SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

PATIENT ENGAGEMENT ADVISORY COMMITTEE (PEAC) MEETING

September 6, 2023
9:00 a.m. EST

Chairperson

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

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

Consumer Representative

Teresa M. Diaz
Co-Founder, Global Patient Advocacy Coalition

Industry Representative

Jijo James, M.D
Chief Medical Officer, Johnson & Johnson Medical Devices Companies & Global External Innovation

Food and Drug Administration

Letise Williams
Designated Federal Official

Kathryn Capanna, M.B.A
Associate Office Director (Acting), Office of Strategic Partnerships Technology Innovation (OST)

Owen Faris, Ph.D.
Principal Deputy Director, Office of Product Evaluation and Quality (OPEQ)

Michelle Tarver, M.D., Ph.D.
Deputy Center Director, Chief Transformation Officer

Alicia Witters
Acting Director/Deputy Director Office of Communication & Education (OCE)

CALL TO ORDER
INTRODUCTIONS

Chairperson Paul Conway called the meeting to order, noting the special nature of the PEAC, as it is comprised solely of patients, caregivers, and patient advocates. He stated the committee's purpose: to provide advice and recommendations to the agency on complex issues relating to medical devices, the regulation of devices, and their use by patients. He noted that with the nonvoting members it constitute a quorum and read the day's agenda: to discuss and provide advice on the FDA topic of advancing health equity in medical devices. He prompted committee members to introduce themselves.

WELCOME FROM FDA COMMISSIONER — DR. ROBERT M. CALIFF

Dr. Califf discussed ways FDA is committed to informing their work with diverse patient perspectives, preferences, and unmet needs. He mentioned FDA's mission to consider the needs and characteristic of all people and populations, which is a complex task for a population of 340 million people. He expressed concern regarding a decreased life expectancy in the US and the low ranking for the US compared to other high-income countries when it comes to life expectancy. He noted the contribution of geographic location and decreased access to health resources in rural areas. He mentioned the disproportionate effects of new diseases like COVID-19 on older adults, pregnant women, children, rural people, and ethnic minorities. As a response, FDA has increased the enrollment of women, older adult, and racially and ethnically diverse patients in clinical trials and brought in voices of historically underrepresented populations to the drug and device development processes.

Dr. Califf mentioned an FDA call to action that covers the following points:

- Create a more diverse, equitable and geographically representative system of evidence generation for decision-making.
- Revamp the public health information architecture, to enable people to see data relevant to their own communities and circumstances.
- 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.
- Reduce the barriers that prevent aggregation of available information, in a way that supports patient-driven research consortia that answers questions of interest to patients, as well as their families, caretakers, and clinicians, while assuring that privacy and confidentiality are maintained.
- Improve assessment of the impact of the healthcare ecosystem and subsystems on health outcomes
- Tackle misinformation and improve education about science.

Dr. Califf further cited the Office of Minority Health and Health Equity (OMHHE) mission to promote and protect the health of diverse populations through research and communication of science that addresses health disparities and advances health equity, noting that in 2021, OMHHE established the Enhanced Equity Initiative, which aims to: increase equity in clinical trials by continuing our efforts to advance diversity and enrollment; strengthen the application of equitable data by funding research that increases data available on the populations we serve; and increase the equity of voices that focus on continuing to understand diverse patient perspectives, preferences, and unmet needs to inform our work.

CONFLICT OF INTEREST STATEMENT
ADMINISTRATIVE REMARKS

Ms. Letise Williams, the PEAC's Designated Federal Officer, read the Conflict of Interest Disclosure Statement. Mr. Ian Burkhart is President of an organization that received

funds from a medical device firm and personally received funds between $5,001 and $15,000. Dr. Stephen Wilcox is Board Chairman for an organization that receives funding from multiple medical device firms that may be affected by the particular matter of this meeting.

Ms. Williams announced Dr. Jijo James, employed by Johnson & Johnson, as the industry representative. She also noted that Mr. Behtash Bahador**,** a guest speaker, is employed by a firm that provides services to medical product developers. She further announced that Russell Fortney, Director, Advisory Committee Oversight and Management Staff appointed Dr. Gwyneth Fischer as a temporary non-voting member.

Mr. Conway provided a general structural outline of the day's meeting.

OPENING REMARKS — DR. JEFFREY SHUREN

Dr. Shuren thanked the Committee for their service and noted that CDRH directly incorporates PEAC feedback. In response to last year's PEAC feedback, CDRH has made available a public resource on AR/VR to better show how AR/VR is being used across medical disciplines. Further, 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. The infographics are available in both digital and print and in English and Spanish (in progress).

Dr. Shuren outlined CDRH's specific objectives to increase health equity: to empower people to make informed decisions regarding their healthcare; to facilitate availability of and access to medical technologies for all populations; to reduce barriers and increase opportunities for participation by diverse populations in evidence generation; and to support innovation of emerging and existing technologies that address health equity by changing healthcare delivery to move care and wellness into the home setting. He highlighted the specific challenge of inequitable access to quality healthcare, noting this can arise from nonexistent treatments and diagnostics, lack of evidence to know whether an existing product benefits a given demographic group, and barriers within the healthcare system itself.

Dr. Shuren mentioned that home health care bridges the gap and noted a specific need to do better in home-directed prevention and wellness efforts. This will require a transformation of our care system and requires that the voice of patients is central to reimagining the home setting. He specifically mentioned digital health technologies that allow for the remote collection of health data in real time. He advised that health equity cannot be achieved in isolation and requires collaboration from patients, providers, industry, taxpayers, and others and closed by recognizing that health equity is one of the most important areas in which to include the voice of patients.

FDA PERSPECTIVE: ADVANCING HEALTH EQUITY IN MEDICAL DEVICES

Dr. Michelle Tarver shared definitions for health equity and health disparities. She mentioned FDA's definitions of race, ethnicity, sex, and age and shared FDA's criteria for evaluating these factors. She emphasized that race and ethnicity are not proxies for biology or genetic anthropology. She defined underrepresented populations and mentioned draft guidance

from FDA and CDRH for serving underrepresented populations, also noting the Breakthrough Devices Program as a facilitator of equitable access. She mentioned the Food and Drug Omnibus Reform Act, which requires the inclusion of diversity action plans for clinical studies. She noted technology's ability to decrease health disparities by increasing access. Four approaches to equity across a device lifecycle are: 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.

Dr. Tarver emphasized the importance of diversity in clinical studies. It supports the generalizability of study results, and 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. Inclusivity, data generalizability, and timely access are all core principles for considering the importance of including diverse populations in the clinical research phase.

Dr. Tarver defined home use as it pertains to medical devices and highlighted the lack of controllability of the home environment, which can impact device performance through environmental or user differences. She shared examples of home use devices, including hemodialysis devices and diagnostic devices like COVID-19 rapid tests and outlined challenges associated with the use of each. She reiterated that opportunities for equitable access are increased by digital health technologies. She noted CDRH's open docket for public input on ways to increase patient access to home use devices. She underscored the importance of clear and effective communication with the public regarding medical devices.

STAKEHOLDER PRESENTATIONS

A Patient's Health Journey — Patrick Gee

Dr. Patrick Gee, a peritoneal dialysis and hemodialysis patient, shared his experience with kidney disease and explored advantages and challenges of home use technologies in the treatment of kidney disease. Home use devices helped him monitor his condition more effectively by using blood pressure monitors, glucose meters, and wearable devices. Medication adherence can be improved by pill organizers and phone applications. Hemodialysis machines and peritoneal dialysis equipment are essential for individuals who require regular dialysis treatments by replicating healthy kidney function.

Challenges include the financial burden of acquiring and maintaining these devices, user difficulties by lack of comprehension and/or training that can be mitigated by comprehensive education, lack of Wi-Fi access in rural areas, and environmental challenges such as difficulty keeping areas clean and lack of safety at home. Home use devices can be challenging to mental health if a patient finds home use and accountability difficult. **Dr. Gee** concluded by urging these factors to be taken into consideration to ensure equitable access.

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

Dr. Roseanne Gichuru, an OBGYN serving women's health in rural and underserved areas, spoke on the use of medical devices as drivers of health equity in those communities. She presented a specific case of a 28-year-old pregnant woman who suffers from diabetes and high blood pressure to illustrate her points. For blood pressure monitoring, the patient can obtain a monitoring device with a prescription that her insurance pays for, by paying out-of-pocket for a store-bought version, or by taking advantage of a program that makes the device available for free. If she can do none of these things, community pharmacies often will check blood pressures for patients once or twice a day, as needed. Data can be collected in three ways: a smartphone app may keep track, the patient may upload the readings into her patient portal, or she can call or bring in the manually-recorded values.

Dr. Gichuru shared hypothetical scenarios: one-on-one visits may be needed if there were not sufficient community resources or home access to blood pressure monitors/glucometers. Language barriers may present if the patient is not English-speaking, so translated user guides that use multilingual pictures and infographics may assist with this. An Amish patient may experience specific challenges related to their community structure and beliefs. Some patients prefer to social distance. All of these points lent to her conclusion: the target audience must be kept in mind when designing a medical device or prescribing them for home use.

Advancing Equity In Medical Devices Innovation — Dr. Jennifer Jones-McMeans

Dr. Jennifer Jones-McMeans, an Abbott employee, shared a clinical trial perspective on health equity in medical devices. She stated Abbott's focus point that those included in clinical trials should be representing those burdened by the disease for which the therapy is being evaluated. To prove change is possible, she cited that half of Pfizer studies in the last couple of years achieved census levels for Black/White/Hispanic participants. She affirmed Abbott's commitment to increasing diversity, with the patient as the focus of improvement of care. Abbott focuses on training doctors and nurses from all communities and on conducting trials in all communities with researchers from diverse populations. She noted that FDA support is crucial to make this happen.

Dr. Jones-McMeans emphasized the importance of integrating an understanding of social determinants of health into the design of clinical trials, noting that Abbott focuses on removing barriers to patients' access to clinical trials. A primary component of this is by reducing the need for travel to large health centers for patient follow ups. When travel is necessary, it can be facilitated by providing transportation and logistics support, lodging, and meals, or in severe cases, bringing the physician to the patient's home. She isolated the issue of unreliable information and stated a need for reliable patient resources, mentioning Abbott's Life-BTK trial as an example of a website for a single source of reliable information. Abbott also conducts a trial called Breathe that incorporates a patient advisory panel, and beyond that, believes in soliciting physician and community feedback to best inform their trial design. Abbott also partners with historically Black colleges to help educate the next generation of diverse physicians.

Designing with the End User in Mind — Jennifer Goldsack

Ms. Jennifer Goldsack, CEO of the Digital Medicine Society (DiMe), whose mission is to advance the ethical, effective, equitable, and safe use of digital technologies to redefine healthcare and improve lives, spoke on digital devices. She emphasized that DiMe does not support tech determinism and does not want to see technology used just for the sake of its use. Rather, DiMe believes that digitally enabled tools can help address persistent challenges like increased access to lifesaving treatments in an affordable manner. She shared statistics about inequitable access: 50 percent of counties in the United States do not have a single mental health care provider practicing in that county, and 50 percent of Black Americans currently live in a county where there is not a single cardiac specialist. NCI Centers of Excellence have substantially better outcomes in remission than local, accessible cancer centers.

Ms. Goldsack noted that there is not a single device category that will solve all the challenges, but rather, the effort needs to be multifaceted and interwoven, with connected medical devices deployed into virtual care in a culturally appropriate manner. Both development and deployment must be equitable and inclusive. She mentioned DiMe's DATAcc collaborative community, an open access suite of tools and resources to support inclusive product design. She highlighted a need to define health care as how good we are at keeping people out of the clinic, not how good we are at treating them once they're there.

OPEN COMMITTEE DISCUSSION

Ms. Edward asked **Dr. Tarver** if FDA has considered putting out radio PSAs to reach communities who listen to a lot of radio, such as, she said, African Americans. **Dr. Tarver** asked **Alicia Witters**, who is in charge of communication efforts at CDRH, to answer; **Ms. Witters** responded that CDRH has not used radio in recent history, but other Centers have.

Dr. James asked **Dr. Jones-McMeans** what challenges are specifically unique to medical devices when it comes to accessible and equitable clinical trial conduction? **Dr. Jones-McMeans** responded that patients are often least aware of their medical device options as compared to drugs and other treatment, as the devices have historically been clinician decision. This can be combatted with general PSA work and general education, she said.

Dr. Yanamala asked **Dr. Jones-McMeans** if her company does post market analyses to determine who the device is actually benefitting and if in silico clinical trials are done to understand and extent devices to target other communities. **Dr. Jones-McMeans** responded that post market evaluation usually follows device approval, and that they are interested in a continual evaluation of how devices are performing in specific populations.

Dr. Sitapati asked **Dr. Gichuru** what the most important considerations are towards the inclusion of populations with variable digital access, literacy, and broadband access when it comes to the design, testing, and access of devices. **Dr. Gichuru** responded that understanding the target community/population helps inform how to communicate with those populations. Cost, insurance access, and availability of technology for charging/updating devices are also crucial considerations.

Dr. Joniak-Grant asked **Dr. Jones-McMeans** and/or **Dr. Goldsack** if real-world user testing is conducted when designing devices. **Dr. Jones-McMeans** responded that for implantable devices, that is not possible. **Dr. Goldsack** added that it is a tremendous idea to do that where feasible and her organization has codified that process.

Dr. Fischer asked **Dr. Jones-McMeans** and **Dr. Gichuru** if they have discussed alarm fatigue with their patient panels and collaborators. **Both** responded they have not, as alarms are not widely used in their arenas of specialty.

Dr. Wilcox mentioned that design history files are important to document safety and access. He also mentioned that simulated environments often substitute for real-world testing.

Dr. Joniak-Grant commented that decentralizing clinical trials permits looking at users in the real-world environment and soliciting user feedback during the clinical trial phase; she likened this to testing video games to identify bugs.

Mr. White requested comment from the presenters on the use of the word 'mistrust' in the context of overcoming community barriers. He suggested 'loss of trust' as an alternative that is more difficult to construe as the community's fault. **Dr. Jones-McMeans** praised this observation and clarified that the medical community rarely perceives this mistrust as the fault of the community. She emphasized the healthcare industry's need to build and deserve the trust from patients and communities. **Dr. Goldsack** also commended Mr. White's question, noting that trust and value are intertwined here. The goal is to develop a product that provides undeniable value and can be administered with trust, and this needs to be considered during the design process. **Dr. Gichuru** added that the most important part of serving a community, especially a rural or underserved one, is to embody humility and appreciate the culture of the community. **Dr. Tarver** added that acknowledging violations of trust is an important component of building and maintaining trust. She emphasized that acknowledging individuals and their personal experience is paramount, and noted that using better labels and language to talk about these issues will help bridge gaps in trust.

Ms. Yanamala asked **Dr. Goldsack** if there is data or insight into how well current communication approaches resonate with individuals from various demographic backgrounds and, if disparities have been identified, what measures are being implemented or considered to ensure inclusivity and accessibility to information. **Dr. Goldsack** responded at length, suggesting referring to the DATAcc website for statistics that may exist on tis matter. She gave an anecdote demonstrating the benefits of virtual remote interpreting that came to popularity in hospitals during the Covid pandemic and illustrated how that decreased burden and inconvenience for doctors and non-English-speaking patients and facilitated equitable access to information. **Dr. Goldsack** urged the medical community to focus on using technology as the solution rather than identifying inequitable access to technology as a problem and straying away from the use of technology altogether. She mentioned overburdened clinicians tending to avoid working with patients who do not speak English due to inconvenience, and suggested clinical decision support systems to design prompts and data-driven approaches to set the physician up for better and more diverse successes.

Ms. Edwards asked **Dr. Jones-McMeans** what Abbott has done to assuage disadvantaged communities' fears that they are being tested on in an unethical manner. **Dr. Jones-McMeans** cited circulation of reliable information, mentioning specifically radio and internet means, about why and how the clinical trial is being conducted safely. The design of these channels should be relatable and personable and targeted at the family of the trial patient, as well.

STAKEHOLDER PRESENTATIONS (CONTINUED)

Understanding Health Equity in Clinical Trials — Tesheia Johnson

Ms. Tesheia Johnson, Director of Clinical Research at Yale School of Medicine, gave a high-level overview of her organization's network of community-based clinics. She shared patient demographic data, explaining that they are a microcosm representative of the overall U.S. demographic. She explained how program leaders are selected by the community and aid in optimizing clinical trials for the target community and shared an example of inclusive language design, sharing data to demonstrate that cultural ambassadors increased retention She cited the MOU with FDA OMMHE as crucial to their successes. She relayed that of prime importance to community understanding of clinical trials has been to ensure members understand the meaning of and importance of regulation, and she concluded by mentioning that her organization's partnerships with FDA have enhanced their trust in the community.

Advancing Health Equity in Medical Devices: Health Literacy and Community Outreach — Behtash Bahador

Mr. Behtash Bahador, Director of Health Literacy of the Center for Information and Study on Clinical Research Participation (CISCRP), described his organization and defined health literacy: the ability to find, understand, and use information and services to inform health-related decisions. Key components of health literacy include awareness of a population's needs, attitudes, and values, cultural competency of language, logic, and experiences, and humility. He urged listeners to take free online evaluations of their own implicit biases, reimagine their thinking patterns, and drop implicit biases.

Mr. Bahador mentioned that CISCRP values educational materials, especially brochures, for outreach to underrepresented groups. He echoed the sentiment that community liaisons are crucial to the development of culturally sensitive and helpful materials for target populations. He highlighted the role of mistrust, confirmed by surveys, held within underrepresented communities. He discerned that information inaccessibility is a barrier to diversity. He shared results from CISCRP's biannual survey — it revealed discrepancies between racial groups in their willingness to share medical records. He shared ways to provide information and services across the life cycle of clinical research, emphasizing the role of information, education, awareness, diversity, and inclusion.

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

Dr. Karriem Watson, Chief Engagement Officer of NIH's All of Us research program, shared his program's purpose: to advance genomics through community engagement by including populations who have been historically underrepresented in biomedical research, and he highlighted the program's community participant engagement framework. He elaborated on the impact of geographic location on epigenetics and explained that their community engagement ecosystem is a key factor in achieving a 50% rate of underrepresented participants. He noted that successful engagement does not always mean enrolling a patient; sometimes, it means building trust by not enrolling a patient.

Dr. Watson stressed the importance of knowledge mobilization, explaining that "hard to reach" is not a term used by All of Us; rather, "under-engaged" is used to put the onus on the organization. He shared examples of engagement protocols used by the program, including English and Spanish versions of key programs and a mobile engagement asset, a traveling van. He concluded with an example of Fitbit data collection to include 41% diverse participants.

OPEN COMMITTEE DISCUSSION & CLARIFYING QUESTIONS

Dr. Peters asked two questions: how can you contribute to communities such that you aren't starting a trial, obtaining data, and then taking it elsewhere with no impact to those who gave their data? How can you prevent breaking trust by taking away a helpful device at the end of a trial that someone otherwise cannot afford? **Ms. Johnson**, in response, related to this struggle and shared her thoughts that intervention and contract negotiation with study sponsors are key and that investigators must be prompted to address issues of access and equity. She emphasized the importance of community-engaged feedback. **Dr. Watson** echoed this sentiment and added that the funder is responsible for ensuring equity is baked into trial design, adding that public-private partnerships with local pharmacies have allowed him, for example, to distribute devices to the community after their trials with blood pressure devices were over. **Ms. Bahador** commented that when sharing success stories, it is important to share methodology and metrics to measure patient engagement, diversity, equity, and inclusivity.

Ms. Edwards asked **Ms. Johnson** if her organization partners with specific churches and if they do presentations at the library, beauty shops, etc. **Ms. Johnson** responded that the 17 churches they partner with help design specific messaging for each of the specific trials and outreach efforts and mentioned their intent to continue bringing in more denominations as partners. She also mentioned that cultural optimization of messages finds even announcements through the health system's platform read at an enormous rate.

Ms. Edwards asked **Dr. Watson** how the mobile engagement van is dispatched; how is it determined which communities have the greatest needs? **Dr. Watson** responded that the van prioritizes locations where there are no local engagement or enrollment sites and partners with organizations in those areas to identify under-engaged populations. **Dr. Watson** further underscored the importance of faith-based partners.

Mr. White asked **Mr. Bahador** if it would be appropriate to include community health literacy as an additional category alongside personal and organizational health literacy. **Mr.**

Bahador responded that this is an excellent point and he would be happy to work with Mr. White to gather terminology and spread the word to improve that initiative and focus.

Dr. Joniak-Grant asked the Committee what steps they would recommend to combat implicit biases in device design and if their experience has led them to identify red flags to look out for during trials or evaluation that signal that bias has not been accounted for. **Dr. Watson** responded that bias can be minimized but not eliminated and that diverse voices during the design process can help eliminate bias. **Mr. Conway** redirected the discussion to focus on clarifying questions for the speakers.

Mr. Burkhardt asked **Mr. Bahador** if his organization's surveys try to match the demographics of the respondents to those of the condition/disease under examination. **Mr. Bahador** responded that no, they do not do that for materials intended to be broad-reaching, but this is done for other study-specific materials.

Dr. James asked **Ms. Johnson** if, based on her expertise, there is anything she feels the committee should know about nuances of medical devices that might impact health equity in running clinical trials. **Ms. Johnson** mentioned issues pertaining to Wi-Fi dependence of devices, sponsor choices to include more than one platform for answering questions and recording, which creates confusion, caregiver burden, mistrust of hospitals, mistrust of data handling for implantable devices.

Ms. Balasa commended **Ms. Watson's** comment that successful engagement is building trust and unity and that enrollment follows from that foundation, asking all presenters to share how they measure success within different communities and if it differs for device trials versus other trials. **Mr. Bahador** responded that surveys are conducted pre- and post- mobile education engagement to determine if the van changes attitudes and behaviors towards research.

Dr. Yanamala asked all speakers how they take into account social determinants of health when collecting and analyzing health data. She also asked what information is important to provide the public for transparency in regard to device trials. **Mr. Bahador** mentioned that plain language summaries are provided at trial conclusion and that some sponsors regularly provide incidental findings to individuals over the course of the trial and sharing unblinding information.

Dr. Fischer asked all speakers to share best practices for recruiting community partners and utilizing them well during earlier phases of clinical trial development. **Ms. Johnson** shared that the educational process for sponsors is one of the most important aspects.

Ms. Diaz asked all presenters what safeguards are in place for device-collected data and if it is shared with participants. **Dr. Watson** responded that safeguards are in place and All of Us works with community partners to share safeguard information with the community. **Mr. Bahador** added that staff should be trained to answer questions on safeguarding data. **Ms. Johnson** contributed that being able to clearly answer patients' questions on who obtains and analyzes data after the trial is a crucial element.

OPEN PUBLIC HEARING

Ms. Williams read the Open Public Hearing Disclosure Process Statement, and **Mr. Conway** announced 11 formal requests to speak, with 10 speakers present.

Dr. Karin Hoelzer, Director of Policy and Regulatory Affairs for the National Organization for Rare Disorders (NORD), gave an overview of her organization. She mentioned that off-label use of devices is regularly seen in the treatment of rare diseases, and this use tends to increase over time due to the progressive nature of many rare diseases. Rare diseases often impact multiple organ systems, making many devices difficult to use for those with impacted vision, mobility, dexterity, etc. Rare disease patients require long use of devices and struggles are seen in relation to battery changes, software updates, and lack of backwards compatibility. She added that asking the patient community what their challenges are is very important, mentioning that needs evolve over time. She stressed mindfulness of unintended consequences and education for patients and families.

Dr. Bibb Allen, a radiologist and Chief Medical Officer for the Data Science Institute, American College of Radiology (ACR) presented his perspective on equity issues in the context of artificial intelligence. He stated that 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.

Dr. Keith Dreyer, Chief Science Officer at ACR Data Science Institute, presented details on information that needs to be disclosed to the public to make AI algorithms trustworthy in the public eye, highlighting challenges in the distribution of this information. He felt it is imperative that that manufacturers disclose information beyond what is in the public domain so that providers can make informed decisions on behalf of their patients.

Dr. Ivor Horn, Chief Health Equity Officer, Google declared health equity to be a core value of Google's work and shared their procedures to ensure that value is upheld. She mentioned scalable, sustainable infrastructure that makes it easy for those who are not experts in health equity to make equitable choices, such as a health equity playbook, communities of health equity champions, and collaborative partnerships with the health ecosystem. She mentioned responsible innovation to prevent acceleration or creation of health disparities as a result of AI adoptions. Google focuses AI efforts to advance knowledge in historically neglected and biased areas. Google is also part of a Coalition for Health AI to empower responsible AI development across healthcare. On behalf of Google, she recommended that FDA learn from Google's HEAL framework, MedPalm system, evaluation standards for innovative technologies, and strategies for supporting design teams.

Dr. Andrew Namen of the American Academy of Sleep Medicine Public Safety Committee discussed inequities in disbursement of PAP devices, specifically detailing the Philips PAP recall and its negative effects on patients. On behalf of his organization, he recommended

FDA adopt guidelines to mitigate inequities, post marketing oversight, equitable corrections, along with device tracking for all devices.

Grace Wickerson, Health Equity Policy Manager at the Federation of American Scientists, spoke on their work in pulse oximetry and summarized concerns voiced at the 2022 PEAC regarding racial disparities in pulse oximetry accuracy. They mentioned that heart rate monitors, continuous blood glucose monitors, and bilirubin monitors all see decreased performance in patients with more melanin, as well, and added that gender and body size impact accuracy. They urged FDA to work to build trust in the data collected by wearable devices.

Ms. Jennifer Doyle, Vice President of Clinical Research and Medical Science at Medtronic, shared Medtronic's methods to increase diverse representation in their clinical trials: understanding patient populations, creating training and tools, developing a budget, patient-facing materials, patient outreach, creating new sites with new investigators, and soliciting patient feedback.

Ms. Madris Kinard, founder and CEO of Device Events, urged FDA to ensure that the devices they clear for market take into account sex, age, gender and ethnicity, and geographic location. She noted that sex, age, and demographic information has been redacted from public view from the FDA's adverse reporting system, which she has put in a request to release for the purposes of the public, device manufacturers, and home health providers. She highlighted that it is difficult for patients to find information on whether their device has been recalled and suggested AARP or Consumer Reports assist FDA with a campaign to educate the public about UDI barcodes and on how to ask for information about their devices.

Ms. Bernadette Lozano, a hip implant recipient, spoke on her implant's failure, highlighting how she had to personally contact the manufacturer because the information was not otherwise made available to her and she had no avenues for advocacy available other than herself. She advised that surgeons be required to put the barcode number on the report that goes to the patient and that a tracking system be implemented for medical devices.

Dr. Diana Zuckerman, President of the National Center for Health Research, spoke as a scientist and a patient with three medical devices. She found information difficult to impossible to obtain to make an informed decision on whether to get her medical devices. She urged FDA to ensure that all populations are studied and that information be made readily available so that everyone can make informed health decisions.

Q & A FOR PUBLIC SPEAKERS

Ms. Diaz asked **Ms. Kinard** if she imagined the un-redacted data would have assurances would HIPAA safety, or if only general data would be collected. **Ms. Kinard** responded that hospital names, doctor names, patient names, etc. would all be redacted, and that sex and age information does not constitute as individually-identifying information.

Mr. White asked **Mr. Dreyer** if he had a percentage of software developers that are willing to share specific information about their algorithms. He could not provide a specific

statistic, but said that almost all of the 100 his organization reached out to were able to provide access after considering the request.

COMMITTEE DISCUSSION OF FDA QUESTIONS

Question One

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. 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. 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?

Ms. Diaz responded to 1A: she would want to know exactly what the device does, possible adverse events, hands-on training for the product, and pathways for adverse event reporting.

Ms. Edward responded to 1A: materials, potential odors, device disposal protocols, how to get help for questions or problems, and where to purchase additional supplies.

Dr. Joniak-Grant responded to 1A: potential disadvantages of use in a nonclinical setting, especially risks, technical capabilities and requirements of the device, how to troubleshoot and maintain the device, what certain device signals may mean, a direct phone number in case of malfunction or emergency, initial setup, calibration, how and when to service the device, constitution of the device for allergy purposes, and characteristics of users included in home use trials.

Ms. Balasa responded to 1A: 24-hour support for troubleshooting and issues and appropriate training. She answered 1C: access to training and troubleshooting support.

Mr. White responded to 1A: if clinical outcomes are changed when used in a nonclinical setting, assurance of 24/7 support, how the device will change home space needs, disposal, social context of perceptions from users and non-users, data security information, and degree of reversibility of the home therapy decision.

Dr. Roy responded to 1A: assurance that she would find out if there were a safety notice or recall and UDI codes.

Dr. Wolf responded to 1A and 1C: data privacy is a concern, and the frequency and specifics of data sharing needs to be made transparent for patients.

Dr. Sitapati responded to 1B: she would encourage acute car and rare or complex at-home care. She responded to 1C: cost is the biggest barrier. She responded to 1A: timeliness, usability, diverse settings and spaces, limited health literacy, 24/7 requirements, feedback loops, handoffs, and the need for spare parts at home.

Mr. Burkhart echoed **Dr. Wolf**'s statement that telling patients data is being tracked can be misconstrued as data is being monitored, causing miscommunications. He answered 1C: he want assurance that intended users were consulted during design and that they reflected his demographic, as well as ease of use and foreseeable problems, and that he is not a guinea pig.

Dr. Fischer responded to 1B: providers want access to home or OTC diagnostics for common infections, especially those that are high-burden or high-cost, such as influenza and strep throat. For 1C: she wants patient and provider access to data from post-market trials that is easily accessible or sent directly to providers for awareness of safety signals, as well as collaboration with CMS to ensure appropriate coding. For 1D: FDA can ensure data is accessible and secure, such as patient-owned data that is provider-accessible.

Dr. Peters responded to 1A: ensuring patient access to someone who speaks their language and understands their educational level and background. For 1C: she has issues with continued access to supplies for her patients and wants to see this remedied.

Dr. Wilcox responded to 1C by providing the example of implanted defibrillators, which allow physicians remote access to the device via the cloud. He suggested FDA and industry can start laying out infrastructure to provide medically-required Wi-Fi signals to patients.

Dr. Yanamala responded to 1C: enhanced post-market surveillance to identify secondary outcomes and risks in real time. To 1D: FDA needs to consider how to ensure interoperability when multiple devices are being used in home settings.

Dr. James mentioned STD testing may be one of many arenas aside from infectious diseases where home testing is desirable, especially for rural populations who may not be able to travel to urban areas for care, and he also suggested looking at medication delivery coupled with digital health tools. For C: FDA can collaborate with other agencies and develop device-specific guidance to help transition a product's use setting; post-market investigations and real-world data should be leveraged to support risk-benefit profiles. For D: effective care at home requires a strong understanding of the end user(s), which can be patients, caregivers, or traveling health providers, and instructions need to be provided in a way that meets the end user's level of comprehension and is also flexible. Stakeholders needs to be flexible to allow for technological advancement. He urged FDA to consider cybersecurity, digital integrity, patient safety, and adequate technical support when looking towards the transition to home-based care.

Dr. Wilcox commented towards B: chronic diseases are best considered as contenders for care to be moved out of the hospital. He emphasized the importance of automation in new technologies.

Dr. Joniak-Grant for 1B: home care should be considered for patients who have diseases that make getting to a healthcare provider difficult, for conditions that require long-term management, and for common diagnostic procedures for communicable diseases. For 1C: industry can facilitate access by reducing cost of devices, increasing ease of use, disseminating detailed device information to healthcare providers. FDA can facilitate access by working with insurance and Medicare to clearly communicate FDA approval and the benefits of in-home use and educating patients regarding their options for in-home devices.

Mr. Conway summarized the Committee's contributions. For A, the Committee brought up the following types of information that should be made available to patients: data access, security, and ownership; training details; troubleshooting and support pathways; device composition; potential allergens/hazards; disposal processes; instructions on how to obtain device-related supplies; long-term device accessibility information; clearly stated advantages and disadvantages; how to report safety concerns; device signals for failure; measurements for clinical outcomes; how to cooperate with care team.

For B, the Committee felt the following diseases, conditions, and aspects of care should be considered for care outside the healthcare setting: acute conditions, chronic and ongoing/long-term care, sensitive and invasive issues like STD testing, specimen collection for those in remote areas, medication management, communicable diseases, chronic pain management.

For C, the Committee suggested FDA can coordinate payment with other federal agencies, particularly CMS, collect real-world evidence, ensuring devices are designed for the particular patient that is receiving the device, patient access to post-trial data safety signals, appropriate coding, ensure infrastructure that the device works within is approved by FDA, build trust. Industry can reduce cost and automate processes, provide clear troubleshooting pathways and escalation procedures, improve device literacy, provide timely responses, and provide access to spare parts.

For D, the Committee highlighted that data should be patient-owned and provider-accessible, care should be tied to an overall care team and home care should be provided in the context of an individual's entire case management, the role of telehealth should be clearly defined, apps should be used, and literacy should be improved.

Question Two

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?

B: FDA is considering three main principles - inclusivity, data generalizability, and timely access - to guide its determination of when studies may be necessary to support market authorization. 1) Do these principles reflect what is most important to patients? 2) Are there additional principles that FDA should consider?

Dr. Wolf responded to 2A with anecdotal information on how to optimize health information/instructions for patients with limited health literacy, noting that implementation of

the knowledge FDA has accumulated on how to do this will be the challenging part. For B, he added that you can only go so far in development before needing real user feedback.

Ms. Edwards, to 2A, suggested health literacy flashcards, simple video that takes into account reading/grade levels, and an option for signal boosters for those with limited Wi-Fi access.

Dr. Wilcox noted that collecting data on study participants' race/ethnicity is often not done but should be done to ensure that devices work for all populations.

Dr. Sitapati commented for 2A that sight is a very limiting factor for device usage and those with poor eyesight should be considered in the design process. She added that images and pictures boost cross-language communications. For 2B, she asked FDA to consider longitudinal opt-in data sharing as a method to have transparent access to data.

Dr. Peters, for 2A, emphasized that caregivers need to be considered as primary users of many devices. Alarms need to be able to be silenced and the burden of alarms must be considered. For 2B, she added that sometimes patients like aspects of the device that are unexpected, and this should be looked at when studying real-world use.

Dr. Yanamala, in response to 2A, noted that devices must be accessible to individuals with reduced functional capabilities. Large buttons, voice commands, and tactile directions facilitate this. Multilingual devices tend to be more accepted by patients. Failsafe measures for when devices lose connectivity, such as locally storing data for a number of hours, should be considered. She asked a rhetorical question: how do we ensure that medical devices are used appropriately by the user?

Mr. Burkhart added that sometimes patients have multiple caregivers, and that needs to be considered, too. For 2B, he commented that large, long studies can delay access for people who otherwise may benefit greatly from a device being approved.

Dr. Fischer responded to 2A: alarms need to be tested in a real-world setting and need to involve the patient community's feedback. For 2B: post-market evaluation is not ideal but may bridge delayed access from large and long studies; this would benefit small market populations.

Dr. Joniak-Grant recommended, in response to 2A, to think about the amount of cognitive energy required, number of steps involved, and complexity of device tasks as it relates to patients on good and bad days. Size, shape, and feel of buttons should be considered, as should colors, font size, animation, flashing lights, and scrolling. Devices should be intuitive enough that if a patient is heavily medicated, stressed, and/or in pain, they can still use it. She added more detailed considerations for tablets, mobile phones, children, pets, and the home environment. She added that FDA should consider whether the industrial sponsor has involved patients throughout the entire process. Users should test the device on good and bad days, and focus groups may aid in development of patient-friendly devices. For 2B, she commented that data validity, proven efficacy, and affordability are important points that should be considered.

Ms. Balasa added to 2A, saying that it's important to consider how a device will integrate into a patient's daily life, such as effects on sleep and hygiene. For 2B, she suggested that inclusion criteria be broadened to include patients with varying levels of disease progression.

Mr. White on 2A: the 'home environment' is really multiple environments and includes wherever the user goes. This presents a challenge that may impact safe and effective device use. Functionality should be environment agnostic.

Ms. Diaz furthered Dr. Wilcox's comment by noting that you can look at prior cases to obtain data on device events.

Dr. James on behalf of industry recommended FDA establish a centralized group as a human factors resource within CDRH to establish consistency in review considerations for medical devices that could be used in a home setting by lay users. He further recommended FDA work closely with international standards group to establish and recognize home-use performance and safety standards to ensure interoperability and standardization of cybersecurity protocols.

Dr. Wilcox suggested that products be sampled on patient populations that are weighted towards the most challenged and burdened by the particular disease state to minimize bias.

Mr. Burkhart concluded by seconding Dr. Wilcox's comment, mentioning that patients who are on a ventilator, for instance, may be difficult to include in a clinical trial, but it is important to consider them, because they often benefit most.

Mr. Conway summarized the Committee's contributions at length. For 2A, highlighted topics include coordination with international standards, user-friendly interfaces, technological issues and access issues, fail safes, alarm systems, environmental issues, compliance issues, and complications due to multifaceted care regimens. For 2B, the Committee agreed the principles set forth are good but could be augmented with factors like diversity, affordability, and data transparency.

Dr. Faris invited the committee to share more thoughts on how FDA can determine when diverse enrollment in a pre-market study is necessary in order to deem a device safe and effective.

Dr. Yanamala responded by emphasizing the importance of shared decision-making tools between providers, caregivers, and patients. **Dr. Peters** brought up that often patients who want to be included lack basic knowledge necessary to participate in trials.

Dr. Wilcox addressed Dr. Faris' question by saying that it's a catch-22; often, you don't know you need more data on a more diverse set until you see a discrepancy in signal for a population. He feels the solution is to collect better data initially with the intention to identify potential discrepancies based on ethnicity, and then after a discrepancy is identified, a requirement can be introduced to prompt further investigation of those groups in future trials.

Dr. Sitapati commented that perfection in this arena is an iterative approach. She suggested trials be more inclusive of populations that are burdened most severely with a given disease.

Dr. Joniak-Grant responded that it is not appropriate to cherry-pick where inclusivity should be mandated, and it should be implemented across the board.

Dr. James seconded Dr. Sitapati's comment and amended that outcomes are often directly proportional to access, and that should be kept in mind.

Question Three

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?

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?

Dr. Yanamala to 3A: context, comparison, and magnitude of effect (CCM) are most important.

Mr. White on 3B: it is important to communicate how the study population compares to the actual affected population. On 3C: adverse events as measured by thousands of hours of use should be available to patients and caregivers and delivered in an easy-to-understand manner.

Dr. Peters, for 3A, mentioned that numeracy and complexity of data needs to be foregone in order to allow patients to make sense of benefits and risks, noting the delicate balance of this. For 3B, she found it important to talk about the population that was excluded from the datasets. For 3C, she believes it is crucial to show effortful thought as a provider by taking the individual as a whole and demonstrating their options based on their individual risk levels.

Mr. Burkhart, for 3B, mentioned that sharing a reasonable amount of demographic trial data is important. He wants to see data available publicly for race, gender, other health factors, socioeconomic status, and geographic location. Patients should be able to see themselves included in the data.

Dr. Wilcox seconded Mr. Burkhart's comment. He added that information should be included on what to expect if you need to transition management of your device to a caregiver.

Dr. Sitapati responded to 3A: quality of life should be conveyed for the benefit, and safety events and failure should be communicated for risks. For 3B: she does not know how to achieve this, but she knows patients want to see their specific scenarios reflected in the data.

Ms. Diaz answered 3A by emphasizing the importance of fully informed consent, full education, clearly-labeled products, and extensive public awareness campaigns.

Dr. Fischer commented on 3C from a provider's perspective, suggesting a patient advisory group or panel that is HIPAA compliant. She suggested that hard numbers be presented as risk labels rather than uncommon, rare, etc.

Ms. Edwards added to 3A that as a patient, she wants to know about study limitations. For 3B, she wants to know demographic information.

Ms. Balasa seconded Dr. Peters' comment that taking the patient's entire health history and lifestyle into account when making individualized recommendations is key.

Dr. Joniak-Grant mentioned, for 3A, that she wants to know differences and degrees of differences observed and what groups they were detected in. For 3B, she wants to know length of study, number of participants in various subgroups, and exclusion criteria.

Dr. James emphasized Dr. Peters, Dr. Fischer, and Ms. Balasa's comments around benefit-risk. He suggested that risk is often weighed more heavily than benefit. A methodology needs to be developed to quantify benefit-risk so as not to exclude benefits that are important to patients.

Dr. Yanamala added that environmental factors should be communicated as limitations in trial design, such as temperature and altitude, which affect vital signs.

Mr. Conway summarized the Committee's contributions, emphasizing that data for 'patients like me' should be available to all populations and that decisions need to be made in the context of the individual.

Question Four

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.

Mr. Burkhart congratulated FDA on their successful efforts thus far to reach out to patient advocacy and support groups. He suggested meeting people where they're at, such as church and sports/recreation.

Dr. Joniak-Grant suggested television for the elderly, print in papers, billboards in rural areas, subway ads in urban areas, and leaflets in provider offices. She also suggested FDA hold industry accountable for tracking patients down to send recall notices. To hear patient perspectives, she suggested reaching out to patient organizations, medical sociologists, researchers in patient spaces, community organizations and leaders, commissioning qualitative research, and sending people out into communities and groups where information is wanted.

Dr. Peters recommended utilizing the talents of community health workers and promoters. She mentioned clinics and mobile vans. She emphasized thinking outside the box and meeting patients where they're interested in talking to you.

Ms. Edwards suggested videos that can be shared on social media, partnerships with community health centers to provide information on medical devices by sponsoring workshops, and working with patient advocacy groups to create materials that public health officials can circulate.

Dr. Fischer pointed out that almost all Americans have cell phones but not broadband access, so text is a prime candidate for communications such as opt-in surveys.

Mr. Conway summarized the above contributions.

CLOSING REMARKS

Mr. Conway thanked FDA, the Open Public Hearing speakers, presenters, and Committee members for their helpful input.

Ms. Capanna on behalf of the entire FDA team thanked the committee members for their time, expertise, and insights. **Dr. Tarver** and **Ms. Witters** echoed these thanks.

Mr. Conway underscored the uniqueness and importance of the PEAC meetings and adjourned the meeting.

I approve the minutes of this meeting as recorded in this summary.

Paul T. Conway
Chairperson

10/21/2023

Summary Prepared By:

Debbie Dellacroce
Translation Excellence
3300 South Parker Road, Suite 200
Aurora, CO 80014
(720-325-0459)
September 25, 2023

I certify that I attended this meeting on September 6, 2023 and that these minutes accurately reflect what transpired

Letise W. Williams -S

Digitally signed by Letise W. Williams -S
Date: 2023.10.03 13:49:26 -04'00'

Letise Williams
Designated Federal Officer