FDA Patient Engagement Advisory Committee

Augmented Reality (AR) and Virtual Reality (VR) Medical Devices

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Disclosure: Founder & President Wellovate LLC

Comments are focused on the salient items relating to each topic discussed

Joseph Morgan MD

- Education and Expertise:
  - Education
    - BS Finance – Clemson University
    - BA Chemistry – University at Buffalo
    - MD – SUNY Upstate Medical University (Syracuse)
    - Anesthesiology Residency – Cleveland Clinic
  - Practicing anesthesiologist
  - Expertise in wearables and physiologic tracking
  - >5 years developing AR/VR solutions for healthcare

- Founder and President of Wellovate LLC
  - Focused on "patient facing" applications of AR/VR, we made the Waya® Health platform
  - National presence with multiple applications. Commercializing solutions for 4 years.

AR/VR Addresses Patient Needs

- Profound ability to achieve high levels of engagement
- Unique ability to manage levels of attention
- Achieves self-efficacy more efficiently via immersive learning
- Enables remote care capabilities far beyond existing telehealth systems
- Broadly capable of addressing biopsychosocial and interrelated aspects of multifactorial disease (e.g. DM, depression, chronic pain, and the like)

Safety Considerations

- Nausea (#1 side effect)*
- Physical injury*
- Neurological considerations*
- Mental health concerns*
- Privacy

**All greatly mitigated through the involvement of clinical experts throughout all stages of development to ensure appropriate design-based mitigation of risks and safety concerns.*

Efficacy and Benefits

- Importance of patient-reported outcomes

- *"statistically significant decrease in pain intensity (p <0 .001) with an average 12% decrease in pain levels and an 92% reduction in anxiety for those in concurrent pain"*
  (DOI: 10.3389/frvir.2021.719681)

Patient Perspectives

- Efficacy determined by patient-reported outcomes
- Patients want more convenient options for their care
- AR/VR is a tool to enhance the provider-patient relationship, not replace it

Provider Decision Making

- *Awareness is a pre-requisite*

- Provider decision making to use AR/VR:
  - Robust clinical data to support use
  - Available on-demand
  - Improves access
  - Achieves engagement
  - More objective assessments with reduced variability
  - Non-pharmacologic treatment modality

Factors to Consider in Evaluating

- Consider if clinical domain experts were involved in the design, development, deployment, application, and evaluation of the solution

- Novel attributes that impact evaluation of safety and effectiveness and bring unique challenges
  - Digital health visualization
  - Tracking & embedded software
  - 3D experience content
  - AR vs. VR
  - AI integrations with AR/VR

Considerations for Vulnerable Populations

- Pediatrics
- Visually impaired
- Hearing impaired
- Cognitively impaired
- Motor impairment

Recommendations

- We believe FDA's current regulatory guidance for SaMD devices, clinical decision support software, and/or mobile device applications are sufficient regulatory frameworks for enabling the industry to proceed with AR/VR applications.

- Clinical experts must be involved at all stages of development

- Accessibility features are important for inclusivity of vulnerable populations