Summary of the Patient Engagement Advisory Committee
July 12 and 13, 2022

Introduction:

The Patient Engagement Advisory Committee to the Food and Drug Administration (FDA) met July 12 and 13, 2022, to discuss and provide advice on: "Augmented Reality (AR) and Virtual Reality (VR) Medical Devices." AR/VR devices are increasingly applied to healthcare settings across the patient care continuum and across multiple medical specialties. These devices pose novel considerations for patients, providers, and FDA. The committee's advice addressed factors FDA and industry should consider when considering the benefits and risks of AR/VR medical devices. The committee also considered potential applications of AR/VR medical devices in vulnerable patient populations, including pediatric patients and patients who are cognitively impaired. The committee discussed ways patient perspectives could be incorporated in the device design process, in FDA's benefit-risk decision making, and in healthcare provider decision-making related to the use and prescribing of AR/VR medical devices.

Presentations:

Jeffrey, Shuren, M.D., J.D., Center for Devices & Radiological Health (CDRH), FDA, welcomed the Committee and public and provided opening remarks.

Leeda Rashid, M.D., M.P.H., A.B.F.M., Physician, Digital Health Center of Excellence (DHCoE), Office of Strategic Partnerships and Technology Innovation (OST), CDRH, FDA, presented an overview on Augmented Reality and Virtual Reality Medical Devices.

Walter Greenleaf, Ph.D., Neuroscientist, Virtual Reality and Digital Health Expert, Stanford University, presented an overview on AR/VR in Healthcare-What is it? How is it Used? What's the difference?

Jennifer N. Avari Silva, M.D., CCEP-PC, FAHA, FACC, Co-Founder & Co-Inventor of Sentiar, Co-Founder & Co-Inventor of Excera presented an Industry Perspective on Developing AR Medical Devices for the Surgical Field

Josh Sackman, Co-Founder and President, AppliedVR, presented an Industry Perspective on Designing Immersive Therapeutics (ITx) for Self-Directed, At-Home Use.

Jeffery I. Gold, Ph.D., Professor of Anesthesiology, Pediatrics and Psychiatry & Behavioral Sciences, Keck School of Medicine, University of Southern California and Juan Espinoza, M.D., F.A.A.P., Assistant Professor of Clinical Pediatrics, Children's Hospital Los Angeles, Keck School of Medicine, University of Southern California, presented Healthcare Provider Perspectives on Pediatric User as

Special Populations for VR Consideration.

Courtney Lyles, Ph.D., Associate Professor, Center for Vulnerable Populations, University of California, San Francisco, presented a Healthcare Researcher Perspective on The Use of VR in Other Vulnerable Populations and Health Equity Considerations.

Sharif Razzaque, Vision Therapy Patient, presented a Patient's Perspective on The Experience of Using VR in a Healthcare Journey.

Anindita Saha, Assistant Director, DHCoE, OST, CDRH, FDA, presented a Recap of Meeting Day 1.

Open Public Hearing:

Eight open public hearing speakers presented and provided comments. Speakers included health research organizations, industry, patients, and patient advocacy groups.

Virtual Breakout Session:

During the Virtual Breakout Session, members of the public discussed a theoretical scenario about an AR/VR medical device offered as a treatment option for a child with autism.

Virtual Breakout Summations:

FDA representatives summarized comments by Virtual Breakout Session participants to the Committee and the public. In the context of the hypothetical scenario, Virtual Breakout Session participants suggested that caregivers should be provided with information about previous patient experiences with the AR/VR medical device, including information about treatment outcomes, the safety and effectiveness of the device, and any relevant information about existing or similar devices.

Participants expressed the significant role healthcare providers have in communicating the benefits and risks of these devices to caregivers and patients, including providing patient education materials and literature about the device as well as clear direction on when treatment should end. This education should cover any need to stop treatment in cases of potential issues with the device, including a discussion of any potential risk of overuse and features to prevent this.

Participants suggested that devices include a smooth on-boarding process for patients, such as an initial introduction to the device that includes any necessary calibration and a check to ensure that the patient can follow the instructions to use the device effectively. Participants noted the potential to combine VR and artificial intelligence (AI) technologies so that devices can be adaptive, with the treatment program only advancing when a patient successfully completes each step. Participants also shared how it is important for caretakers to be able to understand how patients are progressing in their use of the device and recommended features to support this, such as a caregiver view of what the patient is experiencing or an external indicator, such as a colored light, that shows if a patient is progressing successfully.

Participants also voiced interest in monitoring other metrics, such as blood pressure or heart rate, to ensure that a AR/VR experience does not become too intense or that it can be paused or ended if it does.

FDA Questions and Committee Discussion:

The Committee discussed approaches FDA and industry should consider for AR/VR Medical Devices.

The Committee discussed specific considerations for AR devices in the surgical suite. AR devices are used to display surgical 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 presurgical planning and surgical training and education. The role of AR devices across various of surgical procedures is evolving, as are the related benefits and risks of these devices. While use of AR devices in surgery can benefit patients, reliance on AR may create new risks particularly if there is any significant discrepancy between the information the AR device presents to the user and the physical reality in the operating room. To ensure appropriate use of AR devices in surgery, users should have accurate information regarding the benefits and risks of these devices, including fallback plans in the event of device failure. Additional information on the impact of these device on surgical outcomes can help ensure they are used where they are most effective, and the committee discussed how specific training for surgeons can also support safe and effective use of the technology.

The Committee recommended that the informed consent process for surgeries using AR devices include patient education materials about the technology as well as information about the surgeon's training and past use of and experience with the technology. The Committee discussed what information could help patients understand the evidence base supporting the use of AR devices in surgeries. For example, a patient undergoing a procedure may want to know whether the data used in the design and validation of the device reflects the experiences of patients who are similar to them. The Committee suggested patient-facing device labeling and educational materials include information about whether the software development process included people of different disease and demographic backgrounds. The Committee recognized that patients may not always know what to ask during the informed consent process and recommended that FDA and advocacy organizations could play an important role in ensuring that patients are well-informed about the technology and what questions may be useful to ask when considering the use of an AR device as part of their treatment.

The Committee suggested that the surgeon and in some cases the broader surgical team may need appropriate training on the use and introduction of AR technologies into the surgical suite. Surgical skill and experience using the devices may vary and may not be clear to patients. The Committee suggested that information about surgeon and surgical team experience with the technologies could be tracked by manufacturers or that qualification programs could support patient confidence in the use of the technologies.

The Committee discussed how AR/VR devices may be prescribed by doctors for patients to use at home for diagnostic and treatment purposes. AR/VR devices have benefits, such as helping to reduce pain and anxiety, but also involve the risk of side effects like nausea and dizziness. The

Committee considered that these devices are often intended to be used for specific and limited time periods as one part of a care plan to reduce the risk of side effects. The Committee considered that it may also be important to include information about AR/VR device requirements for power, network connectivity, and any physical environment considerations, such as room for a user to move around. The Committee recommended that this and other information could be integrated into an onboarding tutorial built into the AR/VR device. The Committee also emphasized the importance of ensuring that information is provided to the patient or caregiver prior to use in multiple formats, including in formats that are accessible to users and caregivers who are living with sensory or physical disabilities as well as those less familiar or less comfortable with technology. The Committee also discussed the importance of having real-time technical support available to troubleshoot issues during use.

For AR/VR devices that can also be used for non-medical purposes, such as for entertainment, the Committee suggested that patients be provided with information that enables them to distinguish the medical functions of the AR/VR device from the entertainment functions of the device. The Committee discussed the importance of educating patients on how to alert AR/VR device manufacturers and regulators of adverse events in these situations and discussed the need to understand how the availability of both entertainment and medical use of AR/VR could impact adverse events, could impact the duration users interact with the technology, and could impact stop-use criteria and guidance for patients and caregivers.

The Committee commented that the ability for the device to enable more seamless reporting of adverse events and other information, such as Patient-Reported Outcome (PRO) measures, to AR/VR device manufacturers and regulators would be helpful. The Committee noted the potential utility of this reporting approach for AR/VR devices intended for pediatric patients and cognitively impaired patients.

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 device headset hardware is regulated by FDA. However, some AR/VR medical devices use headsets that are consumer products that may be marketed for people over the age of 13 years. During FDA review of an AR/VR medical device, FDA may assess the impact of any non-device functions of such a product, such as entertainment functions, on the safety and effectiveness of the medical device functions. The Committee discussed factors FDA should consider when an AR/VR medical device for children under 13 years relies on hardware originally intended for individuals over the age of 13 years (e.g., equipment size and weight, useability, and potential impacts on a user's sense of reality). The Committee discussed potential proactive mitigations that could be considered in the development of the AR/VR medical device, such as placing a time limit for use or a lock to prevent others that are not prescribed to use the AR/VR device from using it or misusing it. For pediatric patients and those cognitively impaired, the Committee discussed approaches to ensuring that caregivers can confirm the AR/VR medical device is performing properly.

The long-term effects of using AR/VR devices, including how long they can be used safely in an individual session and over what timeframe 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 US market. Longer studies can also lead to patients not participating for the full duration of the study, and that may impact the quality of the information produced by some long term studies.

The Committee advised that FDA take an approach that weighs the benefits and risks of AR/VR medical devices and that FDA should consider how the devices can be best studied and used for both chronic and more acute conditions. The Committee recommended that real-world evidence could supplement FDA's understanding of a device, and that clinical trials should be designed with the possible need to detect long-term and short-term outcomes in mind. Trial design considerations should also address more specific patient characteristics and should address the reality that patients may have multiple conditions (i.e., patient burden) that can impact their ability to participate in certain studies.

In addition to AR/VR manufacturer-provided information, the Committee recommended that FDA consider the full range of its communication techniques when communicating with patients, caregivers, and providers about this technology, including safety communications, website updates, infographics, social media posts, webinars and videos, and FDA press announcements. The Committee also discussed the value of patient communications composed and distributed by other groups, including patient organizations.

The Committee advised FDA and industry to ensure patients and caregivers have the information they need to use AR/VR devices effectively in communities where internet access and other connectivity issues may impact use by marginalized communities. The Committee noted that equity issues start in the beginning, and all groups should be involved and informed in the beginning of the process and during the development and study of a device. The Committee also suggested considering whether there are other ways that AR/VR devices can be made available, such as in public libraries or as offline versions that do not require an internet connection. The Committee advised FDA to review prior PEAC recommendations on how to communicate effectively to communities that are not online or have limited access to technology.

As we learn more about the impacts of AR/VR devices over time, the Committee suggested the approaches FDA and industry use to share with patients any added benefits and/or changes in performance should include involvement and engagement with patient and professional organizations. The evolution of technology may allow medical professionals to communicate with patients about added benefits and changes. Healthcare providers should be contacted first regarding updates to a device and should communicate those updates to their patients.

The meeting closed with a recognition of the continuing and increasing importance of incorporating patient voices into the FDA decision-making process for new technologies, including AR/VR medical devices.