

Psychedelic Drug Legislative Reform and Legalization in the US

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IMPORTANCE Psychedelic drugs are becoming accessible in the US through a patchwork of state legislative reforms. This shift necessitates consensus on treatment models, education and guidance for health care professionals, and planning for implementation and regulation.

OBJECTIVE To assess trends in psychedelics legislative reform and legalization in the US to provide guidance to health care professionals, policy makers, and the public.

EVIDENCE REVIEW Data were compiled from legislative databases (BillTrack50, LexisNexis, and Ballotpedia) from January 1, 2019, to September 28, 2022. Legislation was identified by searching for terms related to psychedelics (eg, *psilocybin*, *MDMA*, *peyote*, *mescaline*, *ibogaine*, *LSD*, *ayahuasca*, and *DMT*). Bills were coded by an attorney along 2 axes: which psychedelic drugs would be affected and in what ways (eg, decriminalization, funding for medical research, and right to try). To explore drivers and rates of legislative reform, data were compared with other state indices including 2020 presidential voting margins and marijuana legislative reform.

FINDINGS Twenty-five states have considered 74 bills (69 legislative initiatives, 5 ballot measures); 10 bills were enacted, and 32 were still active. The number of psychedelic reform bills introduced during each calendar year increased steadily from 5 in 2019 to 6 in 2020, 27 in 2021, and 36 in 2022. Nearly all bills specified psilocybin (67 [90%]), and many also included MDMA (3,4-methylenedioxy-methamphetamine; 27 [36%]). While bills varied in their framework, most (43 [58%]) proposed decriminalization, of which few delineated medical oversight (10 of 43 [23%]) or training and/or licensure requirements (15 of 43 [35%]). In general, bills contained less regulatory guidance than the enacted Oregon Measure 109. While early legislative efforts occurred in liberal states, the margin between liberal and conservative states has decreased over time (although the difference was not significant), suggesting that psychedelic drug reform is becoming a bipartisan issue. In addition, an analytic model based on marijuana legalization projected that a majority of states will legalize psychedelics by 2034 to 2037.

CONCLUSIONS AND RELEVANCE Legislative reform for psychedelic drugs has been proceeding in a rapid, patchwork fashion in the US. Further consideration should be given to key health care issues such as establishing (1) standards for drugs procured outside the medical establishment, (2) licensure criteria for prescribers and therapists, (3) clinical and billing infrastructure, (4) potential contraindications, and (5) use in special populations like youths, older adults, and pregnant individuals.

JAMA Psychiatry. 2023;80(1):77-83. doi:10.1001/jamapsychiatry.2022.4101
Published online December 7, 2022.

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The Controlled Substances Act of 1970 established federal control over possession, distribution, and production of drugs.¹ Shortly thereafter, the Drug Enforcement Agency (DEA) was established to enforce the act, which classified psychedelics, 3,4-methylenedioxy-methamphetamine (MDMA), and cannabis as Schedule I substances with “no currently accepted medical use,” a “lack of accepted safety for use under medical supervision,” and “at least some potential for abuse sufficient to warrant control.”¹ In the intervening years, results from numerous studies in animals² and humans,³ including large multisite clinical trials with psilocybin for treatment-resistant depression⁴ and MDMA for posttraumatic stress disorder (PTSD),⁵ have supported the safety and medical utility of psychedelics and brought about increasing acceptance and interest in the US.

In May 2019, Denver, Colorado, became the first US city to decriminalize psilocybin.⁶ By the end of 2019, many cities were considering initiatives to decriminalize psychedelics. A review panel appointed by the Denver City Council issued a report in November 2021 that did not identify any significant negative association of decriminalization with public safety.⁷ They recommended training for first responders, public health education and messaging, data collection, and ongoing safety reporting.

In late 2020, Oregon became the first state to both decriminalize psilocybin and legalize it for therapeutic use. Oregon Ballot Measure 109 specified extensive guidelines (to be overseen by the Oregon Health Authority) regarding psilocybin production, manufacturing requirements, and licensure; psilocybin extraction; mandatory testing of purity and potency (testing laboratories must be accredited by the Oregon Environmental Laboratory Accreditation Program); record keeping; and facilitator qualifications, training, and licensure.⁸⁻¹⁰ Between February and August 2021, Oregon law enforcement observed an 87% reduction in psilocybin-related arrests compared with previous years.¹¹ As the first state to both decriminalize possession and provide clinical psilocybin services, the Oregon legislation created an advisory board that recently provided recommendations for training, administration, and communication of risks and benefits of psilocybin therapy to clients.¹² Under the current laws, psilocybin use is restricted to licensed facilities with trained counselors; facilities will be able to apply for licenses beginning in 2023.¹³

Political efforts for psychedelics reform have percolated from cities and states to the federal level as the US Congress considers bipartisan legislation that would further limit DEA control of Schedule I drugs.¹⁴ In response, the federal Substance Abuse and Mental Health Services Administration has recently indicated that it may pursue a policy of “harm reduction, risk mitigation, and safety monitoring” regarding emerging substances, such as psilocybin and MDMA, rather than strict prohibition.¹⁵

These legislative initiatives are concurrent with rising scientific and business interests in psychedelics.¹⁶ In recent years, philanthropic funding of research has led to the creation of academic centers for psychedelic science across the country, including at Johns Hopkins Bayview Medical Center; University of California San Francisco; Massachusetts General Hospital; University of California, Berkeley; Mount Sinai; The University of Texas at Austin; Washington University in St Louis; and others.¹⁷ In 2022, the National Institute of Mental Health and the National Institute on Drug Abuse began offering educational programming to support

investigators interested in working with psychedelic drugs.¹⁸ Support of this research by the National Institutes of Health (NIH) brings greater funding and scientific rigor. However, investment in academic research is still an order of magnitude lower than the value of some of the publicly traded companies in the psychedelics space.

Private investment into psychedelic pharmaceutical research and development has surged since 2018,¹⁹ supported by a US Food and Drug Administration (FDA) breakthrough therapy designation for clinical trials of psilocybin for depression and MDMA for PTSD. In 2021, companies invested more than \$730 million in the development of psychedelic drugs and novel drug delivery systems²⁰; in contrast, just \$4 million was invested by the NIH in the same year. While early phase IIb/III results look promising,^{4,5} FDA approval remains just 1 step in a complex process to transform these compounds into therapies. It is not yet clear how to handle potential FDA approval of psychedelics in the context of ongoing DEA Schedule I classification.²¹ Moreover, it is unclear how the health care system would implement psychedelic treatment, which is a dramatic departure from currently available medical and behavioral therapies and raises unique challenges.²²

The future of psychedelics in the US hinges on several factors, including the outcomes of and FDA decisions based on ongoing clinical trials, the potential decisions by the DEA or governing bodies to change the classification of psychedelics, and legislative reform at the state level, which has been the primary driver of cannabis legalization.²³ Cannabis achieved legalization through legislative reform in most states despite continued DEA Schedule I status and the absence of FDA approval. Now, state legislative reforms are shifting the prospects of psychedelics treatment and illicit drug enforcement.

In the present study, we sought to characterize the current state of legislative reform around Schedule I psychedelic drugs. Archives such as BillTrack50 and Ballotpedia make legislature and ballot initiatives publicly available. We used data from these sources to assess trends in psychedelic decriminalization and legislative reform, with the overall aim of identifying whether key considerations for implementation of psychedelics as medical treatments are being addressed.

Methods

We compiled a database of state legislative and ballot initiatives related to psychedelic drug reform introduced in the US beginning with the 2019 legislative session year. We (1) broadly characterized psychedelic legislative reform efforts occurring in the US, (2) compared decriminalization bills based on how psychedelics and psychedelic treatment will be implemented and regulated, (3) compared the 2020 presidential voting margins of states considering decriminalization to assess political drivers of legislation, and (4) developed an analytic model based on cannabis reforms to estimate when psychedelic drugs will likely be legal across the US. We hypothesized that legislation proposed at the state level would vary widely with respect to legislative scope and that right-to-try legislation signed by a conservative president in 2018 would increase conservative state adoption of psychedelic drug reform.

Selection and Coding of Relevant Legislation

Information was obtained from publicly available databases (BillTrack50,²⁴ Ballotpedia,²⁵ and LexisNexis²⁶) and included all bills and ballot initiatives relating to psychedelic drugs introduced into state legislatures between 2019 and 2022 (final search was September 28, 2022). BillTrack50 and LexisNexis are commercial legislation databases that include free and paid services. Ballotpedia is a professionally edited, nonprofit, free online encyclopedia that covers federal, state, and local politics, elections, and public policy in the US. BillTrack50 was used for initial collection of relevant legislation. January 1, 2019, was chosen as the start date because signature gathering for the first enacted decriminalization bill (Oregon Measure 109) began in 2019.

BillTrack50 was searched for legislation mentioning the terms *psilocybin*, *psilocyn*, *psilocin*, *MDMA*, *LSD*, *ibogaine*, *peyote*, *ayahuasca*, or *DMT*. The LexisNexis state legislation database was searched for bills enacted since 2010 that mentioned any of those terms at least 3 times to eliminate irrelevant enacted bills that mentioned the search terms only incidentally, typically by repeating the entire schedule of controlled substances as part of the bill text (eg, when the bill would add or remove an unrelated drug from the schedule). Ballotpedia was searched for ballot initiatives mentioning any of those terms.

Legislation and ballot initiatives were coded by an attorney (J.E.D.) to determine whether the scope of each bill included decriminalization, right to try, funding, policy research, or laboratory or clinical research. Decriminalization was defined as a reduction or elimination of criminal penalties associated with possessing or distributing a psychedelic drug. Right to try was defined as legislation allowing access to psychedelics for a particular patient population, such as patients with terminal illnesses for whom other therapies have not been effective. Funding was defined as any explicit appropriation of funds or budgeted amounts for psychedelic research, treatments, or regulation. Policy research was defined as the establishment of psychedelic therapy advisory boards or the preparation of reports for the legislature, state health department, or similar policy body. Laboratory or clinical research was defined as permitting, funding, or requiring the performance of laboratory or clinical research regarding psychedelic therapies.

Irrelevant bills that did not include at least 1 of those policies were excluded, such as prospective bills consisting of a restatement of the state's schedule of controlled substances laws without changes to Schedule I psychedelics (eg, bills adding new analogs to the schedule). Interrater reliability²⁷ was evaluated by comparing coding for a subset of bills by an independent rater (D.A.P.) for both drug and bill type. Hereafter, *bill* and *bills* refer to both bills and ballot initiatives.

Categorization of Decriminalization Bills by Regulatory Frameworks

To assess the variability in decriminalization legislation, the subset of bills proposing decriminalization was further coded based on the description of the bill's specific regulatory framework. These categories included physician involvement (whether a physician must prescribe the psychedelic or certify a qualifying diagnosis), medical involvement required (whether some clinical practitioner or medical setting, such as a treatment center, is required for legal use), and

training and licensure required (whether the bill indicated that some psychedelic-specific training or licensure would be required to prescribe psychedelics or to facilitate their use).

Comparison of Decriminalization Bills to State Partisanship

To evaluate potential political drivers of decriminalization, political leaning (on the liberal-conservative spectrum) was compared between states with decriminalization bills (active or enacted) and those without. Public data for each state's 2020 presidential voting margin were used as a proxy for each state's political leaning. To assess trends over time, states with decriminalization bills were further divided into those proposing decriminalization before vs after January 1, 2022. Both comparisons were tested using a *t* test of 2 samples, assuming equal variance and 2-tailed $P < .05$ as the threshold for significance. Analyses were performed using Microsoft Excel, version 16.66.1.

Analytic Model Based on Cannabis Reforms

Based on the assumption that psychedelics would follow a similar legislative trajectory to cannabis, medical and recreational cannabis decriminalization data^{28,29} were used to generate 2 analytic models. In each analytic model, the independent variable was years since the first state passed decriminalization (California legalized medical cannabis in 1996, and Colorado legalized recreational cannabis in 2012), and the dependent variable was the cumulative number of states passing decriminalization laws. In this analysis, Washington, DC, was counted as a state; thus, the majority of states was defined as 26 of 51. Then, using the rate of cannabis reform adoption (states per year) and 2020 as the index case of psychedelic decriminalization (Oregon, both medical and recreational), we modeled the rate of future psychedelics reform adoption. From this, we projected the year by which a majority of states will decriminalize psychedelics.

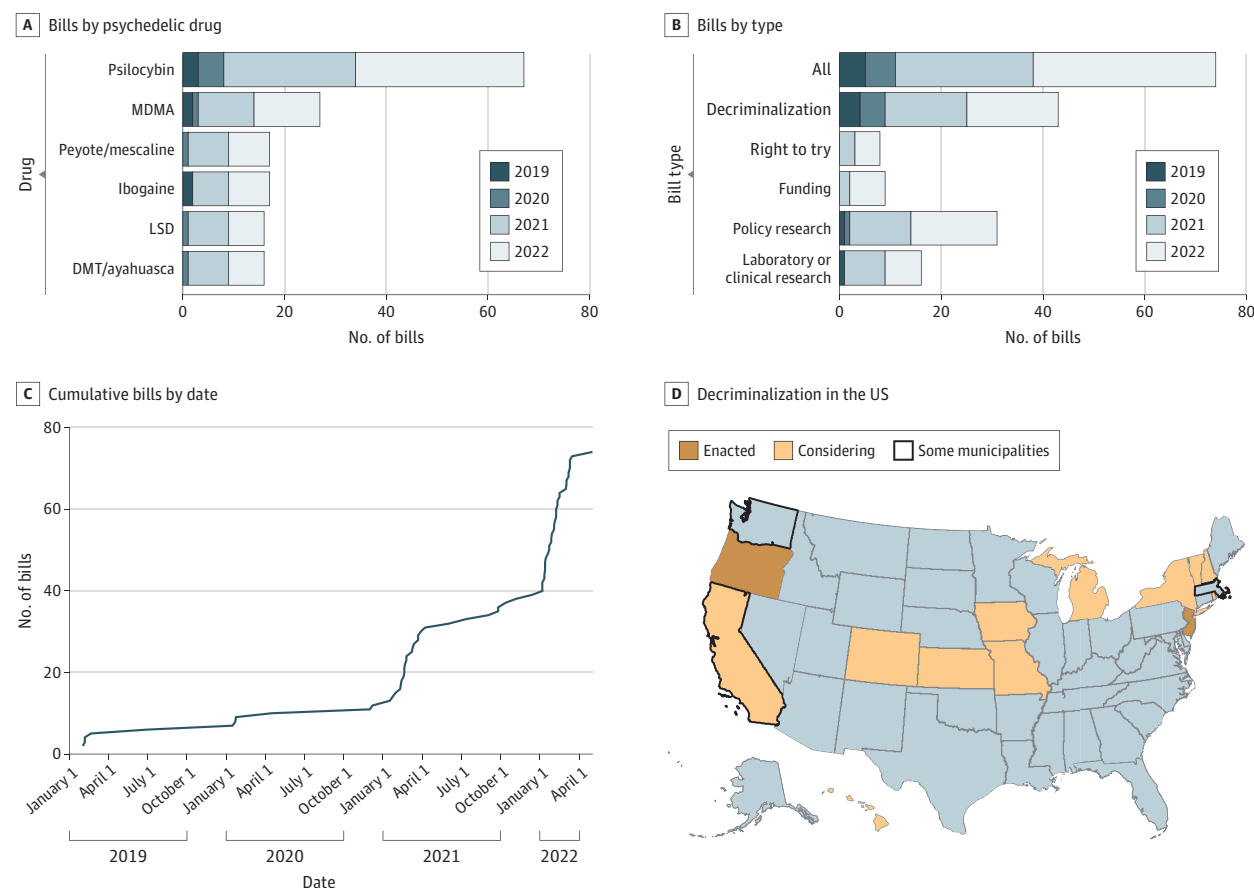
Results

Summary of Legislation

In total, our search identified 648 unique bills or ballot measures (collectively referred to as *bills*); 573 bills not related to psychedelic reform were excluded. One federal bill, US HR7900 (a failed appropriations bill that proposed funding to study treatments, including MDMA and psilocybin, for members of the armed forces on terminal leave), was excluded from further state analysis.

After screening, we found that 25 states considered 74 bills proposing reform of existing laws restricting access to psychedelic drugs or proposing further research into reform legislation. Of those bills, 10 (14%) were signed into law. Those 10 laws were from 7 states (Colorado, Connecticut, Hawaii, New Jersey, Oregon, Texas, and Washington) and included 1 passed by a ballot initiative (Oregon ballot measure 109). Three of those laws mention decriminalization: Colorado passed a trigger law decriminalizing prescription MDMA contingent on FDA approval, New Jersey reclassified possession of psilocybin as a disorderly offense, and Oregon decriminalized both medical and (effectively) recreational psilocybin. As of August 1, 2022, 32 bills (46%) were dead and 32 (52%) remained active. The number of new psychedelic reform bills introduced each calendar

Figure 1. Trends in Psychedelic Drug Reform Bills



D, Decriminalization bills include those that reduced or removed criminal penalties for possession of psychedelics. Some municipalities were municipal legislatures (eg, Oakland, California; Santa Cruz, California; Arcata, California; Ann Arbor, Michigan; Washington, DC; Washtenaw County, Michigan; Somerville, Massachusetts; Cambridge, Massachusetts; and Northampton, Massachusetts) that passed legislation, but legislation was not passed in the

state. *Considering* indicates currently active bills (as of August 1, 2022).

Colorado HB1344 (trigger law decriminalizing prescription 3,4-methylenedioxy-methamphetamine [MDMA] contingent on US Food and Drug Administration approval) was excluded. DMT indicates N,N-dimethyltryptamine; LSD, lysergic acid diethylamide.

year increased from 5 in 2019 to 6 in 2020, 27 in 2021, and 36 by September 28, 2022 (Figure 1C).

Bill Contents

Most bills specifically referred to psilocybin (67 [90%]), with many also including MDMA (27 [36%]), and relatively fewer included other psychedelics such as lysergic acid diethylamide (LSD), ibogaine, and peyote (Figure 1A). A total of 43 bills (58%) proposed reducing or removing existing penalties for possessing or distributing psychedelic drugs (ie, decriminalization) (Figure 1B). Excluding dead or failed bills, 13 states signed or were considering decriminalization laws (Figure 1D). Just under half of the bills (31 [42%]) specifically called for policy research to explore paths to decriminalization. Independent categorization of 53 bills by a second rater (D.A.P.) yielded very high interrater reliability: 100% for all psychedelic drug categories, right to try, and funding; 98% for decriminalization and policy research; and 92.5% for laboratory or clinical research.

Bills calling for decriminalization varied widely in the extent to which a regulatory framework was established for the safe and

effective use of psychedelics. Approximately half (22 of 43 [51%]) called for legalization of possession of at least 1 psychedelic drug for therapeutic (15 bills, although the description of therapeutic varied widely) or recreational purposes. Approximately one-third of decriminalization bills (15 of 43 [35%]) indicated that some training or licensure would be provided to prescribe psychedelics or to provide psychedelic-assisted psychotherapy. Approximately one-quarter of decriminalization bills (10 of 43 [23%]) mandated that access to psychedelics be restricted to some medical environment, such as a registered treatment center (with the implication that health departments would provide further guidance on treatment center requirements). Only 5 legalization bills (12%) explicitly mandated physician involvement in prescribing psychedelics or making qualifying diagnoses.

State Characteristics

In the analysis comparing state political leaning (on the liberal-conservative spectrum) to decriminalization, states considering decriminalization (13 states with enacted or active bills) (Figure 1D) were more liberal leaning than were states not considering decriminal-

ization ($n = 37$) (11.9% vs -11.1% D-R margin [percentage of votes going to President Biden minus votes going to former President Trump in the 2020 election]; $P < .001$, 2-tailed t test). States with decriminalization legislation proposed prior to January 1, 2022 ($n = 9$) had a 16.8% D-R margin, while states with first decriminalization legislation proposed in 2022 ($n = 4$) had a 1.1% D-R margin. This difference was not significant ($P = .12$, 2-tailed t test). From a geographical perspective, bills introduced before 2022 were mostly in coastal states, whereas in 2022, more midwestern states (Missouri, Colorado, and Kansas) introduced decriminalization bills.

Analytic Model Using Cannabis Legalization

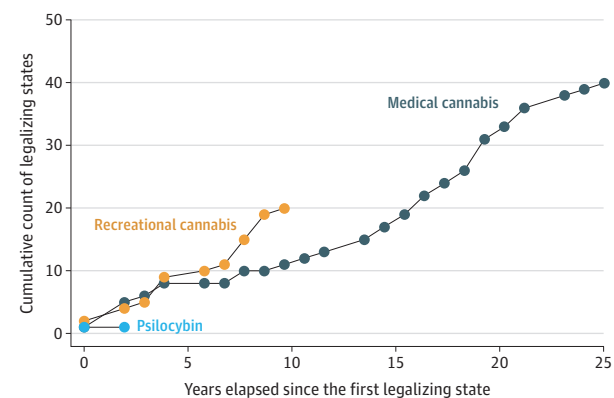
To estimate the rate of psychedelic drug reform adoption in coming years, we made the assumption that psychedelics would follow a similar trajectory to cannabis and thus used cannabis legalization data to develop an analytic model (Figure 2). California was the first state to legalize medical cannabis in 1996. In the 26 years since, 40 states have adopted medical legalization at a roughly linear rate (1.53 states per year; 95% CI, 1.36-1.70 states per year). By comparison, since Colorado legalized recreational cannabis in 2012, 19 states and Washington, DC, have adopted recreational cannabis legalization (1.84 states per year; 95% CI, 1.45-2.23 states per year). With use of 2020 as the year of the first psychedelic decriminalization (Oregon, both medical and recreational), the cannabis models estimated that a majority of states (26 of 51) will legalize psychedelics by 2034 based on the recreational cannabis model and by 2037 based on the medical cannabis model.

Discussion

This analysis of publicly available data established several important findings relevant to developing a cohesive national plan for the safe regulation and administration of psychedelic drugs. First, the momentum behind psychedelic drug reform has been increasing. Since 2019, 25 states have considered 74 bills, with 10 already signed into law. The number of bills considered increased steadily from 5 in 2019 to 6 in 2020, 27 in 2021, and 36 in 2022. Second, bills varied widely in their framework, with a majority proposing decriminalization, of which only a few would require medical oversight and some would not even require training or licensure. Most offered less detailed guidelines and regulations than Oregon's approved decriminalization laws. While early legislative efforts occurred in liberal states, the margin between liberal and conservative states has decreased over time (although the difference was not significant), suggesting that psychedelic drug reform is becoming a bipartisan issue. While proposed laws have differed considerably, all effectively contradicted or sidestepped the Controlled Substances Act of 1970.

It is unusual for a pharmaceutical to be made accessible by legislation rather than FDA regulatory approval, which includes a careful review of drug manufacturing, shipping, efficacy, adverse events, oversight and monitoring, and appropriate postmarket monitoring. The American Psychiatric Association released a position statement in July 2022 that concluded that "clinical treatments should be determined by scientific evidence in accordance with applicable regulatory standards and not by ballot initiatives or popular opinion."¹¹

Figure 2. Comparison of Psilocybin Legalization With Cannabis Legalization



Based on data from cannabis legalization, we projected that most states will have passed legislation legalizing psychedelics by 2034 to 2037. It is possible that psychedelic reform will occur even more rapidly than cannabis reform due to the higher apparent likelihood of FDA approval, the early shift toward bipartisan legislative support, early interest in reform at the federal level, and the fact that marijuana reform has paved the way for increased access to Schedule I drugs. Alternatively, the path to legalization may be slowed if current FDA applications do not result in approval or if the public perceives psychedelics to be more dangerous than cannabis. Another key influence is the amount of money spent on lobbying for legislative reform. New Approach PAC previously focused on decriminalizing marijuana but has turned its focus to psychedelics. For example, New Approach PAC contributed \$2.8 million in support of Colorado Proposition 122, a ballot measure in the November 2022 election.³⁰

Perhaps most important are the issues on which the current decriminalization legislation remains silent: (1) there is no precise mechanism for verifying the chemical content and makeup of drugs procured outside the medical establishment; (2) there has been little discussion regarding training, licensure, and monitoring for practitioners who wish to facilitate treatment (35% of bills delineated treatment requirements, and 12% specified physician involvement); (3) the clinical and billing infrastructure for providing psychedelic-assisted psychotherapy has yet to be developed; (4) to date, there is no clinical consensus on pharmacological interactions with comedications and potential contraindications to treatment (eg, psychotic disorders or cardiovascular disease)³¹; and (5) there is no information to guide use in populations like older adults, children, and pregnant individuals. The minimal involvement of physicians in the majority of these legislations stands in contrast to FDA regulation of esketamine,³² which includes extensive guidelines regarding medical diagnosis prior to initiation and oversight during treatment.

Despite the relative rapidity with which some have embraced psychedelics as legitimate medical treatments, critical questions about the mechanism of action, dose and dose frequency, durability of response to repeated treatments, drug-drug interactions, and the role that psychotherapy plays in therapeutic efficacy remain unanswered. This last point is critical as a significant safety concern associated with drugs like psilocybin, MDMA, or LSD is the suggest-

ibility and vulnerability of the patient while under the influence of the drug.³³ Thus, training and clinical oversight is necessary to ensure safety and also therapeutic efficacy for this divergent class of treatments.^{34,35} Some efforts along these lines are underway in the US³⁶ and Canada.³⁷

Limitations

Our analysis and interpretation are subject to limitations. First, we treated all proposed legislation equally without regard for likelihood of enactment. Second, our definition of psychedelics included MDMA, which has psychedelic effects at higher doses but is not classified as a classic psychedelic. Third, we counted 3 bills introduced in prior legislative sessions (eg, Hawaii SB738 and SB2575) that were reintroduced during the study period. Fourth, our model estimating when states might legalize psychedelics relied on the assumption that psychedelic decriminalization will follow a similar

trajectory to cannabis decriminalization. Fifth, although we acknowledge the sociopolitical importance of municipal and federal legislative efforts, they were not included in the analysis.

Conclusions

The results of our study showed that, after decades of legal restriction, US states have been swiftly moving toward increased access to psychedelics. Decriminalization is just 1 step in a complex process to transform these compounds into safe and effective therapies. This process will have important consequences for the medical and scientific community. Integrating psychedelic treatment into clinical practice will require peeling back many layers of legal prohibition and FDA approval, clarifying prescribing guidelines, and developing treatment models that work for drug makers, physicians, and patients.

ARTICLE INFORMATION

Accepted for Publication: October 6, 2022.

Published Online: December 7, 2022.

doi:10.1001/jamapsychiatry.2022.4101

Author Contributions: Dr Siegel and Mr Daily had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Siegel, Nicol.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: All authors.

Critical revision of the manuscript for important intellectual content: Siegel, Daily, Nicol.

Statistical analysis: Siegel, Perry, Nicol.

Obtained funding: Siegel, Nicol.

Administrative, technical, or material support: Siegel, Daily.

Supervision: Siegel, Nicol.

Conflict of Interest Disclosures: Dr Siegel reported receiving personal fees from Forbes Manhattan outside the submitted work and serving on the scientific advisory board of Silo Wellness (unpaid). Dr Nicol reported receiving personal fees from Novartis; receiving grants from LB Pharmaceuticals, the National Institute of Mental Health, and the Health Resources and Services Administration; receiving nonfinancial support from Usona Institute; and being a paid consultant for IngenioRx, Alkermes, Inc, Sunovion Pharmaceuticals, Inc, and Novartis Pharmaceuticals Corp outside the submitted work. No other disclosures were reported.

Funding/Support: This work was supported by grant GFO010787 from the Taylor Family Institute Fund for Innovative Psychiatric Research (Dr Siegel), grant R25 MH112473 from the National Institute of Mental Health (Dr Nicol), grant UL1 TRO02345 (Institute of Clinical and Translational Science Award 5157) from the National Center for Advancing Translational Sciences (Dr Siegel), grant T32DA007261 from the National Institute on Drug Abuse, McDonnell Center for Systems Neuroscience Award 202002165 (Dr Siegel), and the Washington University Center for Empirical Research in the Law (Mr Daily).

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and

interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: The content is solely the responsibility of the authors and does not necessarily represent the official view of the National Institutes of Health or other supporting institutions.

Additional Contributions: Eapen Thampy, BA, and Representative Anthony Lovasco, BA (Missouri House of Representatives), provided unpaid assistance with interpretation of legislative trends.

Additional Information: A catalog of states and municipalities that have passed psilocybin decriminalization laws is given at https://en.wikipedia.org/wiki/Psilocybin_decriminalization_in_the_United_States.

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