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Medical Use of Psilocybin

Larry Leeman MD, MPH, University of New Mexico

Gary French MD, New Mexico Department of Health

Introduction

- Some psychedelics, such as psilocybin, hold increasing promise for treating various mental health conditions

- Increased interest has led to legislative and executive interest in studying:
  - Effectiveness of psilocybin treatments
  - Feasibility of establishing a program for therapeutic use
  - Need for statutory or regulatory framework

Cannabis

- Daily use
- May be used at home
- No additional therapy
- Numerous qualifying medical conditions
- Many components
- Difficult to study
- No breakthrough therapy designation

Psilocybin

- Not utilized daily
- Used during a dosing session with medical oversight and supervision
- In tandem with psychotherapy
- Mental health conditions
- Single component
- Easier to study
- FDA breakthrough therapy designation

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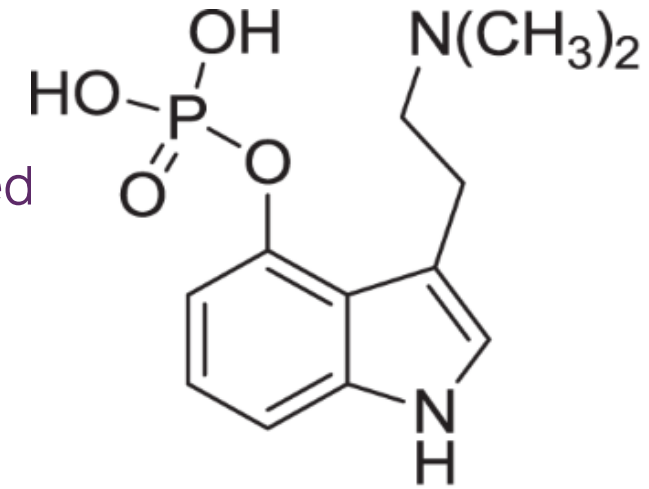
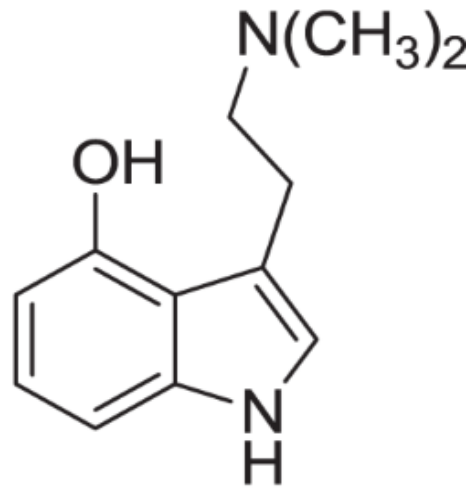
Psilocybin Mushrooms

- Psilocybin is a naturally occurring psychedelic compound
- After intake, the inactive psilocybin is converted in the pharmacologically active psilocin
- Effects include hallucinations, changes in perception, distortion of time, and perceived spiritual experiences
- Effects appear with 15 – 45 minutes and can last four to six hours
- Psilocybin mushrooms are easy to cultivate and can be grown in multiple environments



Psilocybin



Psilocin

Synthetic Psilocybin

- Synthetic psilocybin is a lab created version of psilocybin
- Synthetic psilocybin can ensure supply and control for potency, dosage, and consistency
- Several companies are currently producing synthetic psilocybin, seeking patents, and pursuing FDA approval
- Patents would likely lead to an overall increase in cost to the healthcare system compared to the use of cultivated psilocybin mushrooms

Safety Considerations

- Psilocybin can result in paranoia, loss of boundaries, and distorted perceptions. This can result in injury in uncontrolled settings
- Psilocybin may cause increased heart rate, nausea, and anxiety
- In rare circumstances, some individuals may experience “flashbacks” of their original experience
- Mushroom worker's lung, a hypersensitivity pneumonitis, is an occupational risk for producers

Standard Therapeutic Model

- Integrated with various forms of psychotherapy
- Patients are assessed if psilocybin treatment is appropriate
- 6-to-8 hours of prep with 2 facilitators between the initial intake assessment and the day of dosing
- 6-to-8-hour dosing session conducted in a comfortable setting with session facilitators guiding the process
- 4 hours of post dose sessions

Phases of Clinical Trials

- **Phase 1 trials** – Researchers test a drug or treatment in a small group of people (20-80) for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects
- **Phase 2 trials** – The new drug or treatment is given to a larger group of people (100-300) to determine its effectiveness and to further study its safety
- **Phase 3 trials** – The new drug or treatment is given to large groups of people (300-3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely
- **Phase 4 trials** – After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population, seeking more information about a drug or treatment's benefits, and optimal use

Current Research

FDA Timing Considerations

- Ongoing research suggests promise for treating some behavioral health conditions, but FDA approval is unlikely before 2027, and this would be limited to major treatment resistant depression as other indications such as substance use disorders and end of life anxiety and distress are at least five years from approval.

Depression

- Results from randomized controlled phase 2 trials indicates promise for treatment of depression. Current phase 3 trials are underway at UNM
- Psilocybin has been granted “breakthrough-therapy” status for major depressive disorder and treatment resistance depression

Current Research (cont.)

Substance use disorder

- Research conducted in New Mexico showed decreased alcohol intake after 12 weeks with psychotherapy with psilocybin sessions
- There are active studies looking at the potential benefit of psilocybin for cocaine, amphetamine, and nicotine use disorders

End of life anxiety and distress

- Several phase 2 studies for end-of-life care show promise for decreasing anxiety

State Legislative Legal Landscape

Decriminalization

- In Colorado, individuals 21 and older are allowed to possess psilocybin and give to those 21 and over. Not legal to sell and must use in a private setting

Research

- Several states including Arizona and Pennsylvania have enacted legislation allowing their Health Departments to conduct research for clinical trials

Supervised Use

- Oregon legalized adult use of psilocybin in Psilocybin Service Centers
- Utah enacted legislation creating a pilot program which allows providers at specific health systems to treat patients of psilocybin

Program Considerations - Wait for FDA Approval

- Limited State role – federal government would oversee regulatory aspects

- Cost of psilocybin therapy could be covered by insurance if psilocybin were approved by FDA; however, such coverage would be limited by indication and only depression is indicated in current phase three trials

- Implementation is dependent on FDA approval timeline
  - Regulatory changes would follow at the state level

Program Considerations - Approve for Use in Therapy Centers

- Guidelines for Psilocybin-Assisted Therapy would be based on research protocols
  - Careful screening practices
  - Close supervision of participants
  - Safe psilocybin administration
- This approach minimizes risk
- Preparatory and follow-up visits are recommended
- Requires facilitators who are specially trained and certified
- Requires securing a consistent and viable source for the psilocybin

Program Considerations - Decriminalize and Commercialize

- Administration of psilocybin would be unsupervised
- Individuals may experience subjective benefits, but risk would increase
- Requires regulatory framework to ensure product safety
- Would need to provide legal protections to those who cultivate, possess, sell, distribute, administer or consume
- Would conflict with federal law

Program Considerations- Funding Research

- State could establish a therapeutic psilocybin fund to provide grants to New Mexico research institutions
- Research focused on developing cost-effective approaches could be prioritized
  - Group Therapy Model
  - Whole Psilocybin Mushroom Utilization
- Implementation could happen quickly as numerous research studies are already underway in New Mexico
- May provide basis for future Therapy Center approach

Ethics and Equity

- Given promising research it is likely compassionate or palliative use of psilocybin assisted psychotherapy for end-of-life care could significantly improve quality of life.
- Equity concerns include ensuring access for those without greater financial resources and ensuring workforce is diverse and culturally competent.
- Engagement with Tribes, Pueblos and Nations to protect rights and traditions will be essential. Policy development should be guided by respect for indigenous sovereignty and traditions.

Additional Considerations

- Efforts to support community engagement must be undertaken
- Legislative authorization to conduct research with psilocybin would likely require some level of immunity
- Obtaining a safe supply of psilocybin
- Specialized training of facilitators
- Estimated time to start a program is 3 years

Regulatory Cost

- Costs to the state would be dependent on a variety of factors:
  - Regulatory structure
  - Federal enforcement discretion
  - Collection of taxes and fees
- Estimated costs for Colorado and Oregon to establish a regulatory framework was $4-7 million over a two-year development period.
- Expectation is that revenue from program fees and taxes will cover the costs of these programs once fully implemented.

Clinical Cost

- Current therapeutic model has high staff cost which will not be covered by insurance until FDA approval
- Current models are very safe but high cost presents accessibility concerns
- Current research is being conducted to see if group sessions could help offset the cost
- Use of whole mushroom products as opposed to synthetics could decrease cost

New Mexico Medicaid

- Medicaid cannot cover the cost of psilocybin
- Medicaid currently does not cover the two-provider therapy model use for psilocybin assisted treatment; however, other psychotherapy modes including group therapy could potentially be covered
- New Mexico could decide to cover psilocybin assisted treatment with state funds

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Questions?