AUGMENTED REALITY · PERCEPTUAL MODIFICATION · DIGITAL THERAPEUTICS · FDA DE NOVO PATHWAY · REGULATORY SCOPE EXPANSION · MENTAL HEALTH TECHNOLOGY · AI GOVERNANCE · CLOUD RENDERED REALITY

We Happy Few

Therapeutic Perceptual Modification, Regulatory Pathway Precedent, and the Governance Gap in Cloud Rendered Reality

Real time world generation, AR wearables, and emotional modeling now compose into something new: continuous modification of a person's experienced reality, adapted to their emotional state. It will arrive through legitimate therapeutic channels. The governance for its unique properties does not exist.

Travis Gilly · Real Safety AI Foundation

Travis Gilly, We Happy Few: Therapeutic Perceptual Modification, Regulatory Pathway Precedent, and the Governance Gap in Cloud Rendered Reality, Real Safety AI Foundation, Working paper, June 2026 (v2)

WELLINGTON WELLS, 1964

Joy did not change reality. It changed the perception of reality. And it worked.

In the game, a traumatized population self-administers a drug that makes everything appear pleasant, because opting out makes one a "Downer" and a pariah. The game's central tension is not whether Joy makes people feel better. It does.

> ***The tension is what happens to a society that can no longer perceive the problems it needs to solve.***

SOURCES Compulsion Games (2018), We Happy Few, Gearbox Publishing; Gilly, We Happy Few, sec. I.

THE ARROW REVERSED

Not a privacy violation against a target. A wholesale replacement of the user's experienced reality.

When generation, spatial intelligence, and AR delivery point outward at everything the user sees, the user becomes consumer, subject, and potentially victim at once, and the intervention may be genuinely therapeutic. That is what makes the governance question hard.

> The claim: this capability will enter the FDA pipeline through legitimate channels, on established precedent, and the governance its structural properties require does not yet exist.

SOURCES Gilly, We Happy Few, secs. I, IX.

Feasibility and the Pathway

The components exist, the clinics are already working, and the regulatory road has been walked twice

The novelty is in the composition, not in any individual component.

Three mature capabilities, one unbuilt composition.

REAL TIME WORLD GENERATION

InSpatio-WorldFM: spatially consistent 3D environments from single images, in real time, on consumer GPUs, with multi-view consistency and persistent spatial memory. Objects stay where they were placed.

CONSUMER AR WEARABLES

Camera-equipped glasses in conventional eyewear form, with integrated displays on the near horizon. The question is not whether such devices will exist but when they achieve sustained daily wear.

EMOTIONAL MODELING

Real time emotion detection from face, voice, physiology, and behavior is mature and already deployed in consumer products. Feeding it into an adaptive generator is engineering, not research.

SOURCES Zhang et al. (2026), arXiv:2603.11911; BBC News (Jan. 2026); The Conversation (Sept. 23, 2024); Lui et al. (2022), JMIR Mental Health 9(9), e37354.

Capture, render, monitor, adapt: the loop that replaces direct perception.

RENDERED FOR DEPRESSION

Enhanced color saturation. More apparent sunlight. Smoothed visual clutter. Ambient faces made slightly warmer in expression. Perceived spatial dimensions widened.

RENDERED FOR ANXIETY

Reduced crowd density in peripheral vision. Softened sharp angles. Slowed apparent motion of surrounding objects. Muted harsh sounds.

None of this is speculative. Color and lighting modification, spatial perception alteration, and cross-modal illusion have each been demonstrated independently in AR and VR research. What has not been demonstrated is the unified, adaptive, cloud rendered composition. That is the only missing piece.

SOURCES Regenbrecht et al. (2022), IEEE Pervasive Computing 21(3), 84–91; Wright (2014), Frontiers in Systems Neuroscience 8, 56; Eckhoff et al. (2021), IEEE ISMAR.

The clinics are not waiting. Three programs are already in patients' environments.

EXPANDXR

LLM-driven conversational AR characters overlaid into patients' physical environments for PTSD and anxiety exposure therapy, on HoloLens and Vision Pro.

AR-3MDR

Trauma-processing stimuli overlaid onto real-world walking paths. Published case study: PCL-5 score falling from 60 to 14 over eight sessions.

CREAM DEPRESSION

AR plus EEG neurofeedback overlaying emotionally challenging content onto adolescents' real environments to retrain attention away from depressive cues.

All early stage; none FDA cleared; none generative. Current systems use conventional engines and pre-built content. The next generation uses adaptive generation. The gap is integration complexity, not fundamental capability.

SOURCES Javanbakht et al. (2024), Eur. J. Psychotraumatology 15(1), 2418248; Raboy et al. (2025), Psychiatry & Clinical Psychopharmacology 35(Suppl. 1), S176–S183; Woody (2023), Univ. of Pittsburgh Dept. of Psychiatry.

The regulatory road is not theoretical. It has been walked twice.

ENDEAVORRX · DE NOVO DEN200026 (2020)

The first prescription treatment delivered through a video game, for ADHD in children eight to 12. A genuine therapeutic advance that works with the neurology rather than against it. Expanded to adolescents in 2023; adult OTC clearance in 2024.

RELIEVRX · DE NOVO DEN210014 (2021)

Prescription VR-based CBT for chronic low back pain, extending the precedent from software-only to hardware-dependent immersive systems. A headset is now a dispensable medical device.

The concern is not these products. It is the pathway they created, and where it leads when applied to an intervention that renders the patient's entire experienced reality.

SOURCES FDA (2020a) press release; FDA (2020b), De Novo summary DEN200026; Akili Interactive (2020, 2023, 2024) press releases; AppliedVR (2021); FDA (2021), De Novo summary DEN210014.

Four phases from trial to eyewear aisle.

1 **Clinical trial.** AR environmental augmentation for treatment resistant depression: clinician supervised, session limited, sham-controlled, PHQ-9 at 12 weeks.

2 **De Novo submission.** On the EndeavorRx and RelieVRx precedent, FDA creates a new product code for the new category.

3 **Clearance and indication expansion.** From treatment resistant depression to major depression, generalized anxiety, PTSD, each step on the EndeavorRx trajectory.

4 **Consumer availability.** An OTC "wellness" variant by 510(k), following EndeavorOTC: stress reduction and mood enhancement, no prescription required.

SOURCES Gilly, We Happy Few, sec. III.C; FDA De Novo summaries DEN200026, DEN210014; Akili Interactive (2024).

The Five Properties

What separates a prescribed reality from every drug and device before it

Not bugs in an implementation. Structural features of any cloud rendered perceptual system.

The intervention never changes. The population expands, the indication softens, the oversight attenuates.

OPIOIDS

Acute post-surgical pain → chronic pain management → demand far beyond indicated populations.

BENZODIAZEPINES

Panic disorder → generalized anxiety → subclinical stress and situational prescribing.

ADHD STIMULANTS

Narrow pediatric indication → broad adult prescribing → off-label cognitive enhancement.

ENDEAVORRX

Children eight to 12 → adolescents 13 to 17 → adults, over the counter. Four years, start to finish.

SOURCES Gilly, We Happy Few, sec. IV.A; Akili Interactive (2020, 2023, 2024).

No prior therapeutic, digital or chemical, has carried all five.

1. **Remote mutability.** A dispensed pill is chemically fixed. A rendered reality is a service whose parameters can be changed after deployment, without the patient's explicit awareness.
2. **Platform dependency.** Psilocybin does not require the manufacturer's servers. This treatment ceases to function if the provider folds, repriced, or rewrote its terms.
3. **Perceptual opacity.** Sustained modification erodes the baseline it would be measured against. Removal is not a return to baseline; it is a novel negative experience.
4. **Cultural encoding.** The model must generate some environment, and whatever it generates encodes culturally contingent assumptions. Whose version of "well" is the patient living in?
5. **No patient-side verifiability.** A pill can be lab-tested against the prescription. You cannot lab test a prescribed reality.

SOURCES Gilly, We Happy Few, sec. IV.B; Wright (2014), Frontiers in Systems Neuroscience 8, 56; Reuter (2024), BioPharma Dive.

PSILOCYBIN AS CONTRAST CASE

The molecule was never the problem. The container was.

Psilocybin therapy is built against dependency: two to three supervised sessions, preparation and integration, the therapist as the off-ramp. The same molecule administered daily, without a container, would carry an entirely different risk profile. Session limited AR is the responsible container; the expansion pattern is what dissolves containers.

REMOVAL AS NEGATIVE EVENT

If the therapy is "your environment looks better," discontinuation is not neutral: the real world now looks worse than what the patient adapted to, and the calibration to the actual environment is gone.

No study in the 2024–2026 literature examines this, because no clinical system runs long enough to produce it. The gap is structurally invisible to session-limited trial designs.

SOURCES Carhart-Harris et al. (2021), NEJM 384(15), 1402–1411; Lundin et al. (2023), JMIR Mental Health 10, e43240; Gilly, We Happy Few, sec. V.

In pharmacy, five roles share the chain and every handoff is verifiable. Here, they collapse into the platform.

Who designed the therapeutic template? Who trained the adaptive model? Who can modify parameters after deployment? Is the patient informed when they change? Can the patient reject a specific modification and stay in treatment? For cloud rendered care, one actor designs, generates, delivers, modifies, and monitors, and the patient has no independent check.

THE POLITICAL ACCELERANT

An administration opposed to psychedelic therapy but confronted with treatment-resistant-depression data gets a resolution: the same indication, addressed with technology instead of drugs. Innovation, not decriminalization. The populations most skeptical of institutional medicine may accept it with less resistance precisely because it does not look like medicine.

It looks like glasses.

Populations and Safeguards

Who is affected, and what should be required before clearance

Four affected populations, none represented in the initial clinical trial.

Four populations the trial will never see.

Voluntary users with perceptual dependency. Trials measure eight to 12 weeks. Consumer use has no defined endpoint, and no longitudinal data on sustained modification exists.

Involuntary users under mandate. Insurers, employers, courts, and institutional care all gain incentives to require it. Prescribed reality as a condition of employment, parole, or coverage.

The people around the user. A caregiver whose environment is softened may not notice deterioration. A parent whose anxiety is visually managed may not perceive the danger cues their child needs them to notice.

Those who cannot access it. Once the option to modify reality exists, unmodified reality feels worse by comparison, the same baseline shift documented for photo filters and body image.

SOURCES Gilly, We Happy Few, sec. VII; Fardouly & Vartanian (2016), Current Opinion in Psychology 9, 1–5.

What should be required before clearance.

REGULATORY

Premarket submissions must address all five properties: update and modification protocols, platform continuity plans, baseline preservation, training-data representation analysis, and verification mechanisms or explicit disclosure of their absence.

CLINICAL

Mandatory longitudinal follow-up beyond active treatment; structured removal periods analogous to drug washout; outcome measures for perceptual dependency, adaptation, and baseline drift, not symptom scores alone.

TECHNICAL

Local-first architectures that minimize cloud dependency; environment specifications that are serializable, inspectable, and independently verifiable; modification logs accessible to patient and clinician, an audit trail for experienced reality.

ETHICAL

Consent that names the unique properties: the treatment is rendered rather than fixed, parameters may change, and removal may produce negative perceptual effects with no pharmacological equivalent.

SOURCES Gilly, We Happy Few, sec. VIII.

The citizens of Wellington Wells took Joy because it worked. The question is what they stopped being able to see.

The regulatory pathway exists. The clinical motivation exists. The component technologies exist. The governance for remote mutability, platform dependency, perceptual opacity, cultural encoding, and unverifiability does not.

The gap between "this works for depression" and "everyone should wear these" is the gap that separated post-surgical pain relief from the opioid crisis. The intervention was not the problem. The container was.

SOURCES Gilly, We Happy Few, sec. IX; Compulsion Games (2018).

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