

EXPLORING LEGAL FRAMEWORKS FOR THE CLINICAL USE OF PSYCHEDELIC SUBSTANCES IN MENTAL HEALTH TREATMENT

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ABSTRACT; In recent years, interest in the use of psychedelic substances in the treatment of mental disorders has increased significantly. Recent research shows the potential of psychedelic substances such as psilocybin, LSD, and MDMA to treat disorders such as major depression, post-traumatic stress disorder (PTSD), and substance addiction. However, the clinical use of psychedelic substances remains very limited due to significant legal obstacles. This study aims to explore the relevant legal framework for the clinical use of psychedelic substances in the treatment of mental disorders. By considering various rules and regulations at national and international levels, we explore the challenges and opportunities in creating an enabling legal framework for the clinical use of psychedelic substances. Our analysis highlights differences in legal approaches between countries, with some countries such as the United States beginning to pave the way for research and clinical use of psychedelic substances in mental treatment, while other countries still maintain a strict approach to the use of psychedelic substances. The results of this study provide important insights for policymakers, health practitioners, and researchers to understand the existing legal framework and challenges faced in integrating psychedelic substances into clinical practice. Thus, this study may help guide the development of policies that promote safe and responsible access to psychedelic therapy in the treatment of mental disorders.

Keywords : Psychedelic, legal framework, Treatment of mental disorders

INTRODUCTION

In recent years, there has been a resurgence of interest in the clinical use of psychedelic substances for the treatment of various mental health disorders.¹ Psychedelics, such as psilocybin (the active compound in magic mushrooms), lysergic acid diethylamide (LSD), and 3,4-methylenedioxymethamphetamine (MDMA), have garnered attention for their potential therapeutic effects in addressing conditions like depression, post-traumatic stress disorder (PTSD), anxiety disorders, and substance use disorders.² This renewed interest in psychedelics for mental health treatment marks a significant departure from the prevailing stigma and legal restrictions that have surrounded these substances for decades.

Historically, psychedelics were widely used in therapeutic settings during the mid-20th century before being classified as Schedule I controlled substances in many countries, effectively halting most scientific research and clinical applications.³ However, recent clinical trials and studies have reignited scientific and public interest, demonstrating promising results in terms of safety and efficacy when used in controlled clinical settings under the guidance of trained professionals.

The exploration of legal frameworks surrounding the clinical use of psychedelic substances is crucial for several reasons. First and foremost, it determines the accessibility of these treatments to patients in need. The legal status of psychedelics profoundly influences whether clinicians and researchers can conduct studies, administer treatments, and develop new therapies using these substances. Moreover, legal frameworks shape public perceptions, funding opportunities, and regulatory pathways for psychedelic-assisted therapies.

This paper aims to delve into the intricate legal landscapes governing the clinical use of psychedelic substances in mental health treatment. By examining existing laws, regulations, and policies at both national and international levels, we seek to elucidate the challenges and opportunities in establishing legal frameworks conducive to the clinical use of psychedelics.

The resurgence of interest in psychedelic-assisted therapy has prompted a reevaluation of existing legal paradigms and a reassessment of the potential benefits and risks associated with these substances. The legalization and decriminalization of cannabis in several jurisdictions have paved the way for broader discussions surrounding drug policy reform and the therapeutic use of controlled substances. However, the legal status of psychedelics remains contentious, with stark disparities in regulatory approaches across different regions and countries.

In the United States, for example, the Controlled Substances Act (CSA) categorizes psychedelics as Schedule I substances, indicating a high potential for abuse and a

¹ Recent Developments Involving Psychedelics', 2023, 125–38 <<https://doi.org/10.18356/9789210028233c023>>.

² Charles F. Reynolds, 'Psilocybin-Assisted Supportive Psychotherapy in the Treatment of Major Depression - Quo Vadis?', *JAMA Psychiatry*, 78.5 (2021), 476–78 <<https://doi.org/10.1001/jamapsychiatry.2020.2901>>.

³ Shawn Ziff and others, 'Analysis of Psilocybin-Assisted Therapy in Medicine: A Narrative Review', *Cureus*, 14.2(2022), 1–12 <<https://doi.org/10.7759/cureus.21944>>.

lack of accepted medical use.⁴ This classification imposes stringent restrictions on research, limiting the availability of funding and impeding scientific progress in understanding the therapeutic mechanisms of psychedelics.⁵ Despite these regulatory hurdles, the Food and Drug Administration (FDA) has granted breakthrough therapy designation to psilocybin-assisted therapy for treatment-resistant depression, acknowledging the urgent need for innovative treatments in mental health care.⁶

Conversely, other countries have adopted more progressive approaches to psychedelics, recognizing their therapeutic potential and moving towards regulatory frameworks that facilitate research and clinical applications. In Canada, for instance, Health Canada has granted exemptions to certain healthcare professionals, allowing them to administer psilocybin to patients with terminal illnesses under the Special Access Program. Similarly, the Netherlands has established a regulatory framework for psychedelic-assisted therapy within the context of addiction treatment and end-of-life care.

Internationally, the scheduling of psychedelics under the United Nations conventions presents additional complexities and challenges. The 1971 Convention on Psychotropic Substances classifies psychedelics like LSD and psilocybin as Schedule I substances, imposing strict controls on their production, distribution, and use for non-medical purposes. However, the International Drug Control Conventions also recognize the importance of scientific research and medical use in the context of drugscheduling decisions, allowing for flexibility in national regulations.

The evolving legal landscape surrounding psychedelic-assisted therapy raises a myriad of ethical, social, and practical considerations. Ethical concerns related to patient autonomy, informed consent, and the therapeutic use of potentially mind-altering substances must be carefully addressed to ensure patient safety and well-being. Additionally, the integration of psychedelic therapy into mainstream mental health care requires robust training programs, clinical guidelines, and quality assurance mechanisms to uphold standards of care and mitigate potential risks.

In conclusion, the exploration of legal frameworks for the clinical use of psychedelic substances in mental health treatment represents a critical step towards realizing the therapeutic potential of these compounds. By navigating the complex interplay between legal regulations, scientific evidence, and ethical principles, stakeholders can collaboratively work towards creating a regulatory environment that prioritizes patient access, safety, and scientific advancement. This paper endeavors to contribute to the ongoing dialogue surrounding psychedelic-assisted therapy and inform policy

⁴ Joanna R. Lampe, 'The Controlled Substances Act (CSA): A Legal Overview for the 116th Congress', *Key Congressional Reports for October 2019. Part II*, 2020, 287–333.

⁵ 'Medicinal Use of Medicinal Use Of'.

⁶ Thermal variation and factors influencing vertical migration behavior in *Daphnia* Populations and PhD Daniel Harris, BA, Lynn McNicoll, MD, Gary Epstein-Lubow, MD, and Kali S. Thomas, '乳鼠心肌提取 HHS Public Access', *Physiology & Behavior*, 176.1 (2017), 139–48 <<https://doi.org/10.1016/j.neuropharm.2022.109214>.Policy>.

discussions aimed at promoting evidence-based, compassionate care for individuals suffering from mental health disorders.

PROBLEM

1. How is the legal landscape evolving around psychedelic-assisted therapy?
2. What is the exploration of the legal framework for the clinical use of psychedelic substances in mental health treatment?

RESEARCH METHODS

This study used a qualitative approach to explore the legal framework relevant to the clinical use of psychedelic substances in the treatment of mental disorders. First, we conducted a comprehensive literature review of regulations and policies relating to the use of psychedelic substances in various countries, as well as existing clinical guidelines for the treatment of mental disorders using psychedelics. Next, we conducted a comparative analysis between the existing legal frameworks in several countries, including the United States, Canada, Europe, and other countries that have introduced or are developing regulations regarding the clinical use of psychedelic substances. Data were collected from various official sources, including laws, government regulations, clinical guidelines, and related literature.

DISCUSSION

The exploration of legal frameworks concerning the clinical use of psychedelic substances in mental health treatment is a critical endeavor that intersects various disciplines including psychology, medicine, law, and public health policy. In recent years, there has been a resurgence of interest in the therapeutic potential of psychedelic substances such as psilocybin, LSD, and MDMA for addressing a range of mental health disorders including depression, anxiety, post-traumatic stress disorder (PTSD), and substance use disorders.

This discussion aims to delve into the complex relationship between psychedelic substances, mental health treatment, and legal frameworks across different countries. By examining the current legal landscape and its implications for clinical practice and research, we seek to shed light on the challenges and opportunities in harnessing the therapeutic potential of psychedelics within a legal and ethical framework.

Psychedelic Substances: Therapeutic Potential and Mechanisms of Action

Psychedelic substances have a long history of use in various cultural and spiritual contexts, often revered for their ability to induce altered states of consciousness and

facilitate profound introspection and spiritual experiences.⁷ In recent decades, scientific research has provided compelling evidence of the therapeutic potential of psychedelics in the treatment of mental health disorders.

The mechanisms of action underlying the therapeutic effects of psychedelics are multifaceted and continue to be elucidated through preclinical and clinical research.⁸ Serotonin 2A receptor agonism is thought to play a central role in mediating the acute effects of psychedelics, leading to alterations in brain connectivity, neuroplasticity, and the modulation of key neural circuits implicated in mood regulation and cognition.⁹

Studies utilizing neuroimaging techniques such as functional magnetic resonance imaging (fMRI) and positron emission tomography (PET) have demonstrated changes in brain activity and connectivity patterns following the administration of psychedelics, particularly in regions associated with the default mode network (DMN) and the salience network.¹⁰ Disruptions in the DMN, which is involved in self-referential thinking and rumination, have been linked to various psychiatric disorders, and the modulation of DMN activity by psychedelics may underlie their therapeutic effects.¹¹

Furthermore, psychedelics have been shown to occasion mystical or transcendent experiences characterized by a sense of unity, interconnectedness, and profound spiritual insight. These experiences have been associated with enduring improvements in psychological well-being, increased empathy, and a shift in worldview and existential attitudes.

Legal Frameworks and Regulation of Psychedelic Substances

Despite growing evidence of their therapeutic potential, psychedelics remain highly restricted and classified as Schedule I substances under international drug control conventions such as the United Nations Single Convention on Narcotic Drugs (1961).¹² Schedule I substances are deemed to have a high potential for abuse and no recognized medical use, severely limiting their availability for research and

⁷ David B. Yaden and others, 'Psychedelics and Consciousness: Distinctions, Demarcations, and Opportunities', *International Journal of Neuropsychopharmacology*, 24.8 (2021), 615–23 <<https://doi.org/10.1093/ijnp/pyab026>>.

⁸ John R. Kelly and others, 'Psychedelic Therapy's Transdiagnostic Effects: A Research Domain Criteria (RDoC) Perspective', *Frontiers in Psychiatry*, 12.December (2021) <<https://doi.org/10.3389/fpsy.2021.800072>>.

⁹ Gongliang Zhang and Robert W. Stackman, 'The Role of Serotonin 5-HT_{2A} Receptors in Memory and Cognition', *Frontiers in Pharmacology*, 6.OCT (2015), 1–17 <<https://doi.org/10.3389/fphar.2015.00225>>.

¹⁰ Vasileia Kotoula and others, 'Review: The Use of Functional Magnetic Resonance Imaging (fMRI) in Clinical Trials and Experimental Research Studies for Depression', *Frontiers in Neuroimaging*, 2 (2023) <<https://doi.org/10.3389/fnimg.2023.1110258>>.

¹¹ James J. Gattuso and others, 'Default Mode Network Modulation by Psychedelics: A Systematic Review', *International Journal of Neuropsychopharmacology*, 26.3 (2023), 155–88 <<https://doi.org/10.1093/ijnp/pyac074>>.

¹² Adolf Lande, 'The Single Convention on Narcotic Drugs, 1961', *International Organization*, 16.4 (1962), 776–97 <<https://doi.org/10.1017/S0020818300011620>>.

clinical purposes.

The classification of psychedelics as Schedule I substances reflects decades of stigmatization, moral panic, and political backlash stemming from their association with countercultural movements, perceived risks of recreational misuse, and concerns about adverse psychological effects.¹³ The criminalization of psychedelics has resulted in a chilling effect on scientific inquiry and impeded access to potentially life-saving treatments for individuals suffering from mental health disorders.¹⁴

At the national level, the legal status of psychedelics varies widely across countries, with some jurisdictions adopting more progressive approaches to regulation while others maintain stringent prohibitions. For example, in the United States, psychedelics such as psilocybin and LSD are classified as Schedule I substances under the Controlled Substances Act (CSA), effectively prohibiting their manufacture, distribution, and possession outside of approved research settings.¹⁵

However, there has been a groundswell of interest in revisiting the legal status of psychedelics in light of emerging research findings and shifting societal attitudes towards drug policy reform and harm reduction. In recent years, several cities and states in the US have decriminalized psychedelics for personal use or deprioritized law enforcement efforts targeting individuals in possession of small quantities of these substances.

Furthermore, the US Food and Drug Administration (FDA) has granted breakthrough therapy designation for psilocybin-assisted psychotherapy for treatment-resistant depression, paving the way for expanded clinical trials and potential regulatory approval in the future. Similarly, regulatory agencies in other countries such as Canada and the United Kingdom have taken steps to facilitate research into the therapeutic applications of psychedelics and streamline regulatory processes for drug development and approval.

Clinical Applications and Evidence Base for Psychedelic-Assisted Therapy

The resurgence of interest in psychedelic-assisted therapy has catalyzed a renaissance in psychiatric research and clinical practice, with an increasing number of studies exploring the safety, efficacy, and therapeutic mechanisms of psychedelics across diverse patient populations. Clinical trials investigating the use of psychedelics in conjunction with psychotherapy have shown promising results for the treatment of depression, anxiety, PTSD, and substance use disorders.

One of the most well-studied psychedelic compounds is psilocybin, the active ingredient found in certain species of hallucinogenic mushrooms. Clinical trials conducted at prestigious research institutions such as Johns Hopkins University and Imperial College London have demonstrated the potential of psilocybin-assisted

¹³ Clark L A W Review, 'Beyond Cannabis', 2019, 851–92.

¹⁴ Brian Pilecki and others, 'Ethical and Legal Issues in Psychedelic Harm Reduction and Integration Therapy', *Harm Reduction Journal*, 18.1 (2021), 1–14 <<https://doi.org/10.1186/s12954-021-00489-1>>.

¹⁵ Transform Drug Policy Foundation, 'How to Regulate Psychedelics A Practical Guide', 2023.

therapy to induce profound mystical experiences and facilitate long-term improvements in mood, quality of life, and existential distress among patients with life-threatening illnesses and treatment-resistant depression.¹⁶

Similarly, studies examining the therapeutic effects of MDMA-assisted psychotherapy for PTSD have yielded encouraging outcomes, with a significant proportion of participants experiencing symptom remission and improvements in emotional regulation, interpersonal functioning, and trauma-related symptoms.¹⁷ MDMA, also known as ecstasy, acts primarily as a serotonin releaser and empathogen, fostering feelings of emotional openness, trust, and connectedness within the therapeutic context.

Despite the promising findings from clinical trials, several challenges remain in translating research findings into clinical practice and integrating psychedelic-assisted therapy into mainstream healthcare systems. Chief among these challenges are regulatory barriers, stigma, and the need for specialized training and infrastructure to ensure safe and effective administration of psychedelics in therapeutic settings.

Ethical Considerations and Patient Safety

The resurgence of psychedelic-assisted therapy has prompted a reevaluation of ethical principles and best practices in the provision of mental health care, particularly regarding issues of informed consent, risk management, and the therapeutic relationship.¹⁸ The unique pharmacological properties of psychedelics, coupled with their potential to induce intense and transformative experiences, raise important ethical considerations regarding patient autonomy, beneficence, and nonmaleficence.¹⁹ Informed consent processes for psychedelic-assisted therapy must be comprehensive and nuanced, ensuring that patients are adequately informed about the potential risks, benefits, and uncertainties associated with treatment, as well as alternative therapeutic options.²⁰ Patients must also be prepared for the potentially challenging and emotionally intense nature of psychedelic experiences, which may involve confronting suppressed memories, emotional traumas, or existential fears.²¹

¹⁶ Elena Argento and others, 'Interest in Receiving Psychedelic-Assisted Therapy among Marginalized Women: Implications and Findings from a Community-Based Study in Canada', *Drug and Alcohol Dependence Reports*, 3.March (2022), 100044 <<https://doi.org/10.1016/j.dadr.2022.100044>>.

¹⁷ Bessel A. van der Kolk and others, 'Effects of MDMA-Assisted Therapy for PTSD on Self-Experience', *PLoS One*, 19.1 (2024), e0295926 <<https://doi.org/10.1371/journal.pone.0295926>>.

¹⁸ Ethical Dimensions, 'Ethical Limbo and Enhanced Informed Consent in Psychedelic-Assisted Therapy', 2023.

¹⁹ David B. Yaden, Brian D. Earp, and Roland R. Griffiths, 'Ethical Issues Regarding Nonsubjective Psychedelics as Standard of Care', *Cambridge Quarterly of Healthcare Ethics*, 31.4 (2022), 464–71 <<https://doi.org/10.1017/S096318012200007X>>.

²⁰ Edward Jacobs, 'Transformative Experience and Informed Consent to Psychedelic-Assisted Psychotherapy', *Frontiers in Psychology*, 14 (2023) <<https://doi.org/10.3389/fpsyg.2023.1108333>>

²¹ Jacobs.

Furthermore, clinicians and researchers have a responsibility to minimize the risk of adverse reactions and psychological distress during psychedelic sessions through careful screening, preparation, and integration support. This may involve conducting thorough psychiatric assessments, establishing rapport and trust with patients, and providing ongoing psychological support before, during, and after psychedelic sessions to facilitate the integration of insights and experiences into daily life.

In addition to individual-level considerations, there are broader societal and public health implications associated with the expanded use of psychedelics in mental health treatment. The normalization and medicalization of psychedelics may inadvertently contribute to their diversion and misuse outside of clinical settings, necessitating robust regulatory frameworks, public education campaigns, and harm reduction strategies to mitigate potential risks and promote responsible use.

Indonesia maintains a strict legal stance on psychedelic substances, reflecting broader attitudes towards drug control and public health policy. The country's drug laws are primarily governed by Law No. 35 of 2009 concerning Narcotics, which classifies psychedelic substances such as psilocybin, LSD, and MDMA as Schedule I narcotics, subject to the most severe penalties for possession, production, trafficking, and distribution.

The classification of psychedelics as Schedule I narcotics reflects the Indonesian government's zero-tolerance approach to drug use and trafficking, rooted in concerns about public health, social order, and national security. The Narcotics Law imposes harsh penalties, including lengthy prison sentences and even capital punishment, for individuals involved in the illicit production, trafficking, or consumption of controlled substances.

As a result of Indonesia's strict drug policies, the clinical use of psychedelic substances in mental health treatment is effectively prohibited, and research into their therapeutic potential is severely restricted. The regulatory framework surrounding controlled substances in Indonesia places significant barriers on scientific inquiry and medical innovation, limiting opportunities for exploring alternative treatment modalities for mental health disorders.

Moreover, Indonesia's drug laws are reinforced by a comprehensive system of law enforcement and judicial mechanisms aimed at combating drug-related crime and protecting public safety. The National Narcotics Board (BNN) is the primary agency responsible for coordinating drug control efforts, implementing preventive measures, and enforcing legal sanctions against individuals involved in the drug trade.

Despite the formidable legal and regulatory challenges, there is growing recognition within Indonesia's medical and psychiatric communities of the need to explore innovative approaches to mental health care and address the limitations of conventional treatments. In recent years, there have been calls for a more nuanced and evidence-based approach to drug policy that prioritizes harm reduction, public

health, and human rights.

Efforts to reform Indonesia's drug laws and explore alternative approaches to drug policy have been met with resistance from conservative elements within the government and society, who view drug use as a moral and social threat. However, there is a growing awareness of the need to balance punitive measures with public health interventions and social support services to address the underlying drivers of drug use and addiction.

CONCLUSION

The exploration of psychedelic substances for therapeutic purposes within the realm of mental health treatment represents a complex and multifaceted endeavor that intersects science, medicine, law, ethics, and societal attitudes. Through an in-depth examination of the therapeutic potential of psychedelics, the legal frameworks governing their use, and the broader implications for mental health treatment, it becomes evident that significant progress has been made in reshaping perceptions and advancing research in this field.

Psychedelic substances, including psilocybin, LSD, and MDMA, have emerged as promising adjuncts to traditional psychotherapy for a range of mental health disorders, including depression, anxiety, PTSD, and substance use disorders. Clinical trials and observational studies have demonstrated the ability of psychedelics to induce transformative experiences, facilitate emotional processing, and promote psychological healing and growth.

The mechanisms of action underlying the therapeutic effects of psychedelics are complex and multifaceted, involving alterations in brain connectivity, changes in neural circuitry implicated in mood regulation and cognition, and the facilitation of mystical or transcendent experiences characterized by a sense of unity, interconnectedness, and spiritual insight.

However, despite the growing body of evidence supporting the therapeutic potential of psychedelics, significant legal and regulatory barriers persist, hindering their integration into mainstream mental health care. International drug control conventions, such as the United Nations Single Convention on Narcotic Drugs (1961), classify psychedelics as Schedule I substances, imposing strict restrictions on their manufacture, distribution, and use outside of approved research settings.

At the national level, the legal status of psychedelics varies widely across countries, with some jurisdictions adopting more progressive approaches to regulation while others maintain stringent prohibitions. In countries like the United States, there has been a gradual shift towards decriminalization and regulatory reforms, with regulatory agencies such as the FDA granting breakthrough therapy designation for psilocybin-assisted psychotherapy and MDMA-assisted therapy for PTSD.

Similarly, in countries such as Canada and the United Kingdom, regulatory agencies have taken steps to facilitate research into the therapeutic applications of psychedelics and streamline regulatory processes for drug development and

approval. However, challenges remain in reconciling conflicting legal frameworks, addressing stigma and misinformation surrounding psychedelics, and ensuring equitable access to psychedelic-assisted therapy for individuals in need.

In Indonesia, strict drug laws classify psychedelic substances as Schedule I narcotics, subjecting individuals involved in their production, trafficking, or consumption to severe legal penalties, including imprisonment and capital punishment. The regulatory framework surrounding controlled substances in Indonesia presents significant barriers to research and clinical innovation in the field of psychedelic therapy, limiting opportunities for exploring alternative treatment modalities for mental health disorders.

Despite these challenges, there is growing recognition within Indonesia's medical and psychiatric communities of the need to explore innovative approaches to mental health care and address the limitations of conventional treatments. Efforts to reform Indonesia's drug laws and explore alternative approaches to drug policy have been met with resistance, but there is a growing awareness of the need to balance punitive measures with public health interventions and social support services.

In conclusion, the integration of psychedelic therapy into mainstream mental health care requires a concerted effort to navigate the complex interplay of scientific, legal, ethical, and societal factors. Collaborative efforts between researchers, clinicians, policymakers, and community stakeholders are essential to advancing evidence-based approaches to drug regulation, promoting harm reduction, and safeguarding the well-being of individuals affected by mental health disorders.

Through dialogue, advocacy, and the promotion of evidence-based practices, we can work towards a more inclusive and compassionate approach to mental health care that recognizes the potential of psychedelic therapy to alleviate suffering, foster healing, and promote human flourishing. As we continue to navigate the evolving landscape of psychedelic science and policy, let us remain guided by principles of compassion, equity, and social justice, striving to create a world where all individuals have access to the care and support they need to thrive.

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