Psilocybin Assisted Psychotherapy in Missouri House Bill 1154 (2023)

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Executive Summary - The Controlled Substances Act & HB 1154

On May 13, 2022, the federal Substance Abuse and Mental Health Services Administration, an agency of the US Department of Health and Human Services, wrote in a letter to Congresswoman Madeleine Dean (D-PA) to indicate that they anticipated rescheduling and indicated regulatory approvals for MDMA and psilocybin by the Food and Drug Administration within two years. Since Missouri State Representative Tony Lovasco's (R-St. Charles) House Bill 869 only deals with psilocybin assisted psychotherapy, this monograph will not discuss MDMA.

In 1970, Congress passed the Controlled Substances Act. Following this enactment, the National Conference of Commissioners on Uniform State Laws drafted the Uniform Controlled Substances Act as a model for states to use in updating their drug laws. An explicit purpose of the USCA was to promote uniformity between state and federal statute. The Controlled Substances Act was further revised by the Comprehensive Crime Control Act of 1984 and then by the Anti-Drug Abuse Act of 1986. Under the CSA, the US Attorney General may initiate a formal rulemaking process to designate, delete, or reschedule a drug. The Attorney General has delegated authority to the Drug Enforcement Administration to request an evaluation of a drug from the Secretary of Health and Human Services, who has delegated to the Food & Drug Administration authority to prepare this evaluation.

In 1989, the Missouri General Assembly passed the Comprehensive Drug Control Act, consisting of Chapter 195 (Drug Regulations) and Chapter 579 (Controlled Substance Offenses). Under RsMO 195.015, the "department of health and senior services shall similarly control the substance" to ensure concurrence with any designation, deletion, or scheduling decision of the US Attorney General.

Psilocybin is currently regulated in Schedule 1 in both Federal and Missouri statute. Federal rescheduling of psilocybin will trigger the provision in RsMO 195.015, meaning that the Department of Health and Senior Services will reschedule psilocybin concurrently with federal action.

What this means is that we are no longer talking about legalizing psilocybin - if the US Attorney General's scheduling review concludes as indicated, psilocybin will be legally available for clinical use by prescription. Our aim here is twofold. First, to create affirmative defenses to possession and use for legally prescribed psilocybin so that patients, providers, and manufacturers are not unduly burdened by current statutory penalties (which Rep. Lovasco's proposal currently does). Second, to ensure regulated access at the cheapest possible price so that these therapies are affordable for patients. Because naturally grown psilocybin can be produced at a very low cost, it will be vastly more affordable than synthetic or pharmaceutical options - which is critical, because insurance coverage will not be available for several years (actuaries require several years of population level data to assess risks and costs before policies can be underwritten).

Federal & Missouri History on Investigational Drug Access

Missouri became the 3rd state to pass Right to Try legislation in 2014. This framework allows access to drugs that have passed Stage 1 of a clinical trial and was created in response to the widespread practice of Americans leaving the country to gain access to investigational drugs - a situation that unfortunately continues as many Americans, particularly military veterans, must leave the state or country for psychedelic medicine access. Missouri's statute currently specifies Right to Try access for only terminal conditions and excludes Schedule 1 drugs.

In 2018, President Trump signed a federal Right to Try law, which allows access to investigational drugs for debilitating and life-threatening conditions, and does not exclude Schedule 1 drugs. However, the Drug Enforcement Administration currently disputes that the federal Right to Try statute creates an exception in the Controlled Substances Act for Schedule 1. This issue has been litigated in the Ninth Circuit in recent years as Dr. Sunil Aggarwal sued for Right to Try access for psilocybin for patients in end-of-life situations. Unfortunately, the Ninth Circuit punted on the issue and did not provide a resolution to the question of Right to Try Schedule 1 access.

In 2022, US Senators Rand Paul (R-Kentucky) and Cory Booker (D-New Jersey) filed the Right to Try Clarification Act to clarify that the federal Right to Try statute in fact did allow access to Schedule 1 drugs, specifically highlighting the issues around access to psilocybin and MDMA. Companion legislation was filed by US Representatives Nancy Mace (R-South Carolina) and Earl Blumenaur (D-Oregon). This legislation is supported by the Veterans Mental Health Coalition.
https://www.booker.senate.gov/news/press/booker-paul-introduce-bipartisan-legislation-to-amend-the-right-to-try-act-to-assist-terminally-ill-patients

Recent International Developments

On February 3, 2023, the Australian federal agency Therapeutic Goods Administration (TGA) filed notice approving psilocybin and MDMA for therapeutic use. This makes Australia the first developed country to take action on psychedelic access since the UN Single Convention on Narcotic Drugs in 1961.

https://www.tga.gov.au/sites/default/files/2023-02/notice-of-final-decision-to-amend-or-not-amend-the-current-poisons-standard-june-2022-acms-38-psilocybine-and-mdma.pdf

Depression

Compass Pathways Webcast on Psilocybin Stage 3 Trial - Oct. 22, 2022

https://ir.compasspathways.com/events/event-details/compass-pathways-capital-markets-day

Results from Stage 2 Psilocybin Trial for Depression

Barber, G.S., Aaronson, S.T. The Emerging Field of Psychedelic Psychotherapy. Curr Psychiatry Rep 24, 583–590 (2022). https://doi.org/10.1007/s11920-022-01363-y

In one of the largest clinical trials so far on psilocybin-assisted psychotherapy for major depressive disorder (n = 27), 71% of participants had a clinically significant response to psilocybin 4 weeks after a single dose, while 54% of participants achieved remission from depression over the same time, corresponding with large effect sizes (d = 2.3) [20••]. Of note, this was a crossover trial, which can inflate response rates. Another recent trial found that psilocybin was non-inferior to the commonly prescribed anti-depressant escitalopram, with 30 patients receiving psilocybin and 29 patients receiving escitalopram [34••]. Across these trials, positive benefits often endured for months after just a single psilocybin dose. Many patients have commented that the psilocybin session was among most meaningful experiences of their life [35]. Table 1 provides some details of the clinical trials described above. While some variation exists between psychedelic protocols, the therapeutic process tends to follow a general timeline and structure, which is detailed in Fig. 1.

The pharmacological profile of psilocybin is quite unique when compared to the current anti-depressant treatments available for prescription use today. Most drugs used to treat depression act on a variety of serotonin receptors to inhibit the breakdown or re-uptake of extra-cellular serotonin. In theory these drugs work to, over time, increase the levels of serotonin, thus alleviating depression that could possibly stem from serotonergic deficiencies. This technique is widely considered the best way to pharmacologically treat depression (Paykel 1993, Sclar et al., 1998). Although, considering the delayed action of these prescription drugs, which can be 4-6 weeks, there is a need for faster-action novel treatments: enter psilocybin.

Alcohol Use Disorder

“Percentage of Heavy Drinking Days Following Psilocybin-Assisted Psychotherapy vs Placebo in the Treatment of Adult Patients With Alcohol Use Disorder”, Michael P. Bogenschutz, MD et al, JAMA Psychiatry. 2022;79(10):953-962. doi:10.1001/jamapsychiatry.2022.2096

This study examined a total of 95 participants. 49 subjects received psilocybin and 46 received a control (diphenhydramine). Percentage of heavy drinking days during the 32-week double-blind period was 9.7% for the psilocybin group and 23.6% for the control group, a mean difference of 13.9%.Mean daily alcohol consumption (number of standard drinks per day) was also lower in the psilocybin group.

NYU Langone Statement,
https://nyulangone.org/news/psychedelic-drug-therapy-may-help-treat-alcohol-addiction

Within an 8-month period from the start of their treatment, those who were given psilocybin reduced heavy drinking by 83 percent relative to their drinking before the study began. Meanwhile, those who had received antihistamine reduced their drinking by 51 percent. Among the other key findings, the study showed that 8 months after their first dose, almost half (48 percent) of those who received psilocybin stopped drinking altogether compared with 24 percent of the placebo group.
“Our findings strongly suggest that psilocybin therapy is a promising means of treating alcohol use disorder, a complex disease that has proven notoriously difficult to manage,” says study senior author and psychiatrist Michael P. Bogenschutz, MD, director of NYU Langone’s Center for Psychedelic Medicine.

Opiate Use Disorder (OUD)

Jones, G., Ricard, J.A., Lipson, J. et al. Associations between classic psychedelics and opioid use disorder in a nationally-representative U.S. adult sample. Sci Rep 12, 4099 (2022). https://doi.org/10.1038/s41598-022-08085-4

This study found significantly reduced odds of opiate use disorder (30%) in a large, nationally representative sample of the US population, a finding that replicated conclusions of prior studies. Lifetime psilocybin use was significantly associated with reduced odds of seven out of 11 DSM-IV criteria for opioid dependence and abuse.

Persisting Reductions in Cannabis, Opioid, and Stimulant Misuse After Naturalistic Psychedelic Use: An Online Survey
Albert Garcia-Romeu et al, Front. Psychiatry, 22 January 2020, Sec. Psychopharmacology , Volume 10 - 2019 | https://doi.org/10.3389/fpsyt.2019.00955

> Four hundred forty-four respondents, mostly in the USA (67%) completed the survey. Participants reported 4.5 years of problematic substance use on average before the psychedelic experience to which they attributed a reduction in drug consumption, with 79% meeting retrospective criteria for severe SUD. Most reported taking a moderate or high dose of LSD (43%) or psilocybin-containing mushrooms (29%), followed by significant reduction in drug consumption. Before the psychedelic experience 96% met SUD criteria, whereas only 27% met SUD criteria afterward. Participants rated their psychedelic experience as highly meaningful and insightful, with 28% endorsing psychedelic-associated changes in life priorities or values as facilitating reduced substance misuse. Greater psychedelic dose, insight, mystical-type effects, and personal meaning of experiences were associated with greater reduction in drug consumption.

First-in-kind psychedelic trials treat opioid and methamphetamine use disorders
January 6, 2023 By Katie Gerhards
https://news.wisc.edu/two-first-in-kind-clinical-trials-explore-psilocybin-for-substance-misuse/

> Three million people in the United States have had opioid use disorder, and another 1.5 million people have dealt with methamphetamine misuse within the last year alone. But two new groundbreaking clinical trials out of the UW Transdisciplinary Center for Research in Psychoactive Substances (TCRPS), housed within the University of Wisconsin–Madison School of Pharmacy, aim to address these pressing issues with a promising psychoactive agent: psilocybin.
> The drug has shown encouraging results for patients with depression and with tobacco and alcohol misuse. Now, a UW–Madison research team is investigating the use of psilocybin to aid in decreasing opioid and methamphetamine misuse.

Anxiety/OCD

Psychedelics as Reemerging Treatments for Anxiety Disorders: Possibilities and Challenges in a Nascent Field
Franklin King IV, MD., and Rebecca Hammond, M.D.
17 Jun 2021https://doi.org/10.1176/appi.focus.20200047
Building on work from a previous successful pilot study (53), two recent randomized, double-blind, placebo-controlled trials utilizing a crossover design reported substantial reductions in both depression and anxiety among patients with anxiety and depressive disorders associated with life-threatening or advanced cancer (54, 55). Both studies utilized a single session of psilocybin-assisted psychotherapy, with 60%–80% of participants in each trial reporting sustained reductions in depression and anxiety at 6 months. Improvements in existential distress, well-being, and attitudes toward death were also found. Interestingly, in both trials, the degree to which the psilocybin session induced a mystical experience was found to correlate positively with the effects on anxiety and mood. The effects appear to have been durable, with one study site finding, at 4.5-year follow-up, sustainment of clinically significant reductions in anxiety and depression (56).
Psilocybin has also been proposed as a potential treatment of obsessive-compulsive disorder (OCD). One modified double-blind trial of nine patients found reductions in OCD symptoms following four sessions of psilocybin-assisted psychotherapy in which varying doses of psilocybin were given across a 4-week period (57). Two additional clinical trials are currently under way to study use of psilocybin for OCD (58, 59). Finally, an open-label study using psilocybin-assisted psychotherapy for treatment-resistant depression also found significant reductions in scores on the State-Trait Anxiety Inventory; these results were sustained at 6-month follow-up (60, 61).

Autism Spectrum Disorder

Evaluating the Potential Use of Serotonergic Psychedelics in Autism Spectrum Disorder
Front. Pharmacol., 27 January 2022
Sec. Neuropharmacology
Volume 12 - 2021 | https://doi.org/10.3389/fphar.2021.749068

Due to the limited treatment options for ASD, the development of novel therapies is warranted. Clinical and preclinical trials suggest that psychedelics may improve social behaviour and decrease the burden of co-occurring diagnoses in ASD by targeting synaptic function, serotonin signaling, PFC activity, and thalamocortical signaling. Early clinical trials in childhood ASD suggest that psychedelics might hold therapeutic potential; however, the side effects encountered represent potential limitations to this treatment. It is possible that psychedelics may alleviate a few core social-behavioural features in individuals with ASD, such as social anxiety, but carefully performing a risk-to-benefit assessment is crucial due to the severity of their potential side effects.

Individuals with ASD represent a highly heterogeneous demographic; therefore, only certain subsets of individuals with ASD may respond well to psychedelic treatment options. Clinical trials must proceed with caution because this population is also comprised of children and some individuals with intellectual disabilities, for which obtaining informed consent is a challenge. Future studies must make these considerations when determining if some of the positive findings obtained in the “first wave” of psychedelic research in ASD can be validated when employing contemporary scientific and ethical standards.

Appendix A - SAMHSA Letter

SAMHSA
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane • Rockville, MD 20857
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

May 13, 2022

The Honorable Madeleine Dean
U.S. House of Representatives
Washington, DC 20515

Dear Representative Dean:

Thank you for your letter to Secretary Becerra in which you recommend the establishment of an interagency Federal Task Force to develop and lead a public-private partnership that can address the myriad of complex issues associated with the anticipated approval by the Food and Drug Administration (FDA) of 3,4-methylenedioxymethamphetamine (MDMA) for the treatment of Post-Traumatic Stress Disorder and psilocybin for the treatment of depression within approximately 24 months. The Substance Abuse and Mental Health Services Administration (SAMHSA) was asked to respond on the Secretary's behalf.

SAMHSA agrees that too many Americans are suffering from mental health and substance use issues, which have been exacerbated by the ongoing COVID-19 pandemic, and that we must explore the potential of psychedelic-assisted therapies to address this crisis. SAMHSA also agrees that the use of psychedelic medicines will require a broad-spectrum interdisciplinary stakeholder approach to effectively tackle the complexity of issues that stakeholders anticipate will arise with their introduction.

SAMHSA, in collaboration with the Assistant Secretary for Health, is exploring the prospect of establishing a Federal Task Force to monitor and address the numerous complex issues associated with emerging substances. The Task Force may establish and oversee the functions of a public-private partnership that can broadly focus on addressing numerous complex issues associated with psychedelic (psilocybin) and entactogenic (MDMA) medicines but whose risks to public health may require harm reduction, risk mitigation, and safety monitoring. Collaboration across federal agencies with outside stakeholders will be the most effective way to ensure we are thoughtfully coordinating work on emerging substances such as MDMA and psilocybin.

Thank you for taking the time to elevate this important issue.

Sincerely,

Miriam Delphin-Rittmon

Miriam E. Delphin-Rittmon
Assistant Secretary for Mental Health
and Substance Use

CC:
The Honorable Earl Blumenauer
The Honorable Brian Fitzpatrick
The Honorable Dean Phillips
The Honorable Michael Waltz
ADM Rachel Levine

Appendix B - Press Release From Missouri State Representative Tony Lovasco (R-St. Charles) on House Bill 869

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Tony Lovasco
Missouri State Representative
District 64

102nd GENERAL ASSEMBLY COMMITTEES:

Vice-Chair:
Government Accountability

Member:
General Laws
Ways and Means
Government Efficiency and Downsizing

FOR IMMEDIATE RELEASE
January 19th, 2023

Veterans, Physicians, Law Enforcement Leaders Praise Rep. Tony Lovasco's Bill Decriminalizing FDA-Classed "Breakthrough Treatment" for Severe PTSD & Depression

As Missouri's Incidence of Suicide Among Veterans Leads the Nation, Advocates Seek New Evidence-Based Natural Medicine Approaches for Relief

Jefferson City MO – This week Missouri State Representative Tony Lovasco (R-St. Charles) filed House Bill 869 creating legal access to psilocybin-assisted psychotherapy.

"House Bill 869 is a first step to addressing pervasive mental health crises that affect every sector of our society and economy by creating access to clinically validated therapies," said Representative Lovasco. "I am especially encouraged at clinical research suggesting psilocybin may be a tool to address our opiate addiction crisis."

Johns Hopkins Medical School-affiliated researchers have published over 150 peer-reviewed studies demonstrating the effectiveness of psilocybin, a naturally occurring compound in certain types of fungi, in ameliorating a wide variety of serious mental illnesses, and Missouri-based scientists are doing cutting-edge research in the field. "Significant findings from clinical trials have shown efficacy for psilocybin-assisted psychotherapy in depression and addiction and for MDMA-assisted psychotherapy in PTSD", reported Dr. Josh Siegel (M.D./Ph.D.), a Washington University neuropsychopharmacologist leading psilocybin clinical trials.

"We anticipate regulatory approvals from the U.S. Food & Drug Administration in the next two years; Missouri should build out its capacity to provide access and regulate as appropriate."

Numerous veterans such as Tim Jensen, Grunt Style Foundation Board President and a U.S. Marine Corps veteran, offered support for the proposal. "Our country has done many of our veterans a grave disservice," said Jensen, referencing reports revealing hundreds of previously-covered up incidents of botched surgeries, inhumane medical treatment, and multi-year wait times in the Veterans Administration. "We ask the Missouri General Assembly to consider psychedelics as a form of therapy for veterans and others who have sustained immense psychological and physical trauma."

Law enforcement leaders joined their brothers in uniform to support Rep. Lovasco's proposal. "Like our heroes who fight abroad to keep us safe, law enforcement and first responders routinely experience traumatic events in the line of duty," said New Haven (MO) Police Chief Chris Hammann. "As a result, we face multiple expanding crises including personnel retention, alcoholism, and suicide. Creating legal access to psilocybin-assisted psychotherapy would be a first step to breaking that cycle."

Elaine Brewer, founder of the Humble Warrior Wellness Center, lamented the lengths that wounded veterans must currently go to seek effective treatment. "Missouri leads the nation in suicide among veterans – and yet those seeking psilocybin-assisted psychotherapy must leave the United States for legal access," said Brewer. "While we are encouraged that these therapies will soon be accessible in Oregon, Colorado, and Connecticut, Missourians should not have to leave their state to access lifesaving therapy."

"Missouri is in an ongoing mental health crisis and this legislation provides real hope for stemming our suicide and addiction epidemics," said Alina Robinson, an organizer with grassroots organization Psychedelic Missouri. "Lawmakers should seriously consider Rep. Lovasco's proposal this session.

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