Washington Psilocybin Task Force Meeting #1

June 26, 2023

Washington State Health Care Authority

Welcome and Agenda Overview

Agenda

Agenda Items	Time	Lead
Welcome & Introductions Meeting Overview	1:00-1:15pm *(15 min)*	Charissa Fotinos, MD - Medicaid Director
History, Overview of SB 5263, and Current Scope of Work	1:15-1:30pm *(15 min)*	Hayley DeCarolis – Center for Evidence-based Policy Mike Bonetto – Center for Evidence-based Policy
Initial Overview of Psilocybin Clinical Research	1:30-2:05pm *(35 min)*	Val King – Center for Evidence-based Policy
Initial Overview of Regulatory Structures	2:05-2:30pm *(25 min)*	Duncan Stuard – Center for Evidence-based Policy Mike Bonetto – Center for Evidence-based Policy
Task Force Discussion & Feedback	2:30-2:55pm *(25 min)*	Charissa Fotinos, MD - Medicaid Director Mike Bonetto – Center for Evidence-based Policy
Wrap Up and Next Steps	2:55-3:00pm *(5 min)*	Charissa Fotinos, MD - Medicaid Director

History

Washington State Health Care Authority

Legislation History

2022 regular legislative session

2023 regular legislative session

FY 2021-22 Session: SB 5660 (did not pass)	FY 2021-22 Session: SB 5693 (budget proviso)	FY 2022-23 Session: SB 5263
Proposed a psilocybin program in Washington state very similar to Oregon's psilocybin program.	Established the Washington Psilocybin Work Group, assigned 5 key tasks, and required 2 reports (preliminary due December 1, 2022 and final report due **December 1, 2023**).	Established the Psilocybin Task Force to provide a report on psilocybin services due to the legislature by **December 1, 2023**.

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FY 2021-22 SB 5660

Focus of 2022-2023 Psilocybin Work Group

WA SB 5660 (did not pass)

- Would have established safe, legal, and affordable psilocybin centers for Washington citizens over 21
- Would have created a Washington psilocybin advisory board within department to provide advice and recommendations to the department.
- Would have imposed a 18 month program development period
- Would have directed the Department to adopt rules in following areas: education and training requirements, testing, establishment of a tracking system

Unique to WA SB 5660 (compared to Oregon program)

- **Social opportunity program (DOH):** established equity program to remedy harms resulting from historical injustice and the disproportionate and targeted enforcement of drug-related laws on poor and marginalized communities
- Department may not prohibit use of naturally grown mushrooms that meet quality and safety standards, or mandate the use of patented products or procedures
- Must create micro tier manufacturing endorsement with lower fees to reduce barriers to access
- Must establish rules for circumstances in which psilocybin services can be administered in home of client who is medically unable to travel to center

Psilocybin Work Group Members

Required members	
Director of Health Care Authority (or designee)	A mental health counselor, marriage and family therapist, or social worker with knowledge of psilocybin
Secretary of the Department of health (or designee)	A physician with knowledge of psilocybin
Director of the Liquor and Cannabis Board (or designee)	A health research with expertise in health equity
Director of the Department of Agriculture (or designee)	A representative of the cannabis industry with knowledge of Washington state regulation of cannabis
A military veteran (or representative)	A psychologist with knowledge of psilocybin
Up to 2 recognized indigenous practitioners with knowledge of the use of psilocybin or other psychedelic compounds in their community	A member of the psychedelic medicine alliance of Washington
An individual with expertise in disability rights advocacy	Up to 2 members with lived experience of utilizing psilocybin
A member of the nursing profession with knowledge of psilocybin	An advocate from the LGBTQIA community with knowledge of the experience of behavioral health issues within community

FY 2021-22 Work Group Key Tasks

Work Group Task	Work Group Actions	Date
1. Review the **Oregon Health Authority's (OHA) proposed rules** for the regulation of psilocybin and assess the impact the adoption of substantially similar laws and rules or Senate Bill No. 5660 would have in Washington State and **identify specific areas where a different approach may be necessary or desirable.**	Reviewed OHA implementation at first Work Group meeting Work Group proposed areas where a different approach may be necessary or desirable	June 30, 2022
2. **Review systems and procedures established by the liquor and cannabis board** to monitor manufacturing, testing, and tracking of cannabis to **determine suitability and adaptations required for use with psilocybin** if Washington adopts legislation substantially like the Oregon psilocybin services act or Senate Bill No. 5660.	Jim Morgan, CFO of Liquor and Cannabis Board (LCB), presented the LCB's processes around tracking and licensing cannabis at second Work Group meeting	August 4, 2022

FY 2021-22 Work Group Key Tasks

Work Group Task	Work Group Actions	Date
3. **Review the social opportunity program** proposed in Senate Bill No. 5660 for the purpose of **recommending improvements or enhancements** to promote equitable access to a potential legal psilocybin industry within an operable administrative framework.	Presentation from Oregon Psilocybin Services section about lessons learned from equity subcommittee Equity framing presentation including summary of Work Group interviews and overview of state research	October 31, 2022
4. **Assess functional requirements of Senate Bill No. 5660 that would exceed the expertise and capacity of the Department of Health** and identify opportunities for development or collaboration with other state agencies and entities to meet the requirements.	Presentation from the Department of Health on its Transformational Plan, existing regulatory framework, health professional oversight and regulation, and DOH responsibilities under SB 5660 Presenters included: Lacy Fehrenbach, Christie Spice, and Marlee O'Neill	December 2, 2022
5. Discuss options to **integrate licensed behavioral health professionals** into the practice of psilocybin therapy under the framework of Senate Bill No. 5660 where appropriate.	See above – Department of Health presentation	December 2, 2022

2023 Report Main Conclusions

Key Task 1

The majority of Work Group members were interested in an expanded version of Oregon's psilocybin services program including:

- Microdosing policy
- Exemptions for personal, religious, or indigenous use
- Access to more than 1 strain
- More protections for equitable access
- Cost analysis to ensure sessions remain affordable for average consumer

Key Task 2

Work Group members did not believe the existing monitoring and tracking system LCB uses for cannabis would be an appropriate fit for psilocybin because it was built for a retail tracking model.

2023 Report Main Conclusions

Key Task 3

Members generally supported the social opportunity program and identified areas for it to be expanded including:

- Integrating the SOP into license distribution
  - A certain percentage of licenses would have to be distributed to SOP applicants
- A civil legal aid program/funding for mentorship to help with compliance should be offered
- Distressed area criteria within the SOP should not be exclusive, individuals should be able to apply/petition on a case-by-case basis

2023 Report Main Conclusions

Key Task 4

DOH spoke to the Work Group and outlined how the legislature would need to direct the department to oversee psilocybin under 2 regulatory domains: health and wellness domain and health systems and workforce.

- Legislation would need to require DOH to establish regulatory authority for profession, set scope of practice, and create general requirements for licensure.
- The Department of Health estimates implementation would take 3 years and significant resources including staff and IT infrastructure.

Key Task 5

Current SB 5660 language only authorizes DOH to establish licenses and professions. Integrating behavioral health professionals into the practice of psilocybin therapy would require additional language and changes to the uniform disciplinary act to remove the risk of losing licensure.

Current Work

Legislation History

2022 regular legislative session

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Task Force Members

Required members	
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Secretary of the Department of Health (or designee)	Two physicians with knowledge of psilocybin, experience in mental and behavioral health, or experience in palliative care
Director of the Liquor and Cannabis Board (or designee)	A health researcher with expertise in health equity or conducting research on psilocybin
A member of the psychedelic medicine alliance of Washington	A representative of the cannabis industry with knowledge of Washington state regulation of cannabis
A military veteran (or representative)	Two psychologists with knowledge of psilocybin, experience in mental and behavioral health, or experience in palliative care
Up to 2 members with lived experience of utilizing psilocybin	Up to 2 recognized indigenous practitioners with knowledge of the use of psilocybin or other psychedelic compounds in their community
An individual with expertise in disability rights advocacy	A pharmacologist with expertise in psychopharmacology
A public health practitioner	An advocate from the LGBTQIA community with knowledge of the experience of behavioral health issues within community

2023 Task Force

Must provide a final report by **December 1, 2023**

Assigned activities:

- Review available **clinical information** around specific clinical indications for use of psilocybin, including what co-occurring diagnoses or medical and family histories may exclude a person from use of psilocybin. Key areas include:
  - Populations excluded from existing clinical trials
  - Factors that are considered during medical intervention
  - Consideration of participant diversity in clinical trials
  - Identify gaps in clinical research
- Review and discuss **regulatory structures** for clinical use of psilocybin in Washington and other jurisdictions nationally and globally
  - How do various regulatory structures address concerns around public health and safety?

Clinical Research Strategy

Summary of Oregon's Rapid Review

Washington State Health Care Authority

Findings

Key questions addressed:

- Risks and benefits of controlled and unsupervised psilocybin use for selected conditions
- Whether the risks and benefits varied by personal or clinical characteristics
- Available risk assessment tools for patients and providers, and
- Risks and benefits of different sources of psilocybin

Searched for randomized controlled trials and systematic reviews published before May 2021

Benefits and Risks of Psilocybin Use

Oregon review primarily identified Phase 1 and Phase 2 clinical trials reporting about supervised use, and a few observational studies of unsupervised use

High level findings:

- Psilocybin may reduce depression, anxiety, and overuse of tobacco and alcohol, when used under clinical supervision with co-occurring counseling
- May reduce depression and anxiety during palliative care
- Short-term risks included minor physical symptoms (e.g., vomiting, headache), and temporary thought and affect disorders (e.g., paranoia, grief)
- Long-term negative effects were rare (e.g., worsening depression)

Screening Tools for Potential Users of Psilocybin

Oregon rapid review did not identify any validated risk assessment tools for evaluating the likelihood of individual benefit or risk with use

Authors identified commonly used screening practices intended to exclude participants who may have higher risk of adverse effects

Risks and Benefits of Different Sources of Psilocybin

- Controlled trials typically reported using biosynthesized psilocybin
- Uncontrolled or observational studies reported mushroom consumption as the dominant source for unsupervised settings
- Concentrations of psilocybin and psilocin varied by dried mushroom weight in summarized studies, but there are established methods of analyzing concentration and potential contamination in commercial products

Limitations of Studies Summarized

- Controlled studies excluded participants with comorbid medical and psychiatric conditions, which may limit the generalizability of findings beyond these populations
- Lack of diversity in study populations (e.g., participants were typically White, college-educated, cisgender men)

Oregon's Next Steps from Rapid Review

1. Gather information not represented in current published literature.
2. Consider the risk of bias in included studies, including early stage of this research.
3. Create a "living review" to capture emerging findings.
4. Consider requirements for licensing, continuing education for providers and informed consent process for consumers.
5. Support dosing parameters to maximize benefit and minimize dependence and risk.
6. Consider screening processes for potential consumers.
7. Consider voluntary monitoring of service and consumption to increase knowledge base about risk and benefits in diverse populations.
8. Use a range of research to develop regulatory framework.
9. Prioritize cultivation of Psilocybe cubensis on grain-based substrates, instead of dung or wood, to minimize toxicity concerns.
10. Explore feasibility of DNA sequencing of fungi and fungal tissues for licensing and quality control.
11. Develop screening requirements for potential contaminants.

Method for Updating Rapid Review

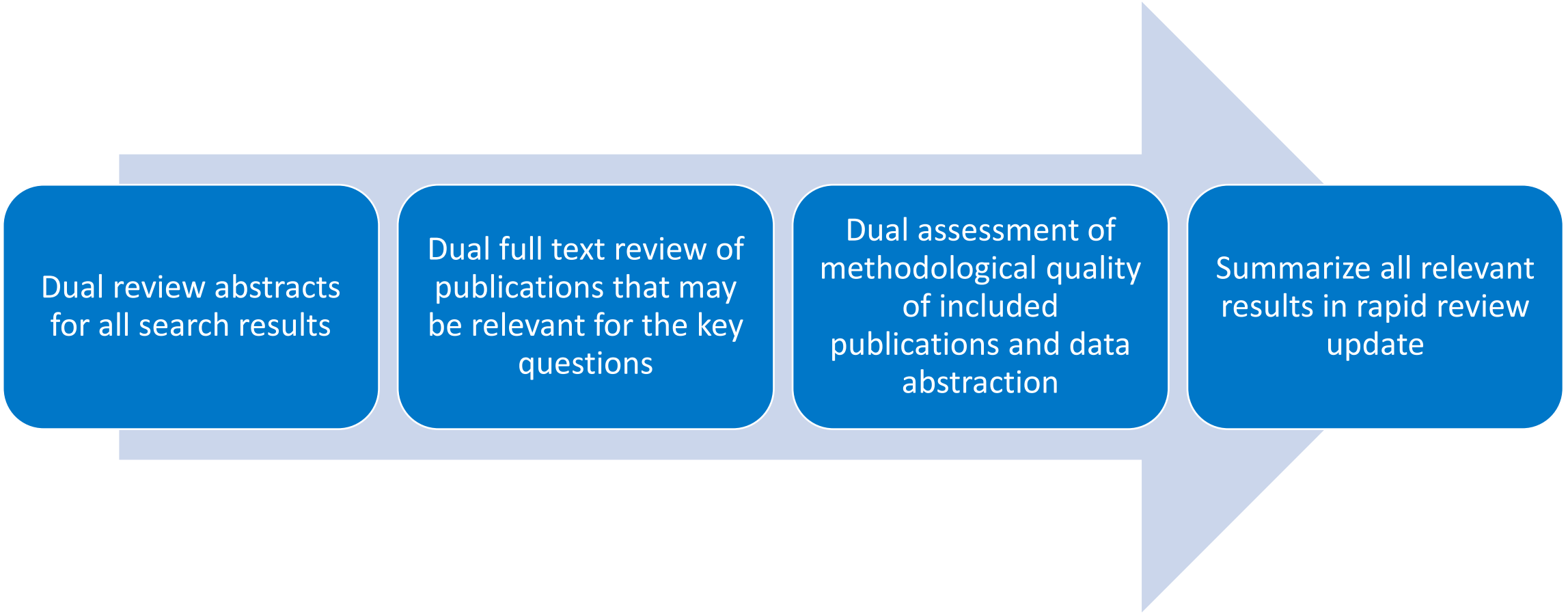
Washington State Health Care Authority

Key Questions

1. Risks and benefits of psilocybin in controlled settings for improving symptoms and quality of life for:
    a. Depression
    b. Anxiety disorders and obsessive-compulsive disorder
    c. Trauma-related disorders, including racial trauma
    d. Substance use disorders
    e. Palliative care
    f. Spirituality
    g. Other conditions
2. Risks and benefits of unsupervised psilocybin use
3. Provider or patient risk assessment tools for psilocybin use
4. Relative potential risks of different sources of psilocybin

Clinical Evidence: Search for RCTs and Systematic Reviews

Process From Searches to Inclusion in Update



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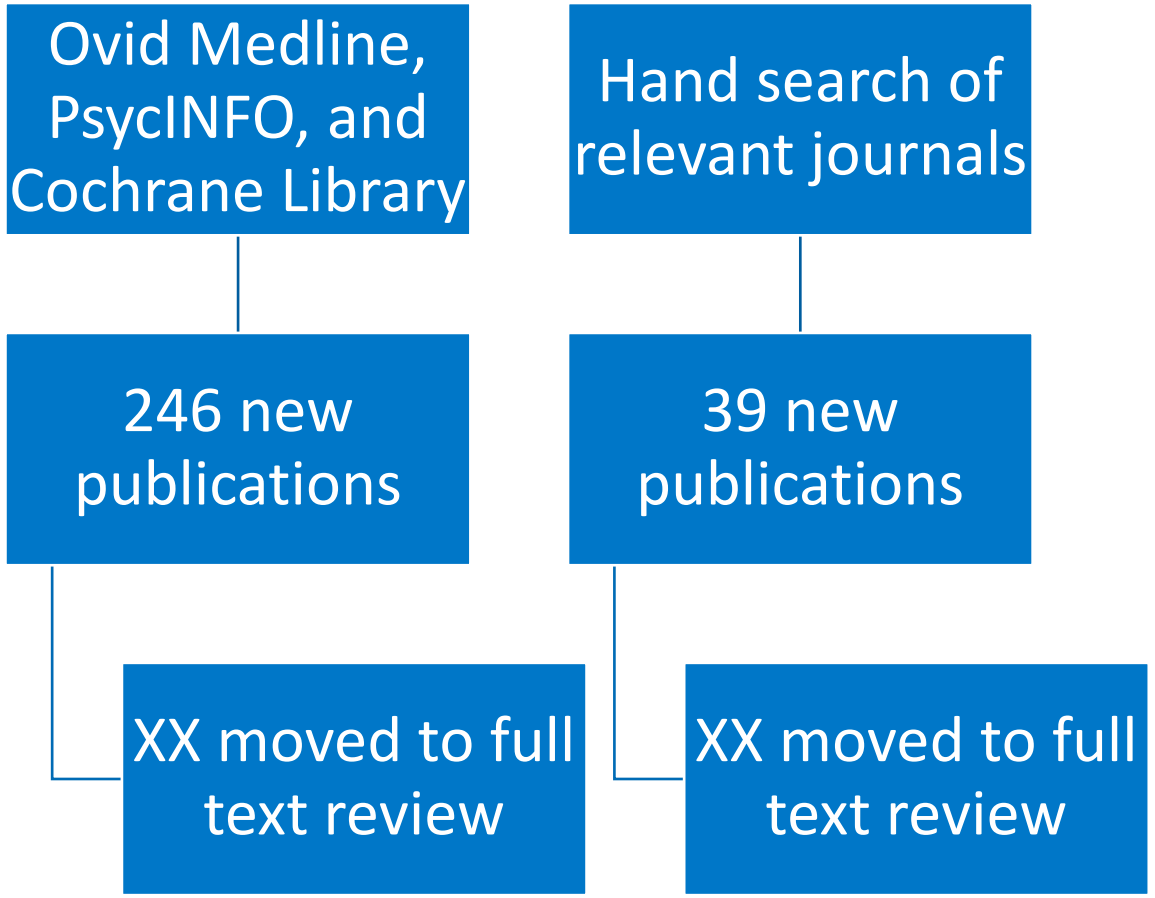
Initial Search Results



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Assessment of Methodological Quality (Risk of Bias)

Good	• Clear reporting of methods and mitigation of potential biases and conflicts of interest
Fair	• Incomplete information about methods that might mask important limitations or a meaningful conflict of interest
Poor	• Clear flaws that might introduce serious bias

Overview of Regulatory Structures

Background

This workgroup was tasked with “Reviewing and discussing regulatory structures for clinical use of psilocybin in Washington and other jurisdictions nationally and globally. This should include discussing how various regulatory structures do or do not address concerns around public health and safety the task force has identified.”

This presentation will cover international regulatory structures, the domestic regulation of ketamine therapy, and the use of ayahuasca in the U.S. through religious exemptions

In a future presentation, existing regulatory models of other U.S. states will be reviewed, and potential regulatory models and their equity implications will be evaluated

International Regulatory Structures

Psilocybin is considered an illegal substance in most countries, and is listed as a schedule I drug under the 1971 United Nations Convention on Psychotropic Substances

Countries without full illegality vary in how psychedelics are used, regulated, and enforced

Nations follow one of three general models

- Full legality—the drug is not and has never been illegal in the country
- Non-enforced Illegality—Though the drug may be technically illegal, there is no prosecution by law enforcement, so the drug can be used and distributed with little risk to the individual
- Medical Legality—Psychedelics are legal for specific individuals with medical exemptions

International Cases

The Netherlands

- An incident involving the suicide of a French tourist after using psilocybin led to calls from politicians in the Netherlands for stricter regulation of mushrooms
- Psilocybin was banned in 2007, though truffles remained legal
  - Truffles are mushrooms that grow underground, and continue to be sold in the Netherlands legally through a loophole in the law
- Research exemptions continued to be offered after the 2007 shift to illegality

Canada

- Psilocybin was made legal in 2020 in select cases for individuals through s. 56 exemptions under the Controlled Drugs and Substances Act
  - In 2022, Health Canada amended the Special Access Program (SAP), which allows medical professionals to request psilocybin therapy for end-of-life care, or where other therapies fail to help a patient

International Cases

Brazil

- There are no instances in Brazil of law enforcement taking any action against any individuals possessing or selling psilocybin mushrooms
- Traditional ayahuasca practitioners won a series of legal battles against the Brazilian government in 1992 to retain full legal access to use of the psychedelic
- There are a variety of research institutions in Brazil that are doing work on the use of psychedelics, with an emphasis on ayahuasca

Australia

- Australia has legalized MDMA for the treatment of PTSD and psilocybin for treatment resistant depression
    - Psychedelic therapy will be legal by July 2023 in strictly controlled medical settings
- Specifically authorized psychiatrists will be able to prescribe treatment to individuals with certain diagnoses
- This legalization comes with a rescheduling to Schedule 8 for therapeutic use
    - It remains in schedule 9 for unauthorized use

International Cases

Jamaica

- Psychedelics have never been illegal in Jamaica
- In 2021, legislators in Jamaica revised drug regulations, allowing for easier growth and distribution of cannabis and psilocybin
    - The first legal psilocybin “smart shop” opened in Jamaica in 2023

Notable Mentions

- Ibogaine remains an unscheduled drug in Mexico
    - Treatment centers continue to proliferate with little to no legal risk
- Peru has legalized Ayahuasca
- Multiple countries have decriminalized all drugs, including Uruguay, Portugal, Switzerland, and more

Regulation of Ketamine Therapy

Ketamine is a Schedule III substance that is approved by the FDA for use on individuals with treatment-resistant depression

- A prescription version of ketamine called esketamine (Spravato) was approved in 2019 by the FDA
  - Intramuscular Injections and dissolving tablets are becoming more popular as well
- The guidelines state that it can only be used "under the supervision of a health care provider in a certified doctor's office or clinic."

There is significantly less regulation involved in ketamine therapy due to its drug rescheduling

- Due to the lack of regulation, the degree of talk therapy, medical training, and facilitator guidance can vary greatly
- Costs of a single session can range from $400 to $800

Ayahuasca Use in the U.S.

Gonzales v. O Centro Espírita Beneficente União do Vegetal was a 2006 Supreme Court case in which the Court maintained the right for certain religious organizations to continue practicing and consuming a Schedule I controlled substance

- The church involved was Uniao do Vegetal (UDV), a New Mexican branch of a Brazilian church that uses a sacramental tea containing ayahuasca
- The only other organization to have secured legal protections for sacramental ayahuasca is Santo Daime, another Brazilian religion founded in the 1930s

    Santo Daime has approval to use ayahuasca only in specific states, including Washington and Oregon

Ayahuasca churches have rose in popularity along with the psychedelic movement, which has resulted in greater scrutiny

- There has been an increase in seizures as religious organizations without explicit legality push the boundaries of religious freedom exemptions

Task Force Discussion & Feedback

Questions?

PsilocybinWG@hca.wa.gov

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