UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN Services

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

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PATIENT ENGAGEMENT ADVISORY COMMITTEE

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JULY 13, 2022

10:00 a.m. EST

Via Zoom Videoconference

PANEL MEMBERS:

Paul T. Conway	Chair
Amye L. Leong, M.B.A.	Voting Member
Bennett R. Dunlap, M.S.	Voting Member
Monica Parker, M.D.	Voting Member
Phillip X. Rutherford	Voting Member
Mary (Suzanne)Schrandt, J.D.	Voting Member
Teresa Diaz Co-Founder	Consumer Representative
Heather R. Adams, Ph.D.	Temporary Non-Voting Member
Colleen M. Gallagher, PhD, LSW, FACHE	Temporary Non-Voting Member
Grace Levy-Clarke, M.D.	Temporary Non-Voting Member
Omer Liran, M.D.	Temporary Non-Voting Member
Naiem Nassiri, M.D.	Temporary Non-Voting Member
Diane M. Johnson, M.S.	Industry Representative
Letise Williams	Designated Federal Official

FDA Representatives:

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, OST

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

FDA Presenters:

Anindita Saha
Assistant Director, Digital Health Center of Excellence, Office of Strategic Partnerships & Technology Innovation, CDRH, FDA

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MEETING

(10:00am)

MR. CONWAY: I would like to go ahead and call this meeting of FDA's Patient Engagement Advisory Committee on July 13th, 2022, to order. My name is Paul Conway and I have the honor to serve the FDA and my fellow patients as the chair of this committee. Outside of this committee I serve as the chair of policy and global affairs for the American Association of Kidney Patients, the largest independent kidney organization in the United States. I have a background in federal and state government agency management, I'm a kidney patient of 42 years.

As a patient I lived nearly three years on dialysis and for the past 25 years my life has been extended by the anonymous and generous give of a donor whose own life was cut short due to an accident.

For those who were unable to watch our proceedings yesterday, or if you are watching and listening to the proceeding of the PEAC for the first time and will be joining us today, I believe it is important to take a moment to highlight and repeat the distinctive nature of the FDA's advisory committee process.

The Patient Engagement Advisory Committee is the only FDA advisory committee that is comprised solely of patients, caregivers, and patient advocates. The stated purpose and general function of the committee is to provide advice and recommendations to the agency on complex issues related to medical devices, the regulation of devices and their use by patients.

Our first meeting occurred in the fall of 2017. The advisory committee structure and process is the most formal way that the U.S. Food and Drug Administration can

receive advice from the American public on scientific matters. From this standpoint alone the creation of the PEAC by FDA was a significant and substantive recognition of the importance of patient, consumer and caregiver insights on matters that are within the regulatory purview of the FDA. As you will hear shortly, the PEAC is comprised of members with unique lived experiences as patients, caregivers, and patient advocates. Throughout the course of our advisory committee operations our deliberations have been informed and have benefited from a wide variety of expert participants. For example, joining the PEAC today and yesterday are additional experts participating with insights in bioethics, neurodevelopment, human factors, augmented reality, virtual reality, mixed reality, ophthalmology, and pediatrics. Yesterday the committee heard a tremendous series of presentations on augmented reality and virtual reality medical devices. The committee appreciates the great investment of time and expertise and perspectives offered by the patients, patient advocates, device developers, medical industry experts, researchers, and medical professionals. We also listened very, very closely to the statements of those who participated in the open public hearing. And we listened closely to the summations of public insights gained from members of the public who registered and participated in our virtual breakout sessions. Together the public insights and expert presentations have provided this committee with a great depth of information for today's discussions. The elevation of patient consumers and their unique insights across the medical device development lifecycle and within the FDA processes is part of a far broader and more profound evolution in how patients and their experiences are valued by experts in the medical professions, government, industry, and academia. This evolution is associated with the creation in higher

acceptance of the science of patient insight data. And my fellow PEAC members and I are very pleased to continue to make contributions to the FDA and this emerging science. But to be perfectly clear, our works as a committee would not be possible without the tremendous investment of time and expertise by the general public, patients and patient advocates who have worked closely with us over the course of the past five years.

I will remind the audience of some elements we stated yesterday that also apply to today's discussion. I note for the record that the nonvoting members constitute a quorum as required by 21 C.F.R. Part 14. I would also like to add that the committee members participating in today's meeting have received training in FDA device law and regulations. For today's agenda the committee will continue to discuss and provide advice on augmented reality, AR, and virtual reality medical devices.

AR/VR devices are increasingly applied to healthcare settings across the patients' care continuum. From diagnostics to clinical decision making, to surgical support, and to directly treating patients, AR/VR devices are used across multiple medical specialties. These devices have novel attributes and considerations for patients and providers that impact FDA's evaluation of the device's safety and effectiveness. The novel attributes of digital health visualization, tracking techniques, embedded software among other factors present unique challenges for pre and post market evaluation. The advice provided by the committee will address factors FDA and industry should consider when evaluating the benefits, risks, and the extent of uncertainty for AR/VR medical devices. The committee will also consider specific challenges related to specific populations, for example, pediatric patients or patients cognitively impaired who may use this

technology. Additionally, the committee will discuss ways patient perspectives could be incorporated in FDA and industry benefit-risk decision making, as well as the healthcare provider decision-making process related to using or prescribing the technology.

Now, I would like to lay out a few ground rules. If a panelist would like to ask a question today, please physically raise your hand and I will get to your questions as we proceed throughout the day. We want to prevent multiple persons from speaking over each other since this entire meeting is being transcribed, and the work of the transriptionist is highly important for our proceedings and it's a tremendous task for them. .

We have six questions we'll be addressing today. Many of them have subcomponents so there are almost a total of 11 different questions we'll be answering as a committee and deliberating , and I would ask my fellow committee members to keep that in mind when answering specific questions. We would like to get everyone on the record with their viewpoints since we have a tremendous and rich complement of thought comprised here on the committee.

Before I begin, I would like to go ahead and ask our distinguished Committee Members and FDA experts, identified on the meetings roster attending virtually to introduce themselves.

Committee members, I'm sure you have done this now, but please go ahead and turn on your video monitors if you have not already done so, unmute your phone before you speak. I'll call your name then please state your area of expertise, your patient and/or caregiver role as it pertains to PEAC, your position and professional affiliation. And off the top I'll start with my colleague, Bennet Dunlap. Go ahead.

MR. DUNLAP: Good morning. Bennet Dunlap. Thank you, Paul. I am the father of four now adult children, two of whom were diagnosed very young as Type I diabetes patients. That led me to be an advocate for safety and accuracy in the devices that they use. I had the pleasure of engaging with the FDA on a number of issues and creating the process of bringing the diabetes community and the FDA together in dialogue. It's a thrill to continue that process here with the PEAC and to work with my colleagues here on this panel with you all. Thank you.

MR. CONWAY: Thank you very much, Bennet. Amye Leong.

MS. LEONG: Good morning, all. My name is Amye Leong from Santa Barbara, California and I am president and CEO of Healthy Motivation, a consulting company that operates internationally. Healthy Motivation started out with me just as a motivational speaker because I was asked so many times to speak around the country and then eventually throughout the world. It was also prompted by my being diagnosed with rheumatoid arthritis at the age of 18, totally crippled and in a wheelchair by 22. Lived five years in a wheelchair. Interesting experience, not something I ever want to go to. Isn't it amazing how when you hit bottom, that propels you forward.

Since then, I have had -- excuse me, experienced 21 joint replacements and including an infection in a recent joint, so I feel like I'm very schooled in the area of care. I deal a lot at the international level with getting disciplines that work in musculoskeletal medicine, so orthopedics, physical medicine and rehab, rheumatology, the technology companies, medical device companies to begin to worth together with patient organizations and get the patient engagement angle.

I'm delighted to be serving the beginning of my second term with the PEAC.

Patient engagement has been my mantra since I was a teenager when we didn't put those two words together and so it's very exciting for me to work at the international level including United Nations and then nationally with the Arthritis Foundation, the American College of Rheumatology and the United States Bone and Joint Decade, for which I serve as an executive officer and on the executive committee. Thank you.

MR. CONWAY: Thank you very much, Amye. Dr. Monica Parker.

DR. PARKER : Good morning, everybody. My name is Dr. Monica Parker. I am personally the primary caregiver for a 96-year-old parent who suffers from Alzheimer's dementia. In the last six months I lost her sister who was 93, with the same disorder. In any event, professionally I am a family physician and geriatric primary care provider. I currently serve as both the outreach recruitment and education director and minority engagement core director for the Goizueta Alzheimer's Disease Research Center at Emory University where my main job is educating and recruiting persons of color, now everybody, for clinical research participation in Alzheimer's and related dementias research.

MR. CONWAY: Great. Thank you very much, doctor. Mr. Philip Rutherford.

MR. RUTHERFORD: Good morning, everyone. My name is Philip Rutherford. I am a person living in sustained recovery from substance use disorder. And in my professional life I'm the Chief Operating Officer of an organization called Faces and Voices of Recovery. And we advocate for people in recovery from substance abuse disorder, and glad to be here.

MR. CONWAY: Thank you very much, Philip. Ms. Suzie Schrandt.

MS. SCHRANDT: Thank you. Good morning, everyone. I'm Suzanne or Suz

Schrandt. Really privileged and honored to be with all of you. I've served on the PEAC for several years now. I'm a long-time patient advocate. I was diagnosed with polyarticular JIA. I was diagnosed long enough ago that we called it JRA back then, right around my 14th birthday, and so have been really thrown into patient advocacy and patient engagement from a very early age.

I've had the privilege and opportunity to work in a variety of capacities at PCORI, at the Arthritis Foundation, with the NIH, with a number of international and national organizations, really just focused on how we co-create healthcare solutions with patients, operating under that mantra of "nothing about us without us" and so I think the FDA really epitomizes that mantra with this committee and with a lot of the work going on. So again, thank you for the opportunity to be here. I look forward to our time together.

MR. CONWAY: Great. Thank you very much, Suz. Ms. Teresa Diaz.

MS. DIAZ: Good morning, everyone. My name is Teri Diaz, and I am cofounder of GPAC which is the Global Patient Advocacy Coalition, as well as a co-facilitator for the Breast Implant Health Summit. And I was bedridden from a medical device that once I had it removed, I became better and was not given proper informed consent. So, both of my organizations work really hard to make sure that patients are given proper informed consent before they elect in any medical procedure.

MR. CONWAY: Great. Thank you very much, Teri. Dr. Heather Adams.

DR. ADAMS: Good morning, everyone, and thank you for allowing me to participate. I am a pediatric neuropsychologist at the University of Rochester Medical Center in Rochester, New York, where I serve as associate professor in the department

of neurology. My research and clinical interests span a lot of areas but particularly pediatric rare diseases and any conditions that result in neurodevelopmental impact on children. I also serve as an advisory panel member to the PCORI rare disease advisory panel. Thank you.

MR. CONWAY: Great. Thank you very much. Dr. Colleen Gallagher.

DR. GALLAGHER: Good morning. I'm Colleen Gallagher, and I'm here as a bioethicist today, and my primary role in doing bioethics work is as the executive director of Clinical Ethics and chief of the Section of Integrated Ethics at the University of Texas MD Anderson, Cancer Center. I also work with national and international groups where for example, I'm a research scholar with the UNESCO chair for bioethics and human rights and other organizations I've done worked on informed consent, with The European Commission, things like that, so I've done a variety of things. And it is my pleasure to have spent yesterday learning a lot, and especially of the questions asked by PEAC, and hopefully we'll have a great discussion today. Thank you.

MR. CONWAY: Great. Thank you very much. Dr. Grace Levy-Clarke.

DR. LEVY-CLARKE: Good morning. I am a board-certified ophthalmologist and associate professor and director of the Uveitis Services at West Virginia University Eye Institute. I bring a background of five years at the NIH doing clinical research in rare diseases that affect the eye. Spent some time also in industry but have overall 25 years of clinical experience. In patient advocacy my interest is bringing together all the stakeholders who can help patients who have rare diseases that affects the eyes. Thank you.

MR. CONWAY: Great. Thank you very much, doctor. Dr. Omer Liran.

DR. LIRAN: Yeah. Hi everyone. I'm Dr. Omar Liran, working in Los Angeles, California. I'm a board-certified psychiatrist and assistant professor of psychiatry at Cedars-Sinai Medical Center. I'm also the co-director of Virtual Medicine where we connect research in AR and VR technologies, and we use the technologies clinically. It's an honor to be here. Thank you.

MR. CONWAY: Great. Thank you very much, Doctor. Dr. Naiem Nassiri.

DR. NASSIRI: Hi. Good morning, everybody. Nice to see everyone again. I'm Naiem Nassiri, I'm an associate professor of vascular surgery at Yale University. I'm also site chief of vascular surgery for the VA Healthcare system in Connecticut. I have a robust practice in complex minimally invasive aortic surgery and also a co-director of our vascular malformations program with an international referral basis. Happy to be here.

MR. CONWAY: Great. Thank you very much, Doctor. Ms. Diane Johnson.

MS. JOHNSON: Good morning and thanks for inviting me to be on this panel. My name is Diane Johnson. I work for Johnson & Johnson med tech companies in policy organization, and my focus is on FDA policy, guidance documents, things of that nature, and global harmonization related to all digital health products, trying to ensure patient access across the globe to these critically important products.

MR. CONWAY: Great. Thank you very much, Diane. Now our FDA professionals, Ms. Kathryn Capanna.

MS. CAPANNA: Good morning, everyone. Thanks for joining us for day two. I'm Katie Capanna. I'm a deputy division director at FDA Center for Devices in our office of strategic partnerships and technology innovation, and our group coordinates and

manages the Patient Engagement Advisory Committee, and we very much appreciate all of you spending your time with us here again today.

MR. CONWAY: Thank you very much, Katie. Mr. Brendan O'Leary.

MR. O'LEARY: Good morning. My name is Brendan O'Leary. I'm the acting director for the Digital Health Center for Excellence at FDA Center for Device and Radiological Health. Thanks again to everybody for sharing their perspectives on these important issues.

MR. CONWAY: Thank you very much, Brendan. Ms. Angela Krueger.

MS. KRUEGER: Good morning. I'm Angie Krueger, the deputy director for regulatory policy in the Office of Product Evaluation and Quality in CDRH, and our office is charged with executing the premarket/ postmarked, and compliance and quality review for medical devices.

MR. CONWAY: Great. Thank you very much, Angie. And then Ms. Annie Saha.

MS. SAHA: Good morning, everyone, I'm Annie Saha, and I'm the Assistant Director of our Digital Health Center of Excellence here at CDRH and look forward to today's discussion.

MR. CONWAY: Great. Thank you very much for your introductions and your affiliations. Now I'll go ahead and turn to Letise Williams, the designated federal officer for the Patient Engagement Advisory Committee who will make some introductory remarks. Go ahead, Letise.

MS. WILLIAMS: Good morning. I will now read FDA's conflict of interest disclosure statement, Particular Matter of General Applicability for the Patient Engagement Advisory Committee. July 13th, 2022, meeting.

The Food and Drug Administration (FDA) is convening today's meeting of the Patient Engagement Advisory Committee under the authority of the Federal Advisory Committee Act (FACA) of 1972. With the exception of the industry representative, all members and consultants of the Committee are special Government employees or regular Federal employees from other Agencies and are subject to Federal conflict of interest laws and regulations.

The following information on the status of this Committee's compliance with Federal ethics and conflict-of-interest laws covered by, but not limited to, those found at 18 U.S.C. §208, are being provided to participants in today's meeting and to the public.

FDA has determined that members and consultants of this Committee are in compliance with Federal ethics and conflict-of-interest laws. Under 18 U.S.C. §208, Congress has authorized FDA to grant waivers to special Government employees and regular Federal employees who have financial conflicts when it is determined that the Agency's need for a particular individual's services outweighs his or her potential financial conflict of interest.

Related to the discussions of today's meeting, members and consultants of this Committee who are special Government employees or regular Federal employees have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their spouses or minor children and, for purposes of 18 U.S.C. §208, their employers. These interests may include investments, consulting, expert witness testimony; contracts, grants, CRADAs, teaching, speaking, writing, patents and royalties, and primary employment.

For today's agenda, the Committee will discuss and make recommendations on the topic of Augmented Reality (AR) and Virtual Reality (VR) Medical Devices." AR/VR devices are increasingly applied to healthcare settings across the patients' care continuum. From diagnostics to clinical decision making, to surgical support, and to directly treating patients, AR/VR devices are used across multiple medical specialties. These devices have novel attributes and considerations for the end users that impact FDA's evaluation of the device's safety and effectiveness.

Based on the agenda for today's meeting and all financial interests reported by the Committee members and consultants, a conflict-of-interest waiver has been issued in accordance with 18 U.S.C. §208(b)(3) to Dr. Omer Liran. Dr. Liran's waiver addresses his employer's future licensing potential of the VR Software application. Dr. Liran is identified as a co-inventor and developer of a VR Software. Dr. Liran and his employer are entitled to revenue if the software application is licensed, but they do not currently generate any revenue.

The waiver allows this individual to participate fully in the Committee deliberations. FDA's reasons for issuing the waiver are described in the waiver documents, which are posted on FDA's website at http://www.fda.gov/AdvisoryCommittees/default.htm. Copies of the waiver may also be obtained by submitting a written request to the Agency's Division of Freedom of Information, 5630 Fishers Lane, Room-1035, Rockville, MD 20857.

Ms. Diane M. Johnson is serving as the industry representative for Digital Health Technology/Artificial Intelligence and is acting on behalf of all related industry. She is employed by Johnson & Johnson.

We would like to remind members and consultants that if the discussions involve any other products or firms not already on the agenda for which an FDA participant has a personal or imputed financial interest, the participants need to exclude themselves from such involvement and their exclusion will be noted for the record.

FDA encourages all other participants to advise the Committee of any financial relationships they may have with any firms at issue.

A copy of this statement will be available for review and will be included as part of the official transcript.

Thank you.

For the duration of the Patient Engagement Advisory Committee Meeting on July 13, 2022, Dr. Heather R. Adams has been appointed to serve as a Temporary Non-Voting Member.

For the record, Dr. Adams serves as a consultant to the Gastrointestinal Drugs Advisory Committee in the Center for Drug Evaluation and Research.

This individual is a special Government employee who has undergone the customary conflict of interest review and have reviewed the material to be considered at this meeting.

The appointment was authorized by Russell Fortney, Director Advisory Committee Oversight and Management Staff, on June 15, 2022.

Before I turn the meeting back over to Mr. Conway, I'd like to make a few general announcements.

In order to help the transcriber, identify who is speaking, please be sure to identify yourself each and every time that you speak.

Transcripts of today's meeting will be available from Translation Excellence, Inc., 1050 Connecticut Ave., N.W., Washington, DC 20036. Tel: 720-325-0459

The press contact for today's meeting is Lauren-Jei McCarthy. For the record, FDA has received 2 written comments. Thank you very much. I will now turn the meeting over to the Chair, Mr. Conway.

MR. CONWAY: Thank you, Ms. Williams. I want to provide a brief overview of how today's meeting will run. During the morning FDA will provide a recap of yesterday's meeting. After the recap, the Committee will proceed with Committee Discussions of the FDA Questions. At approximately 12:00 PM we will break for 30-minutes for Lunch. Afterwards, we will return and resume Committee discussion of the FDA Questions. Following our discussion of these questions, I will give closing remarks.

It is now approximately 10:26 and we will proceed with a day one recap from Office of Strategic Partnerships and Technology, CDRH. Ms. Saha, you can go ahead and begin your remarks. Thank you.

MS. SAHA: Thank you, Paul. And good morning again. I'm Ani Saha and I would like to thank all the invited speakers, breakout session participants and open public hearing speakers for their thoughtful engagement perspectives. We heard a few recurrent themes throughout the day on health equity, patient engagement, considerations in vulnerable populations, along with generating the evidence and understanding the evidence to assess AR/VR devices. As you heard from Dr. Shuren our Center’s 2022 to 2025 strategic priorities place a special focus on health equity and our commitments to bridging the health technology divide to meet the needs of all patients and consumers. Technology, including digital health technology, should be designed,

and targeted to meet the needs of diverse patient populations. We heard from many of the speakers about how digital health technologies like AR/VR can help bridge the gap by bringing healthcare directly to patients where they are, whether that's at home, at work, in cities, or in rural communities, and if this can facilitate the participation of diverse populations in clinical studies, and provide other opportunities for improved data collection to understand the long-term outcomes of the use of AR/VR devices.

While digital health technologies have the opportunity to improve health equity, we also must be mindful of vulnerable populations including those who are affected by the digital divide such as those living in rural communities, those living in poverty as well as patients who require additional consideration such as children, cognitively impaired patients, and patients recovering from substance abuse disorders. AR/VR has broad uses across the healthcare spectrum and is being studied and used across many different clinical applications including but not limited to mental health, different types of rehabilitation, as well as ophthalmology. AR/VR is being used to provide objective assessments in clinical care including patient generated health data and clinical outcome assessments. AR/VR is being used for surgical planning and image guided surgery. We've also heard the potential of future uses of AR/VR as the technology continues to evolve and continues to be studied.

Many of the speakers highlighted the need to engage users who are both patients and healthcare providers thoroughly in the development process to ensure that AR/VR devices are designed to meet the needs of stakeholders who are using the device as well as those who may be -- the device may be used on or with. Speakers highlighted that even with the digital technologies are being used by surgeons it's still important to

understand how this device will impact patients and understand what outcomes are important to patients when their surgeon is using AR/VR device. Developers of AR/VR… I'm going to switch maybe to a headset.

MS. WILLIAMS: No. You might just have to speak a little louder, Ani.

MS. SAHA: All right.

MS. WILLIAMS: That's a little better.

MR. CONWAY: That's better.

MS. SAHA: Sorry about that. Apologies for that. I think I will try to restart what I was previously saying. Many of the speakers highlighted the need to engage users for both patients and healthcare providers early in the development process to ensure that AR/VR devices are designed to meet the needs of those stakeholders using the device as well as those who this device may be used on. Speakers highlighted even when a device is used by a surgeon, it's still important to understand how to use the device with patients and understand what outcomes are important to patients when using an AR/VR device. Developers of AR/VR devices both in the lessons learned, and the development process have to focus on the user interface and experience, the technical specifications and the digital needs of how hardware and software work together. Developers spoke to the considerations of being compliant to standards and to protect privacy to ensure cybersecurity of the devices, a challenge and concern we heard regarding how the headset and the software interact. We heard discussions around the device maintenance including training, software updates, and cleaning and care. In particular the speakers from the breakout rooms and discussions and open public hearing speakers mentioned the challenges that patients face in the updates of the device to

ensure the device remain safe and effective in the care of themselves on or their family member. We heard specific concerns about using AR/VR devices overall and specifically in vulnerable populations. Yesterday's participants spoke about the uncertainty of the long-term effects of AR/VR data devices, data sharing and privacy, potential for addiction and impacts on perception of reality in children with developing brains or individuals with cognitive challenges. The presenters, committee members and open public hearing speakers, raised a number of topics for discussion today including, what's an appropriate dose or time for using AR/VR devices for different patient populations to achieve effective results without experiencing additional risks. How much monitoring should be done when using the device? Should the device determine when a patients in distress (indiscernible) urgently interrupt treatment or patients or caregivers or the healthcare provider. When would an interruption in treatment be warranted, and how should the treatment be safely stopped during use? If the treatment needs to be paused or stopped altogether what would the impact be on patients? What are possible interactions that patients on prescribed medications could have with the AR/VR device. Would certain medications impact their ability to respond appropriately through device of treatment? Is the treatment developmentally appropriate for the patient? Can patients become addicted to these devices? Additionally, how may that affect patients who already suffer from addiction issues?

We also heard about the need to assess headsets and the technology to ensure appropriate sizing and fit for pediatric population. Understanding whether the headset might be too big or too heavy, whether children have the neck strength for it. Presenters also highlighted the need for additional considerations to think about when

pediatrics might be wearing a headset, and earphones because that could affect the ability of the provider to see or speak with the patient.

There are also questions about how the VR can impact eyesight or brain development. We heard about concerns about prolonged screen time, and the impact it might have the effectiveness of the AR/VR device. Both in the speaker presentations and the breakout scenario summations, we heard the types of information people want to hear about AR/VR devices before determining whether to consent to a device being used in care for themselves or a loved one.

Some of the key themes that emerged from the discussion include the need for healthcare providers to clearly communicate the benefits and risks of the devices as many of the breakout rooms also noted that their providers are a trusted source. In order to do so, providers need to have adequate information through informed discussion. People also wanted to be able to learn about the technology and impact from others who use the device whether through patient groups or peer to peer discussion. Some of the breakout room participants indicated an interest in being able to pursue their own independent research as well as review of the literature.

We also heard from the moderator there's interest in different methods for getting the benefit risk information, along with information about how a patients progressed over time. These included ideas like instructional videos, training page, story boards and dashboards were some examples that were given. We also heard that instructions or trainings, as well as simulated experience as being important for caregivers so that they can understand what a family member might be experiencing. As you can hear, yesterday provided a rich background for informing today's discussion. To

enable the greatest benefit of AR/VR crisis for public health it's really critical that patients and healthcare providers have the trust and confidence and the information used to develop and evaluate them. Transparency, inclusivity, and engagement can foster better trust in AR/VR devices. We look forward to hearing the committee's deliberations on the questions and with that I turn it over to you and I am so sorry about all of that extra noise.

MR. CONWAY: Thank you very much, Ani, and thank you, and the FDA for providing an excellent summary for day one of the PEAC meeting on augmented reality, virtual reality medical devices and also thank you for mastering the realities of an online PEAC meeting. We appreciate it, it's a dynamic environment and you did quite well, so thank you.

It's now approximately 10:36 and I would like to resume the committee meeting. At this time let us focus our discussion on questions from the FDA. Committee members, copies of the questions are included in the materials you were previously provided. I would ask that each committee member identify themselves each time he, she or they speak to facilitate the transcription. I would also like to remind members of the committee that this meeting is classified as a particular matter of general applicability because the issue to be discussed by the committee is a particular matter that is focused on the interests of a discreet and identifiable class of products but does not involve specific parties or products. I would like to remind public observers that this meeting -- that while this meeting is open for public observation, public attendees may not, except at the specific request of the committee chair, ask questions. At this time, I would like to ask FDA to please read the questions. Commander Chinyelum Olele,

please go ahead and proceed. Thanks, Commander.

CMDR OLELE: Question one. Augmented reality AR and virtual reality VR medical devices have promise to improve patient outcomes and access to care. AR/VR devices rely on a variety of technical considerations related to how the information and data are presented to the user, sensing and feedback capabilities, and specific network and infrastructure requirements. Example, internet physical environment for optimum performance. Next slide.

AR devices are used to display navigational information as an adjunct to standard surgical procedures and provide information such as computer-generated, anatomical images to help guide surgical procedures. Other uses of AR devices include pre-surgical planning and surgical training and education. 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, such as through improving surgical accuracy, reliance on AR may produce new risks due to the interaction between real and virtual information. 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.

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?

MR. CONWAY: I'll start identifying folks who have their hands raised but again the

objective here is that I'll try to get insights from each one of you, so if you have a little patience as we go ahead and proceed here. I would like to go ahead and start with Dr. Parker.

DR. PARKER: Key questions for inserting the device would be, before you use this device what has been the data that allows us – allows you to advise this as a safety thing for us i.e. how many people has this device been tested in, has it been tested in people like me, whatever “me” is, and what is the efficacy or what sort of adverse are side effects have there been. Second of all, what kind of training have you had and what kind of training or support will you receive for managing this device in the future? And if I have complications, who do I address? Who will address those things for me?

MR. CONWAY: Great. Thank you very much. Dr. Nassiri?

DR. NASSIRI: Yes, thank you. So, I think as a vascular surgeon who's kind of at the front line of a lot of artificial intelligence-based mechanisms for optimizing imaging, I think it's important to keep in mind that this is an evolving and growingly smarter and growingly more intelligent platform. So it is not just limited to a few numbers of surgeons who are qualified to utilize the platform but rather the technology and the machinery itself by virtue of being used more and more, becomes more and more intelligent, so we are dealing with not just a finitely defined technology that then is given or made available to a select few surgeons and then they through virtue of using the experience that they have become, (indiscernible - 00:01:03) of using it, but rather this is a computer based platform that is using artificial intelligence to become smarter the more it is used.

So, I think that's an important topic to keep in mind and educate the patients for

that. And also, to kind of help educate them on how, by virtue of using these platforms we are doing away with some of the other potentially harmful techniques that have been employed up to this point.

So, case in point, right now one of the platforms that is being used or I have been approached to start to employ is artificial based -- artificial intelligent based identification of branch vessels in the aorta, when we perform complex minimally invasive inter-vascular aortic interventions. We traditionally have to rely on contrast -- contrast infusion inside the patient which can damage the kidneys, and also an exorbitant amount of radiation – ionized radiation that can lead to all kinds of neoplastic processes.

These AI and AR based platforms can potentially mitigate and do away with a lot of those harmful effects. I think it's important to keep the patients educated about that process.

And lastly, I think it's very important for the industry to be a much more proactive and helpful in helping to educate the patient, and I would urge the FDA to be a source of some of this information by virtue of it being the entity that gives the final okay for a lot of these things to come into play.

MR. CONWAY: Great. Thank you very much, Doctor. Amye, go right ahead. You're muted, Amye.

MS. LEONG: As someone who not by choice has gone through 21 different surgeries now, the distinction I had to make in yesterday's wonderful presentations and very diverse presentations were those – those items of AR and augmented – virtual and augmented, was that you know what is the point at which it touches me, the patient, or

anything that is inside of my body? What I have seen in surgeries so far, or talked about with orthopedic surgeons only in particular, is that the augmented reality or the virtual reality being able to see a joint – see the joint, a connection, and what's around it, if it's deficit, if it's thin, if there's osteoporosis. Those are the kinds of things that would not have been seen before. So, this serves as an ad junk to a surgeon's ability to do the intended job much more precisely without hopefully harmful negative effects to me as a patient. Now we look into those kinds of things that are growing. And as we heard yesterday, this whole industry if you will, is evolving very quickly. We had several speakers speak to that. And the concern I was feeling inside of me growing was that, how aware are these various companies of the safety features, of the engagement side of this that CDRH is heralding, and I think that's an important piece, but how useful can it be and to what kinds of populations? We think about diversity, and I can tell you that as I've traveled the world on behalf of the United Nations in the area of bones and joints, those institutions for which we're more heavily funded, more well-endowed, have the higher technology. Those that were not – had lower technology, lower access and they were doing it the good old tried and true ways, as surgeons have been taught. So, we still have that disconnect in the look of digital assistance and the whole AR/VR perspective, and I think that from a federal standpoint, how to balance out the development to help more people is, to me, an important key for the FDA to see, as well as quality control and patient engagement from the very beginning.

So, I see this as a patient wanting to know, just as what's been iterated before, but in addition to how is it being used on me? Will it feel it? Will I not? Or is this your educational tool. And how does it show difference in me versus anybody else? So, is it

my body picture taken and virtualized in a way that the surgeon can more adeptly see what's going on and what needs to be done? So, there's a lot of questions related to that. Privacy of that information, areas of how do I address this with my family, how do I explain this to other physicians that when I come back from that hospitalization and surgery, I come back into my community and how do I explain this? So, there is a real disconnect in terms of information from I'll call it big city, high technology, well-endowed institutions and smaller towns that don't have it. And how do we justify this from a -- not justify it but how do we promote that from a national level so that the equity piece is improved. Thank you.

MR. CONWAY: Thank you very much, Amye. Philip, go right ahead.

MR. RUTHERFORD: Sure. I've got to learn to get me hand up sooner because a lot of the things have already been said are comments that were kind of throating around in my head. So yes, on the equity piece. What has -- how does this work with people that look like me. In a past life, I was a software guy so I'm kind of interested in the software development, and I believe it was Dr. Nassiri talked about this being an evolving concept, so I'm interested in how many clock hours the surgeon has with the particular technology and what is the -- I'm interested in the changes that have happened to the software over a period of time because as the technology changes, the software changes. And what does that look like, what is the training regimen associated with that, and who is doing the oversight and kind of what are the checks and balances associated with that, and I think there probably needs to be some regulation around that. And I don't think there is -- I don't know that there is a clearly defined path of that. Maybe there already is and I'm just unaware of it. But I feel like this is sort of new

ground for regulatory practice as it pertains to software lifecycle management, and I'm -- if there is -- if this is already figured out, somebody please just tell me to be quiet, but I don't know if that's -- if that's all been mapped out yet.

MR. CONWAY: Okay. Excellent observation. Thank you very much. Let me go to Suzie right now. Suzie Schrandt.

MS. SCHRANDT: Great. Thank you so much. So, I think in terms of information that needs to go to the patient what I know I would care about is their ability to override whatever the tool, the technology is that you're using. That balance between the clinical skill and the experience of the surgeon and whatever the technology is telling you, and I would maybe amplify this in situations where the patients are conscious. If the patient is awake during a procedure and reporting that something feels wrong, then I want that to be the guiding force and not whatever the technology says.

In terms of training and like Amye, I've also had many joint replacements and surgeries, and I've actually experienced a pretty serious medical error related to one of my surgeries, so I immediately go to patient safety, and I think about patient safety leaders like (indiscernible) and others who talk about surgery is a team sport, and it's very dangerous to have hierarchy in a surgical suite. You need everyone from the head surgeon down to sort of the least credentialed I guess is the most diplomatic way to say, anyone who's in that room needs to be an active part of the team, and they need to be equally powered.

And so, when we think about training, I think it's critical that it's not just the surgeon that we're talking about. If only the surgeon is the person trained to use the device or the AR, what does that do to the hierarchy of that entire surgical team? Isn't it

important to train the entire team so everyone feels again sort of equally powered? Because I think you run the risk of almost creating a digital divide right in the OR so I just want to make sure everyone is having access equally to training, to use, because it really -- we can't -- we don't want to further widen the hierarchy that can already happen in a surgical suite, so thank you.

MR. CONWAY: Thanks, Dr. Liran?

DR. LIRAN: Yeah, thanks. As a patient I would be naturally skeptical of the technology. I would want to know is this a cool gimmick or is this actually helpful, and what is the data behind it? What is the FDA's position on it, which is what's important that we make the right one. And if the surgeon relies on it, what backup plan is available if the device fails? We all know technology fails at the worst of times, so we have to make sure that there's some kind of a backup plan. And finally, I want to know how much experience this specific surgeon has with the technology because this new technology requires training, and I would want to know if this is surgery 1,000 or the first one for this specific surgeon. Thank you.

MR. CONWAY: Great. Thank you very much. Heather Adams.

DR. ADAMS: Thank you. Yeah, I think a lot of my questions have already been raised. I had to do with different topics within the realms of safety and efficacy of this approach. You know of course, I would be curious as a patient why my surgeon was using this device, and not just how it would aid in the surgery but what aspects of the surgery it would be used for, and what would be different about the surgery using the augmented reality device or equipment versus without, whether it's in terms of the time or the cost or the outcomes, what's the comparative safety profile for using AR versus

not and what's the comparative effectiveness for this type of surgery using AR versus not. And what's the surgeons and the surgical team's success rate and complication rate using these supplemental or augmented reality devices versus not. So, along the lines of the questions that have been raised already, I think.

MR. CONWAY: Okay. Thank you very much. Grace?

DR. LEVY-CLARKE: I would like to reiterate what some of the other panelists have said. I would think that as a patient I would want to know if the hospital has an outlined protocol for software and for the hardware, for failure analysis and effectiveness. I would want to know if this is a hospital-based protocol, or if this is a protocol that is universal, so a national white paper by – that people who have used this technology.

And on the second point I would want to know if there's a standardized certification either through the manufacturers or if, as a group you know like the AMA, the medical association, or the specialty board, if there's any certification that's needed.

And during the transition we know that when a new technology comes on, there's still going to be a need for the surgeon to understand how to go back to earlier forms of this surgery. So, I would want to know if my surgeon has been trained not just in this technology, but if they're able to go on and do, do the surgery if there's a failure in the AR/VR. Thank you.

MR. CONWAY: Great. Thank you very much. Dr. Gallagher?

DR. GALLAGHER: So, I think I'm approaching this a little differently just starting off with what is the informed consent process in the first place? So, I think the surgeon would have to be able to explain the surgery in such a way to say this is what I'm going to do, this is how I'm going to do it. And if there's a possibility of using or showing the

patient what the augmented reality objects are going to do, that would be great. I think that there is also the question of does the patient get to choose whether or not that digital information is used or not, is a piece of it. And I also have a thing about – I think the surgeon should be able to describe their own education and the education of their team. Similar to what Ms. Schrandt said, you know we have the situation where you know a surgeon isn't the only one in the room. And even if they are the one trained in using the device, how they do what they do affects how what everybody else does. So, if they've got, you know, a nurse next to them, a fellow next to them, whatever they -- whoever is next to them has to know how their job changes based on what's happening and what equipment is being used.

The other thing is you know training people to do something is very important but it's also important to know that the person can do the surgery with or without that additional equipment because I think we have a problem if we say okay, you know we're going to train all these people to do this and but all the people coming up might not be able to learn how to do it without it. So, we have to make sure that the training goes in both directions, in how to use these things as well as what to do when you can't use them. And I think the surgeon should be prepared to answer questions in the informed consent process about whether or not the equipment is self-contained and powered compared to are we using Wi-Fi through general Wi-Fi of the institution or does it have its own little network. Those kinds of things I think become important as well. I can go through more specifics, but I think you get the general idea

MR. CONWAY: Thank you very much. Bennet?

MR. DUNLAP: So, I think it's difficult enough to schedule a treatment these days

let alone to shop for it. You know you get into a situation well I don't want the guy to use virtual reality headset, well you don't get care from that guy. And I'm not sure that VR is really any different than any of the rest of the very complex tools that are used in healthcare these days. You know the classic Monty Python bit about the machine that goes ping has to be in the operating room, emphasizing that nobody knows what any of them do. And I'm not sure that it's the surgeon's job on the team that Suzie spoke about to do this. I think the team should have an empowered healthcare communicator who can step away from the minutia that the surgeon may and should be fully aware of. Would be able to explain in real simple human terms that these are the risks you're facing, the totality of the risks, why you're having this treatment and these are the tools, not just the VR set but these are the tools that our team is going to employ to provide you care, these are the risk trade-offs. You know the reason we're doing a VR set is we get a better look at blood vessels and more accurate in our treatment. That's what was just explained to us but maybe in more detail. So, I think the team should have a good health communicator and I think it is probably incumbent on the regulatory process that they start encouraging broad communication of all the processes and all the risks as opposed to just VR and AR. Thanks. Sorry, I probably went on long.

MR. CONWAY: Thank you very much, Bennet. Philip, I see your hand is up. I don't know if you have an additional comment. Okay. Thanks, Philip. Dr. Nassiri?

DR. NASSIRI: Yeah, thank you. I just you know kind of wanted to address some of the points that were raised in terms of the dynamics within an operating arena and in terms of starting new programs from scratch, especially those that revolve around new technologies.

While a couple of things, you know I think nowadays you know we are shifting more towards a team-based approach. It really does take a village, especially when introducing new technology and you know oftentimes we partner very closely with industry to help create in-service examinations and we identify for example nursing or technical champions that are interested in a certain program and they really kind of become our you know, colleagues and partners in terms of troubleshooting a certain platform and sometimes some of them actually wind up knowing the platform much better than the surgeon who is operating in terms of whatever pertains to the patient care element. But at the same time I think it's important to make sure that that hierarchy is preserved because ultimately it is the responsibility of the surgeon who decides that this – the risk versus benefit ratio of this particular technology is in the favorite of the patient and also we are shifting more towards a more idiosyncratic and patient centered and tailored era of medicine where not one size fits all. So, you really have to have that shared decision making process with the patient and determine together whether this is the right choice to go forward or not. And if you do decide to go you know, in the era of high-volume places, high volume centers having demonstrated improved outcomes time and time again especially for more complex procedures that are being turned down elsewhere. We have plenty of data to demonstrate that by high volume surgeons and high volume centers continuously improve -- have better outcomes for these complex procedures especially patients that are seeking you know second, third, fourth opinions for recalcitrant and oftentimes more involved pathologies, it is important to make sure that we do respect that hierarchy and that there is ultimately – the ultimate expertise is within the realm of the

operating surgeon along with the team. And so that team needs to be identified. So that expertise is shared not just by the surgeon operating but the whole team that's involved in providing that care to that subgroup of patients.

MR. CONWAY: Okay. Thank you very much. Teri, go right ahead, Teri Diaz.

MS. DIAZ: Thank you. Most of my questions have already been put forth but one of the questions that I have as a patient would be, who would be monitoring that software? Who would be making sure that it's accurate, that it would be as close to the reality that is being portrayed?

MR. CONWAY: Okay. Thank you very much, Teri. Are there any other comments? Because I do have comments here by Dr. Steven Wilcox who had a conflict, but I want to make sure that these comments are included in the record.

So why don't I go ahead and provide his comments on A and B basically. On the question of regarding for patients and what would be in their interest, he would want to know, as in his comments, he said he would want to know how the system is being used? What type of system it is? And significant information about the system's track record in regard to previous procedures and ideally real data and at least assurance from the surgeon that the outcomes have been better than previous systems or iterations.

And then in regard to the second component of the question, he indicated that he would want to know the number of procedures of the same general type that the medical professional has performed, and ideally some record of his or her outcomes compared to others.

He also indicated that as an insider, he thought it was particularly important to

realize that he would be shocked if actual patients have the wherewithal to ask the right questions essentially. And he indicated that he's always been skeptical – skeptical of the accuracy of procedures. For example, tumor removal performed by using conventional imaging to define what to excise in the relevant procedures.

He indicated he has little confidence that they don't usually remove some combination of too much or too little and that AR/VR technology has the potential to really improve accuracy, but the images themselves need to be accurate. It would be terrible if the technology produced realistic images that the surgeon could perfectly follow but which did not accurately portray the relevant structure.

He went on to say that having witnessed many surgical procedures, I know that surgeons vary enormously in their skill level. It seems to correlate pretty well with the number of procedures they perform, so data on actual clinical procedures would be even better but the healthcare system appears to conspire to keep patients from acquiring this information. From their point of view the nightmare scenario would be if the bottom half of the bell curve couldn't get any work, a situation that better and more accessible outcomes of data could create.

Listening to that, I'll turn to the committee and ask are there any other opinions or views for question one that you would like to go ahead and get out here? Dr. Nassiri, I see your hand up. I don't know if that's still up or you had another point to make.

DR. NASSIRI: Yes, sir. I just want to applaud I believe Mr. Wilcox. I hope I'm not mispronouncing the name. I think it's very important for the FDA and all parties involved to really -- the point that was made is a very important one, and this is by no means a negative comment certainly on my surgical colleagues, but it is very important

to notice that you're right, not all surgeons are created equal. When we talk about some of these complex procedures naturally, we are using, for the sake of the argument here, this advanced technology for relatively challenging scenarios. The hospital administrations, especially in the private sector, perhaps a little bit less than high level academia but much more so in private entities have done a phenomenal job of identifying the surgeon, the Doctor and the provider and making the sort of advertisement of the bringing in the patient to the healthcare system. You can no longer find surgeon credentials. It is a very difficult system. If you go online and you search for Dr. So and so at such and such hospital you're going to have a very hard time distinguishing between this particular surgeon or provider, versus another one because the healthcare system – the hospital administration does not want you to know that, and they don't want to allow that particular surgeon to develop any sort of kind of face, if you will, or the ability to be able to market him or herself, market is perhaps not a good word, but for them to develop a reputation, because they fear that if that particular surgeon or doctor winds up leaving the healthcare system they may actually lose out some of those patients. So, this is one of those things that's really not talked about, but the private sector of hospital administration has done a great job of de-identifying that. So if you are a patient and you have no "in" into the healthcare system and you don't have a way of knowing who does what, there is no way for to know “Bob” from “Joe” and Joe may have tremendous experience and insight and there's no way for you as the patient to know that. So, I think it's very important for the FDA to be cognizant of that and help perhaps identify you know, champions or centers of excellence, that do this and have the healthcare system and the team who is really

involved in providing that care. So that's an excellent point that I just wanted to reiterate.

MR. CONWAY: Great. Thank you very much. Is there anyone else on the committee who has not had a chance to speak yet who would like to go ahead and make a contribution on this before I pick up some other comments and then move on summarization? Amye, I saw you waiving your hand. Go ahead.

MS. LEONG: Yeah, I would just like to follow up on Dr. Nassiri. Certainly, from a patient and patient advocate's perspective, you know we sign a confidentiality or nondisclosure and authorization that basically identifies that surgeon – one surgeon and/or his representative. And I can tell you I am that one patient advocate, hopefully not the only one, who crosses out all the other names. And because I've talked to my surgeon to make sure that he is the lead, and he is there in the surgical suite. I think what's interesting is in all my 20 some odd operations, now granted it's all orthopedics related and bone and joint related, that in no way has any healthcare professional surgeon ever said this is how I'm going to do this. It's a joint replacement surgery. There is a little bit of modification in terms of you know, that particular joint, what are some of your issues, osteoporosis, whatever it might be, but nowhere is there an avenue to seek agreement from the patient on the methodology used by that particular surgeon, whether it's AR/VR or whatever. And so, when I think about changing that whole process, to me as it results to AR and VR is how are you using the tech -- this type of high-tech technology in your work, in my case? And as that is described to me, and hopefully it is described to me, then I can let them know whether I'm for it or not for it or I ask the many other questions that many of my colleagues have raised.

But I can tell you that, as the current environment, as Dr. Nassiri has said, it's absolutely true. They're the ones who are the perceived experts. That's why we're going to them. That's why I picked that doctor versus any other doctor. But where that changes is when you're out and you have no opportunity for approval of what's next is -- and hopefully you rely on the expertise of the doctor in that case, is when after you're put out in whatever way that is, and they go into my leg, let's say as an example, and finds that additional help is needed, meaning a trauma surgeon help. So, while my surgeon is an orthopedic surgeon, he's not a trauma surgeon. So, we actually brought in someone. I did not find out about this until after surgery. And of course, I had to say why? What made your prompt to put a hold on my surgery while I was still out and go grab the resident trauma surgeon? So, he told me the situation, but it was always -- it was after the fact of course. But the end result, was still the same. Give Amye the best possible joint replacement and take out the infection you know as best we can and put her on antibiotic course. So, the environment of today is that you've hired me as -- if I'm the surgeon, you've hired me for my expertise. I will do it and I will avail myself of all the available technologies, new or old, and you're going to have to trust me. So, the interface of where we seek that information, that nod, that approval as a patient advocate, I think a lot of environment is going to have to change in order for any of us, advocates or not, are strong enough to say so you're using AR? So, what does that mean and how are you going to use it? And oh, I'm not sure about that, so bringing up a whole big can of worms that needs education. So, I think that being aware of the realities of the situation and how we can pave the way for more patient empowerment and education is very, very important. I'm not saying stick with that status quo. What

I'm saying is let's take advantage of those technologies. But to the extent that we rely on that surgeon to use the best methods possible is really key. Thank you.

MR. CONWAY: Great. Thank you very much, Amye. At this point I would like to just go back and ask Dr. Nassiri a question that I was listening for an answer for. I might have missed it. But Dr. Nassiri, from your standpoint and your professional background, on the specific part of the question in terms of assuring that surgeons are appropriately trained, what is your recommendation, not just in terms of immediate, at the front end, but ongoing?

DR. NASSIRI: So that's kind of a loaded question and I think since we're speaking very broadly there are various technologies that we're speaking of here. There are technologies that many of the folks here on this panel by virtue of being seasoned patients or being involved in the development have been involved with but there are -- there are certain technologies pertaining to what we're talking about here that are artificial intelligence based as well, meaning that in addition to training the software that's involved, training the personnel that's going to be setting it up, the technical troubleshooting team, the nursing personnel who is going to help assemble some of this and then also finally the surgeon who is going to be utilizing the technology. We should be cognizant of the fact that some of this involves ongoing improvement of the software itself by virtue of utilizing artificial intelligence, which makes itself more intelligent the more it's used.

For example, the best way I can describe it is right now we're currently using CT scans to superimpose and show branches of the aorta and superimpose that on x-ray images that are used intra-operatively. The more the softwares communicate, just like

the human brain, the more they utilize this the smarter the system gets and the more accurate it can help identify these branches and so the surgeon confidence in that software over time grows because the system becomes more efficient. And so, you know I think it would be helpful to help identify surgeon champions along the United States or even globally, and these surgeons can then go out to various centers and help educate others who will have met the credentials by virtue of having all the right team players involved, having the right collaborators involved. Like right now for example, when we do a lot of our complex cases, we do it in collaboration with colleagues in cardiac surgery. We know that those outcomes are better. So I think helping to identify pioneers in the field who have been using the technology from the get-go, and then allowing them to then go out and then credential other surgeons who want to embrace the technology, and then having for example another technology-based platform that remote surgical proctoring systems where it allows you to, under full HIPAA regulations and guide lies in respect to thereof, allows other surgeons to proctor others and to help troubleshoot and to make themselves available operatively, preoperatively or postoperatively.

MR. CONWAY: Okay, thank you very much. Are there any other comments on this? If not, I'll give one comment and then real move to summarize. I don't see any other hands raised. I'll just give a comment from my perspective on the second part of the question, in terms of the assurance on training and appropriateness. I do think that there is a role for medical schools and also for specialty boards on certifications and credentials to make certain from the patient perspective there is ongoing training in an evolving environment. And sometimes medical professionals may not like to hear that

but it's the independent certification and credential I think that's very important and also the role of the medical schools to capture evolving technologies to make certain that the next generation of medical professionals who might take just a second -- take it for granted the technology that they understand not only the technology but legitimate patient concerns as they're in that environment. So, Commander, at this point FDA in regard to question number one, I'll try to answer this in two parts in terms of what the committee generally believes on each section.

In terms of information that you would want your surgeon to share with you during the informed consent prior to surgery that would involve an AR device. There's a recognition generally by the committee that there is a dynamic and changing environment in healthcare today and that inherent in that there are different barriers. There are barriers in terms of insights and transparency into who might be working with you as a medical expert, and there are also barriers that are presented by education that is needed on what is the specific technology that is being brought to bear here, and the role in your own care. In specifics, there are numerous concerns about data in terms of what data supports AR devices, whether or not that data is reflective of patient populations so that a patient can know whether or not these devices were used on people like me. I think you've heard that several times.

There is also a strong interest for the same on the software development side of it and whether or not the software is reflected of development that was inclusive and involved people of many different backgrounds.

The other issues that have been raised are about informed consent and choice. Does a patient consumer have true choice in the process? Do they have a say as to

whether or not that device is going to be used or not? There are concerns about data and FDA's role in assessing the data or regulating the data that goes into the development of these devices. There are also very strong feelings that you have to be aware of the fact that the surgeon himself or herself – that medical expert is in an environment where they may not be simply looking at the device. They may also have some or they may not have some insight into the underlying technologies and software, but you would want to ask those questions if you were an informed patient. And that issue in particular, about being an informed patient and knowing what questions to ask I think Amye hit on that very strongly that that is probably going to be a role for advocacy organizations to inform patients on what to ask.

Other aspects that were brought up were whether or not these devices, AR devices, have been used in different situations or for different types of patients that might have conditions like me, that would be a patient question to ask, and what their background is on that. That's generally what we believe on the first part of the question.

As far as the second part of the question, this one also was reflected of a changing environment. I think we heard strongly that not all surgeons are created equal, and we also heard a shared opinion across many of the comments that systems are often put forward, but actual individual medical experts, and the skills of the doctor in particular are not, and that may not be transparent to patients. And so, you want to make certain that the surgeon is appropriately trained on AR devices and that the message you're hearing as a patient isn't simply from a medical system saying that we have the latest but that the medical professional, in particular, has been trained on the latest and the

device that would be brought to bear on you.

A lot of different questions that have been raised. Philip raised a very good point about the technical details of the software systems, how much experience is on that, what type of training goes into the machines in the development of the software training. And then the distinctions about AI systems and how dependent that surgeon is on AI. I believe Dr. Nassiri outlined this quite well in terms of the artificial intelligence evolution that's happening and these things that systems can become smarter, but the question will also always be the background not only of the surgeon but of the medical team as well.

Other questions that have been raised about the technology is how long does the clock run on it? How current is it? And in terms of training, what specific training do they have? Is it just on the device? Is it on the underlying software systems? And whether or not the surgeon themselves can speak to not just their training but the training of the overall team that's being brought into the suite for the patient.

I think generally that captures the first part and the second part of the question. The question to FDA, is this adequate for question number one?

MS. CAPANNA: This is Kathryn Capanna, FDA. Thank you, Paul, and thank you everyone. That was incredibly comprehensive, a very wide-ranging discussion. For the purposes of the committee's deliberations on the FDA's question I'm going to set aside for a moment topic on the AI speaking instead on the AR/VR components of the technology. And I'll also set aside the topic on practice of medicine or regulation oversight by other entities. I do have a follow-up question. I'm wondering if anyone on the committee could elaborate on. You all touched on you know interest in information

or data around how the technology influences surgical outcomes, and so given you know the early state of the technology and you know uncertainty or current knowledge gaps around such data you know, I would like to hear any elaboration on recommendations or advice on how to communicate, given you know, where we are in the current gaps, you know, you all talked about you know the challenges of communicating this type of uncertainty in an informative and clear way to patients so it would be very helpful to FDA to hear any further elaboration on that point.

MR. CONWAY: Great. Thank you very much, Katie. Let me go ahead and start with Bennet on that.

MR. DUNLAP: So to the question of evolving information, I think in Paul's closing comments about the importance of third party standards, boards and processes -- or review boards is really important and I think that there should be in the review process and approval process for devices, not just for specifically this device, a process of assuring that ongoing quality over time is achieving a promise of the devices used. And I think Paul's comment particularly about independence is particularly relevant. Too many particulars, I'm particularly sorry for that.

MR. CONWAY: Thank you, Bennet. Suz?

MS. SCHRANDT: Yeah, just one quick response to what Katie was just asking in terms of uncertainty, and I would just suggest that the field of diagnostic quality and diagnostic safety there's really a whole sort of enterprise around appropriately communicating medical uncertainty, and so I would flag that as a potential resource. A lot of modalities – I mean of course the patient engagement person is going to say these are all cocreated with patients. That's really the best way to build that language out

because you're really balancing truthful and honest and complete information, and the truthful, honest fact is that there is uncertainty, but we don't want to create unnecessary angst or worry so there's this natural tension. So, I'm happy to follow up in some written way with some specific references from the diagnostic quality community has been looking at this for a long time.

MR. CONWAY: Great. Thanks, Suz. Dr. Parker?

DR. PARKER: Dr. Nassiri in his comments indicated that he felt from an education standpoint that FDA should be a repository of this kind of information with respect to device use and how it works. On the same note, in as much as many of these devices are basically -- we're basically conducting on-the-job kind of like research in an IRB approved study you have a data safety monitoring board that reviews periodically the project, -- the progress if you will of the project. It seems to me that on some level when you're introducing newer devices, in this realm that there should be a similar process. And maybe the FDA is the entity that would be requesting and storing that kind of data.

MR. CONWAY: Thanks, Dr. Parker. Amye, go right ahead.

MS. LEONG: Yeah, thank you.

MR. CONWAY: You are muted, Amye.

MS. LEONG: Sorry. I was unmuted. I think in an era where new things evolve and there's a discordance between geographics, if you will, size of organizations, endowment of organizations, in terms of the degree to which and expertise in, as to how we get into the whole digital med tech universe. Having a repository is an important piece, whether it's a set-aside journal with a very specific, wide based area

where people who are developing – in the development phases can go to see what else is going on, again peer reviewed research. But almost in another format of developing and sharing ideas. Of course, there's always the propriety pieces of that, but I'm not sure that the FDA should be that repository. I think the FDA should be in support of a -- not to say the FDA is not neutral, the FDA is neutral. But certainly, an industry-led repository that encourages development, publishing, even just program development of opportunities in this area has to grow, because I still -- maybe some of you do remember the days of Beta versus VHS or yeah beta versus VHS and how the industries competed against one another. And eventually you know one ate up the other and the rest of us in the public just went, wow, what happened to my Beta -- Beta tapes and things like that. So I think that the approach is more of encouragement to the industry, if you could -- you know is there a professional organization for clinicians, for researchers, for developers, advocacy organizations with a high, high interest in this area to come together, to talk shop, to develop, to grow, to collaborate, that would be a wonderful opportunity. And I know that there are some funding foundations that would be very interested in that – neutral funding foundations would be very -- would be very interested from that. So, you know promoting that kind of effort would I think be one of the purviews of the FDA, and from this committee as well. Thank you.

MR. CONWAY: Great. Thank you very much, Amye. Dr. Gallagher?

DR. GALLAGHER: Thank you. I think I want to say we can take some lessons from the idea of robotic surgery and how it came into fashion and learn from some of that information so that we know that you know, the robotics get much better as they proceed. We know people's skills get better. Those kinds of things are important. But

we also know that it's not available everywhere. And so, I think as we look at how well it does you know that's great. But the big piece of that, I think in terms of how we inform patients as well as build skill, is to be able to explain to patients that the surgeon is still in control of what they're doing. You know they're using this equipment. We use lots of high-tech equipment all the time, so you know we have to help build up the confidence in the people who are utilizing the technology. So, I think that's important.

But I think we do have to keep -- have some place, similar to some of the other things that FDA has that says you know, here's some patient related outcome kind of information about how this all works, whether they're happy with it, not happy with it, those kinds of things. I think the other piece is in terms of how do we develop those kinds of things can really be industry driven, because industry while it wants to compete, they all want to succeed until they want to buy each other out. So, I think it's important to encourage you know, the industry -- the industries because it's all not one industry, I think there are multiple parts to this, that they work together as much as they can and I'm sure that medical journals and healthcare journals of different types pick up all kinds of articles on those subjects.

MR. CONWAY: Great. Thank you very much, Colleen. Philip, go right ahead.

MR. RUTHERFORD: Yeah, I just – as I listened to the conversation, and I'm not a clinician so I don't have anything to weigh in on that, I just want to tether us back to equity as we talk about this, just because all of these things are dependent on a person being in the space to receive the services. And as I think about this, I just wonder about -- I wonder about equity and I wonder about how people get to the surgeon's knife so I just want to flag that for -- for conceptually as we think about this, I want to

keep talking about equity and making sure -- so this technology is wonderful and all of the nuance of it bears discussion but I just want to -- want it on record that it's really important to me that we ensure that this technology is available. And I know other people have said that, but I said it again. That's all.

MR. CONWAY: Thank you very much, Philip. Dr. Nassiri, your comment and then, Katie I'll give the last comment and hopefully that will be responsive. Go ahead, Dr. Nassiri.

DR. NASSIRI: Yes, thank you. It's a great question. I think the FDA already has a very robust platform in place vis-a-vis the physician-sponsored applications. I believe a lot of these equipments before they're sort of made available through post approval studies and what not and prior to becoming FDA approved, go through that process in investigational device exemption. I think helping to identify centers of excellence again that are pioneering or partnering with industry along with the FDA's approval to help implement this technology and then to help identify, very carefully, the inclusion and exclusion criteria for the patient, so that's on one end.

The other thing that sort of comes in from a more patient oriented side now, for example, this panel here by virtue of being seasoned patients or being involved in healthcare is a very sophisticated panel. As to go back to what Phillip just said, not everybody has that experience. Some patients may be new to the disease process, and it may really be the wild wild west for them. And so not everyone is going to be able to go on PubMed and Google the exact terminology, the proper terminology to help identify a peer review journal, and then review a meta-analysis and then decipher, based on that, what they're going to use. And so to put on all on a 15-20-30 minute

consultation period for a surgeon to go through everything they need to go through to explain that to the patient – it's just Utopian and ideally that would be great but the fact of the matter is it won't, and the patients leave more than ever confused and very scared. Especially in the era of Dr. Google and I heard a couple of points here about the industry kind of taking -- the problem with industry is they just at the end of the day let's be honest they want to sell products so I'm just being honest. I mean the reality is that for patients to get their information from industry sponsored sources be it YouTube or other places, me personally, I don't advocate for them to do that. And so could it be a situation where the FDA -- and I don't want to put all the stuff on the FDA, but a reliable entity such as the FDA can help create – or partner with physicians to help create sites that are government approved and are peer reviewed and are reliable, Including folks, such as the people that are on this panel, who are kind of involved in that process, and to help identify online sources for patients that are in layman's terms that everybody can understand, in various languages, and give them access to this information and then help point out hey these are ae the questions you may want to ask your surgeon.

I think one specialty that's done a good job of this is you know the American Board of Plastic Surgery by virtue of being so many cosmetic surgeons out there, there are folks that put these sort of -- these are the things you want to make sure that your surgeon has. I think we could learn from them, frankly. But I do think it needs to be a reliable source, it needs to be a government approved entity and it needs to be simple enough so that everybody can understand, and I think that would be a wonderful collaborative venture with everybody.

MR. CONWAY: Great. Thank you very much, Doctor. And I'll give you a brief

comment too, Katie. I believe that at least from the standpoint in the kidney population, the heart population, there are two things that you're hearing here, and especially from Dr. Nassiri and from Philip. So, you have warehouses or sources of highly credible information on emerging technologies and those are important. And I think there will always be multiple ones and the assignment of credibility will vary depending on the patient and education and background and their access.

But I think as much as we focus on where are credible sources of information that are transparent and accessible, the other thing has to be -- that has to be focused on here is what is the means of dissemination? And going to the point that Philip raised about whether or not that person has access to it, they may first learn from it from another person, or from someone else who shares that illness or from a patient advocacy organization. So I would say in terms of directing the routes, the role of advocacy organizations, as trusted sources of information, of people who have suffered in the same way, should not be discounted in as much as we focus on where things are warehoused we should focus on the means of communicating and elevate the role of organizations that know communities quite well, are trusted brands within communities and that would probably be one of the highest ways of getting dissemination on new technologies so hopefully that has been responsive to you.

MS. CAPANNA: Yes, it is very. Thank you very much.

MR. CONWAY: Now I'll go ahead and move on to question number two.

CMDR OLELE: This is Commander Chinyelum Olele for FDA. VR devices may be prescribed by doctors for patients to use at home for diagnostic and treatment purposes. These devices may have different benefits such as helping to reduce pain and

anxiety and involve a risk of side effects like nausea and dizziness. These devices are generally meant to be used for specific time periods, as part of a care plan and to reduce the risk of experiencing side effects. There may also be additional information that is critical to the use of the device, including information about internet requirements, physical environment, et cetera. What information should be available to the patient or caregiver prior to use, for example, in an onboarding tutorial through the device itself, in addition to device labeling to help patients and caregivers safely and effectively use these devices at home?

MR. CONWAY: Great. Thank you so much, Commander. So, in the interest of time, we have about 20 to 25 minutes to answer this. And I'll go ahead and ask for folks to start putting your hands up. And again, I'm trying to make certain that everybody's included in this, so I will get to you. I'll see – so who would like to go ahead and start. Suz, why don't you go ahead? You're muted.

MS. SCHRANDT: I just have a -- there we go, sorry. I just think we can actually leverage some of what we just learned through the rapid upscale of telehealth during the pandemic. And I know one of the things we heard working with patients a lot was that there's a real chicken on the egg problem when we try to provide training related to technology. So, for example, you can't teach someone how to access a patient portal by giving them a video that they have to access in their patient portal. So, you have to start with where they are. And so, I think you need non-tech training. So, whether that you know hard copy, whether it's sitting in an office with someone, there has to be something non-tech to help train tech, especially for people who are just not tech savvy like me. So just that chicken or the egg I think is an important thing to keep in mind.

MR. CONWAY: Great, thank you very much, Suz. Dr. Parker?

DR. PARKER: To piggy-back on what Suz said I think it's having access to technical support much like we have access to technical support for using our different devices in our home like our computer or internet, that kind of thing, immediate access of viable technical support, an adviser or person who or people who can walk people through something.

MR. CONWAY: Thank you very much, Teri?

MS. DIAZ: I like the visual aspect of watching a video beforehand to, you know -- for visual learners. And I also would advise that there would be like a patient checklist over the adverse events that could happen to the actual patient, like the dizziness and things so that they are completely aware of what they are using.

MR. CONWAY: Great. Thank you very much, Omer?

DR. LIRAN: Yeah, I would add to that the patient should stop using if they experience side effects such as headache, nausea, neck pain or fatigue and to reach out to their doctor to discuss the side effects should it happen. Also, to limit time of use of the device, so they're not using the device for an extensive amount of time where those side effects may become more profound. Thank you.

MR. CONWAY: Great. Thank you very much. Philip?

MR. RUTHERFORD: So yes, to what has been said. And I wonder if we could go the next step and include some sort of -- some sort of diagnostic in the device to ensure that the device is being used properly. So, on the flip side, we do whatever training is appropriate, obviously needs to be culturally competent, but on the flip side, some sort of query to the device that says, hey is this device being used within whatever tolerance

the manufacturer has described.

MR. CONWAY: Great. Thank you very much. Great point. Amye? You're muted, Amye.

MS. LEONG: Thank you. I kind of want to go back before I state my comments, to yesterday, and ask for a point of clarification. I understood yesterday that the VR and AR technology was or could be contained inside the headset and that it's two to 3 pounds or whatever and there's issues with that. What I then heard, I think it was Emmy, one of our patient presenters, was that the opportunity for misuse, and that there was a difference between – you can use the headset for your entertainment but that the medical software is something that is added to that, or you would buy the whole thing. And I'm not really sure. So, my question has to do with if we're talking about medical VR and AR, to me there's an assumption that the software goes with the hardware and I am hearing different things from yesterday, that they could be perceived differently. People can go out and buy the headset now and do all kinds of games and climbing or whatever they do. Is the software on a medical software side is something that is then just bought, encouraged, taught by the medical professional for this patient to use, and is that just a software piece that goes with the headset? So could someone clarify that and then I'll go into what I'm going to say.

MR. CONWAY: Great. Thank you, Amye. Brendan O'Leary from FDA can give you a clarification. Go ahead, Brendan.

MS. LEONG: Thank you.

MR. O'LEARY: Thank you for the question. This is Brendan O'Leary for FDA. Augmented and virtual reality devices are typically what FDA refers to as multiple

function device products, meaning in this case they are products include both medical device functions regulated by FDA as well as other functions that do not meet the definition of a medical device in our statute and are not regulated by FDA, particularly when these medical functions are intended to be deployed on consumer products or headsets that include other uses like entertainment.

And so, in the case of augmented and virtual reality products, it's typically the case that on the one hand you have a headset or a platform that is not a medical device. And on the other hand, you have a device function deployed on that platform for a medical purpose. FDA has a multiple function device products policy that ensures that FDA can obtain the information needed to assure the safety and effectiveness of that device function in the context of its use, meaning as deployed on a consumer product such as an AR/VR headset, for example. Typically, this is accomplished by assessing the impact that other functions of the platform have on the safety and effectiveness of the medical device function under review. Through these impact assessments and other information about the device function under review, FDA can then ensure that the medical device meets our standards for safety and effectiveness.

MS. LEONG: Okay. Thank you very much, very insightful, and informative. I think that when we talk about overuse that's where the bridge goes between entertainment and our headset versus the medical side of this. And while approval is toward the medical side of this as it relates to FDA and not on the entertainment side, how do we keep that separate? So, the questions I have on the tutorial is you know when it is a medical software program to be added objective your entertainment headset and what are those differences, what are those concerns that the developer should have in terms

of overuse, underuse, and whatnot. So, I think that tutorial has to be very specific to usage on the medical side and be totally separate from any kind of entertainment functional use. It has to be done in lay language, nontechnical, as has been said by other colleagues. The device labeling has to be very clear. Troubleshooting has to be -- and I encountered it myself, I have a new method of infusion, it's a ball, pressurized and it gets connected to my PIC line and I sit there for an hour and a half and let it slowly go in me, which is completely different than putting on gloves and doing all the of the things about sterility and then using needles to get in. So, it's evolving and I'm as a patient so happy not to be dealing with needles. But so, you know there's multiple functions of different kinds of things, and the technology is really – the opportunity is there.

The patient checklist, absolutely. And that's got to be as easy to read as possible. And also, there should be in my view a pre and post evaluation. I don't want to call it a test. An evaluation by the patient. A patient-reported outcome. Tracking the number of days you use it, if it's not tracked already in the VR or AR, and how – was it easy for them, did they have difficulties, usage and usability issues would be clearly, hopefully articulated so doing some sort of patient PRO in this area for them – for the patients and their families to take a look at I think is an important added piece. Thank you.

MR. CONWAY: Great. Thank you very much. Heather and Colleen, I'll get to you. Thank you for your patience, Heather.

DR. ADAMS: Sorry. Were you calling on me or on Colleen?

MR. CONWAY: Yes, Heather.

DR. ADAMS: Okay. Thank you. Thank you so much. Yeah, you know I think many

of the other panelists have articulated a lot of the thoughts and the questions that I had. I think that some of the other questions I had were related to troubleshooting, so if I do run into a problem, you know who do I call? My doctor may not have the tech knowledge to be able to work me through a problem so having that information. Just thinking about the gadgets and devices that we use now medically every day, usually there's a help line you can call, and that would obviously need to be tied in with health related you know understanding of why you're using the device.

I think the other, the other thought I had, the other question I might have would be linked to the prior discussion about where a repository for information about devices or AR systems gets hosted so that information could be fed in and tracked over time. And just as with you know, our everyday devices like this, if you have a problem the app will say do you want this trouble information to be sent to the company so they can track it in the database. I wonder about having something like that for the AR/VR devices where if you do have an issue that it's not just you calling your doctor and then the doctor has to do some voluntary reporting but there's some place where information gets collected across a number of different patients, to understand whether there are any patterns that are arising that are concerning.

MR. CONWAY: Great. Thank you very much, Heather. Grace?

DR. LEVY-CLARKE: So, I would agree with what Amye said. When I reviewed this question I thought that what would be nice is if we have a PRO, but instead of the patient we could have the caregiver, the parent, especially if we're dealing with children, or with patients with cognitive disability, have the patient, have that person be able to evaluate the device and fill out the PRO on a continual basis, and that

information could be utilized, similar to like a post-marketing type of tracking.

MR. CONWAY: Great. Thank you very much. And Colleen go right ahead. Thank you for your patience.

DR. LEVY-CLARKE: Great, so I'm thinking about a home use kind of thing and I'm thinking about whether it's an over-the-counter thing or something prescribed and I also have to think about how people learn. So, we know we have auditory learners, visual learners, people who need to read something to understand it and people who might have to experience it to understand it best. So I think that whatever we can do to make sure that all of those are addressed somehow is important, but especially if something is prescribed and has those side effect issues that we are aware of or other ill-effects that something may happen, if it's a prescribed item I would hope the office of the prescriber would have the equipment or whatever available to actually teach someone how to use it on site.

And if not, at least have some other methods such as videos available, some auditory things. So I'm thinking about people -- since VR equipment tries to -- primarily uses the eyes to change the environment, can sometimes -- you have to consider what are we trying to change so we may have people who don't hear well, so we have to kind of look at you know make sure we have written things for them, so you know we have to just look at different types of education and make those available as part of it. But again, for the prescribed things that have more ill-effects that we are aware of there should be a place and time for the person to actually learn and walk through and have an experience before they use it as home if at all possible.

MR. CONWAY: Great. Thank you very much. And before I move to put in

Dr. Wilcox's comments, I wanted to ask Dr. Parker, you've got your hand up. I didn't know if you that had been left up or if you had another comment, Dr. Parker. She may have left that up.

DR. PARKER : No. I didn't take it down, sorry.

MR. CONWAY: No problem. Okay. Thanks, Dr. Parker. In regard to this question, Dr. Wilcox had added a comment that we find in our work, although admittedly we haven't collected real data on the subject that well done step-by-step videos are superior to conventional IFUs in teaching people how to use devices. Ideally the healthcare professional would walk the patient through such a video and test them in some way to show that they know what to do. I would like to see the physician tell the patient what side effects to look for and what to do if they occur. Perhaps a checklist style document that they would keep with the device. Regular check-ins with patients would also help but maybe most importantly I would like to see the device transmit to the clinicians whatever data are important, i.e., time of use, duration of use, et cetera. So, I wanted to make sure that comment got in there on the record. And then at this point FDA, I would like to go ahead and summarize with generally what the committee believes for question number two, unless there's any other comment here that I missed. I think I got everybody. Okay.

So, in general, in answering question number two, the committee has kind of approached this with insights on the means of a tutorial and the content, also with some key points added to it. So, in terms of the means of communication, I think the point has been made that based on the lessons of tele-health there are multiple ways that people learn. They learn virtually, through video, but it's also important to have

non-technologically based educational components, print components and other things that are available to patients and caregivers.

One of the key factors that was raised is the access to troubleshooting and technical support. Preferably a person that you actually talk to, not something that you're simply interfacing with, another piece of technology, and that it be available in real time for the patient.

One of the other things that was raised, was a key distinction when we start to get into the education of tutorials and the content, and this was a point that Amye brought up and others kind of echoed which is the distinction that FDA was able to clarify on whether or not the device itself and what it's being used for is clearly articulated or whether or not there's any potential for confusion on a medical device usage versus an entertainment device, and devices that are for multiple functions.

In terms of the content of education, this was also very important, that there is again, the need for very clear patient information in terms of adverse events, especially if this is a prescribed technology, that some of those things within that would not simply be adverse events but stop use criteria, if it's being used too much and information on the time of use. And also, in terms of cultural competence, I think Philip brought up a very good point here, which is, is there an ability for the device to query whether it's being used correctly or not. I think I'm characterizing that, Philip, correctly the back and forth with the device with perhaps the manufacturer or some type of oversight.

One of the other things that was raised here as a key point is the ideal or the goal perhaps of having a patient reported outcome, and that be enabled through the device or somehow be able to be captured. Not simply in a static way but also in an ongoing

way, and that that be available for caregivers as well as patients, especially those who are taking care of adolescents or those who may be cognitively impaired.

In general, that's where the committee came down and I would ask FDA is this adequate or if FDA has follow-up?

MR. O'LEARY: Paul, this is Brendan O'Leary for FDA. I'll just one follow-up question. There's been some helpful discussion about patient-reported outcomes and monitoring, and I'm interested in any additional thoughts folks have on the timing or frequency of that kind of information.

MR. CONWAY: So, in response to Brendan, let's go for show of hands, and we'll go ahead and start with Heather.

DR. ADAMS: Thanks. You know I think that's real (audio cutting out).

MR. CONWAY: You just got muted, Heather.

DR. ADAMS: Sorry. Sorry about that. I imagine that it's going to depend on the indication, the reason that the device is being used, and the target symptoms, what's being treated. You know there may be a particular timeline that needs to evolve before you see effect, and so I think that it might depend from condition to condition and from you know approach to approach in terms of how the system is being used for the patient.

I would say certainly you would want to have a baseline assessment before you initiate therapy but then the follow-up, frequency and the time span between each follow-up would probably vary as with the type of PR that's being collected. I'm not sure that it can be prescriptive for like one size fits all, but maybe other folks have thoughts on that

MR. CONWAY: Thank you, Heather. Grace?

DR. LEVY-CLARKE: I think for the devices that are going to be used by minors or patients with cognitive disability, I think it would be really instructive to have those done during the testing period or prior to registration of the device because I think then you would know for sure if the device -- if the users would be able to adequately report adverse events, because if the devices are going to be used by minors, or someone who's cognitively impaired, then it's important that whoever the caregiver is understands the device themself so that they're able to adequately report adverse events.

MR. CONWAY: Great. Thank you very much. Diane? Diane Johnson, thanks.

MS. JOHNSON: So as part of the process of validating medical devices, and in particular software type driven devices and devices with interfaces, we conduct human factor studies. And the human factor studies have to be performed on an appropriate population, so be that the caregiver or the user. So those sorts of studies would be conducted as part of the generation of data that an industry member would report to FDA.

MR. CONWAY: Great. Thanks, Diane. Suz?

MS. SCHRANDT: Yeah. I think one of the keys is that the questions that are asked really need to be co-created with the end user because typically what happens in PROs that aren't co-created is that patients can only respond to the questions they're asked, and so we may ask about dizziness but a patient may be, I don't know, seeing spots. And if we're not asking, “Did you see spots.” or “Did you have this specific visual disturbance” we're not going to get that data so it's just really important that whatever

vehicle we're using, however we're asking the questions, the questions themselves are informed during early pilot testing with -- in partnership with patients who have used and tested the part -- whatever the intervention is.

MR. CONWAY: Great, thanks, Suz. I'll go to Omer and then I'll make a last comment, Brendan. Go right ahead.

DR. LIRAN: Okay. Regarding the patient reporting the outcomes, the frequencies, so when validating software there are usually end points when the software is expected to work. I would base the outcome, duration, and frequency on whatever that software validation is and that's going to vary from software to software, from device to device. And regarding adverse events, I think there should be reported at any time as they occur. There should be some sort of a portal to make that easy, just like there are mitigation – ways to report mitigation, adverse events in real time. Same thing should be done with these devices. Thank you.

MR. CONWAY: Great. Thank you. And just, Brendan, a quick comment. In terms of patient reported outcome data, the point that I would make is the construction of the question, as Suz mentioned here, is very important, because the question that we often ask is are you trying to get to a qualitative analysis or a quantitative analysis. And so my thought on this would be that for a PRO it is something that is asked not simply just during treatment but post treatment, going to the specific issue of how do I feel, because often that's the one obvious question that doesn't get asked in new technologies, did it make a qualitative difference for the person and what they manage.

And then for the caregiver, for the overall care, and the comprehensive care they have to give in a patient, in a family or to a loved one, did it make a difference. So that

was just one point I wanted to add. And at this point I would ask, Brendan, has this been responsive to your question?

MR. O'LEARY: Thank you, Paul, for the comment and the summary. This is Brendan O'Leary for FDA. And thanks to the committee for the helpful discussion. Yes, this has been responsive.

MR. CONWAY: Great. At this time, we'll now take a 30-minute lunch break. Committee members, please do not discuss the meeting topic during the break, amongst yourselves, or with any virtual member of the audience. The meeting will reconvene at 12:32. At that time we will continue with committee discussions of FDA's questions. Thank you very much.

[Lunch break]

MR. CONWAY: It's now 12:32 p.m. and I would like to resume this committee meeting.

At this time let us continue our discussion on questions from the FDA. I would like to ask again that each Committee member to identify themselves, each time he, she, or they speak, to facilitate the transcription. I would also like to remind members of the Committee that this meeting is classified as a Particular Matter of General Applicability because the issue to be discussed by the committee is a particular matter that is focused on the interests of a discrete and identifiable class of products but does not involve specific parties or products. I would like to remind public observers at this meeting that while this meeting is open for public observation, public attendees may not participate except at the specific request of the Committee chair. At this time, I would like to ask FDA to Read the questions. Commander, go right ahead.

CMDR OLELE: Commander Chinyelum Olele FDA. Question three, AR/VR medical devices may improve the diagnosis and treatment of various medical conditions in children and in people living with cognitive and mental health conditions. To safely and effectively use AR/VR technology, the user should be familiar with how to use the technology and have the appropriate strength, motor, mental, and sensory capabilities. In the pediatric population AR/VR devices may have unknown and unanticipated long-term effects on mental health and neurological development.

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 use headsets that are consumer products that are generally marketed for people over the age of 13. During FDA review of the AR/VR medical device, FDA may assess the impact of the consumer product hardware on the safety and effectiveness of the medical device. 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? Example, equipment sizing, usability.

MR. CONWAY: Great. So, as we go into answering question three, I'll remind folks that we have a total of six questions over the course of the day that we're answering. We have four this afternoon. We're due to conclude around 2:00 or so. And some of those questions have subcomponents. So, I'll be looking for your answers and insights on this. We'll go ahead and start with Philip, and I'll make certain that I hit everybody. Go right ahead, Philip.

MR. RUTHERFORD: It's a little bit outside of my realm but I'm curious about the neurological impacts. Like I assume there has to be quite a bit of neurological testing for

products that are targeted for adults but if we're using something for children in a product that is targeted for adults, I would feel like that would need to be tested on children first. That's all.

MR. CONWAY: Great. Thank you very much, Philip. Heather, go right ahead.

DR. ADAMS: Thank you. This is Heather Adams. I agree with Mr. Rutherford's comments about making sure that there's safety testing for children with -- in the context of the developing brain and continued brain growth and development, until probably young adult years or beyond.

I think that the questions that I would raise would have to do with – for the hardware particularly, making sure obviously that it is not just comfortable but safe for children to use. Also, that there are child safety locks or restrictions on the use, and some ways to manage or limit use by other children so that the device is only used for the child for whom it's intended.

MR. CONWAY: Great. Thank you very much. Omer?

DR. LIRAN: For the FDA should consider devices that have been validated for the specific population that they're looking at, in regard to those devices marketed for age 13 and up, usually the limitation is the interpolar distance that the lenses can get to. In those cases, I would recommend looking at the effects that have an inappropriate IPD may have on children and other adults whose head size may differ from average. I think that the FDA should consider each device on its own and look at the sizing, look at the comfort level, and the interpolar distance. Thank you.

MR. CONWAY: Great. Thank you very much. Any other comments on this? Suz or Bennet?

MR. DUNLAP: Suz can go first.

MS. SCHRANDT: It's out of my area of expertise but something that might be relevant, just having been a pediatric patient and doing a lot of work with pediatric onset illness, so it's really, really hard for kiddos who grew up with a condition to know what's normal and what's not. We really lose our baseline. And so I think that would probably be relevant in evaluating how a modality was being used for treatment, so just kind of being able to somehow establish baseline, what's normal, what's not normal, just kind of -- I would just flag that it's that particularly hard when it's a pediatric population who either have congenital or pediatric onset illness, it's just very hard to distinguish or know, even recognize what's normal and what's not normal and what you should be actively reporting versus what's a sort of normal expectation of the use of technology, so I don't know if that's helpful but that's what's top of mind.

MR. CONWAY: Thank you very much. Grace?

DR. LEVY-CLARKE: I think creating a repository from previously registered devices would be helpful to track some of the adverse events because I know we have devices that have been approved in the ophthalmology space where they're using commercial headsets with a software for amblyopia so I think tracking some of the adverse events from these usages would be instructive. As to how we could approach other types of devices that have more invasive technology, so the devices -- the device I'm referencing is one that's mainly a digital device, so it's using a headset just with a software. It does not have any AR or VR capabilities, but I think just tracking some of the adverse events from these types of devices would be instructive as how we should move forward using these devices.

MR. CONWAY: Okay. Thank you very much, Grace. Amye?

MS. LEONG: Yeah, to add onto what my colleagues have said, I do believe that there is a distinction we're trying to make between a medical software, whether it comes with a headset or not, versus the entertainment side of the headset which is probably all too well -- all well known by the younger generation, if you will. But I think that we have to focus on what we can control in the sense of a medical device, medical software. And I think that's where the usage comes in. How to segregate that if you will, I can use that word, separate that from entertainment use, does the entertainment use track you, how long you're on it, how many times you're on it, how many times during the week or times in the day you're on it, and that would be separate, and that information, as my colleague has just said, would be useful information in the development phase of a medical software and the appropriate headset to go with that.

But in an under age 13 population, to me some of the suggestions that have been done by some of the speakers from yesterday was that there was a screen, that the parents or caregiver could see that is simultaneous to what the patient is seeing in that instrument. I think that kind of activity is useful, helpful, if there is a caregiver, hopefully an adult, parent, interested in the usage, and particularly if it's a medical protocol for that child or young adult to use, it's very important. But separating it out so that the child knows that play is one thing on the headset, and the medical device or whatever it might be, has its own goal and it might be a plateful way of getting to that goal in the software but that is separate and it's going to be tracked, and hopefully viewed simultaneously, in real time, by the parent. So, I think that that separation is really important, but we could learn from that experience in the entertainment field or

entertainment software side but it's at the same token making sure that, especially in the vulnerable populations, it's not just pedes, but the seniors as well that they are actually doing it. So, we talked earlier about pre and posttest and PROs and that kind of thing. I think it absolutely applies to children under the age of 13 as well with their caregivers. Thank you.

MR. CONWAY: Okay. Thank you very much. Philip, I'm going to come to you, and then Bennet, I'll come back over to you. Go right ahead, Philip.

MR. RUTHERFORD: Yeah. Just something that – and I think when Amye said this it got my attention. The distinction between medical and entertainment – I'm thinking about Facebook or Meta or whoever they are most recently, some of the information that came out about their treatment or their understanding of the adolescent mind and the use of some of their products targeted specifically at those. I do have some concerns, and I don't know if it's FDA's purview on the stuff. I recognize these are consumer products. But I think it's at least worth noting that we should be paying attention to what is happening with these products for -- certainly for children under 13, if they have access to it. And like I said it may not be FDA's role to regulate that, but somebody should be looking at that because we have firsthand evidence that private sector organizations are not necessarily concerned with the safety and well-being of children as it pertains to this. That is all.

MR. CONWAY: Great. Thank you very much, Philip. Bennet?

MR. DUNLAP: Just adding slightly to what he just said. I think that consumer devices, and using that as an example, those companies are excruciatingly good at long tail tracking, and how that tracking enter -- works with software that is a medical device

or software that's part of a medical device has to be really clearly understood, particularly with kids.

MR. CONWAY: Okay. Thank you very much. Heather, I see your hand up and I don't know if -- go right ahead.

DR. ADAMS: Yeah. Thank you. I had just realized that we began on a theme of representation which has been raised before with other questions that when we think about the hardware for these devices for young children, for those with rare diseases, even older children as well for those with rare diseases, they may have differences in, for example, their interpolar difference that is not the standard for their age group compared to typically developing children, there may be other aspects of patient morphology or cranial morphology that are relevant or other aspects of their body that are relevant for fitting devices for these individuals.

MR. CONWAY: Thank you very much. Colleen?

DR. GALLAGHER: Yeah, I'm just thinking about the weight of headsets and where that weight is placed so one thing to pay attention to is whether or not it's a headset that really fits over the eyes and is just attached to the back of the held compared to something that rests on top of the head and if the weight requirements might be different for those. I'm thinking not just age but also of weakness and is it something that needs to be used while the person is sitting up or lying down or walking around, because I think that makes a difference as to the length of time that they'll be able to use the device.

MR. CONWAY: Okay. Great. Thank you. Any other comments before I read those from -- that we have – that were submitted to us by Dr. Wilcox? I'll go ahead and give

you his comments.

In regard to question three, Dr. Wilcox said that he questioned whether or not the use of 13 plus, 13 years plus consumer devices should be allowed for clinical use by children in the first place. He indicated that he would like to see the arrow, so to speak go in the other direction. Why couldn't medical device companies develop platforms that could accommodate multiple clinical uses as well as consumer entertainment. That should be easier to regulate. In terms of the factors to consider, wouldn't be the same -- wouldn't they be the same as anything else, safety and effectiveness. If consumer devices are to be used, then actual used consumer devices found in people's homes should be used in the usability testing and clinical trials. And I think his point kind of dovetails into some of the things that Amye has raised a few times here, and also Phil. Any other comments that folks would like to make? And if not, I'll go ahead and move to summarize for FDA.

FDA, in regard to question number three, the committee generally feels as though there are multiple issues that ought to be considered here, not simply in terms of the specifics of hardware but also some of the underlying issues in terms of the data use of the software and that type of thing. So, in terms of listing the factors, there are specific physical factors and physical requirements regarding the weight of devices, the manner in which somebody would wear the device, how that impacts them. There are also issues of great significance that the committee feels strongly about regarding developmental status, especially among adolescents, and that had may vary among different children and among different conditions. That there has to be a way to consider substantively adverse events, whether that's through a repository or constant

tracking.

And you've heard a common theme here across several of these questions already, which is the distinction that has to be drawn between devices, as Amye said, for play and for medicine, that it's very clear what is for entertainment and what is for medicine.

There's also a question that was raised here in a point that those products that are developed specifically for adolescents and the underlying software, Phil has made a very good point here, based on current news events of the day, that many of the companies that are in this space have particular knowledge about the development of children and what types of things children interact with and that should be taken into account, whether those are positive or negative. Those insights should be looked at and that somebody should be looking at the use of these devices among young people, whether that's FDA or not, somebody has to constantly monitor how this is being used. And the point that Bennet made which is the long-term tracking capacities of private sector companies that are involved in software and devices that are targeted towards young people, asking the questions of how that data is being used and how that data is being collected.

Some of the other things that you've heard here were in regard to safety. Again, not simply in terms of adverse events but proactive things that could be factors in the development of these devices, such as limits on use, locks and preventions, preventing those who are not prescribed the use of the device, other adolescents from using them or misusing them. And then you also heard a rather creative thought that for those who are adolescents, and those who may be cognitively impaired, is there an element to this

that could be included where the caregiver also has insight into what that experience or how that device is working for the intended consumer. At this point I'll stop and ask FDA that's adequate or if there are follow-up questions from the FDA.

MR. O'LEARY: Brendan O'Leary from FDA. Yes, thank you, that's an adequate response. I appreciate it.

MR. CONWAY: Thank you very much. So, moving on to question number four, go ahead, Commander.

CMDR OLELE: Commander Chinyelum Olele for FDA. Question four. 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?

MR. CONWAY: Thank you very much, Commander. Now we'll go ahead and roll into question four, and I'll be listening for your answers on both elements of the question, A and B. Let's go ahead and start, and we'll start with Dr. Nassiri.

DR. NASSIRI: I think as with everything else in medicine it's a balancing act in the scale – you know the risk versus benefit ratio. If it's an immanently life-threatening ailment where again, in this whole concept of shared decision making with parents and loved once, especially when we're talking about vulnerable populations such as the elderly and children, if we're dealing with an imminently life-threatening condition, that obviously tilts the scale in favor of more aggressive treatment at the expense of perhaps less clear long-term data.

If, however this is something that is more of a quality-of-life issue and there are alternatives that are a bit safer, perhaps we could pursue a more conservative route of waiting to see what the long-term data shows. So, I think that sort of revolves around the concept of shared decision making if we're focusing exclusively on vulnerable populations here including the patient, the loved ones and then the physician as well as the peripheral folks such as the industry and everything else that comes into the picture

MR. CONWAY: Okay. Thank you very much, Doc. Grace?

DR. LEVY-CLARKE: I think the very first question that I would say for Part A is I would agree with my colleague, that you need to look at the risk-benefit ratio. So, I think if we're looking at greater risk then I think you want to have more data to really support the safety and the efficacy. Also I think in terms of the length of time that we should look it we would be able to use standard of care for certain types of clinical issues, for example, as I stated before in one of the previously approved digital device,

the wear time for the patient would be similar to the other standard of care, which in that case it was a (indiscernible) for patients with amblyopia so we could use the standard of care to help guide us as to the time limits especially in vulnerable populations. Again, I think we would have to look directly at the risk versus the benefit ratio to decide if this is a treatment modality that we need more information on or we need information on more quickly.

MR. CONWAY: Great. Thank you very much. Suz?

MS. SCHRANDT: Yeah, thank you. Suz Schrandt. I think in a perfect world -- first of all I agree with everything that's been said. Really everything is a benefit risk analysis. And I think in a perfect world the duration would be in perpetuity, but that's not realistic. And so, what I immediately think of is what is already going on that the FDA can leverage? And you know we see this in post market surveillance of drugs. If you go to where patients are already gathered, patient advocacy organizations, online communities, and parents of children with special needs, might be the most vocal activated groups of people, they are already collecting and sharing data about treatments. And although this is newer technology, that could be a source that helps better inform from lived experience what's out in the real world with use of these devices. So, it's not a perfectly -- it's not directly responsive to the question but it's sort of -- it's a bonus answer.

The second piece, the answer to the second part of the question from my perspective is in terms of what to collect. This goes right back to that need for not just PRO data, because I think we think of PRO data in a very specific way. What I would say is that we need to be capturing real world data, directly from patients and families,

caregivers, whomever, about exactly how they used the device. Not only their experience. But we -- you know a great analogy right now is with COVID vaccine guidelines in people in my community who are immune compromised, there are specific guidelines around stopping immunosuppressant therapy in a period of days before and in a period of days after and so when machine is doing to do an analysis of efficacy on those vaccines, that is what they use, they use those guidelines. That is not what's happening in the real world. Patients may or may not follow those guidelines. So, the same thing goes here. If we're going to analyze and understand risks, we need to know how they're actually being used, not how they were designed to be used. And so, I think there has to be an entire stream of data dedicated to capturing real-life, real-world data from the end user.

MR. CONWAY: Great. Thank you very much. Colleen?

DR. GALLAGHER: Thank you. So I think for question, Part A, I'm thinking of the difference between an intervention that is designed to be temporary or short in duration compared to something that is used over a longer time to make a larger impact and seeing that the time frame for looking at what's happening with the effectiveness of that and any side effects or whatever could be done a little bit differently. So if it's something where the change is short duration, let's say must be is doing this if anxiety because they're going to have a test or something like that you know, that's one level of things, and you can still have a long duration study over all, but the patients themselves or participants in the study only have to be on for a short duration to be able to answer questions. So, I think it's making that determination. If something's designed to say okay, we're going to use this over the next, you know, so many months to get a change

then you can make it a longer thing and you own want to again keep the participants on for the shortest duration possible but gather a length of data so you may have to extend the study itself time wise, but the patient participation can be shortened based on what the desired intent is.

And to Part B I'm thinking about patients who use the devices and the methodologies and don't feel they're seeing a big benefit, maybe a small one, but their families or caregivers may receive a secondary benefit from their use of it because they may see things and understand things differently, so I would say to be sure to also collect information about how the quality of life changes not only for the participant but also for their family members or caregivers.

MR. CONWAY: Thank you very much. Heather?

DR. ADAMS: Thank you. This is Heather Adams. So, when I think about question 4-A, which has to do with duration of a clinical study, I think about characteristics of the patients and characteristics of their condition and then characteristics of the intervention. So, in terms of characteristics of the patient I might think about factors such as burden, and time and what's asked of them, and what's reasonable to ask of them over what period of time for duration of a clinical study.

In terms of the condition that's being treated you know I guess I would want to know what's the natural history of this condition? Is it a static condition? Is it dynamic? Does it have a waxing and waning course? Is it degenerative? You know do you have additional symptoms that evolve over time? Because I think all of those things are going to guide the duration of your clinical study just as it would for any, any study where it's an AR/VR study or a non-AR/VR study.

And I guess another thing I would be curious about would be the intervention itself. One question would be if this patient was receiving a non-AR/VR intervention for the same target, for the same condition, what would be the duration of that intervention? And how similar is that to what's being proposed for the AR/VR platform for delivery?

And then the final question I might have is, how different is the AR/VR system or treatment from the non-AR/VR approach? And if it's -- if it's very similar maybe you might expect a similar type of duration of study, if the pacing of the intervention is similar, just delivered through this other medium. But if it's something that is really qualitatively different then perhaps you might expect a different timeline and there might need to be similar preparatory work to figure out what the timeline of that clinical study should be before you might see a signal for safety and/or effectiveness depending on the focus of the study.

MR. CONWAY: Great. Thank you very much, Heather. I don't see any other hands so I'm going to take this moment to go ahead and indicate what Dr. Wilcox had left with us. And this is how he responded to question number four.

As stated, there will always be a trade-off between making something available and making sure it's safe. I would propose that whenever there is a question about safety for a device that ideally could use longer studies to mandate careful post market studies to supplement the premarket data. The factors that seem most relevant to me are severity of the condition that it treats, and two, not just the effectiveness per se, but how much of a difference it really makes in terms of saving lives or making lives less miserable. And I would think that experimental use for preference suffering from

particularly severe conditions might be warranted. With that said, Dr. Wilcox's comments, any other thoughts before I move to summarize this for FDA? Any other thoughts on question four? Okay.

Seeing none, FDA, in regard to question number four, the committee generally believes the following, and I'll address this in two sections. In terms of the balance of the public interest for long-term data and study quality, some of the key factors, and what you heard clearly was a weighing out of risk/benefit in terms of whether or not the treatment that's required is aggressive or whether or not it's something for a condition that is more of a chronic or static condition. And that some of the other things that should be kept in mind are in terms of including real world data and information in terms of not how it's supposed to be used, and how that's measured, but how it's actually being used. And I would say that's responsive on both A and B.

One of the other things that the committee discussed and viewed was the issue on whether short-term or long-term of a clinical trial really must also take into account the data collection, what side effects are, whether that's short-term or long term. And that we also heard about the characteristics of patients and of the conditions that they should also be taken into account, especially in terms of patients in regard to patient burden, and again on the side of the conditions, that factors relevant to the type of condition that it is, whether it is waxes and wanes or whether it's static.

In regard to safety and effectiveness data that would be helpful after a device is on the market – proposed market, the committee discussed issues related to the type of data and the amount of data relevant and related to the amount of risk that's posed. That in terms of tapping expertise on lived experience, that advocacy organizations and

in particular one that was raised were parents of adolescents with special needs, may be a source of expert information for what should be monitored or what should be included for patients.

Again, this issue of RWE and how devices are actually used as a source of information or point of information, it's very important.

And then the other point that was raised under this was very important one regarding primary and secondary participants. So, if the AR/VR device is designed for a patient consumer who is an adolescent or cognitively impaired, you might generate one set of data that's important to them, but there may also be a set of data that's very important to parents and caregivers that may not be tracked but may also be very important for folks to know.

I'll stop there and ask if that's generally responsive to FDA or if FDA has follow-up questions that they would like to go ahead and pose.

MS. SAHA: Thanks, Paul. This is Annie Saha on behalf of the FDA team. First of all, hopefully my audio is better now but on behalf of the FDA team, yes, that was responsive to our question.

MR. CONWAY: Great. Thank you very much. I'll ask Commander to move on to question number five.

CMDR OLELE: 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? And 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?

MR. CONWAY: Great. Thank you very much, Commander. So, on this one there are four subcomponents. And I'll ask our committee members to identify which one you're hitting, if you're trying to hit all of them. It will make it easier for note taking and summarization. So let me go ahead and ask Dr. Nassiri to go first and then we'll start moving through.

DR. NASSIRI: Thank you. I will make statements that pertain to all four. This sort of goes back to what I said earlier about the importance of creating credible, easy to get to, easily navigable, websites or a source that is approved by the FDA, that is government approved where folks can be directed to that are not necessarily just YouTube videos on how to or the IFU, industry sponsored platform, such as that, so that

patients and caregivers all can have access to that, and I think to have physician partners that can join the effort in terms of creating such a platform, it would be very helpful.

And then that second part would be, and I think that cost winds up being an issue. This is similar to patients with complex wounds where you have visiting nurse services. A patient has a wound vacuum machine, some complex wound care where the family member, even sophisticated family members may not be able to help them with. So you know, holding the insurance companies and the third-party payers responsible for some of the troubleshooting elements of this is also very important, and perhaps that could be bundled into the purchase overall price, whether that's negotiated with the industry and third party payers, and who pays for that ultimately I think is really going to help make the lives of the patients and their loved ones easier.

MR. CONWAY: Thank you very much, Doc. Teri? You're still muted, Teri.

MS. DIAZ: Yeah, sorry about that. So I basically, as a patient, I know that it's very difficult to get information on products that I've used by me thinking ahead of time to go right to the FDA website and check out to see if there's any information on that product or you know what side effects are happening with a certain medication you know to -- for me personally to follow up, so my recommendation would be to possibly have a registry so that when there are new available notices or if there's any new information that it directly gets sent to the provider or the healthcare provider so that they can share that information, or the actual patient.

MR. CONWAY: Great. Thank you very much. Philip?

MR. RUTHERFORD: Yeah, similar to what Dr. Nassiri said, involving other payers in disseminating this -- and I, by the way, I'm responding specifically to B and C, involving

other payers in the dissemination of that information, specifically in communities where internet access is a challenge in marginalized communities where medicated funds are being distributed I almost feel like the manufacturer should have a higher level of responsibility to disseminate that information.

Another thing as a lay person, I frequently see things about products and the description of side effects and risks are at the end of commercial and it's 12 things that can go wrong up to and including death. And that -- it's almost become just sort of -- I sort of stopping listening at that point so perhaps exploring other modalities or methods for communicating risk other than every single thing under the sun can happen if you use this product, but use this product, so some other strategies for that.

MR. CONWAY: Thank you very much. I think we all know what you're talking about. Omer?

DR. LIRAN: Yeah, hi, Omer Liran here. So, this is regarding those patients who may lack internet access. So, for prescription-based devices the prescriber should be able to provide information and the device itself should come with very clear simple instructions and labeling that should accompany the device when the patient takes it home.

And for software that does not come with a specific device, the software itself should provide the information. even without internet access, when you first done the headset and start the software it should give you basic information for its use, effectiveness, and safety. Thank you.

MR. CONWAY: Great. Thank you very much. Amye?

MS. LEONG: Okay, thank you. I think when it comes to information about side

effects, how should industry, or developers, or FDA or patient groups or professional groups get this out, it's going to be dependent end upon usage within that discipline. So, I'm thinking in bones and joints of usage of AR and VR for training of surgeons, training of rheumatologists, not necessarily training of patients. In -- if I drill down more specifically to the professional groups, which I'll also a part of, is that there are study sections that have cropped up by the sheer will and interest of the health professionals and physicians themselves to basically do more research, to collaborate on more research, to identify how they can further the research in the area of their therapeutic areas. And I think that's where the biggest attraction comes in for people like me. I want to hear about how these kinds of AR/VR opportunities or pathways usage are used in the rheumatologist and orthopedics fields. Though I should be interested in what's going on in ophthalmology because that also effects people experiencing bone and joint disorders, I'm more interested in hearing from people who are academy members of the American College of Rheumatology and Orthopedics. So, for them to do that for themselves within that discipline is very important.

At the same token, the patient organizations have a very strong role in this to take the information from our health professionals and utilize lay language into popular consumer articles that are online, whatever it is you want, however you want to convey it. But there's that sense of responsibility.

For a patient to say, “I would like to go to only a surgeon who does AR and VR.” There's nowhere you can go, not even in Google, as good as Google is, to get that information. Physicians don't necessarily release that in their little bios about themselves affiliated with hospitals and things like that. So, I think that this is a

multi-pronged approach that is utilized within each silo as long as the silos are working together. I think that's really the important piece.

The role of the patient organizations really to me has the stronger and primary -- well not primary, stronger role to use words that their people, people like me would use in a way that makes sense. And so not to reinvent the wheel every single time but to take what is emerging and evolving in a particular discipline in this area of AR/VR, and then translating it out to a larger platform would be really important. Thank you.

MR. CONWAY: Sure thing. Thank you very much, Amye. Grace?

DR. LEVY-CLARKE: Thank you. This is Grace Levy-Clarke. So, I would like to address -- I'm going to actually start first with D and then move upwards. I believe that for official updates any major changes regarding risks and benefits should really start at the level of the physicians. So, the HCPs, the healthcare providers should really be targeted for major updates.

And then I think the responsibility should then be for the healthcare providers to really provide clear updates to patients. And in this regard, I will go up to A, I believe that when patients are going to be really oriented to new technologies, they should really be time taken out so they can ask questions specifically about some of the things that are in the label, because I think the fine print becomes very overwhelming. And I think that is whereas a patient advocate, I'm very, very focused on making sure that patients understand the overall impact that their new technology is going to have on their treatment modality.

And then in terms of Part B, I think it's really important that whoever

the -- whoever the healthcare personnel is at the home level, they should be involved in understanding how to appropriately store the device, and also be aware of the potential side effects.

And then part C, I think for me this brings up the space of equity. And I would have to agree with Philip, that what I believe we should be doing as patient advocates is really ensuring that at the level of the clinical trials and the studies – we should really be making sure we're involving all the socioeconomic and demographic groups, because I think if they're not involved in the actual study, then they're not going to be aware of the new technologies that are coming up. And when they become approved, they're not aware of how these technologies will impact them. And I think that's an important part that we're missing right now as far as patient advocacy and clinical trials.

MR. CONWAY: Great. Thank you very much, Grace. I'll go ahead and go to Colleen and then Suz. And Philip, I see your hand up. Go ahead, Colleen.

DR. GALLAGHER: Thank you. This is Colleen Gallagher. I'm thinking about a couple different issues. One is the idea of where the internet is or isn't the best all the time. I'm thinking possibly for all of this creating info graphics that can be sent with devices, because I think people understand those a lot better sometimes than three or four pages of worded stuff.

But I'm thinking if you have things such as you know when your internet isn't good, and that can happen anywhere you know maybe you should make sure that other people aren't using the internet at the same time, you know put those kinds of things in that kind of sense. It may not be specific to the medical device but it's good safety information so the device will work better, those kinds of things.

When thinking about what FDA industry and other stakeholders and patient groups can do, I think it's generally helping people understand what good practices in using it, if you've got to use it in your home. And for most of this is sounds like we're talking about VR vs. AR because most of this is VR that we're sending home with people so I think there might be some specifics around that.

And I think the primary place that people are going to get that information is likely to be from their advocacy groups, their patient groups, and things like that. But anything that FDA or industry can do to help make those things better, great.

And I think as we learn the impacts of the devices over time, the approaches that FDA and industry can use to share is to actually say, we learned this. You know, you've told us this about this equipment, and acknowledge that it's not just oh, here's a new set of information. We got this information from you. It helps people, A, to trust that the information came from other people who have used the devices. Or be impacted by their use somehow. And it also shows the iterations of things so that as new things are developed, people can utilize former information.

MR. CONWAY: Great. Thank you very much, Colleen. We'll go to Suz and then Heather. And Philip, if you do have more, I'll come back to you as well. Okay.

MS. SCHRANDT: Great. Thanks so much and I think I'm picking up a little bit on what Colleen was just speaking about and certainly endorse all the comments from apply colleagues. Specific to item C, where there are concerns about sort of effective use in communities where internet or other connectivity issues may arise, and I might be reading too much into the question, but to me this is partially about information and guidance about use. But these feel like things that should really be an integral part of

the design phase and early testing and partnering with diverse communities and understanding these limitations. I mean I think at a very threshold level if we develop a tool that can truly only be used in some communities, in some parts of the country at sometimes, I have concerns about who that leaves behind. And I'm not a tech person but I think about things like is there some way to build in redundancies or fail-safes or some way to make part of the tech downloadable and so it's ready to go when the person takes it home and there's not a need for connectedness. Would it be possible to develop different versions or adaptations such that it would be appropriate to use the device in a public setting like a public library where there's Wi-Fi available. So, I just think there's a lot of (indiscernible) that if we don't think about it until we're communicating on the label, that's way too far downstream so we need to be thinking about this way upstream and sort of all the factors that promote usability and feasibility especially across diverse stakeholder types.

MR. CONWAY: Great, thanks, Suz. Heather.

DR. ADAMS: Hi, this is Heather Adams. I'll just address a couple of points. I think all of the points have been well spoken to already. Regarding point A, when other methods should FDA or other stakeholders use to consider communicating to patients the intended use, I think that there's an exciting opportunity to leverage the technology that is at hand. So, think about ways that, in addition to the standard labeling of printed documentation or even info graphics, that the AR/VR technology itself can be leveraged to communicate information. Maybe there's an opportunity before a device is used for the first time, or periodically during its use, that there's you know that review of this is what this device is for and these are the important things to know about using this

device, so that that gets communicated in a way that's really accessible and, again, I'll say it, leverages that technology. And I think that connects to my second comment which had to do about Point B, how should FDA communicate this to caregivers and if there are ways to do that in addition to the standard ways built into the device as well.

In addition, I think about some of the things that we do from an informed consent process and research. I have an IRB role at my institution, and we like to see consent forms and consent processes that have a talkback, so you simply don't dump the information on someone, but you provide an opportunity for exchange of information in a way to truly access understanding in the information that's being conveyed. And typically, we're given way more information than we can process all at once particularly when we're having to make healthcare decision and integrate all of that information we've been given as well

MR. CONWAY: Great. Thank you very much. Bennet?

MR. DUNLAP: Sorry, I was just processing that. We get too much of the process comment there, I was kind of lost in that. To 5-A and to some extend B the question is what other methods could FDA, industries and others use to communicate, and I think that, Paul, you made a comment in regard to the last question, about utilizing consumer advocacy groups, and I think that that really is an opportunity to do more. I know that in the diabetes space we had some webinars even before Zoom with FDA on safety of devices with CDRH. They were very successful. We had hundreds of people participating and it was actually a really wonderful opportunity for 2-way communication in the definition of risk be defined by patients as well as by the legal process. And maybe one comment would be don't let lawyers write anything. It's never

clear.

MR. CONWAY: Okay. I'm not certain our purview includes putting other industries out of business.

MR. DUNLAP: Just that one. Shakespeare had thoughts on that.

MR. CONWAY: Well, I see that you're classically inspired. Thanks, Bennet. Any other comments on this because I would like to get Dr. Wilcox's observations in here as well? If not, I'll go ahead and put in Dr. Wilcox's observations.

Dr. Wilcox indicated that as stated, there's always a trade-off between making something available and making sure -- actually my apologies. On question number five Dr. Wilcox indicated, and I'll do these by each subcomponent. I would like to see a website with a video and text information with the same information provided on a USB drive along with a detailed user tailored guide to supplement the IFU. In regard to 5-B he indicated that he could not see any reason that the information provided to the caregiver wouldn't be the same provided to the patients.

On 5-C, he indicated that an easy-to-use illustrated guide, as above, and if the problem is significant enough, a standalone device that could accompany the prescribed device that provides video or other AV presentations. In regard to 5-D, on the longer-term side, providing post market information should follow the logic of recalls. The manufacturers and/or distributors should keep accurate regularly updated contact information for users and send them text messages as well as posting on their websites and sending emails. Texts are harder to miss than emails. So, a couple of different perspectives there. Let me go back and ask committee members, any other thoughts, or comments that you have on the comments of question five? If not, I'll go ahead and

move to summarize for FDA.

And so, to FDA I'll go through each of these components as best as possible, to summarize the committee's concerns. In regard to methods for communicating out to patients and others the intended use of AR/VR medical devices, you heard a number of different items here that are traditional and some that are more creative or on the cutting-edge side. On the traditional side, high use of info graphics, the use of credible, dedicated websites, either through FDA or through partnerships with physician organizations. Registries of providers and users would be a source.

There was reference to advocacy organizations, and the past work of FDA in terms of working with FDA on webinars and other understood means of communications and collaborations with patient organizations. You also heard that patient organizations bear a responsibility and a duty for communicating out once they receive credible information through things such as publications and articles. Amye made that point.

And then in terms of new technology, patients must be able to ask questions about the labels of devices and their overall impact as they're being developed early in the process, is one approach. That's on 5-A.

In regard to 5-B, in terms of how FDA should communicate risks to caregivers and those who might be supporting in home device, a number of different thoughts here. In particular, the role and responsibilities of third parties, especially payers have in this process. There's a recognition there's a cost to this but there's also a cost to patients of not doing it. Payers must be involved.

In terms of caregivers, some type of enablement for caregivers to be able to understand actually how the device works in more important granular detail on how

devices should be stored and obviously what the adverse effects or events could be for those who are involved.

On 5-C, in terms of how the FDA and industry could inform patients about effective use on AR/VR devices in communities where internet access or other connectivity issues might impact the use, a lot of thinking here by the committee, and I'll summarize it, that for marginalized communities in particular, Medicare populations and communities across the country, that a high degree of responsibility rests with those who are involved in the development of these devices and for insurers, that they have a role in terms of informing patients of their availability.

In terms of equity issues, that it starts at the beginning, that you have to make certain that all groups are involved and informed when new technologies are being developed and they should be put at the front end of the process. And particularly Suz raised this in terms of it's a little bit late if you're trying to educate a population on the evolution of technology in AR or in VR devices. They should be involved in the design phase of the device, and that that could be a potential consideration for FDA to recommend, especially strongly. And that other means of connectivity or other means of use should be taken into account, meaning are their other ways that that device could be enabled, through publicly available web access in public settings, or are there versions where the same device could be used but not have to be tethered to be online in terms of downloadables.

I would also suggest that some use of prior PEAC meeting minutes be used here because we did spend a tremendous amount of time I think taking a look at the diversity of communities across the United States, not just in terms of sociodemographic makeup

but also in terms of rural and urban communities and where they're located in terms of how to communicate effectively to communities that are not online, or to populations that have tough access issues.

In terms of 5-D, the committee generally felt that in terms of learning about the impacts over time and the approaches that FDA and industry could take to share with patients added benefits and changes in performance, that there has to be some type of involvement in engagement with professional organizations, and also that the evolution of technologies across disciplines might offer an opportunity, within the medical professions, for the medical professions to communicate out with patients, added benefits and changes.

And Colleen made a very good point here that I think it's directly tied to what our mission is, is that the simple approach of we learned X, or we learned this information from you, i.e., real data insights that are coming from patient consumers, should be relayed back to them. And that is something that the FDA and industry would be able to do.

And on a final point in terms of risk benefit, that HCPs should be contacted first. And then in a waterfall fashion, HCPs should update patients, and they bear a responsibility to do that. I'll stop here and ask FDA if this is adequate or if FDA has any follow-up on any of the components of question five.

MS. SAHA: Thank you, Paul. We do have one clarifying question, it's a particular comment from Dr. Levy-Clarke but certainly recognize if other committee members have anything to add we welcome that feedback. Just wanted to clarify who you were thinking, in terms of who should be targeting physicians, in terms of giving them

updates if there are changes in the benefits and risks of the technology, would that be FDA, would that be industry, you know, some other stakeholder?

DR. LEVY-CLARKE: So, let me make sure I understand your question. If there's an update in the labeling?

MS. SAHA: Right, or we learn overall there might be some change in terms of how we understand the benefits and risks of the AR/VR devices.

DR. LEVY-CLARKE: So, if I just use my understanding from previously registered devices or drugs, if there's an update that requires a label change, then that's going to be FDA driven. And once that's FDA driven then the HCPs or any -- you know anyone who is using the device, or the drug would be automatically updated and then it's going to be there you know, clinical responsibility to make sure that the end users are updated also.

MR. CONWAY: Does that answer your question, Ani?

MS. SAHA: Yes, thank you. And overall, yes, we find the discussion very helpful and adequately responsive to the question, the multi-pronged question.

MR. CONWAY: Okay, great. Thank you very much. I would now ask Commander if you could go ahead and read question number six.

CMDR OLELE: Commander Chinyelum Olele for FDA. Question number six. Manufacturers, device user 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. CONWAY: Great. Since this is our last question let's go ahead and start out with Philip.

MR. RUTHERFORD: Before I get to how the FDA should communicate, I just want to point out that we spent a couple of days talking about the absolute brilliance of this technology and how much it can help people. I think if it's that brilliant, I like the idea of it reporting to the FDA or to the consumer even if there are errors or adverse effects. I don't -- it doesn't make sense to me that we would have something that's this smart technically and then depend on a human to report to us that it doesn't work, right? So, it makes sense to me that the device itself should be feeding information back to the FDA and back to whoever else about what it is doing.

And then for the FDA to communicate – how the FDA should communicate that information out, that's really more of a -- that's really more of an administrative issue. I just want to make the point that I had a brilliant IT director, so brilliant in the fact that he now works for the private sector making a lot more money, but he said we let robots do things that robots are good at so if it can understand that it's making a mistake it should report that without human intervention back to someone. Thanks.

MR. CONWAY: Thank you very much. Any other comments on question number six? Go right ahead, Omer.

DR. LIRAN: Yeah, so the FDA should communicate in several ways. If again this is a device that's been sent to consumers, then it should be on the label and the label

should probably include info graphics that have a human centered design approach in creating it. If this is software, then it has to be embedded in the software. Maybe on first launch there has to be call this number or visit this website to report adverse events, to notify people what to do in such a case. I think it's important to collect safety data with these devices because they are novel. And in studies don't generally have equity amongst all populations no matter how we try it control for demographics there are going to be some populations who we haven't tested the device on, so I think it's very important especially this early on to try to collect as much safety data as possible and communicate that in the clearest way to the consumer. Thank you.

MR. CONWAY: Great. Thank you very much. Amye?

MS. LEONG: I would like to address just the last half of the question, where to report issues, particularly -- or including when there are issues with consumer product headsets. I think that again goes to what I spoke about earlier and many others have, when you have a medical software and/or a medical software integrated into the headset or whatever it is, that is one thing. But when you combine usage of a consumer product that either might be already had by the family because in younger families -- I won't say younger families, younger patients may be more up on it, and may be more attracted toward digitally oriented kinds of things so there's more of an incentive and wow isn't this novel and unique and I want to be the one doing it kind of thing, or be a part of it.

But where those two mix I think is the issue. And so, the question first begs has -- has the FDA ever been in a situation where use of a totality system, that part of that system is utilized or has been utilized by the consumer for, as we've said,

entertainment purposes. And yet we're also possibly looking at that system, or at least developers are, using it in a medical situation. So, if you can help me answer that question first, then I can go in with further comments.

MR. CONWAY: I would ask the FDA, Brendan, I don't know if you want to talk about whether or not the FDA has experience with dual use devices like this potentially?

MR. O'LEARY: Brendan O'Leary for FDA. I think Angie Krueger from our Office of Product Evaluation and Quality will take this question.

MR. CONWAY: Thank you.

MS. KRUEGER: Hi, this is Angela Krueger. Amye, just to get to your question because it's an important one, we do have experience with that, and we do coordinate with other government partners. Examples might include the Consumer Product Safety Commission or the CPSC, or the Federal Trade Commission, the FTC, and we do have MOUs that govern our communications with them and sharing of information. And we have coordinated with them, for example, on safety communications and sharing information when it's appropriate and necessary.

MS. LEONG: Okay. Now knowing that track record, I would say that it's important to distinguish medical use side versus entertainment side. When the person subject, whether they are from a vulnerable population or not, when they insert that medical software, you know, do they know there's a particular goal that they have to achieve, they have to get to the end of the program, it's going to be -- that data is going to be gathered. They're going to be given some sort of input. I'm just throwing these things out because I don't know. They will be informed as to whether or not – while they've completed that day's activities, they've got tomorrows to look forward to or whatever.

So, there's some sort of measurement, guidance, self-monitoring, but yet that is part of the data system. That all has to be very uniquely different and subject to more rigorous FDA and developers' perusal and use versus the entertainment side. So how you keep that separate but the same and keep the enthusiasm and the innovation is something I guess as someone had said, it depends on the software, depends on the goal, it depends on the usage, and it depends on the patient. So, lots to consider. Thank you.

MR. CONWAY: Thanks, Amye. Suz.

MS. SCHRANDT: Yeah, so I really appreciated the comments from I think it was Philip and I'm not sure who else about, you know, the ability of the device itself to report safety information. And I think that sounds great in theory, but I think I might be a little too skeptical that that is completely foolproof. And I think at the end of the day, humans are using these devices. And so, there's no substitute for patient report. And I think patients still can be -- patients or families can still be really important purveyors of that real world data to corroborate whatever's you know pinging from the device. I think about I use an elliptical machine all the time but I don't have the heart monitor set up and so it tells me every workout my hard rate is zero which clearly would be a problem if that was true. And so, I just think -- I mean you could ask me any question and my answer would be we need a vehicle for patients for report their experience data. And so, the answer to the specific question is it should be visible, understandable, big flashing letters right on the package that you know where to report concerns or experience data from your use.

MR. CONWAY: Thank you very much. Colleen?

DR. GALLAGHER: Again, this is Colleen Gallagher. So, in this instance I'm agreeing

with Suz that because these devices and software or whatever are interacting with humans, I think that some of what might be discovered comes from a human factor side of things. So, we don't want people calling the FDA and saying oh, I have a problem because I can't turn it on. But I think if we can find a way to work with the companies who do receive those kinds of things from the consumer end saying okay you know I'm 65 years old and I don't know how to use this, I don't know how to do whatever. Whatever little, whatever experience they have, if there's a way to collect some of that data, when it's being used for medical purposes, so that there could be a review done to say is there something on the human side for which we need to help better instructor something like that to make it safer. That would be my concern.

MR. CONWAY: Great. Thank you very much. Diane and then I'll go to you, Bennet.

MS. JOHNSON: So, I think these types of devices, they provide us with an interesting opportunity with respect to adverse events and performance issue, why we can instrument software to report some types of issues, like if it crashes when you launch it you know we can be notified of those sorts of things immediately. Where you still need the intervention from the patient is the software's not going to know the headset made me dizzy, so I think that it's important to differentiate between those things that do require reporting from a person, from a patient, or a caregiver versus those that can be instrumented in the software in a self-reporting fashion.

MR. CONWAY: Thank you very much. Bennet?

MR. DUNLAP: Bennet Dunlap. To the voluntary reporting, the not required reporting, I would love to see some way of doing that either through the device or even

more importantly, the process of reporting a medical device error is brutally difficult. You know I have a matter's theory in health communications. I struggle to fill out a report. I would hope that maybe the FDA could take a little look internally and see how we can make that process more patient friendly.

MR. CONWAY: All right. Thank you very much, Bennet. And Amye, I see your hand up. I'll take your comment and then we'll put in the comments from Dr. Wilcox. You're muted, Amye. Okay, Amye.

MS. LEONG: Yeah, sorry. What I basically wanted to say is that it is required by the FDA, and I know like Bennet how difficult it is to fill out, and it's difficult for us, think of vulnerable populations or anybody quite frankly. So absolutely, I would second Bennet's suggestion in terms of looking at that. Even have some of us who have been through the process take a look at it for our different populations, and that's the end of it. Thank you.

MR. CONWAY: Great. Thank you very much. Let me go ahead and put into the record here the comments of Dr. Wilcox in response to question number six.

Dr. Wilcox said he would like see FDA affirmatively reach out to users rather than wait for voluntary information to come in or require documented post market studies, providing a carefully crafted form to be filled out would be helpful. I'm not sure existing forms are as effective as they might be. Kind of echoing some of the comments that you heard here just a few minutes ago.

Before I move to summarize the answers to question number 6, on behalf of the committee to FDA, any other comments? Diane, I see your hand up. That might still just be a markup. Go ahead, Diane. You're on mute.

MS. JOHNSON: Sorry, that was just me forgetting to put my hand down.

MR. CONWAY: No problem at all. Any other comments? If not, I'll go ahead and summarize. So, for FDA, I would say to FDA, that the committee generally believes that in terms of how FDA should communicate about how and where to report issues, including where there are issues with consumer products, you again heard a theme here that's been consistent throughout the day in terms of the distinctions between medical devices and consumer devices. You heard from FDA talk about the MOUs that they have in place with the Consumer Product Safety Commission and with the Federal Trade Commission, and I think the committee generally believes that in terms of moving ahead on this there's going to have to be a clear delineation about what you do in terms of communicating things out when there are mixed devices and how to make that accessible, not just to patient consumers but how you make that information available to regulators and to industry as a factor.

You heard a couple of different things in regard to labeling on devices. In terms of human awareness and human use, humans are involved with the medical devices, it needs to be obvious, it needs to be everywhere, and it needs to be abundantly apparent not just to patients but also to caregivers that are involved in that process.

On the technology side, again in a similar vein, I think Philip hit this square on the head that if devices are really that intelligent, and what we're envisioning is a bold new world of innovation, then perhaps built into that twice, devices could in and of themselves report back but recognizing some of the other committee concerns here that again this is in a human environment with humans doing human things, choosing to do certain things as outlined and choosing not to do certain things as outlined of best

practices. And in that regard, any contact, information should be abundantly clear.

One of the last things that you heard here was in terms of ease of use in facilitating reporting back of information, whether it's an adverse event or a significant issue, that it must be easier for patient consumers and caregivers to communicate back to the agency when they see something in order for the agency to be able to proactively stay on top of issues that they are seeing.

With that I'll stop and ask FDA if this is responsive and if you would like to pose any questions to the committee.

MS. KRUEGER: Thank you for that summary, Dr. Conway. This is Angela Krueger for FDA. We would be interested in hearing more about -- understanding that time is short -- specifics on whether FDA should communicate and how it should communicate information about reporting. We heard a lot about labeling updates, for example. It's a very common way for information to be conveyed to patients. Are there other mechanisms that FDA should explore that aren't already being used?

MR. CONWAY: Who would like to go ahead and give a comment on that? Omer?

DR. LIRAN: Yes, I mentioned that perhaps embedding that information into the software itself would be helpful for patients. They can lose the label but they're not going to lose the software. There should be a way for them to get information for how to report adverse events through the software or at least information should be somewhere in the software for how to go about and do it.

MR. CONWAY: Thanks, Omer. Philip?

MR. RUTHERFORD: There's probably some privacy concerns here, but I just think about how we communicate as a society, and what about social media as a vehicle, and

not necessarily broad -- not necessarily broadcasting but some sort of communication vehicle between people that have the devices or are using the headsets and their relative social media connections. Just about everyone I know has something like that. It's a very direct method of communication. It's how most people do.

MR. CONWAY: Okay. Thank you. And go right ahead, Grace.

DR. LEVY-CLARKE: I think my only concern would be you want to make sure that we don't -- we don't forget patients with audio/visual disabilities or patients who have cognitive disabilities who might not be as -- you know might not be into the social media realm. So, what we want is – we want to make sure that the communication is clear and equitable and will not cause confusion. And so, I say we look the once that initial communication is out, then I think it's fine that we use every – every media available. But that initial communication needs to be fair, equitable and clear.

MR. CONWAY: Great. Thank you. FDA, is -- my apologies, Colleen?

DR. GALLAGHER: No problem. This is Colleen, and I guess I want to say sometimes old school still works. So, I'm going to say public -- you know public service announcements, press releases, things like that, about things that are big enough to cause people to have to act differently with the device or something would be a way to go.

MR. CONWAY: Great. Thank you very much, Colleen. At this point what I would like to do is go ahead and thank the committee and the FDA for their contributions. I would also like to thank again the open public hearing speakers, industry, healthcare providers, healthcare researchers, patients, and the FDA for their remarks during day one and day two of this meeting.

Before we adjourn, I'll ask FDA officials if they have any concluding remarks. And I would like to make one brief remark here, that the pattern of innovation and the pace of innovation in United States in medical devices and across healthcare is rapid and it's encouraging and very optimistic for patients. But one thing is quite clear that when folks talk about patients and patient consumers, we need to be very clear about what audience they're talking about, and it's not a monolithic establishment. What we're talking about are folks in a patient consumer community that is very diverse.

You heard over the past two days about adolescents, and their caregivers and their parents. You heard about those who have many different challenges in life, multiple comorbidities, people who have other challenges. They too are patient consumers in this process, and that's why it's very important that the committee here, the Patient Engagement Advisory Committee, has been empaneled by the FDA, because we can't always take for granted that every sector of the medical device spectrum will take into account and weigh equally the input of patients and patient consumers and caregivers but that's what our role is. And so, as a committee we're very proud to be a part of this process for FDA.

And in regard to AR and VR, I think the overwhelming theme that you've heard her is perhaps trust but verify. And I think that's very important. Because the promise of innovation means the potential to save suffering and save loss of life. But what it means is that for the future and for those who are coming after us, and for patients who may be in need but not know it today, that the role and insights that we've been able to put forth in this process are critically important to the future path of innovation and hopefully to better health outcomes. But we don't trust one single entity in the process.

That's why patient voice has to be raised and patient insights has to be respected across medical device development.

So, at this point I'll return to FDA representatives and ask if you have any concluding remarks. Ms. Capanna, Mr. O'Leary, Ms. Krueger, or Ms. Saha?

MS. CAPANNA: This is Katie Capanna. On behalf of the entire FDA team, I would like to thank each member of the committee for spending the last two days here with us.

We thank you for sharing your time, your expertise, and your thoughtful perspectives, and thank you also to the speakers and other members of the public that contributed to the discussion today and yesterday.

This meeting and your contributions underscore how essential it is that we continue to examine important issues related to medical device innovation and regulation through the lens of the patient. The PEAC is a critically important way that helps FDA understand and incorporate patient perspectives and experiences into our work, so we thank you all. We appreciate you.

MR. CONWAY: Thank you.

MR. O'LEARY: This is Brendan O'Leary for FDA. Each of you has provided valuable perspectives about how the innovation we're seeing in this space can be successfully harnessed to provide safe and effective medical technologies that benefit patients, particularly patients who have not been adequately served by what we have in place today as well as their loved ones and their caregivers. And so, as our distinguished committee chair said at the outset, the Patient Engagement Advisory Committee makes an impact. FDA will be taking your advice back to help inform our regulatory efforts

related to these technologies going forward. Thank you.

MS. SAHA: Ani Saha, FDA. So, thanks -- sorry, jumped ahead of you, Paul. Thank you to the PEAC members for sharing your important factors and insights that FDA should consider when assessing AR/VR devices, including those considerations on health equity in vulnerable populations and like children and those who are cognitively impaired. As you heard from my fellow FDA staff members, the insights we heard from you will not only help FDA but also help the broader healthcare ecosystem to advance the safe and effective use of AR/VR devices for all patients who could benefit from them.

MS. KRUEGER: This is Angela Krueger for FDA. I wanted to thank you for the opportunity to participate in the discussion over the last two days. I'm really struck by the breadth of the discussion and the diversity of perspectives and feedback that you've shared with FDA. It's very valuable to us, and I want to thank you for your time and participation.

MR. CONWAY: Thank you very much, to the FDA officials. And thank you each for on your public service, to the FDA and to the United States. These are not easy times in the United States, but your service to the country is well recognized by the PEAC committee and those who have been watching, and we appreciate your advocacy on behalf of patients and medical innovation.

Thank you all for joining us at the Patient Engagement Advisory Committee, where the patients and care partners provide our perspective to FDA's Center for Devices and Radiological Health. Your participation today and yesterday will be an initial step in helping to assure the needs and experiences of patients are included as a part of FDA's

approach as it pertains to augmented reality and virtual reality in medical devices. This meeting of the Patient Engagement Committee is now officially adjourned. Thank you.

[End of meeting]