



**The Journal of Robotics,
Artificial Intelligence & Law**

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“Take Two MOBAs and Call Me in the Morning” — Video Games May Soon Be Prescribed to Treat Medical Conditions

Stuart Irvin, Rujul Desai, Olivia Dworkin, and Beth Braiterman*

In this article, the authors explain that video games can be used to treat medical conditions and the Food and Drug Administration has demonstrated a willingness to authorize a video game as safe and effective for medical uses in appropriate circumstances.

Video games, and the industry that develops and distributes them, have long been criticized (whether fairly or unfairly) for causing physical and psychological harm to those who play them.

The physical injuries attributed by some to video games include various repetitive stress disorders, including carpal tunnel syndrome, tennis elbow, and “gamer’s thumb.” There have been various attempts to link video games to obesity, although a recent review of clinical studies found¹ ambiguous evidence on the extent to which video game play is significantly associated with obesity. There is also a reported risk of seizures in some individuals who play video games, as the full-screen warning on some console games explains.

The psychological harm that is alleged to be associated with video games has been harder to study and quantify. While the World Health Organization (WHO) included² “gaming disorder” as a behavioral addiction in its diagnostic system, the International Classification of Diseases, in 2018, also noted³ that studies suggest that this gaming disorder affects only a small proportion of people who engage in video-gaming activities. The approach of the WHO to gaming issues has been controversial. The UK’s Chief Medical Officer conducted a comprehensive review of the research on screen-based activities and mental health in children in 2019 and concluded that the “research does not present evidence of a causal relationship between screen-based activities and mental health problems.”⁴ Against this backdrop of allegations aimed at video games, it is somewhat surprising to many when they learn

that video games are being specifically developed to be prescribed by health care professionals to help treat patients with a variety of medical conditions, including patients with attention deficient hyperactivity disorder, or ADHD. Some early successes in using video games to treat ADHD suggest that video games have the potential to become an important tool for practitioners dealing with many different medical conditions, and there is increasing evidence of safety and efficacy.

Do I Need an Rx for My Controller?

When developed for medical purposes, video games may be medical devices, which in the United States are subject to the authority of the Food and Drug Administration (FDA). Section 201(h) of the Federal Food, Drug, and Cosmetic Act defines a “medical device” to include an instrument, apparatus, implement, machine, contrivance, implant, or in vitro reagent that is intended to diagnose, cure, mitigate, treat, or prevent disease in man.⁵ That definition does not expressly include (or exclude) software, but over many years the FDA has established a regulatory approach for software intended to be used for one or more medical purposes.⁶ In fact, FDA has authorized non-gaming prescription digital therapeutics, or PDTs, which use software to treat or manage a wide array of diseases and conditions. So, while it might at first seem that the regulatory processes of the FDA are better suited for more traditional medical device products—like heart stents or MRIs—the FDA has demonstrated a willingness to authorize a video game as safe and effective for medical uses in appropriate circumstances.

For example, in June 2020, the FDA authorized⁷ EndeavorRx the first game-based PDT to improve attention function in children with ADHD. Created by Akili Interactive, EndeavorRx specifically targets⁸ cognitive processes involved in attention function and delivers therapy through an immersive video game experience. The FDA found that EndeavorRx improved attention function in children ages 8 to 12 with certain types of ADHD and authorized⁹ the video game for marketing in the United States as a PDT. In January 2023, Akili released¹⁰ new data showing safety and efficacy of EndeavorRx in adolescents, and the company stated its intention to seek FDA authorization for marketing to patients ages 13 to 17. Since June 2020, the FDA has also reviewed and authorized

marketing of virtual reality (VR)–based PDTs to improve vision¹¹ in children with lazy eye and reduce chronic pain.¹²

Just What the Doctor Ordered

Gaming’s entry into the health care sector has been underway for some time. For more than a decade, researchers have been looking¹³ for ways to use video games to improve health outcomes, particularly in the areas of psychological and physical therapy. Video games are an attractive treatment option for doctors, patients, and health insurers, given the potential for higher engagement and retention rates, as well as the cost advantage and convenience that comes from digital distribution.

With over 227 million¹⁴ people in the United States already playing video games every week, and approximately 74% of U.S. households¹⁵ already having at least one person who plays video games, the infrastructure to deploy digital therapeutics through video gaming is already in place, and is growing rapidly. As video games are used to treat more conditions and become more widely researched and better understood, there may be more widespread acceptance and understanding of improved health care outcomes that could come with game-based PDTs.

FDA Approval Before App Store Approval?

A game developer needs more than a license to Unreal or Unity and programming skills in order to create and market a PDT. The burden (and cost) associated with obtaining marketing authorization for a medical device varies depending on its “risk class” and whether a similar device already exists, but it generally is significant. The FDA imposes requirements for devices starting as early as product design, and continuing through testing and clinical studies (if required), submission and review of a marketing application (if required), and then post-market obligations. For example, even after a PDT has marketing authorization from the FDA, the manufacturer is responsible for monitoring and reporting safety concerns, and many times cannot make changes to the PDT without additional authorization from the FDA.

As the experience with EndeavorRx shows, authorization can be secured and video game products can be marketed as PDTs, but the

FDA process is by no means a rubber stamp. It can be expensive and time-consuming for developers and comes with both pre-market and post-market requirements.

Ready Payer One—Is My Grand Theft Auto Covered by Insurance?

A game developer may be willing to make the investment in securing approvals for a video game as a PDT for the simple reason that PDTs, when properly prescribed, may qualify for insurance reimbursement. In August 2022, Highmark, a provider-payer organization, became the first large commercial insurer to expressly state¹⁶ in its medical policy that it will cover PDTs—including EndeavorRx—when prescribed by a provider and used appropriately according to the product’s marketing approval. PDT manufacturers also have achieved¹⁷ some success facilitating access to PDTs for state Medicaid program beneficiaries. In January 2023, Pear Therapeutics announced¹⁸ that two of its non-gaming PDTs, which are used to treat substance and opioid use disorders, will be listed on the Florida Medicaid preferred drug list alongside more traditional drugs and biologics; this follows news of a pilot program¹⁹ with California’s Medicaid program to support the implementation of the state’s Recovery Incentives Program.

Insurance reimbursement could represent a new source of revenue for game developers and for many gamers a video game will be a lot more fun if Aetna, Blue Cross, or CIGNA is paying the cost.

Conclusion

The FDA, applying the rigorous requirements of the Federal Food, Drug, and Cosmetic Act, has already concluded that a video game can be authorized and marketed for medical purposes. Video games have obvious advantages when it comes to patient engagement and retention rates, and come with the cost advantages of digital distribution and potential insurance reimbursement. That said, video game developers will need to clear regulatory hurdles before marketing a game as a PDT—which can be expensive and time consuming—so do not expect to get a prescription from your doctor for *Fortnite* or *Elden Ring* anytime soon.

Notes

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