Psychotherapy Drugs for Mental Health

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SUMMARY

Traditional mental illness medications are not effective for many people, carry the risk of serious side effects, and, at best, only address symptoms. However, a renaissance of psychotherapeutic research demonstrates that psychotherapeutic substances like psilocybin and MDMA may actually modify the course of illnesses and offer long-term or permanent relief.

Currently, psychotherapeutics are classified as Schedule I substances under federal and Utah law, making it illegal for people to access them, even under medical supervision. Utahns using them risk criminal punishment and also their health as the purity and potency of psychotherapeutics purchased on the black market is difficult to determine.

Utah should strongly consider establishing a legal framework for practitioners to administer psychotherapeutics to patients in a safe, supervised setting. Their use will give patients greater freedom to find options that work.

Mental health patients should be able to legally access and use psychotherapeutics under medical supervision, for medicinal purposes.
Utah Has a Mental Health Problem

Utah has the highest rates for mental illness (29%), adults reporting a major depressive episode (11%), serious suicidal thoughts (7.63%), and making suicide plans (1.9%). And while the national suicide average is just under 14 per 100,000, Utah’s rate is 21 per 100,000. Suicide is the leading cause of death for Utahns ages 10-24 and the second leading cause of death for those ages 25-44. So serious is mental illness in Utah’s young adults that in 2017, House Concurrent Resolution 16 declared mental health to be a public emergency at higher education institutions. Despite a recognition of the gravity and severity of the problem, current efforts have not made significant progress toward reversing the trend.

Current Medications Don’t Work for Everyone

Current psychiatric medications on the market have significant shortcomings. Perhaps their most problematic feature is that they “are purely symptomatic, with no known or proven effect on the underlying disease. They are like fifty variations of aspirin, used for fever or headache, rather than drugs that treat the causes of fever or headache.”

This would perhaps be forgivable if they were truly effective at treating symptoms, but frequently they aren’t.

One study of eighty-one, randomized, double-blind clinical trials submitted to the US Food and Drug Administration examined the efficacy of antidepressants in treating major depressive disorder. Only half of the trials were successful and, overall, drugs were only marginally more effective than a placebo. A meta-analysis of benzodiazepines in treating generalized anxiety disorder found no convincing evidence that they were effective in the short term. The limited benefits of current drugs must be weighed against potential risks. Benzodiazepines can cause dependence and are frequently misused recreationally. Some research suggests antidepressants may actually cause an increase in suicidality. Even newer generation antidepressants can cause a host of side effects including emotional blunting that persists even after discontinuation.

Certainly, some people experience an improvement in symptoms while taking currently-available medications. However, the scientific literature and the experiences of people who have used them have yielded mixed results. There are significant benefits to be gained from adding additional tools to the mental health toolbox.

“New” Alternatives

Psychoactive substances have been used by humans for millennia. Psilocybin mushrooms are depicted in cave paintings as far back as 5000 B.C. The ancient Greeks used ergot, a fungus containing LSD, in the kykeon they drank during the ceremony of the Eleusinian Mysteries. Native Americans created peyote effigy sculptures in 3700 B.C. And when the Spanish

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conquistadors arrived in the New World, native cultures were using psilocybin mushrooms, peyote, and psychoactive morning glory seeds.

Despite this history, western science remained largely unaware of psychotherapeutics until the 1950s, when the field of psychopharmacology was in its infancy. At that point hallucinogens were widely studied for their use in treating a variety of mental ailments including addiction and depression. By 1965, over one thousand scientific papers had been written about them. ¹⁰

These studies showed great potential for hallucinogens to treat mental illness. Unfortunately, some drugs “escaped the lab” and their recreational use became a key feature of the 1960s counter-culture. This ultimately led to them being listed as Schedule I controlled substances as part of the “War on Drugs,” bringing further research to a halt.

It was only in the 1990s that investigators were able to resume research and results have been very promising. While each psychotherapeutic is chemically unique with distinct uses and mechanisms of action, some generalizations can be made about how they function.

Psychotherapeutics work by increasing brain plasticity.¹¹ Our brains are not static. Rather, they are constantly forming new connections at a cellular level as we have new experiences. This is referred to as neuroplasticity.

By increasing neuroplasticity, psychotherapeutics give patients the chance to reset their brains, potentially replacing ingrained, harmful thought patterns with

<table>
<thead>
<tr>
<th>Current Schedule</th>
<th>Therapeutic Uses</th>
<th>Side Effects</th>
<th>Risk of Dependence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psilocybin</td>
<td>Depression,¹² anxiety,¹³ addiction,¹⁴ obsessive compulsive disorder (OCD),¹⁵ chronic pain¹⁶</td>
<td>Panic if taken in the wrong setting, gastrointestinal upset¹⁷</td>
<td>None¹⁸</td>
</tr>
<tr>
<td>LSD</td>
<td>Addiction, anxiety, depression,¹⁹ chronic pain²⁰</td>
<td>Minor, including headache, migraine, diarrhea, and flashbacks²¹</td>
<td>Very low²²</td>
</tr>
<tr>
<td>MDMA</td>
<td>PTSD,²³ eating disorders,²⁴ addiction²⁵</td>
<td>Minor, including nausea, feeling cold, loss of appetite, headache, fatigue, anxiety²⁶</td>
<td>Low²⁷</td>
</tr>
<tr>
<td>Ayahuasca</td>
<td>Addiction,²⁸ depression²⁹</td>
<td>Nausea, vomiting, temporary exhaustion, temporary insomnia³⁰</td>
<td>None³¹</td>
</tr>
<tr>
<td>Mescaline</td>
<td>Anxiety, alcoholism, OCD,³² depression, addiction³³</td>
<td>Nausea and vomiting (when consumed as peyote). Acute anxiety, panic, and disorganized behavior³⁴</td>
<td>None³⁵</td>
</tr>
<tr>
<td>Ketamine</td>
<td>Depression, anxiety,²⁶ PTSD,²⁷ addiction,³⁸ bipolar disorder, autism spectrum symptoms³⁹</td>
<td>Nausea, vomiting, dizziness, diplopia, drowsiness, dysphoria, and confusion⁴⁰</td>
<td>None, when administered in a clinical setting⁴¹</td>
</tr>
</tbody>
</table>
new, healthier ones. The benefits are amplified when therapists are available to help the patient process and integrate his experience into daily life. Thus, psychotherapeutics may offer a longer-term solution that actually modifies the course of mental illness.

Conversely, traditional antipsychotics address symptoms, not causes. They work by adjusting levels of chemical neurotransmitters in the brain: SSRIs, prescribed for depression, impact serotonin levels; benzodiazepines, prescribed for anxiety, enhance gamma-aminobutyric acid. But chemical levels aren’t the cause of depression or anxiety, so the underlying pathology isn’t fixed and any beneficial effects wear off as the drug is metabolized. To experience any relief, patients must take these drugs indefinitely.

No wonder many who have tried psychotherapeutics have found them to be life-changing and preferable to prescription medications they have tried.

Are Psychotherapeutics Addictive?

Psychotherapeutics have a low potential for addiction. Methamphetamine, cocaine, and opioids act primarily on dopamine receptors, the brain’s reward circuitry, creating a “high.”

Addiction is a product of the brain being rewarded every time the person consumes one of these drugs, endlessly reinforcing a cycle of continued use. Over time, the brain can become so accustomed to artificially high levels of dopamine that a person experiences physical withdrawal symptoms when they can’t access dopaminergic drugs.

By contrast, psychotherapeutics act primarily on other chemical receptors in the brain so they don’t invoke the same dopamine pathway to addiction. They do not create compulsive drug-seeking behavior, nor do people experience withdrawals after use. Additionally, the hallucinogenic experience is often physically and emotionally draining, decreasing the desire and capacity to use psychotherapeutics habitually.

What About Crime?

Substance addiction has often been correlated with property and violent crime. By definition, addicts continue to use even though it impairs their ability to fulfill basic work, family, and societal obligations. Addicts frequently turn to property crime to fund their addiction or to violence as they seek drugs on the black market.

However, psychotherapeutics cannot be lumped in with drugs like heroin, cocaine, and methamphetamine. As discussed above, they do not cause addiction or the criminal behavior associated with compulsive drug seeking. In fact, lifetime use of psychotherapeutics is strongly correlated with lower odds of criminal outcomes, greater odds of successfully completing supervised probation, and decreased risk of committing a violent crime against an intimate partner. In short, use of psychotherapeutics leads to decreases in crime, not increases.

Are Psychotherapeutics Safe?

Psychotherapeutics are safe in terms of toxicity and the likelihood and severity of side effects. It is virtually impossible to ingest a deadly dose of LSD, psilocybin, mescaline, or ayahuasca. And while death is a rare but potential side effect of MDMA and ketamine, in a clinical setting with a controlled dose, the risk of death can be all but eliminated. Most side effects are minor such as nausea, headache, and fatigue. Many studies have shown that use of psychedelics is not associated with development of future mental illness or decreased cognitive function.

Set and Setting: The Importance of Medical Supervision

The most significant unifying feature of psychedelics is that in sufficient doses, they cause significant alterations in perception. In this disoriented state, patients are physically and mentally vulnerable.

For physical protection, patients require supervision to ensure they do not do anything to harm themselves.
Researchers recommend taking precautions such as checking for sharp corners on furniture and ensuring patients can’t fall from windows.\textsuperscript{51}

To minimize the possibility of a “bad trip,” it is crucial that use of psychotherapeutics occur in an appropriate set and setting. “Set” refers to the patient’s preparation, expectation, and intention. “Setting” refers to the physical, social, and cultural setting in which the psychotherapeutic is administered. Both shape the patient experience and contribute to the efficacy of treatment.\textsuperscript{52}

For example, in a 1955 study, alcoholics stayed in a hospital for two to four weeks. During that time they talked about their addiction and also about the likely effects of ingesting LSD or mescaline. Toward the end of their stay they received a single dose of LSD or mescaline.

After being released from the hospital, they were encouraged to participate in Alcoholics Anonymous. Half of the alcoholics were improved or very much improved, meaning they abstained from alcohol and had stable relationships and employment.\textsuperscript{53}

While the administration of a psychotherapeutic was part of their recovery process, the set and setting in which it was administered, as well as the follow-up, were critical to making the experience a turning point, rather than a transitory recreational high.

People accessing and using psychotherapeutics now without the guidance of medical professionals and without the ideal set and setting are at a greater risk for experiencing adverse side effects and for injuring themselves or others while under the influence of psychotherapeutics. They are also less likely to reap the full potential benefits of psychotherapeutic medicine. However, until psychotherapeutics are legalized, patients and the public will continue to incur these risks.

Legal Status in Other Jurisdictions

Other jurisdictions have legalized or decriminalized the use of some psychotherapeutics. Spain, Uruguay, the Czech Republic, and Portugal have decriminalized the possession of user amounts of all drugs, including psychotherapeutics. Ayahuasca, which originated in Indigenous cultures in South America, is legal in several South American countries including Bolivia, Brazil, Colombia, Costa Rica, Ecuador, and Peru, though some countries only permit use in a ceremonial context. Psilocybin mushrooms are legal or decriminalized in Austria, the Czech Republic, the Netherlands, and Jamaica. Yet in none of these jurisdictions has the proverbial sky fallen.

Closer to home, several states are making efforts toward medical use of psychotherapeutics. Texas passed legislation in 2021 to study MDMA, psilocybin, and ketamine in treating veterans with PTSD. Connecticut passed legislation to study psilocybin; the subsequent report found that psilocybin is safe and effective for treating a variety of behavioral issues and recommended that it be legalized for medical use once approved by the FDA. Colorado has a natural medicine measure on the ballot for November 2022. Oregon has
legalized medicinal use of psilocybin and is currently creating a framework for implementation.

In some cases, cities are leaping ahead of states. In the last three years Seattle, Washington; Ann Arbor, Michigan; Oakland and Santa Cruz, California; Somerville and Cambridge, Massachusetts; and Washington, D.C., have passed ordinances making enforcement of some psychedelics the lowest priority, effectively decriminalizing their possession.

The results of city experiments in decriminalizing psychedelics are promising. Denver was the first city to decriminalize psilocybin possession in May 2019 and simultaneously created a review panel to track the outcome of decriminalization. In November 2021, eighteen months into the experiment, the panel issued a report finding that there was no significant increase in psilocybin distribution arrests, no cartel or organized crime elements surrounding distribution, and no adverse public health or negative safety trends. Johns Hopkins Centers for Psychedelic Consciousness Research took advantage of Denver’s decriminalization to conduct a survey of psilocybin users and found that most used psilocybin for self exploration or mental health and 90% felt the experience created a positive change in well-being or life satisfaction.

Ketamine, a Utah Case Study

Ketamine, a psychotherapeutic drug, is already being legally administered to patients throughout Utah. Initially used as a general anesthetic, it was listed as a Schedule III rather than a Schedule I substance, so it has never been banned. In subanesthetic doses, it induces the hallucinations which are characteristic of psychotherapeutics. In 2000, its value as an antidepressant was recognized, leading to ketamine clinics opening across the country and in Utah to provide ketamine-assisted therapy to patients.

Concerned about patient safety, Utah passed a bill in 2017 creating a database to record any adverse events related to outpatient anesthesia. Since ketamine is an anesthetic, the bill covers ketamine-assisted therapy as well as dental and other procedures where patients receive anesthesia. The bill also mandated informed consent from patients, continuous monitoring of patients, and life-support training for those administering the drug.

The reporting requirements have proven that ketamine-assisted therapy is very safe. Only five adverse events had been reported as of 2020 when the most recent report was issued, and all involved anesthesia for dental work, not ketamine clinics. There also has not been any reported increase in the illicit use of ketamine.

Utah’s first foray into the medical use of a psychotherapeutic has been a success. It has yielded significant benefits for patients, has not led to an uptick in crime or additional difficulties enforcing other drug laws, and all these benefits have been achieved with minimal regulation. There is no reason to think that Utah cannot expand this model to include additional psychotherapeutic drugs with similar success.

SOLUTION: PROVIDING SAFE ACCESS FOR PATIENTS

The ideal psychotherapeutic framework will provide safe and supervised access for patients while still allowing law enforcement to effectively counter illicit use. Too much bureaucracy will drive up costs, limit supply and providers, and push patients back underground. We propose the following framework.

1. Production: Producers Create and Store Psychotherapeutics

Producers will be required to register identifying information and production location with the state. So long as they produce and store their product at the registered location and give product only to a registered transporter, a qualified pharmacist, or a testing facility, they are immune from criminal prosecution under Utah Code §58-37-8.

2. Testing: The Utah Department of Agriculture Conducts Batch Testing

Producers will send batch samples for safety tests before the product is sent to pharmacists.
3. **Transportation:** Transporters Move Product Between Producers, Pharmacists, Providers, and Test Facilities

Transporters must register identifying information including vehicle information with the state. Product must be stored in a clear container that is labeled with the contents, weight, pickup location, and dropoff location. Transporters must maintain a log of pickups and dropoffs including times and dates, name of person who sent and accepted receipt of product, and the content and weight of what was transported. Product can only be transported between registered producers, qualified pharmacists, qualified providers, and testing facilities. If they abide by these requirements, they are immune from prosecution under Utah Code §58-37-8.

4. **Qualified Pharmacists:** Qualified Pharmacists Compound Medicine for Individual Patients and Check for Drug Interactions

To qualify to work with psychotherapeutics, a licensed pharmacist must complete sixteen hours of training and obtain a license from the state to distribute psychotherapeutics to providers. If they abide by these requirements, they are immune from prosecution under Utah code §58-37-8 for distributing psychotherapeutics. Pharmacists are responsible for giving medicine in the appropriate dosage and form for a given patient, checking for drug interactions, appropriately storing product as they would other controlled substances, maintaining a log of where product originated and to whom it was dispensed, and labeling and packaging product for individual patients.

5. **Administration:** Qualified Personnel Diagnose and Determine When Psychotherapeutic Treatment Would Be Safe and Appropriate and Administer Psychotherapeutics in a Controlled and Supervised Setting

To be a qualified provider, a person must already be licensed as a doctor, psychiatrist, psychiatric nurse practitioner, physician's assistant, or psychologist in Utah and must complete the sixteen-hour course outlined above for qualified pharmacists. After completing this training, they can obtain a license from the state to administer psychotherapeutics without being subject to prosecution under Utah code §58-37-8. Providers are responsible for making a diagnosis; knowing a patient’s medical and psychological history, current medications, and any contraindications; and determining whether psychotherapeutic treatment is safe and appropriate.

**Endnotes**

5. Ni A. Khin, MD; Yeh-Fong Chen, PhD; Yang Yang, PhD; Peiling Yang, PhD; and Thomas P. Laughren, MD, “Exploratory Analyses of Efficacy Data From Major Depressive Disorder Trials Submitted to the US Food and Drug Administration in Support of New Drug Applications,” Journal of Clinical Psychiatry, 72, no. 4 (April 15, 2011): 464-72. https://doi.org/10.4088/JCP.10m06191

For the remainder of the endnotes, please visit Libertas.org/psychotherapy.
PUBLIC POLICY BRIEF

Psychotherapy Drugs for Mental Health

FREQUENT RECURRENCE TO FUNDAMENTAL PRINCIPLES IS ESSENTIAL TO THE SECURITY OF INDIVIDUAL RIGHTS

UTAH CONSTITUTION ARTICLE I, SEC 27