

The Psychedelic Psychotherapy Paradox: Ethical Analyses of Informed Consent, Trial Criteria, and Social Justice

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Abstract:

Driven by a convergence of cultural shifts and major regulatory advancements—such as the April 2026 U.S. Executive Order on serious mental illness and the subsequent issuance of FDA National Priority Vouchers—global interest in psychedelic medicine is accelerating. Globally, the regulatory landscape varies significantly; approaches range from fully authorized medical frameworks in Australia and Canada, to compassionate use pathways in Switzerland and Israel, and functional legality or decriminalization models in the Netherlands, Jamaica, Portugal, and Spain. This paper evaluates these international discourses surrounding the production, regulation, and clinical application of multiple psychedelic classes. Crucially, the paper navigates profound ethical and clinical tensions. First, it contrasts the medicalized "psychedelic renaissance" with Indigenous traditions that honor plant medicines as sentient entities. Second, it interrogates the prevailing "drug as catalyst" dualism in psychedelic-assisted psychotherapy. The paper argues that while current clinical trials narrowly evaluate the acute safety of the medicine alone, these fundamentally holistic treatments demand an equally holistic trial scope. Specifically, it makes the case for measuring the cumulative impacts of both the medicines and specialized, somatic trauma-informed modalities—such as Accelerated Experiential Dynamic Psychotherapy (AEDP) and Eye Movement Desensitization and Reprocessing (EMDR)—in an alchemic, integrated sense. It concludes by highlighting the paradox where strict trial exclusion criteria bar the severely ill populations these medicines aim to serve.

Keywords:

Psychedelic-Assisted Psychotherapy, Biomedical Ethics, Trauma-Informed Modalities, Global Health Policy, Neuroplasticity.