

**SUMMARY MINUTES**

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**

**MEDICAL DEVICES ADVISORY COMMITTEE**

**PATIENT ENGAGEMENT ADVISORY COMMITTEE**

**July 13, 2022**

**Via Video Conference**

**Attendees:****Chairperson**

Paul T. Conway  
Chair, Policy & Global Affairs  
American Association of Kidney Patients

**Voting Members**

Amye L. Leong, M.B.A.  
Healthy Motivation  
Patient Engagement in Care & Translational Research

Bennet R. Dunlap, M.S.  
President, Your Diabetes May Vary Consulting  
Diabetes Patient Advocacy

Monica L. Willis Parker, M.D.  
Assistant Professor, Dept. of Neurology  
Director, Minority Engagement Core  
Goizueta Alzheimer's Disease Research Center  
Emory University

Phillip X. Rutherford  
Chief Operating Officer  
Faces & Voices of Recovery

Mary (Suzanne) Schrandt, J.D.  
Founder, CEO & Chief Patient Advocate  
ExPPect, LLC

**Temporary Non-Voting Members**

Heather R. Adams, Ph.D.  
Associate Professor  
Departments of Pediatric & Neurology  
University of Rochester School of Medical & Dentistry

Colleen M. Gallagher, Ph.D., LSW, FACHE  
Executive Director, Clinical Ethics, Chief  
Section of Integrated Ethics in Cancer Care, Medical Executive  
The University of Texas MD Anderson Cancer Center

Grace Levy-Clarke, M.D.  
Director  
Uveitis Services, Department of Ophthalmology  
West Virginia University

Omer Liran, M.D.  
Assistant Professor of Psychiatry  
Department of Psychiatry & Behavioral Neurosciences  
Cedars-Sinai Medical Center

Naiem Nassiri, M.D.  
Associate Professor  
Department of Surgery, Division of Vascular & Endovascular Surgery  
Clinician Educator Track  
Yale University School of Medicine

### **Industry Representative**

Diane M. Johnson, M.S.  
Senior Director, North American Policy  
Global Digital Health Policy Lead  
Johnson & Johnson

### **Consumer Representative**

Teresa Diaz  
Co-Founder  
Global Patient Advocacy Coalition (GPAC)

### **Food and Drug Administration**

Letise Williams, Designated Federal Officer

Kathryn Capanna  
Deputy Director, Division of All Hazards Response, Science & Strategic Partnerships, Office of Strategic Partnerships Technology Innovation (OST)

Brendan O'Leary  
Acting Director, Digital Health Center of Excellence (DHCoE), OST

Angela Krueger  
Deputy Director, Regulatory Policy, Office of Product Evaluation and Quality

Anindita Saha  
Assistant Director, DHCoE, OST, CDRH

**FDA Presenter**

Anindita Saha  
Assistant Director, DHCoE, OST, CDRH

**CALL TO ORDER**

**Panel Chairperson Paul T. Conway** called the meeting to order at 10:00 a.m. He reasserted the Patient Engagement Advisory Committee's purpose and history. He acknowledged the contributions from participants through the first day of the meeting, especially members of the public. He noted the presence of a quorum and affirmed that Committee members had received training in FDA law and regulations.

**Chairperson Conway** stated the day's agenda: to discuss and provide advice on augmented reality (AR) and virtual reality (VR) medical devices. He noted that AR/VR devices raise novel concerns for patients and providers in pre- and post-market considerations and stated that today the Committee will give advice on factors FDA and industry should consider when evaluating the benefits, risks, and the extent of uncertainty for AR/VR medical devices, with consideration for specific populations. He emphasizes the duty of the Committee to discuss ways to incorporate patient perspectives into decision-making for the FDA, industry, healthcare providers, and other patients who use or prescribe AR/VR.

He then asked members of the Committee and the FDA staff to introduce themselves.

**CONFLICT OF INTEREST STATEMENT**  
**TEMPORARY-NONVOTING MEMBER STATUS STATEMENT**  
**GENERAL ANNOUNCEMENTS**

**Letise Williams**, Designated Federal Officer, reported that Dr. Omer Liran was issued a conflict of interest waiver. She announced that Ms. Diane M. Johnson would serve as the Industry Representative and that Dr. Heather R. Adams, who serves as a consultant to the Gastrointestinal Drugs Advisory Committee in the Center for Drug Evaluation and Research, would serve as a temporary non-voting member.

She then made general announcements regarding speaker identification and disclosures, transcript availability, and written comments received. She introduced Lauren Jei-McCarthy as the FDA press contact.

**RECAP OF MEETING DAY 1**

**Anindita Saha** thanked the speakers, breakout session participants, and open public hearing speakers for their perspectives, which she will summarize. Recurring themes included: health equity, patient engagement considerations, vulnerable populations, and a need to generate evidence to assess AR/VR device efficacy. She referred to the 2022 – 2025 plan to focus on health equity and meeting consumer needs. Speakers raised some general points:

- AR/VR can bring healthcare directly to patients.
- Diverse populations must be included in clinical studies.
- Improved data collection is necessary to understand long-term outcomes.
- Vulnerable populations have decreased accessibility to AR/VR treatments.
- Special considerations are necessary for specific populations particularly: children, patients recovering from substance abuse disorders, and cognitively impaired patients

She discussed benefits of AR/VR technology across the healthcare spectrum, including:

- clinical applications in mental health, various rehabilitations, and ophthalmology
- its ability to provide objective assessments in clinical trials and provide patient-generated health data
- surgical applications

She acknowledged speaker perspectives on:

- a need to engage both patients and healthcare providers during development
- meeting patient and stakeholder needs
- patient understanding of AR/VR technology
- a need for developers to focus on:
  - a) user interface and experience
  - b) technical specifications and hardware/software needs
  - c) privacy protection
  - d) cybersecurity

Breakout room participants' concerns included:

- headset-software interactions
- long-term updates to the device to ensure safety
- using AR/VR in vulnerable populations
- uncertainty in long-term effects of AR/VR
- data sharing and privacy
- the potential for addiction to the VR experience
- altered perceptions of reality in the developing brains of children
- use by individuals with cognitive challenges
- appropriate dosage and timing for device use in various populations
- risk management and mitigation

- device monitoring, patient protection, and automatic shutoffs
- patient impact upon stopping treatment
- medication interactions and other contraindications
- developmental appropriateness in children
- use by individuals who suffer from addiction issues
- ensuring appropriate sizing/fit for pediatric patients
- altered brain development and effects on eyesight
- prolonged screen time's impact on device efficacy

**Ms. Saha** continued with a summary participants' ideas on instructing, training, and educating patients and their families. She noted that healthcare providers are a trusted source of information for many, and providers must clearly communicate benefits and risks of device usage to patients. Other ideas for disseminating knowledge of AR/VR medical devices include:

- Peer-to-peer discussions and patient groups.
- Independent research and literature review.
- Instructional videos
- Training pages/dashboards
- Simulated experiences for family/caregiver understanding

**Ms. Saha** concluded by emphasizing the importance of transparency, inclusivity, and engagement to advance AR/VR devices and prompted the questions for committee deliberation.

## **COMMITTEE DISCUSSION OF FDA QUESTIONS**

**Chairperson Conway** noted the time as 10:36 a.m. and prompted **Commander Chinyelum Olele** to ask question one.

### **Question 1**

**Commander Chinyelum Olele** read: augmented reality AR and virtual reality VR medical devices have promise to improve patient outcomes and access to care and rely on a variety of technical considerations. The role of AR devices across various types of surgical procedures is currently evolving, as the related benefits and risks of these devices are more clearly understood. While data from AR devices may benefit patients, to use the AR device appropriately, users should have accurate information regarding the benefits and risks of these devices. Future research is needed to assess surgical outcomes related to use of these devices, and surgeons may need specific training on how to optimize the use of this technology.

The two-part question:

- a. What information would you want your surgeon to share with you during the informed consent process prior to a surgery that will involve an AR device;

- b. What would assure you that the surgeon is appropriately trained to use a specific AR device?

**Dr. Parker** added some key considerations for the question:

- a. What data allows you to advise this as a safe thing?
- b. How many people has this device been tested in?
- c. Has it been tested in people like the patient?
- d. What is the efficacy?
- e. What sort of adverse are side effects have there been?
- f. What kind of training or support have you had, or will you receive for managing this device in the future?
- g. If the patient has complications, who do they address?

**Dr. Nassiri** answers the question first. He spoke on the importance of educating patients on how the machines function and on how AI optimizes imaging.

**Ms. Leong** added she would want to know the direct physical interaction between the patient and the machine, such as what they will feel and what their experience might be.

**Mr. Rutherford** contributed about how software changes over time and the impact that may have on a trainee or physician utilizing the device.

**Ms. Schrandt** commented that the patient ability to override the technology tool they are using is critically important and the balance between the clinical skill and experience of the surgeon and whatever the technology is communication must be amplified, especially in circumstances where the patient is conscience. She would want the patient to be the guiding force over what is being captured over the technology. She also underscored the patient experience and a need for accessible trainings to all members of a surgical team to eliminate medical hierarchy issues.

**Dr. Liran** said knowing practical helpfulness, supporting data, backup plans for failures, and the surgeon's particular experience with the equipment are the most important facets.

**Dr. Adams** relayed that safety and efficacy were her primary concerns: why to choose AR; how it works; its specific, personalized uses; the difference between AR and surgery in terms of cost, outcomes, safety profiles, and effectiveness; as well as the surgical team's completion and success rates.

**Dr. Levy-Clarke** said she would desire to know other patient experiences, the hospital's outlined protocol for hardware and software, standardized certifications, and device history.

**Dr. Gallagher** detailed the aspects of informed consent: showing the use of the technology, providing a choice of whether digital information can be used, disclosing the surgeon and team's backgrounds and trainings, and the medical team's dynamic. She also stressed the need for medical professionals to be properly trained in alternate procedures for when the technology is unavailable.

**Mr. Dunlap** added his belief that a professional healthcare communicator work with the provider's team to interface with and educate patients, rather than unloading that responsibility to the doctors themselves.

**Dr. Nassiri** gave another contribution: practically, surgeons should be most informed on the device's usage and that hierarchy of knowledge in a team permits diversity of expertise.

**Ms. Diaz** provided that her main considerations are who monitors the software for accuracy. She further elaborated on comments from **Dr. Steven Wilcox** read by the Chair in his absence, who wanted to know the type of device/system, how it is used, and the surgeon's experience and outcomes for the specific procedure. He noted many patients are not capable of making informed inquiries. He also voiced concerns regarding variable accuracy of the AR/VR protocol between different anatomies, inconsistent skill levels between surgeons, and the inaccessible nature of a surgeon's clinical history. **Dr. Nassiri** applauded **Mr. Wilcox's** comments and expounded upon the deliberate obfuscation of surgeons' rates of success to promote individual and institutional success.

**Ms. Leong** spoke, as a patient advocate, of doctors' tendency to not explain their procedures despite the importance of doing so. She reiterated the importance of patient education and availability to choose skilled surgeons, voiced potential difficulties in advocating for AR/VR, and highlighted that patient choice is contingent on the availability of skilled doctors.

**Chairperson Conway** asked **Dr. Nassiri** what he would recommend for immediate and ongoing training for surgeons, to which **Dr. Nassiri** responded that this depends on the type of technology and stated that expert users of technology should educate other surgeons, and that medical schools are responsible for training upcoming generations. **Dr. Nassiri** continued on the barriers to the informed consent process, such as inclusivity in clinical trials, consumer choice, regulatory information, preexisting patient knowledge, and AI adaptations.

**Kathryn Capanna** solicited advice from Committee members' on how to communicate necessary information to patients to help inform FDA deliberations. **Mr. Dunlap** suggested long-term review boards for each product. **Ms. Schrandt** offered written references on diagnostic quality's relationship to patient engagement.

**Dr. Parker** expressed a desire for a safety-monitoring board to report on projects' rapid progress for FDA regulatory purposes. In response, **Ms. Leong** asserted the medical industry should work with professional organizations for clinicians, researchers, developers, and advocates to grow the field collaboratively, and that these organizations could inform FDA.

**Dr. Gallagher** reiterated the importance of patient understanding and of considering patient outcomes in regulatory processes. She commented on productive competition between medical device companies and inter-field collaboration.

**Mr. Rutherford** emphasized his concern for availability of the technology to all populations.

**Dr. Nassiri** provided comments on the usefulness of social organizations that partner with industry and FDA in considering inclusivity, adding that patient informed consent can be enhanced with online content outlining accurate medical information in layman's terms.

In some final comments, **Chairperson Conway** addressed **Ms. Capanna's** concerns and added that establishing reliable means of dissemination of transparent information is of prime importance; he addressed **Mr. Rutherford's** concerns and underscored that trusted advocacy organizations are key to increasing medical literacy across diverse communities.

## Question 2

**Commander Olele** read question two: along with medical information, other information can be critical to the use of the device, including information interest internet requirements, physical environment, et cetera. What information should be available to the patient or caregiver prior to use? For example: an onboarding tutorial through the device itself to help patients and caregivers safely and effectively use these devices at home?

**Ms. Schrandt** began by mentioning the usefulness of telehealth for delivering tech-based training, while stressing a need to supplement virtual trainings with in-person trainings. Expanding, **Dr. Parker** mentioned a need for immediate availability of support staff for any tech-based trainings.

**Ms. Diaz** advised video presentations for visual learners and patient checklists to educate on potential adverse events.

**Dr. Liran** stressed the importance of contacting a doctor if side effects are experienced and of limiting device usage to prevent side effects.

**Mr. Rutherford** suggested implementing diagnostic measures into the device itself to ensure proper use.

Clarifying for **Ms. Leong** on the use of commercially available AR/VR hardware for medical software, **Brendon O'Leary** confirmed that multiple-function devices are common for AR/VR. **Ms. Leong** then inquired towards developer considerations to keep entertainment functions separate from medical functions. She also added to **Ms. Diaz's** idea of a patient checklist, suggesting pre- and post-evaluations for the patient's perspective on usability.

**Dr. Adams** contributed some questions. First, who should provide troubleshooting information? Secondly, if troubleshooting data is sent to a company for tracking, how patient data privacy might be addressed?

**Dr. Levy-Clarke** mentioned variability in the learning styles of patients and also suggested PRO evaluations for post-market evaluations.

Chairperson Conway read **Dr. Wilcox's** written comment that suggested step-by-step videos, testing patients to ensure they can use the device properly, providing detailed side effect information in a checklist, regular patient check-ins, and transmission of important data to the clinicians.

**Chairperson Conway** summarized the Committee's contributions:

- a. People have different learning styles, so modes of training should vary.
- b. Both telehealth and non-telehealth training is important.
- c. Troubleshooting and technical support should be available in real-time.
- d. Separating entertainment and medical usage of AR/VR devices is of concern.
- e. Patients must receive clear information on potential adverse events.
- f. Patients should be informed on what side effects require stopping treatment.
- g. AR/VR devices could automatically relay health information to clinicians.

**Brendan O'Leary** followed up with a question regarding the time and frequency of collecting patient-reported outcomes. **Dr. Adams** stated this depends on the condition and treatment approach but universally requires baseline assessments. **Dr. Levy-Clarke** emphasized the role of caregivers in relaying outcomes. **Ms. Johnson** mentioned human factor studies, and **Ms. Schrandt** brought up that checklist evaluations restrict patients to answering pre-constructed questions. **Dr. Liran** asserted that frequency of data collection depends on software and devices and suggested easy access to a patient portal for reporting and to mitigate adverse events.

**Chairperson Conway** addressed **Mr. O'Leary's** and **Ms. Schrandt's** points, noting that "How does the patient feel?" is an important open question to include in PRO evaluations. He then prompted the Committee to reconvene at 12:32 p.m.

### Question 3

**Commander Olele** presented the third question:

Some AR/VR medical devices are developed specifically for a medical purpose, meaning the headset hardware is regulated by FDA. However, some AR/VR medical devices are generally marketed for people over the age of 13. What factors do you believe FDA should consider when an AR/VR medical device for children under 13 relies on consumer product hardware intended for individuals over the age of 13? For example, equipment sizing and usability.

**Mr. Rutherford** and **Dr. Adams** mentioned a need for long-term neurological tests related to brain growth, and **Dr. Adams** included comfortable hardware, time limits for device usage, safety locks, and preventing access from other children.

**Dr. Liran** considered inter-pupillary distance and the effects of incorrect sizing.

**Ms. Schrandt** mentioned difficulty defining a healthy baseline for chronic patients to establish guidelines for device use, particularly in congenital- or pediatric-onset diseases.

**Dr. Levy-Clarke** suggested close tracking of adverse events.

**Ms. Leong** entertained the ideas of external, real-time parental monitoring and controls.

**Mr. Rutherford** emphasized his concerns regarding regulation of the private sector.

**Mr. Dunlap** noted that long-term data tracking needs to be clearly understood.

**Dr. Adams** reiterated that patient morphology must be taken into consideration.

**Dr. Gallagher** mentioned that headset weight and bodily orientation influences usability.

**Dr. Wilcox** submitted a written statement read by Chairperson Conway, that age 13+ consumer devices shouldn't be used clinically; rather, medical device companies should enable some recreational functions in their regulated devices.

**Chairperson Conway** recapped the main concerns:

- a. Hardware specifications
- b. Data usage of the software

- c. Physical factors, including weight and fit, and their impact on efficacy
- d. The development of adolescent brains and variance of effects between individuals
- e. Tracking of adverse events through a repository or constant tracking
- f. The boundary between play and medicine
- g. Organized/central monitoring of device usage amongst young people
- h. Data collection from private companies
- i. Usage limits, locks, and restricted aspects
- j. Caregiver ability to report patient experience

#### Question 4

**Commander Olele** read the fourth question:

The long-term effects of using the AR/VR devices, including how long they can be used safely in an individual session and over what time frame the devices should be used, may not be well known for certain patient groups and for certain medical conditions. To assure timely access to safe and effective technology and facilitate medical device innovation, FDA balances the amount of information collected before the device can be marketed with the information that could be collected after the device is on the U.S. market. Typically for longer studies, patients may stop participating in the study, i.e., loss of follow-up or missing data that may impact the quality of the long-term studies.

- A. Balancing the public interest for long-term data and study quality, what factors should FDA use to determine the duration of a clinical study for AR/VR devices used in the treatment of cognitively impaired persons and children?
- B. In addition to safety and effectiveness data, what information would be helpful to patients and caregivers to help inform their decision to use an AR/VR device after a device is on the U.S. market and when it is used in children and people who are cognitively impaired?

**Dr. Nassiri** and **Dr. Levy-Clarke** invoked risk-benefit ratios: aggressive treatment is appropriate for life-threatening conditions, but for quality-of-life issues, more long-term data should be acquired before use.

**Ms. Schrandt** agreed, and she added that the FDA should consider lived experiences. She subsequently stated that patients do not always use treatments as designed, and this should be considered in decision-making.

**Dr. Gallagher** mentioned that short-term treatments may permit a longer usage time than long-term treatments and emphasized the importance of family members'/caregivers' perspectives in aiding patient decisions.

**Dr. Adams** posed burden, time, reasonable asks, and realistic treatment timelines in clinical studies as considerations for the FDA. She accounted for the history of the condition and the differences between AR/VR and non-AR/VR-based approaches regarding patient decisions.

**Dr. Wilcox** submitted written statement read by Chairperson Conway, that suggests a desire for long-term data and affirmed risk-benefit ratios and lived experiences as important factors in the decision-making process.

**Chairperson Conway** presented the overall consensus:

- A. Key factors in balancing public interest for long-term data and study quality:
  - a. Risk-benefit analysis
  - b. Aggressive or non-aggressive treatment
  - c. Chronic or static condition
  - d. Short-term versus long-term data collection
  - e. Short-term versus long-term side effects
  - f. Patient burden
- B. Criteria for evaluating safety and effectiveness:
  - a. Post-market data and issues related to data collection
  - b. Lived experiences
  - c. Information relayed from advocacy organizations/parents/caregivers
  - d. Device-transmitted information
  - e. Importance of different data to patient and provider

#### **Question 5**

**Commander Olele** read question five:

Patient and providers need information on the benefits and risks as well as how to appropriately use AR/VR devices whether used at home or in a clinical setting by providers. To ensure that patients and providers are able to use AR/VR medical devices as intended, the FDA and industry have a variety of communication mechanisms. Some examples of FDA's current communication tools for medical devices include safety communications, website updates, social media posts, and FDA press announcements. Information about the side effects, intended use and instructions for use of AR/VR devices is available in the device labeling.

- A. What other methods should FDA, industry, and other stakeholders like patients group and healthcare professional organizations consider when communicating to patients to the intended use of AR/VR medical devices?
- B. How should FDA communicate risks to caregivers of vulnerable patients, someone who may not be wearing the device and is not intended user but who may be tasked with supporting the in-house time as part of product labeling.

- C. How should FDA and industry inform patients about effective usage of AR/VR devices in communities where internet access and other connectivity issues may impact use?
- D. As we learn more about the impacts of AR/VR devices over time, what approaches should FDA and industry use to share with patients any added benefits and/or changes in performance?

**Dr. Nassiri** addresses the four components by saying: easily accessible, government-approved platforms must be available; additionally, it is important to consider overall costs.

**Ms. Diaz** proposed an FDA registry to quickly distribute notices and updated information to providers and patients.

**Mr. Rutherford** addressed B and C, respectively: funds should be allocated specifically for outreach in marginalized communities, particularly those with restricted internet access; and side effects should be presented in a less overwhelming fashion so patients take them seriously.

**Dr. Liran** added that in communities without internet access, providers should give take-home materials for education on hardware and treatment, and that software should come with a physical manual.

**Ms. Leong** contributed that specialists should convene to advance AR/VR treatments in their field. She emphasized the responsibility of patient organizations in relaying information.

**Dr. Levy-Clarke**, in response to part D, stated that healthcare providers should be the targets of updated information, and providers should relay that information comprehensively to patients. To part B, she identified proper storage and side effect awareness for home healthcare personnel. For part C, she underscored the importance of including diverse socioeconomic and demographic groups in clinical trials/studies.

**Dr. Gallagher** identified some issues: internet quality varies by location, and if other people are using the same internet, the device may not perform as well. For her, advocacy and patient groups are primary sources of information, followed by FDA/industry information. She also suggested that the FDA could cultivate public trust by disclosing more information from outcomes of other device users.

**Ms. Schrandt** endorsed the above and added to question C: early design and testing must partner with diverse communities to permit usage in populations with limiting circumstances.

**Dr. Adams**, to part A, responded that AR/VR technology itself can be a source of information. To part B, she called for the FDA to communicate with caregivers outside technology, and she attributed good decisions to a two-way exchange of information between provider and patient.

**Mr. Dunlap** addressed A and B by suggesting safety webinars with two-way communication about patient risk and legal risk.

**Dr. Wilcox** submitted a written statement read by Chairperson Conway, that indicated, for each successive sub-question: the use of video and text information on a USB drive with supplemental user-tailored information; that information available to caregiver and patient should be identical; use of illustrated guides and/or standalone device demonstrations; and that the existing recall process can be used to provide information updates.

**Chairperson Conway** summed the Committee's thoughts on Question 5:

To Part A:

- a. Use of infographics
- b. Credible and dedicated websites from FDA or partnership organizations
- c. Registries of providers and users
- d. Advocacy organizations collaborating with FDA

To Part B:

- a. Payers must be involved
- b. Caregivers must understand device operation, storage, and adverse effects

To Part C:

- a. Developers and insurers have a role in communicating availability in marginalized communities
- b. All groups should be informed of new technologies
- c. Communities should have involvement in the design phase
- d. FDA could recommend developers to design with communities in mind
- e. Alternate means of connectivity are possible, such as offline hardware

To Part D:

- a. Engagement with professional organizations is necessary
- b. Evolution of technologies may add benefits across disciplines
- c. Medical professionals must communicate changes with patients
- d. Data insights from prior consumers should be relayed to new patients
- e. Healthcare providers are primary manufacturer contacts who update patients

**Ms. Saha** asked a clarifying question of **Dr. Levy-Clarke**: who should update physicians on benefits and risks? FDA? Industry? Another stakeholder?

**Dr. Levy-Clarke** responded that FDA-driven label changes provide automatic updates to healthcare providers that can then be communicated to end users.

## Question 6

**Commander Olele** conveyed the sixth and final question:

Manufacturers, device users, facilities, and importers are required to submit to FDA certain types of reports for adverse events and product problems about medical devices. FDA encourages healthcare professionals, patients, caregivers, and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use

errors, product quality issues, and therapeutic failures, but such reporting is not required. How should the FDA communicate about how or where to report issues with AR/VR medical device systems, including when there are issues with the consumer product headset?

**Mr. Rutherford** remarked that this is an administrative issue.

**Dr. Liran** suggested transparent instructions for reporting adverse events and to obtain as much safety data as possible.

**Ms. Leong** inquired into the FDA's role in regulating consumer devices, to which **Ms. Krueger** clarified that the FDA coordinates with the CPSC, FTC, and have MOUs to facilitate securely sharing safety and other information. **Ms. Leong** voiced further concerns on the nuances of entertainment- versus medical-based data gathering in consumer devices.

**Ms. Schrandt** commented on the fact that machinery is not foolproof in relaying data, so big, flashy lettering on the package displaying where to report concerns and patient experiences.

**Dr. Gallagher** concurred, emphasizing that patients should have an avenue to report experiential issues, such as needing better instructions.

**Ms. Johnson** differentiated between reporting performance issues versus for reporting adverse events.

**Mr. Dunlap** suggested making FDA error reporting processes more patient-friendly.

**Ms. Leong** added that error reporting can be even more difficult for marginalized populations.

**Dr. Wilcox** submitted a written remark read by Chairperson Conway that the FDA should actively reach out to users.

**Chairperson Conway** presented the highlights of question 6:

- a. Distinguish between medical and consumer devices
- b. MOUs in place from the FDA with CPSC and FTC
- c. Delineate communications about mixed-use devices
- d. Make information accessible to consumers, regulators, and industry
- e. Labeling must be very obvious to patients and caregivers
- f. Devices could recognize and report medical concerns automatically
- g. Users may not follow best practices
- h. Increase ease of relaying patient-reported issues and adverse effects to FDA

The FDA posed questions to the Committee:

**Ms. Krueger** requested more information on ways to quickly report information to patients.

**Dr. Liran** mentioned that reporting information could be embedded into the software.

**Mr. Rutherford** noted that social media is how most people share information currently.

**Dr. Levy-Clarke** voiced her concern that communication must be equitable for patients with disabilities.

**Dr. Gallagher** responded that public service announcements and press releases can be effective.

### **Closing Remarks**

**Ms. Capanna** thanked the PEAC Committee and recognized the Committee's importance in incorporating patient perspectives into FDA regulatory decisions.

**Mr. O'Leary** emphasized the benefit of the PEAC meeting in ensuring safe and effective innovative medical technologies.

**Ms. Saha** recognized the contributions of the Committee to the issues of health equity and vulnerable populations.

**Ms. Krueger** thanked the Committee.

**Chairperson Conway** expressed his appreciation for the Committee's contribution to ensuring patient needs and experiences are incorporated into regulatory processes. He adjourned the second day of the two-day meeting.

I certify that I attended this meeting on July 13, 2022 and that these minutes accurately reflect what transpired.

Letise W. Williams -S      Digitally signed by Letise W.  
Williams -S  
Date: 2022.09.06 09:42:02 -04'00'

Letise Williams  
Designated Federal Officer

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

  
Paul T. Conway  
Chairperson

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