June 17th, 2022

CDRH Patient Engagement Advisory Committee
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Ave., Bldg. 66, Rm. 5441
Silver Spring, MD 20993

RE: Document #2022-08013/Docket #FDA-2022-N-0008; Augmented Reality (AR) and Virtual Reality (VR) Medical Devices

Dear CDRH Patient Engagement Advisory Committee,

The XR Association is pleased to submit comments in response to the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) Patient Engagement Advisory Committee's meeting regarding Augmented Reality and Virtual Reality Medical Devices.

The XR Association (XRA) represents the broad ecosystem of the XR industry including headset manufacturers, technology platforms, component and peripheral companies, internet infrastructure companies, enterprise solution providers, and corporate end-users. The founders of XRA are Google, HTC Vive, Microsoft, Meta Platforms (formerly Oculus by Facebook), and Sony Interactive Entertainment. XRA's membership also includes companies focused on the medical applications of XR including MyndVR[1], Mieron[2], Immersive Worlds[3], and Elm Park Labs[4]. XRA is leading the way for the responsible development and adoption of virtual reality (VR), augmented reality (AR), and mixed reality (MR) - collectively "XR" technology - by convening stakeholders, developing research and best practices, and advocating on behalf of our members and the broader XR industry. Our mission is to promote the responsible development and thoughtful advancement of XR that foster positive societal outcomes.

XR technologies are still maturing but have already demonstrated significant benefits to health care and are improving patient outcomes. The discussion below will highlight how AR and VR devices and software have facilitated new breakthroughs in behavioral therapies, pain management, and physical therapies. We believe XR technologies are the future of health care for both providers and patients and we look forward to working with the FDA to realize XR's potential to improve people's lives.

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[1] https://www.myndvr.com/
[2] https://mieronvr.com/about/
[3] https://www.immersiveworlds.com/healthcare/
[4] https://www.elmparklabs.com/about

1. Benefits of Medical Extended Reality

Over the past decade, patients, physicians, and health care providers have benefited from new innovations that are specifically intended to be medical extended reality (MXR) technologies. The MXR industry is advancing rapidly and the market for these devices is expected to increase from $1.5 billion in 2021 to over $18 billion by 2028.[5] This section will explore the latest applications for AR/VR devices to highlight the unique benefits of MXR for patients. It should be noted, however, that while XR holds remarkable promise for health care – particularly in the realm of patient therapeutics - many of the AR/VR devices used in healthcare settings are manufactured as general purpose devices and are not intended to be medical devices. The intended purpose of XR devices and software should be an important factor in the FDA's work on MXR. Regulators should consider the differences between general purpose HMDs and software programs and those that are specifically developed for medical interventions.

Mental health: Virtual reality-assisted cognitive behavioral therapy (VRCBT) has been used to successfully treat patients with anxiety. Exposure therapy, where the patient is exposed to the source of their anxiety, is a fundamental aspect of cognitive behavioral therapy (CBT). However, there can be a number of safety and logistical challenges in exposing patients to the source of their fear in reality (e.g., if a patient has a fear of flying or of heights it can be challenging to identify an appropriate therapeutic environment). With MXR, therapists can develop natural-feeling VR experiences that are calibrated to a patient's specific stage of treatment. The virtual environment can also be programmed to evolve alongside the patient's condition and recovery, giving doctors greater control and precision over their patient's CBT treatment.

Some studies have found that VR treatment for anxiety disorders can also be more effective than standard CBT.[6] Recent innovations have demonstrated success in the delivery of automated VRCBT where a virtual therapist guides the patient through treatment.[7] One study of over 300 patients used VRCBT to treat everyday social anxieties common with agoraphobia (e.g. taking public transit or going to a store) and found that automated VRCBT "led to significant reductions in anxious avoidance of, and distress in, everyday situations compared with usual care alone."[8] Automated VRCBT could help increase patients' access to psychological treatment as these programs are more easily scalable.

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[5] *Augmented and Virtual Reality in Healthcare Market to Reach USD 18.7 Billion by 2028*, Globe Newswire, January 2022, available at https://www.globenewswire.com/news-release/2022/01/11/2364598/0/en/Augmented-and-Virtual-Reality-in-Healthcare-Market-to-Reach-USD-18-7-Billion-by-2028-Powered-by-Increased-Investment-in-the-Healthcare-AR-and-VR-Vantage-Market-Research.html

[6] *Virtual reality compared with in vivo exposure in the treatment of social anxiety disorder: A three-arm randomised controlled trial*, Bouchard, S., Dumoulin, S., Robillard, G., Guitard, T., Klinger, É, Forget, H., et al, British Journal of Psychiatry Vol. 210 Issue 4 (2018), available at https://www.cambridge.org/core/journals/the-british-journal-of-psychiatry/article/virtual-reality-compared-with-in-vivo-exposure-in-the-treatment-of-social-anxiety-disorder-a-threearm-randomised-controlled-trial/D541B09E2FF234FA82A7001AB44E3989

[7] *Inside the Effort to Expand Virtual Reality Treatments for Mental Health*, McElvery, Raleigh, Smithsonian Magazine (2022), available at https://www.smithsonianmag.com/science-nature/inside-the-effort-to-expand-virtual-reality-treatments-for-mental-health-180979995/

[8] *Automated virtual reality therapy to treat agoraphobic avoidance and distress in patients with psychosis* (gameChange), Freeman, Daniel, Lambe, Sinead, Kabir, Thomas, Petit, Ariane, Rosebrock Laina, Yu, Ly-Mtt et al, The Lancet Vol. 9 Issue 5 (2022), available at https://doi.org/10.1016/S2215-0366(22)00060-8

For patients, one of the main benefits of VR cognitive therapy is that there is greater flexibility with VRCBT than with traditional treatment. For example, with traditional CBT grading exposure a patient with agoraphobia may have to go to a crowded marketplace with their therapist in order to face their fear, potentially exposing the patient to an awkward situation and risking their medical privacy. With VRCBT, treatment can be administered in a comfortable environment such as the therapist's office or a patient's home which is more conducive to recovery. One meta-analysis confirmed that VRCBT produces similar therapeutic effects as standard cognitive behavioral therapy, but the potential for remote treatment had the added benefit of convenience and timeliness for the patient.[9]

One patient population that has greatly benefited from VRCBT is veterans. Between 11-20% of veterans who served in Operations Iraqi Freedom, Enduring Freedom, and Desert Storm have post-traumatic stress disorder (PTSD), while up to 30% of veterans who served in Vietnam are estimated to have had PTSD.[10] In a study funded by the Office of Naval Research, the Virtual Reality Medical Center and Naval Medical Center San Diego studied the used of Virtual Reality Graded Exposure Therapy (VR-GET) and found a "significant reduction of symptoms" for veterans diagnosed with PTSD post-combat deployments.[11] More recently, the U.S. Departments of Defense and Veterans Affairs published a study testing VR-GET on two combat veterans who were diagnosed with PTSD but did not receive treatment in the initial years following their deployment. At the end of the 14-month treatment course both patients had resolved their symptoms. Following their treatment, the veterans said they wished they had access to VR-GET either prior to or during combat deployments.[12]

A recent meta-analysis found that patient outcomes with VRCBT outperformed that of waitlist control groups and that VR treatment for PTSD was at least as effective as other psychotherapies.[13] Another study demonstrated that multi-modular motion-assisted memory desensitization and reconsolidation (3MDR) treatment, which combines VR cognitive therapy

[9] *Virtual Reality-Assisted Cognitive Behavioral Therapy for Anxiety Disorders: A Systematic Review and Meta-Analysis*, Wu Jinlong, Sun Yi, Zhang Gongwei, Zhou Zhenhui, Ren Zhanbing, Frontiers in Psychiatry Vol. 12 (2021), available at https://www.frontiersin.org/article/10.3389/fpsyt.2021.575094

[10] *National Center for PTSD*, U.S. Department of Veterans Affairs, available at https://www.ptsd.va.gov/understand/common/common_veterans.asp

[11] *Reality graded exposure therapy with physiological monitoring for the treatment of combat related post traumatic stress disorder: a pilot study,* Wood DP, Webb-Murphy J, McLay RN, et al., Stud Health Technol Inform (2011); available at https://pubmed.ncbi.nlm.nih.gov/21335883/

[12] *Combat-Related Post-traumatic Stress Disorder: A Case Report of Virtual Reality Graded Exposure Therapy With Physiological Monitoring in a U.S. Navy Officer and a U.S. Army Officer*, Wood, D. P., Roy, M. J., Wiederhold, B. K., & Wiederhold, M. D., Cureus, Vol. 13 Issue 11 (2021), available at https://doi.org/10.7759/cureus.19604

[13] *Efficacy of immersive PTSD treatments: A systematic review of virtual and augmented reality exposure therapy and a meta-analysis of virtual reality exposure therapy*, V. Eshuis, M.J. van Gelderen, M. van Zuiden, M.J. Nijdam, E. Vermetten, M. Olff, A. Bakker, Journal of Psychiatric Research Vol. 143 (2021), available at https://www.sciencedirect.com/science/article/pii/S002239562031089X

and eye movement desensitization and reprocessing (EMDR), "reduced symptoms in male military veterans with treatment-resistant PTSD."[14]

MXR has also been used to treat anxiety in pre-surgical patients. Preoperative stress and anxiety can be associated with postoperative challenges such as increased pain, nausea, and longer recovery times. Based upon the success of using VR therapy for anxiety-based disorders, physicians have increasingly turned to virtual reality to help calm patients and educate them regarding their surgical procedures. For instance, Stanford Medicine uses VR to educate patients undergoing complex and lengthy surgeries to reduce nervousness.[15] One study of over 100 female patients undergoing gynecological surgery found that a 10-minute preoperative VR intervention resulted in decreased Hospital Anxiety and Depression Scale (HADS) depression scores and 82% of the subjects reported the treatment as 'Good' or "Excellent".[16] VR has been shown to be especially impactful in reducing anxiety for children in healthcare settings. In one example, Microsoft's HoloLens was used to educate a thirteen-year-old female patient about her complex heart surgery to reduce her pre-surgical anxiety.[17]

Furthermore, XR has been used to reduce anxiety and distract patients during intravenous procedures. VR Vaccine is a virtual experience where a child "becomes a hero, and the vaccine shot a shield that helps her defend the realm against an enemy invasion."[18] The program was successfully used to reduce fear and nervousness in children receiving vaccinations. The potential of this form of treatment has been reinforced by clinical research. One study examined the potential to use VR to reduce pain and fear in children receiving injections in the emergency room. This study of over 100 young patients found that pain and fear scores were significantly lower in children that used VR versus those that received a routine injection.[19]

VR treatment may also be used to help combat depression and improve overall mood in patients.[20] One researcher examined over 400 patients that participated in 30-60 minutes of recreational use of VR. In this thesis study, patients overwhelmingly self-reported increases in positive emotions (e.g. excitement, enthusiasm, alertness, interest) and decreases in negative

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[14] *Randomized controlled trial of multi-modular motion-assisted memory desensitization and reconsolidation (3MDR)for male military veterans with treatment-resistant post-traumatic stress disorder*, Bisson JI, van Deursen R, Hannigan B, Kitchiner N, Barawi K, JonesK, et al, Acta Psychiatrica Scandinavica Vol. 142 (2020), available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/acps.13200?src=getftr

[15] *Virtual reality system helps surgeons, reassures patients*, Stanford Medical Center Development, available at https://medicalgiving.stanford.edu/news/virtual-reality-system-helps-surgeons-reassures-patients.html

[16] *The use of pre-operative virtual reality to reduce anxiety in women undergoing gynecological surgeries: a prospective cohort study*, Chan, J.J.I., Yeam, C.T., Kee, H.M. et al., BMC Anesthesiology Vol. 20 Article 261 (2020), available at https://bmcanesthesiol.biomedcentral.com/articles/10.1186/s12871-020-01177-6

[17] *How HoloMedicine® was used to educate and comfort a pediatric patient prior to a heart surgery*, apoQlar YouTube (2021), available at https://www.youtube.com/watch?v=RxkAYNkdGVI&t=5s

[18] *VR Vaccine* (2017), available at https://lobo.cx/vaccine/

[19] Distraction using virtual reality for children during intravenous injections in an emergency department: A randomised trial, Chen YJ, Cheng SF, Lee PC, Lai CH, Hou IC, Chen CW, Journal of Clinical Nursing Vol. 29 Issue 3-4 (2019), available at https://onlinelibrary.wiley.com/doi/10.1111/jocn.15088

[20] *How gaming on the Oculus Quest can help people overcome depression*, Robinson Noah, Medium (2021), available at https://psychnoah.medium.com/how-gaming-on-the-oculus-quest-can-help-people-overcome-depression-d8f25b7fc1aa

emotions (e.g. distress, scared, irritable, ashamed).[21] While additional clinical research is needed, these initial findings demonstrate another unique benefit of XR technologies for improving patients' mental health.

Eating disorders, which can be some of the most challenging mental illnesses to treat, have also seen improvement with the use of MXR. Physicians can use VR to expose patients to food or their own body image in a realistic, controlled format.[22] One meta-analysis examining the use of VR treatment for patients with anorexia nervosa, bulimia nervosa, and binge eating noted that many patients showed "increased motivation for change" and demonstrated less regression between sessions.[23] In sum, VR exposure therapy has been shown to produce better patient outcomes for individuals struggling with eating disorders than traditional treatment.[24]

Dementia and cognitive decline: Studies show that VR can effectively treat patients suffering cognitive decline as well as seniors living with advanced dementia like Alzheimer's disease and Huntington's disease by helping them recall old memories that were otherwise unattainable due to illness or inaccessibility. VR reminiscence therapy, where a senior patient is immersed in a familiar environment from their past, is increasingly used and has been shown to improve mood, reduce levels of anxiety, depression, confusion and hostility, and improve patients' quality of life.[25][26] Elderly patients receiving this treatment can access a variety of experiences, such as traveling around the world, or even use programs specifically tailored to their life like visiting their childhood home or attending their grandson's wedding.[27]

VR reminiscence therapy can also be used to bring together an elderly patient's loved ones who may live far away. XRA member companies, MyndVR and HTC have partnered on MyndConnect, which is specifically designed to support social engagement for the elderly community.[28] One study found "strong evidence" that patients using VR to interact with family were more "conversationally and behaviorally" active, demonstrating the power of VR to

[21] *Using Virtual Reality to Regulate Affect for Patients with Substance Use Disorder*, Robinson Noah, Graduate School of Vanderbilt University (2019), available at
https://ir.vanderbilt.edu/bitstream/handle/1803/14319/Robinson,Noah.pdf?sequence=1

[22] *Virtual reality in the treatment of eating disorders*, Riva G, Malighetti C, Serino S., Clinical Psychology & Psychotherapy Vol 28 Issue 3 (2021), available at https://doi.org/10.1002/cpp.2622

[23] *The Use of Virtual Reality in Patients with Eating Disorders: Systematic Review*, Clus D, Larsen ME, Lemey C, Berrouiguet S, Journal of Medical Internet research Vol. 20 No. 4 (2018), available at
https://www.jmir.org/2018/4/e157/

[24] *Virtual reality in the treatment of eating disorders*, Riva G, Malighetti C, Serino S., Clinical Psychology & Psychotherapy Vol 28 Issue 3 (2021), available at https://doi.org/10.1002/cpp.2622

[25] *Reminiscence therapy using virtual reality technology affects cognitive function and morale of elderly with dementia*, Tominari, Maho et al, Alzheimers & Dementia Vol. 16 Issue S7 (2020), available at
https://doi.org/10.1002/alz.047538

[26] *Impact of Virtual Reality (VR) Experience on Older Adults' Well-Being*, Lin Charles X, Lee Chaiwoo et al, Human Aspects of IT for the Aged Population (2018), available at https://www.springerprofessional.de/en/building-an-ontology-for-eldercare-service-in-china-with-a-hiera/15929672

[27] *V.R. 'Reminiscence Therapy' Lets Seniors Relive the Past,* Fuchs, Matt, New York Times (2022), available at
https://www.nytimes.com/2022/05/06/well/mind/virtual-reality-therapy-seniors.html?referringSource=articleShare

[28] *MyndVR and HTC VIVE Partner up to Overcome Isolation in the Senior Care Metaverse with MyndConnect™,* MyndVR (2022), available at https://www.myndvr.com/single-post/myndvr-and-htc-vive-partner-up-to-overcome-isolation-in-the-senior-care-metaverse-with-myndconnect

enhance the social relationships of elderly patients with cognitive impairment.[29] In this study, the patients were more engaged with their family members compared to telephone calls, suggesting improved quality of life for the patients and benefits for the patient's family and friends as well.

One review published in the Journal of Alzheimer's Disease assessed existing studies on the benefits of VR for people living with Alzheimer's when coupled with the use of contemporary neurodegeneration models and screening methods. The review found that VR is emerging as a viable method not only of therapy but also of diagnosis.[30] Given the prevailing emphasis on early diagnosis, cognitive-behavioral paradigms developed to target neuroanatomical sites compromised early in Alzheimer's disease are vital. Such assessments have been overlooked in the past, potentially owing to difficulty in application and replication. VR paradigms overcome these limitations.[31]

Another neurodegenerative disease treatment that has seen promise with MXR is Parkinson's Disease (PD). A study published in the Journal of Personalized Medicine tested the use of VR and motor imagery training against standard therapy for patients between the ages of 50 and 80. The research revealed that patients who received the VR treatment showed "significant improvements in resting tremors, rigidity, gait, posture, body bradykinesia, arising from a chair, and rapid alternating movements" compared with individuals in the control group that received traditional care.[32] The findings suggest that VR may be more effective in treating adults with PD than routine therapy.

Pain management: XR experiences have been found to substantially reduce pain in patients, demonstrating two unique benefits of AR/VR devices. First, the feeling of embodiment generated by VR devices, and the feeling of immersion in a digital world, helps to better distract patients from their pain, providing relief. Second, and perhaps more significantly, VR treatment overloads the brain with positive stimuli which helps to block pain signals from ever reaching the brain. These unique benefits of XR experiences suggest AR/VR devices could be a viable non-pharmacological supplement for traditional pain management.[33] Physicians have been exploring virtual reality technologies as an alternative to pain relieving prescriptions, including

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[29] *Testing the Feasibility of Virtual Reality With Older Adults With Cognitive Impairments and Their Family Members Who Live at a Distance*, Afifi, Tamara PhD, Collins, Nancy L. PhD., et al, Innovation in Aging Vol 5 Issue 2 (2021), available at https://doi.org/10.1093/geroni/igab014

[30] *Use of Immersive Virtual Reality in the Assessment and Treatment of Alzheimer's Disease: A Systematic Review*, Clay F, Howett D, FitzGerald J, Fletcher P, Chan D, Price A., Journal of Alzheimer's Disease Vol. 75 (2020), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7306888/

[31] *ibid*

[32] *A Randomized Controlled Trial of Motor Imagery Combined with Virtual Reality Techniques in Patients with Parkinson's Disease, Kashif, Muhammad, Ashfaq Ahmad, Muhammad A.M. Bandpei, Hafiza A. Syed, Ali Raza, and Vishal Sana, Journal of Personalized Medicine Vol. 12 No. 3 (2022), available at https://www.mdpi.com/2075-4426/12/3/450#cite*

[33] *Interacting with virtual objects via embodied avatar hands reduces pain intensity and diverts attention,* Hoffman, Hunter G., Sci Rep 11, 10672 (2021), available at https://doi.org/10.1038/s41598-021-89526-4

opioids.[34] Identifying alternatives to pharmacological pain management is an imperative as the United States continues to face an opioid crisis.[35]

A U.S. Department of Veterans Affairs study published in 2021 tested VR pain management on veterans experiencing acute or chronic pain. Researchers found that VR treatment resulted in a 12% decrease in pain levels.[36] Furthermore, the researchers discovered that "the VR experience was also an enjoyable experience for our patients, with varying levels of enthusiasm described, and minimal or no side effects […] Veterans were found to have an increased willingness to explore other non-pharmacological interventions for pain and anxiety." These findings suggest MXR has the additional benefit of opening-up patients to new possible interventions to manage pain.

Another area where VR has successfully been used to manage pain is with phantom limb pain (PLP). Phantom limb pain can be sporadic and unpredictable, making it more challenging to treat than other common chronic pain conditions. Given that veterans are a high-risk population for limb amputation and subsequent PLP, the Veterans Affairs Office of Research and Development funded a project to examine the use of VR treatment for PLP.[37] The study tested three different VR environments that included the use of a bicycle pedaler. The researchers found statistically significant reductions in phantom limb pain intensity. The study also demonstrated that VR treatment could reduce unpleasant phantom limb sensations which cannot be treated through traditional interventions but remain bothersome to patients.

One emerging area of study is whether virtual reality can serve as an adjunct to anesthesia to reduce patient pain and anxiety pre-surgery.[38] General anesthesia can trigger negative side effects such as upper airway obstruction, which has led to the usage of regional anesthesia for certain ambulatory surgeries. In these instances where peripheral nerve blockers are used, patients remain conscious which exposes them to the surgical environment which may be distressing and result in poorer postoperative health outcomes. One observational study investigated 100 patients undergoing upper limb orthopedic surgery under regional anesthesia, half of which received intraoperative VR distraction protocol. Researchers found that patients that received VR treatment reported significantly higher postoperative satisfaction scores, a

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[34] *Virtual Reality for Pain Management in New York: An Alternative to Opioids*, Miranda Felde, MHA, CPHRM, Vice
President, Patient Safety and Risk Management, the Doctors Company, December 2018, available at
https://www.thedoctors.com/articles/virtual-reality-for-pain-management-in-new-york-an-alternative-to-opioids/#
[35] *Issue brief: Nation's drug-related overdose and
death epidemic continues to worsen*, American Medica Association (2022), available at https://www.ama-assn.org/system/files/issue-brief-increases-in-opioid-related-overdose.pdf
[36] *Effect of Immersive Virtual Reality on Pain and Anxiety at a Veterans Affairs Health Care Facility*, Rawlins Caitlin R., Veigulis Zachary, Hebert Catherine, Curtin Catherine, Osborne Thomas F., Frontiers in Virtual Reality 2 (2021), available at https://www.frontiersin.org/article/10.3389/frvir.2021.719681
[37] *A Virtual Reality Intervention for the Treatment of Phantom Limb Pain: Development and Feasibility Results*, Thomas Rutledge, PhD, Deborah Velez, GNP, Colin Depp, PhD, John R McQuaid, PhD, Garland Wong, R Carter W Jones, III, MD, PhD, J Hampton Atkinson, MD, Bosco Giap, Alex Quan, Huan Giap, MD, PhD, Pain Medicine, Vol. 20 Issue 10 (2019) available at https://doi.org/10.1093/pm/pnz121
[38] *Virtual reality as an adjunct to anesthesia in the operating room*, Faruki, A., Nguyen, T., Proeschel, S. et al., Trials Vol. 20 Article 782 (2019), available at https://doi.org/10.1186/s13063-019-3922-2

sentiment that remained two months after surgery. The study also reported that VR was "associated with fewer intraoperative hemodynamic changes in blood pressure and heart rate with reduced occurrence of tachycardia episodes."[39]

MXR for pain management in young patients is another promising area of treatment. Although limited, there are several studies demonstrating how XR devices can be used to effectively treat pain in children. Children are especially well suited for AR/VR interventions given they are digital natives and have greater comfort with technology than other age groups. A pilot study of 51 children between the ages of 7 and 21 tested the use of a single VR session for postoperative pain.[40] The study found that the guided relaxation-based VR session reduced pain for patients, suggesting that XR devices should be further researched as a viable alternative to pharmacological medications for postoperative pain in pediatric patients. Another study tested the use of virtual reality compared to a video displayed on a tablet during intravenous insertion for pediatric patients between the ages of 8 and 17 in the emergency department. Patients that received treatment via a VR device reported clinically significant reductions in pain, further highlighting the benefits of VR treatment over other forms of digital therapies.[41]

Additional research is needed to fully understand the effectiveness and secondary impacts of using XR pain management for children. The Interdisciplinary Network on Virtual and Augmented Technologies for Pain (INOVATE-Pain) collaborative was recently established to bring together clinicians, researchers, scientists, and software engineers to build evidence-based support for the use of immersive pain interventions for pediatric patients.[42] Initial reports from this group emphasize the importance of multi-disciplinary collaborations in building greater understanding of how MXR devices can be used to treat children.

Diabetes: Immersive technologies have been used to increase patient engagement with diabetes self-management education and support (DSME/S) treatments. Traditional DSME/S often see low patient participation, especially among minority or rural populations. Virtual worlds have been used to create personalized learning experiences and DSME/S treatments for patients with type 2 diabetes. XRA member company ImmersiveWorlds has worked with the Boston Medical Center to create and clinically test new treatment modalities and protocols for patients with type 2 diabetes.[43] One clinical study with over 100 participants found that the "experience of three

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[39] *Virtual Reality for PEripheral Regional Anesthesia (VR-PERLA Study),* Alaterre, Camille et al., Journal of Clinical Medicine Vol. 9,1 (2020), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7019894/

[40] *Guided relaxation-based virtual reality transiently reduces acute postoperative pain and anxiety in a pediatric population*, Olbrecht VA, O'Conor KT, Williams SE, Boehmer CO, Marchant GW, Glynn SM, et al., Br Med J (2020), available at https://www.medrxiv.org/content/10.1101/2020.09.18.20192740v1.full-text

[41] *Virtual Reality to Reduce Procedural Pain During IV Insertion in the Pediatric Emergency Department: A Pilot Randomized Controlled Trial*, Litwin SP, Nguyen C, Hundert A, Stuart S, Liu D, Maguire B, Matava C, Stinson J. Clinical Journal of Pain Vol.37 Issue 2 (2021), available at https://pubmed.ncbi.nlm.nih.gov/33177370/

[42] *Leveraging Virtual Reality and Augmented Reality to Combat Chronic Pain in Youth: Position Paper From the Interdisciplinary Network on Virtual and Augmented Technologies for Pain Management*, Logan DE, Simons LE, Caruso TJ, Gold JI, Greenleaf W, Griffin A, King CD, Menendez M, Olbrecht VA, Rodriguez S, Silvia M, Stinson JN, Wang E, Williams SE, Wilson L, Journal of Medical Internet Research Vol. 23 No. 4 (2021), available at https://www.jmir.org/2021/4/e25916

[43] *Healthcare*, ImmersiveWorlds, available at https://www.immersiveworlds.com/healthcare/

domains of presence (self, physical and social)" contributed to greater engagement with DSME/S programs.[44]

Physical and occupational therapy: The use of XR for physical and occupation therapy has grown in recent years and became a critical part of treatment during the pandemic because care could be delivered remotely. During VR occupational therapy (OT) patients can control digital representations of themselves (avatars) to retrain or relearn activities of daily living (ADLs). Treatment can range from playing games to virtually practicing real life skills and activities (e.g. dishwashing, making coffee, brushing teeth, or opening a door). VR occupational therapy can also provide unlimited rooms and experiences for patients to practice ADLs, a major advantage compared to traditional OT which is limited to a singular environment within the therapy room. Physical therapy (PT) treatment in VR can also be more engaging than traditional repetitive PT exercises. For instance, VR physical therapy can be a game where the patient catches butterflies or plays a tennis match. This strengthens upper body movements and improves hand-eye coordination. Other virtual PT treatments can improve balance and strengthen walking through gait training.[45]

A meta-analysis and systematic literature review contends that VR rehabilitation programs are more effective than standard rehab programs due to three unique aspects of VR: excitement, physical fidelity, and cognitive fidelity.[46] Patients often find VR environments novel and more engaging than traditional PT/OT therapy programs, making individuals more motivated to complete their treatment programs. Another benefit of VR therapy is that treatment is often more physically and experientially similar to real life than traditional therapy exercises. Moreover, immersion in virtual environments stimulates several sensory systems, especially sight and hearing, which in addition to strengthening the motor control can also activate and strengthen neurological pathways. XRA member company Elm Park Labs has developed a solution that is currently progressing through FDA evaluation with the goal of approval for commercialized use. The system is designed for human neurological motor sensory, balance and responsiveness within an Immersive Simulation.

Virtual reality-based rehabilitation programs have also become an important part of treatment for nervous system disorders. For example, rehabilitation for cerebral palsy often seeks to correct abnormal posture and movement patterns to support functional use of the upper limbs. XRA member company Mieron provides in-clinic and at-home therapies for patients with cerebral palsy to strengthen gross motor skills and balance. A study examining VR therapy for children with cerebral palsy found that the VR treatment resulted in improved motor and functional development using the Bimanual Fine Motor Function (BFMF) test to measure hand functioning,

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[44] *Patient engagement and presence in a virtual world world diabetes self-management education intervention for minority women*, Mitchell S, Bragg A, Gardiner P, De La Cruz B, Laird L. Patient, Patient Education and Counseling Vol 105 Issue 4 (2022), available at https://doi.org/10.1016/j.pec.2021.06.033

[45] *Select Rehabilitation and MyndVR Announce Strategic Partnership to Deploy VR Therapy*, MyndVR (2022), available at https://www.myndvr.com/single-post/select-rehabilitation-and-myndvr-announce-strategic-partnership-to-deploy-vr-therapy

[46] *A meta-analysis and systematic literature review of virtual reality rehabilitation programs*, Howard, Matt C, Computers in Human Behavior Vol. 70 (2017), available at https://mattchoward.files.wordpress.com/2015/04/howard_chb_2017.pdf

the Gross Motor Function Classification System (GMFCS) to test functional levels, and the Functional Mobility Scale (FMS) to test mobility.[47][48] The results suggest that VR treatment could be especially beneficial to pediatric patients with cerebral palsy.

Stroke recovery and motor rehabilitation: Patients undergoing treatment for stroke recovery have greatly benefitted from VR treatments. One study highlighted improved walking and increased activation in cortical regions of stroke survivors after virtual reality-enhanced treadmill training and found that cortical recruitment was associated with better walking function.[49] Another study examined the efficacy of multi-user VR environments for rehabilitation of the upper extremities in stroke survivors. In this study, 93% of the patients reported "satisfaction with the amount of arm movement induced." Notably, in this study multiple patients were able to receive treatment remotely in the same VR environment, at the same time. The success of this remote treatment could be greatly beneficial in addressing the shortage of physical and occupational therapists in rural areas where rates of stroke exceed that of urban areas.[50]

The Brazilian Research Institute for Neuroscience and Neurotechnology (BRAINN) published a paper, "Biomechanics Sensor Node for Virtual Reality: A Wearable Device Applied to Gait Recovery for Neurofunctional Rehabilitation," that earned a Best Paper award in the Virtual Reality category at the 20th International Conference on Computational Science and its Applications (ICCSA 2020). The study described in the paper resulted in the development of a wearable device called Biomechanics Sensor Node (BSN) that captures user data and controls virtual environments, as well as a new software solution integrating the BSN with Unity Editor, one of the most widely used game engines and virtual world-building programs. Integration of the wearable with the Unity software means patients undergoing motor rehabilitation can interact with VR environments while the therapist views data for the movements performed during the session. The benefit of this data cannot be underestimated and is cited as "one of the great benefits of V.R. therapy" because the clinician can identify exactly what the "patient accomplished [...] and where adjustments are needed." [51]

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[47] *Cerebral Palsy Exercises with Virtual Reality*, Mieron VR (2020), available at https://mieronvr.com/blog-post/cerebral-palsy-exercises-with-virtual-reality/

[48] *Effect of virtual reality therapy on functional development in children with cerebral palsy: A single-blind, prospective, randomized-controlled study*, Metin Ökmen, B., Doğan Aslan, M., Nakipoğlu Yüzer, G. F., & Özgirgin, N., Turkish Journal of Physical Medicine and Rehabilitation Vol. 65 Issue 4 (2019), available at https://doi.org/10.5606/tftrd.2019.2388

[49] *Cerebral Reorganization in Subacute Stroke Survivors after Virtual Reality-Based Training: A Preliminary Study*, Behavioral Neurology, June 2017, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5506482/

[50] *Cerebral Reorganization in Subacute Stroke Survivors after Virtual Reality-Based Training: A Preliminary Study,* Xiao X, Lin Q, Lo WL, et al. Behav Neurol. (2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5506482/
Behavioral Neurology, June 2017, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5506482/

[51] *Meet Virtual Reality, Your New Physical Therapist*, Tugend, Alina, New York Times (2021), available at https://www.nytimes.com/2021/04/21/health/virtual-reality-therapy.html

2. Advantages of MXR for Patient Care

Numerous benefits of AR/VR medical devices and treatments have been described throughout this paper. However, from the patient perspective, there are several unique advantages of AR/VR medical devices that merit highlighting again.

Tailored care: Augmented reality and virtual reality medical treatments provide the architecture to customize and tailor treatment in ways that are not often available with traditional interventions. This paper discussed how therapists using VRCBT grading exposure can customize VR environments. For example, a clinician treating a patient for fear of flying can determine whether to introduce turbulence into the environment and can carefully control the severity of the turbulence the patient experiences. This allows treatment to better track onto patients' progress and recovery. VR environments can also be customizable to ensure patients feel safe and comfortable during treatment by resembling familiar places or experiences.

These devices also create new health data points for physicians, providing greater insight into the recovery and rehabilitation of a patient. In a healthcare setting, these metrics can allow physicians and care providers to modify experiences and treatment courses as patients progress. In the future, health care providers will be able to receive real-time updates on a patient's condition (e.g. taking a vision test at home using an AR/VR device). Real-time information will allow physicians to track medical progress and clinical outputs more accurately.

Embodiment: The unique features of MXR, such as 360-degree field of view, ability to interact with an environment, auditory and in some cases tactile cues, combine to give users the sense of self-location, the sense of agency, and the sense of body ownership.[52] MXR can also maximize cognitive engagement by stimulating the "visual thalamus and cortex, activating both subcortical, threat detection and response pathways as well as cortical, [and] conscious pathways."[53] As a result, immersion, or the feeling of presence in a virtual environment, is much stronger with AR/VR than with traditional 2D visual stimuli.

Several studies have found that the immersive nature of MXR can facilitate greater enjoyment for patients and improve their experience of medical treatment.[54] One study testing the use of VR in older adults with cognitive decline found that 61% of patients displayed signs of enjoyment when undergoing VR treatment and 73% were interested in participating in more immersive

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[52] *The Sense of Embodiment in Virtual Reality*, Kilteni, Konstantina, Groten, Raphaela, and Slater, Mel, *Presence: Teleoperators and Virtual Environments Vol. 21 Issue 4 (2012), available at* https://doi.org/10.1162/PRES_a_00124

[53] *Digital Therapeutics, XR, AI, Precision Medicine The Future of Sensor-Driven Health*, Greenleaf, Walter, Stanford University Virtual Human Interaction Lab (2020), available at https://www.slideshare.net/waltergreenleaf/digital-therapeutics-xr-ai-precision-medicine-the-future-of-sensordriven-health

[54] *Improving the Intensive Care Patient Experience With Virtual Reality—A Feasibility Study*, Ong, Triton L. PhD; Ruppert, Matthew M. BS; Akbar, Maisha BS; Rashidi, Parisa PhD; Ozrazgat-Baslanti, Tezcan PhD; Bihorac, Azra MD, MS; Suvajdzic, Marko PhD, Critical Care Explorations Vol. 2 Issue 6 (2020), available at https://journals.lww.com/ccejournal/Fulltext/2020/06000/Improving_the_Intensive_Care_Patient_Experience.3.aspx

treatments.[55] Patients' enjoyment of the embodiment sensation indicates that MXR may help patients stick to their treatment courses and could be a factor for why MXR therapies are, in some cases, more impactful than other standard interventions. One meta-analysis examining why XR therapies are effective suggests that greater research should be done to better understand the correlation between embodiment in VR, enjoyment, and patient outcomes.[56]

Accessibility and convenience: The Covid-19 pandemic ignited an acceleration of telemedicine and MXR has the potential to greatly increase access to health care. Several studies referenced in this paper highlight the ability for physicians and clinicians to remotely treat their patients via virtual reality. One study even demonstrated success in treating multiple patients through one simultaneous VR experience. MXR can also facilitate more immediate care because patients can access therapeutic content whenever they need.[57]

A 2021 study by GoodRx Research found that more than 80% of counties in the U.S. do not have access to the medical services necessary to maintain the health of their community.[58] Many factors can limit access to healthcare including mobility impairments, lack of access to public transportation, caregiving responsibilities, and job commitments. These challenges make expansion and advancement of remote treatment a top priority.

The ability to provide treatment remotely can help reduce transportation and wait times for patients. For example, using an at-home vision test via XR, patients could avoid an unnecessary and potentially time-consuming visit to the doctor's office. These unique attributes of AR/VR technology can allow patients to receive care even when they do not live in close proximity to specialists or in areas where there are physician shortages. This is especially advantageous for rural communities which are often underserved and have difficulty accessing traditional models of health care.

3. Challenges of MXR

As with any new and emerging technologies, there can be engineering and policy challenges that must be overcome to optimize their potential and ensure safety. MXR devices are no different. In this section we will outline some of the regulatory and logistical challenges the FDA should consider when studying MXR devices.

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[55] *Older Adults With Cognitive and/or Physical Impairments Can Benefit From Immersive Virtual Reality Experiences: A Feasibility Study*, Appel Lora, Appel Eva, Bogler Orly, Wiseman Micaela, Cohen Leedan, Ein Natalie, Abrams Howard B., Campos Jennifer L., Frontiers in Medicine Vol. 6 (2020), available at https://www.frontiersin.org/article/10.3389/fmed.2019.00329

[56] *A meta-analysis and systematic literature review of virtual reality rehabilitation programs*, Howard, Matt C, Computers in Human Behavior Vol. 70 (2017), available at https://matthoward.files.wordpress.com/2015/04/howard_chb_2017.pdf

[57] *Digital Therapeutics, XR, AI, Precision Medicine The Future of Sensor-Driven Health*, Greenleaf, Walter, Stanford University Virtual Human Interaction Lab (2020), available at https://www.slideshare.net/waltergreenleaf/digital-therapeutics-xr-ai-precision-medicine-the-future-of-sensordriven-health

[58] *Mapping Healthcare Deserts: 80% of the Country Lacks Adequate Access to Healthcare*, Nguyen, Amanda PhD, GoodRx Health (2021), available at https://www.goodrx.com/healthcare-access/research/healthcare-deserts-80-percent-of-country-lacks-adequate-healthcare-access

Research: Research into the health care applications of AR/VR medical devices is still relatively nascent, despite rising interest. Although there is a growing body of work examining VR devices, many of which are referenced in this report, there are significant research gaps regarding the health care applications for AR devices. While these devices are often lumped together, it is important to recognize that VR and AR devices can have different health care uses and facilitate different patient experiences.

Across many health care applications, MXR is often used as a supplement to traditional interventions and not as a standalone treatment. Further research should be conducted into AR/VR medical devices as the sole or main intervention for patients. Another challenge is that existing studies often include relatively small sample sizes. Larger samples and more diverse subjects will be needed in future clinical studies to fully ascertain the effectiveness of these technologies in a medical setting.

Another important area that merits further research is the effect of MXR devices on children. Several of the studies referenced in this report examined MXR therapies, such as pain management, for young patients. Industry, researchers, and regulators should be leveraging these existing studies to get answers to questions around how XR impacts children's physical and mental development.

Cost: Over the past several years the costs of AR/VR devices has considerably decreased, but the devices may still be out of reach for lower income patients. Additionally, many MXR software programs may not be covered by insurance. Reducing the cost of MXR is important for increasing access. Representatives Mike Thompson (D-CA) and David McKinley (R-WV) and Senators Jeanne Shaheen (D-NH) and Shelly Moore Capito (R-WV), have introduced legislation which would extend Medicare coverage for prescription digital therapeutics, including MXR.[59] By expanding Medicare coverage, the cost burden of MXR would be significantly reduced so more patients, especially the elderly, would have access to these cutting-edge treatments.[60] Appropriately, this legislation would only require FDA regulation of prescription digital therapeutics if medical treatment is the main intent for the product's use.

Training: AR/VR medical devices are part of an ecosystem of emerging technologies that are advancing rapidly, often faster than educational programs can keep up. It is essential to ensure that health care providers are properly trained in not only how to use the technology, but also how best to apply it to meet the needs of their patients. Increasing and facilitating access to training with MXR should be a priority for the healthcare sector. It will also be important to identify best practices for training and educating patients.

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[59] *XR ASSOCIATION ENDORSES LEGISLATION TO EXTEND MEDICARE COVERAGE TO XR-BASED TREATMENTS*, XR Association (2022), available at https://xra.org/xr-association-endorses-prescription-digital-therapeutics-act-of-2022/

[60] *Thompson Introduces Bipartisan, Bicameral Bill to Ensure Access to Prescription Digital Therapeutics,* Office of Rep. Mike Thompson (2022), available at https://mikethompson.house.gov/newsroom/press-releases/thompson-introduces-bipartisan-bicameral-bill-to-ensure-access-to

Data security: Increasing reliance on digital therapeutics such as MXR will increase the amount of patient data that will need to be protected. The FDA has already established that this is a priority area for regulators and the health care industry.[61] Careful consideration will also be necessary for supporting health data portability to different platforms and health care providers.

Ergonomics and form factor: Special consideration should be given to the comfort of AR/VR devices when being used in a health care setting. It is important that AR/VR medical devices should be accessible to all patients, regardless of physical ability. The XR Association has worked with industry partners, disability advocacy groups, and members of the disabled community to establish best practices for inclusive design that enable use of XR by everyone.[62]

Manufacturers of VR and AR head-mounted display (HMD) systems have made significant advancements in recent years to reduce and/or better distribute the weight of the devices and increase the comfort of the user. The ergonomics of AR/VR devices are extremely important when looking to treat special populations such as the elderly or individuals with memory loss who may not understand or like the sensation of having a device over their face. Technological innovations will continue to improve the form factor of AR/VR medical devices which will help facilitate their use for a wider array of patients.

Another area where XR technology has shown great improvement in recent years is reducing the sensation of visually induced motion sickness (VIMS). VIMS can be triggered by visual/vestibular conflict which arises when a VR user is physically stationary but is moving in a virtual environment.[63] Feelings of nausea could be detrimental to the use of AR/VR therapies and is an area of ongoing research and development within the XR industry.

Content: Certain patient populations may struggle with standard XR content. For example, MyndVR, which focuses on senior communities, has specially curated content that is more calming and comforting to older populations than your average immersive experience. Anecdotally, seniors tend to respond better to natural, real-world content than content that resembles fantasy. It is also important that XR treatment for seniors takes into account camera motion, camera height, pacing of video and audio, font size, and music selection as some modifications may be necessary to support elderly patients.[64]

High-speed internet: Lack of access to 5G networks continues to be a barrier for widespread adoption of AR/VR medical devices. High-performance broadband is essential to the successful use of AR/VR medical devices. Unreliable internet access could disrupt patient treatment and inhibit or negatively impact care. Lack of high-speed internet also restricts the ability to use these

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[61] *Cybersecurity,* Food and Drug Administration, available at https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity#workshops

[62] *XRA'S DEVELOPERS GUIDE, CHAPTER THREE: Accessibility & Inclusive Design in Immersive Experiences*, XR Association (2020), available at https://xra.org/wp-content/uploads/2020/10/XRA_Developers-Guide_Chapter-3_Web_v3.pdf

[63] *Utilizing Accurate Terminology to Describe Symptoms that May Arise from the Use of Extended Reality Equipment*, XR Association, available at https://xra.org/research/visually-induced-motion-sickness/

[64] *Interview*, Miranda Lutz, Director of Public Policy, XRA; Chris Brickler, CEO and Co-Founder, MyndVR; Ted Werth, CFO MyndVR, (June 8th, 2022)

devices where they are needed most – in rural medical deserts where healthcare options are limited.

4. Considerations for regulation of MXR Devices

As stakeholders look to establish best practices for a regulatory framework, it is important to recognize that many of the AR/VR devices used in health care settings are manufactured as general purpose devices and are not intended to be medical devices. Headset manufacturers often cannot predict all the ways their devices will be used and how certain software programs may impact functionality. Furthermore, many companies in the XR industry will be unfamiliar with FDA regulations which could ignite risks of unintentional regulatory violations. The intended purpose of XR devices and software should be an important factor in the FDA's work on MXR. There are many general health and wellness devices and software on the market that are not intended to be used for medical treatments and should not require regulatory supervision. Regulators should consider the differences between general purpose HMDs and software programs and those that are specifically developed for medical interventions. For this reason, fora that bring together different perspectives from the technology and medical industries are especially important.

That said, MXR devices that are developed specifically for use in patient treatment should meet high safety standards. But technology advances rapidly, often faster than FDA approvals can allow. These dynamics underscore the importance of a regulatory approval process that validates safety and effectiveness and also takes into account the unique nature of MXR as cutting-edge technology which will undergo more frequent updates compared to traditional medical devices.

XRA is supportive of collaborative efforts like the Center for Medical Innovations in Extended Reality (MIXR) which will help to identify the pain points of bringing AR/VR devices to market, such as needing to seek regulatory approval for every MXR device for each procedure. MIXR will develop scientifically based recommendations for streamlined and standardized regulatory requirements that allow patients to receive innovative treatments faster and more effectively.[65] MIXR and other multi-disciplinary collaborative initiatives that are bringing together academic researchers, government agencies, and industry experts are essential to identifying a balanced approach to regulation that fosters innovation, protects patient safety, and allows for streamlined access to AR/VR-based care.

5. Conclusion

The available body of evidence demonstrates the vast benefits of AR/VR medical devices across a wide array of patient treatments. We believe that MXR will be an integral part of the future of health care and we encourage greater research in this area. Multi-disciplinary collaboration will be essential to unlocking the potential of these emerging technologies. It is imperative that the private sector, academia, patient groups, civil society, and the government work in lockstep to

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[65] *New Center Brings Virtual Reality Research Into Focus*, University of Maryland (2022), available at New Center Brings Virtual Reality Research Into Focus - UMB News (umaryland.edu)

bring together the diverse perspectives necessary to tackle the challenges and potential risks of MXR. We support the FDA's and other government agencies' efforts to establish collaborative programs and research opportunities that incorporate all of these stakeholders and provide formal mechanisms for patient feedback. We encourage the FDA to consider how government agencies can foster incentives for innovators to conduct research and formulate endpoints that meet the needs of vulnerable populations such as children, the elderly, the cognitively impaired, and those with limited access to healthcare.

The XR Association is committed to the development and adoption of XR to help individuals and enhance society as a whole. We hope the information we have provided helps the FDA CDRH Patient Engagement Advisory Committee better understand the benefits of MXR to patients. We welcome further discussion on this topic and are glad to answer any questions you may have.

Sincerely,

Elizabeth Hyman
Chief Executive Officer
XR Association