

We Happy Few:
Therapeutic Perceptual Modification, Regulatory Pathway Precedent, and the Governance
Gap in Cloud Rendered Reality

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ABSTRACT

We analyze an emergent governance challenge arising from the convergence of three maturing capabilities: real time 3D world generation models capable of producing spatially consistent environments from single images, consumer AR wearables with integrated cameras and displays, and AI driven behavioral and emotional modeling. We argue that these capabilities, when combined, enable a qualitatively new category of intervention: continuous modification of a user's perceptual experience of their physical environment, rendered in real time and adapted to their emotional state. We further argue that legitimate therapeutic applications of this capability will enter the FDA regulatory pipeline within the near term, using the De Novo pathway established by EndeavorRx (DEN200026) and RelieVRx (DEN210014) as precedent. While we explicitly support the clinical evaluation of such interventions on their therapeutic merits, we identify five structural properties of cloud rendered perceptual modification that distinguish it from all previously cleared digital therapeutics: remote mutability, platform dependency, perceptual opacity, cultural encoding in training data, and absence of patient side verifiability. We examine the historical pattern of therapeutic scope expansion (from indicated use to consumer wellness product) across pharmaceutical and digital therapeutic domains and argue that the delivery mechanism's unique properties require governance frameworks that do not yet exist. We conclude with specific recommendations for regulatory, clinical, and technical safeguards.

Keywords: augmented reality, perceptual modification, digital therapeutics, FDA De Novo pathway, regulatory scope expansion, mental health technology, AI governance, cloud rendered reality

I. INTRODUCTION: THE ARROW REVERSED

The same convergence of capabilities analyzed here has a documented inward application: one person modifying their perception of another person's body through AR wearables, without the target's knowledge or consent. That application is a perceptual violation directed at a specific target, with clearly assignable perpetrator and victim roles. The arrow points at the observed person.

This paper examines the reverse vector. When the same convergence of capabilities, real time generation, spatial intelligence, and AR delivery, is directed not at others but at the user's entire perceptual environment, the result is not

a privacy violation against a specific target but a wholesale replacement of the user’s experienced reality. The arrow points outward, at everything.

This reversal changes the harm profile entirely. The nudification threat involves a perpetrator and a victim with clearly assignable roles. Environmental perceptual modification involves a user who is simultaneously the consumer, the subject, and (potentially) the victim of the intervention. The ethical analysis is correspondingly more complex, because the intervention may be genuinely therapeutic.

The video game *We Happy Few* (Compulsion Games, 2018) provides a useful narrative anchor for the threat we describe. In the game’s fictional setting, a population traumatized by a historical atrocity takes a drug called Joy that makes everything appear pleasant and normal. Joy does not change reality; it changes perception of reality. The population self administers because opting out (being a “Downer”) makes one a social pariah. The game’s central tension is not whether Joy “works” in the narrow sense of making people feel better. It does. The tension is what happens to a society that can no longer perceive the problems it needs to solve.

We argue that the technological equivalent of Joy is architecturally feasible, that it will enter regulatory and commercial pathways through legitimate therapeutic channels, and that governance frameworks adequate to its unique properties do not currently exist.

II. TECHNICAL FEASIBILITY

A. *Component Stack*

The perceptual modification system we analyze requires three integrated capabilities.

The first is real time 3D world generation. InSpatio-WorldFM (Zhang et al., 2026) demonstrates that spatially consistent 3D environments can be generated from single images in real time on consumer GPUs (RTX 4090 class). The system maintains multi view consistency (generated content does not drift or change when the user looks away and back) and supports ultra long inference without content degradation. WorldFM’s explicit 3D anchoring provides the spatial memory necessary for persistent environmental modification: objects remain where they were placed, rooms maintain their generated characteristics across viewpoint changes.

The second is consumer AR wearables. Meta Ray-Ban smart glasses provide continuous camera input in a conventional eyewear form factor, with documented privacy concerns around covert recording and bystander data collection (BBC News, 2026; The Conversation, 2024). Meta’s Orion prototype and Apple Vision Pro demonstrate the trajectory toward integrated camera and display devices. The form factor question is not whether such devices will exist but when they achieve sufficient display quality and social acceptability for sustained daily wear.

The third is behavioral and emotional modeling. Real time emotion detection from facial expression, voice, physiological signals (heart rate, skin conductance via wearable sensors), and behavioral patterns (movement speed, social interaction frequency, location patterns) is a mature capability deployed in consumer products (Lui et al., 2022). The integration of such signals as input to an adaptive generation system is a software engineering task, not a research frontier.

B. *Integrated Operation*

The combined system operates as follows. AR glasses with cameras capture the user’s physical environment in real time. A generation model (WorldFM class) processes the captured environment and renders a modified version, overlaying the physical world with generated elements. An emotional and behavioral model monitors the user’s state through available signals and adjusts generation parameters accordingly. The modified environment is displayed through the AR

glasses, replacing or augmenting the user’s direct perception.

For a user experiencing depression, the system might enhance color saturation, increase apparent sunlight, smooth visual clutter, make ambient faces appear slightly warmer in expression, and widen perceived spatial dimensions. For anxiety, the system might reduce crowd density in peripheral vision, soften sharp angles, slow apparent motion of surrounding objects, and mute harsh sounds.

These modifications are not speculative. Each individual manipulation has been demonstrated independently: color and lighting modification in AR (Regenbrecht et al., 2022), spatial perception alteration in VR and MR environments (Wright, 2014), and cross modal perceptual illusions through AR overlay (Eckhoff et al., 2021). What has not been demonstrated is their integration into a unified, adaptive, cloud rendered system driven by real time emotional modeling. The novelty is in the composition, not in any individual component.

C. Current State of Clinical AR for Mental Health

A systematic review of the 2024 to 2026 literature reveals early but active clinical work on AR based mental health interventions, none of which yet combines world model generation with adaptive emotional response.

ExpandXR uses AI enhanced AR to overlay 3D characters and scenarios into patients’ physical environments for PTSD and anxiety exposure therapy, deploying LLM driven conversational AR characters through HoloLens or Apple Vision Pro (Javanbakht et al., 2024). AR-3MDR adapts multi modal memory desensitization and reconsolidation to AR headsets, overlaying trauma processing stimuli onto real world walking paths, with a published case study showing PCL-5 scores dropping from 60 to 14 over eight sessions (Raboy et al., 2025). CREAM Depression (University of Pittsburgh) uses AR plus EEG neurofeedback to overlay emotionally challenging content onto adolescents’ real environments and retrain attention away from depressive cues (Woody, 2023). All are early stage. None are FDA cleared. None use generative world models.

The gap between current clinical prototypes and the system we describe is integration complexity, not fundamental capability. Current systems use conventional 3D engines and pre built content. The next generation will use adaptive generation. The clinical motivation (treating depression, anxiety, PTSD through perceptual intervention) is already present. The delivery mechanism is what changes.

III. REGULATORY PATHWAY

A. Established Precedent: EndeavorRx

EndeavorRx (AKL-T01) received FDA De Novo authorization (DEN200026) in June 2020 as a prescribed digital therapeutic for attention improvement in children aged 8 to 12 with ADHD (U.S. Food and Drug Administration [FDA], 2020a; Akili Interactive, 2020). It was the first prescription treatment delivered through a video game. The clearance established several principles.

A software based intervention can be prescribed as a medical device. A game like interface does not disqualify a product from medical device classification. De Novo classification creates a new regulatory category that subsequent devices can reference via 510(k). And clinical efficacy measured by functional outcomes (TOVA attention scores) rather than traditional symptom scales is acceptable for clearance (FDA, 2020b).

EndeavorRx subsequently received label expansion to adolescents 13 to 17 in 2023 (Akili Interactive, 2023) and adult clearance as EndeavorOTC via 510(k) in 2024 (Akili Interactive, 2024). This trajectory, from narrow pediatric indication to broader adult OTC availability in four years, illustrates the expansion pattern we analyze in Section IV.

We want to be explicit: EndeavorRx represents a genuine therapeutic advance. Gamification of attention training is clinically sound, particularly for ADHD, where dopamine dysregulation makes traditional training modalities ineffective precisely because they fail to engage the attentional circuits they aim to strengthen. The intervention works with the neurology rather than against it. Our concern is not with EndeavorRx itself but with the regulatory pathway it created and where that pathway leads when applied to qualitatively different interventions.

B. Established Precedent: RelieVRx

RelieVRx (formerly EaseVRx) received De Novo authorization (DEN210014) in 2021 as a prescription VR based CBT program for chronic low back pain (AppliedVR, 2021; FDA, 2021). This clearance extends the precedent from software only (EndeavorRx on a tablet) to hardware dependent immersive systems (VR headset required). The regulatory pathway for XR based therapeutics is not theoretical; it has been walked twice.

C. Projected Pathway for AR Environmental Augmentation

Given these precedents, a plausible regulatory trajectory for AR based therapeutic environmental augmentation proceeds as follows.

Phase 1 involves clinical trials. A sponsor conducts a randomized controlled trial of AR environmental augmentation for treatment resistant depression (defined as failure of two or more adequate medication trials). The intervention modifies the patient’s home environment through AR glasses: enhanced lighting, warmer color temperature, reduced visual clutter, subtle positive environmental cues. The control condition uses a sham AR overlay (non therapeutic visual elements). The primary endpoint is PHQ-9 score reduction at 12 weeks. We note that the intervention in such a trial would be clinician supervised, session limited, and indication specific.

Phase 2 involves De Novo submission. Using EndeavorRx and RelieVRx as precedent, the sponsor submits for De Novo classification. The submission argues that AR environmental augmentation is distinct from existing device categories and requires a new classification. FDA creates a new product code.

Phase 3 involves clearance and indication expansion. Following clearance for treatment resistant depression, subsequent trials target broader indications: major depressive disorder, generalized anxiety, PTSD. Each expansion follows the EndeavorRx trajectory from narrow to broad.

Phase 4 involves consumer availability. Following the EndeavorOTC precedent, an OTC variant is submitted via 510(k) for “wellness” applications such as stress reduction and mood enhancement without a prescription requirement.

We do not argue that this trajectory is inevitable. We argue it is architecturally plausible given existing precedent and that governance frameworks should be prepared for it.

IV. THE SCOPE EXPANSION PATTERN

A. Historical Pattern

The expansion from indicated therapeutic use to broad consumer availability follows a documented pattern across pharmaceutical and digital therapeutic domains.

Opioids were evaluated for acute post surgical pain. Indication expanded to chronic pain management. Consumer awareness drove demand beyond indicated populations. The intervention did not change; the population expanded, the indication softened, and oversight attenuated.

Benzodiazepines were evaluated for panic disorder. Indication expanded to generalized anxiety. Prescribing expanded to subclinical stress and situational anxiety. The same expansion pattern.

Stimulant medications for ADHD followed a comparable trajectory: from narrowly indicated pediatric use to broad adult prescribing, with significant off label use for cognitive enhancement in non ADHD populations.

EndeavorRx itself has already traversed part of this trajectory: from children 8 to 12 with documented attention deficits, to adolescents 13 to 17, to adults without age restriction, in four years.

B. Unique Properties of AR Perceptual Modification

The scope expansion pattern is concerning for any therapeutic category. But AR based perceptual modification possesses five structural properties that distinguish it from all prior digital therapeutics and from pharmacological interventions. These properties are not bugs in a particular implementation; they are intrinsic to the delivery mechanism.

Property 1: Remote mutability. A prescribed medication has a fixed chemical composition. Once dispensed, the pharmacist, the manufacturer, and the prescribing physician cannot alter what the patient ingests. The molecular structure is static. A cloud rendered perceptual environment is a service, not a product. Its parameters can be modified remotely after deployment. The therapeutic reality a patient experiences on Tuesday does not have to be the reality they experienced on Monday. Updates can be pushed without the patient's explicit awareness. This is how all cloud based software operates; it is standard engineering practice. But when the software in question constitutes your experienced reality, standard engineering practice has non standard consequences.

Property 2: Platform dependency. Psilocybin, once ingested, does not require Pfizer's servers to remain online. The therapeutic experience is self contained; it occurs between the molecule and the patient's neurochemistry. No ongoing relationship with the manufacturer is required for the intervention to function. Cloud rendered perceptual modification requires continuous platform operation. If the service provider goes offline, discontinues the product, changes pricing, or modifies terms of service, the therapeutic intervention ceases to function. The patient's treatment is contingent on a business relationship, not on a physiological process. The history of digital health companies (including Akili Interactive's \$34 million sale to Virtual Therapeutics in 2024 after commercial struggles with EndeavorRx distribution; see Reuter, 2024) suggests that platform dependency introduces discontinuity risks that pharmacological treatments do not face.

Property 3: Perceptual opacity. When a patient takes a pharmacological intervention, they generally know they have taken it. The act of ingestion is conscious and discrete. They can choose to skip a dose. They can observe their unmedicated baseline by simply not taking the medication. Sustained perceptual modification erodes the baseline against which modification is measured. After six months of daily use, the user's sense of their "normal" environment has been replaced by the augmented version. Removing the augmentation is not returning to baseline; it is a novel negative experience, because the user has adapted to the augmented environment. This is not speculation; sensorimotor adaptation research demonstrates that virtual environment exposure produces measurable aftereffects in perception and motor control that persist beyond the exposure period (Wright, 2014). The longer the exposure, the stronger the adaptation. The result is that the patient cannot meaningfully assess whether the intervention is helping, because the only comparison available is between the augmented state and the removal state, and removal is itself a negative experience. This is structurally distinct from medication, where drug holidays and washout periods provide genuine baseline comparisons.

Property 4: Cultural encoding in training data. A pharmacological intervention operates on neurochemistry that is, with individual variation, biologically consistent across cultural contexts. Serotonin reuptake inhibition works via the same mechanism regardless of the patient's cultural background. A generative model trained on image data encodes

the cultural assumptions present in that data. If the training data for “healthy environment” or “comforting space” overrepresents specific architectural styles, color palettes, lighting conditions, or spatial arrangements, the therapeutic reality generated for all patients will reflect those specific cultural norms. A patient in rural Appalachia receives a therapeutic environment shaped by training data that may disproportionately reflect urban coastal aesthetics. A patient in Lagos receives an environment shaped by data that may disproportionately reflect Western domestic interiors. This is not a solvable bias problem in the conventional sense. The model must generate some environment. Whatever it generates encodes assumptions about what “better” looks like. Those assumptions are culturally contingent, and no amount of dataset diversification eliminates the fundamental question: whose version of “well” is the patient living in?

Property 5: Absence of patient side verifiability. A patient can take a prescribed medication to an independent laboratory and have its chemical composition verified against the prescription. The medication is inspectable, testable, and independently verifiable. This property is foundational to pharmaceutical regulation; it is what makes quality control, counterfeiting detection, and adverse event investigation possible. There is no equivalent verification mechanism for a prescribed reality. The patient cannot capture their AR environment, send it to an independent lab, and confirm “this is what my doctor ordered.” The perceptual experience is ephemeral, subjective, and controlled entirely by the rendering system. If the parameters are modified (by update, by error, or by design), the patient has no means of independent verification. This is the sentence that should concern regulators: you cannot lab test a prescribed reality.

V. THE DEPENDENCY QUESTION

A. *Psilocybin as Contrast Case*

Psilocybin assisted therapy provides a useful contrast. Psilocybin temporarily dissolves default mode network activity, allowing patients to perceive their circumstances from altered perspectives. The therapeutic mechanism is precisely the perception alteration. And clinical trials show efficacy for treatment resistant depression (Carhart-Harris et al., 2021).

But the therapeutic model is structured to prevent dependency. Treatment involves a small number of supervised sessions (typically two to three), with extensive preparation and integration therapy before and after. The molecule is the catalyst; the therapeutic work happens in the integration. The therapist is the off ramp.

If psilocybin were administered daily, without integration support, without defined treatment duration, and without a clinician managing the process, the risk profile would be entirely different. The molecule would be identical; the container would not.

AR perceptual modification as currently conceived in the clinical prototypes is session limited: clinician supervised sessions of defined duration. But the expansion pattern documented in Section IV.A shows that session limited interventions expand to continuous use when commercial incentives and patient demand align. The question is not whether the initial clinical application is responsible. The question is what structural protections ensure the intervention remains contained as it expands.

B. *Removal as Negative Event*

If the therapeutic mechanism is “your environment looks and feels better,” then removal of the therapy is not a return to neutral. It is an active negative experience: the environment suddenly looks worse than what the patient has adapted to. This creates an asymmetry that does not exist for most pharmacological interventions, where discontinuation returns the patient to their pre treatment state (withdrawal syndromes excepted and acknowledged as a known risk class).

For AR perceptual modification, the “withdrawal syndrome” is not a pharmacological artifact but a perceptual one: the real world looks bad because it is being compared to the generated world, and the patient has lost the calibration

to their actual environment. No study in the 2024 to 2026 literature examines this phenomenon, because no existing clinical AR system operates at sufficient duration to produce it (Lundin et al., 2023). The gap is not merely unstudied; it is structurally invisible to current trial designs that use session limited protocols.

VI. WHO CONTROLS THE DIAL?

A. Decomposing the Control Question

When someone's experienced reality is rendered by a system, five distinct control questions arise, each of which may have a different answer. Who designed the therapeutic environment template? Who trained the generative model that adapts it to the patient's emotional state? Who has access to modify parameters after deployment? Is the patient informed when parameters change? Can the patient selectively reject specific modifications while remaining in treatment?

In current pharmacological practice, the answers are relatively clear: the pharmaceutical company designs the drug, the FDA evaluates it, the physician prescribes it, the pharmacist dispenses it, and the patient takes it with informed consent about its fixed properties. Each actor's role is defined, and the product's characteristics are verifiable at each handoff.

For cloud rendered perceptual modification, several of these roles collapse into the platform operator, and the verifiability that underpins the entire chain disappears. The platform designs, generates, delivers, modifies, and monitors the intervention. The patient experiences it without independent means of verification.

B. The Political Accelerant

An additional dynamic deserves attention. Administrations ideologically opposed to psychedelic therapy but confronted with clinical evidence for treatment resistant depression face a dilemma: the data supports an intervention they cannot politically endorse. AR based perceptual modification offers a resolution. It addresses the same indication (treatment resistant depression) without the cultural and political baggage of Schedule I reclassification. It is technology, not drugs. It is innovation, not decriminalization.

This creates a scenario in which political incentives actively accelerate the regulatory pathway for AR therapeutics, potentially bypassing the deliberation that novel intervention categories warrant. The same populations most skeptical of institutional medicine, those who distrust pharmaceuticals and the FDA, may accept the technology version with less resistance precisely because it does not look like medicine. It looks like glasses.

VII. AFFECTED POPULATIONS

A stakeholder harm analysis identifies four populations affected by the expansion from indicated therapeutic use to broad consumer availability, none of which are represented in the initial clinical trial.

The first is voluntary users who develop perceptual dependency. Clinical trials measure efficacy at 8 to 12 weeks. Consumer use has no defined endpoint. The absence of longitudinal data on sustained perceptual modification means this population's risk profile is unknown.

The second is involuntary users whose participation is mandated. Once an intervention is cleared and cost effective, insurance companies, employers, courts, and institutional care settings have incentives to mandate its use. "Prescribed reality" could become a condition of employment, parole, or insurance coverage. The patient's autonomy over their own perception is mediated by institutional requirements.

The third is people surrounding the user whose reality does not match the user's. A caregiver whose environment is artificially softened may not notice deterioration in their care setting. A parent whose anxiety is managed through environmental calming may not perceive danger cues that their child needs them to notice. The modification of one person's perception has externalities for those who depend on that person's accurate perception.

The fourth is people who cannot access the technology and experience comparative perceptual poverty. Once the option to modify reality exists, unmodified reality feels worse by comparison. This is the same dynamic documented for social media and appearance: the availability of filters and editing tools changes the experienced baseline for everyone, including those who do not use them (Fardouly & Vartanian, 2016). The unaugmented world becomes, subjectively, a lesser place to be.

VIII. RECOMMENDATIONS

A. Regulatory

AR based perceptual modification interventions submitted through the De Novo pathway should be required to address the five structural properties identified in Section IV.B as part of their premarket submission. Specifically, sponsors should be required to document update and modification protocols (what can change after deployment and who authorizes changes), platform continuity plans (what happens to patients if the service discontinues), baseline preservation protocols (how patients maintain access to their unmodified perceptual baseline), training data documentation including cultural and demographic representation analysis, and patient side verification mechanisms or explicit disclosure of their absence.

B. Clinical

Clinical trials of AR perceptual modification should include mandatory longitudinal follow up extending beyond the active treatment period, specifically examining perceptual adaptation and removal effects. Trial designs should include structured "removal periods" analogous to drug washout periods, with validated measures of perceptual recalibration. Outcome measures should include not only symptom scores but measures of perceptual dependency, environmental adaptation, and baseline drift.

C. Technical

The development community should prioritize local first architectures for therapeutic AR, minimizing cloud dependency and maximizing patient side control. Therapeutic environment specifications should be serializable, inspectable, and independently verifiable, analogous to how pharmaceutical formulations are documented and testable. Modification logs should be maintained and accessible to the patient and their clinician, creating an audit trail for the patient's experienced reality.

D. Ethical

The informed consent process for AR perceptual modification must address the unique properties of the intervention, including the fact that the therapeutic experience is rendered rather than fixed, that parameters may change, and that removal may produce negative perceptual effects not experienced with pharmacological withdrawal. Consent frameworks developed for static interventions are structurally inadequate for dynamic, adaptive, perceptual ones.

IX. CONCLUSION

We have argued that cloud rendered AR perceptual modification will enter clinical and regulatory pipelines through legitimate therapeutic channels, using established De Novo precedent. We have identified five structural properties that distinguish this intervention from all prior digital therapeutics. We have documented the historical pattern of scope expansion from indicated use to consumer availability and argued that this pattern, applied to perceptual modification, raises governance challenges for which no current framework is prepared.

The intervention may be genuinely therapeutic. The clinical question is not our concern. Our concern is the delivery mechanism's properties: remote mutability, platform dependency, perceptual opacity, cultural encoding, and absence of verifiability. These properties are not implementation details; they are structural features of any cloud rendered perceptual system. They will persist regardless of the therapeutic validity of any specific application.

The regulatory pathway exists. The clinical motivation exists. The component technologies exist. The governance frameworks do not. The gap between "this works for depression" and "everyone should wear these" is the same gap that separated "this works for post surgical pain" from the opioid crisis. The intervention was not the problem. The container was.

The citizens of Wellington Wells took Joy because it worked. It did make them feel better. The question the game asks, and the question this paper asks, is what they stopped being able to see.

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