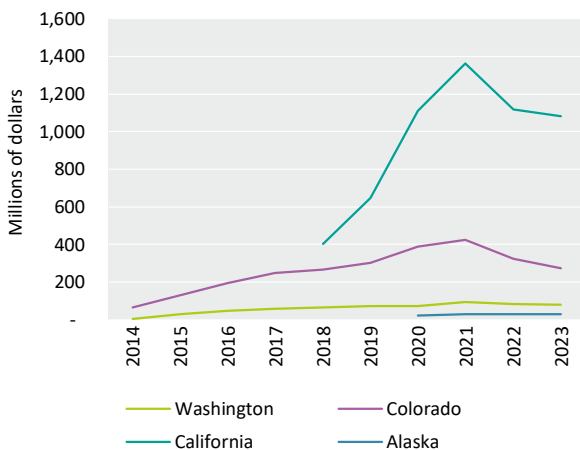


a waiting period, which may extend to years, before an individual's record is expunged.<sup>103</sup> Such requirements disproportionately effect economically disadvantaged groups.<sup>104, 105</sup>

### Revenues and taxes from cannabis increased as result of legalization but have remained stable in recent years

The legalization of the supply chain for non-medical cannabis, including the for-profit production of a range of cannabis products, has generated substantial revenues for corporations investing in the cannabis industry and for the jurisdictions that have legalized non-medical cannabis. Legalization of non-medical cannabis has had a clear impact in terms of the amount of taxes collected from the cannabis market and has added a new resource to the budgets of jurisdictions that have legalized non-medical cannabis. However, the revenue collected from cannabis taxation, while it may appear substantial in terms of dollar amounts, remains relatively small as a percentage of a state's overall revenues and constitutes less than 2 per cent or less of the revenues of states that have legalized non-medical cannabis.<sup>106, 107</sup>

**FIG. 48** State revenue from cannabis sales, United States, 2014–2023



Source: Alaska Department of Revenue – Tax Division; California Department of Tax and Fee Administration; Office of Research and Analysis, Colorado Department of Revenue; Washington Department of Revenue, 2023.

## Developments around psychedelics

Most of the currently known psychedelic substances, such as LSD, MDMA, mescaline and psilocybin, are controlled substances under Schedule I of the 1971 Convention, to account for the possibility of their use for scientific purposes, and of very limited medical use.<sup>108</sup> In recent decades, driven in part by the globally increasing burden of disease attributed to mental health disorders,<sup>109</sup> there has been a renewed interest<sup>110</sup> in the therapeutic use of different psychedelic substances for the treatment of a range of mental health disorders.<sup>111, 112</sup> A relatively recent wave of clinical trials, mainly in high-income countries, is showing early and somewhat promising results on the potential use of some psychedelics to treat a range of mental health disorders that are resistant to conventional treatment, in combination with psychotherapy.<sup>113, 114</sup> As yet, there is no medical market authorization<sup>115</sup> for psychedelics in any country and many clinical trials do not generally result in a market authorization. As at February 2024, there were more than a thousand registered clinical trials for various psychedelic therapies involving MDMA, psilocybin, LSD and ketamine in different phases of development. Despite initial results, however, there is still a long way to go before therapeutic guidelines, including for the screening of people and for the facilitation and supervision of psychedelic intake, are developed and such therapies are regulated and integrated into medical practice.<sup>116</sup> Nevertheless, the Federal Drug Administration of the United States granted breakthrough therapy designation for MDMA-assisted psychotherapy for the treatment of PTSD in 2017,<sup>117</sup> and, in 2024, for a psilocybin analogue for adjunctive treatment of major depressive disorder<sup>118</sup> and for a form of LSD to treat generalized anxiety disorder.<sup>119</sup>

It should be noted that two recent literature reviews of clinical trials involving psychedelics have identified some challenges and expressed concerns about the implementation of such clinical trials. These concerns include small sample size, absence of control groups, biases in the selection of study participants, short duration of the study, and missing information on adverse events, among others.<sup>120, 121</sup>

Recently an expert advisory committee of the US Food and Drug Administration also expressed similar concerns on the recent Phase 3 trials of MDMA highlighting issues about possible biases in the trials, including the issue of double blinding, and not being transparent about abuse, safeguards or efficacy of the follow-up therapies. Another concern that has also arisen recently relates to whether

**TABLE 2** Summary of psychedelic clinic trials, 2024

	STAGE OF CLINICAL TRIALS				FUNDED BY			
	Phase 1	Phase 2	Phase 3	Phase 4	United States National Institute of Health	United States federal agency	Industry	Individual universities, organizations
LSD	20	20	3	0	1	0	15	21
MDMA	30	34	6	1	0	5	24	21
Psilocybin	54	82	5	0	7	0	27	112
Ketamine	176	275	214	383	48	35	121	821

Source: ClinicalTrials.gov.

Note: The table includes trials being conducted in various countries, mostly in high-income countries.

a drug regulatory body can approve medication-assisted psychotherapy beyond its purview of approving medicines and medicinal products. This highlights the complexity and constraints of a medical therapy that could eventually come out of experimentation and have the potential to open up parallel markets of psychedelics used for alleged medical benefits outside of a formal medically-approved context.

Potential therapeutic use of psychedelics has also kindled commercial interest and investment, whereby venture capital firms see opportunities for investment and profits, which can be observed in the increasing number of clinical trials funded by individual organizations and the industry. The commercial interest in psychedelics is also seen in other areas as part of a broader development – the “psychedelic renaissance”<sup>122, 123</sup> – which is creating an enabling environment for unsupervised access to psychedelics.

Although the promise of a therapeutic benefit from psychedelics may be appealing, it has been argued that overly rapid developments in terms of commercialization, regulatory changes in some jurisdictions and non-medical use practices may short-circuit the prudent therapeutic use of psychedelics, including adequate screening, facilitation and supervision, and have the potential to adversely affect the quality and rigour of clinical research that is usually associated with the development of therapies with a “new” class of drugs.<sup>124, 125</sup>

### Regulatory changes around psychedelics

Recent changes in policies have facilitated access to psychedelic substances for medical use in Australia and Quebec, Canada, and in two jurisdictions in the United States. Australia is now the first country where the

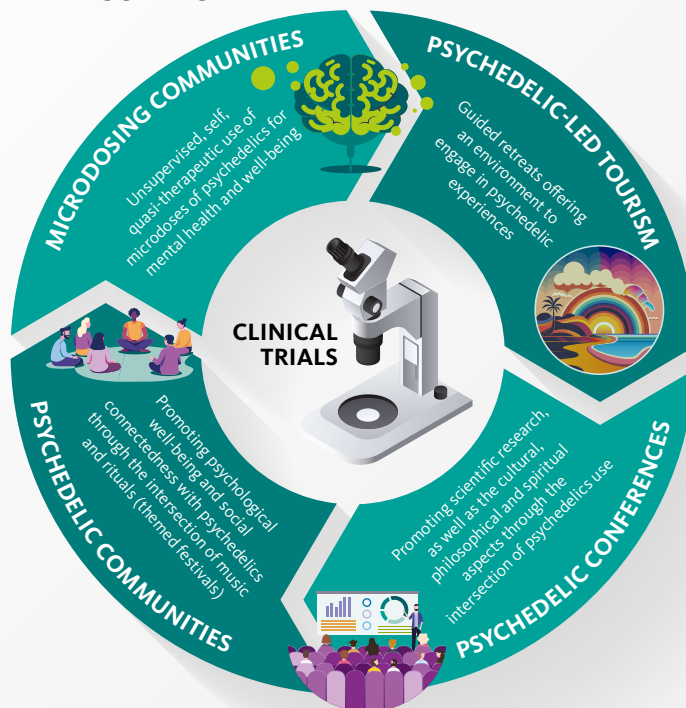
medical use of psilocybin and MDMA is allowed; as of July 2023, authorized psychiatrists can access MDMA for the supervised treatment of PTSD and psilocybin for the treatment of treatment-resistant depression.<sup>126</sup> However, as yet no supply chain mechanism has been developed and many stakeholders in Australia have opined that there is insufficient evidence to support the widespread clinical implementation of psychedelics in the country.<sup>127</sup> Also, in 2022, health coverage for the treatment of psilocybin-assisted psychotherapy was approved in Quebec, Canada.<sup>128</sup>

In 2020, Oregon approved “quasi-therapeutic” use of psilocybin, including the regulation of the supply chain and the retail sale and purchase of psilocybin products. As a result, anyone over the age of 21, with or without a diagnosis of a mental health condition, can consume psilocybin in a “supervised” setting; a prescription or a referral is not required for a person to access psilocybin services, but they do need to complete a preparatory session with a trained facilitator<sup>129</sup> before consuming psilocybin at a facility licensed by the state for the provision of psilocybin services.<sup>130, 131, 132</sup> In 2022, Colorado “decriminalized” the personal possession, growing, sharing and use, but not the sale, of five natural psychedelic substances by individuals aged 21 and over, and approved their use in “licensed” facilities with a plan to expand the types of substances permitted in order to include DMT, ibogaine and mescaline by 2026.<sup>133</sup>

### Environments enabling the use of psychedelics, beyond supervised medical use

Within the “psychedelic renaissance”, there are other developments that go beyond clinical trials and that are distinct from traditional use by Indigenous communities. Microdosing<sup>134</sup> communities, psychedelic conferences,

## PSYCHEDELIC “RENAISSANCE”



festivals and retreats are all contributing to the development of an enabling environment for the non-medical use of psychedelics. Most of these developments are unprecedented in their scope and reach and seem to outpace scientific developments and the evidence of their effectiveness when administered as part of supervised psychedelic-assisted therapy in a controlled environment.

Underpinning the “psychedelic renaissance” is an impetus for the commercialization, especially through financial investments, of psychedelic developments with a view to promoting the use of psychedelics under supervised or unsupervised care, in anticipation of the outcome of scientific research.<sup>135, 136, 137</sup> By March 2020, there were more than 50 publicly traded companies related to the development or administration of psychedelics in the United States.<sup>138</sup> By 2027, the psychedelics industry in the United States is projected to rise five times from the 2020 valuation of the companies, signalling a persistent investment interest in the field of psychedelic substances.<sup>139</sup> Some of the early non-profit organizations funding or undertaking research on psychedelics have become public companies and are now accepting external investment.<sup>140</sup>

Another example of the increasing commercial and public interest in psychedelics in recent years is the upsurge of psychedelic integration training programmes, workshops and referral networks, as well as the high number of people who are volunteering to be enrolled in clinical trials on psychedelics.<sup>141</sup>

### Unsupervised (or non-medical) use of psychedelics: microdosing communities

Microdosing – the practice of using low sub-perceptual doses of psychedelics substances – has garnered increasing attention in recent years owing to its perceived potential benefits for mental health and well-being, prompted by early accounts from users about its perceived positive effects and by preliminary findings in clinical research.<sup>142</sup>

Research on the benefits of microdosing has shown mixed results, however. Whereas observational or qualitative studies of people’s self-reports have indicated their satisfaction with the effectiveness of microdosing, randomized controlled studies have not shown clinically significant effects.

Some studies have shown that microdosing could potentially lead to improved moods, reduced stress and enhanced creativity,<sup>143</sup> but recent large-scale randomized control trials involving the microdosing of LSD and psilocybin have either not demonstrated anti-depressant, anxiolytic or pro-cognitive effects, or they have shown suboptimal results.<sup>144 145 146</sup>

Recent research has also highlighted the potential for bias in microdosing studies, particularly in those involving self-blinding citizen science initiatives, where participants randomly assign themselves to the placebo or control group; such participants may inadvertently influence their own assessments of the effects of the treatment, as they are susceptible to “expectancy” bias and are more at risk of giving false positive findings and thus influence the study outcomes.<sup>147, 148</sup> Altogether, the practice of using repeated minimal doses of psychedelic substances is still underresearched, and there is limited clinical evidence of its effectiveness or safety.<sup>149, 150, 151, 152</sup>

Despite the mixed findings, the practice of microdosing seems to have become increasingly popular. An online survey based on a convenience sample of more than 110,000 people, characterized by an overrepresentation of Internet users in Europe, the Americas and Oceania, found that 5.6 per cent of the respondents had microdosed using either LSD or psilocybin in the past 12 months in 2020. The results showed an increase of 80 per cent in those reporting microdosing with LSD compared with 2018 (3.9 per cent in 2018 as compared with 2.2 per cent in 2020).<sup>153</sup> The majority of the respondents who had microdosed in 2020 (55 per cent) reported that they had microdosed specifically for the self-treatment of a diagnosed psychiatric condition or a specific worry or concern (emotional distress), while the remaining respondents reported microdosing only to improve general well-being.

The research into the nature of microdosing has called for a cautious approach to the practice, especially to differentiate between the potential risk associated with prolonged and repeated microdosing and the more limited physiological safety risk posed by a few “macrodoses” administered weeks or months apart in the context of either supervised use or psychedelic-assisted therapy.<sup>154</sup>

### Psychedelic conferences

The large number of conferences on topics relevant to psychedelics, including on the experiences of participants, also points to a growing diversity of and interest in psychedelics. The conferences not only encompass scientific research but also the broader cultural, philosophical and

spiritual aspects of the use of psychedelics. The increase in the number of conferences dedicated to these topics signifies a shift away from the stigma and marginality that psychedelics once faced<sup>155</sup> and towards an open dialogue about their potential impact on people’s well-being. This burgeoning interest is prompting further mainstreaming and exploration of the potential benefits of psychedelics for individuals and communities, beyond their supervised therapeutic use.<sup>156</sup>

In 2023 alone, UNODC identified a total of 35 major conferences on psychedelics, of which 14 were aimed at an expert audience, usually academic in nature. Eight were motivated by commercial interests in psychedelics, often organized under the themes psychedelic “entrepreneurship”, or new psychedelic drug development and its economic impact.

Thirteen other conferences were aimed at a much wider audience whose common interest was psychedelics and their potential therapeutic benefits. One such conference had the participation of over 12,000 people, including 500 educators from 52 countries that offered 30 workshops focused on the “promise of psychedelics in cultural, medical and traditional environments”.<sup>157</sup> A review of the content of the psychedelic conferences suggests that many of these conferences have been defined using themes such as “psychedelic consciousness and its communal aspects”, “mindfulness”, “self-realization” and “self-care”, while others were gender-focused or meeting points for people with mental health disorders to learn about the potential therapeutic effects of psychedelics. Central to the conferences aimed at the general public are the experience-driven groups, whose identity is often derived from their psychedelic substance use and their contemplative practices.

### Psychedelic communities

Psychedelic rituals and retreats emphasize the importance of contextual elements (the so-called “set and setting”) in modulating the psychoactive effects of psychedelics.<sup>158</sup> Psychedelic communities reportedly promote psychological well-being and social connectedness through the use of psychedelics and the influence of music and rituals, based on the premise that group settings can enhance the effects of psychedelics by promoting feelings of interconnectedness and shared experience.<sup>159, 160, 161</sup> These communities are not a new phenomenon, but the rationalization of psychedelic substance use through a reliance on emerging clinical research that is taken out of context – a decontextualization that is often motivated by broader commercial interests – has emerged recently.<sup>162, 163, 164</sup>

### Psychedelic-themed festivals: transformational festivals

Beyond the conferences and communities, psychedelic-themed festivals serve as other venues for psychedelic communities to come together, which have the aim of “trans-personalism”, “collective ecstasies”, “mindfulness” and “spiritual health”.<sup>165, 166, 167</sup> While psychedelic-themed festivals have a long history, dating back at least to the 1960s, there is a new variety of festivals that emphasizes the perceived positive impact of psychedelic substances as their defining character. Centred around community-building over shared interests and beliefs, transformational festivals offer an intersection between music, arts and psychedelic substances, alongside workshops and events aimed at increasing knowledge of spirituality among participants.<sup>168</sup> What sets transformational festivals apart from the earlier psytrance festivals – which focused mainly on psychedelic music, art and community – is their professed holistic approach, which incorporates spiritual practices, meditation, well-being and mindfulness, along with the primary elements of music and use of psychedelics.<sup>169</sup>

### Psychedelic-led tourism and retreats

Spanning North America, Latin America and Europe, the festivals’ reach has been expanding and attracting more participants and attendants, contributing to psychedelic tourism. This form of tourism is advertised as a type of travel whereby individuals embark on journeys to specific locations or engage in structured retreats to explore the spiritual, recreational and therapeutic elements of psychedelic substances in a “supportive environment defined by common beliefs and interests”.<sup>170</sup>

Psychedelic tourism encompasses guided retreats, which are structured programmes or organized events that offer individuals a supportive, albeit clinically unsupervised, environment to engage in psychedelic experiences. These retreats typically combine the use of psychedelics with “quasi-therapeutic” or spiritual practices such as meditation, group therapy or shamanic ceremonies, with the purported goal of promoting personal growth, self-exploration and healing under the guidance of facilitators.<sup>171, 172</sup>

At the centre of these retreats is *ayahuasca*, a psychoactive brew indigenous to the Amazon and Orinoco basins and facilitated by “shamans and folk healers”.<sup>173</sup> However, these retreats are often implemented in forms that are divorced from their Indigenous origins. Moreover, *ayahuasca* retreats and other Indigenous retreats have become subject to commercialization and the colonization or appropriation of Indigenous cultures in attempts to adapt the ceremonies to a non-Indigenous audience,

whose focus is the psychoactive elements of the ceremonies, rather than the Indigenous spiritual dimensions and settings.<sup>174, 175</sup> Accordingly, these retreats tend to function as a means to establish the unsupervised, “quasi-therapeutic” use of psychedelics with psychotherapeutic modalities that favour some aspects of Indigenous spiritualities and abandon others according to the needs of participants.<sup>176, 177</sup>

### Towards risks of misuse and abuse of an unregulated practice

While it is key to promote the medical use of psychedelics when it is supported by rigorous scientific evidence, many questions about the potential health risks and benefits of using psychedelics remain unanswered. The discussion surrounding access to and the use of psychedelics embedded in the “psychedelic renaissance” is advancing beyond the realms of their demonstrated therapeutic use and the outcomes of clinical research. It seems that public interest in and private sector attention to this issue are greater than shown in the current scientific evidence regarding the effectiveness of psychedelics in improving mental health and cognitive functions. The conditions of the therapeutic setting for psychedelic therapy that effective medical use seems to require are also more demanding than those offered in “psychedelic renaissance” events. The risk is that the perception of psychedelics as the “silver bullet” for mental health disorders and overall mental or spiritual well-being, which is advocated for by a growing number of advocacy groups and commercial interests, will move faster than scientific evidence, opening up the market to unsupervised, “quasi-therapeutic” or spiritual and recreational use before supervised therapeutic use, including adequate screening and facilitation, can be established. This may trigger the development of unsafe markets for psychedelic use in different settings, in turn carrying the inherent risks of misuse and abuse of an unregulated practice. Those risks have been observed in the initial development of many psychoactive substances, such as heroin or cocaine, in relation to their marketing, unsupervised self-medication and non-medical use over the past century and beyond.<sup>178, 179</sup>

Most of the developments related to psychedelics are taking place in Western countries or have participants who are mostly from Western countries. As with any other drug, the non-medical use of psychedelics may start to expand in affluent communities, but once it becomes more established and spreads to impoverished, marginalized and minority groups, it may increase the aggregated harm. Such groups often face an issue of equity, they may not have the necessary social capital and resources to prevent

harmful consequences and thus may end up bearing the brunt of high rates of harmful substance use, substance use disorders and a limited access to drug services.<sup>180</sup>

There are some similarities and differences in the way developments for psychedelics and cannabis appear to be evolving outside the medical realm. For cannabis, the impetus for regulatory changes for both medical and non-medical use, which started in North America, has expanded to Western Europe and other regions, albeit slowly. For both cannabis and psychedelics, commercial interests and the media have facilitated the increasing perceptions of their benefits or decreased risk perceptions among the general population in many countries, which has, together with pressure from advocacy groups, most likely influenced regulatory changes for both substances. However, the overall interest in the potential therapeutic benefits of psychedelics and developments promoting an overall enabling environment seem to be growing at a fast pace. Overlooking the apparently unlinked initiatives discussed in this chapter is likely to accelerate the development of commercial, for-profit supply chain mechanisms for psychedelic substances, similar to the development of commercial cannabis markets.<sup>181, 182, 183, 184, 185, 186</sup>

One major difference seems to be that, while the processes to legalize or regulate cannabis for non-medical use have mostly been driven by normalizing recreational use, the impulse to legalize psychedelics or to deregulate psychedelics seems to be motivated more by the desire for unsupervised therapeutic use within the overall realm of mental health, mindfulness, spirituality and overall well-being.

The pressure imposed by commercial interest and advocacy groups that emphasize psychedelics as the solution to major mental health disorders and well-being may also influence the outcome of current and future clinical trials and could undermine the authority of rigorous scientific research for determining therapeutic benefits, uses and practices.<sup>187, 188</sup> An unregulated or poorly regulated non-medical, commercial supply of psychedelics may also compromise the public health objectives of improving health, social well-being and quality of life while mimimzing the health risks associated with the use of psychedelics.