





Crafting effective regulatory policies for psychedelics: What can be learned from the case of cannabis?

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Abstract

The turn of the century brought a resurgence of interest in psychedelics as a treatment for addiction and other psychiatric conditions, accompanied by extensive positive media attention and private equity investment. Government regulatory bodies in Australia, Israel, Canada and the United States now permit use of psychedelics for medical purposes. In the United States, citizen action and corporate financing have led to petitions and ballot initiatives to legalize psilocybin and other psychedelics for medical and recreational use. Given this momentum, policymakers must grapple with important questions that define whether and how psychedelics are made available to the public, as well as how companies produce and promote them. The current push to broaden the production, sale, and use of psychedelics bears many parallels to the movement to legalize cannabis in the United States and other nations—most notably, the use of poorly-evidenced therapeutic claims to create a de facto recreational market via the health care system. Experience with cannabis highlights the value of debating the question of legalization for nonmedical use as such rather than misrepresenting it as a medical issue. The lessons of cannabis policy also suggest a need to challenge hyping of psychedelic research findings; to promote rigorous clinical research on dosing and potency; to minimize the influence of for-profit industry in shaping policies to their economic advantage; and to coordinate federal, state, and local governments to regulate the manufacture, sale and distribution of psychedelic drugs (regardless of whether they are legalized for medical and/or recreational use).

KEYWORDS

cannabis, drug policy, ketamine, psilocybin, psychedelics, regulation

THE PSYCHEDELIC RENAISSANCE AND THE PUSH FOR LIBERALIZATION

The turn of the century brought a resurgence of interest in investigating psychedelics as a form of treatment for addiction and other psychiatric conditions. A loosening of restrictions on scientific testing and increasing funding for research over the past decade has given rise to a growing number of clinical trials of psychedelics for substance use and other psychiatric disorders [1, 2]. Psilocybin has emerged as a

promising treatment for alcohol and nicotine addiction and represents an important area for further research [3–5]. Nonetheless, the evidence base supporting the use of psychedelics in treating addiction remains underdeveloped and many studies do not meet the quality standards required for clinical trial research (e.g. most have low sample sizes and inadequate blinding to condition) [6–8]. The most recent comprehensive review concluded that most claims about the medical benefits of psychedelic drugs are reliant on a small number of studies conducted with limited scientific rigor [9]. Despite this, psychedelics

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have captured major public attention and sparked a growing cultural movement promoting their use that has important implications for the field of addiction.

Public interest in psychedelics has been driven in no small part by the extensive publicity these drugs have garnered in recent years. Social media content on psychedelics has expanded dramatically over the past decade, often overstating research findings and creating wildly inflated expectations of their potential benefits [10]. Mainstream media coverage of psychedelics has also increased. The *New York Times*, for example, published 38 articles covering psilocybin in 2019 alone. Although these news reports were more measured than social media coverage, they too often exaggerated research findings and conveyed greater certainty about the therapeutic effects of psychedelics than is warranted by the evidence [6].

At the same time, grassroots advocacy promoting psychedelic use for various purposes has surged. These efforts, perhaps best exemplified by the ‘Decriminalize Nature’ movement, have focused on publicizing the perceived benefits of psychoactive plants, framing psychedelic access as a human rights issue and promoting the decriminalization of personal use.

This heightened attention has been accompanied by increased psychedelic use. In the United States (US), the use of psychedelic drugs—including lysergic acid diethylamide (LSD), psilocybin and ketamine—has increased steadily among adults over the past decade [11, 12]. Prevalence has increased most rapidly among adults age 19 to 30 years; with lifetime use of psychedelics more than doubling from 3.4% in 2012 to 8.0% in 2022 [13]. Although global data on psychedelic use is unavailable, prevalence studies of past-year psychedelic use in other Western nations reveal similar trends [7]. There is also emerging evidence of an increase in emergency department visits and hospitalizations associated with psychedelic use. In California, a hub of psychedelic drug industry and culture, psychedelic emergency and inpatient episodes increased by ~55% from 2016 to 2022 [14].

Global private investment in psychedelics has soared in recent years. The US Food and Drug Administration’s decision to award psilocybin a ‘breakthrough therapy’ designation for clinical trials in 2019 arguably spurred major venture capital investment in the psychedelic industry [1]. Between 2017 and 2021, private investment in psychedelics jumped from just \$13 million to over \$1.6 billion [15]. Since 2021, six major psychedelic drug companies have gone public, including the United Kingdom (UK)-based Compass Pathways and Ireland-based GH Research, both currently valued in the hundreds of millions of dollars.

This combination of public interest and private investment has increased pressure on governments to liberalize access to psychedelics. The US Food and Drug Administration approved esketamine for treatment-resistant depression in 2019. State-level ballot initiatives that ask voters to legalize psilocybin and other psychedelics for medical and recreational use have become more common in the United States. In tandem, from 2019 to 2022, elected state legislators introduced more bills to liberalize psychedelics, increasing from five such bills in 2019 to 36 bills in 2022 [15]. Although the content of these bills varies, most propose the decriminalization of one or more psychedelics—most frequently, psilocybin and 3,4-methylenedioxy-methamphetamine (MDMA). California recently proposed legislation

to legalize use of several psychedelic drugs under the supervision of authorized ‘therapeutic facilitators.’ [16] There have been legislative victories in Oregon, which passed a law legalizing use of psilocybin, and Colorado, which passed legislation allowing the legal use of a range of psychedelic drugs [17]. Both of these states will soon license psilocybin providers to operate facilities where residents can receive psychedelics under supervision. In addition, 18 US cities have decriminalized personal use of psychedelics.

Steps to expand access to psychedelics for therapeutic use are also being considered by government regulatory bodies in several countries [18]. In 2019, Israel became the first nation to allow ‘compassionate use’ of psychedelics and other drugs when prescribed by a physician. In 2020, Canada began allowing patients to seek medical exemptions to its law banning psychedelic use. In 2023, the Australian Therapeutic Goods Administration allowed the compassionate prescribing of MDMA for PTSD and psilocybin for treatment-resistant depression by approved psychiatrists. In the United States, the Food and Drug Administration is expected to approve MDMA, and potentially psilocybin, for therapeutic use in the near future. Moreover, over a dozen nations in Europe, South America and the Caribbean have decriminalized possession of psychedelics for personal use [18].

As governments continue to pursue policies liberalizing psychedelics, there has been relatively little discussion regarding how this can, and should occur, in a way that protects public health. Many basic questions must be addressed to ensure safe and effective rollout of any psychedelic liberalization policies. For example, should psychedelics be legal for nonmedical use? What might the consequences be of decriminalizing or allowing the retail sale of psychedelics for recreational use? Who should be allowed to manufacture and distribute psychedelics? Should the pharmaceutical industry be allowed to contribute to the shaping of policy on the sale and regulation of psychedelics? How can governments provide accurate information about the risks and benefits of psychedelic use to the public? How will health systems identify and help people who suffer serious adverse health consequences that arise after psychedelic use? The experience of cannabis policy offers many clues on how to answer these questions.

PARALLELS WITH THE MOVEMENT TO LIBERALIZE CANNABIS

The current movement to broaden access to psychedelics and decriminalize their use bears many parallels to the movement to legalize cannabis in the United States and other nations. As with psychedelics, many nations initially decriminalized cannabis possession and use. This was followed by calls for clinical research on medical uses and then moves to legalize cannabis for medical use, recreational use, production and sale. At present, 48 nations have passed laws allowing the medical use of cannabis. Eight countries have fully legalized adult cannabis use, and two others—Australia and the United States—allow the drug to be consumed recreationally in subnational districts [17]. In the United States, 38 states and the District of Columbia allow cannabis for medical use, and 24 states have legalized recreational use [19, 20].

The movements to liberalize access to both cannabis and psychedelics have been driven by political advocacy and legislative change. Efforts to liberalize cannabis have been steered by small, but highly energized, well-funded and politically organized coalitions focused on promoting state ballot initiatives and legislation. As with psychedelics, the movement to expand access to cannabis initially focused on achieving change at the local level. Although the psychedelic movement is at much earlier stage of development, there are signs that liberalization of access to these drugs may happen even more quickly in the United States, given the recent decisions by Oregon and Colorado to move rapidly to full legalization [15, 16].

Both of these movements frame increased access to their drug of choice as the answer to a diverse array of problems. Both cannabis and psychedelics have been touted as transformative treatments of intractable forms of human suffering that mainstream medicine has failed to address [21, 22]. Proponents of medical cannabis use claim it can treat chronic pain, movement and neurological disorders, reduce the risk of opioid overdose, treat opioid use disorder and even cure some cancers [23]. In the case of psychedelics, proponents have argued that they can effect rapid recovery from post-traumatic stress disorder, depression, anxiety and addiction [9]. Some medical benefits of cannabinoids have been substantiated by scientific evidence—for example, in the treatment of nausea and vomiting [23]. However, evidence is much more equivocal for the conditions they are used most frequently to treat, namely, chronic pain, anxiety and sleep disorders [23], and there is no evidence that cannabis either reduces the risk of opioid overdose or treats opioid use disorder [24, 25]. By framing these drugs as medicines, advocates can portray governments as obstructing citizens' access to them, and they can create harm by encouraging people with serious disorders to use drugs that are not effective [25].

These grassroots movements have also forged an alliance with industry and wealthy enthusiasts to promote the goal of legalization. In the case of cannabis, investors early on saw a commercial opportunity in liberalization. Commercial interests donated extensively to state and local campaigns to pass legislation to legalize cannabis. For example, in the United States, the cannabis industry spent \$23 million in 2022 on five state legalization initiatives, representing 95% of all political donations that year. The industry has also been hugely influential in setting the regulatory standards for commercial entities, often authoring the bills voted on in state legislatures. The same industry that has been heavily involved in efforts to legalize cannabis is now major players in the efforts to transform psychedelics into a major business opportunity. This has produced a high-level of regulatory capture reminiscent of the cannabis industry, in which oversight boards often have industry representatives on them.

'LESSONS LEARNED' FOR AN EFFECTIVE ROLLOUT OF PSYCHEDELIC THERAPEUTICS

Given these parallels, there is much to be learned from the case of cannabis that can inform efforts to liberalize access to psychedelics.

Cannabis legalization has presented enormous challenges for governments, which have struggled to craft effective policies to minimize risks to public health. Legalization of medical cannabis by ballot referenda and state legislation has meant that medical use has been promoted well ahead of evidence on its efficacy and safety and with little attention to possible harms [26]. Both the laws and their implementation have been controlled largely by for-profit entities with few regulatory guard rails and limited medical oversight. The long-term effects of these choices are only beginning to be understood. For example, the lack of adequate regulation of high dose tetrahydrocannabinol in many states has raised significant concerns about overconsumption and drug diversion. For example, in the state of Maine, residents can legally purchase up to 150 000 standard doses of cannabis per month, a number far beyond what any person could reasonably consume [27].

Effective regulation of cannabis has been particularly challenging because of limited coordination across state and federal levels of government. For example, in the United States, states have legalized adult cannabis use while it remains illegal under federal law, which still designates cannabis as a controlled substance. Moreover, the lack of appropriate regulatory oversight at state and federal levels has left local jurisdictions with responsibility for regulating advertising and distribution of cannabis. This has produced highly variable state policies and uncertainty among the public about what is and is not permitted.

The public has also been exposed to a great deal of misinformation about cannabis. It has been promoted by enthusiasts as a harmless herb, despite evidence of negative effects on mental health, cognition, pregnancy outcomes [28] and impaired driving and motor vehicle accidents [29]. Proponents have also made claims about the health benefits of cannabis that have no basis in scientific evidence that have in some cases been used to achieve de facto legalization through the medical system [30]. In the United States, it is widely recognized that medical cannabis licenses are routinely used to obtain the drug for recreational purposes.

The impending liberalization of psychedelics runs the risk of reproducing all of these problems. The burgeoning psychedelic industry is already making strong claims about the safety and efficacy of these drugs based on weak trial evidence [9]. The putatively 'transformational' medical uses of psychedelics in treating serious mental disorders have featured prominently in the case that advocates have made for allowing easier adult use of psychedelics³¹ Indeed, some leading advocates of therapeutic psychedelic use have been explicit in their plan to use evidence of their therapeutic use as a way of liberalizing adult access to psychedelic use [31].

Poorly regulated adult use of psychedelic drugs could undermine their effective therapeutic uses by reducing incentives for conducting clinical trials, seeking licenses to commercialize them or by increasing the risk that widely publicized adverse events among psychedelic drug users will undermine public support for their therapeutic use. Poor regulation could thereby lead to renewed demands to tighten their regulation, as happened in the 1960s and 1970s. Concerns that this may occur have been expressed by leading contemporary psychedelic researchers [32]. Policy makers have an opportunity to chart a different course on how policy choices are defined, how the public is

informed about the merits and drawbacks of these choices and how policy decisions are implemented.

There is much that we can learn from the legalization of cannabis—and the problems that have arisen—to inform safe and effective policy in the case of psychedelics. We offer two recommendations for stakeholders in the field of addiction. First, the public and policy makers should openly debate whether psychedelics should be legal to use recreationally because people want to use them (i.e. not because they are seeking treatment for a disease). This debate should be strictly separated from the question of whether psychedelics have health benefits and be assigned the status of medicines. Conflating these two questions may damage the credibility of psychedelic therapeutics, risk patient health and also have deleterious effects on democratic trust to the extent that voters feel manipulated into legalizing these drugs for spurious reasons. Second, researchers should refrain from exaggerating the implications of findings from early-phase clinical trials. Researchers and public health officials must clearly communicate information on the risks of medical and nonmedical psychedelic use to the public.

Governments must minimize the role of industry in shaping psychedelic policies to their economic advantage. In the United States, in Colorado, the medical cannabis industry strongly influenced the implementation of legalization of adult use, creating a regulatory environment that maximized industry profits. This same industry has also played a crucial role in making the state the first to decriminalize nearly all psychedelics. Public and scientific stakeholders must place limits on the role of the pharmaceutical and medical cannabis industries in influencing regulatory decisions, by curtailing industry's undue influence in public policy while ensuring that regulatory guidelines are grounded in scientific evidence.

The safe rollout of therapeutic psychedelic use will require clinical research on appropriate indications and contraindications. Should governments opt to legalize psychedelics for medical purposes, licensure criteria for prescribers and therapists and hospitals will be critical. Finally, effective regulation of psychedelics will not come about without better regulatory enforcement and national government oversight than has been the case for cannabis in the United States. Devolving authority to local jurisdictions to regulate external signage, operating hours, outlet density, creating uneven regulations has created a highly variable and porous regulatory environment.

Should the public choose to legalize psychedelics, recent experience with cannabis liberalization suggests a number of issues that will require attention to ensure that implementation occurs as intended:

1. When regulatory policies regarding drug dosage are lacking, manufacturers are likely to produce high-potency products for which there is little evidence of safety or efficacy. Consequently, policy makers should consider limits on the potency of drugs made available for medical and recreational purposes. These limits should be consistent with available evidence regarding safety and efficacy.
2. Governments will need to decide what limits on advertising to impose on psychedelic drugs. In addition to considering direct

marketing to prescribers and consumers, it will also be necessary to regulate drug packaging and use of warning labels. Regulations on advertising must also take into consideration how false claims regarding evidence and drug safety and effectiveness will be addressed.

3. Policy makers should also attend to the need for public education regarding psychedelics. There is an opportunity for governments to do things differently than they have done in the case of cannabis, where few public education efforts have been mounted to ensure the public understands the benefits and risks of the drug.
4. As noted above, state and national involvement in crafting regulatory policies regarding distribution and sales is essential. Laws governing the distribution of psychedelics will differ depending on whether liberalization occurs for medical or recreational purposes. In the case of medical liberalization, policy makers must decide who will be licensed and how their practice will be supervised. In both medical and recreational scenarios, it will be necessary to clarify where psychedelic drugs can be sold and dispensed, and who can purchase them.
5. Taxation of revenue from drug production, distribution and sales will be an important issue to consider should psychedelics be legalized for recreational purposes. The hope for significant tax revenue has been persuasive to lawmakers in US states that have legalized cannabis. However, these revenues have been lower than anticipated in many states, because cannabis sales have displaced some purchasing of other highly taxed good such as alcohol and tobacco, and as maturation of cannabis markets has resulted in decline in cannabis prices. The fact that most psychedelic drugs will not be used as frequently as cannabis is good reason to believe that they will not generate a large tax revenue.

CONCLUSION

Psychedelics may someday prove to be safe and effective treatments for addiction. If that is the case, they should be welcomed, as long as approvals for medical use are not used to create a for-profit recreational industry. In any event, as the psychedelic liberalization movement gains momentum, corporate actors should be prevented from harnessing the unbridled enthusiasm of psychedelic advocates to push through ill-considered legislation that has potential to bring societal harms. Leaders in science and public health should play a leading role in shaping public policy debate and ensuring that accurate, balanced information is presented to the public about the potential benefits and harms of psychedelic use.

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Christina M. Andrews: Conceptualization (equal); writing—original draft (lead). **Wayne D. Hall:** Conceptualization (equal); writing—review and editing (equal). **Keith Humphreys:** Conceptualization (equal); writing—review and editing (equal). **John Marsden:** Conceptualization (equal); writing—review and editing (equal).

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