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The frontiers of new psychedelic therapies: A survey of sociological themes and issues

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Abstract

Psychedelic compounds are on the cusp of being approved by medical regulators for treatment-resistant mental health disorders. Following promising clinical trials, and as rates of mental ill health rise globally, psychedelic medicine presents a new paradigm for treating depression, anxiety, addiction and post-traumatic stress disorder. The novelty of psychedelic therapies, the cultural stigma they elicit, and the challenges of regulation and implementation urgently call for a sociological lens onto this emerging field of psychiatry. This article identifies key sociological issues related to the medicalisation of psychedelic-assisted therapies. It begins with a brief overview of the field's history and current treatment approaches. We then identify and critically examine three areas of sociological interest: the of role advocacy in the advancement of scientific research and the destigmatisation of psychedelics; issues related to the medicalisation and pharmaceuticalisation; and integration into healthcare systems. The challenges and affordances of psychedelics to existing therapeutic models, regulation and monetisation are highlighted, and the socio-political context of the pharmaceutical industry, research, investment and implementation is examined. Drawing on health science literature in this field, the article offers a sociological lens on clinical psychedelic

medicine as an emerging and potentially paradigm shifting field of psychiatry and psychotherapy.

KEYWORDS
health advocacy, medicalisation, mental health, psychedelic medicine, psychedelic-assisted therapies, psychiatry

1 | INTRODUCTION

Psychedelic medicine is emerging as a promising clinical modality for a range of treatment-resistant mental health disorders. Following its early promise in the 1950s and 1960s and its subsequent decline in the early 1970s (Oram, 2018), the past decade has seen concerted effort to destigmatise and promote the therapeutic benefits of psychedelic-assisted therapies (Noorani, 2020; Sessa, 2012). Clinical trials are yielding encouraging results, leading to excitement from researchers and prominent advocates about new treatment options. With growing evidence demonstrating efficacy and safety, psychedelic compounds are on the cusp of being approved by medical regulators in a number of countries. As rates of mental illness continue to rise globally, psychedelic medicine presents a new paradigm for the treatment of depression, anxiety, addiction and post-traumatic stress disorder (PTSD). Given the novelty of this therapeutic modality, the cultural stigma psychedelics elicit, and the challenges posed to medical research, regulation and implementation, a sociological lens is urgently required to illuminate the societal implications of the so-called *psychedelic renaissance* (Sessa, 2012) and its incorporation into clinical psychiatry.

The term *psychedelic*, first used by Humphry Osmond (1957), means 'mind manifesting'. It describes the 'classic psychedelics'—lysergic acid diethylamide (LSD), psilocybin, mescaline and n.n–dimethyltryptamine (DMT)—and hundreds of synthetic and naturally occurring compounds that have similar neuropharmacological action and/or subjective effects. Understandings of the therapeutic value of psychedelics are varied and contested, both within and beyond Western medical frameworks. Indigenous knowledges, modern spiritual beliefs and underground therapeutic practices have contributed to contemporary discourses of psychedelic medicine. Yet it is largely the emerging scientific understandings and clinical trial results—at times informed or supported by or even at odds with traditional or alternative perspectives—that have generated large research programmes, institutional legitimacy and public interest. While the field of psychedelic medicine encompasses a diverse range of social actors and a wide variety of interests and influences, in this paper, we focus primarily on formal health care and developments that have followed promising clinical trials investigating psychedelic-assisted therapy for severe mental health conditions.[1]

Psychedelics are a unique class of psychoactive drugs (Nichols, 2016). Under their effects, users can experience profound mental states often involving 'a perception of sacredness and a direct intuitive knowledge characterised as ineffable; a sense of transcendence of time and space; experiences of oceanic boundlessness [and] significantly higher levels of peace, harmony, joy, and happiness' (Winkelman, 2017, p. 3). At higher doses, users commonly report mystical-type experiences and a sense of ego dissolution (Griffiths et al., 2006; Nour et al., 2016). Psychedelics can elicit dreamlike experiences populated with hallucinations, bizarre visions, synaesthesia, childhood memories and personal revelations. These compounds stand in stark contrast to conventional psychiatric pharmacology, which seeks to normalise mood. It is precisely these profound and extraordinary subjective experiences that researchers suggest underpin the therapeutic mechanism (Yaden & Griffiths, 2021). Psychedelic medicine thus presents a radical intervention in mainstream psychiatry. Here we focus primarily on developments in the United States (US), United Kingdom (UK) and Australia, but acknowledge that this is a flourishing research field internationally.

Drawing on emerging literature from the health and social sciences, this article identifies key sociological issues related to the medicalisation of psychedelics. We begin by briefly charting the history and current direction of the field. We then identify and critically examine three key areas of sociological interest: the role of advocacy in the

advancement of medical research and the destigmatisation of psychedelic compounds; issues arising from medicalisation and pharmaceuticalisation; and integration into healthcare systems. The challenge psychedelics pose to existing therapeutic models, regulation and monetisation are highlighted, and the socio-political context of the pharmaceutical industry, research, investment and implementation is examined. We also note the longstanding 'underground' use of psychedelics and the broader psychedelic cultures that have evolved alongside and in conversation with scientific and medical discourse. However, our primary focus is the field as it is unfolding in medical research settings. The article offers a lens for understanding the implications of psychedelic assisted therapy as an emerging field of psychiatric medicine and psychotherapy.

2 | HISTORICAL SKETCH AND OVERVIEW

Psychedelic substances have a long history of use for ceremonial, spiritual and healing purposes. Naturally occurring compounds such as psilocybin, mescaline and DMT are well documented as having shamanic and medicinal value for many traditional cultures (Grob & Grigsby, 2021). Western medicine and science began researching these compounds in the early twentieth century, with German studies in the 1920s examining the psychological effects of mescaline (Jay, 2019). Further research interest followed Albert Hofmann's chance discovery in 1943 of the effects of LSD—a compound that he had first synthesised several years earlier (Hofmann, 1979; Langlitz, 2013). During the 1950s and 1960s, as interest grew in the therapeutic potential of psychedelics, clinical trials and experiments became widespread in Europe and the US (Dyck, 2008; Nichols, 2016). Psychiatrists and psychologists investigated the use of psychedelics to treat mental health disorders and neuropharmacological studies led scientists to make major breakthroughs in neurochemistry with the discovery of the role of serotonin in brain function (Nichols, 2016). While there were some problems with study designs and the methodologies employed in this early period (Carhart-Harris & Goodwin, 2017; Wheeler & Dyer, 2020), many trials yielded promising results (Grinspoon & Bakalar, 1979). Despite this, the first wave of psychedelic research began to recede in the late 1960s and clinical studies largely ended in the early 1970s, following the US government's scheduling of psilocyn and LSD as Schedule 1 substances, a precedent that shaped domestic policies around the world (Gardner et al., 2019).

Several factors contributed to the shifting research landscape, including new regulatory controls, a waning of interest on the part of pharmacological industries and the difficulties associated with getting the compounds approved as medicines (Langlitz, 2013; Oram, 2018). Under strict legal controls and with a decline in corporate pharmacological interest, research became more difficult, less appealing, and largely came to a standstill for several decades. Politics and public hysteria surrounding illegal drugs linked psychedelics to the counterculture and anti-war movements, painting a picture of moral decline and exaggerating the dangers of these substances (Chi & Gold, 2020; Gardner et al., 2019). As a result, very little scientific or medically sanctioned research was conducted until the second wave of psychedelic research, which began in the 1990s. However, research did continue quietly and independently (Sessa, 2016). The community of psychotherapists and scientists associated with Alexander and Ann Shulgin is perhaps the most prominent example of researchers practicing psychotherapy with both scheduled and unscheduled psychoactive substances without regulatory approval (Shulgin & Shulgin, 1991, 1997). Others, like Stanislav Grof, who was involved in the first wave of psychedelic research, first in the former Czechoslovakia and later at the Maryland Psychiatric Research Center in the US, continued to develop his research during this period by attempting to reproduce similar altered states without administration of psychedelic compounds (Grof, 1988).

The resurgence of clinical psychedelic research began to take shape in the 1990s with Rick Strassman's study of the biological and subjective effects of intravenously administered DMT (Strassman & Qualls, 1994; Winkelman & Sessa, 2019). However, it was a study from Johns Hopkins University led by Roland Griffiths (2006) examining the psychological effects of psilocybin on mystical-type experiences which established the methodological frameworks that have come to characterise current research. Griffiths' research is considered 'the first well-designed, placebo-controlled, clinical study [of a psychedelic compound] in more than four decades' (Nichols, 2006, p. 284). This ground-breaking

study produced astounding results: '67% of the volunteers rated the experience with psilocybin to be either the single most meaningful experience of his or her life or among the top five most meaningful experiences of his or her life' (Griffiths et al., 2006, p. 276). Perhaps more notable, in follow-up analysis, the researchers found significant increases in the personality trait of *Openness*[2] in participants—much higher 'than changes in personality typically observed in healthy adults over decades of life experience' (MacLean et al., 2011, p. 7). The suggestion of personality plasticity has supported the case that psychedelics might present a novel therapy for treatment-resistant mental illness.

Griffiths' (2006) research reinforced findings from the 1950s and 1960s, prompting a new wave of trials. Two recent studies, conducted at Johns Hopkins University (Griffiths et al., 2016) and New York University (Ross et al., 2016), investigated treating life-threatening cancer anxiety with high-dose psilocybin in combination with before and after supportive sessions and/or psychotherapy. Both studies advanced the field by generating evidence of rapid and enduring anti-anxiety and anti-depressive effects of psilocybin assisted-therapies (Carhart-Harris & Goodwin, 2017; Nichols, 2016). Those encouraging results, along with Carhart-Harris, Bolstridge, et al.'s study of psilocybin therapy for treatment-resistant depression (2018), make a strong case for further research (Meikle et al., 2020). Critically, for each of these trials, psychotherapy and 'integration'—the process of integrating the insights and mental processes experienced in the acute phase of the experience into one's regular life—have been integral to the trials. This has both set a precedent for the conduct of further research and reinforced the value, perhaps the necessity, of psychotherapy in combination with psychedelics (Carhart-Harris, Roseman, et al., 2018; Johnson et al., 2008).

Recent research has advanced understandings of how psychedelic compounds affect brain function and there is now emerging evidence of the neuropharmacological underpinnings of their effectiveness for treating psychological disorders. Unlike the widely used selective serotonin reuptake inhibitors antidepressants that increase levels of serotonin (the 'feel good' neurotransmitter) in the brain, classic psychedelics act as agonists at the serotonin 2A receptor (Johnson et al., 2019), broadly affecting perception and cognition in ways not yet fully understood. Studies have established links between these mechanisms and more general brain function and subjective experience. An influential hypothesis posits that psychedelics decrease the operation of the default mode network (DMN; Carhart-Harris, 2019), a part of normal brain function connected to self-referential mental activity (Davey et al., 2016). The theory of DMN dysfunction emerged in line with research suggesting 'a consistent biological correlate of multiple psychiatric disorders' (Doucet et al., 2020, p. 1) and is an important example of contemporary scientific discourse on psychedelic pathways of action. With these disruptions of intrinsic brain networks, researchers have found an increased global functional integration of the brain (Carhart-Harris, 2019). While this work is still in its infancy, emerging findings suggests that DMN disruption, increased global connectivity and the neuroplastic functions (Ly et al., 2018) associated with psychedelics are key factors in their therapeutic action (Nutt, 2019).

Over the past 20 years, clinical trials and research publications have increased dramatically (Winkelman & Sessa, 2019). A 2020 systematic review documents 43 clinical trials of psychedelic-assisted therapies conducted since 1990 (Wheeler & Dyer, 2020), while Perkins et al. (2021) identify around 100 psychedelic clinical trials currently underway globally. Brazil, Canada, Israel, UK, US, Switzerland and Spain are amongst the countries where clinical studies have recently been undertaken (Bache, 2020; dos Santos et al., 2021; Inserra, 2019). MDMA-assisted therapy for treating PTSD is already in phase 3 trials with promising results prompting recommendations for expedited clinical evaluation (Mitchell et al., 2021). Likewise, psilocybin was recently granted 'breakthrough therapy' status in the US for the use in treatment-resistant depression and major depressive disorder (Nichols, 2020). Over the coming years, there will be many more trials and it seems likely, especially in the case of MDMA, that psychedelic compounds will be approved as therapeutic medicines in several national jurisdictions.

3 | ADVOCACY

The resurgence of research interest in psychedelics and the expansion of clinical trials has taken place against the backdrop of support and advocacy from key organisations, prominent individuals and academic research groups in respected universities. This has been critical to both the increasing public attention to psychedelic therapies and to their growing legitimacy. The promotion of medical research in this field can be usefully understood as a form of *health advocacy*—the application of information and resources to reduce health problems and effect systemic change (Christoffel, 2000). Strategic efforts to promote psychedelic-assisted therapies have sought to counter entrenched social stigma, secure public confidence and generate funding for clinical trials (Gardner et al., 2019; Langlitz, 2013; Noorani, 2020). Traditional and new media have also been important to the field's development, amplifying the voices of prominent advocates and widely disseminating research findings.

Groups promoting the benefits of medical research on psychedelics have been active internationally (Gardner et al., 2019). In the US, the Multidisciplinary Association for Psychedelic Studies (MAPS) has played a prominent role advancing psychedelic therapies nationally and internationally. Founded in 1986, MAPS is a non-profit research organisation promoting psychedelic research and education (MAPS, 2021) through direct funding and assistance with clinical trial design and regulatory approval processes (Giffort, 2020). Other non-profits have also been active in the US, including the Heffter Research Institute, founded in 1993, which also helps fund, design and review clinical trials, and the Usona Institute, founded in 2014. Similar organisations have emerged elsewhere, such as the Australian non-profits, Psychedelic Research in Science and Medicine (PRISM) and Mind Medicine Australia (MMA) and the Beckley Foundation in the UK.

Organisations like MAPS and PRISM, as well as university research institutes, such as the Centre for Psychedelic Research at Imperial College London (UK), and the Johns Hopkins Centre for Psychedelic and Consciousness Research (US), provide an important institutional base for the legitimation of psychedelic medicine. Gardner et al. (2019, p. 96) note: 'These and other advocacy organizations have been pivotal in securing the philanthropic support needed to conduct psychedelic research'. They further note that funding from philanthropic bodies has been essential because large pharmaceutical companies have shown little interest in a drug and treatment model limited to only a small number of dosings (see too Perkins et al., 2021; Strauss et al., 2016). Philanthropy has enabled the establishment of major research programmes and, in the UK, the first formal research centre devoted to psychedelic medicine, the Centre for Psychedelic Research at Imperial College London, established in 2019. Upon its opening, the Centre's founder, Dr Robin Carhart-Harris, reflected that the 'new Centre represents a watershed moment for psychedelic science' and he described it as 'symbolic of its now mainstream recognition' (O'Hare, 2019).

The Imperial College Centre placed public engagement and research translation as important priorities. It partnered with filmmakers to create the documentary, *The Psychedelic Drug Trial*, aired on BBC television (Eastall, 2021). It followed a trial comparing psilocybin to a standard medication for depression, closely examining the experiences of several trial participants. People featured in the film spoke of the positive impact of psychedelic therapy on their long-standing depressive mood disorders. Carhart-Harris noted that 'it is this kind of public engagement that helps spread the word and really put it in the public domain and into public consciousness, and that helps to move the needle along' (Imperial College London, 2021).

Martin Williams, Executive Director of the Australian non-profit, PRISM identifies a 'global movement' toward the embrace of psychedelic medicine. Critical to this, he suggests, has been 'a very strategic approach by a number of well organised, effectively run organisations' in the US as well as in the UK, Switzerland, Israel and Canada (ABC Radio, 2021). Williams credits the strategies of these organisations with contributing to a shift in media representations of psychedelics, an increasing interest in medical treatments and greater community awareness. His reflections, echoed by others (e.g., investigative journalist, Michael Pollan), suggest that there has been a broad cultural shift, which has not only seen increased interest from mainstream media, but critically more favourable coverage, with positive stories growing and negative reporting diminishing. Williams links this to an increasing preparedness for

regulatory authorities to acknowledge the therapeutic potential of the very substances that were previously reviled (ABC Radio, 2021).

In addition to the advocacy of established organisations, the benefits of psychedelics have been advanced through interventions by prominent individuals and journalists. According to Aday et al. (2019), 2018 was a 'watershed year' for psychedelic science. While clinical trials and publications in respected journals advanced scientific knowledge, in the public sphere Pollan's, *New York Times* best-seller, *How to Change Your Mind: The New Science of Psychedelics*, took this knowledge to wider audiences. Pollan has said that his book tapped into a social receptiveness to these ideas, a culture 'ready to have this conversation' (London Real, 2018). Not only was the book widely discussed by mainstream media, it led to the American entrepreneur, lifestyle guru and investor, Tim Ferriss, funding the Centre for Psychedelic Research at Imperial College London (Aday et al., 2019) and the newly created Centre for Psychedelic and Consciousness Research at Johns Hopkins University. Ferriss is one of a number of prominent advocates, publicly discussing and widely promoting the benefits of psychedelics based on his own positive experiences (Ferriss, 2020).

While interest in psychedelic therapies increases and the benefits are promoted by medical researchers and popular non-specialist advocates, tensions do exist in relation to future visions of key players. On the one hand, there is concern that psychedelic therapies could be restrictive to the point of being cost prohibitive and thus only a treatment option available to few. On the other hand, there is concern that without strict safeguards, appropriate training of therapeutic guides and regulatory control that the experience of the 1960s may be repeated. In short, it is the view that a 'safety first' and cautious approach is essential. Those favouring strict models of medical research caution against a 'Carte blanche availability to practitioners, without specific protocols and appropriate training' which they argue could be 'harmful to individuals and detrimental to the field' (Perkins et al., 2021, p. 2). This is driven by concerns that enthusiasm generated by high-profile advocates could ultimately undermine the promise of psychedelics if the field is not advanced carefully based on high-quality and robust scientific research.

4 | MEDICALISATION

A sociological lens of medicalisation helps to illuminate the socio-medical frameworks and discourses that structure the advocacy and research paradigms that will shape the entry of psychedelic therapies into formal healthcare. Psychedelics present an unusual case for the creation of a medical treatment insofar as they have long histories and diverse cultural imaginaries attached to them. Not only have psychedelics been used outside Western medicine for thousands of years, they have also been used therapeutically within Western contexts but outside of formal medical frameworks. This has largely been in the form of 'underground' therapies, which Inserra (2019) notes have persisted since the 1950s. The medicalisation of psychedelics thus provides a striking example of a cultural form being co-opted and reconceptualised in medical terms, providing a window onto the broader processes of medicalisation (Conrad, 1975; Illich, 1974; Zola, 1972), biomedicalisation (Clarke et al., 2003, 2021) and pharmaceuticalisation (Abraham, 2010).

Medicalisation refers to social processes by which non-medical problems are constructed in medical terms. It is useful for understanding how medical knowledge increasing came to structure narratives of normativity in psychiatry (and beyond) through the classification of mental health problems.[3] The concept of psychedelic medicalisation provides a framework for explaining how psychedelic-assisted therapy has entered the sanctioned fields of scientific research, experimental psychiatry and government regulation through medical discourse (Gearin & Devenot, 2021; Giffort, 2020; Noorani, 2020). As Gearin and Devenot (2021, p. 3) argue: 'What has emerged is not simply the defining of human problems in medical terms and services, but the tight definition of [psychedelic] substances as medicines, and the profound and potentially diverse changes to consciousness they induce as medicinal and healing'.

The medicalisation of psychedelic practice began in the mid-twentieth century but underwent a hiatus as controls introduced in the late 1960s halted psychiatric and medical research into psychedelic compounds. As Dyck (2008, p. 5) puts it, 'LSD shed its early persona as an experimental pharmacological agent from the 1950s and slowly transformed, in the 1960s, in the public view, into "acid", a revolutionary street drug'. In part, this had the effect of pushing psychedelic

therapies underground. Developing outside the authority of science and medicine, heterogeneous therapeutic practices and cultures emerged (Sessa, 2016). Without the authoritative limitations of Western medical frameworks, practitioners were free to integrate novel approaches, spiritual practices and traditional forms of psychedelic healing from a range of Indigenous cultures into their therapeutic practices.

The work of Alexander and Ann Shulgin is documented in their 'fictional' accounts *PiHKAL* (1991) and *TiHKAL* (1997), which describe the creation and therapeutic exploration of hundreds of psychedelic compounds. These books provide a window into a creative and pioneering scientific and therapeutic practice that operated underground amongst a community of psychotherapists and scientists in San Francisco. Without regulatory oversight, these clandestine research groups operated with an openness to experimentation, integrating spiritual approaches that treated individual problems as a part of the biographical unfolding of a person. While this is only one example of underground psychedelic exploration, it illustrates how the criminalisation of psychedelic compounds facilitated the development of illicit therapies. It also reveals that despite the mainstream retreat, there has been an enduring interest in the use of psychedelic compounds, coupled with therapeutic support, as a treatment modality. While operating outside psychiatric medicine and formal research, this forms an essential part of the wider socio-cultural and unregulated history and trajectory of psychedelic medicine.

The current wave of popular interest in psychedelics has also been adaptive to wider cultural and social trends. The high-tech cultures of Silicon Valley, the wellness industry and new age spiritual movements have all been receptive to the perceived benefits of psychedelics, including for enhancing creativity, productivity, spirituality and general well-being. These perspectives draw on scientific research findings and combine them with their own particular values, ideals and lifestyles. For example, a recent *Netflix* reality series, *The Goop Lab*, co-produced with Gwyneth Paltrow's wellness company Goop, features several experts and profiles the value of psychedelic therapies from a wellness perspective (Goop Lab, 2020). Popular podcasts such as *The Tim Ferris Show* and *The Joe Rogan Experience* regularly feature high-profile psychedelic researchers, advocates and celebrities promoting the science of psychedelic medicine and/or attesting to its life-saving and transformative potential. Celebrity accounts and public testimony often include descriptions of underground experiences and trips to international psychedelic tourist hotspots like Mexico, the Netherlands and Amazonian locations where psychedelic therapists, clinics and retreats are tolerated (Cary, 2020; Hartogsohn, 2020). Such portrayals in the popular media alongside a constant stream of scientific 'breakthroughs' have generated a flourishing alternative travel industry for those seeking psychedelic healing and enhancement. In these contexts, therapeutic approaches are often inspired by modern interpretations of traditional shamanic and spiritual practices. Yet they are also increasingly informed by clinical and psychotherapeutic approaches promoted through scientific and medical discourses. The current mainstreaming of psychedelics thus reflects a cross-pollination of traditional insights, contemporary spiritual practices and cutting-edge science.

The second wave of psychedelic research currently underway has been carefully orchestrated to re-enter the scientific and medical establishments. Gifford (2020) describes how various psychedelic interest groups and individuals connected to the Esalen Institute in California, for example, worked towards mainstreaming psychedelic research as legitimate and respectable to the scientific and medical community. Since the 2000s, psychedelic science has rapidly re-emerged in medical research and scientific discourse. Publications on classical psychedelics increased significantly in this period, reaching an all-time high in 2020 (Lawrence et al., 2021). Indeed, research papers in the current wave now surpass the total output of the first wave of psychedelic research, and this shows no signs of abating. Public information in the mainstream media is dominated by research findings from major universities, organisations and commercial ventures. The language focuses on neuroscientific, pharmacological and psychiatric breakthroughs and discoveries. Medicalisation, pharmaceuticalisation and biomedicalisation are thus helpful conceptual frameworks for understanding how science and medicine have and will continue to configure research and application of psychedelic-assisted therapies.

5 | HEALTHCARE INTEGRATION

The anticipated rescheduling of psychedelic compounds following recognition of their medicinal and therapeutic application raises several questions regarding what psychedelic medicine and psychotherapy would look like in practical application. Alongside the questions surrounding medicalisation outlined above, it seems pressing to consider how psychedelic therapies might be integrated into existing healthcare systems. Here we consider this in relation to existing approaches to treating mental health disorders, the regulation of therapeutic substances, and processes of commodification, investment and monetisation.

5.1 | Therapeutic approaches

To what degree psychedelics could be considered medicines in their own right is still unclear (Garcia-Romeu & Richards, 2018). Current knowledge demonstrates that well-structured psychotherapeutic support coupled with high-dose administration maximise the benefits of psychedelics (Garcia-Romeu & Richards, 2018). Current best practice involves intensive screening, psychotherapy, the provision of multiple sessions and structured programmes of integration to ensure insights generated within sessions are assimilated into everyday life (see Johnson et al. (2008) and Garcia-Romeu and Richards (2018) for detailed accounts of therapeutic programmes). These processes, deemed essential for both the safety and efficacy of treatment, present major challenges for the mass roll out of psychedelic therapies into existing healthcare systems. Of these, the labour costs associated with such intensive therapeutic programmes and the connected issue of accessibility are problematic in terms of scalability (Nutt & Carhart-Harris, 2021). It is likely that qualitative differences in healthcare systems and the balance of public/private healthcare provision will determine the degree to which these issues can be mitigated.

Established models of high-dose psychedelic therapies for treatment-resistant mental health disorders are strongly oriented towards a psychotherapeutic approach. This diverges from the dominant pattern whereby psychiatric medications such as antidepressants are taken daily 'to correct or ameliorate an underlying presumed pathological brain state' (Grob & Bravo, 2019, pp. 23–24). In the case of depressive disorders, this approach aims to relieve the patient's symptoms and foster brain function conducive to restructuring core psychological processes with the hope of lasting cognitive change (Harmer et al., 2017). In contrast, high-dose psychedelics are commonly administered over just one to three sessions with the intention of fostering a mental state whereby the patient's normal psychological defences are loosened and the mind is more open and accepting of new insights and self-reflection (Grob & Bravo, 2019). This therapy is premised on intensive consultation with support staff before, during and after the session to integrate psychedelic experiences into the patient's everyday life (Grob & Bravo, 2019; Johnson et al., 2008; Richards, 2017). While this approach has demonstrated much promise, prominent researchers highlight difficulties related to scalability, cost and training of therapists as key challenges in making treatment widely available (Carhart-Harris & Goodwin, 2017).

Other forms of psychedelic-assisted therapy currently being investigated may provide alternatives to the intensive psychotherapeutic approach outlined above. Microdosing—the administration of very low, imperceptible amounts of psychedelic compounds (most frequently LSD and psilocybin)—has, over recent years, grown in popularity both as a therapeutic treatment and for general well-being.[4] There is much suggestion and some evidence (Hutten et al., 2020) that microdosing psychedelic compounds may have beneficial effects on mood and cognition. While this research is in its infancy, phase 1 trials suggest the feasibility of developing new research programmes to evaluate efficacy (Family et al., 2020).

If future trials suggest that long-term low-dose psychedelic administration is safe and effective, this will prompt significant consideration of the role and importance of psychotherapy. The microdosing model presents a highly attractive alternative for consumers and providers concerned about the cost, accessibility and labour-intensiveness of current approaches. Microdosing has the potential to bring psychedelic therapies into alignment with the mainstay of

psychiatric practice, that is, prescribing medicines to be taking daily over long periods. In this respect, we might anticipate the downplaying of the radical proposal prompted by psychedelic-assisted therapies of treating the root causes of mental health problems rather than their symptoms. Furthermore, microdosing seems to be much better suited to monetisation and the interests of both the pharmaceutical and wellness industries. Several products are in production or development, including a ketamine nasal spray by Janssen Pharmaceuticals (already on the market in the US and EU) and a psilocybin nasal spray by US company Silo Wellness (Aday et al., 2020).

5.2 | Regulation

Any changes to existing regulatory control of psychedelic compounds are likely to involve complex deliberative processes. The legal and cultural settings in the various countries where psychedelic medicines are proposed will shape processes of reclassification, regulation and control of these compounds (dos Santos et al., 2021). Negotiating the stigmas and remnants of the War on Drugs, the tensions between medicalisation and decriminalisation, as well as the structures of proposed regulation, will challenge authorities and likely have profound consequences for the rollout of psychedelic therapies in the future.

While the mechanics of regulatory and legal frameworks are jurisdiction specific, there are several likely, and not mutually exclusive, common legal pathways. These range from specific medical controls allowing prescription for sanctioned therapeutic use through to processes of decriminalisation and/or legalisation. Noorani (2020) outlines important considerations regarding the difficulty of aligning proposals for medicalisation with arguments for decriminalisation and/or legalisation. He suggests that pro-medicalisation arguments tend towards articulating programmes of psychedelic therapy that delineate frameworks for 'proper use' and conditions of 'abuse', arguments that are at odds with those advocating for an end to the criminalisation of psychedelic substances (Noorani, 2020). Furthermore, if medicalisation 'leads to bifurcated scheduling and the approval of diluted therapeutic forms', there is a concern that those seeking help may be presented with a choice between 'relatively ineffective but legal psychedelic therapy or more effective but criminalised underground psychedelic therapy' (Noorani, 2020, p. 38).

Decriminalisation and legalisation present their own problems. Deregulation and a proliferation of psychedelic-assisted therapy raises safety issues regarding the ability for practitioners to safely screen patients and provide high standards of care. This has been a point of concern in the Netherlands where practitioners are administering psilocybin-containing truffles in therapeutic contexts by taking advantage of a legal loophole exempting psilocybin-containing rhizomatic fungi from legal controls (Cantizani Lopez, 2021). Likewise, in the context of decriminalisation, the blurred boundaries between recreational and therapeutic use raise issues for regulating psychotherapeutic practice. These kinds of problems may also arise alongside the off-label prescription of psychedelic compounds. While it is not considered a classic psychedelic, the dissociative anaesthetic ketamine is available off-label for treating depression and anxiety in several countries. However, such practice obviates the need for psychotherapeutic guidelines. While practitioners must follow procedures outlined for moderate conscious sedation, this does not extend to the patient's ongoing psychological care, a striking point of difference from the rigorous guidelines proposed for classic psychedelic-assisted therapies (Johnson et al., 2008; Richards, 2017).

The pace and detail of regulation will have significant consequences for ways in which psychedelic-assisted therapies might be implemented and integrated into healthcare systems. Advocacy organisations such as MAPS have developed detailed regulatory guidelines for approved treatments (Doblin, 2015). MAPS' recommendations closely follow the medicalisation model, taking into account 'misuse (unintentional and/or uninformed), abuse, diversion, and the potential negative effects of information about approved medical use on nonmedical use patterns' (Doblin, 2015, p. 365). The prominent consensus of medical regulation advocates is for a slow and prudent approach. Yet divergent views exist in the wider psychedelic community. This is evident in the debates surrounding medicalisation versus decriminalisation (Noorani, 2020) and also *within* the ranks of those advocating a medical approach. For example, a recent application for rescheduling of both MDMA and psilocybin for medical use in Australia revealed divergent

perspectives between prominent advocacy organisations. While MMA has already submitted a rescheduling application (MMA, 2020), PRISM has argues that caution and further research is needed before rescheduling is considered (Williams & Bright, 2021).

5.3 | Commodification, investment and the monetisation

There is little doubt that private interests will play a major role in shaping any future roll out of psychedelic-assisted therapies. With the recent popularisation of psychedelics and the early successes of clinical trials, there has been a rapid market response. Indeed, a prospective industry has developed, pointing to an expansive monetisation of the field. The forms these ventures take will be responsive to the regulatory models that emerge in various jurisdictions and to the character of national healthcare systems. A major concern for researchers, medical professionals and commentators alike is the potential disjuncture between for-profit business models and public health (Noorani, 2020). Disquiet ranges from issues such as the efficacy of large-scale profit-driven psychotherapy through to structural critiques of neoliberal capitalism. Many of those involved in the broader psychedelic movement have long hoped that psychedelic medicine might initiate a radical rethink of mental illness (Giffort, 2020; Richert, 2019). However, several of the emerging for-profit models suggest that discourses of medicalisation and pharmaceuticalisation are strongly entrenched in the mental health field, providing existing frameworks for private interests to both capitalise on and influence the future of psychedelic therapies.

The speculative psychedelic market has rapidly grown. CNBC reports that upwards of $US800 million of venture capital has been invested over the past 4 years (Costa & Shead, 2021). The major players, publicly listed companies Compass Pathways and Atai Life Sciences, are both valued in the billions of US dollars and have attracted interest from billionaire entrepreneurs such as Paypal founder Peter Thiel and German investor Christian Angermayer. Many smaller psychedelic start-ups have also emerged with a range of interests spanning the pharmaceutical, psychotherapeutic and wellness industries. The possibilities of monetisation are expansive and are looking well beyond the more traditional fields of pharmacology, psychotherapy and education. New technologies such as brain interfacing, virtual reality, wellness apps and genetic screening are some possible future applications. The potential of this industry presents an attractive speculative investment opportunity. While this was until only a few years ago limited to entrepreneurs sympathetic to the cause, it is now attracting capital from diverse actors including big business and industry (Hausfeld, 2020b).

Patent applications for psychedelics reflect a major point of contention. In particular, Compass Pathways' already-granted patent of their psilocybin formulation and their broadly defined patent applications for the administration of psilocybin and the therapeutic conditions of its administration has worried researchers and commentators (Hausfeld, 2020a; Love, 2021). A high-profile public dispute between Tim Ferriss and Christian Angermayer (Angermayer, 2021; Ferriss, 2021) is instructive. Ferriss expressed concerns about patents hindering scientific research and reasonable competition, while Angermayer championed the merits of for-profit competition for effective scaling and delivery. Others have been vocal in encouraging open science as an important principle for research and development. The non-profit medical research organisation Usona Institute—another key player in the synthetic production of psychedelic compounds and psychedelic trials—has followed an alternative model by openly publishing articles on the manufacture of psilocybin (Hausfeld, 2020a). A recent statement calling for open science and open praxis initiated by long-time advocate Robert Jesse has attracted signatures from leading psychedelic researchers, practitioners and organisations (Jesse, 2018). The statement sets out an ethical framework of cooperation and non-interference, representing an alternative vision to competitive business models and aggressive corporate tactics.

Much of the debate surrounding the commodification and monetisation of psychedelic-assisted therapies is set against wider discussions regarding profiteering and ethical conflicts in for-profit pharmaceuticals and mental healthcare provision (Das, 2011; Mosher et al., 2013). At present it seems unlikely that psychedelic medicines will follow the precedents of widespread antidepressant prescription that does not require the coupling of psychotherapeutic care.

However, there are some examples, including the off-label administration of ketamine and psychedelic microdosing, which point to the possibility of ongoing and regular drug administration, which would fit with existing commercial pharmaceutical models.

As the psychedelic-assisted therapies proposed by most researchers differ significantly to protocols for antidepressant medication, this will engender novel commercialisation. There are various possible for-profit frameworks that range from individual practitioners administering compounds and psychotherapy in private practice through to largescale business models with standardised protocols and teams of psychotherapeutic personnel. Most critics are concerned with the latter, especially in the case of large organisations who are aiming to patent, control, and brand the entire process—from drug synthesis and development, through to training, administration and psychotherapy. Not only does this raise concerns about monopolisation, but it also threatens the development of heterogeneous, culturally responsive and innovative therapeutic approaches.

Discussions concerning the commercialisation of psychedelic-assisted therapies evoke several underlying sociological issues. Given that psychedelics fit into a well-established and diverse cultural milieu that found much of its character during the 1960s and 1970s counterculture movements, their co-opting into mainstream medicine and psychiatry conflicts with some of the long-held beliefs of these communities. Critically, for many the commodification and monetisation of psychedelics is at odds with their perceived spiritual and social-transformative potential. These perspectives problematise modernity and capitalism as root causes for the global mental health crisis and for shaping our understandings and treatment of mental illness under the discursive conditions that benefit profit making and capital extraction. Despite these critiques, there are perspectives that, while sympathetic to these idealistic values, prioritise best practice and scalability in the face of inevitable commercialisation. The recent flurry of commercial enterprise and investment in this field provides a sobering reminder to those who had hoped that psychedelic-assisted therapies might provide a radical rethink of how society addresses mental illness. Even so, the likelihood of a heterogeneous implementation of psychedelic treatments means that while some aspects are likely to be co-opted into the existing frameworks set by largescale pharmaceutical companies, there will be opportunity for unique and novel approaches to develop that break with the existing paradigm.

6 | CONCLUSION

Psychedelic therapies present a promising alternative paradigm to current pharmacological practices for the treatment of mental health disorders. Decades of political intervention, including the so-called War on Drugs and the resulting stigma associated with the use of these compounds, hindered the advancement of psychedelic medicine until recently. Yet the last decade has seen a burgeoning of high-quality research and clinical trials that have coupled psychotherapy and pharmacology. This development, along with promising study results and advocacy from respected organisations, researchers and prominent individuals, has rehabilitated the reputation of psychedelics. A cautious approach has shaped both research and advocacy, although tensions do exist between various groups with different visions for the future. In this context, exactly how psychedelic-assisted therapies might be integrated into existing health systems remains an open question, one that will arguably be of much interest to health sociologists and public health experts as the field rapidly expands. In particular, the relationship between the pharmacological mechanisms of psychedelics and the role of psychotherapy will be closely monitored, and will likely determine not only the extent to which psychedelics lead to novel modalities for treatment-resistant disorders, but also whether the use of psychedelics without psychotherapy is safe and efficacious.

Research and extensive trials will no doubt play a significant role in determining how psychedelic therapies might be integrated into healthcare systems. Biomedicalisation and monetisation will continue to shape the field, accelerating scientific knowledge and the commercial rollout of these treatments. The scientific exploration of the many novel and as yet untested psychedelic compounds, the discoveries that further research and clinical trials in this area will inevitably make over the coming years and the possibility of increased access to new psychedelic treatments with

established efficacy, make for an exciting era of neuroscience and psychiatry. This is good news in the context of rising rates of mental illness worldwide, offering hope for people with treatment-resistant disorders. Psychedelics present a unique pharmacological paradigm for psychiatry. Their historic and continuing use as shamanic healing tools, as instruments of countercultural movement and for spiritual insight form a cultural imaginary that cannot be entirely divorced from their medical and psychiatric potential. Psychedelic therapies will continue to be co-opted, medicalised and commercialised but their cultural baggage—namely the ongoing stigma associated with the prohibition of recreational use of these substances—and peculiar mechanism of action will also likely prompt a conversation, if not a rethink, of current approaches to the treatment of mental illness.

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ENDNOTES

[1] We include some discussion of other psychoactive substances such as the entactogen 3,4–methyl enedioxy methamphetamine MDMA and the dissociative ketamine, both of which are not generally considered psychedelics but are understood to have similar modes of therapeutic action.

[2] The five-factor model of personality is a widely accepted taxonomy of personality traits. Often referred to as 'the big five', it describes five broad domains: Neuroticism, Extraversion, Openness, Agreeableness and Conscientiousness (MacLean et al., 2011).

[3] As documented in successive publications of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM).

[4] For examples of psychedelic microdosing presented in popular culture, see Ferriss (2019), Waldman (2017) and Leonard (2015).

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