And too often, diagnostics and treatments exist, but barriers in our healthcare system create seemingly insurmountable obstacles. In fact, CDRH has a unique role to play as compared to other parts of the FDA when it comes to access to care.

As you heard from Dr. Califf, the U.S. spends more money on healthcare than any other high-income country. But at the same time, we have an average lower life expectancy than all those other countries. And in part because too many in our country do not have access to quality healthcare. A key solution is to move healthcare from brick-and-mortar healthcare facilities to the home setting. Digital health technologies can help bridge the gap by bringing healthcare, as well as prevention and wellness, something we as a nation do not do well, directly to people wherever they are, at home, at work, at school, in cities or rural communities, what we call the home setting, and can facilitate the participation of all populations in clinical trials. Digital health

connect technologies are that opportunity to connect people with their providers from a distance to provide screening, diagnosis, management of conditions, and in some cases, treatment and intervention. And this is not simply a lift and shift of care in brick-and-mortar healthcare facilities into a person's home, but transforming how we deliver care, prevention, and wellness to people throughout their life and assuring that the voice of patients is central in reimagining the home setting so that they have the experience and outcomes they want.

We also see the ability for digital health technologies to transform how we study medical products. Wearables and sensors give us the ability to collect data about the performance and medical devices and how to optimize use. Digital health technologies can enable remote data collection for decentralized clinical trials, improving the ability of individuals to participate in and have access to clinical investigations. Digital health technologies can help facilitate the development and use of innovative clinical endpoints and allow us to capture real-world data and patient-generated health data to support medical device marketing authorization decisions.

The steps necessary to assure health equity cannot be done in isolation, and they will require collaborative approaches. Which is why we are partnering with patients, healthcare providers, industry, payers, and others to help advance solutions that promote health equity along the total product life cycle of medical devices, including access to care. One such activity is our participation in several collaborative communities that are working to address health inequities. For example, the MedTech Color Collaborative Community on Diversity and Inclusion in Medical Device Product Development and Clinical Research is focused on advancing the representation of persons of color in medical device product development and clinical research. This community, like others in which CDRH participates, brings together patient organizations, healthcare providers, industry, researchers, payers, and others to solve shared challenges in a holistic manner. Achieving health equity is vital to the health and well being of our people and

our nation. I can think of few other issues where understanding and including the voice of patients is paramount.

I look forward to hearing and learning from our PEAC members and other stakeholders who will speak so that we together and work to advance health equity. And now I'll turn it back over to our chair, Paul Conway.

Mr. Conway: Thank you very much. Dr. Shuren. We appreciate it. Now it's just about 10:45 A.M. and we'll go ahead and proceed with FDA's presentation. I'll remind public observers at this meeting that while the meeting is open for public observation, public attendees may not participate except at the specific request of the chair. FDA will have 20 minutes to present. FDA will provide an overview on advancing health equity and medical devices by Dr. Michelle Tarver, Deputy Center Director and Chief Transformation Officer at the Center for Devices and Radiological Health. Go ahead, Dr. Tarver, you can begin your presentation.

FDA Perspective: Advancing Health Equity in Medical Devices — Dr. Michelle Tarver

Dr. Tarver: Thank you very much, Mr. Conway, and I'd like to thank all of the PEAC members for spending time with us this morning and providing expertise on these topics. So, I'd like to also thank everybody who's tuning in virtually. I'm going to take a moment to discuss the opportunities. We all have to advance with medical devices, but the particular focus on home use devices.

Over the past few years, we increasingly have heard the term health equity echo in many chambers, however, it's often been used interchangeably with other terms. I hope you will indulge me a bit as I define some terms. And please note that I will be sharing definitions throughout this talk to ensure that we all have a common understanding as we move forward in our discussion. Using the definition from the Centers for Disease Control and Prevention, health

equity is a state in which everyone has a fair and just opportunity to attain their highest level of health.

A related term, but not synonymous, is health disparities. It is often the metric by which we measure progress towards optimal health. It is the preventable differences in the burden of disease or opportunities to achieve optimal health. In the United States, conversations around health equity and health disparities have revolved around factors like race, ethnicity, sex, age, geography as well as other characteristics. There are many examples of disparities associated with these characteristics, whether as Dr. Califf alluded to, it'd be overall life expectancy, chronic health conditions, like high blood pressure or cancer or diabetes, or reproductive outcomes, like infant mortality. We have often observed worse health outcomes in racial and ethnic minorities and those living in rural settings. These poor healthcare outcomes are tragedies for individuals, families, and society as a whole. It is often asserted that social determinants of health impact a wide range of functioning and quality of life outcomes. These social determinants of health are conditions in which the environment where people are born, live, work, play, worship, and age affect a wide range of health, functioning, and quality of life outcomes and risks. However, these variables are often difficult to measure, may impart their impacts over protracted periods of time, variable exposures over time, and make interactions with each other as well as other factors that can be quite challenging to measure or account for all of these effects in a clinical study that is primarily designed to evaluate the safety and effectiveness of an investigation or a medical product.

Instead, we often see researchers attempt to use other groupings, such as race, ethnicity, or ancestry to often and perfectly collect information on some of these social determinants of health. I want to be very clear though. Race and ethnicity are social, culturally-defined terms. They are not proxies for biology or genetic anthropology. However, like other communities,

cultural factors do determine how people share certain genetic features and it may also impact biology. But they are not synonymous, and we should not ascribe value that way. Their definitions and resultant categories can vary within the United States and across the globe. So, the FDA has issued final guidance documents to help define what is meant by the terms, race, ethnicity, sex, and age, and has shared standard approaches to collecting this information. The standardized approaches are critically important to ensure consistency and transparency when communicating the results of FDA trials.

The guidance documents on the collection and reporting of race and ethnicity data in clinical trials was informed by the Office of Management and Budget Directive 15. This guided document details three steps that are critical to collecting race and ethnicity data. First, it should be collected by self-report. Second, respondents should be asked their ethnicity. And third, they should be allowed to check all relevant racial categories that apply to them. The Center for Devices and Radiological Health issued complimentary guidance documents that highlight the importance not only of collecting, but also analyzing and reporting information on race and ethnicity as well as sex and age in medical device clinical studies. This information may help healthcare providers and patients make informed decisions regarding their care.

These guidance documents have been good first steps to help address health equity. Members of the clinical research enterprise actively acknowledge that certain groups are underrepresented in clinical study cohorts. An underrepresented population refers to a subgroup whose representation is disproportionately low relative to their numbers in the general population, or the population of people living with a given disease. In an effort to encourage the medical product industry to improve enrollment of these groups, FDA issued a draft guidance document recommending diversity plans that proactively work towards, including underrepresented racial and ethnic groups in trials. CDRH also specifically issued a draft

guidance on select updates for the breakthrough devices program. The draft document indicates that the program may be applicable to certain medical devices that provide for more effective treatment or diagnosis of life threatening or irreversibly debilitating diseases or conditions and populations impacted by health or healthcare disparities. The Breakthrough Devices Program is intended to provide patients and healthcare providers with timely access to medical devices by speeding up development, assessment, and review for pre-market approval, 510K clearance, and a novel marketing authorization. These draft guidances are not final or for implementation at this time, but they do shed light on the efforts the Agency is exploring to help advance health equity.

Congress, as you heard from Dr. Califf, also underscore the importance of addressing underrepresentation of demographic groups and clinical trials. The Food and Drug Omnibus Reform Act of 2022, also called FDORA, built upon the draft guidance issued in April of 2022 and now requires the inclusion of diversity action plans for clinical studies across medical products that includes devices, drugs and biologics. These diversity action plans will not only be for racial and ethnic minorities, but will also apply for people of various ages and sex with consideration of other factors. The agency will be holding a public workshop on enhancing clinical study diversity on November 29th and 30th of this year, which will further discuss approaches that foster inclusive trials across all medical products.

As you heard from Dr. Shuren, CDRH is leaning forward and taking proactive steps to further advance health equity by exploring opportunities to bring care closer to where people live, work, learn, and play. Technology may be a tool to help bridge that divide in healthcare outcomes experienced by so many groups by helping to advance healthcare, quality of life, and wellness for all. We firmly believe that no person should be left behind in healthcare. And as you heard from Dr. Shuren, there's a number of different objectives associated with the strategic priority, which include empowering people with the information they need to make informed

health decisions, facilitating the availability of and access to medical devices, reducing barriers to participation in the evidence generation process, and supporting innovative approaches and devices that address health disparities.

To most effectively achieve these objectives, it's important to consider ways to achieve health equity across a total product life cycle of medical devices. Whether it is determining what conditions a medical device will address and the features that might make it more accessible to communities experiencing health disparities, or designing and conducting clinical studies that allow for greater participation from underrepresented populations, to considering how accessible the medical device will be to communities bearing a greater proportion of the disease burden, and also monitoring that device's performance once it's in general use to confirm it performs as expected in various demographic groups, the opportunities to proactively incorporate health equity considerations abound.

A lack of diversity, equity, and inclusion in clinical research can undermine the principal goal of improving the health of all patients, as we just alluded to. As part of our strategic priority, we are committed to developing a framework for when a device should be evaluated in a diverse cohort to support a marketing authorization. When data on diverse study cohorts are analyzed and clinically meaningful information is clearly communicated to the public, patients and health care providers can have much greater trust in their diagnoses and treatment decisions.

Diversity in clinical studies matter. It matters not only for supporting the generalizability of study results, but research suggests that a lack of representation may have an adverse economic impact on healthcare, may hinder innovation, may undermine public trust, may lead to lack of effective access to effective medical devices, and can compound health disparities in populations. We have highlighted 3 principles of clinical research that would be important underpinnings of any framework related to health equity. The first principle is inclusivity, which

aligns with the concept of justice or fairness, in distributing the benefits and burdens of research on participants.

The second principle is the need for data generalizability to the intended use population for a given device. It is important that a device will work similarly for all people living with the disease, and in situations where it does not, that information is clearly communicated to the users of the device. This may need to take into consideration in which groups the greatest burden of the disease is born, whether there are features of the device that may be impacted by certain features of the user, as well as where the device will be used.

And lastly, timely access is important. A device that could markedly improve the lives of patients cannot affect this change if it is not available as a treatment option or not accessible or affordable to the populations that need it most.

You have heard us refer to home use device a number of times today. So I'm going to take a moment again to define the term. Home use is not isolated to the traditional definition of a home. Instead, it refers to any device labeled for use in an environment outside of the professional health care facility. This might be a house or an apartment, a vehicle, an outdoor environment, school, work, or other independent living retirement homes and other facilities, and the device may be used by a patient or their family member directly, or by providing assistance to those using the device.

The United States is experiencing dramatic shifts in where health care is delivered, and it is likely that this shifting will persist and expand. With the closure of hospitals and clinics across rural America and the reduction in the clinical workforce, we are facing the challenging of worsening health care outcomes and under-resourced communities. Hence, moving some medical devices to the home may be an opportunity to prevent this gap from widening and optimally an opportunity to help close it

However, to effectively achieve this goal, we must consider a few important facts. The first is that the home environment in general is less controlled than the healthcare setting, lacking the supporting infrastructure and some of the important safeguards. The issues that are often left to healthcare providers or the healthcare system to address fall on the shoulders of the person using or administering the device, which would be the patient in the home setting. Hence, managing repairs, maintenance and cleaning regimens are important to ensure that a medical device continues to perform as intended. The environment in which the device is used can also impact its performance, such as the humidity in the room, the temperature, ambient noises, how clean the use area is, and the transport ability of the device.

It's also important to consider factors that could delay the steps to use the device, impede or delay reading of the results or outputs and impact the delivery of treatments, for example, interruptions and Internet service or power outages. It's also important to match the user of the device to the usability of the device. Hence, ensuring the device is intended to be used in the home setting, requires that it is simple to use across physical and cognitive abilities, has clear and easily interpreted instructions, is supported by user friendly training and good customer support services.

But it's also important to remember that choices may be limited and some of the features may be limited when a device either moves to the home setting or was designed to be used in the home setting. I want to share with you a couple of examples of what I mean by a device that is used in the home setting. One of them is a medical device that is life supporting and used to deliver treatment at home. And I think you've heard some of our PEAC panel members mention it, which is a home hemodialysis device. These devices are streamlined versions of devices used in dialysis or healthcare facilities. Dialysis is a treatment that people who are living with in stage kidney disease undergo 3 to 4 times a week, and it takes a number of hours out of their day to

receive this treatment. Home hemodialysis offers them the opportunity to receive this treatment from the comfort of their home and have more frequent episodes of dialysis.

But in order for this technology to be effective in the home, there were some features that needed to be changed. First, the device needed to be portable. The preparation of the dialysis solutions had to be streamlined, and that the packaging of the tubing sets and the hemodialyzers, could not be individual components, but also that had to be preassembled. So all of these are important to facilitate use in the home.

Devices also can be diagnostic. A very familiar example to many of us is the over the counter COVID-19 test, which is commonly referred to as rapid test. The person who uses this test collects the sample, performs a test, and reads their result compared to some internal control. I'm not going to go into a lot of detail about these tests. It's important to know that they contain detailed and accessible instructions for use, include minimal components, and have been made widely available to achieve multiple impacts.

You heard Dr. Shuren talk about the opportunities available with digital health technologies, and I want to reiterate that sentiment. They hold the promise of being an ideal option for use in the home by enabling remote data collection in decentralized clinical trials, as well as facilitating the monitoring of clinical care. They may also help increase diverse clinical trial cohorts by increasing access for underrepresented communities, as well as facilitate access to clinical care. Lastly, these technologies may help facilitate the collection of evidence to support innovative clinical endpoints, as well as improve the measurement and understanding of traditional ones. Accessible digital health technologies that are effectively integrated into healthcare platforms may help transform the delivery of care, extending the reach of timely diagnostic and clinical therapies to touch the people who need the most.

As you may have noted, CDRH opened a docket soliciting input from the public on the ways in which FDA can increase patient access to home use medical devices to help address health equity. We appreciate all those who have provided comments to the docket received to date, and we will take that feedback under consideration along with recommendations we received from our illustrious Advisory Committee Panel today.

In all of our collective efforts to advance health equity, it is critical that we clearly, transparently communicate with the people living with health conditions and utilizing medical devices. For the more than 190, 000 different medical devices at CDRH regulates, the Center strives to provide new information concerning the benefits and risks of marketed medical devices, clearly transmit information about device safety and effectiveness, including unanticipated adverse events to health care providers, patients, and consumers so that they can all make informed treatment and diagnostic decisions together. Much of this information is shared digitally through our website, email blasts, and social media posts. We have taken additional steps to provide this much needed information in multiple languages and are exploring ways to make the right information available at the right time to help inform the right health decisions for people living with various diseases and conditions.

CDRH is committed to putting all patients first, which means ensuring they have access to the medical devices to improve their health and quality of life, that they have opportunities to contribute to the evidence generation process, and that they have the information they need to make informed health decisions with their care teams.

We look forward to hearing the discussion today and the recommendations from the committee to help inform additional steps we can take together to ensure everyone has an equal opportunity to use medical devices that help them realize their highest attainable level of health. Thank you. I'll turn it back to you, Chairperson Conway.

Mr. Conway: Great. Thank you very much, Dr. Tarver, for your substantive and expert presentation. We deeply appreciate it. We will now take a 10-minute break. Committee members, please do not discuss the meeting topic during the break, amongst yourselves or with any virtual member of the audience. The meeting will reconvene 11:15. At that time, we will continue with presentations, hearing from a patient, health care provider, industry, and a non-profit. Thank you.

Stakeholder Presentations

Mr. Conway: We will now proceed with a presentation by Dr. Patrick O. Gee, Sr., a peritoneal/hemodialysis patient entitled, *A Patient's Perspective, A Patient's Health Journey*. Then, Dr. Roseanne Gichuru, an obstetrics and gynecology specialist, will give a healthcare provider perspective entitled, *Medical Devices as Drivers of Health Equity in Women's Health in Rural and Underserved Communities*. This will be followed by an industry perspective on advancing equity and medical device innovation by Dr. Jennifer Jones-McMeans from Abbott Vascular. This presentation will be followed by a nonprofit perspective on designing for the end user in mind by Jennifer Goldsack from the Digital Medicine Society, DiMe. You each will have 10 minutes to present. You may now begin your presentations.

A Patient's Health Journey — Patrick O. Gee

Mr. Gee: Hello. My name is Patrick Gee, and I'm a former peritoneal dialysis, in-center hemodialysis patient currently six and a half years into a kidney transplant. And today I want to share not only my experience, but in general patients living with kidney disease and talk about digital health and medical devices.

Living with kidney disease can present numerous challenges affecting a person's overall health and quality of life. However, advances in medical devices have provided individuals with kidney disease a range of tools to help them manage their condition, offering several benefits

while also presenting some barriers. This article aims to explore the advantages and challenges associated with the use of medical devices in the management of kidney disease.

One of the primary benefits that I dealt with in dealing with medical devices is the ability to monitor my condition more effectively. Devices such as blood pressure monitors, glucose meters, and wearable devices can provide valuable data about one's health parameters, enabling them to track and manage their kidney disease with great precision. Regular monitoring allows for early detection of any changes or abnormalities, facilitating timely medical interventions and preventing potential complications.

Another significant advantage of medical devices is the ability to improve medication adherence. Individuals with kidney disease often have complex medication regimens requiring them to take multiple medications at specific times throughout the day. However, it can be challenging to remember and also adhere to such strenuous schedules consistently. Medical devices such as organizers or medication reminder apps can help individuals stay organized and ensure that they take their medications as prescribed, promoting better disease management and improved health outcomes.

Additionally, medical devices play a crucial role in the treatment of kidney disease particularly in cases of renal failure. Devices such as hemodialysis machines or peritoneal dialysis equipment are essential for individuals who require regular dialysis treatments. These devices effectively remove waste products and excess fluids from the body, replicating the function of healthy kidney. By utilizing these medical devices, individuals with kidney disease can maintain a more stable state of health and experience and improve quality of life.

Despite numerous benefits, the use of medical devices in managing kidney disease can also present certain barriers. One of the primary obstacles is the financial burden associated with acquiring and maintaining these devices. Many medical devices for kidney disease management

can be costly, and not all individuals have access to adequate health coverage or financial resources to afford them. This financial barrier may limit the availability and utilization of these devices, hindering optimal disease management.

Another barrier is the potential for technological complexities, or user difficulties. Some medical devices may require a certain level of technical expertise or training to operate correctly. Individuals with kidney disease may face challenges in understanding and effectively using these devices, leading to sub-optimal results or improper utilization. Therefore, it is crucial for health care providers to provide comprehensive education and support to ensure individuals can use these devices correctly and derive maximum benefits from it.

Other obstacles to consider is, people that may live in rural areas or may lack access to broadband Internet or Wi-Fi connectability. These two can be an obstacle and a barrier to deal with. Also to consider environmental challenges, that some folks may not live in very clean environments, and it's not due to them not having a lack of cleaning supplies, but it just could be the area. Some folks live in very violent neighborhoods. When you think about the mental duress of trying to utilize these devices at home, it can certainly present not only a physical challenge, but also a challenge to one's mental health.

In conclusion, medical devices have revolutionized the management of kidney disease, offering numerous benefits to individuals with this condition. These devices enable better monitoring, improved medication adherence, and essential treatment options, ultimately leading to enhanced disease management and improved quality of life. However, barriers, such as financial constraints and technological complexities, along with environmental barriers and also some social barriers, really need to be addressed to ensure equitable access, optimal utilization of these devices. By overcoming these barriers, individuals living with kidney disease can

experience enhanced care and improve health outcomes. Thank you so much for allowing me to share my experience.

Medical Devices as Drivers of Health Equity in Women's Health in Rural and Underserved Communities — Dr. Roseanne Gichuru

Dr. Gichuru: Good morning. My name is Dr. Gichuru. I am a board certified OBGYN. I focus on women's health in rural and underserved areas. I will be speaking about the use of medical devices as drivers of health equity in those communities. I'm going to use a case presentation to illustrate on the points I am making. We have a 28-year-old. This is her first pregnancy. She is seven months pregnant. She is coming into the office for her routine prenatal visit. She was recently diagnosed with diabetes and high blood pressure. Based on those diagnoses, we are going to need to monitor her blood sugars and her blood pressures at home for the course of the pregnancy, and subsequently, postpartum.

To be able to monitor her blood pressures at home, she will need a blood pressure monitor, as pictured below, and generally she would need to check her blood pressures about two to three times a day. Those blood pressures will need to be transmitted to her care team. Now, to get the device into the patient's hands, this may happen one of three ways. One, the clinician writes a prescription, and the insurance company pays for it. Number two, the patient picks up the device from her local pharmacy or local store. That would generally be an out-of-pocket cost. Number three, there are some health systems that will make these devices available to the patient for no additional cost. For patients who are not able to access these devices, there are some pharmacies out in the communities that will check the blood pressure for the patient once or twice a day, as needed. Patient can then transmit this information to her care team.

Now, once the patient has the devices, the next thing we need to do is to collect the data. We can do this one of three ways. Number one, if the patient has a smartphone, she can

download an app that interfaces with the physician's office health help platform, and that way the clinical team can see her blood pressures more often in real time. Number two, the patient can document her blood pressures and upload them to the patient portal. Number three, she can document the values and call them in or bring them to her next appointment, as desired.

With regards to diabetes, the diabetes screening device is called a glucometer. This is a little bit more involved with regards to usage. Generally, the patient would need to check her blood sugars about 3 to 4 times a day and document these values and get them to her clinical team.

Now, I'm going to use a hypothetical case scenario to illustrate my points. So if this particular patient was getting care through an underserved clinic, she may need to come in for a one-on-one visit to be able to get her vitals and her blood sugar and blood pressure readings evaluated. Number two, if this patient is a farm worker and predominant language is Haitian Creole, then she would need to get this device as well. The important thing here because of the language barrier is to ensure that the patient is able to, one, use the device, whether it is teaching the patient through a one-on-one meeting with the office nurse or using the user manual, reading the information on there, the information is best delivered translated into the Haitian Creole language. If this is not possible, then putting a pictorial in the user manual may also assist the patient with familiarizing and utilizing the device. The last option is for the medical device to have an online link for which the patient can access the video online and be able to watch it and learn how to use the device. Similarly, if she does have a smartphone, the smartphone platform should be able to translate the information so that she is able to read and use the app to be able to transmit this information to the clinical team.

The last scenario, if this pregnant patient was part of the Amish community. Now the Amish do it a little bit differently, and in this specific scenario, we would need to account for

cultural practices as well as communication within the Amish village. So normally within the Amish community, they generally have a midwife or a community caregiver, who is a care provider who is able to provide care for them during the course of the pregnancy, perform the delivery, as well as take care of them post-delivery. In this case, the Amish midwife would be the one using the medical devices. If say, for instance, the organization or the group needed to communicate a new device, communication wise, the Amish community culturally are not early adopters of technology. For instance, the community that I worked with, they generally did not have cell phones. What they did have was a landline, and that landline was shared by multiple families in the area. If I needed to communicate something to patient in, say, family A, I would call the landline and leave a voicemail for the patient in family A's voicemail, and they would subsequently get back to the clinical team, on average, within 24 hours. Similarly, if we were rolling out a new device, we would definitely engage the community care provider as well as transmitting that information, either through a community engagement platform, say town hall, or put it in the local paper.

Lastly, generally at the height of COVID, what we were seeing with the need for social distancing, a lot of patients decide to continue social distancing, and many of them actually opted to get a fetal heart monitoring device for home use. That way, when we call them, and when we called for their telemed visit, they were able to use the blood pressure cuff that they already had. If we were monitoring blood sugars, they would report those. But they would also use fetal heart Dopplers to report to us what the baby's heart rate is.

So in conclusion, in using medical devices at home, it is important to keep in mind the target audience. So is it pregnant patients versus just GYN patients? The age group: younger patients tend to have tend to be more technologically savvy, tend to use social media more often than, say, the older patients. Number three, you also need to look at the community that you're

targeting, the cultural practices, as well as the language barrier, if any. Thank you. I appreciate your time.

Advancing Equity In Medical Devices Innovation — Jennifer Jones-McMeans

Dr. Jones-McMeans: Hello. My name is Jennifer Jones-McMeans. I'm the Divisional Vice President of Global Clinical Affairs for Abbott's basket of business. Today I'll be speaking to you on advancing health equity in medical devices, giving a clinical trial perspective. My conflict of interest is that I'm an Abbott employee.

At Abbott, we are focused on helping people live fuller, healthier lives, maximizing their potential at all ages and all stages of life. And to do this, we have a very broad product portfolio that is focused on health care. And that is cardiovascular care, diabetes care, diagnostics, neuromodulation, which is focused on treating chronic pain and movement disorders, nutritional care, as well as generic medicines. And looking at this broad portfolio, you can only imagine that when it comes to conducting clinical trials, we also have a very broad portfolio of clinical trials that we conduct on a regular basis.

And as we've been doing this work over the past few years, we've identified that clinical trials have a diversity problem, and that's why we're taking action to make research more inclusive. As we conduct our trials, we have a focus point that those included in our clinical trials should be representing those burdened by the disease for which we're evaluating therapy. Now, clinical trials have not always been representative of the U. S. population. If we look at the left, based on some census data, we see that Hispanics make up about 16 percent of the US population, African Americans about 12%, and Caucasian and other about 72%. But when you look at clinical trial participants, it doesn't match, where Hispanic population represents about 1% of clinical trials, 5% for African Americans, and 94% for Caucasian or other.

Now, in the last year or two, there have been some commitments and momentum to improve clinical trial diversity. And we see on the left here, there's been commitment across the pharmaceutical and medical device industry. And then when we look on the right, Pfizer has actually reported out their metrics compared to the US census data, and they reported that more than half of the Pfizer trials achieved census levels for Black, African American participants, White participants, Hispanic or Latino participants, demonstrating that change is occurring and is happening.

Now, in Abbott, we have an ideal ecosystem that we are working for clinical trials and increasing diversity in health. And we look at it as a patient focused team sport where the patient is the focus of the improvement of care, and the patient from diversified backgrounds is included in that. And we have a commitment across industry to create equitable science, but that means it's multilayered and it involves multiple individuals at that table. We are focused on training doctors and nurses from all communities. We are also focused on outreach to trial participants from all communities and making these trials more accessible to individuals from underserved communities. But this also means that we must have strong relationships with patient advocates to serve as ambassadors. And then we have to focus on the talent within healthcare settings, research settings, and who are from diverse backgrounds themselves and supporting them in their development in the area of clinical trial work. But in doing all this, we work with guidance from government agencies, such as the Food and Drug Administration, all making this infinity circle that will be continuously improved upon so that we can actually eventually continue to increase the numbers of diverse populations in clinical trials.

Now, with this clinical trial work, we have to remember the importance of social determinants of health. Who we are as humans, our biology, our presentation of disease is impacted by our societal context. That means that how much money we make, where we live,

our education, access to education, how much we have, how much we may not have, our food access, as well as our community, social context, our social support, stresses, and accessibility of health care, that impacts our disease and impacts who presents with disease. So when we think about diverse populations, we must integrate these elements of social determinants of health in understanding how we best develop a trial that supports all patients.

Also, something that we must look at is critical barriers to enrollment. There are certain barriers that we have to tackle, and we have to keep them in front of us and figure out how do we lower these barriers to make it easier for diverse populations to participate. And this ranges from everything from mistrust that may be in certain communities, a lack of comfort with the process of actually accessing health care and participating in clinical trial, lack of reliable information, a single source of reliable information, the time and resource constraints that can pull on a patient and their family participating in the trial, and general lack of awareness.

And so at Abbott, what we've done is we focused on what barriers that can we remove at patients accessing clinical trials. And one focus area is decentralizing trials, making it such that a patient doesn't have to go always to the large academic center or large hospital center to be seen for patient follow up. Now with medical devices, I will say that many of them require a procedure to be done, but we can make that access to the physicians more accessible and the follow up for those patients easier. We can provide transportation support, logic, lodging, and meals for those longer visits or overnight stays, even bringing the clinical trial visits to the patient's home such that if they don't have the social support to get them to their care provider, we can bring it to them.

Something that's very important is that currently, we are in an information age where there is so much information that it's very hard to discern what is reliable and what is not. And so having patient websites, patient videos, radio ads, general educational resources for patients and

families about their disease, about therapeutic options, and what a clinical trial is very important. And I will also lastly say translation services. Knowing that we have patients who are from multiple backgrounds, different languages, providing them these services, providing the site these services so that patients understand and can have a discussion about potential clinical trials that may be available to them.

One example of this is we put such inputs in a trial called Life-BTK, which is a trial that is investigating a device to treat the arteries below the knee that can be diseased. And with this, we took a very strong approach to make sure that we were reaching out to the communities that are impacted by this disease. And so this website provided a single source of reliable information for patients and families to refer to just to find out what peripheral artery disease is, what critical endoscemia is, why it would be important actually to understand what therapeutic options they have and the potential of benefit of participating in clinical trial. And what was important is, as we put video on and information, we needed to make it such that it was very relatable to patients and their families.

Another step that we're taking in a trial called Breathe, which is a pulmonary embolism trial that we will be looking into working with FDA on, is bringing in a patient advisory panel. This would actually bring in a level of patient involvement of people who have had pulmonary embolism in the past, understanding their experience and their feelings toward participating in a potential clinical trial. But also creating a panel with these patients so we can discuss the clinical trial, how it was designed, and get feedback from them on how the trial is potentially going to be conducted, and eventually just ensuring that we can get this feedback and potentially implementing it into how we make this trial more diverse and more accessible to patients.

Another step is not just staying with what the patients need. That is actually, again, a center point. But we also have to focus on what I had spoken on before. How do we actually

support physicians, researchers that are developing in their career? And so Abbott has had some commitments with scholarships to historically Black colleges and universities and nursing associations that will help educate the next generation of diverse physicians. And also, extending to outside of Abbott itself, but also to advisory boards, to get the feedback from physicians, community members, on how we can best conduct our clinical trials to support diversity.

And lastly, once a protocol is approved, the work doesn't stop there. We work to create programs to support patients, physicians on again, education, referral processes, all of those touch points that will make health care more accessible in general. At the end of all this, we have a future vision to future reality. Our focus is to evolve to meet the societal needs when it comes to health equity, provide tools, patient tools for patients, families, and physicians to best improve access to care, access to clinical trials, and with all of this, keeping patients at the center of this multi-level care team that it will take to conduct this work.

Designing with the End User in Mind — Jennifer Goldsack

Hello, everyone, my name is Jen Goldsack, and I'm CEO here at the Digital Medicine Society, or DiMe. DiMe is a global nonprofit, and our mission is to advance the ethical, effective, equitable, and safe use of digital technologies to redefine health care and improve lives. With that in mind, the focus of my talk this morning, as we think about designing with the end user in mind and advancing health equity and medical devices, will be on digital devices in particular.

Though, while that's the focus, not just of my talk this morning, but of all of the work that we do at DiMe, it's important to start by noting that we're not tech determinists. Success for us is not shoehorning digital technologies into every nook and cranny of healthcare delivery and calling it success. What we think about is the promise for these new medical devices, these digitally enabled tools, that really help us address some of the most pressing and persistent challenges that our health care environment has faced for decades. We need to think about

improving access, equity, efficiency. We need to think about outcomes, equitable outcomes. We need to think about developing new products and solutions where currently a diagnosis might mean that you don't have access to a lifesaving treatment or any kind of therapeutic benefit because the science isn't there yet. We have to think about our ability to deliver healthcare at a price that society and individuals can afford. That's what we think about when we think about success in the digitization of health care. And when I think about digital medical devices, I'm thinking about, how do we use these as tools to power a fundamentally different kind of health care delivery.

Now, that's not to say that the products themselves aren't important. We have had too many stories in recent years about the inequity that are associated with digital products. One of the top stories that caught all of our attention during the pandemic were the disparities in performance across different pulse oximeters depending on your skin tone. That's unacceptable. And what we've seen in the news recently is article after article that the algorithms that we are relying on for clinical decision making are not equitable. And those decisions favor people of higher socioeconomic status and White Americans. This is not acceptable. We have to assume that equity in the performance of digital medical products is table stakes. That's nonnegotiable.

And yet, if we want to think about re-imagining a healthcare system that works for everyone in the digital era, we have to think not just about the products, but we have to think about the problems that we're trying to solve for. I'm going to share some statistics with you. 50 percent of counties in the United States do not have a single mental health care provider practicing in that county. 50 percent of Black Americans currently live in a county where there is not a single cardiac specialist. We also need to think about another statistic. So if you are a patient with cancer and you go to an NCI Center of Excellence, of which there are a few, and they are very geographically remote from most Americans, your outcomes are nine times better

at these Centers of Excellence compared to your local cancer treatment facility. We have to not only develop digital medicine devices that are in and of themselves equitable, but we have to think about developing products that are actually solving some of the most pressing and persistent challenges to health equity. It has to be a one-two punch. This is the opportunity of a lifetime to reimagine health care as we digitize. It's not an either-or, and it's a yes-and.

As I talk about all of this, it's important to consider that there's not a silver bullet solution in the form of a digital me medical device. We are not going to be able to solve all of the challenges that we face with a single product or even with a single product class. On the screen now, you can see a matrix that we actually built out with our colleagues at the VA. We went through and considered the different kind of digital health technologies that exist today. And just a quick disclaimer, because this is important. Not all of these digital tools are medical devices, but many of them are. Digital products that are enabled by artificial intelligence and machine learning, augmented reality, virtual reality, mixed reality, the use of remote patient monitoring, the use of digital therapeutics, the use of mobile health applications — these are digitally enabled medical devices, and you can look at all of the different benefits that they confer.

But what's interesting is there's not a single product type that solves or addresses all of the different areas where healthcare is ripe for improvement, where we can advance health equity using these tools. The only way that this comes together and is a comprehensive solution is when we start deploying these connected medical devices into virtual care. When we think about building care around the patient and not the clinic, we think about using these tools to develop culturally appropriate care, to meet the patient where they are and to deliver the care they need when they need it. This is when these digital medicine devices start to get powerful. And this is where we have to be thinking about health equity. It's not just about equitable and inclusive product development. It's about how we deploy these new product classes, too.

So we've done some work through a collaborative community DATAcc, a hard one acronym for the digital health measurement collaborative community that we are proud to host with experts from across industry and with FDA participation. And so acknowledging that we need both inclusive product development and inclusive and equitable deployment of these tools in order to transform healthcare in the digital era, we went ahead and built two toolkits, both of which are open access, both of which you can pick up today. So we thought about, gosh, what does it mean to do inclusive digital product development? And we realized that we needed to articulate the incentives for actually taking the time to build digital medical devices that work for everyone. We needed to provide evidence that these approaches were reliable and trustworthy. We needed to actually articulate the process of inclusive design. And in doing so, we built off FDA's medical device development lifecycle, annotating it for, one, digital products and, two, inclusive design at every step. And then we put together a suite of open access tools and resources to support this inclusive product design. So through this toolkit, resources and best practices are clearly articulated for building inclusive digital products.

And then we went further and did the piece that I've been trying to emphasize today, which is not just about the medical device, it's how we deploy it in practice. And as part of this second toolkit, we created resources for patients, participants, and communities, also for clinical researchers and for practicing clinicians and health care executives to think about selecting tools that were built for every person our health care system exists to serve and deploying them in a thoughtful and intentional way so that they are solving the most pressing health care challenges for those individuals and they do so in a way that is truly equitable.

So hopefully this was useful to you as you think about, why is it important to prioritize equity in health care? We have the opportunity of a lifetime as we digitize health care to fundamentally reimagine what it means to care for someone. When we have these digital medical

products, when we have connected technologies, when we can use them to overcome challenges of place and access and the maldistribution of clinical experts and the patients who need them, I imagine a future in which a successful health care system is defined by individual health. How good are we at keeping them out of the clinic, meeting them where they are, keeping them healthy? Instead of how good are we at treating their illness once they present sick at the doors of the clinic, and we're evaluating ourselves by the patch up job that we can do. This is possible when we use high quality, trustworthy digital tools.

But if we want this reimagined system to be a system that works equally well for everyone, if we make sure that we are not just improving healthcare for some, but that we are using the digitization of healthcare to bring everyone with us, we must design a system that works for everyone. That means that we need to do inclusive, thoughtful digital medical product design. And we need to think about the problems we are solving for using these tools and how we deploy them for success. Thank you so much for the opportunity to present today, and I look forward to the discussion.

Open Committee Discussion

Mr. Conway: Great, thank you very much. I'd like to thank Dr. O' Gee, Dr. Gichuru, Dr. Jones-McMeans, and Ms. Goldsack, as well as the FDA for their presentations. Now we will have open committee discussion, clarifying questions from the committee. As a reminder, although this portion is open to public observers, public attendees may not participate, except at the specific request of the committee chair. Additionally, we will request that all persons who are asked to speak identify themselves each time. This helps greatly with the transcription.

So let us go ahead and begin. Does anyone on the committee have any clarifying questions for Dr. Tarver, Dr. Gichuru, Dr. Jones-McMeans, or Ms. Goldsack? Due to a schedule conflict, unfortunately, Dr. Patrick O. Gee Senior is not available for follow-up questions. So

for committee members, please turn on your video monitors, unmute your phone, state your name when you speak, please put yourself back on mute once you're done speaking. You can physically raise your hand or indicate in the chat, and I'll go ahead and I'll call on you. Let me go ahead and start now with Necie Edwards.

Ms. Edwards: Necie Edwards. And my question is for Dr. Tarver. You mentioned earlier about methods of communicating with the public. And one of the questions that I have for you is about radio. Because with radio, for example, in the African American community, we typically listen to a lot of radio. Not radio just for politics, radio concerning our health and overall well-being. And most times that is a far greater trusted resource. Now, I used to host a live radio show, and I did allow public service announcements on my show. So my question, Dr. Tarver, is, has the FDA considered putting out PSAs? Maybe the FDA has, and I just simply wasn't aware of it. Or have you considered going on the air with media campaigns? And not just that, actually being a guest on some of these shows. Thank you.

Dr. Tarver: This is Michelle Tarver. Thank you very much, Ms. Edwards, for that question. I'm going to ask Alicia Witters, who is leading our communication efforts at CDRH to comment on that question.

Ms. Witters: Sure. Thanks, Michelle. Again, this is Alicia Witters. CDRH has not used radio, at least not in recent history. I cannot recall a case where we've used that. I do know that some other centers have used it, so some other components of FDA that regulate different products, not medical devices. I think it is something that we would be interested in and would consider, and I think part of what we are looking for during this call, this meeting today, is these types of ideas being generated so that we can really consider some different ways of reaching out to different, you know, targeted populations in particular in the future.

Mr. Conway: Great. Thank you very much. Any other questions here? Again, this is time for clarifying questions of the preceding speakers. Go right ahead, Dr. James.

Dr. James: Hi, Jijo James, and thank you for the great presentations. My question is for Dr. Jones-McMeans. Beyond the challenges or the differences in decentralized trials between therapeutics and devices, do you see any other challenges that are specifically unique to medical devices when it comes to access and equity and conducting clinical trials?

Dr. Jones-McMeans: Thank you. This is Dr. Jones-McMeans. I think it's a very good question. With medical devices, many times we recognize that the patient may not always be aware of what options that they have within medical devices. Many times they are aware of certain drugs and therapeutics from that area, but medical devices, if you think traditionally, the decision by which, what's potentially available for them may be more in the hands of the physician. And so, having that, if you take that a step further with clinical trials, clinical trials in which they're in the medical device space and the cardiovascular space, there may not be the level of awareness that potentially some other therapeutic areas may have. So that is why we know we have to be more intentional.

And number one, doing general PSA work of making awareness of the diseases that, certain diseases that may require a medical device, a solution, and basically making patients aware of what options that they have before we even get to the level of what a clinical trial is. I think part of our responsibility is just general education around certain diseases that require med devices and then educating them on potentially what is a clinical trial, including in the investigation of a medical device retainer. So I think we have several layers of education to our patients that we're very happy to support.

Mr. Conway: Thank you very much. Now what I'd like to do is go ahead over to Naveena Yanamala. You have a question?

Ms. Yanamala: Yes, my question is to Dr. Jones again. I had a question about whether you consider, when your device, to develop a device for a particular disease, do you actually look into either a post market analysis where you actually look at the devices benefiting? Because people come in all shapes, forms, and their pathophysiology is completely different. And do you do any in silico clinical trials to understand and extend these devices to target other communities, to bring in or advance health equity for devices?

Dr. Jones-McMeans: This is Dr. Jones-McMeans again. I feel that that is a very good question. Well, I will say this. When the device, the device is under investigation, many times our therapeutic device has not been evaluated in a post market setting. So it's our first pass. And so, as you saw with the example, with the Life BTK trial, we had to work to be intentional, understanding the disease landscape, and who's impacted by the disease, to be intentional to say we've got to be as inclusive as possible and reduce barriers to ensure that we were including a greater number, or I should say, a number of patients of color. I would say, as we move into the post market setting, that is definitely an area of interest that we continue to expand on that, because being that when we're in this investigational early clinical stage, or pivotal clinical stage, we don't have all of that detail and we may need to work with FDA to continue to bridge that information, so that we are continuing to understand how is the device performing in specific populations.

Mr. Conway: Great. Great. Thank you very much. Now I'd like to go over and ask Amy Sitapati, go right ahead.

Dr. Sitapati: Thank you. This is Dr. Amy Sitapati and my question is for Dr. Gichuru. Dr. Gichuru, what are the most important considerations to inclusions of populations with variable digital access, literacy, and broadband when it comes to the design, testing, and access of devices?

Dr. Gichuru: This is Dr. Gichuru. Thank you for your question. So number one, understanding the target community or the target population. Understanding the culture of the population. So for instance, with the Amish population. They don't tend to be early adopters of technology, so understanding how to best communicate, to get the information to them. As I had mentioned, town halls go a long way. Newspaper communication goes a long way. Engaging and leveraging the community caregiver or the community midwife. When you look at the immigrant farm worker community, number one would be communication, any language barriers. Culture, too, becomes a very big issue, or becomes something significant that needs to be addressed, and encountered, addressed for.

And I'm sorry, one more thing, cost. Especially in the obstetric space. The pregnancy as it is tends to be quite expensive. If you consider for or against insurance and insurance coverage. Even for patients that have insurance coverage with the need for lab testing, imaging, those costs do end up adding up. If you consider folks who do not have insurance coverage, everything tends to be out of pocket. And while there are programs to help alleviate or at least decrease the amount of out-of-pocket cost, cost is still an issue. The last thing I would add also is technology and availability of technology. So, when you look at the rural communities, it's one thing to say that yes, you have the internet access, you have the broadband. But is it consistent? Do the devices need to be charged overnight? Are they updating overnight? Those kinds of things definitely limit or present a formidable challenge to the application of medical devices at home.

Mr. Conway: Thank you very much, Doctor. I would like to go over to Dr. Elizabeth Joniak-Grant. You have a question.

Dr. Joniak-Grant: Thank you. Elizbeth Joniak-Grant. My question is for Dr. Jones-McMeans and it's possible that Jennifer Goldsack may have a comment as well. I'm wondering

if in sort of looking at having these advisory patient panels, in terms of design, has there been any consideration of looking at user testing where people are using them in real world settings? So, outside of sort of trying to come up with the ideas about what might impact using a device, actually seeing them use the device in a setting and what could be aspects that come into play for design.

Dr. Jones-McMeans: This is Dr. Jones-McMeans again. Thank you, Elizabeth, for your question. In the medical device areas that, currently, that I was speaking on, it would not be possible because these are implantables. And so I really can't speak on whether or not any user testing, because it's just, it's not possible because it requires a physician to treat.

Ms. Goldsack: And this is Jennifer Goldsack, happy to weigh in. It's a tremendous idea and where it is feasible, and I think Dr. Jones-McMeans gave an example of where it may not be. We absolutely recommend this approach. So, if we think about the digital health collaborative, digital health measurement, collaborative community work that I described around inclusive product development, the most important thing to stress there is that patient engagement, and representative inclusive patient engagement, is not a one and done moment. That there's a whole series of steps where these products are being designed that we need to be thoughtful in how we engage representative groups of patients from the entire community that product can potentially serve, every step of the way.

So, what you'll see there is there's 3 or 4 opportunities where user testing is highly recommended in order to make sure there's an iterative process to develop a product that ultimately works for everyone. So, I strongly agree that that's absolutely something we should be doing, and that's something that we have codified and actually have supporting resources already, for folks who are keen to do that and are keen to reap the benefits of developing a

product that does look like for everyone, which also expands their commercial market. So there's certainly incentive to do those extra steps too.

Dr. Joniak-Grant: Thank you.

Mr. Conway: Great. Thanks. Dr. Gwenyth Fischer, go right ahead.

Dr. Fischer: Hi, this is Dr. Gwen Fischer. I have a question for Dr. Jones and Dr. Gichuru. I'm curious if either or both of you has discussed with your patient panels, or with those that you're working with, about alarm fatigue and the use of home monitoring devices. This is an issue we've seen in pediatrics. Curious if this is a more generalizable issue in progressing home devices. And if you have, whether or not you've been able to engage your patient panels on addressing this issue for future design and development.

Dr. Jones-McMeans: This is Dr. Jones-McMeans. We have not, in the patient panels that we have been working on for the therapeutics, we have not been able to, we do not have those discussions because, as noted, many of the devices are implantables which they would not be associated with an alarm.

Dr. Gichuru: This is Dr. Gichuru. From an OB perspective, no current concern for alarm fatigue, in part because the conversations that we have in patients, and I'm specifically addressing the obstetric patient here, is we have blood pressure cutoff. So if your blood pressure is above a certain amount, you need to give the office a call immediately. So we have the conversations with regards to what ranges are normal, and what ranges you should be calling your physician or your clinical team for. From a GYN perspective, it's the same approach, it's a conversation. I'm thinking more specifically with home devices, with regards to pelvic floor muscles and some of the devices that are out there to help strengthen the pelvic floor. Alarms are not an issue there.

Mr. Conway: Great. Thank you very much, Doctor. Dr. Stephen Wilcox, go right ahead.

Dr. Wilcox: Thanks. So, most of the emphasis of the talks was on clinical trials. But wouldn't you agree that these same issues obtained for the other things that have to go on in parallel with the clinical trials typically, which is the creation of a design history file, which includes various procedures that one engages in, to make sure the device is as error free as it can be made and as usable. As it affects safety and access. One comment I want to make too, about Elizabeth's question, about real world testing. But there are a couple of problems with that. One is that it, that they're usually not approved for real world testing. But the other problem is, to find an error you have to know what the person was intending to do. And so that's why simulated environments are typically used to serve that purpose.

Mr. Conway: So, would anybody like to comment on that before we go to the next question? Any of our guest speakers? I'll come back to a point on that, Dr. Wilcox, when other folks have asked their questions. I'll go to Dr. Elizabeth Grant.

Dr. Joniak-Grant: Should I hold my comment on that until later, or?

Mr. Conway: No.

Dr. Joniak-Grant. I will just leave it. Okay. I guess, my comment would be, is for looking at users in the real-world environment. I think this could still be part of the clinical trial, especially as we decentralize clinical trials. And, sometimes observing them, you can have individuals who can ask the user in these situations, thankfully, what were you intending to do? What were you trying to do? It sort of reminds me of user testing that they do with video games to discover bugs and those types of things. And so I think there would be some ways that we could incorporate these types of things, in clinical trial design and evaluation.

Mr. Conway: Great, thank you very much. I'm going over to Dave White. Go right ahead, Dave.

Mr. White: Thank you. This is Dave White. I have a question for all the presenters, and it's regarding a word that I saw on Dr. Jones-McMean's presentation regarding some barriers that need to be overcome, and the word was mistrust. For some reason, this just struck me when I saw the word today, and it occurs to me that I have a problem with the word because it can be construed to, by some people, to maybe the affected community is at fault. You know, they're mistrustful, where that isn't the case, and I was wondering what the presenters think about sort of evaluating that word and replacing it with something along the lines of loss of trust.

Dr. Jones-McMeans: If I may, this is Dr. Jennifer Jones-McMeans. Thank you, Dave. I think that is an excellent comment that you're making. So, let me make sure I clarify that at no time is there an expectation or a thought that the mistrust is actually being put on the patient population as being wrong. That is absolutely not it. I think if I can clarify more, is that we know that there have been generations of medical inequities that have occurred. And I think societal happenings (phonetic) has occurred that has created a level of mistrust when it comes to health care in general. This does not mean that it is the fault of the patient population at all. If anything, we put it out there as something that we actually have to improve. Creating not just the access, but a trustworthy system that individuals feel invited and welcomed, and believe as though, as an industry, I am presenting a clinical trial that they can actually believe that I'm good, that, you know, of course through code of conducts and whatnot I will always form and do things for the best patient. But that there's a real, appreciated and genuine trust that, as an industry, we are presenting. And so I think that you bring up an excellent point. It's never being put on the individual, but rather, how can I do better, as an industry? How can we provide better health care and potentially clinical trial outreach to patients?

Mr. Conway: Great. Thank you very much. Is there anyone else that would like to comment on Dave White's question?

Ms. Goldsack: This is Jennifer Goldsack. I'd love to. I think, Dave, your question is really, really important. I think trust is incredibly fragile. First of all, we have to earn it and then we have to maintain it. And so, I think not only do we need to think about trust in the kinds of products that we develop and how we use them, I also think that we need to talk about value. And I'll give you an example that may sound silly, but it's one that works for me.

I don't particularly trust my bank. I don't particularly trust how they use my data, but I use a banking app every day because it solves a big problem for me. It gives me much more convenience. It gives me much better access. And it's pretty usable. And so I think there are two pieces. There's the trust element, which is absolutely necessary, critical, and we have to do the work to earn it. I also think that part of this, and this gets back to the language issues, we talk about things like mistrust. Sometimes you also hear words like adherence or compliance. Again, like someone's doing something wrong, which I don't find to be helpful.

If we are building high value solutions in a way where we've actually tested them with the individuals we want to use them, we don't have to measure things like adherence and compliance, because the value is there and the trust is there. No one has to tell me. I don't need metrics or a monitor to tell me how much to use my smartphone. I know I use it too much. And why do I? Because it's really useful and it solves a lot of problems for me. And so I think we have to think not only about trust and thoughtful earning of trust and the language we use, but also value to the individuals that these products are here to serve. We can't try and impose them upon people. We have to earn trust and we have to deliver value.

Mr. Conway: Great. Thank you very much. Let me go over to Dr. Gichuru. Do you want to comment on Mr. White's question? Go right ahead.

Dr. Gichuru: I do. This is Dr. Gichuru. As a physician who is working in rural and underserved communities, and I will approach this from a humanity perspective. I have found

that as the outsider going into these communities, the most important thing is humility and appreciating the culture of the community within which I am going in to serve. Now, it's as simple as the patient comes in, you have a conversation. In that visit, the patient has determined are you are they going to be able to trust you, and if we're able to establish or at least begin creating that rapport in the initial visit, if six visits down the line, I'm saying, hey you now have diabetes, you now have high blood pressure, there's this device that can help monitor this condition, that you may need to use. That, I have learned, goes a longer way.

So, meeting the patient, meeting the community, and approaching them from a place of humility as the outsider. A willingness to learn and appreciate the culture and their viewpoints. And it's a very nuanced approach, and it's a very nuanced perspective. Some label it as the art of practicing medicine. That has probably contributed to my success as a rural physician, than any other thing, with regards to creating and establishing and enhancing patient relationships, physician-patient relationships. Thank you.

Mr. Conway: Great. Thank you very much, doctor. And Dr. Tarver, did you want to add a comment also?

Dr. Tarver: I just wanted to add, I think, Mr. White, that's a really important question and an important comment. I think you've alluded to the importance of trusted relationships, and I think you've heard a number of the speakers talk about the importance of creating trust, but also acknowledging individual violations of that trust. And so it's not always just at the community level. It can be very much at the local level. And as we are looking to bring patients more effectively into the clinical trial enterprise, as well as into the care paradigms, it's important that we look at communities, not as just communities, but also as individuals and what their personal experience may be, with fostering trust with the health care system. So, I agree. Labels and language matter, and how we talk about it will help to bridge those gaps.

Mr. Conway: Great, thank you, Dr. Tarver. Dr. Joniak-Grant, I have a couple of folks that are before you. Did you want to comment on Dave White's question or did you have another one?

Dr. Joniak-Grant: I have a separate question, thank you.

Mr. Conway: If you can hold on one second, I appreciate it. Thank you. Let me go to Naveena Yanamala, you have a question.

Ms. Yanamala:I am Naveena Yanamala. I have a question for Jennifer Goldsack and also the panel here, about patient engagement and communication strategies. So, are there any insights or data on how well current communication approaches resonate with individuals from various demographic backgrounds? And a continuing question is, have we identified any disparities in reaching different segments of the population? If so, what strategies or adaptations have been considered or implemented to ensure inclusivity and accessibility to information?

Mr. Conway: And just for clarification, Naveena, who do you want to have comment on that off the bat? One of the speakers? Or are you also asking for other committee members to comment?

Ms. Yanamala:So first the speaker, Dr. Goldsack.

Dr. Goldsack: Thanks Naveena, great question. This is Jennifer Goldsack. So, two big questions there. I'll try and answer them completely, but briefly. The first one, I'm not familiar off the cuff with data in support of using these tools and the most successful methods of interacting with different patients. However, we do have, on the DATAcc website, the digital health measurement collaborative community website, a whole catalog of evidence, which you can search, and if it exists, it is comprehensive, we scrape everything, we keep it up to date. It is there.

I am going to give you an anecdote though, and I'm going to talk about a physician friend of mine who works at a local hospital to me, Moffitt Cancer Center here in Tampa. And

he was reflecting on his experience caring for individuals with cancer during the pandemic, and how easy it was to access the appropriate translator at the time in which it was needed. That, instead of having to pick up the phone and wait for someone who might be on the other side of campus to come to a patient's room, or to come to a clinic, that they could immediately get on with a virtual interpreter to be able to have a meaningful conversation with the patient without forcing delays because of a language barrier and making it more burdensome for patients who don't speak English.

It's also interesting to think about, what are some of the features of the technology industry that are so amenable to driving and improving equity in health care. It's this notion that technologies by definition, in sort of every other industry, are what we would describe as really modular. We can switch things out very easily. It's all layers. It's all stacks. So we can think about, what is culturally appropriate language? What are examples? What are references that we may choose to really personalize? And, you know, when we personalize medicine well, by definition, it is equitable. So how can we use some of the key features of the sort of digital era to actually create communications capabilities, that's what we should be looking for in the sort of user testing that we were just discussing and we can constantly get feedback. We can constantly improve. This should also be features that we build in, and it's more than possible at very, very low cost in the digital era. And Naveena, I'm going to need you to remind me of the second question. I'm so sorry.

Ms. Yanamala:So, are there any identified disparities in reaching different segments of the population?

Dr. Goldsack: Many, unfortunately. And, you know, they've been discussed today. We can, you know, there are many different features of a digital divide. Whether it's sort of tech literacy, whether that's, you know, connectivity, there are all sorts of issues there. If I'm going to stand

on my high horse, and someone's given me the opportunity, so I will, I think we need to think differently. We need to think about how terrible the disparities are, in terms of health and health care today. And we can focus on, gosh, what are the problems, around sort of the digital divide? Maybe we shouldn't use these tools.

I'm not dismissing the fact that we need to overcome those challenges, but let me give you another example that I think is more powerful. There are definitely occasions, whether it's within clinical trials or within routine clinical care, that a patient who perhaps doesn't speak English as their first language comes into a visit room, and they might be a great candidate for a clinical trial, or they might be a great candidate for a new medical product that could really improve their lives or even save their lives. But that physician, who's working 12-minute centers for nine hours a day, might make an assumption, not because they're doing anything wrong, but because they're exhausted, that that individual, that treatment protocol is going to be too challenging. There's no way they'd be able to participate in that trial.

Instead, we can use things like clinical decision support systems. We can use all different sorts of prompts, nudges, data-driven approaches to actually tee up for success a conversation that wouldn't have happened otherwise. As a reminder to the clinician, that this person might be eligible for a course of treatment or a trial opportunity that they wouldn't have thought about before. And then to provide resources for both the clinician and the patient to make that happen. I'm much more excited to talk about those kinds of opportunities for technologies, and rather than nibble around the edges and say, oh gosh, you know, should we, shouldn't we? One, let's design products and technologies and let's insist that they're inclusive and we have the infrastructure to roll it out. And then let's think about solving the big challenges with these tools. So again, I'd refer you to that, a library of different, sort of evidentiary frameworks and publications that we have on the DATAcc website.

But, as the PEAC, I really want to ask you, if I may be so bold, not to think about the limitations of technology vis-à-vis inclusion and disparities in equity, but really actually think about how can we use these tools in ways we've never been able to care for people before, to include more people and to do so in an equitable way.

Mr. Conway: Great. Thank you very much. We just have a couple of minutes left before the break. So let me go to Necie Edwards. Thank you for your patience, Necie. And after that, we'll go to Dr. Elizabeth Joniak-Grant. Go right ahead, Necie.

Ms. Edwards: Thank you, Mr. Chairman. My name is Necie Edwards, and my question is for Dr. Jones-McMeans. My question for you is, when I think about clinical trials, many people also think about the elephant in the clinical trials in our community, African American community. You're thinking about Henrietta Lacks, they're thinking about Tuskegee. I saw the same thing that happened when it came down to COVID, where many people were afraid to get the vaccine, people of color, for fear that they were being tested on again. So my question for you is, what are some of the things Abbott has done to address some of these concerns? Have you run across this in any of the trials, getting people to sign up?

Dr. Jones-McMeans: Thank you, Necie. This is Dr. Jennifer Jones. Great question. So, on one of my slides that I didn't mention is that some of the tools that we use. One of them, I will say that we had to, that I feel that has become a very necessary approach that we will take, continue to take, is reliable information. So I think I heard you, earlier on, speak about radio media. So one of the biggest, so we took a large campaign focus on radio media. In which we did reach out with one of our programs on many of the radio shows as well as the levels of media and engagement, because we do know that, as you said, the elephant in the room is that there are areas, there are communities, me also being from the African American communities, where there is this historical context. So, how is it that we are going to take forth to, number one,

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educate on the disease, but also just show a level of transparency and, you know, why a clinical trial is something to be considered. Why is it, why is a clinical trial considered, you know, a safe? We see it as almost as a care for where you're going to really get excellent care.

And so, our approaches to this were doing the website, making the website very relatable by patients. Putting on, actually on the website itself, we actually have videos that from physicians that talk about the importance of the treatment options, the importance of clinical trial participation. Radio shows, we're able to do radio interviews where we were interviewed by the community on the disease itself, the importance of understanding the disease, the importance of clinical trial work. So, taking these different approaches by which we can be participating with communities and be seen as a part of it, I think it is like a first step in order to go back to what Dave had asked about the whole thing. The whole level of the word mistrust. You know, I think if we spin it around and just say, creating just a trusting environment. It is, again, it is our work to do that. I feel like it's industry. It is our work to create environments doing it, and using different ways of communicating patients being part of it, will be important.

And I'll give you one example, in one of the trials that we did use media website. One of the physicians came back to us and said, you know, what you gave is different ways of communicating where if the patient came in, and let's say they were able to get a brochure that talk to them about clinical trials, maybe they would actually say, hey I'm willing to be in the trial. But then they go home and they go to their family, and their family's saying, I'm not feeling good about this. Like, why would you want to be in a clinical trial? We also had a different layer of which the family could access information together. So, they could access the website, they could access the videos. They could maybe even hear us on the radio. So, having

this tiered approach of helping families feel comfortable with the information, even outside of the doctor's office, is something that we aim to do.

Ms. Edwards: Thank you.

Mr. Conway: Thank you very much. And let me ask Dr. Joniak-Grant. Do you have a question now or do you want to hold that so we can go ahead with the schedule?

Dr. Joniak-Grant: I can go ahead and hold it until the committee discussion, that would be fine.

Mr. Conway: Okay, great, thank you very much. At this time, we'll go ahead and take a break for lunch. Committee members please do not discuss the meeting topic during the break amongst, yourselves or with any virtual member of the audience. The meeting will reconvene at one o'clock PM. At that time, we will continue with presentations, hearing from a clinical researcher, a health literacy expert, and a government researcher with community engagement experience. Again, we'll reconvene at one o'clock PM. Thank you.

Stakeholder Presentations (Continued)

Mr. Conway: It's now one o'clock and I'd like to welcome everyone back from lunch. We will now proceed with a presentation about a clinical researcher's perspective on understanding health equity in clinical trials, by Tesheia Johnson, from Yale School of Medicine, followed by a health literacy expert perspective on advancing health equity and medical devices, health literacy, and community outreach, from Behtash Bahador from the Center for Information and Study on Clinical Research Participation, CISCRP. You each have 10 minutes for your presentations. You may now begin your presentations.

Understanding Health Equity in Clinical Trials — Tesheia Johnson

Ms. Johnson: Hello, my name is Tesheia Johnson. I'm the Director of Clinical Research at the Yale School of Medicine, and I am delighted to be here today to talk to you about our experience in addressing health equity issues in clinical trials. I don't have any relevant financial relationships to disclose. This is just a high-level overview of who we are.

We're a very large health system site that, the map of Connecticut here shows you. Our coverage area, we're a multi hospital site. But another important aspect is all of the blue dots represent our community-based clinics, which essentially are our practice sites. There over 300 of them across the state, but also integrated are deeply rooted in what we do in our community relationships. And you can see some of those represented by the church steeples that are across the state. And this is our clinical catchment area, but also what we consider to be our clinical research hub.

This is just a high-level representation of the demographics of who we see in our clinical practice. And what you'll notice here is that the demographics of our clinical catchment area greatly mimic the demographics of the US. And also, unfortunately, the disproportionate number of minorities, underrepresented minorities, who were impacted by COVID, which is also pretty representative of what happened in the U.S. And so we very much see ourselves as a microcosm of the U.S.

The way we think about clinical trials is in this very integrated approach. And so we message the fact that clinical research and clinical trials are part of how we see providing the best care, ensuring that the clinical research and clinical research participation are presented as options within the context of care. And we do this in a very deeply rooted community engaged approach that's bidirectional and partnered with the community. And so a lot of this is around

messaging specifically developed by the community leaders. And you see this, represented here, on the screen.

Really importantly, this bi-directional partnership we're moving into year 13. So this has been a long-standing partnership, and this was actually the celebration that we had at Yale with the FDA Office of Minority Health and Health Equity around our clinical trials diversity innovation day for our 10th anniversary a few years ago, prior to COVID. Really important and key to the community programs and how we think about clinical research is that our program, which is a partnership with the AME Zion churches, African Methodist Episcopal Zion churches of Connecticut, and several community-based organizations, including Junta for Progressive Action, which is primarily Latino facing, is our program leaders are actually selected by the community. So we're not assuming who has a sphere of trust.

The community leaders are letting us know that our commitment to the partnerships are not trial or molecule specific. They are actually commitments to the program itself and to the organizations. We have compensation for the time and effort that our partners spend with us, that they also help us set our strategic priorities. And really key to this is that everyone who participates in the partnership has significant training in clinical research. Many of the individuals you see here pictured, who are a part of our initial program focus, and they have over 300 hours of training. Also really important is they help us to think about each trial that we're bringing on board, not only how we might optimize specific work of the clinical trial, but they help us think about patient burden and uptake issues. They also help us make sure that our trials are accessible. So, much of our activity, when possible, is done in a decentralized way and could be done within the context of their organizations.

Really importantly, in some specific examples, was in 2020, our community leaders became very interested in heart disease and stroke prevention. And so, a very concrete example

relevant to this meeting was they became aware of a cardiac device that really had potential, had shown potential in trials to reduce stroke risk, but felt that the cardiologists indicated the community really didn't understand when this device was recommended. And so the community leaders implemented a campaign. These are, what you see here, are some of their live radio shows where they were talking about cardiovascular risks, but also the importance of understanding this device and some of the risks associated with it. So really, kind of making the FDA labeling instructions translated into some culturally appropriate language to improve the uptake and understanding of the benefits of this device.

You can see, and you'll be getting a copy of my slide, some links where you can hear more about some of these activities of our community leaders. But really importantly, this has been an incredibly successful partnership, leading us to tremendous growth within the context of our clinical research, but also, when we started this partnership more than a decade ago, our representation and clinical trials of underrepresented individuals or persons of color was around 2 percent. Across our entire trial portfolio, it's closer to 35 percent, but where our cultural ambassadors are specifically engaged, it's around 61 percent. And that’s an average that has been over multiple years. And also the retention rates are just incredible, from 97 to 99 percent retention to through the end of the trial.

We feel like a key part of some of these successes has also been our partnership and our MOU with the FDA Office of Minority Health and Health Equity. What you see here are essentially the terms of the MOU and some of our accomplishments over the years. We also have recently been awarded a grant from the Office of Minority Health and Health Equity, where we've attempted to really understand some cultural and linguistic, and methods of communications utilizing some of our technology. And so, this has been a really important way that we've looked at clinical research.

We also, to the point of decentralized trials and bringing trials closer to the community, we have a new partnership funded by pharma, that's a part of, where we're partnered with Morehouse Vanderbilt and the RCMI institutions to initiate clinical research in the community. And we're really excited about that as well.

I just wanted to end on some important points that are really relevant and key to this meeting. Our partnerships with the community have led us to this incredible success, but knowledge alone is not power. We need to make sure that community members actually understand the importance of regulation and the meaning of regulation. We feel like that's been an important component to how we build trust, that it's taken these long-term and sustained investments. I've included here a few of the questions that were key to our partnership in addressing.

Also, I wanted to leave this group specifically with a few points related to our FDA partnerships and how we think about some of these activities. Decentralized trials, we feel like, has tremendous potential to bring clinical research closer to the community. However, it's not a magic bullet. We need to make sure that we consider patient burden and we're not just transferring tasks from the clinical research sites to the patient home. Multiple technology solutions often add tremendous patient burden and expense, and also add to lack of satisfaction with trial participations. And our partnership with the FDA has been really meaningful and we feel like tremendously has enhanced the trust of our community locally, not only in the FDA review process, but, as you can see from our example, address some issues that are post approval, related to uptake. With that, I'd like to stop. When you receive my slides, you'll have some additional content that could give you more information on our program and our success. And again, thank you for the opportunity to speak to you today.

Advancing Health Equity in Medical Devices: Health Literacy and Community Outreach

— Behtash Bahador

Mr. Bahador: Hello, everyone. My name is Behtash Bahador, and I'm the Director of Health Literacy at CISCRP. I'm so happy to be here speaking with you about advancing health equity in medical devices. CISCRP stands for the Center for Information and Study on Clinical Research Participation. We are an independent nonprofit organization, and since 2003, we have engaged patients and the public as partners in clinical research. We collaborate with a number of different stakeholder groups, from foundations and associations to industry, including pharma and biotech, as well as academic institutions and government agencies. Our work is really centered around collaborating with patients and the public to understand their needs, and then working with researchers and other stakeholder groups to help meet those needs throughout the process of clinical research. Of course, being the Director of Health Literacy, I like to look at health equity through the lens of health literacy.

A lot of folks think that health literacy is just restricted to understanding information. However, when you look at the definition, you see that it's actually the ability to find, understand, and use information and services to inform health-related decisions. Healthy People 2030 added to the definition of health literacy to also place the onus to support health literacy on organizations. And so, organizations equitably enabling individuals to do the finding, understanding, and using of information and services becomes a critical component of health equity in research and in product development.

As we know, equity and equality are not the same thing, where equity is, again, about understanding and meeting the needs of those individuals and populations who most need to have their needs met. Historically, you may have seen images such as this to represent equality versus equity, but we've come to understand that even these are problematic, showing only

individuals of color standing behind dilapidated fences on wooden crates hundreds of yards from a baseball game, rather than being a part of the baseball game and not standing on wooden creates. Therefore, there are much better and more up to date images that we can use to represent the difference between equality and equity.

A key component of equity and health literacy is, as I mentioned, first having awareness of what are the needs of this population, learning and understanding their attitudes and values. Next is the part that most folks think about, cultural competency, where we match the audience's logic, language, and experiences in our communications. However, a third and really important component of this is humility. Everybody, from researchers to any other folks that work in clinical research or have an impact in clinical research, taking the time to examine their own attitudes and beliefs. This is not just about explicit bias, but it's also about implicit bias, and there are tests that can be done that are out there free of charge. And if you do engage with those tests, I encourage you to take the results in, take some time to set them aside, and then come back, reflect again, and think about how you might think about things differently, come up with solutions in a different way, that maybe perhaps put aside some implicit biases that we are all prone to hold.

At CISCRP, we've taken all of those practices and concepts that I've just mentioned, and we've put it into play, particularly in the co-development of our educational materials, especially our brochures. These brochures are intended for various different populations that have been underrepresented in clinical research. Racial and ethnic groups, as well as age groups, such as pediatric populations. How we did this work was to make sure that we have individuals on the team, we brought in community members, individuals that are subject matter experts in their own lived experience, and then other subject matter experts who have worked with those communities, to help us in the initial development of the content. Then we took it to

an anonymous survey to get feedback from 500 members of those communities. This allowed us to ensure that the materials are culturally relevant and competent, but also that we are indeed addressing the key concerns and barriers to participating in research and also helping to truly guide decision making. Not just providing information, but providing the steps that folks may need to take in order to engage with clinical research.

Through all of our research at CISCRP, we found a number of different barriers to diversity. A lot of this stems from mistrust. Folks do not want to participate in research because of particularly the past injustices that have created fear of harm and unethical treatment in research. However, we know that it's not just those past injustices, but the current injustices that folks face on an everyday basis. That may be in clinical research, but it's more so in their regular care, in their daily care, in how they're treated at various different institutions. And whether they are provided access and coverage for products, medical products, and treatments that they may need. The research community not acknowledging the past or current injustices that folks face has been an important focus for us, to change that, and we have done so.

Accessing information, as I mentioned in the definition of health literacy earlier, continues to be an important barrier to having more diversity in research and product development. And so, we need to think about the use of technology. And of course, this also extends to devices. Not everybody has access to internet. Not everybody is able to use devices, and taking these considerations into account can help us not only to have better participation in trials, but also to ensure that products that are developed, including devices, are actually more equitable for all of the populations that need to use them. All of this information, by the way, will be provided to you in slides, and there are additional slides that provide some more details and more insights in the appendix.

As we come to a close here, I do want to share some insights from CISCRP, a biannual survey that we do. We conduct this in order to gain the insights about the perceptions and experiences that members of the public, past trial participants, and patients in general have, about research and research participation. In our most recent survey, from two years ago, although we have a new one coming out, you can see that respondents said they're comfortable with providing access to the medical records. They're comfortable with completing parts of research studies in their home. Using personal computers and even conducting simple medical procedures, again using devices. However, we did observe that there are some differences in these preferences along racial and ethnic groups. And so these are the types of things that really help us to understand what actions we need to take to ensure there is equitable access to research, first of all, and then equitable enablement and efficacy of devices for these various different populations.

Taking a step back and thinking about health literacy across the life cycle of clinical research. How can we provide information and services across the life cycle of clinical research in order to help folks from before the time they get into a study, to when they are in the study, to after? There's a number of different ways that we do this. I'm not going to go through each one of these, but it is important to consider that these are all connected. And that starting early, having an understanding of the various different needs of populations, providing the information, not only to those individuals and communities, but to researchers, so that they can then implement across the life cycle of research. For us, general education and awareness continues to be an important part of our work. We want to enhance the public's awareness and literacy of clinical research, the importance of participating in clinical research, and changing the perceptions of individuals who do.

And finally, highlighting the importance of diversity, equity and inclusion in research. And this also includes not just communicating with patients in the public about DEI, but also making sure that researchers themselves are fully engaged in understanding the importance of having diversity in research. Our approaches go from grassroots campaigns to more innovative ways and solutions to engage with folks, such as having a pop-up pharmacy that is empty. But also, recently, we have relaunched our educational RV, which is an experience where folks go onto the RV, there's essentially an exhibit that shares information about clinical research, and this year's iteration is partly funded by the FDA's Office of Minority Health, and it does focus on diversity, equity, and inclusivity.

I know that was quite a bit of information, but I hope that this was very helpful for folks. And again, thank you for the work that you do as part of the Patient Advisory Committee. I applaud you, and I hope I provided you with some things that you can take away and apply in your every day. Thank you so much.

Mr. Conway: I'd like to go ahead and thank Ms. Tesheia Johnson and Mr. Behtash Bahador for their presentations. We will now proceed with a presentation on the NIH All of Us research program by Dr. Karriem Watson, Chief Engagement Officer, All of Us Research Program, National Institutes of Health. You may now begin your presentation. Thank you.

The NIH All of Us Research Program: Accelerating Health Research Through Community Engagement — Dr. Karriem Watson

Dr. Watson: Thank you so much. While the slides are being pulled up, it's exciting to be here today. And I want to thank you all for the invitation from the FDA to the Center for Device and Radiological Health, to present on our All of Us research program. And you'll actually hear in our presentation, a lot of the same things that you've heard from my colleague, from our other partners, about the importance of centering communities' voices in this work, the importance of

making sure that engagement is bi-directional, the importance of making sure you include participants and community members as partners, and that you build upon the assets and the rich knowledge that community members already bring to this work. So, excited to build upon the dialogue that's already happening.

My name is Dr. Karriem Watson. I am the Chief Engagement Officer of the NIH All of Us research program. And so today, what we hope to accomplish is to introduce the All of Us research program to some of you who may not be aware of what the All of Us research program is, to discuss the importance of advancing genomics through community engagement by including populations who have been historically underrepresented in biomedical research. Another thing you heard here today already, the importance of diversity, equity, inclusion. And lastly, to highlight the program's community participant engagement framework. You've heard already a lot of what should happen. Hope to provide you a little bit of an example of how we actually do some of this work through an adapted ecological model. Next slide.

The All of Us research program, unlike some research studies that are looking to answer a particular research question, the All of Us research program is setting out to enroll a million more people over the next 10 years that can truly drive precision medicine and drive genomics research. To date, the All of Us research program is the largest genomic research program in the world, with over almost 700,000 participants enrolled, with data on over 475,000 participants, bio samples on over 491,000 participants, including information from electronic health records. The mission of the All of Us research program is to accelerate health research and medical breakthroughs, enabling individualized prevention, treatment and care for all of us. The All of Us research program really is built on the fact that, this concept that, medicine is no longer never had, and it really has never been, an all in one one-size-fits-all approach. We understand now that where we live, we often say that someone's DNA or their ZNA, their zip code, their

zip code neighborhood association is going to be just as important to their health outcome as their DNA. And understanding this from an epigenetic perspective is so important.

We also like to pride ourselves in the All of Us research program in understanding that place matters. And historically, one of the reasons why we have not seen the diversity and including participants in research, is because place also matters. Historically, for example, research is not often conducted in places and spaces where populations who carry the greatest burden disease get their care. For example, fairly qualified health centers. If you look at this map in the light blue, this is a depiction that shows that the All of Us research program has been intentional in our recruitment of our sites and our participant engagement. And today we've enrolled at least one participant from every state and U. S. territory across the U.S., and the darker areas in blue here represent those health care provider organizations which are recruitment partners. Next slide.

One of the key factors in our success has been our network, what we call our community engagement ecosystem. That has allowed us to ensure that our diversity, equity, inclusion numbers are over 80 percent of our participants are what we call underrepresented biomedical research. That's just, that's also populations beyond just race and ethnicity, but approximately 50 percent of our participants are actually diverse in terms of race and ethnicity. I'm trained as a cancer disparities researcher. And my work was in community-based participatory research, and I often had to deal with large secondary data sets that were not reflective of the populations that I served or populations that carried the greatest burden of disease, but through intentionality, through community partners, through community engagement, and through intentional site selection, we've been able to achieve something unprecedented in genomic medicine, with about 50 percent of our participants underrepresented by race and ethnicity. And you'll see that breakdown there on the left. Next slide.

How do we do this work? We do this work through an adaptive ecological model that we call the community and participant engagement framework. I love what one of my colleagues said earlier, that knowledge alone is not power. We so believe in that. And so we think about this concept from an ecological approach of outreach and awareness. Making sure that we reach out to people to make them aware of the importance of not just our program, the All of Us research program, but the importance of precision medicine, the importance of research. We then talk about education and access, understanding that what it takes for some populations to access a clinical trial or access research can be filled with a lot of barriers. So how do we mitigate those barriers? Then we engage, enroll and retain.

One of the things we pride ourself on, in our program, is that successful engagement doesn't always end up with recruitment in a program, and that’s because that successful engagement may be building trust. It may be building a partnership. It may be addressing some of those historical issues that have led to some of the reasons why populations have justified medical mistrust. We don't talk about medical mistrust in the All of Us research program as if it's often not justified. There's a reason why certain populations do not participate and have not participated in their research. And some of that has been because of systemic racism and exclusion, lack of access, and lack of awareness. And we address those things head on in our program. And then we engage participants as partners. And we also think about knowledge mobilization. How do we get that information out to our partners? Next slide.

This is an example of one of our partners. We are very fortunate in the All of Us research program to have a network of over 115 national community engagement partners. And what you'll notice is that our partners that we work with, they reflect populations who are historically under-engaged or underrepresented in research. We actually don't use the term hard to reach populations in the All of Us research program, because we don't believe that

populations are hard to reach. We believe that populations are under-engaged. When we think of terms like hard to reach that puts the onus on the population, but under-engaged puts the onus on the entity to say that we need to do more to do the outreach and the partnership development.

This example of work by one of our national engagement partners, the National Alliance for Hispanic Health, who's been very instrumental in supporting the fact that the All of Us research program has about 16 to 17 percent of our participants self-identify as Hispanic or Latino. We also pride our program on the fact that when we launched our program, it was launched in both English and in Spanish for the complete experience of the program. With the help of the National Alliance we've been able to reach over 3000 participants and having quality conversations, when they've been able to work with an event called the mobile engagement asset. You'll see it, that's a van at the top of the program. That van has been that mobile engagement asset, that's what you call the MEA, is so instrumental in getting the word out to populations who historically would not have access. And then you'll see at the bottom, even thinking about how do we get the knowledge that we've learned from our program out to our participants. And this is just an example of how we operationalize our framework with one of our national partners. Next slide.

And I'll end with talking about a research spotlight. One of the things that we often hear in our program is the digital divide. Understand that there's still a large portion of the population that don't have access to devices and don't have access to innovative ways. Our program is unique in that we collect a multitude of data types. In addition to the biological samples of blood, the blood and saliva that allow us to get to the genomic data, we also collect survey data and even Fitbit data. And in that Fitbit data, we've been able to include over 41 percent diverse participants through intentionality and partnership development. So hopefully

through letting you know, our partnership work and our site selection, our other engagement ecosystem, you've seen that we're committed to intentionality, intentionally including populations who have been historically underrepresented in biomedical research. And I hope to be able to answer your questions during the discussion section. Thank you all so much for your time and attention today. Next. My information to reach me is actually here.

Open Committee Discussion & Clarifying Questions

Mr. Conway: Great. Thank you very much, Dr. Watson. Truly appreciate it. And also the role of NIH today in your presence. Now we'll go ahead and do open committee discussion and clarifying questions from the committee. As a reminder, this portion is open to public observers. Public attendees may not participate except at the specific request of the committee chair. Additionally, we request that all persons who are asked to speak identify themselves each time for the purpose of the transcription. So let us go ahead and begin. Does anyone have any questions from the committee, or any clarifying questions, for Ms. Tesheia Johnson, Mr. Behtash Bahador, or Mr. Karriem Watson? Committee members, please turn on your video monitors, unmute your phone, and state your name when you speak. Please place yourself back on mute once you're done speaking. You can physically raise your hand or do it on the platform, and I'll call on you. Why don't we go ahead and start with Anne Peters. Doc, go right ahead.

Dr. Peters: Yes, I loved all three presentations, and you're sort of preaching to the choir because for the past 23 years I've been embedded in basically an FQHC in East Los Angeles doing community-based research. But I have two questions that I'd love to get your input on. The first is, is when I first started working in East and South LA, they said, why should we do research with you, because all your researchers come from your academic institutions, spend a year or two here with us, and then you leave. You take all your data and you give us nothing

back. And that's a big issue, because I think that still happens, and I'll bring that back in a minute.

But the other problem is that when I try to do a multi-center protocol, the protocols aren't written for my population. They're written for the standard people who do protocols. And because I do device research, that means that a lot of the information is written at an 11th grade level and has helplines that don't speak the language and don't understand my patients. And so, I have a real problem trying to fit my patients into protocols. And that's hard. It's a barrier for me and then my patients. So I try to have my patients choose what trials they want. So I'm just now doing a study in patients with an automated insulin delivery system. And just yesterday, even though this patient knew at the end of the trial, the device would be taken away, she said to me, 'How can you do that? This device has helped me so much. How can you stop it when the trial ends?' And she can't get it through her insurance because it doesn't pay for this device. So how do you reconcile all of this, and what advice do you have for me in doing clinical trials in devices in my underserved population?

Mr. Conway: So if one of our speakers would like to go ahead and take that on?

Ms. Johnson: This is Tesheia Johnson. I'd be happy to at least share our experiences with that, and we can relate as well. Our catchment area does include three FQHC partners that we're working with, and we have research active there. And, you know, one of the goals of our cultural ambassadors program is actually to try to address some of those issues up front. So, if we have protocols where we really have concerns about whether our entire catchment area will be able to participate, including, you know, populations that have been more marginalized or underrepresented in research. We try to take it to the sponsor early to say, you know, are there opportunities still? We recognize where we are in the studies, but are there opportunities for us to address some of these issues that will really be barriers? In some cases there are, that is

limited. And we know that generally, especially if we're talking a later phase trial where they're seeking market approval of a device or a drug. But we still try, and we're hoping that education will penetrate and be able to address it in our NIH studies and our agency studies, where we're dealing with not-for-profits and we have more flexibilities. We actually really push the investigators hard to address those and that investigator-initiated research.

And then the last thing about access, we also have that same conversation up front to say, look, are there going to be access studies at the end of this? Are you going to have programs where participants are going to be able to address these issues post-trial? And so really having that community engaged feedback from individuals who are truly educated about what all of these pieces are, so that we can have these conversations as part of our negotiations in accepting the trial. It's not always successful. But that's why I think meetings like these are so important, to say to sponsors of research that these are really important issues. And the issues of trust and an access are going to continue unless we're really able to address them in a systematic way and they're not all one-offs on the trial level. So, you know, that's really been our experience. We have had some successes doing that. And so I'd encourage you to have that input early so that you can try to have it as part of a contract negotiation conversation.

Dr. Watson: Yeah, and I'll just echo that briefly. I think of the role of the funder, I also think as the funder it is also our responsibility to make sure that equity is baked into it. For example, when we did our Fitbit study, we were very adamant about addressing the fact that if we would have worked with only our participants who already had Fitbits, that population would not have been diverse. It would not have been reflective of populations who carry, you know, live with the health disparities that we're trying to address. So we were intentional about identifying a cohort, a convenient sample, that actually was diverse, and making sure that those who didn't have device, that we provide the device, and wrote it into the pilot project that you would be

able to keep the device at the end of the study. And I can't agree with my colleague more that to have those conversations up front in the negotiation. And I also used to run research at the FQHC prior to joining the NIH and those are some of the conversations I would have when building the research project.

And I also, ironically enough, found that public and private partnerships were another way that I could often, on the back end, provide some of the device and support that may not have been a part of the grant budget, if you will, but a public private partnership sometimes allowed that. Like, we had a home, a blood pressure project, through the FQHC that provided home monitoring blood pressure kits, but then once the study was over, as you can imagine, then the patients had to return those blood pressure kits. I worked with the local pharmacy to get those blood pressure kits to get donated to the FQHC so that we could then provide our patients, that the FQHC, with blood pressure kits after the study, so that they wouldn't feel that it was helicopter research and that they only had that device for the time period of the research.

Mr. Conway: Thanks, Dr. Watson. Behtash, do you want to respond to Dr. Peters?

Mr. Bahador: Really, again, just to backpack on what folks have said, absolutely 100 percent. It's really great to hear, you know, Dr. Watson talk about some success stories, because, you know, the winds of change take time to, you know, wear down mountains, and certainly have been mountains built up here, you know, the barriers that really prevent us from having equity in representation and in trials. So, it does take time. Having said that, what's really also important is continued sharing of not just the success stories, but also methodology to actually, you know, sort of have metrics, and gain, measure impact around these patient engagement and diversity, equity, inclusivity, you know, projects. Because a lot of sponsors will be looking at, you know, how to balance us bringing this new product, this new device to as many patients as possible, as quickly as possible, versus investing more time to really adequately ensure

diversity adequately, and then subsequently adequately ensure access. So the more that we have the data out there, the metrics, you know, the learnings, publications, et cetera, that support, taking the time to make sure that we're doing all these activities that we've talked about, the better off that we'll all be.

Mr. Conway: Great, thank you very much. Let me go ahead over to Necie Edwards. Necie.

Ms. Edwards: Hi, my name is Necie Edwards, and I have two questions. One is for Ms. Johnson and one is for Dr. Watson. So I want to start with Ms. Johnson. You, when you put your slides up, and by the way, I've enjoyed all of the presentations, but on your slide, Ms. Johnson, I saw that it mentioned that with the healthcare ministries and the churches, how they are involved and AME is one of your partners. So, was it the community that selected the churches? Because I was wondering if you all had ever considered partnering, in addition to AME, with COGIC (Church of God in Christ), as well as the Baptist Church. I know within the Baptist churches, many of them also have health ministries. And also, the communities, it sounds like they are very engaged. So, do you also do presentations at the libraries? Many people of color, also I've seen presentations done in beauty shops, barbershops, as well as churches.

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I think this is what Necie was referring but would love additional input

And then for Mr. Watson, you mentioned for All of Us, it sounds like your organization is all over various communities. So how do you determine which one has the greatest needs? Because when you mentioned about the van, in my mind, as you were speaking, I was trying to visualize, and I said to myself, wow there must be a lot of vans because how are you, you know, hitting the ground in all these different communities. Thank you.

Mr. Conway: Go right ahead, Ms. Johnson.

Ms. Johnson: Thank you for the question. And I agree with your comment earlier, by the way, you can see that we were on the radio shows and that's a really fantastic way of reaching the

audiences. But in terms of the partnership with the churches, we started with the AME Zion churches of Connecticut, because that actually was a denomination that was identified by community, and early focus groups, before we started this partnership, as one of the denominations that might be easier to organize because of the structure of the church. That they had a structure sort of like a corporation, in that within each church there was a health minister that was assigned. And so, it'd be an easier way for us to get started. In our, the partnerships that I mentioned at the end of our slides, our new partnership, a grant from pharma, as well as some of our work with the FDA, we're bringing in other partners and other denominations. But I think one of the great things about the partnership as it stands now, it's 17 churches. But those individuals, what they do for us, is help us address access across our entire portfolio and throughout our entire catchment area.

So, although they are the partners who've had all of the dedicated training, when we have a specific opportunity, and this gets to the second part of your question, they then determine how we best go about messaging or access, whether that be a recommendation specifically to add content to the radio show, or, you know, YouTube videos, or it could be that they'll propose presentations, which could be done in barbershops, beauty salons, in churches and libraries, we've had them all over the place. Two Saturdays ago, we were in one of the local community parks in the neighborhood, with a large health fair that had table tents for 30 of our trials, because they thought that that was the best way to actually message about some of that research. So, the beauty of the partnership is that they help us determine how we then message with each one of the activities that we're doing. And so it's not limited to just the things that we've talked about.

And then the last thing I'll mention, one of the other things that I think is not always thought of, especially in underrepresented populations, is the messaging from the health center.

But in our research with our FDA Office of Minority Health and Health Equity, we're actually seeing that if we culturally optimize the message, even the messages we send out through our MyChart and through our health system, get read at an enormous rate. And so it's really about that partnership that helps us address the right message at the right time. And the right method of getting out to them. I hope that answers your question.

Ms. Edwards: Thank you.

Dr. Watson: And I'll be brief, just, I know, in the interests of time. Thank you so much for your question. So, in giving you a little bit more detail about the MEA, it's a mobile engagement asset. So, here at the NIH, and the All of Us research program, we have a network of over 115 community partner organizations that actually receive an award from the NIH to provide engagement support. One of those partners is an organization, a montage marketing, through, and they provide what they call mobile engagement assets. Those vans. The way we determine the geographical place, so that van has what we call the All of Us journey tour. It takes a tour across the entire U.S., but it prioritizes sites and going to places where we don't have local engagement and enrollment sites. So, the van would not likely come to Chicago, because we have three enrollment sites at Chicago at UIC, University of Chicago, and Northwestern. But it would go to Colorado. And when it's in Colorado, it would partner with one of our local community engagement partners, or our national community engagement partners, to prioritize a population who is under-engaged. So, we really do a network analysis, if you will, to say, where do we not have an enrollment footprint? And then we try to situate our mobile engagement assets in those communities. And I just want to underscore the importance of faith-based partners. National Baptist Convention USA has been one of our national community engagement partners since, for over five years now in our program, helping a lot with faith-based engagement too. So, thank you.

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Ms. Edwards: Thank you.

Mr. Conway: Thanks Dr. Watson. Dave White, go right ahead.

Mr. White: Thank you. This is Dave White. My question is for Behtash, but other presenters can feel free to comment as well. One of your slides, you broke down health literacy into two components, being personal health literacy and organizational health literacy. And it occurred to me that, perhaps community health literacy might be considered for inclusion as well. I say that because I had the privilege of working for a gentleman who founded a nonprofit, and he was so convinced that if a community galvanized to take charge of improving its own health outcomes, that that's really where the magic happens. And that's where, you know, health equity can be addressed not only with medical devices, but in health care overall. And just listening to everyone's comments and presentations, all revolving around the word community, I was wondering if you would consider including community health literacy in that paradigm, or is it part of organizational health literacy? And I'll just stop there.

Mr. Bahador: I think that's an excellent point. You know, the addition of the organizational health literacy component to the definition in Healthy People 2030 was really meant to address the concern that, by focusing only on personal health literacy, we place the onus entirely on individuals, right? To find information, understand information and services. And so adding that organizational component was meant to address that, you know, alleviate some of that, and make sure that you know, as Dr. Watson said, that other stakeholders, other than the, you know, the individuals or the patients or the public, are taking up the mantle to help improve health literacy. And having said that, you know, perhaps unintentionally, I think a lot of folks are, CISCRP included, but probably the All of Us campaign too, from what I've heard today, and also from what I know about it, we do take sort of that community-based approach, right? And so I think it's an excellent idea, to sort of, you know, view things from that lens. And it's

something that, you know, if you'd like to, yeah, work together to sort of get that out into the ether so more folks can recognize that and, you know, use that terminology to move forward their initiatives and their focuses, I'm more than interested to work with you on that.

Mr. Conway: Great. Thank you. Any of the other speakers want to comment on what Dave White asked? If not, we'll go ahead to Dr. Joniak and Grant, if you have a question.

Dr. Joniak-Grant: Yes, thank you. So this is really a question for the panel, but Dr. Bahador mentioned the importance of recognizing, and grappling with implicit bias. And we know this contributes, right, to inequity in devices. So, what I'm wondering, is sort of what steps would you all recommend that can be taken to sort of combat implicit bias in device design, and are there, in your experience, any sort of red flags to look out for when you're looking, reviewing a clinical trial or doing an evaluation of device, that might signal that that really hasn't been taken into account before it goes to market, right, it all becomes apparent unfortunately, usually quickly.

Dr. Watson: Sure, I'll start. Okay. I think one, that I really appreciate that comment. I think one of the most important things, although the All of Us program is not doing device research per se, I think the concept of implicit bias is generalized across a lot of other areas. And one of the areas we see it, for example, we do a lot with artificial intelligence and machine learning in our platform. And one of the things you have to do in those settings with implicit biases, A, acknowledge that it will exist. You know, I'm public health trained and one of the things we like to say in public health is that you will never eliminate bias. You will only minimize bias. And I think if you go into research design with the concept that you have eliminated bias, and that you do not have implicit bias, then that is part of a huge problem upfront. You have to acknowledge that it will exist and do your best to mitigate it.

I think another thing that we've seen, that we've learned from the community, with the community, is the importance of diverse voices and diverse backgrounds, even in training, at the table, to help mitigate some of that bias. Because when it, particularly for us, when it comes to artificial intelligence and machine learning, we often say that the algorithms out are only as good as the experiences in. So you have to have diverse voices at the table, helping to design the research and design the product, so that you can take the lived experience and all those things into account when it comes out. And Dr. Peters described it. You know, I worked in the FQHC as well, and did implementation science. When things are not designed for and with the community, and you try to implement those processes in the community, those findings are often not generalizable. And so, it's really important to have diverse stakeholders at the, diverse, excuse me, partners at the table and helping design that research and acknowledging that that bias is there. To mitigate it, but it's, I don't know, ever feel that we eliminate it.

Mr. Conway: Great. Thank you very much. Let me just jump in here, folks on the questions themselves. So, the ideal here is that you're posing questions to the speakers that help inform the discussions later, on the questions from FDA. And so what we're really doing is driving for clarifying questions on the presentations, again that help inform how you're going to be answering and discussing things later. But I just want to put that out there because we're not debating amongst ourselves or anything like that. And the content that we're trying to get from the speakers is for clarification, to inform that later discussion. So, let me now run over to Ian. And go ahead, Ian.

Mr. Burkhardt:Yes, this is Ian Burkhardt. My question is for Behtash. When you're looking at the surveys that you put out, for your pamphlets and the information that you generated, and you said you got over 500 responses from those surveys. Do you try to match the demographics of the respondents to the condition or disease that you're looking at, specifically?

Mr. Bahador: Yes. And thank you for the question. In this case, we're disease agnostic, right? So, we haven't targeted those specific materials to individuals that have a particular condition, nor any particular therapeutic area. We do that with other materials that are, you know, study specific or, again, you know, condition specific or disease specific. But just to go back to those particular brochures, each one of them were tested with 500 individuals from the respective community that we were hoping to reach. So, whether that was Hispanic and Latino communities, or Black and African American communities, or LGBTQ+ communities, within each of those, 500 individuals. And so, you know, in total 2,500 individuals. Hopefully that helps clarify.

But, again, just to go back to the other part of that. Definitely, you know, anytime we create any materials, we want to, at the very least, have it reviewed by individuals that are representative of those who would actually receive the material. And so, we would do that through what we call review panel. And then there are, you know, ascending levels of, you know, sort of patient engagement and patient insights that you can get through different methodologies. But a great question again. Thank you.

Mr. Conway: Great. Thank you very much. Thank you, Ian. Dr. James.

Dr. James: Hi, Jijo James. Again, great, great presentations. My question is primarily for Ms. Johnson and perhaps Dr. Watson as well. Again, given your role in community engagement, given your role in having conducted both pharmaceutical and medical device trials, and given the topic today around advancing equity for medical devices, anything that you feel this committee should know about the uniqueness or nuances around medical devices that might impact health equity? Specifically, when it comes to running clinical trials.

Ms. Johnson: You had a great, great question. Sorry. Tesheia Johnson. I forgot to announce when answering, but that's a fantastic question. I think devices do present quite a few

challenges, in the context I'll say first of when we're studying devices, there's oftentimes access issues with the devices themselves when we're putting them in a community setting. There are issues, as an example, a lot of the devices communicate through Wi-Fi and other things. And so we know the Wi-Fi issues that, those things are well known. But a lot of, especially in my marginalized communities, Wi-Fi might even be something that, they're responding to surveys or device activities within the context of using a personal cell phone. And then, if the study is not considering patient burden, as it relates to things like their plans, they might run out of minutes, and other kinds of things, that are specifically related to that population. It becomes an access issue. It becomes an issue for reimbursement, and it will limit participation.

Also, oftentimes, especially in device studies, we find that sponsor's studies, they like to throw on multiple devices, answering multiple questions, and it also creates kind of confusion for the patient. Sometimes they're coming from different vendors. Different vendors will have different passwords. All of those things add to sort of this landscape of patient burden that's not really addressed generally in protocols. And so I think, you know, really considering those kinds of issues when protocols are in the design phase, and having adequate representation across multiple communities so they're really thinking about sort of these lived experience aspects. Also in device studies, sometimes with populations where there there's caregiver burden. And caregiver burden isn't adequately thought about. So I think this entire issue of a burden is one specific that we should look at.

And then, a really unique, some unique challenges that we see in device trials related to two things. In our experience in minority populations, there's generally a distrust of activities related to hospitalizations. And so, really a messaging around, importance of messaging around hospitalization and hospital-based research, has become an important aspect to how we think about recruitment and how we address it proactively in advance of that, of enrollment, and

there should be campaigns specifically targeted around some of these issues where there's specific trust.

And then, there's also, we are seeing with minority participants, in particular populations of color, when there's something implanted. There's a real distrust, like, what are they doing with that information? What kind of data are they seeing? Do they have ability to see other kinds of data besides the data that they're telling me about? Can they track me in some way that's inappropriate? And so really, all of these things really not only affect the participation within the trial, but we know from our work in the example that I specifically talked about, we know that there's a concern, after, even after approval, did the FDA consider all of these factors? And so I think that there's really important things that this committee could think about in the context of both design as well as the post uptake that would really enhance trust by populations of, by all populations, and not just populations of color, marginalized populations.

Mr. Conway: Great. Thank you very much, Ms. Johnson. Let's go ahead to Ella Balasa. Go ahead, Ella.

Ms. Balasa: Yes, thank you. I'm Ella Balasa. I first want to say, to Karriem Watson, I commend your comment, where you stated that successful engagement isn't just recruitment, but it's, you know, building trust and unity and then your recruitment can follow if that that foundation is built with that population. This is to all the presenters. Can you share some specifics on how you measure success with different communities, using some of those various innovative engagement strategies that you mentioned, like the pop-up pharmacy with the mobile engagement asset or vehicle. I really want to understand how that, the success, how that's measured and what's the impact and how that differs, be for the recruitment of device trials versus other regular trials.

Mr. Bahador: I can jump in very quickly. Hi. Hello. This is Behtash Bahador. Thank you for the question. So, just specifically, to try to be as brief as possible, for that FDA grant funded mobile education initiative, we will be providing a pre and post survey to measure the perceptions of research and understanding of research of individuals that go through that sort of mobile educational exhibit. It's essentially an intervention, and we'd like to measure the impact of that intervention, on the day of. And then a few weeks later, those individuals will again receive another survey, to further assess not just their perceptions and knowledge, but also how this may or may not have changed their behaviors towards research. And that does include, of course, as you mentioned, not just have you thought about participating in trials, but have you thought about getting involved, being on an advisory committee, or otherwise engaging in clinical research in a way that can have a positive impact for your community.

Mr. Conway: Thank you, Behtash. Let's go over to Naveena Yanamala.

Ms. Yanamala:I'm Naveena Yanamala. Thank you for the great presentations. And my question is to all the speakers today. Underserved communities often face social determinants of health that significantly impact their well-being. Given that, how do these aspects are taken into account when you are collecting data and analyzing health data to provide a more holistic view of health equity? And following up question is, what information is important to be provided to the public for transparency when it comes to clinical trials involving medical devices?

Mr. Bahador: I may be able to help with the second part of that question, just because CISCRP and myself have worked a lot in providing plain language.

Mr. Conway: Can you just go ahead and state your name for the record?

Mr. Bahador: Sure can. Yeah, this is Behtash Bahador. So the second part of your question about providing results of trials with devices, we've worked a lot on sharing results of trials in a plain language summary for clinical studies of other products. Biologics, vaccines, other

medicinal interventions. And so a lot of sponsors that are doing that are following standards that arise from the requirement in their European Union to provide a plain language summary at the conclusion of a trial. And so there are lots of guidances out there, some that we've also helped to work on, that really lay out sort of 10 high-level elements of information that should be reported from the trial, including results and safety. And folks are taking some slightly different approaches to fulfilling that, but I think sharing information in a plain language summary is critically important.

Then the other part of that, which I won't take too long to talk about, is individual results. That's more of an emerging area. Some sponsors are doing that regularly, at least providing incidental findings, during the trial, to individuals. Or at least sharing unblinding information, making sure that they know what intervention they took or used during the trial. But there's a lot more that can go into determining how individual results should be provided in trials. There is also a pretty large guidance document on that out there.

Mr. Conway: Great. Thank you very much. Let me go to Dr. Fisher. Go right ahead, Dr. Fischer.

Dr. Fischer: Hi, this is Gwen Fischer. I just have a general question for all of the speakers. Wondering if you have practical examples for how you have seen community partners utilized well for some of the earlier phases of clinical trial development, such as protocol development, and if you have best practices for how to appropriately recruit and utilize those community members to assist with protocol development.

Ms. Johnson: I'm happy to address, you know, from our experience. I'm sorry, Tesheia Johnson speaking here. One of the important aspects, the most important aspects, for us, in utilizing the community partners, is the educational process for them. I think that by having them really understand what we're trying to achieve within the context of the trial. And that has included

for us, in any way, education from biostatisticians on the on important aspects of study design as well as RIRB on issues related to risk benefit and other kinds of things. And so, really having these community members and leaders who are knowledgeable about all aspects of research weigh in on our research, not just the early phase, has been key to success because they're able to really understand not only what's required related to regulatory approval and by the FDA or EMA, but also IRB and what patients have to consider. And so their advice comes as real true experts in the space of trial design and community. And that that's helped us immensely to address some of the issues within the context of the earlier phase device studies.

Mr. Conway: Great, thank you. And then, to wrap up here, Teresa Diaz, go right ahead.

Mrs. Diaz: Teresa Diaz, so this question is for all the presenters. You all spoke about a little bit of mistrust with data. Do you have any safeguards in place to protect that data? And do you share it with your participants?

Dr. Watson: Yes, I'll start. This Karriem Watson, All of Us research program. We do have safeguards in place. As you can imagine, one of the areas of engagement that we actually have in our research is actually tribal engagement. And, so you can imagine that we're actually leading up to, we're getting ready to have a tribal consultation on September 28th to actually talk publicly about how we safeguard the data and talk about the processes and the procedures. We actually work with health literacy partners to actually communicate how we safeguard that data to communities, because that was one of the big levels to address a medical mistrust that we found, is that people wanted to know, because we collect HER data along with biospecimen data and survey data. So you can imagine that our participants really wanted to know. So we work with our participant ambassadors, who are actually participants in the program. And we test message with them to say, is this description of the message and how we protect that data, the research, we have a research access board that actually determines how we design the

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research studies that will be available to the public, and even make sure that polarizing language is not included in the description of that data. And all of those things have participant and community oversight in how we describe that process.

Mr. Conwy: Great. Thanks, Dr. Watson. Tesheia or Behtash?

Mr. Bahador: Yes, this is Behtash Bahador. I just, two points. One, I wanted to clarify, CISCRP doesn't conduct any clinical research ourselves. We certainly partner with organizations that do, but we do conduct, you know, patient insights research. And so if we do, you know, gather information in surveys or from the folks that that collaborate with us, yes, of course we have safeguards in place. Couldn't agree any more with Dr. Watson, in that the communication of information to prospective participants and their families and their communities, making sure that that's clear is incredibly important.

And just the last point that I would say is that, sort of logistically and organizationally, make sure that the staff, you know, that are working on the research program can also answer those questions. And that maybe there is a designated, you know, data officer that folks can reach out to in case they have questions, because ultimately, you know, if you provide information in a very clear way and you tell them we're taking care of this, and then folks still have questions, they want to call and talk to somebody, who is, you know, empowered to be the, you know, official coordinator of data for that study, then you should be able to reach that person if you're a participant.

Mr. Conway: Great. Thank you very much. And Tesheia Johnson, I'll turn to you. You have less than a minute, if you could go and give a response.

Ms. Johnson: Thank you. Yep. I'll just, this is Tesheia Johnson. I'll just add one important point for consideration, also. Not just during the trial, but data post-trial, we found to be a big issue for the community. Who has access to the data after the trial closes, and being able to

address that, and having an appropriate response for not only your participants, but your community, is an important aspect of what we found to enhance stress as well.

Mr. Conway: Great. Thank you very much. We'll now take a 10-minute break. Committee members, please do not discuss the meeting topic during the break, amongst yourselves or with any virtual member of the audience. The meeting will reconvene at 2:15 PM. At that time, we'll proceed with Open Public Hearing. Thank you.

Open Public Hearing

Mr. Conway: We will now proceed with the Open Public Hearing portion of the meeting. Public attendees are given an opportunity to address the committee and present data, information, and views relevant to the meeting agenda. Ms. Williams will read the Open Public Hearing disclosure process statement. Now, go right ahead.

Ms. Williams: Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the Open Public Hearing session of the advisory committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the Open Public Hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you may have with a company, or group, that may be affected by the topic of this meeting. For example, this financial information may include a company's or group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you, at the beginning of your statement, to advise the committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking. Thank you.

Mr. Conway: Thank you. FDA has received 11 formal requests to address this committee. We had one person who's not able to join. Speakers who submitted their request to speak by the deadline indicated in the meeting's federal registered notice will be given five minutes to speak. And let me say that again, it's five minutes. We will begin with the Open Public Hearing with a presentation from Dr. Karin Hoelzer from the National Organization of Rare Disorders. Dr. Hoelzer, you may begin your presentation.

Dr. Hoelzer: Hello, I'm Karin Hoelzer. I'm the Director of Policy and Regulatory Affairs for NORD, the National Organization for Rare Disorders. It is my pleasure to provide comments on advancing health equity in medical devices. NORD is an umbrella organization founded by patients for patients to improve the life of people with rare diseases through advances in care, research, and policy.

So what are rare diseases, and how are medical devices used in our community? In a nutshell, rare diseases are those that impact fewer than 200,000 individuals. There are more than 7,000 known rare diseases, that together affect more than 30 million Americans. Our rare disease patients rely on a variety of different devices, including class one, two, and three devices for various functions and organ systems. And on this slide, you see a variety of examples of the types of devices that are commonly used. Given the challenges of product development for rare diseases, off label use is extremely common in our space. Also, many of our patients are what we call medically complex. meaning that they rely on more than one medical device to manage their disease. Devices often play a key role in allowing our patients an independent life in their home.

That being said, many rare diseases are chronic and progressive, which not only means long use, but an increasing dependence on devices over time. Rare disease patients face a variety of challenges in equitable device use. First, many rare diseases impact multiple organ

systems, and devices can be very hard to use for individuals that struggle with challenges related to vision, mobility, dexterity, verbal skills, etc. Because rare diseases are often chronic and require long use, our patients commonly struggle with things like battery changes, software updates, a lack of backward compatibility, etc. Often, our devices require specialized consumable products like feeding cubes or formula, that are often not compatible because similar devices from different manufacturers, which magnifies supply chain shortages and can really disrupt the use of the device.

Oftentimes, devices for us are used beyond the evaluated population groups, comorbidities, and use contexts. I wanted to share a few of our lessons learned in trying to increase the diversity, equity, and inclusion in the rare disease space. The first thing we have learned is that many of our patients face more than one barrier to equitable access, and not all patients are the same. So it's really important to ask the patient community and not assume. Engaging historically underserved populations is hard and might be even harder than anticipated. So knowing your blind spots is really important. Successful engagement requires trust, which is built on a long view and strong ties to the community. So realistic expectations and good partners are key. Also, we've learned that diversity, equity, and inclusion can look very different for different patient populations. And what we found helpful is to start by asking who has been historically left out and why.

Remote technology can be a tremendous asset in more equitable access to care, and really improve the patient centricity. For instance, by making clinical trial participation more feasible, bringing a higher level of care into the home, and giving patients more insights and better tools to control their disease symptoms. But what we've learned is that patients need support to ensure that these remote technologies can be used safely and effectively. The needs will vary by patient and context of use, and they might evolve over time as the patient moves

across the trajectory of his or her disease. It's important to be mindful of potential unintended consequences, and to understand the patient community and their unique needs. Again, off label users or users in specific sub populations may require additional support that may not have been obvious at initial clearance or approval.

Finally, a word about education. Educating rare disease patients and families is a key priority for us at NORD, and we've learned that patients have unique insights. Nobody is a better expert into living with their disease than they are. But, patients need education and support, and asking the right questions is key. There's an inherent tension between the complexity of the regulatory system and the time that a patient can spend. So setting realistic expectations is key. On this slide I'm providing my contact information, and thank you very much for your time.

Dr. Allen: Hello, everyone. I'm Bibb Allen and I'm a radiologist from Birmingham, Alabama, and it's a privilege for me to present to the FDA patient engagement committee about health equity and medical devices, and in particularly health equity as it pertains to software medical device, which encompasses artificial intelligence. I do not have any conflicts of interest, although I have been an officer of the College, and now the Chief Medical Officer for the Data Science Institute. And it's through these opportunities that I've learned that medical specialty societies have a unique opportunity to be an honest broker working with industry and regulators, to ensure that we can promote safety and efficacy in our care for our patients. We're pleased to see HHS's continued focus on health equity. That is certainly true within the medical community as well. And when we look at issues related to medical devices, and in particular, AI.

I want to call your attention to this study from the GAO from September of 2022, where they looked at some of the reasons for the slow adoption of AI in health care, and they found

that incentives and resources were two of the main considerations. And they wrote many health care systems operate on razor thin financial margins, and that robust insurance reimbursement programs will be needed to prevent a two-tier health system. When we look at all the different ways right now that we're trying to pay for AI in health care, it's a very complex landscape. CMS considers AI software as a service, and they have promoted various ways for paying for AI in the various fee schedules. But these are quite disparate and particularly confusing to end users and most developers. We're certainly pleased to see CMS officers write about the opportunities for payment for emerging technologies and are intrigued by the possibility of a parallel review program in which CMS and the agency together can engage with manufacturers regarding evidence development that would allow FDA-cleared tools to get a path, a quicker pathway into adoption because of payment policy.

I think one of the questions, some of the questions, that we have, does the software add value for patients and beneficiaries? Will the software be widely generalizable to diverse patient populations? And can we determine what the appropriate reimbursement is? We saw that, in the last cycle, CMS proposed the development of a C Code that would go from FDA clearance straight to payment for the service. And some of these services are being paid in the OPPS. But there is concern that this will create a large number of individual codes, and really concern is that, will every code that garners FDA clearance actually add value for our patients and the end user stakeholders. So CMS ended up not finalizing this rule, but I think, as we look forward at health equity, and we see other agencies doing that, our key takeaways are that we would like to see improved transparency for end users to help mitigate bias, and then have payment policy that ensures a level playing field for equitable payment policy to prevent a two-tier system.

In summary, the lack of reimbursement for AI is limiting its adoptions, and that many academic and well-funded institutions will likely be early adopters, but small and rural facilities and institutions that are under-resourced may not be financially able to adopt AI, leading to two tier systems, which can disadvantage those who may benefit the most. A reimbursement pathway that parallels FDA clearance is welcome, but it has challenges both for payment policy development and the regulatory process. Thank you very much for allowing us to be here today.

Dr. Dreyer: Hi, this is Keith Dreyer, Chief Science Officer at the ACR Data Science Institute, and Chief Data Science Officer at Mass General Brigham Harvard Medical School. Thank you for the opportunity today to speak on AI medical device transparency. I have nothing to disclose, except to those positions that I had mentioned earlier. When we look at activities going on throughout the U.S. in AI in healthcare, we see a very active industry. If you look specifically in the middle area here, this is from the AICentral.org website, where a lot of the algorithms that are FDA approved are displayed for consumers to be able to review. We see that there's rapid growth, particularly in the last 5 or 6 years, of algorithms that have been approved by FDA. This has created some confusion with the transparency of the information and decision making processes at the time of purchasing. And it's really because of these hundreds of manufacturers that need to deliver information to tens of thousands of consumers, potential consumers, and purchasers, and all the way out to patients. The testing results that are achieved by the manufacturers, as certainly submitted to FDA and is used as part of the FDA clearance process. Also, those clearance summaries are available to consumers through your website, the FDA website, and they can also respond with medical device reports for information to be able to move.

But there's still some deficient information that would be necessary and helpful to be able to help the consumers to see more transparent access to the AI information. And just

exactly what are those is what I want to explore. So there are clearly the clearance summaries, but there's additional information that is important. And the other question is, how can AI consumers acquire that information? Some of the thoughts initially were that FDA would be able to supply that, but for a variety of reasons, that's not really an option, in part because of IP information from manufacturers, et cetera. So, the American Cultural Radiology Data Science Institute is taking on an AI transparency initiative, which I want to describe because I think it's one approach while we only cover medical imaging algorithms, which is about 80 percent of the market that's available today through FDA approved algorithms, it is an effort that we think is very important. So we asked the manufacturers directly for information regarding their algorithms. This is things like the simple ones like model identifiers, exactly what the product is when it was submitted, clearance dates, but even beyond that, the type of category, for CAD, for example, and then model characteristics, inclusion, exclusion criteria, indications for use, model performance regarding the study type and the references that they use, the age range, gender ratio, ethnicity, ratio, et cetera. Training data sets, the size of them, the age range and distribution, and again, geographic breakdown, manufacturers, scanners, all of that kind of detail. And then finally model limitations.

This is a growing list, but it's a start. You can see it's pretty extensive and what we do ask vendors, we do this and through PDF digital submissions to those vendors directly. And I have to admit, we have a very good response. Vendors seem very eager to be able to make this information available to their potential customers for decision making processes. So this constructs a visualization inside of the website at the ACR transparency initiative for potential purchasers to look at. This would be a roll up of that particular vendors view of all of their algorithms, and when you click in further, you can see a full view of all of the marketplace that's available and then drill in to see all of those transparency components that are available.

So it's really this, as we anticipate, not just giving the clearance summaries available and other public domain information, but information that is captured by the manufacturers and not always available. Not because they don't want to be forthcoming, just because it's very difficult to make that information available in a common place. And so this is the initiative that we're taking on, and releasing it later this calendar year.

In summary, for the advancement of health equity and medical devices, we feel it's imperative for manufacturers to disclose information beyond that which is in the public domain, enabling providers to execute informed and judicious decisions on behalf of their patients. Thank you very much.

Ms. Horn: At Google, we believe we have a responsibility to carefully consider our impact on health equity, and ensure our product services and research help everyone around the world achieve their full health potential. By making health equity a core value of our work, we have a responsibility to carefully and intentionally consider how these decisions impact equity in health. Thank you for this opportunity to share what we do, how we work, and how we partner to integrate health equity into our products, services, and research discoveries at Google.

Infrastructure is a critical component of incorporating health equity into our work at scale. The health equity team's responsibility is to build a scalable, sustainable infrastructure that makes it easy for our colleagues who are not equity experts to do the right thing when it comes to health equity. Our goal is to see all product development efforts include equity by design, in a way that is actionable and sustainable. To achieve this, we believe teams must have access to embedded health equity expertise, a health equity playbook with tools and resources to do their work, a community of health equity champions so as they learn they share, and collaborative partnerships with the health ecosystem to encourage shared learnings. These

elements have emerged as our best practice and approach to successfully meet and support the pace of technology innovation.

Google has long been committed to innovating responsibly. This is reflected in our AI principles, which we published in 2018. In health equity, we feel it is our obligation to go a step further in the application of our AI principles. First, to ensure that AI avoids creating and reinforcing unfair bias, we believe that AI should not accelerate or create health disparities. To address this, we developed the Health Equity Assessment of Machine Learning Performance, or HEAL, framework, which is designed to quantitatively assess the performance equity of health AI technologies. Specifically, the HEAL framework measures if an AI tool's performance is more equitable. We define equitable as performing better for groups with on average worse health outcomes, as compared to others. As part of this framework, we measure model performance with respect to disparate health outcomes, which may be due to a number of factors that include structural inequities, such as demographic, social, cultural, political, economic, environmental, and geographic factors.

Second, in order to uphold high standards of scientific excellence, we believe that AI should advance knowledge in historically understudied, neglected, or biased areas, while developing and deploying new technologies quickly. The health equity team partnered across Google on MedPalm to design more equitable generative AI models in health. We have identified five important elements to embed health equity into generative AI models. Participatory research and design, harm, bias, and equity specific use case evaluation, transparency and documentation, algorithmic procedures to detect bias, and interdisciplinary collaboration that incorporates social drivers of health in the social context in which it occurs.

We recognize that we cannot do this alone. Google is a founding member of the Coalition for Health AI, partnering across the private sector, academics, and government, to

empower responsible AI development across health and healthcare. We also believe it is important that communities impacted by health disparities are equal partners to building AI responsibly, in a way that is trustworthy. To that end, our partnership beliefs extend to contribute to the ecosystem by elevating health equity research and entrepreneurship through such efforts as the Google Health Equity Research Initiative, which supports researchers looking at new ways to use wearable devices to mitigate health disparities. Companies like Acclinate, a Google for Startup company, using Google Cloud to work with communities to increase diversity in clinical trials, and the Human Pangenome Project, a consortium of researchers, creating a new resource that better represents the human genetic diversity.

We recommend that the FDA consider some of these learnings, particularly concepts included in the HEAL framework, and our work embedding health equity in MedPalm, as standards when evaluating innovations, and our approach in supporting teams that are building products to improve on health outcomes and reduce disparities. Thank you.

Dr. Namen: Hello. My name is Dr. Andrew Namen. I'm a member of the American Academy of Sleep Medicine Public Safety Committee. I wish to discuss with you guys inequities regarding disbursement of refurbished replacement positive airway devices, or PAP, in the recent Respironics PAP recall. In this Phillips Respironics recall, about 5 million patients had PAP and assisted ventilation devices. In June of 2021, when the recall was announced, particularly due to patients concerns of sinus and pulmonary syndromes and the advent of new cancers. This was believed to be due to particulates released as a result of off gassing of volatile organic compounds from polyester containing polyurethane sound abatement foam. Due to these concerns, FDA MDRs were announced and published, as below. Recall challenges in production as well as delivery were outlined.

The magnitude of the recall was significant. It was going to take months to years to replace, and the challenges in communication were noted as they were sparse, insufficient, and fragmented. Choices for patients regarding maintaining current therapy versus discontinuing treatment versus costly alternatives were identified. The AASM member survey was birthed as a result of these concerns to have greater understanding. It involved 427 participants of multiple specialties and specialty interests, as well as a broad range of practices, incorporating all 50 states. So one of the most important questions is how did patients address the recall? Certainly, they were provided different positional therapies or alternatives to PAP devices, but a majority sought a replacement of their device. This would lead to long delays, and patients who were not accustomed to accessing information, limited.

This would also lead to unacceptable risks. The AASM sought to understand these determinants to inequities, and identifying that some patients drop in and out of healthcare, have difficulty accessing information regarding the recall and mitigation processes, or some that require additional support to obtain a registered device. It was noted, many AASM members reported, anecdotally, how they felt vulnerable populations were disproportionately affected, and this was further supported by certain academic communities that also had that heightened concern.

Currently, in 2023, the magnitude persists. Up to 70 percent of academic or physician practices identify that ongoing challenges to the recall, and needing to help with the registration process. The AASM and multiple circulations, as well as proceedings, sought to identify the systematic causes to PAP delivery inequities. It was identified early in some publications, the absence of industry-wide tracking technologies, that there was really no true guidelines that existed to mitigate inequities, and several environmental factors, especially a lack of

transparency as the replacement protocol noted. This created an erosion of public confidence. Several key points.

The impact of the Philips PAP recall is ongoing. Over 70 percent of respondents treat patients with recall needs. There are inequities in alternative therapy approaches, especially the costly ones. And some providers have actually seen, in a majority, negative health outcomes for their patients. And finally, there were ASM members reporting a loss of trust among patients regarding the entire process of replacement and recall. So we have several recommendations of requests. Regulatory oversight, particularly guidelines to mitigate those inequities. Post marketing oversight, equitable correction and corrective actions should be sought, and device tracking for all devices. Thank you for your time and patience.

Ms. Rickerson: Hello, thank you for offering the chance for me to speak today. My name is Grace Rickerson, and I'm the Health Equity Policy Manager at the Federation of American Scientists. We're a D.C.-based nonprofit that's focused on bridging the science and technology community with federal policymakers to make evidence-based science policy decisions. And today I will be speaking about issues of racial, size, and gender bias in home use digital monitoring technologies, that are of the focus of this patient advisory committee meeting.

To start, I'll speak a bit more about my work on pulse oximetry and why it has been a key window into investigating the issues of racial and gender bias in medical devices. So as many of us know, pulse oximeters are a critical technology for measuring blood oxygen content. And today pulse oximeters are ubiquitous for everyday Americans. We see them built into smartwatches, purchased at pharmacies for home health monitoring, and many other use cases of these technologies. Merging algorithms or even incorporating pulse oximeter data to predict future illness. As of now, about 30 percent of U.S. adults report owning a wearable health monitoring device to track health symptoms.

But these devices, as investigated by a November 2022 advisory committee meeting of the FDA, are less accurate and dark-skinned individuals. Seven common wearable watches, such as a Fitbit and Apple watch, have been shown to be inaccurate when used by persons with darker skin tones or even larger body sizes. And as these devices we see are becoming more popular and central to decentralized clinical trials and home monitoring use, we see an increasing risk and liability of these devices, causing harm through erroneous decision making.

So as patients see this data and interpret it for healthcare decisions, and it gets loaded into digital health monitoring apps, we could potentially see increased risk as people make clinical decisions based off this data. With kind of an example of COVID-19, where this issue of racial bias came into the forefront, patients were deciding whether to go on, you know, go to the hospital based on their pulse oximeter reading. And that is essentially a very high risk as we move to digital health monitoring, as growing, as a key technology to home health delivery use. Without effective guidance, wearable device users and users of home use technologies, such as off the shelf pulse oximeters, are at severe risk of harm in interpreting the sensor outputs. And really, it's not just pulse oximeters. Heart rate monitors, continuous blood glucose monitors, and bilirubin monitors, for pediatric patients, are all prone to the same bias based on skin pigmentation.

Further, we've studied how other key monitoring technologies are also prone to bias based on gender and body size. So universal home use blood pressure monitors are incredibly inaccurate. A recent study in JAMA Internal Medicine discovered that automated BP monitors overestimated systolic blood pressure by about 5 to 20 millimeters per, in patients who are too small for the standard cuff size, and four millimeters by people that are too large for the cuff size. So about 40 percent of people in the trial ended up being misclassified as hypertensive, using the standard cuff for monitoring hypertension. So this creates again, this high risk of

patients using these technologies to interpret how to change lifestyle or drug dosing, and I think as we think about equity and medical devices, there's an importance to actually assessing these technologies for efficacy, if they're going to be used at scale, and especially important as we think about them as endpoints and clinical trial design, given that those data points would then be used to approve drugs that would then be used by hundreds and thousands of patients around the country.

So why I think this patient advisory committee is important for this current topic is to evaluate the accuracy of these over-the-counter devices, that often miss rigorous evaluation by the Food and Drug Administration. I believe there's a tremendous opportunity to collaborate with the standards community, such as at NIST, academic community, private stakeholders, and FDA leadership, to ensure that there is built trust in the data collected by these wearable devices, so as to ensure that patients are given adequate diagnoses. This is will be a critical part of the future of digital health technologies, and essential for this committee to consider today. So thank you.

Ms. Doyle: Thank you to the Patient Engagement Advisory Committee and to FDA for the opportunity to speak with you today. I'm Jen Doyle, Vice President of Clinical Research and Medical Science at Medtronic, and Medtronic is a global healthcare technology company focused on addressing the most challenging health problems facing the world today. Our company's mission is to alleviate pain, restore health, and extend life for patients. We share in FDA's commitment to driving enrollment of representative populations in our clinical trials. At Medtronic, we've been on a journey over the past two years to increase diverse representation in our clinical trials, to better reflect the populations that we intend our technologies to be used in, from a global, ethnic, gender, and racial perspective.

We began with a programmatic approach to understand the patient populations in each of our disease, state, and therapy areas, and then we looked closely at our historical clinical trial enrollment. This helped us to determine where the largest gaps were and where we needed to prioritize their efforts. We've piloted and now begun to scale deployment of a variety of different approaches, to enable our sites to enroll and retain diverse study participants. We began first by creating tools, materials, and training to support our existing sites and investigators, as they were also implementing changes in their clinical research approach. Examples of this include providing unconscious bias training to our clinical study staff, as we kick off a new trial. Looking closely at the study budget, that we work with at the site, making changes to address health inequities. Examples are device provisioning, or paying for out-of-pocket expenses if a patient would be faced with additional cost of disposables by participating in one of our trials. We've implemented new and broader approaches to patient recruitment, though patient-facing materials that, of course, are translated into appropriate languages, but also modifying to include racially and ethnically diverse images. We've done direct to patient social media outreach, where we are encouraging patients to self-refer for trial participation, which we have found helps to minimize bias since some underserved patient populations may not participate in the typical care pathway where we would enroll subjects typically. We've also been focused on identifying new sites. So in the past, we have repeatedly worked with the same sites over and over for many of our trials. So we're now intentionally focused on identifying and training new sites with diverse investigators, that care for diverse populations. We've also began to formalize our patient engagement efforts in the area of study design. So, speaking to patients that are representative of our target patient population, to gain their feedback on potential barriers to enrollment, is a focus for us. And then finally, we have, through our decentralized clinical trials program, have been deploying many different data collection

approaches, whether it's patient-reported outcomes recorded through an app on the patient's phone, but also, you know, expanding our network of satellite sites that allow patients to be seen in a place that's more convenient for them, minimizing travel time and costs instead of traveling to a larger site.

So, through the deployment of these various approaches, we've learned a lot. Increasing representation is complex, and we have found that typically we need more than one tool or tactic in order to move the needle in any one study. Also, what drives the patient to participate in a trial is very personal and can really vary from study to study. So our approach must match those patient needs, and that patient input, and the onset of the study is going to be critical for our success. It's important that we work together to overcome these barriers, and to further improvement in this space. We believe collaboration and knowledge sharing across the entire health care ecosystem is going to be critical to create a more inclusive environment for all patient populations. Thanks for the opportunity to provide my thoughts. I look forward to the discussion from the committee as well as a future collaboration with the stakeholders, including patients, physicians and the FDA. Thank you.

Mr. Conway: Thank you. Our next speaker is Madris Kinard, founder and CEO at Device Events.

Ms. Kinard: Hi, this is, you able to see my screen? Anyway, so this is Madris Kinard, I am the founder and CEO of Device Events, and I previously worked for the FDA as the UDI program manager. That would be the bar coding that you would now see on medical devices, as well as the subject matter expert for Maude, which is where the adverse event reports are contained, that are submitted to the FDA. I've also been an author for JAMA Internal Medicine commentary and the Journal of Ethics. So, feel free to take a look at some of that if you ever have any questions. I have not been paid to attend or present today. I wanted to also point out

that I'm a member of the MDIC Science Patient Input working group, and a member of the Patient Safety Action Network and Breast Implant Safety Alliance. So I'm here both as a business owner, but also as a data and patient advocate.

Equity and inclusion for all people and populations is at the forefront of our discussions primarily around clinical trials. But we also need to be sure that devices that are getting cleared or approved by the FDA are taking sex, age, gender and ethnicity, and even geographic location, into account. It's also critical moving forward that we use the data we already have to learn from the past and present. One of the things I wanted to point out today is that the FDA has now received 17 million adverse event reports, and those are publicly available, but a little bit difficult to access using the FDA system. As you can see here, we're now up to about three million reports per year. One of the reasons that I wanted to speak today is because those adverse events show 25 years of data and the sex, age, and demographic information has been redacted from the public view for those 25 years. I have put in a request for that to be released, and hopefully that's something that CDRH will be able to do. If CDRH were to unredact these fields, scientists, care providers, and patients would have over 25 years of data that could be used for retrospective studies to better understand the efficacy of a device used in pediatric patients, the elderly, and diverse populations.

Device companies could also use this data to design more innovative devices. If the FDA were to unredact this data, we would have access to the age, sex, and demographic data that's reported by, here you can see, almost two and a half million physicians have reported to the FDA. We would have data from these various groups that we can use. You may notice other caregivers are listed here. Home health providers are a group we really need to work with more. And so other in blank, I did take a look to see what those were. And those are primarily for the diabetic testing devices and Alaris pumps. And I'm not sure why those didn't include a reporter

occupation. The practice of medicine has changed drastically in the last 10 years, and it's not all due to COVID.

What can we do to bring safe, effective, and innovative digital health technology to patients? We have EHRs that allow patients to view visit summaries and test results. What data do we have on usage? There are watches and devices to monitor heart health and diabetes. How can patients be sure their device has not been recalled or even check to see if it is FDA approved or cleared? It's very difficult to find that information. Could AARP or Consumer Reports assist the FDA with a campaign to educate the public about the UDI? A lot of people don't know to ask for the information on the device that was implanted on them. And that's something that is now available on the majority of devices. How are we engaging home health care workers? Are we engaging home health care workers? And how can we reboot the MedWatch or smartphone application, which was a phone app that allowed the public to send adverse event reports to the FDA? There is a MedWatch program that already exists, but you have to either fill out a form or go onto the FDA website to submit. This MedWatcher app that was previously used, is a shorter version of the adverse event report, and it was tested by physicians at a children's hospital in Boston, and then used by many patient groups. If you've heard of the eSure device, many of those women use that phone app to submit their adverse event reports to the FDA. How can we include the UDI barcodes in the reports that we're now sending? So how can we continue this discussion beyond today and affect change? Those are my questions for the group, and my comments. Certainly, feel free to reach out to me if you have questions and I will stay on the call for a while, if there are any questions for me. Thank you for allowing me to speak today. I really appreciate it.

Mr. Conway: You're welcome. Thank you very much. Our next speaker is Bernadette Lozano.

Ms. Lozano: Yes. Hi, this is Bernadette. Does everyone hear me?

Mr. Conway: Yes.

Ms. Lozano: Oh, thank you. A couple of months ago, this year, so I'm 21. I had an implant done on my right hip. And so, walking down the street earlier this year, it goes bad. So in less than two years, I'm up for a second surgery. So I have the second surgery done. And all this process, I'm hearing a lot of information that's very useful to me because, as an individual, a private citizen, I myself made contact with the manufacturer. I myself took it upon myself to get more information about the barcode number, about the part that went bad, about the x-rays. Because all this information was never really given to me, as a person that needs to receive a device implant that's going to be beneficial for my life. And, turns out that, once I started contacting the manufacturer on my own, good thing I was not a lawyer. Good thing I was, didn't have anything in any court of law. They released information that was very useful for me. And when I backtracked and tried to work with the doctor about why the information I had already, from a manufacturer, they, people just don't want to talk to me anymore.

So, the best thing that I can do is recommend that, and I have to agree with some of your speakers here, that there's no tracking system. When you have a surgeon's report, and that surgery is done by the surgeon, the surgeon needs to put a barcode number or a serial number next to the part, on that report. Because that report goes to the patient. So, first of all, that will be helpful, not only for the doctor, but for the patient. And secondly, as much as we try and incorporate AI with hopefully the manufacture of devices, we have to remember that even when you do a 3D, when you develop a device using a 3D method, those are recalled.

So, I guess what I'm trying to point here is that I could not find any advocacy for myself. I had to find it myself. I had to work through the whole process of finding my own doctor for a revision surgery, finding information on my own, hoping that the doctors would really be open to talking to me about the device, about the manufacturer used, but no, that was

just a big wall to work over, to climb over. And so, as a citizen, as a private citizen, I would just encourage everyone here, that I think we're forgetting about that patient advocacy legislation from 2005. That it's supposed to protect the patients. But in a way, it's not. So I think if we start having a tracking system, to helping the patients and the doctors, when these things fail, that would be a great help to private citizens, to doctors that try and doing their best to help us. And that's what I'd like to put forward. Thank you very much.

Mr. Conway: Thank you. Our next speaker is Dr. Diana Zuckerman, President of the National Center for Health Research. You may go ahead and begin your presentation.

Dr. Zuckerman: Thank you very much. Can you hear me?

Mr. Conway: Yes.

Dr. Zuckerman: I'm Dr. Diana Zuckerman and I'm President of the National Center for Health Research. We're a patient-centered public health think tank, that has been on the forefront of advocacy for diversity in clinical trials, and for safe and effective medical products. We do not accept funding from companies that make the products that we evaluate. So we have no conflicts of interest. We've heard great presentations today, focused on important strategies to enhance equity. And I'm going to focus on a more basic issue, ensuring that all patients can make informed decisions about medical devices.

I'm speaking today as a scientist and as a patient. When I started working on these issues, I was a healthy young scientist. I now have three medical implants in my body. And they've all been great, but in all three cases, there was no publicly available research studies that enabled me to make an informed decision about which implant to get, and even today, there are no long-term data to help me make informed decisions for the future.

I'll briefly describe a study we published almost five years ago, entitled Diversity in Medical Device Clinical Trials. Do we know what works for which patients? We studied all 22

high risk devices that FDA approved over a recent 4-year period. Only three of the 22 devices studied the impact of age, sex, and race, on safety and effectiveness. And just over half of these 22 studies, for 22 devices, reported safety and effectiveness for at least 1 demographic group, which was usually sex, but whether they reported them or not, the number of patients, especially patients of color and people over 65, that number was usually too small to provide any meaningful information. In some cases, there were just one or two patients in that group. So, for example, some devices were approved for all adults, even though the oldest adults studied were 65 years old. And when they were reported, they were reported to FDA advisory committees, but they were not put on the label that physicians and patients have access to.

So, why does this matter? Number one, there were just too few Black patients in these studies, or any people of color, to draw conclusions. If there were five, perhaps 10, usually fewer, the percentage doesn't matter. You just can't draw conclusions. You cannot generalize from such small numbers of people. A drug-coated balloon catheter used for blockages in legs. The men did better than placebo in that study, who had a balloon catheter that did not have drugs on it, the placebo group of women did better than they did in the new drug-coated catheter group. And it was quite a big difference, a difference between 70 percent success rate with placebo, versus 51 percent for the new device, for U. S. women. And that information was not put on the label and therefore not easily available. Another product was a test for colon cancer, that had 16 percent false positives for people in their 50s, which is not great, but they had a 26 percent false positive rates for people over 69. Again, people want to know which test is going to be best for them. Do any of us believe that it was impossible to find more than two or three or even 10 people of color, or people over 65, to study for these potentially life-saving devices? In conclusion, the companies need to do a better job, and we've heard today that they are trying, but the FDA can also do more. FDA is the only HHS agency that does not require

diversity in clinical trials, but even if they don't require diversity, why are they approving high risk devices for all adults, that were not studied on people of color or adults over the age of 65 or 66? There are plenty of us to study, and I hope that you on this very important advisory committee will urge the FDA to ensure that all of us are studied, so that we all can make informed decisions. Thank you very much.

Mr. Conway: Thank you. Let me go ahead and pose a question to the FDA technical team. We had one speaker that dropped due to technology. Is she back?

Mr. Veizis: She unfortunately could not make it. She lost power. So she's unfortunately, couldn't be able to make it.

Mr. Conway: Okay. Thank you very much, I appreciate it. I'd like to thank all of today's Open Public Hearing speakers. We very much appreciate your willingness to share your perspectives with us, and the amount of time it takes you personally to be ready to participate with us. I now pronounce the Open Public Hearing to be officially closed. We will proceed with today's agenda. We will now have open committee discussion and clarifying questions from the committee. As a reminder, although this portion is open to public observers, public attendees may not participate except at the specific request of the committee chair. Additionally, we request that all persons who are asked to speak identify themselves each time. This helps the transcriptionist identify the speakers. So let us go ahead and begin. And what I'll ask our committee members here, is to direct specific questions to specific speakers, given the amount of time that we have, where possible. So does anyone have any clarifying speakers for the Open Public Hearing speakers? Go ahead and raise your hand, and I'll recognize you. Why don't we go ahead and start with Teresa Diaz. Go right ahead, Teresa.

Q & A for Public Speakers

Ms. Diaz: Teresa Diaz. I have a question from Madris. You were talking about the data and collecting it, and how they could retract it. Would that data be, is there insurances for safety for HIPAA, or is it just general data that you would be collecting?

Ms. Kinard: Yes, so this is Madris Kinard. Can you hear me? Okay. Thank you for your question. The data that I had requested to be released, one of the reasons that it wasn't released previously was because there were fewer number of adverse events, and there was thought that you could potentially identify an individual based on the information in the report. With that being said, hospital names, doctors' names, patient names, those are all redacted and would continue to be redacted. The data that would become available is a field that says age, a field that says sex, and then perhaps some demographic information, although the FDA has changed what they're collecting there, in recent years. But at least the sex and age information I think is crucial. And then as we move forward, and the FDA has better data on the demographics, that, perhaps they find a way to release that as well. It's not a HIPAA issue. It, as long as you don't have you know, you have 17 million reports at this point, so it would be very difficult to individually identify a patient.

Mr. Conway: Great. Thank you. Dave White.

Mr. White: This is Dave White. My question's for Keith Dreyer. You mentioned that many software vendors were very willing to share information regarding the specifics of their algorithms. I was wondering if you could be a little more specific as to perhaps a percentage of the vendors who are willing?

Mr. Dreyer: Yeah, this is Keith Dreyer from the American College of Radiology's Data Science Institute. Thanks for the question. With this, the effort of reaching out to vendors directly, started about 30 days ago. So, we started with the vendors that had the most published

algorithms. So, some are in the seventies and, you know, the bulk are in the one or twos. So, I'd say we reached probably the manufacturers of about 100 of the 300 algorithms that we're looking for. And those hundred were eager to participate. There was some pause, in the fact of questioning whether some of the components of what we were asking for was intellectual property, but they seem to find clearance through their general counsel. So, I can't say that we're going to get 100 percent support from the industry, but it seems so far like it's pretty high. We've had nobody say no, as of yet, if that helps.

Mr. White: Thank you.

Mr. Dreyer: Sure.

Mr. Conway: Great. Thank you. Any other questions from the committee members to individual public speakers? Okay, not seeing any. We'll go ahead and take a 10-minute break. Committee members, please do not discuss the meeting topic during the break, amongst yourselves or with any virtual member of the audience. The meeting will reconvene at 3:22. At that time, we will proceed with committee discussions of the FDA questions. Thank you.

Committee Discussion of FDA Questions

Mr. Conway: It's now 3:23 PM, and I'd like to go ahead and resume this committee meeting. At this time, let us focus our discussion on questions from the FDA. Committee members, copies of the questions are included in the materials you were previously provided. I'd like to ask that each committee member identify themselves each time they speak to facilitate the transcription. I'd like to remind members of the committee that this meeting is classified as a particular matter of general applicability, because the issue to be discussed by the committee is a particular matter that is focused on the interest of a discrete and identifiable class of products, but does not involve specific parties or products. I would like to remind public observers at this meeting that while

this meeting is open for public observation, public attendees may not participate, except at the specific request of the committee chair. At this time, I would like to ask the FDA to please read the questions. Commander Chinyelum Olele please go ahead and proceed.

Question One

Commander Olele: Commander Olele for FDA. Question one. With changes in technology and healthcare, medical technologies are increasingly being used outside of clinical care settings, such as in the home. Increasing patient access to healthcare, prevention, and wellness through the use of such medical technologies, particularly, those with digital capabilities may benefit patients by bringing healthcare directly to patients wherever they are - at home, at work, in cities, in rural communities - which has the potential to help bridge gaps in health equity. The FDA is committed to facilitating access to medical devices designed to be safe and effective when used outside of clinical settings while reducing and mitigating problems that can occur in the home environment.

A. Some technologies currently used in healthcare settings could be adapted for use and other settings with design changes, additional training, or instructions for a patient and/or caregiver or other modifications. As a patient, what information would you want to know to feel comfortable using a medical device in a nonclinical care setting?

B. Certain diseases or conditions may have diagnostic and/or treatment options or other aspects of care that are amenable to moving outside of a healthcare setting. This may include transitioning to over the counter access or involve monitoring or periodic visits with a healthcare professional to ensure appropriate use and treatment adherence. What diseases or conditions or aspects of care for certain patient populations may warrant consideration due to the potential for a large benefit from having medical technology that can be used outside a healthcare setting (for example: at home, work, school)?

C. What actions could be taken by industry or the FDA to facilitate patient access to medical devices designed to be safe and effective outside the clinic setting?

D. The home setting could be an environment to support wellness and prevention as well as for clinical care and evidence generation for clinical investigations. What actions could be taken by the FDA and industry to establish such an environment that meets the needs and provides the experience expected of patients and consumers to support the integration of medical technologies in the home setting?

Consider the following. Number one, experiences patients and consumers will want in such an environment. Two, the key features of such an environment for patients and consumers to have that experience. That ends question one.

Mr. Conway: Great. Thank you very much Commander. So for my fellow committee members here, what I'd ask you to do is be as direct as possible in responding to it and let me know if there's a particular part that you're responding to, and if you're not responding to another part. Because we will do a summarization of this, of each question for the FDA that we need to pose back. Why don't we go ahead and start with Teresa Diaz. Go right ahead, Teresa.

Ms. Diaz: This is Teresa Diaz. I am responding to question 1A. As a patient, the main thing that I would want to know, this is answering the FDA's question, would be exactly what the device does. Total informed consent, education about it, what could be some adverse events from this product, and I would love to have hands-on training for that product. I think that would be really important, so there's no user error. And if there is something that goes wrong with the product or with how it is affecting the patient, where do they report that adverse event to?

Mr. Conway: Great. Thank you very much. Why don't we go to Necie Edwards. Go ahead Necie.

Ms. Edwards: Necie Edwards, I'm addressing question number one. So as a patient, some of the things that will make me feel comfortable using a medical device in a nonclinical care setting is as follows. Number one, some devices that are wearable, the materials that they are made of, some of them do sometimes do carry a scent with them. I've used a device that was great. One problem, I couldn't continue to use it because of the odor, the way that it smelled. The more I used it, it gave me migraines and I could not get any assistance in terms of how to properly use it, how to eliminate that odor.

The other thing is, how do you properly dispose of the device? That would be something that's very important to me for medical devices. Due to age, wear and tear, you need to properly dispose of them. And how do I get help if I have any questions or problems? And where to go to purchase the supplies that I may need. Thank you.

Mr. Conway: Great. Thank you very much, Necie. Dr. Elizabeth Joniak- Grant.

Dr. Joniak-Grant: Hi, Elizabeth Joniak-Grant. This is for 1A. To be comfortable with using something, I would want to know the potential disadvantages of using in a nonclinical care setting, especially if these are additional risks. I would want to know requirements depending on the device obviously, voltage, internet, computer, mobile, tablet capabilities. What to do if the power goes out, what to do if the internet goes out and I need one of those. How to maintain, keep it clean. I'd like to know if there are certain things like blinking lights or shifts and sounds that may look problematic, but are actually okay, and those that are not okay. I've had devices and I'm standing there going, is this what it's supposed to be doing or not? I don't know. Is it working correctly? I would like a direct phone number to a person in case of a malfunction or potential emergency situation. This would be very much a case if it's a life-sustaining equipment or to reach someone after hours.

I'd also like to know how to do initial setup. But how do you set up if you move? A lot of times, devices will say, okay, here's your initial setup, but then if you go and you travel or you go to stay overnight at someone's home and you have to take the device, there isn't a way to say, do you go through this whole initial setup again? Is it different? Is it abbreviated? How does that work? I'd want to know if there were concerns related to calibration. How frequently it had to be serviced, where to get parts, and I would want to know, for lack of a better word, device ingredients for any type of allergies. For example, I have reactions to stainless steel, so to know what some of the components are perhaps to avoid allergic reactions. And finally, I would like to know the characteristics of users that were included in any home-use trials to see how I would fit into those groups. Thank you.

Mr. Conway: Great. Thank you very much. Let me go over to Ella Balasa. Go right ahead, Ella.

Ms. Balasa: Hello, this is Ella Balasa. I have a comment on 1A. I would, as a patient, want to be able to have 24-hour support for troubleshooting or other issues that arise when I'm using a medical device at home. I would also, along those lines, want to have, and others said this as well, but appropriate training. Especially dependent on the level of invasiveness or complexity of the device would depend on what type and what level of training and depth that would be needed and I want to make sure that I would feel comfortable with that.

And then to answer 1C, what actions can be taken for patients to feel safe and have that be effective outside the clinical setting. Again, with training, I think that must be provided. Personnel should be provided that can have this training in the home setting for supporting patients and making sure that they feel comfortable and having that available when needed. And to come out and have troubleshooting or other issues that arise is a really important component.

Mr. Conway: Great. Thank you very much. Dave White. Go right ahead.

Mr. White: Dave White answering question 1A as well. I would want to know if clinical outcomes are enhanced or reduced when the device is used in a nonclinical setting. To follow up on Ella's comment regarding 24/7 support, I'd like to know not only is it available, but that it works. In my experience using an overnight cycler, that wasn't always the case. I'd like to know how the device will change my home environment space needs. Again, disposing of used materials and social context of perceptions of other people as well as self-perception. Of data security, what happens to the data points that are being generated at home when they travel from point A to point X? What happens to the data when it arrives? And who has access to it? We've had presenters from all of us, Yale School of Medicine and CISCRP that are obviously using best practices, but what about the rest of industry? I'm not so sure. I want my data to be secure at every stop and between every stop. I'd like to know how reversible the decision to switch to a home therapy is and how difficult switching back to the original treatment would be. Because I've experienced being happy and then unhappy with a home therapy but having the option to go back to my original therapy and I really appreciated that.

Mr. Conway: Great. Thank you very much, Dave. Rita Roy, go right ahead. Go ahead, Doc.

Dr. Roy: Yes. Hello. I'm responding to question 1A, and as a patient with devices implants in me, I think the most important thing that I think would be helpful would be to know outside of a clinical setting to have assurance that if there were some recall or safety notice with the device that I could be assured that I could find that out. And I know the UDI codes, we heard about that today, but I think there's still a lot of confusion around knowing exactly what's been put into your body and how to stay abreast of information as that becomes available.

Mr. Conway: Great. Thank you. Dr. Wolf.

Dr. Wolf: Thank you. This is Michael Wolf. Responding probably to both 1A and 1D, probably fits in the middle, but I agree with everything that's been said, so I don't want to be

redundant. But one thing in our research that we've noted when we try to implement from a health system perspective, devices to patients, is providing information regarding. And I think this was somewhat touched on earlier about if this is a tether to clinical care and at what frequency might your care team, if they are actually viewing this data, how often they're looking at it. Because patients sometimes have had experiences with us telling us that they have expectations that because they're being monitored in such a way, or they think that this is being shared with their care team, when maybe it's not. Or that the expectations from the care team is that they are monitoring it more closely than they may. And so, just how the data is getting to whoever, if it is being shared, how often and how frequent it's being shared, I think is a pretty important thing to level expectations.

Mr. Conway: Great. Thank you very much, Doc. Amy Sitapati. Go right ahead.

Dr. Sitapati: Hi, thank you. Amy Sitapati. I'm responding to question one starting with B. In terms of disease and conditions, I would encourage acute care at home as an important highlight as well as rare conditions with complex impact requiring devices at home that are of acute nature.

In terms of 1C, patient access. I would say cost is universally the biggest barrier to access, so very important to consider. And then 1A, and perhaps C, in terms of the overall actions that we could have, timeliness, usability, diverse settings and spaces, limited health literacy, 24/7 requirements, feedback loops, handoffs, and the need for spare parts at home.

Commented [WL6]: I think this was "Overall"

Mr. Conway: Great. Thank you very much. Ian Burkhart, go right ahead.

Mr. Burkhart: Hi, this is Ian Burkhart. I first want to echo what Dr. Wolf said about the fact that if patients are being told that data is being tracked, they generally are under the assumption that someone is reviewing that data. And that can cause some miscommunication between patients and their care team. Additionally, I want to address section 1C, and I would want to be assured

that individuals who are the intended users of these devices were consulted during the development, knowing that it was designed for patients like myself. And that I will be able to easily use it and that any kind of problems that are foreseen have probably already been worked out. And I'm not going to be the guinea pig testing it once it's been cleared.

Mr. Conway: Great. Thank you very much, Ian. Dr. Fischer.

Dr. Fischer: This is Gwen Fischer. I'm replying to question 1B, 1C, and 1D as from the perspective of a provider. For 1B, speaking as a provider, we would like access to home or over the counter diagnostics for common infections. Specifically ones that are frequently seen in clinic and the ER and are a high time and cost burden in the ER, in particular. Examples of these would be influenza and strep throat diagnostics that are available to home or over the counter for patients. Providers believe that this will decrease barriers to diagnosis for patients and families and also increase access to care for these fairly common diseases for patients.

Regarding 1C, patient and provider access to data from post-market trials that is easily accessible and possibly sent directly to providers so that they're aware of any signals that are appearing in post-market trials for medical devices at home. And secondly, working in parallel with CMS to ensure appropriate coding for providers to manage home devices via telehealth visits. This is a current barrier for being able to work with patients at home, that there's not an easy way sometimes to bill or code for those visits.

And then finally, 1D, actions that the FDA could take ensuring data is both accessible and also secure for the patient, but making sure that it is patient-owned data as well as provider-accessible. Thank you.

Mr. Conway: Thank you very much, Dr. Peters.

Dr. Peters: Yes, this is Dr. Anne Peters, and I'm responding to questions A and C from the perspective of a provider. So, everyone said great things, but when I have patients who call who

need help, not only do they need someone who speaks their language, they need to speak to someone who understands their educational level and background. So, they speak to the patient in a way the patient can understand, and that helps ensure device safety.

For 1C, the biggest problem I have is with access to continued supplies for my patients. So, they end up getting a prior auth, they can have something for a month, whatever it is runs out, a continuous glucose monitor sensor, whatever. Then they run out of supplies before the end of the month or the prior auth didn't work. And then they end up with a week or two of a gap when they can't use the device. And that's really hard on people who've grown to depend on the device and we've taught how to use the device. So, we need to have continued safe access to device supplies.

Mr. Conway: Great. Thank you very much. Dr. Wilcox.

Dr. Wilcox: Yes. So, I'm responding primarily to 1C. So, what can the FDA or industry do? I think we have one interesting model and that's implanted defibrillators. The implanted defibrillators communicate to the cloud, and therefore, to the physician who can make remote changes in the device, and it's essentially plug and play. And I think that's the model. The problem is there's a trade off between the infrastructure necessary for that sort of thing and ease of use, you can make it really easy to use if you do that. If you have remote access, remote data, and remote control, but that requires an infrastructure. So, maybe one thing that could happen is to start defining part of that infrastructure, that wireless infrastructure whatever is required, as part of the medical device. So that Medicaid, Medicare, or whatever could pay for part of the necessary infrastructure as well as the device per se.

Mr. Conway: Got it. Thank you very much, Doc. Let me move to Naveena Yanamala. Go ahead, Naveena

Dr. Yanamala: Dr. Naveena Yanamala, I'm responding to 1C and 1D. First, I'll respond to 1C. I think that the enhanced post-market surveillance is very important because sometimes medical devices that are definitely designed for home-use device or home-use application often are reported with primary outcomes and primary benefits and risks. Once they are released into the market, there are secondary outcomes as well as other risks that may be identified in the community. So having real time information of half the manufacturers maintaining the data and regulatory agencies reporting that data back to the patients for transparency would be a great idea for enhanced surveillance and enhancing the trust for use.

And for 1D, there was this recent study that we were doing where we had a digital scale combined with a cuff blood pressure monitor together with a bio vital 24/7 monitoring system of all the five bio vitals. And interoperability has been a major hurdle when you are actually monitoring patients at home. And these are acute high-risk patients, as Dr. Sitapati was mentioning, heart failure patients and cardiology. So how do we ensure interoperability when multiple devices are being used at home for chronic or acute management is another question to be considered for 1D in home settings. Thank you.

Mr. Conway: Thank you very much. Dr. James, go right ahead.

Dr. James: Hi, Jijo James presenting an industry perspective, and I'd like to respond to BCND. I think in addition to what Dr. Fischer mentioned, there are opportunities beyond respiratory devices to even think about diagnostic tests that carry social stigma and are invasive for a patient, could be related to STDs. Also Improve provides important access for patients who may be uncomfortable in a traditional medical setting. A remote specimen collection provides a major opportunity for providing care to rural populations who may otherwise be unwilling to travel or participate in a traditional healthcare setting. And we could also be looking at medication delivery, of course, depending on the medication and medication management. And

this may be appropriate if coupled with digital health tools and there could be significant benefits here because improved adherence can improve outcomes and mitigating risk of incorrect drugs. A dosage could also save lives.

Moving on to C, talking about what the agency could do to facilitate access, I think it is laudable that CDRH has made advancing health equity one of the centers three priorities for 2022 to 2025. How would they accomplish this on their own? They require to be able to collaborate with agencies like HHS, CDC, CMS and NIH, and we would encourage the FDA to do that.

Secondly, it would be helpful to develop device-specific guidance that could help transition a product's use setting and this should hopefully be risk-based and the requirements for bridging data need to be clear out here. There could be opportunities to leverage existing post-market authorities in lieu of certain pre-market clinical study requirements to facilitate the use of post-market surveillance and real-world data and real-world evidence can also provide additional evidence to support the risk-benefit profile.

And lastly, when we talk about the home setting, again, I think effective care at home requires, as we've heard all day, a strong understanding of the end user. And not just the end user in terms of the patient, but the caregiver and the traveling health provider as well. So, we need clear and consistent expectations for moving the device from prescription use to OTC, and there needs to be a balance that such guidance is not overly prescriptive, but allows for technology advancements in regulatory agility. We should also consider the potential for telehealth visits to provide physician oversight for product use. That's if needed. And also think about, as we think about stakeholders, encourage all stakeholders to think about this flexibility. For example, education could be provided through an app or video, quick reference guides may contain non-mobile instructions to support users of various backgrounds and literacy levels. And lastly, I'd

say as we've heard today, the agency should consider cybersecurity, digital integrity, patient safety, and adequate technical support as we look at this transition.

Mr. Conway: Great, thank you very much, Dr. James. Dr. Wilcox.

Dr. Wilcox: I would like to say one thing though and that is just to the question, I believe it would be B, which syndromes might lend themselves to moving out of the hospital? I think my feeling about that is that they tend to be chronic diseases as opposed to acute. Nobody's going to expect to do home surgery, but in just about every chronic disease, it seems to me, ought to lend itself to some form of automation. Now, another thing the FDA specifically could do is to put more pressure on us in industry to automate components of the devices. Right now, there's a lot of pressure to make sure that there are not use errors. We go to great lengths to make sure there aren't use errors, but we don't get too much pressure back from the agency to say, not only do you have to get rid of use errors, but why haven't you automated components X, Y, and Z? As we move into this digital age, I think that's going to be more and more feasible.

Mr. Conway: Great. Thank you very much. And Dr. Joniak-Grant, go right ahead.

Dr. Joniak-Grant: Speaking to 1B, the diseases and conditions, I would say that patients who have diseases that make getting to a healthcare provider especially difficult, particularly pain conditions or conditions that impact their sensories, functionality, or where management and treatment is especially a time-consuming process. Also, diseases and conditions that have long-term management. And to echo what someone else mentioned, but this time from the patient perspective, communicable diseases that are really common and straightforward to treat. With young kids at home, I am forever traipsing to the doctor for a strep test to say, yep, that's what it is, yep, get the prescription. So, if there were ways to do those at home, that would be well worth it.

Speaking to 1C, I think things to facilitate access that industry could do is working to have these devices not be cost prohibitive. And ease of use, disseminating information to healthcare providers, not just regarding that the device exists and what it does, but, which patients could benefit the most from it. How to obtain it. Being transparent about benefits and risks and working with insurance coverage and working with healthcare providers to figure out how to manage that.

In terms of what FDA could do, I think a lot of it involves working with insurance and Medicare to clearly communicate FDA approval and the benefits of in-home use. I know I have a device that my insurance supposedly covers, but they only cover it from a specific manufacturer. That manufacturer does not actually make this device, so I can't get it through my insurance. And I'm sure we've all experienced lots of pieces like that. Another thing I think FDA could do is educate patients regarding their options for in-home devices with web pages, maybe pamphlets with healthcare providers, but to just start getting some of the information out there that these things do exist and are options.

Mr. Conway: Great. Thank you very much. Not seeing another hand raised. I'll go ahead and attempt a response to FDA with the richness of the answers that we have here. FDA, in regard to question number one, let me go ahead and answer this by section to give you highlights for tracking if you can. So, we heard several different things in response to part A in terms of what makes patients feel comfortable. Several different themes emerged off of that. Data access, data security, who owns the data. Types of training and how that scales with complexity of the devices. Who do you call when it's not working? And who do you get? Do you get an 800 number? Do you get a live person? And what does that exactly look like? And then there are a whole series of other issues that are of great importance as well. In terms of the composition of what a device looks like, what's it made out of? What are the components that are in it? Do those

pose a risk? And then how do you dispose of it? Where do you get supplies on the logistics side? So you get used to a device and you need to be able to keep using it. How accessible are those? And then probably just as importantly an overall theme across a lot of these issues is what are the disadvantages in addition to what the advantages are? And are those clearly stated if it is being contemplated for something that's at home? What does it do? Does it have informed consent? How do folks close the loop on issues of safety at the practical level? What does it sound like? What does an alarm do? Is it real or is it not? What do people have to react to? In terms of clinical outcomes, how does it work? Is it enhancing what patients are already going through? How does that work with your care team? And then some of the other things that were mentioned is the clarity of instruction, how well the training is, and things of that sort. And let me go ahead and I'll do this section by section, then I'll come back around and ask if that's adequate to FDA. Okay?

Under section B, other types of diseases and conditions, other aspects of illness, several were recommended. A general sense that, in terms of acute conditions, it would be very good to do that. In some of the examples that were given ran the gambit of influenza. Some of the other issues that were raised were about chronic care, ongoing, and then, in particular, issues that patients might see as invasive to them if they had to go to a healthcare setting or to interact with a healthcare professional. STDs were mentioned. Specimen collection, especially for patients that lived in remote areas, possible management of medications. And whether or not from the over the counter aspect could it work to leverage other digital tools or digital tools that patients are using. And again, communicable diseases was hit on. Some of the other disease types that were mentioned were those that dealt with pain and chronic pain management and sensory issues. And then a final thought are diseases and conditions that require long term management.

Under Section C, actions by industry and FDA to facilitate access. Some of these issues actually cross back and forth with FDA and industry. But in terms of FDA you heard several different themes regarding payment issues in coordination with other federal agencies, in particular CMS. You also heard the use of other data or evidence, such as real-world evidence. Better efforts to identify what the risk-benefit ratio is, based on patients. I think Ian made a very important point, as a patient. Are they designed for the particular patient that they're going into and was that at the front end or does the patient feel like, with this particular device they may be a guinea pig in a test and it's not well sounded out with the target population? Patient access to post-trial signals in data so they can keep making informed decisions about the use of it at home for confidence. Appropriate coding. You heard that from a provider perspective. And again, this goes to ease of use for patients, but also particularly providers to make things available for payment issues to patients. Dr. Wilcox offered an interesting model in terms of defibrillators and how they can be adjusted remotely. And made the suggestion that infrastructure in particular beyond merely the device, but the infrastructure within which the device works might also be included in terms of what gets reviewed or approved by FDA. And again, another point that hit here was post-market surveillance in primary and secondary outcomes. Yanamala raised that point as an issue of trust. On the industry side, it was very important to a number of folks of who benefits from it. What is the trade-off? The cost of it. Industry could do more to reduce the cost. Dr. Wilcox actually made the point that FDA should, as much as they pressure to deal with error information, also insist that industry automate and be clear on how their automation processes work. That to feel safe, from the patient side of it, and I think consensus of the committee is that how things get troubleshooted. That's something that industry could be clear about. They could be clearer about issues regarding literacy and the timeliness of responsiveness. If there is an issue

how it gets handed off. Devices that industry has a role in saying that in terms of care and also access to spare parts was a key issue.

Under Section D, in terms of use for wellness, prevention, and evidence. On the industry side, I think these are issues that go back and forth between industry and FDA. How is it tied to an overall care team in the other care plans that a patient may be under? How is data accessible? Is data patient-owned, and provider-accessible, I think was a key point that was made and FDA clearly has a role in that. Dr. Yanamala also talked about interoperability and risk to patients in how that is considered both by FDA and industry. Understanding how care is given in a practical setting. And then some of the other issues that were raised for D in terms of use for wellness and prevention and evidence is anticipating how it would work or how telehealth ties into it, the use of apps, and also the overall issue of literacy. So I'll stop there and pose a question to FDA that's a combination of general beliefs and concerns. FDA, Is this adequate?

Dr. Faris: Hi, this is Owen Faris. I'd like to thank the panel for an incredibly thoughtful discussion and for all of the helpful comments and suggestions. And thank you, Chairman, for a really great summary of all of those thoughts and ideas. I think we have what we need for question one.

Question Two

Mr. Conway: Great. Thank you very much. I'll ask Commander to go ahead and read question two.

Commander Olele: Commander Olele for FDA. In certain device areas, a subpopulation of users may respond to a medical device differently than another subpopulation. Intentional design of the device with the user in mind, appropriate human factors and usability testing in clinical study evidence can play an important role in ensuring medical devices are developed and perform as intended to meet the needs of potential users.

A, with the end users in mind, what aspects should the FDA and industry consider during medical device design and evaluation to confirm devices can be safely and effectively used by all potential users, particularly in the home-use setting. Consider the following.

One, ability for individuals with reduced functional capabilities (physical, sensory and cognitive) to safely and effectively use the device.

Two, ability for individuals with limited health literacy to understand how to safely and effectively use the device.

Three, technology aspects that may limit or impact safe and effective device use in certain populations or locations (for example, broadband Internet requirements in rural settings).

Four, other aspects of the home environment that may limit or impact safe and effective device use (for example, presence of children or pets, access to caregiver assistance, ability to travel).

Five, elements of the device-user interface that may limit or impact safe and effective device use (for example, controls, visual displays, alarms, labeling, training).

Six, conditions or diseases where current scientific knowledge suggests we might anticipate meaningful differences and overall benefit-risk profile among diverse groups of patients (for example, where treatment A is better in one group and treatment B is better in another group).

B, the evidence from clinical studies that include diverse cohorts of patients may be necessary to determine whether or not that device is safe and effective in support of market authorization. In some cases, this may result in larger, longer studies, which could delay access to a new technology. The FDA is considering three main principles - inclusivity, data generalizability, and timely access - to guide is determination of when such studies may be necessary to support market authorization.

Number one, do these principles reflect what is most important to patients?

Number two. Are there additional principles that FDA should consider? Please explain your response. This ends question two.

Mr. Conway: Great. Thank you very much, Commander. I tell you what, this is a very important question given the conversations that we had today and the presentations as well. So what I'd like to do is go ahead and break this into two pieces and if we can, just let me know what you're responding to in section A, and then the subheaders for that. Or if you're taking a look at the second part of it, or I can come back around and do a second round on question B so you guys are focused on that. But let me go ahead and start and we'll go ahead and start with Dr. Wolf. Go right ahead, Doc.

Dr. Wolf: Yeah, this is Michael Wolf. I'll be, again, very abbreviated, make sure that I don't take too much time. But first off, responding to 2A and from my own background, I've done a lot of work on how do you optimize health information and instructions for patients with limited health literacy. And there's a lot of evidence-based practices that the FDA, at least my familiarity with the work that they've done really well in the prescription medication space. In other aspects of the FDA, I think there's a lot known on how to optimize that to address that diverse audience. And I don't want to belabor that point, but I think it's oftentimes implementation that is challenging. And what can be a part of the industry to ensure in the design and evaluation of medical devices in the same way that other products that are regulated by the FDA, that I think there's a lot that could be leveraged that wouldn't require reinventing the wheel here.

For part B, I think the big question I ask about, the larger studies would be there's a lot of talk about fit for use of real-world data and evidence that you're getting from electronic health workers and whatnot. I don't know the quality of that same level of evidence and what possibly could the FDA do to ensure that you're getting the best data possible to understand in the post-

market surveillance space how people are experiencing medical devices. Because I think to a point, you can only go so far in the development before really needing to understand how diverse groups are experiencing the products and where there may be need for constant improvement. So I'll stop there.

Mr. Conway: Great. Thank you very much, Doc. Necie Edwards, go right ahead.

Ms. Edwards: Necie Edwards, and I am responding to question 2A-1, two, and three, starting with number one. The first thing that comes to my mind is utilizing health literacy flashcards. They could be four by five, colorful picture, with the steps to make it for people to better understand visually.

Number two, also there should be some type of simple video that takes into account reading levels, grade levels.

Question 2A-3, technology aspects. There are some medical devices, for example, in a healthcare clinician's office that, let's say you're in a rural area, you're in a remote area, the signal is not all that great. Some of those devices, the manufacturers, I know several, have added a signal booster so that the clinicians can get the access that they need. So, when you think about these medical devices that patients are using, I think the manufacturers need to consider the zip code of various populations where people live. Because in some of these communities that have low Wi-Fi or broadband where they can't get a signal, add a separate piece to that to help boost the signal so people can get the signal that they need. Thank you.

Mr. Conway: Great. Thank you. Dr. Wilcox.

Dr. Wilcox: As far as I'm concerned, this is by far the most daunting of these questions. Let me give a quick example, let's say we're doing a study of a device for diabetes. So, we would typically have maybe five separate groups or so, and each which creates an X number of cells. So we end up having to test maybe 90 people for the validation research for our submission.

Now, the scary part is ethnicity. We're finding more and more examples where something works, say, with people with a European heritage, but it doesn't work so well with, let's say, Asians or African Americans. So, what are we going to do about that? That's really the scary question, because you could easily define five ethnic groups. So, multiply that 90, we started with a study of 90 people, now we've got a study of 450 people and the cost and the time goes up enormously, and also the timing for recruiting. By the way, some of these are really difficult to recruit, especially because we normally want to use real patients. The recruiting time can go up dramatically, particularly for more unusual, more rare diseases. So, what are we going to do? A study with 450 folks for an Abbott or a J&J is not necessarily a big deal, but for a startup, it's got some great new technology, they can really make it different. So, I'm thinking one of the things we ought to be doing that we're not particularly doing now is recording the results by race. Just break it down by race or ethnicity and start looking to see if we're seeing any differences. And if we do, then go back to a larger sample size to look more carefully at those kinds of issues. That's one thing FDA could do immediately is start requiring the recording of ethnic data and looking at those results would probably require a modestly larger sample size, but not necessarily multiplying it by five, like my example.

Mr. Conway: Great. Thank you, Dr. Wilcox. Amy Sitapati.

Dr. Sitapati: Hi, Amy Sitapati. My comments will be for 2A, small one, small two, and B. As a physician, patient, and caregiver living with neuropathy, who uses bifocals, I would just ask when we're talking about abilities, sight is really important. Also dexterity having the hand dexterity just for some of the basic function. And sound, especially for those who might have advanced aging as well, since it's very common to have loss of hearing. So, those are really fundamental abilities to consider in the device use. I think also with the health literacy questions, so this is 2A little two, again literacy, but also linguistic inclusion. I think sometimes we can find

ways to have images and pictures included that help persons with limited ability to understand English and Spanish if they can't be on the display.

And then for the question 2B on evidence, I would ask the FDA to consider post-market invasive device longitudinal opt-in data sharing as a method to have transparent access to data and deidentify data sets via registries or something of the sort.

Mr. Conway: Great. Thank you very much. Dr. Peters.

Dr. Peters: Hi. Yes, this is Dr. Ann Peters and I'm going to discuss. 2A-1 and five, and then 2B. So first off, in terms of looking at individuals who will use these devices, be sure to always consider the caregivers. Because caregivers are really important for kids, for disabled adults, and then as people get older, it's often not the person themselves using the device, it's in conjunction with the caregiver or solely done by a caregiver.

Second, for 2A-5, alarms are really important to consider. Because they can really be disruptive to the human being wearing the device. I have patients who won't wear devices because of the alarms. I have patients who are not allowed to have alarms at work. And if you can't silence the alarms when you need them silenced, it really disrupts your life. It makes people aware you have a chronic condition. And there are some types of diabetes devices where both the pump and the sensor both alarm when your sugar goes low. So it's really important to consider the burden of alarms.

And then finally, for 2B, in terms of the effectiveness or how you look at the devices as you're studying them, one of the things that I've found in my population is that as I use a device with my patients, what I find is that they actually like it in different ways than I anticipated. I'm a diabetologist. I look at glucose levels, but they actually often find the devices make them feel safer. They give them a sense of empowerment. They do all sorts of things that many of them aren't even measured by PROs that make the devices good for them. So, I would say that during

studies even, you might want to modify what you're looking at in terms of outcomes to see if it's effective in ways that are new and perhaps unexpected in a certain population.

Mr. Conway: Thank you very much. Naveena go right ahead.

Dr. Yanamala: I'm Naveena Yanamala. I'll be responding to 2A-1, two, three, and five. One and two together corresponds to the accessibility and inclusivity part of it. So, it is important to ensure that the device is accessible to individuals with reduced functional capabilities. With experience and clinical research and patient engagement and patient compliance on home-use devices, this is a perspective from that. People often prefer large buttons, voice commands, as well as tactile directions. Not only just showing them the direction but highlighting and popping out the buttons is often useful for its effective use.

The second thing I have observed is that devices with multilingual capabilities and translation have been more compliant to be accepted by patients for home use and potential recruitment into clinical studies as well. So I think that targets both one and two of health literacy as well as reduced capabilities, because cognition abilities are also very important. Ensuring that the tactile advancement or tactile capabilities into medical device apps and other data-driven technologies is very important.

Coming back to 2A-3 and five together, technology is a barrier. So I've seen some medical devices, definitely home-use devices have this failsafe mechanism. Most importantly, with continuous monitoring systems. Let's say you have a power outage or Internet break or something that happened. I've seen some devices implement on-device stories for temporary purposes that can hold data for four hours to eight hours that have helped with continuous monitoring devices, not disrupting the care that is given to these patients. So that I think FDA and industry can string such fail safe mechanisms is very important.

Last but not least, safety measures. How do I ensure as a physician or a clinical researcher in the field of cardiology that the device is given to a patient? And the patient who is intended to use it is actually using it? So, how do I ensure an appropriate use of devices? One example I can quote here, if there is a surgery being done and often if you're snoring, we test the patient for sleep apnea. And we send a patient, let's say, with a home-use device to come back to us and record it to ensure that they should be qualified for a procedure. There may be a potential risk that the patient actually is measuring sleep apnea clearance on somebody else and not himself. So how do we regulate medical devices to ensure such risk is not happening? That's all I have. Thank you so much.

Mr. Conway: Sure. Thank you very much. Ian.

Mr. Burkhart: This is Ian Burkhart. I have a short clarification to 2A-1. Based on what Dr. Peters mentioned, making sure that we include the caregivers, but also understand that many people have multiple caregivers that might be helping. So, many times for the post-surgery or appointment where they're being introduced to a device, they have one caregiver with them. And then, how is that managed and who can provide education to subsequent caregivers, even after they're used to a device?

My other comment is for section 2B. Talking about how taking devices for market authorization that might result in larger, longer studies that could delay access. I think that's a really challenging problem. And there needs to be a little bit of a sliding scale there for balancing the speed of which these devices are going out and how much that impacts on the quality-adjusted life years for the individual with a certain disease or condition. Because there's plenty of people who just aren't around long enough to see devices that actually could have improved their quality of life. And especially balance that with the efficacy for scaling it to larger patient populations. Obviously, it needs to be safe and have some level of efficacy for it to even

get out to be approved. But before we transition to other populations, see if we can balance that to make sure that more people have access to it.

Mr. Conway: Thank you, Ian. Yeah, thank you. Dr. Fischer.

Dr. Fischer: This is Gwen Fischer I'm responding as a provider to 2A-5 and 2B. For 2A-5, I just want a second and expand on something that Dr. Peters said about alarm settings that this is a key component of safety and the ability for a patient to be comfortable at home with a device. As an example, many of our pediatric patients who are on tracheostomy ventilators at home, their families will turn off the alarms because they're constantly going off, which is a key safety risk for those patients. So making sure that alarms are tested in a real-world setting. And also advocating for patient community involvement on alarm use for devices, particularly critical devices such as ventilators.

And then for 2B, I just wanted to make a comment that larger and longer studies will absolutely be a significant deterrent for pediatric trials and possibly other small market trials due to the lower market return and cost of those pediatric or small market trials. Post-market evaluation may be stopgapped to assist with that for looking at safety metrics and incorporating a larger slice of the population. Not ideal, but a potential way to increase the signal across a more diverse population. And also considering use of real-world evidence in virtual patients, both of which I know are current initiatives of the FDA and would certainly benefit small market populations.

Mr. Conway: Great. Thank you very much, Doctor. Dr. Joniak-Grant

Dr. Joniak-Grant: Hi. Thank you. So, speaking to 2A-1, I'd recommend thinking about the amount of cognitive energy required, the number of steps involved, and the complexity, thinking about patients on their good days and their bad days. The size, shape, feel of buttons. Another thing would be especially if you're doing things on apps, but the impact of background and text

colors, font size, animation, flashing lights, scrolling. I'm thinking about when people have a migraine that perhaps has been going on for two weeks, scrolling and sounds and every flash, they can see flickering that other people can't pick up in their line of vision. And looking at screens can be really difficult. I think is it intuitive enough that if a patient is in heavy pain or medicated or caregivers are overloaded and stressed, can they still figure it out?

In terms of 2A-3, is there optimized viewing for tablets and mobile phones? So, for example, with tablets don't just expand the view, have it actually work for tablets. Give people options to look at it in landscape and an increased font and reader options as well as integrated text to talk. One thing to consider is if you have to seek help, do you have to seek help from your mobile phone where you're also maybe using an app and trying to toggle back and forth between multiple screens to figure out what needs to be done?

In terms of 2A-4, children and pets, are buttons enticing to little ones? Is there a big green glowing button like there is at my father's pacemaker machine that his grandchild takes everything he has not to push that button every time he walks past the room. What about if there's pets in the home? Especially cats. Cats like warm equipment. They like to walk across things. How easily can things be turned off accidentally? And other things in the home environment. Temperature has been mentioned, but also what about dust? If you live in areas with lots of sand, pollen, we have a pollen season here where if you're outside for just a few minutes, your phone is coated in pollen. So, to consider those types of aspects.

And then in terms of evaluation the FDA, what they should consider during evaluation, I think has industry-involved patients throughout the process versus this one and done approach. Have potential users use the device in a variety of ways on good days and bad and maybe even consider have they done things like focus groups to test pictures and drawings or test directions to see how well people understand them.

And finally, to speak to 2B, I think those three principles are really important, but I think data validity is another one, as well as affordability. Timely access absolutely matters, but many patients expressed, as was mentioned earlier, that they're very tired of feeling like guinea pigs, and I hear that a lot. Especially when certain devices could be used for years and years and years and they feel that they may be pushed to market very quickly. So, I think it's, Important that efficacy be strongly established because using medical devices can often come at a significant cost to patients. And often they're having to choose between trying device X or device Y, and if they try one that turns out to not have as great of efficacy, they may not have the opportunity to ever try device Y. So, I think it's a very fine line that we walk, but needs to be considered. Thanks.

Mr. Conway: Great. Thank you very much. Ella Balasa. Go right ahead.

Ms. Balasa: Hi, Ella Balasa. I'm providing a comment generally to 2A. I think it's really important when designing medical devices to consider how it will integrate into a person's daily life. How easily, and especially when it comes to a wearable kind of device, how cumbersome this device is to wear on the body if it affects sleep patterns long term, also hygiene and cleanliness, how easy or difficult it is to keep clean with wearing such devices.

And then also to comment on 2B-1 and talking specifically about the inclusivity portion. I think it's important to consider inclusion and exclusion criteria and the broadening of those criteria to include patients that may have varying levels of disease manifestation. To make sure that information is gathered on patients across the spectrum of disease that's being affected.

Mr. Conway: Great. Thank you very much. Dave White.

Mr. White: Thank you. Dave White responding to question 2A-4 other aspects of the home environment that may limit or impact safe and effective device use. One aspect of the home environment is that it's multiple environments. I would like a device to work as well at home, as

it does at work, as it does at school, as it does in the ballpark, ideally. And additionally, some people are housing challenged and moving from environment to environment can be challenging. I think Ian touched on that, I didn't even think of that. In every environment, you're encountering possibly having to work with a different care partner. So I think that device functionality needs to be environment agnostic.

Mr. Conway: Thank you very much, Dave. Teresa.

Ms. Diaz: Teresa Diaz. I'm going to expand on what Dr. Wilcox was talking about with 2B-1 with the studies. I am very familiar with device events and what Dr. Wilcox was saying is how difficult it is to get this world data. And I'm very familiar with device events, working with Madris Kinard and she has a way to get that old data. And instead of using new studies, you could go back and look at prior cases, prior events so that it would be less cumbersome.

Mr. Conway: Thank you very much. Dr James.

Dr. James: I thank you. Jijo James responding on behalf of industry for question 2A generally. And I know we've spoken about this a lot today, but human factors and usability is an important factor in the development design and review of devices intended for use in a nonclinical setting as we're talking about in home-use. But right now, there's no centralized human factors resource within CDRH and we would recommend establishing a centralized group, to establish consistency in the review considerations for medical devices that could be used in a home setting by lay users.

Secondly, it would be also helpful if the FDA were able to work closely with international standards groups to establish and recognize home-use performance and safety standards. And I think it's Dr. Yanamala who mentioned interoperability. This would go a long way to not just ensure interoperability, but ensure standardization of cybersecurity standards for home

technologies, ensure data security, privacy, and perhaps seamless integration with different devices and systems.

Mr. Conway: Great. Thank you very much, Doctor. Dr. Wilcox.

Dr. Wilcox: Yeah, I just wanted to address something that Dr. Sitapati mentioned, which is that the issue of disabilities and the fact that many of the conditions that these devices are designed for create all sorts of difficulties in using those very same devices. One of the ways that's addressed now is to use representative samples of actual patients. And so, that's one way that's being addressed, but what could be done perhaps, and we've occasionally done this, is to weight the sample toward those who are the most challenged with the theory or the basic concept that if the people who are the most challenged can use it, then it's probably going to be okay for everybody else.

Mr. Conway: Thank you very much, Doctor. Ian, looks like you may have the last comment here.

Mr. Burkhart: Yeah, thank you. I just have a quick comment to add on to what Ella mentioned as far as inclusion exclusion criteria. I work with a lot of researchers and a lot of times inclusion exclusion criteria is really built to make it easier on either the clinicians doing the research or the industry to make sure that they have the best opportunity for success. And they often exclude patient populations that might be the best ones to benefit from these devices. So I know that it can be challenging, to maybe have someone included who's on a ventilator in a clinical trial. But sometimes people like that are really the golden window of who's going to benefit best. And I think that needs to be reevaluated.

Mr. Conway: Great. Thank you very much. Sure thing. At this point, FDA, what I'd like to do is try to summarize this. FDA, in regard to question number two, the committee generally believes, and I'll answer this in two sections, Section A and Section B, that on Section A there are multiple

different factors here that the agencies should consider based on the committee and in regard to the end users. In terms of design and evaluation, I'm going to blend a bit of one through five here at the strategic level. There are a couple of things that have been raised. Coordination with international standards of what is defined as over the counter or home device, elevation of human factors, engineering an interface, how that actually works. And then, in terms of the actual specifics of design and how things are taken into account for patients, you heard a tremendous amount of detail on things related to technology and interface, such as buttons, their size, the shape, the feel, font size, how they scroll, voice command, all of these things I think are important for industry and for FDA. But you also heard a lot of other things that have been mentioned here about cognitive impairment, the amount of energy it takes for a patient that's dealing with a chronic condition to simply get through their day in addition to having to manage devices at home. Reduced functionality of a person, linguistic inclusion and linguistic barriers, reading levels, age, and whether or not the person is dependent upon other types of medical devices, things as simple as eyeglasses and how important that plays in terms of practically, what does it mean when something is taken home.

In terms of some of the tech issues, other tech issues that were raised, very important ones, in terms of rural communities whether or not industry has taken into account things like signal boosters for people that live in areas that have limited broadband. And then also targeting down in terms of zip codes and understanding where people are and where they live and the communities that they live in based on zip code and what challenges that may face. Again, on the technology side, one other thing to mention is how they're designed in terms of what they can be used with including tablets or text to phone. A very important issue as we start to take a look at the issue of safety is failsafe and what does that actually mean? And how does that define in a home real-world setting? What does that actually look like to a patient? Whether or not enough

data is saved, whether or not there could be a continuation of the care. How alarm systems are set up. Not just in terms of their sights and sounds, but also in terms of who else might be using them, how else they actually are used in the home. I think Dr. Peters made a very good point about that in terms of that if you want a device that actually follows a patient during the course of a life. How alarms work and whether or not they're acceptable in a workplace or in different settings is vitally important to the patient.

The other thing on the safety side is the factors of children and pets. What are they attracted to? What might they inadvertently misuse or cause a problem with. Environmental factors also, such as dust and sand. And then, I think Dave White made a great point here, which is in regard to many Americans who don't have necessarily home security or who define home as kind of a moving target at times. Does it work? And is the intention here for something to be as intuitive to a patient where they live, where they play and where they work? And does it work in all those different environments? In terms of other safety issues, a key point was made about who is actually using it in the household, or whether or not a person may be delivering specifications on behalf of another person and how do you control for that, or how do you anticipate that for safety?

In terms of different types of conditions, and how do you sort that out, I think that Dr. Wilcox made a very good point about diabetes as an example, also people with disabilities and whether or not in terms of segments of populations, if maybe perhaps data could be weighted in that regard. Ian made a very good point about the fact that the term caregiver sometimes is in singular, not plural. And that understanding that for patients with chronic disease and acute conditions, oftentimes the handoff, or what we would call the continuity of care, can involve multiple teams, short term, midterm and long term and the turnover of people. And are these

devices understandable? And those technologies understandable given what a patient faces, which is multiple care teams?

And then, in terms of a common theme, I think you heard that in terms of populations, cognitive impairment, people with disabilities, oftentimes some of these things are being designed perhaps with one treatment or one intention, not understanding the multiple cofactors that other people are dealing with, or the fact that technology has to be open to track the path of a patient working through an acute condition or a chronic condition. I'll stop there and then move over to part 2B and summarize that.

A number of different issues were raised on this. Some of pretty profound importance in terms of evidence for clinical trials and the principles. I think there was general consensus that the principles that FDA has put forward and anticipates are good. There are some other concerns that people would, I think, augment those with and those include different things, like in terms of demographics. Dr. Wilcox made a very important point in regard to trying to get to an ideal population whether or not the numbers that are involved in trying to identify or get to a certain point in a trial might have an increased difficulty in terms of length of time or recruitment goals. We also heard that in terms of beyond patient-reported outcomes or beyond what might be anticipated by researchers or scientists, in terms of where you want to go or the outcome that you should be open to other things that patients find important and that should be captured. I think Dr. Peters characterized it as you might find new data and things that are more meaningful in some ways to the patients themselves and be open to that. Several times Ian made this point, others made this point that larger studies can delay access and there's a balance there. A suggestion was made on sliding scale because the ultimate end user in many cases is the patient that's in the most distressed situation, and that in the pursuit of an ideal trial or a target in the trial, that might create a delay. That person that it might be intended for may never see it in their

lifetime. And I think that's an important point to keep in mind. Dr. Fischer also raised the issue of larger studies having a disincentive, especially in the pediatric population. Other points that were raised in terms of importance were data validity, affordability, efficacy, inefficacy in terms of patient choice, because oftentimes patients might have the option of choosing one thing, but they may not have the opportunity to choose other devices. So, information and data on what is efficacy for different populations is very important. I'll stop there and ask FDA, is this adequate as a summary for question number two?

Dr. Faris: Hi, this is Owen Faris. Again, thank you to the committee for a really thoughtful discussion. We all took a lot of notes, and I'm sure it's going to be really helpful to us. I'd like to just invite the panel for any additional comments regarding 2B and I'll just put a couple of comments out to maybe support that conversation. Dr. Tarver's presentation this morning talked about FDA's commitment to develop and publish a framework that would outline the considerations that the agency should think about for when we should determine that a diverse enrollment is necessary to support an assessment of the safety and effectiveness of a product. We heard a lot of great suggestions and acknowledgements of the limitations and challenges that such a requirement would place. We heard some suggestions of things that we could do in the post-market of using registries and real-world data to assess the performance of a product in a diverse population. We heard suggestions about inclusion criteria to make sure that the tent is big in those studies and that diverse patient populations are invited to participate. I think I'd like to invite, if there's any additional discussion and recommendations, about how FDA should think about situations, patient conditions, device characteristics, where diverse enrollment in a pre-market study is necessary in order to make an assessment that the device is safe and effective and should be authorized for market.

Mr. Conway: Great. Let me go ahead and take that. Dr. Yanamala, go right ahead.

Dr. Yanamala: I'm Naveena Yanamala. I will be responding to Dr. Faris's question. I think one thing that may be useful is shared decision making tools between the providers, caregivers, and the patients. So how do I know that with the given conditions, because everybody is precise these days? We are moving from 4P to 5P medicine. Which is going to be not just precise, preventive, predictive precise as well as participatory. In those cases, how do we promote that decision making that we give the power to the patient itself is something that we should consider even in the pre-clinical study. Sorry. I meant to say pre-market studies where the phase one or phase two clinical trials is happening because oftentimes, we get complex cases for clinical trials recruitment as well, where the surrogate can sign for consent, but what is patient's decision there and language barriers. If the language barrier poses a major hurdle, then the surrogate consent comes back in. How do we give back that decision-making power that is well-informed and effective for the use of medical devices? That's one consideration I wanted to raise here.

Mr. Conway: Great. Thank you. Dr Peters.

Dr. Peters: Yes. Hi, this is Dr. Anne Peters. So, this may be a little off topic, but I don't think it is, is that in clinical trials, one of our problems is that our patients who want to be included lack the basic knowledge to be in that trial. So, say it's with a continuous monitor. They don't really understand what glucose levels mean. And so, when we put a device on the market, we're basically assuming a baseline understanding of the disease data, what the device is being used for. And I think one of the reasons things don't work is because people come to the device with all sorts of different levels of knowledge. And I think that for the FDA to consider that we want to make sure that the playing field is level and people start using devices. And so, that might mean that people need more education prior to using and implementing the devices, and that should not only be included in trial design, but in actual use, because I think it's what we assume, but isn't really true in all cases.

Mr. Conway: Great. Thank you, Dr. Peters. Dr. Wilcox.

Dr. Wilcox: Yeah, I want to address that specific question of how do you know when you're going to need a more diverse sample for your research? Now, my experience is with usability testing, just to be clear, not clinical trials. But it's a catch-22. You don't know it's there. It's an empirical question. You don't know if you need it until you start collecting the data. In the case of disabilities, yeah we know what disabilities to expect with a product for diabetes care and what have you. But in the case of ethnicity, that's the tough one. I just think we need to collect better data. And then, when we find some initial evidence that it may be working better with one ethnic group than another, then we should have the requirement of looking into that difference specifically, more deeply.

Mr. Conway: Great. Thank you, Dr. Wilcox. Dr. Sitapati.

Dr. Sitapati: Hi, Amy Sitapati responding to more details on 2B. I think that perfection here in getting to the solution might be an iterative approach and perhaps what we need to think about are where the areas where we see the highest signal for national disparities in health outcomes and burden of disease. And at the very least, those devices that are informing the solutions to help care for those diseases should also be inclusive of the populations with that. So, for instance, if we think about hypertension or CVD or CKD, perhaps we're being intentionally more inclusive of our Black and African American patients. If we have diabetes and poor diabetic outcomes, loss of sight and limb, perhaps we're being more inclusive and thoughtful about Latinx and Spanish speaking populations. If we're thinking about maternal health outcomes Black African American and Pacific Islanders. If we're thinking about cancer treatments, again, the rural, but this won't address rare disease and other factors. But I think at the very least should help to inform an approach.

Mr. Conway: Thank you very much. Dr. Joniak-Grant.

Dr. Joniak-Grant: Elizabeth Joniak-Grant. I think it's important that we be intentionally inclusive whenever we can. Obviously we'd want to have it more heavily weighted in cases where there seem to be that there will be these strong outcomes, but I think maybe thinking about a baseline of what that looks like. True inclusivity means inclusivity wherever we can. So, I think we need to try to not start cherry picking already at the starting line of where it needs to be done, and maybe where it doesn't need to be done, and have the goal be that it just gets done.

Mr. Conway: Great. Thank you. Dr. James.

Dr. James: Jijo James and I just wanted to follow up on what Dr. Sitapati just said, I completely agree with her on the outcomes. The only caveat that I would add out there is a lot of times those outcomes are directly proportional to access as well. So just keeping that in mind as we build these requirements in and not confounding the two.

Mr. Conway: Great. Thank you. I'll go back over to Dr. Faris and ask if that is responsive.

Dr. Faris: Yes, thank you very much for the additional comments and insight. I think we have what we need.

Mr. Conway: Okay. Thank you very much. Commander, if you could go ahead and read question three.

Question Three

Commander Olele: Commander Olele for FDA. Question three, as more diverse patient groups are included in clinical studies of medical devices, it is important to communicate potential differences in the level of benefits and risks various groups of patients may experience.

A, what information do you think is most important to convey publicly about these differences in benefits and risks?

B, what information do you think is most important to convey publicly about the study population included in the study?

And C, is there additional information you think patients and caregivers should have available to aid their individualized discussion of benefits and risks of various treatment options with healthcare providers? That ends question three.

Mr. Conway: Great. Thank you very much and to the committee, we're getting in the home stretch. We have two questions. This one, we're going to break it into the three components, which is communicating on public risk and benefit, more information about the study population, and information that folks need to do individual decision-making or better individual decision-making with their healthcare providers. And if you can address your comments in those silos, it would be great. Let's go ahead and start. Okay. Thank you very much. Naveena.

Dr. Yanamala: I'm Naveena Yanamala, I'm addressing 3A specifically. I think it is CCM, context, comparison, and magnitude of effect. So, when I go and talk about the context, providing a context of the observed differences by explaining how they relate to the underlying disease, should be communicated very clearly when we are publishing the studies and clinical studies with medical devices. So, this allows the patients to understand the potential impact on their health outcomes and comparison. So, often there is a question that is posed. How does this treatment compare to the other device? There are similar devices often on the market, medical devices. When it comes to both the invasive home-use monitoring, there are several that are coming up on the market. So, offering comparisons with the standard option, treatment options, or other comparable medical devices to treat the same disease can help patients access whether the observed differences are clinically meaningful to them or even to understand if they align better. If a given medical device would align better with their preferences both culturally and personally and to their lifestyles and context. When I say context, I mean providing the context of observed differences both based on the treatment mechanism as well as the broader clinical landscape. Last but not least, the magnitude of effect. Using the device, how does it improve

both the outcomes as well as the morbidity as well as the lifestyle changes and how does it help them improve their life better around a given health condition. Thank you.

Mr. Conway: Great. Thank you very much. Dave White.

Mr. White: Thank you, Dave White responding to 3B. I would want to know how the study population compares to the actual affected population. For example, about one in three people with end stage kidney disease identify as Black. And as a former dialysis patient, and possibly future, I would want to know if to study population of any new devices for home-use under consideration matched or exceeded my cohort's percentage of the affected population. I could also say the same thing about hypertension.

And responding to 3C, additional information, I think patients and caregivers should have available, I would think adverse events possibly measured by 1000 hours of use. But some measure that would be broken down in a way that's easily understandable and could facilitate a shared decision-making discussion between a patient and a clinician.

Mr. Conway: Great. Thank you very much, Dave. Dr. Peters.

Dr. Peters: Yes. Hi, this is Anne Peters. I'll talk about 3A first. I think it's hard to rationally discuss benefits and risks, even though it's very important because everybody hears the risks and sometimes they don't often hear the benefits. And as a physician, I spent a lot of time trying to balance that for patients. What is the risk? What is the benefit? And give options. But I think we need to avoid too much in terms of numeracy, percents of things or how you look at it. I think you have to have really simple explanations for people looking at the risks and trying not to minimize them, but to make them make sense for that individual. In terms of looking at the population that was included in the studies in 3B, I think it's important to talk about the population that was excluded. Why did they exclude people with kidney disease? Was it because

this drug affects kidneys or because they just decided not to look at it in that population? It's very important to be clear on the exclusions.

And finally, additional information. I think that what patients want to know from me is that I thought about something. So, what I do, and I think you could do this with AI, but I take the patient and who they are, and I look at the risks and the benefits, and I say, you're at low risk for this complication from this drug or device because of X, Y, and Z. So, they know I've thought about the risks in the context of this individual, and then give them a sense of the benefit and risk to them, because otherwise people just get scared. So, I try to make it about the person and really a considered approach that doesn't hide it, but really talks about it.

Mr. Conway: Great. Thank you very much, Dr. Peters. Ian.

Mr. Burkhart: Hello, this is Ian Burkhart. I have a response to 3B. I think once again it's enough of a balance as far as how much of the information you can share without impacting patient privacy. But really being able to share the demographics of the individuals who were involved in the trial and what their outcome was and breaking that down by race, gender, other health factors that they might have, socioeconomic status, and geographic location. I think that can help then make a patient have a better decision making process if they can see themselves included in the data.

Mr. Conway: Great. Thank you very much, Ian. Dr Wilcox.

Dr. Wilcox: Yes, Stephen Wilcox. I completely agree with what Ian Burkhart just said. It really is about transparency, using a diverse population as diverse as you can, and then being as transparent about it as possible, including the outcomes. But I wanted to bring up something else. We're always trying to make the design of a device so that it can be used by everybody. But it's quite common that at a certain point, especially if it's a progressive disease, a transition has to be made from the individual using the device to a caregiver using the device. And that's information

that's not typically included in the material with a device. What are the criteria for whether or not a caregiver has to be involved when to expect perhaps a transition? The use by a caregiver and so on. I'd like to see some guidance along those lines.

Mr. Conway: Great. Thank you very much, Doctor. Dr. Sitapati.

Dr. Sitapati: Hi, Amy Sitapati, responding to 3A and B on benefit and risk. I think quality of life is the benefit. Safety events and failure, really important for risk. And then, in terms of the study population, I don't know the how, but I know maybe the what. It is patients like me and people increasingly want to look in big data and understand. If I'm a cancer survivor and I was exposed to high-dose steroids, should I get the implant and when? If I have a trait with a chronic condition, what's the chance of infection? If I'm getting a gender inclusive surgery and get the implant, what's the chance for failure? Patients like me are what patients are looking for, but I don't know the how.

Mr. Conway: Thank you very much. Dr. Wilcox, I think you may still have your hand up. Let me go to Teresa.

Dr. Wilcox: Sorry.

Mr. Conway: No problem at all.

Teresa Diaz: I'm going to be answering for 3A, the benefits and the risks. I really feel like informed consent, fully-informed consent, full education, clearly-labeled products. Public awareness campaigns between social media, radio, whatever to get that education out there on that product.

Mr. Conway: Thank you very much. Dr. Fischer.

Dr. Fischer: This is Gwen Fischer commenting on 3C from a provider's perspective. Many of our patients, especially looking at a complex or critical device asked for interaction with other

patients or caregivers that have had that experience with that device. So perhaps an access to a patient advisory group or panel, keeping in mind the HIPAA issues around that.

Secondly, just expanding a little bit on what Ian and Dr. Peters both said about information on risks that families and patients may want. We found that the words common, not common, and rare are typically less concrete than what a lot of our patients are asking for. They frequently want numbers, so if numbers are available, something like 20 percent risk of stroke versus not common is a much more concrete and helpful way to phrase something or way to give parents information so that they can really have a concrete idea of the risk of something that they're about to undertake.

Mr. Conway: Great. Thank you very much, Doctor. Necie.

Ms. Edwards: Hi, Necie Edwards here. I'm addressing 3A and 3B. So, for 3A, from a patient perspective, I will be concerned about the limitations of the study including the limitations of the study design, the sample size, and the statistical methods used. So, for example, a study may be limited by the small number of patients who were included in the study, but this can make it difficult to detect small differences and benefits and risk. And then for 3B regarding the study population, what comes to my mind is a patient that would matter. Ian mentioned earlier about the demographics, but besides the age, gender, race, ethnicity, and socioeconomic status of the patients who were involved in the study. I was thinking about a study, for example, if it finds that a medical device is effective in reducing pain in a population of White women, that may not be generalizable geared towards patients for a population of Black men. Otherwise, sometimes they try to lump us all together, but they don't take into consideration some of the differences. Thank you.

Mr. Conway: Thank you. Thank you very much, Necie. Ella.

Ms. Balasa: Ella Balasa. This is a comment to follow-up to what Dr. Anne Peters said about the benefit and risk and having that conversation with the patients to determine what the limitations of a specific device would be. For a patient based on their lifestyle, their comorbidities, their current state of health and various other factors and really being transparent in that so that there can be the best determination made of whether a certain device is best suited, based on that for a particular patient.

Mr. Conway: Great. Thank you very much, Ella. And, Dr. Joniak-Grant, if you can be brief on this, and then we'll have Naveena, and then we'll move on. Go right ahead.

Dr. Joniak-Grant: Absolutely. I'm going to try to only say stuff that hasn't been said. So for 3A what exactly were the differences and the degree of differences observed and in what groups? For 3B, I would want to know the length of this study, the number of participants in various subgroups, and then if certain groups were not included or not included at sufficient numbers, I would want that to be stated, to just be obvious. Not that I have to figure it out myself.

Mr. Conway: Okay. Thank you very much. And Dr. James, go right ahead.

Dr. James: Sorry, it took me a minute out there. Jijo James, I just wanted to emphasize what Dr. Peters, Dr. Fischer, and Ella just said around benefit-risk. I think we do take a risk-based approach to benefit-risk. And what do I mean by that? We count the same risk multiple times, but we don't do a good job of counting benefits, especially benefits that matter to patients. And we need to do a better job of that and probably develop some kind of a methodology to quantify benefit-risk so that we're not talking in degrees, but in numbers and update those risks or that score as products remain in the market. Because again, a lot of this work happens upfront pre-market, but we don't take the effort to update the risks and benefits. And a lot of times those risks go down based on what you're seeing in the population as it may go up as well. Likewise with the benefits.

Mr. Conway: Great. And Naveena, I'll give you the very last word on this.

Dr. Yanamala: I'll be very brief. I'm Naveena Yanamala. One question following Dr. Peters's comment about exclusion right here that popped up was geographical diversity. The information of geographical diversity is important because we know that the temperature, altitude can actually influence the vital signs and other things, which aren't also comorbid conditions, often which become the inclusion exclusion criteria. So, there should be information that should be communicated, like a disclaimer or a limitation. Somebody was pointing it out previously in the discussion about it has not been tested in this population. So, how do we control for such benefits and risk when evaluating special subpopulations?

Mr. Conway: Okay. Thank you very much. FDA in regard to question number three, the committee generally believes that in terms of communicating benefits and risks, which would be basically 3A, the information most important to convey publicly about these differences ranges across from comparative data in terms of how does this risk-benefit compare to a device in similar class versus another device? What's the magnitude of impact of risk in regard to morbidity and lifestyle? Other key things are the context of it. The effects on a particular disease, impacts on individuals, clinically important in the meaning of importance to patients, the issues of quality of life versus a device that may fail, limitations on design. Critically important also is informed consent and how it is labeled. And Dr. James raised the issue of quantifying risk, not just at the front end, but longitudinally after it's been in the marketplace.

In regard to information about study populations I think it was stated right off the bat by Dr. Sitapati, which is patients like me. That's a core question. So who was included and who was excluded as a population and who were those groups and what are their numbers? Dave White raised a very good point about does the study actually compare to populations that match the cohort of importance or the intended consumer user. Did a study include the target population or

the ultimate end users or not? You heard more again about transparency and the outcomes. Better definitions about common and rare and how that was included in a study population. Whether or not data is generalizable. There was a concern that things may separate out by age, gender, and race, but it's not always generalizable. And having patients know that information up front is important.

And then in terms of other information for individuals to make decisions with their healthcare provider, Dr. Peters raised the point that it has to be in the context of the individual and the person that providers should be encouraged to provide the context of what the risk balance means to an individual person. Another issue that was raised by the committee of concern is the criteria for at some point when it transitions over and it involves more than just the patient, it may actually involve use by the caregiver. There were suggestions made on how to get some of that data, whether or not it's having a patient panel or not. Again, the issue of common or rare was brought up. And then in terms of how you discuss relative risk to a patient in terms of percentages and what that actually means. And is it meaningful to a patient or not? I'll stop there and ask FDA is this adequate?

Dr. Tarver: This is Michelle Tarver, FDA. Thank you very much, Mr. Chairman and the panel members. This was very helpful. Thank you.

Mr. Conway: Great. Thank you very much. With that, I'll go ahead and ask Commander to read question number four, the last question.

Question Four

Commander Olele: Commander Olele with FDA. Question four. Digital media has allowed the FDA and industry to share information efficiently with audiences who are comfortable users of such technology. However, these communications are not able to reach all patients and consumers who use medical devices. Studies suggest certain groups are less likely to utilize or

rely on digital forms of communication, whether due to age or generational differences, lack of access to reliable broadband service (commonly found in under- resourced urban and rural communities), cultural or other factors. What methods or approaches should the FDA and industry consider reaching individuals and communities who have limited digital literacy, engagement, or interest in digital media? Please consider both dissemination of information as well as hearing about needs and concerns of such individuals and communities. This ends question four.

Mr. Conway: Great. Thank you very much to my fellow committee members, I might suggest we do something like this, given the breadth of experience that's represented on the committee, there are two things here. One is an issue of tactics that you might recommend, and the other is in terms of engagement, hearing back from specific audiences and different communities. So, I'll put that out to you, and let's go ahead and start the responses. Who would like to go ahead and start? And we'll start with Ian. Go right ahead, Ian.

Mr. Burkhart: This is Ian Burkhart. I want to first give a little bit of a nice plug to the FDA, because I think they have done a good job of reaching out to patient advocacy and support groups. And I think that's a great way to meet people where they are. Because if some one individual might have an issue with communication digitally, generally someone in their community may not. And so there, there might be a way to still get that information, both to and from. Additionally, just meeting people where they're at, whether that be a church, sports, or recreation teams and trying to find those types of groups to be included. Because, like I said before, it's relatively unlikely that a whole community is going to be shut out of using forms of digital communication. There's still a chance, but it's unlikely. Thanks.

Mr. Conway: Thank you. Sure, Ian. Thank you. Dr. Joniak-Grant.

Dr. Joniak-Grant: Thank you. Elizabeth Joniak-Grant. In terms of tactics for disseminating information, television is one thing, elderly people still watch a lot of television. Print in terms of papers, billboards could be a possibility in rural areas, subway ads in urban areas, leaflets in healthcare provider offices. There was some mention of radio earlier on in terms of recalls, I think this is more specifically for industry. If you can find me to mail me a bill, I think you can find me to send me a recall notice. So, I think that's something that FDA needs to hold industry to a little bit more. And in terms of hearing about their needs and concerns, one option is reaching out to patient organizations, which has been done. Medical sociologists, researchers that are in these patient spaces, community organizations and community leaders. Also thinking about maybe commissioning some qualitative research, whether that's interviews or focus groups. But really sending people out into the field or out into particular communities or patient groups where you're trying to find out more information.

Mr. Conway: Great. Thank you very much.

Dr. Joniak-Grant: Thank you.

Mr. Conway: Dr. Peters.

Dr. Peters: Yes, this is Dr. Peters. So I've worked in many settings where the digital literacy level has been very low and it's been very hard to communicate that way. And there are all sorts of workarounds and I think the most important thing for me as a provider is to realize that my job is to have many different ways to communicate. And sometimes a family member will be the one who will look at the phone or the app and help. But really you want patients to be independent that way. So a telephone call can work for certain people if you need to reach them. We've given people smartphones, but that then ends up having difficulty with broadband and things. But we have community health workers, we have promoters. There are ways that there is ongoing community outreach and that can be used to help people. And then we always have our clinic

available so people can come in, they can bring their devices, we can do the program and we can do whatever they can't do. And I like the idea of having mobile vans, for instance. Some places use those. We've used them for dentistry and asthma in LA County, where if a van came and they could help you troubleshoot and figure out what you needed to do every week, it can really help in terms of transferring data and learning what you need to do. I think there are a lot of tactics that can be employed as long as people are willing to think outside the box and really meet the patients where they're interested in talking to you.

Mr. Conway: Great. Thank you very much, Dr. Peters. Necie.

Ms. Edwards: Hi, Necie Edwards. What I want to add to the conversation about tactics is as follows, and maybe the FDA is already doing this. The FDA could create a video that explains the benefits and risks of medical devices, could be posted on the FDA website and shared on social media. Also, number two, the FDA could partner with community health centers to provide information about medical devices. The health centers could then offer educational workshops and could provide patients with access to computers and internet connections. And, in addition to that, work with patient advocacy groups to create materials tailored to specific populations geared towards older adults as well or people with limited English proficiency. I know in my county here in Lake County, Illinois, the health department oftentimes is the leader here who is really great about putting out information, engaging in the community. So, I think public health is also a resource. Thank you.

Mr. Conway: Great. Thank you very much. Any other last comments that I may have missed on question four? Dr. Fischer, go right ahead.

Dr. Fischer: This is Gwen Fischer, just to point out that about a quarter to a third of Americans don't have broadband, but almost every adult in America does have a cell phone. So using text is a great way to communicate. And I think the government COVID opt-in surveys are a good

example of how that worked for them. So, thinking about patients signing in as an opt-in service with either a company or the FDA after receiving a medical device for optional follow-up and critical information might be one way to disseminate information about specific medical devices.

Mr. Conway: Great. Thank you very much. At this point, FDA, I'd like to go ahead and summarize for question number four. In regard to the question number four, the committee generally believes that in terms of tactics and engagement, I might be able to use that to summarize this in terms of tactics that could be used for dissemination. Obviously there's social media, and then there are a series of different communications platforms, television, radio, print media, billboards for rural areas, leaflets for doctor's offices. A point was made that on medical recall information, leveraging the power and operational capacities of industry, that if they can send you a bill, they can probably send you a recall notice. Other types of outreach in terms of mobile vans, better incorporation and utilization of public health officials. Understanding that broadband does exist nationwide and making a better use of text messaging. And then not forgetting the basics of the communications networks of the family. And telephone calls going out in the communications within a family and within friends and networks like that.

In terms of engagement and reaching out and leveraging the insights of other organizations, and with that, their communications platforms. You heard about engaging patient advocacy organizations, patient organizations, support groups, professional organizations, the faith-based community and churches, community health centers, recreational teams and sports teams, researchers, professional communities, and then conducting qualitative research to understand more about the unique needs of different communities. I'll stop there and ask FDA if this is responsive.

Ms. Witters: This is Alicia Witters. I just want to thank you all for your thoughtful consideration of this question. We find the response adequate. Thank you.

Mr. Conway: Great. Thank you very much. At this point, what I'd like to do is thank the committee and the FDA for their fantastic contributions throughout the day. I'd also like to thank, again, the open public hearing speakers, the time they invested to participate, patients, industry, healthcare providers, healthcare researchers, community engagement experts, and FDA for their remarks. I want to ask the FDA representatives if they have any concluding remarks. Ms. Capanna, Drs. Tarver and Owen, and Ms. Witters.

Ms. Capanna: Hi, this is Kathryn Capanna. On behalf of the entire FDA team. I'd like to thank each member of the committee for taking the time out of your busy lives to contribute to this essential discussion today on advancing health equity with medical devices. We thank you for sharing your expertise, your insights with us on strategies that FDA and medical device industry can consider to influence medical device innovation to make a difference for patients who may have been medically underserved in the past or patients that face disparities in the current healthcare environment. This meeting and your contributions underscores the importance of continuing to examine challenging issues through the lens of the patient and the peak is a cornerstone in our efforts to understand and incorporate patient perspectives and experiences into FDA's work. So, thank you to all of you. We appreciate you.

Mr. Conway: Great. Thank you very much, Dr. Tarver.

Dr. Tarver: This is Michelle Tarver. I just want to echo our heartfelt thanks for the work that you all did. The diligent responses you provided to the questions and the thoughtful insights that we heard, not only from you, the members of the patient engagement advisory committee, but also the speakers, the open public hearing speakers and everyone who participated over the course of the day. So, I just want to say, thank you. And we look forward to reviewing the recommendations you provided and determining what our next steps will be.

Mr. Conway: Great. And Ms. Witters.

Ms. Witters: I don't really have anything to add on top of what Katie and Michelle have already shared. Just, thanks again to you all. Appreciate your feedback and your careful consideration today.

Adjournment

Mr. Conway: Great, thank you very much. I'd like to thank you all for joining us at the patient engagement advisory committee, where the patients and care partners provide our perspective to FDA's Center for Devices and Radiological Health. It's known as CDRH. You've heard it a lot throughout the day. Your participation and discussion for the committee today were an important step forward in helping to assure the needs and experiences of patients that are included as a part of FDA's approach to advancing health equity and medical devices. And then I just want to say this final word, so that you folks know this quite well. You had an opportunity to participate in the PEAC, and as we said at the beginning, it's quite unique for the FDA. It is a patient centered advisory committee. Most unique, it's the one that the FDA stood up. It was bold when they did it. And we should be grateful as a patient community, I believe, that they've leaned forward. It has national recognition and global recognition of excellence for including patient insights, real-world evidence, and trying to bring things back to the person, every person who deals with medical issues. And these are U. S. civil servants that we participated with today at the FDA, from the Commissioner on down the line. A real example of leadership in a time, sometimes, when people don't see it that often, but I'd like to thank the FDA personally, and I'd like to thank each of my fellow committee members for their excellence today and their contributions. So with that, this meeting of the Patient Engagement Advisory Committee is now adjourned. Thank you.