

Executive Summary

Objective: Drafting of a bill that establishes access to psilocybin-assisted therapy for New Mexicans in need of mental health and substance abuse treatment. A comprehensive bill would include an ethical framework for service provision, provider training requirements, and for the regulated production and administration of psilocybin products.

- Given the persistent rise in mental illness, substance abuse, and drug overdose mortality in New Mexico legislation that promotes the availability of novel evidence-based treatments are warranted.
- Traditional plant medicines such as psilocybin-containing mushrooms are increasingly being recognized as highly effective treatments for certain mental health conditions and substance use disorders. A fast-growing body of scientific evidence from clinical studies attests to the efficacy of these medicines, and *often in clinical scenarios where standard treatments have failed*.
- The FDA has designated psilocybin as a ‘breakthrough therapy’ for depression based upon clinical trials conducted in 2018 and 2019. In addition, psilocybin-assisted therapy has proven efficacy for anxiety disorders, post-traumatic stress disorder (PTSD), substance use disorders (SUDS) and existential distress in patients suffering terminal illness.
- Psilocybin has a very favorable safety profile: it is not addictive, there is virtually no risk of a lethal overdose, and adverse reactions are frequently transient in nature and successfully mitigated by appropriate screening, structured therapeutic settings, and trained personnel.
- Psilocybin-assisted therapy would only be offered in the context of a unique treatment paradigm where the medicine is administered in a very limited number of sessions, typically one to three, while in the presence of certified provider(s), and only after a comprehensive assessment and medical evaluation is completed. Each active session is scheduled for a whole day and typically, the individual remains onsite overnight for safety monitoring. Much of the therapeutic benefit is derived from subsequent drug-free integration sessions that are delivered over weeks and months.
- New Mexicans who will benefit from equitable access to psilocybin-assisted therapy include:
 - individuals who have been diagnosed with difficult to treat forms of mental illness,
 - individuals who struggle with addiction and substance abuse,
 - individuals who have suffered severe trauma, including first responders, veterans, and victims of domestic abuse, and
 - individuals facing existential distress due to a diagnosis of a terminal illness.
- There is a national trend to offer legal access to plant-based and psychedelic medicines, including psilocybin, through state-level legislative action. At the federal level, initiatives focused on changing the scheduling / regulatory status of psychedelic medicines are also underway.
- In addition to alleviating suffering of New Mexicans, provision of legal access to psilocybin-assisted therapy entails economic opportunities for New Mexico, including the production of the medicine, distribution, quality assurance services, and the education and training of producers and therapeutic providers, both in New Mexico and nationally.

Objective

Petition the NM Department of Health to establish:

1. a framework for the therapeutic administration of psilocybin and psilocybin-containing mushrooms for specified mental health indications,
2. a review panel to assess the effects of this measure, and
3. a board for licensing and regulating the manufacturing, transportation, delivery, sale, and purchase of psilocybin products and for the provision of psilocybin services within the state of New Mexico.

Brief Social and Historical Background

For centuries, plant- and fungi-based medicines have been used in many different cultures for a variety of purposes, however, their benefits have been slow to find acceptance in contemporary western allopathic healthcare systems. As a result, support for high quality research on the potential benefits of these medicines has been lacking and instead, and with only a few exceptions (e.g., peyote within the Native American Church, ayahuasca within the União de Vegetal), their use has been criminalized. However, as a society, we are currently experiencing a definitive shift in how psychedelics are evaluated within an emerging new paradigm that capitalizes on the vast healing potential of these traditional medicines for many debilitating conditions. Due to a dramatic increase in the number of clinical research studies demonstrating the safety and efficacy of these medicines, an increasing number of states are taking legislative action to remove the legal obstacles to therapeutic access [1]. Initiatives at the federal level focused on changing the scheduling / regulatory status of psychedelic medicines are also underway.

Rationale for Legal Access to Natural Psychedelic Medicines

Unmet Mental Health Need for New Mexicans

Our nation, and residents of New Mexico in particular, are facing a mental health crisis with depression, anxiety, post-traumatic stress disorder (PTSD), isolation, existential distress, and substance abuse all on the rise. Recent data shows that over one quarter of American adults suffer from a diagnosable mental disorder each year, including 9.5% suffering from a depressive disorder and about 18% suffering from an anxiety disorder [2]. Substance use is a notable challenge in New Mexico and drug overdose mortality rates in New Mexico have been significantly above the national average for many years. For example, in 2020, New Mexico saw 39 deaths/100,000 population vs. 28.3/100,000 nationally [3].

Despite the variety of approved treatments for these conditions, efficacy is variable with regard to symptom reduction and the duration of benefit, with many treatments requiring ongoing pharmacological treatment that carries inherent risks and economic burdens [4][5][6][7].

Evidence-Based Psilocybin-Assisted Therapy

Research at institutions like Johns Hopkins, NYU, and UCLA has shown that psychedelic-assisted therapy, when facilitated by trained professionals, can be an effective treatment for depression, anxiety, and other mental health disorders [8][9]. In 2018 and 2019, the FDA designated psilocybin, the active ingredient in psychedelic mushrooms, as a ‘breakthrough therapy’. The FDA’s designation was based upon clinical data from two separate studies showing that psilocybin-assisted therapy represents a substantial improvement over available therapy for the serious conditions of treatment-resistant depression and major depressive disorder [10]. In addition to depression, a growing body of clinical studies is demonstrating efficacy of psilocybin for the treatment of anxiety, PTSD, addiction, and existential distress. Since 2010, there have been over 400 publications on psilocybin [11], and as of July 2022 there are over 100 psilocybin studies registered on clinicaltrials.gov, the NIH’s clearinghouse for current clinical trials.

In addition, anecdotal evidence of life-altering, and even life-saving therapeutic experiences with psilocybin support these clinical trial data. One such powerful story is that of Chad Kuske, an Oregon-based retired Navy SEAL who spent a decade unsuccessfully struggling with PTSD and depression before finding his life changed after psilocybin therapy [12].

Safety

Compared to existing pharmaceutical agents, psilocybin has a very favorable safety profile:

- *Low addiction potential:* Psilocybin is not associated with compulsive use or uncontrollable drug-seeking behavior and therefore is not considered addictive.
- *No lethal overdose potential:* The recommended therapeutic dose for optimum effects is 20 - 30 mg for an average-sized individual (70 kg or 154 lb.) for whom the median lethal dose (LD50) is 19,600 mg, making it virtually impossible to ingest a lethal dose of psilocybin [13]. The half-life (i.e., the amount of time for the body to eliminate 50% of the drug) is 3 hours [14].
- *Predictable and manageable side effects:* Some acute effects of psilocybin may be uncomfortable or anxiety-provoking, e.g. nausea, headache, increases in heart rate, increases in blood pressure, grief, fear, feelings of isolation, and paranoia. In the vast majority of cases, these effects are transient and can be mitigated by trained personnel [15].

Availability of Systematic Treatment Approaches

Psilocybin-assisted therapy protocols typically consist of one to three supervised active drug sessions separated by weeks or months. Each psilocybin session is staffed for a full day because the acute drug effects may last for up to 6 hours. In clinical studies, participants are expected to stay the night within a facility to assure safety. A substantial portion of therapeutic benefit is thought to be dependent on the subsequent integration of memories, thoughts and feelings that surface during the active psilocybin session, thereby promoting a deeper and more durable therapeutic effect. Thus, psilocybin and other psychedelic treatments are unlike other pharmacological therapeutic interventions due to a unique mechanism of action that can be optimized through the integrative work that takes place days and weeks after a single intervention.

Therapeutic Indications and Target Populations

Psilocybin-assisted therapy has proven efficacy for major depressive disorder, anxiety disorders, PTSD, substance use disorders and existential distress in patients suffering terminal illness [16]. Thus, the beneficiaries of psilocybin-assisted therapy encompass all walks of life, races and ethnicities. Individuals in trauma-prone professions, such as veterans and first responders, are especially likely to benefit, and especially when standard therapeutic measures were ineffective. Currently, lawful access to psilocybin-assisted therapy is only possible when individuals live near or can travel to an academic center that offers enrollment in a clinical trial. Otherwise, individuals wanting psilocybin-based interventions seek underground providers, which is illegal, risky, and frequently exploitative. Legislative changes that codify treatment delivery parameters are needed to provide New Mexicans equitable access to psilocybin-assisted therapy within a framework of technical competency, ethical standards, and safety.

National Trends and State-based measures promoting Legal Access to Psilocybin-Based Therapies

A variety of state-level bills and measures have recently been enacted, or are currently in deliberation, for access to psychedelic medicines. These range from legalization or reduced penalty statutes (e.g., CO, NJ, WA) to regulated therapeutic access (OR) and working groups to study medical use (CT, TX, UT). An additional twelve states are currently deliberating bills for legal access to psychedelic medicines [17]. Two bills of particular relevance as models for New Mexico are from Oregon and Washington:

Oregon: In 2020, Oregonians voted to create the first government-regulated psychedelic therapy program through the passing of Measure 109, which directed the Oregon Health Authority to create a state-regulated program to allow trained practitioners to administer psilocybin-assisted therapy at licensed centers to adults 21 and older. The program is on track to launch in 2023.

Washington: On January 5, 2022, Washington lawmakers introduced SB 5660, a bill that would legalize the supported use of psilocybin by people 21 years of age and older. The Psilocybin

Wellness and Opportunity Act would enable the Washington Department of Health to issue licenses to psilocybin manufacturing facilities, testing labs, service centers, and facilitators. It would also create the Washington Psilocybin Advisory Board to advise the Department on creating rules for the Act's implementation. As of July 2022, SB 5660 is in committee [18].

A Proposal for Psilocybin-Assisted Therapy as a Treatment Option in New Mexico

At this time, New Mexicans do not have legal, safe, equitable, or timely access to psilocybin-containing mushrooms, a treatment modality that has been granted 'breakthrough therapy' status by the FDA. This lack of access causes unnecessary personal, familial, economic, and societal hardship, and therefore, initiatives that successfully facilitate access to psilocybin-assisted therapy are consistent with a moral imperative of legislative bodies to promote the health and well-being of the citizens they represent. The real-world implementation of psilocybin-assisted therapy in New Mexico will require thoughtful legal and regulatory changes. To this end, NMPSS desires to work collaboratively with the NM legislature to draft a bill that considers the following elements:

- establishing rules by a certain date,
- developing a psilocybin facilitator training program approval system,
- establishing a license granting, tracking and compliance case management system,
- codifying production and distribution parameters and associated quality assurance standards,
- securing and designing a product tracking system,
- establishing an equity and justice centered approach to background checks of providers,
- setting processes and procedures for all programs with strict ethical and safety standards,
- establishing and supporting a Psilocybin Advisory Board and subcommittees,
- creating educational and training standards for our regulatory community and the public.

Conclusion

Psilocybin-assisted therapy offers new hope to all New Mexicans suffering with serious mental health conditions. Within a proper framework, this evidence-based treatment could be provided across different settings, for a variety of different conditions, and for subpopulations that are traditionally underserved. Given the overall safety profile of psilocybin-assisted therapy and the accumulating evidence for efficacy, the absence of legislative action at this time would be conspicuous, and arguably indefensible. The realization of psilocybin-assisted therapies in New Mexico will benefit a wide range of stakeholders, including those involved with creating the infrastructure for the manufacture and provision of this medicine which promotes economic and employment opportunities for New Mexicans.

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