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Policy & Law in Psychedelics: Navigating Evolving Frameworks

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Biographical and Disclosure Information

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Allison Hoots, Esq. works as an attorney advising on contractual, transactional, employment, corporate/business formation, healthcare, constitutional, and intellectual property law at **Hoots Law Practice PLLC**.

She has unique experience advising in all areas of the psychedelics space, including practitioners as psychedelic assisted therapy providers, risk reduction support service providers, ketamine practitioners, and therapists, as well as other harm reduction and psychedelic endeavors. She advises churches on liability issues and defensibility of the ceremonial use of psychedelic sacraments, pursuant to the right to religious exercise and the Religious Freedom Restoration Act.

Outside of her legal practice, Allison is **Executive Director & Board Member of Sacred Plant Alliance**, a self-regulating organization of religious practitioners dedicated to the legal, safe, ethical, and sincere ceremonial use of entheogenic sacraments.

Allison is also **Law and Drug Policy Reform Advisor for the Chacruna Institute for Psychedelic Plant Medicines**. She was the primary author of Chacruna's Guide to RFRA & Best Practices for Psychedelic Plant Medicine Churches.

Additionally, Allison is **Head Policy Counsel for New Yorkers for Mental Health Alternatives** to develop policy creating legal access to psilocybin and for drug policy reform in New York State. She is the primary author of the New York bill currently introduced as NY A2124 and NY S5303, a psilocybin permit model based in a public health framework.

Disclosures: Neither I nor my spouse/partner has a relevant financial relationship with a commercial interest to disclose.

I am an attorney, just not your attorney…

Please note that no information provided here today constitutes legal advice and this communication does not create an attorney-client relationship; all information is for general educational purposes only.

Do not rely or act on the basis of the information provided in this presentation. It is necessary to seek qualified legal counsel specific to any situation and jurisdiction.

Controlled Substances Act

The Controlled Substances Act (CSA) is the federal U.S. drug law that regulates, and generally prohibits, the manufacture, importation, possession, use, and distribution of certain substances.

There are state analogs with similar prohibitions.

Schedules I-V of the CSA

The CSA's classification of "drugs, substances, or chemicals" of substances into its five schedules (Schedule I-V) is based on an eight-factor analysis:

1) the active or relative potential for abuse;
2) scientific evidence of its pharmacological effect (if known);
3) current scientific knowledge regarding the drug, or substance, or chemical;
4) history and current pattern of abuse;
5) the scope, duration, and significance of abuse;
6) what, if any, risk there is to the public health;
7) its psychic or physiological dependence liability;
8) and whether the substance is an immediate precursor of a substance already controlled with the CSA schedules.

Schedule I of the CSA

Schedule I includes drugs, substances, or chemicals that are defined as drugs that are determined to have high potential for abuse, no accepted medical use, and a lack of accepted safety for use under medical supervision.

Substances in this category include LSD, heroin, psilocybin, and marijuana, 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote.

Schedule II of the CSA

Schedule II includes drugs, substances, or chemicals that are defined as drugs that are determined to have high potential for abuse, no accepted medical use or a currently accepted medical use with severe restrictions, and abuse of the drug or other substances may lead to severe psychological or physical dependence.

Schedule II substances include combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.

Schedule I and II of the CSA

The main difference between Schedule I and Schedule II substances is that the federal government has determined that Schedule I substances have no medical value and Schedule II substances do; however, both are deemed as having a "high potential of abuse" and "dangerous".

Schedule III of the CSA

Schedule III includes drugs, substances, or chemicals that are defined as drugs that are have a potential for abuse less than the drugs or other substances in schedules I and II, have a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence.

Schedule III substances include products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, and testosterone.

Schedule IV of the CSA

Schedule IV includes drugs, substances, or chemicals that are defined as drugs with a low potential for abuse and low risk of dependence.

Some examples of Schedule IV drugs are: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol.

Schedule V of the CSA

Schedule V includes drugs, substances, or chemicals that are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics.

Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin.

Federal Analogue Act

The Federal Analogue Act of the CSA anticipates scientific development and creation of novel substances. The Analogue Act captures any substance that is similar is chemical structure of effect of a Schedule I or II substance by broadly including them without specificity.

- Any substance with a similar chemical structure of a Schedule I or II substance is an "analogue" and treated as a Schedule I substance.

- It defines a "controlled substance analogue" as any substance that "has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to…a controlled substances in schedule I or II" or a person represents or intends the substance to have such an effect.

Regulatory Bodies

Drug Enforcement Administration (DEA) regulates manufacturing and distribution of controlled substances pursuant to Controlled Substances Act, CSA, 21 U.S.C. §§ 801 et seq.

Food and Drug Administration (FDA) regulates the approval of new drugs for interstate marketing. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.

States regulate the practice of medicine and licensed healthcare professional's scope of practice: State licensing boards and applicable state department.

DEA Involvement with CSA

The U.S. Department of Justice Drug Enforcement Agency (DEA) is responsible for applying the CSA.

DEA also reviews applicants and monitors registrants for licenses to use substances controlled pursuant to the CSA.

– Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner

– Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter

– Narcotic Treatment Programs

– Domestic Chemical

Psychedelic Access Frameworks

Clinical Research: DEA approved research; significant increase in medical journal articles, media coverage, pharmaceutical companies with psychedelic substances in development.

Medical: FDA approved drugs.

Adult/Supported Use: State access models. See Oregon and Colorado; New Mexico.

Recreational Use: Deprioritization or decriminalization.

Religious Use: First Amendment + RFRA

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Clinical Research and Medical Access

Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) is an agency of the Department of Health and Human Services (HHS). The FDA was established to enforce the Pure Food and Drug Act in 1906 with the objective of protecting the health of the public and ensuring the quality of food, medicine, and cosmetics. The Food, Drug, and Cosmetic Act (FD&C Act) was passed by Congress in 1938 and initially only required proof of safety before a drug could be brought to market. In 1962, this requirement was expanded to include “substantial evidence” of a drug's efficacy.

FDA's Definition of "Drug"

The FDA defines "drug" as:

- A substance recognized by an official pharmacopeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.

FDA Drug Approval

FDA regulates substances are that are manufactured, processed, or distributed in commerce for use as a food or drug, the terms 'food' and 'drug' are explicitly excluded from the definition of 'substance' in the CSA.

In collaboration with the DEA, ensure that drugs, or pharmaceuticals, released into the market

- demonstrate sufficient safety and efficacy
- drugs comply with consistent and quality manufacturing standards
- labeling and disclosures.

Demonstrable Medical Value, Safety, and Efficacy

For any substance to have demonstrable medical value and be legally used for medical purposes, it must undergo a rigorous drug approval process to demonstrate dose response, safety, and efficacy.

Multiple FDA-approved clinical trials that are done in stages and are categorized as Phases I, II, and III).

- Phase I is used to study the substance's basic safety profile and dose range.
- Phases II and III are used to further evaluate evidence of safety, and also to evaluate efficacy using randomized controlled trials (RCT) to measure the impact of the drug on study participants

Prescribing FDA Approved Drugs

When a drug receives FDA approval, added to a Schedule in the CSA that allows prescription: Any schedule other than Schedule I.

DEA registered practitioners can prescribe it:

- Either on-label (i.e.: for the indication that the drug received FDA approval to treat), or
- Off-label (i.e. for a use not indicated by FDA approval)

Off-Label Prescription

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FDA Modernization Act of 1997 implemented reforms to advance scientific research by increasing patient access to experimental drugs and speeding up the review process for new medications.

Authorized for the "off-label" use of medication

- When a drug that is approved for one purpose by the FDA is prescribed for another purpose or through another route of administration
- In accordance with a physician's clinical judgment based on experience
- Based on available research that the off-label use is medically appropriate for patient.

FDA Breakthrough Therapy Designations

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A breakthrough therapy designation is for a drug that treats a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies.

The FDA will expedite the development and review of such drug.

Breakthrough Therapy Designations awarded to:

- MDMA-assisted therapy for PTSD (MAPS, 2017)
- Psilocybin for treatment-resistant depression (Compass Pathways, 2018)
- Psilocybin for major depressive disorder (Usona Institute, 2019)
- Psilocybin for major depressive disorder (Cybin, March 2024)
- LSD for generalized anxiety disorder (MindMed, March 2024)

Re-Scheduling of Substances Issues

- Federal re-scheduling
  - HHS re-scheduling recommendation;
  - DEA interim final rule re-scheduling within 90 days
- State re-scheduling: approx. 50% of states have auto-rescheduling consistent with DEA action
- Bifurcated scheduling – Approved drug product newly scheduled and available for prescription, while class of substance, including natural compound (i.e. psilocybin), remains in Schedule I

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State Access Models:
Legalization (Adult/Supported Use)
Decriminalization, & Deprioritization

State Regulated Models: Legal Access

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State legalization despite federal prohibition.

State regulation of adult use, whether medical or supported, is authorized by the state, outside federal regulation, and provides different variations:

- Licensing of users
  - Requirements for access
  - Manner of use
  - Age restrictions
- Licensing or certification of support services (facilitation or therapy)
- Sourcing (user growing or licensed cultivation)
- Taxation
- Unauthorized use: Decriminalization, deprioritization, criminal penalties.

Oregon Regulated Framework

Approved by ballot in 2020 as Measure 109:

Access to Psilocybin

- Individuals over the age of 21
  - Facilitated sessions
  - Only at state licensed service centers
- Licensed facilitators
- Not as licensed healthcare professionals, but may be separately licensed
- Must disclose not for therapeutic or medical use
- Must be grown by licensed cultivators and distributed to service center
- Unauthorized use decriminalized under Measure of 110 (recently repealed)

Colorado Regulated Framework

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Approved by ballot in 2022 as Proposition 122:

Access to "natural medicines" including dimethyltryptamine (DMT), ibogaine, psilocybin and psilocyn, and mescaline (excl. peyote)

- Individuals over the age of 21
  - Facilitated sessions
  - State licensed service centers
- Licensed facilitators
  - Released June 2024
  - Levels of licensure: Facilitators and Clinical Facilitators
- Regulated cultivation

Colorado Personal Use Decriminalization

- Decriminalizes personal use and noncommercial sharing of natural medicines
- "Bona fide harm reduction and support services" with compensation

Colorado: Types of Facilitators

DORA's rules for Colorado's psychedelic therapy program include:

Two main license types for facilitators:

- Clinical Facilitator License for those with an existing physical or behavioral health practice,
- Facilitator License that allows those without a separate clinical license to become facilitators after completing a state-approved training program.

These two license types ensure that those with existing medical and mental health practices can become facilitators, clearly define facilitators' scope of practice based on their expertise and training, and increase accessibility of the program.

Exclusion for practitioners of religious, spiritual, or indigenous ceremony

Licensed Healthcare Professionals

Under all frameworks, needs for licensed healthcare professionals:

- Preparation
  - Screening prior to use of psychedelics
  - Psychedelic-assisted therapy: therapeutic support
- During a psychedelic experience
  - Administration and/or support
  - Whether authorized to provide facilitation within scope of practice
  - Other "hat" solely as facilitator
- Integration
  - Psychedelic-assisted therapy: therapeutic support
- Emergency services

Federal Prohibition Issues

State regulatory models in conflict with federal laws

Prohibition ties hands of certain healthcare professionals

DEA licensed professionals

- Prescribers subject to federal laws
- Example: Georgia pharmacies dispensing cannabis under medical model
  - DEA Memorandum titled "Guidance to Pharmacies on the Dispensing of Certain Tetrahydrocannabinols (THC)"
    - Emphasized the requirements of a DEA registrant to abide by "all relevant federal laws and regulations,"
    - Seemed to conclude unlawful conduct of such dispension of cannabis contained more than the 3% currently allowed by federal law.

State Legal Protections for Licensed Professionals

State laws that explicitly authorize licensed healthcare professionals to provide services and how or ability to receive services.

- Clear definition of scope of practice
  - State regulated healthcare
  - Type of licensure
  - Specific set of activities allowed to perform under license
- Content of informed consent
- Protection of license
- Issues of custody, liability, etc.

Right to Recommend Psychedelics

Due to federal prohibition and lack of FDA approval, physicians cannot "prescribe" controlled substances

Medical professionals may have right to discuss with patients

In 2002, Ninth Circuit holding in *Conant v. Walters* affirmed clinicians right under the First Amendment to engage in free speech to recommend medical marijuana when medically appropriate.

- Open and honest conversations about potential benefits and risks without fear of penalties
- Constitutional protection of physician-patient communications

Unclear how this protection will be applied in other circuits.

Importance of seeking medical boards perspective and codification of *Conant*

Insurance for Licensed Professionals

Malpractice insurance coverage only applies to scope of practice

Based on state regulation of healthcare practice

Issues in coverage of off-label prescription, i.e. ketamine

Exclusions in insurance policies

- Any illegal activity

Advertising of psychedelic-assisted therapy may complicate coverage or ability to get insurance until legal clarifications on these services.

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Religious-Based Exemptions from CSA

Right to Religious Exercise

Federal Law and State Laws Protect Right to Religious Exercise

Constitutional Guarantees:

Under federal law, the First Amendment guarantees that "***Congress shall make no law*** respecting an establishment of religion, or ***prohibiting the free exercise*** thereof…"

Law must also be applied.

Standards of Judicial Review

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The standard of review for the violation of a constitutional right is strict scrutiny, but not if law of general applicability.

- Rational basis test
- Intermediate scrutiny test
- Strict scrutiny test

In 1990, Employment Division v. Smith held generally applicable law that allegedly violated a constitutional right did not require strict scrutiny.

- Claimants had used peyote in ceremony
- Denied unemployment benefits.
- Controlled Substances Act was violated and generally applicable, i.e. did not target religion.

Religious Freedom Restoration Act of 1993 (RFRA)

Government shall not **substantially burden** a person's **exercise of religion** even if the burden results from a rule of general applicability, except when the law is in the furtherance of a **compelling governmental interest** and is the **least restrictive means** of doing so. 42 U.S. Code Section 2000bb-1

- RFRA allows persons (and corporations) who use psychedelic sacraments to make claims or raise defenses in sincere religious exercise
- RFRA was designed "to protect the ability of the **religious minorities** to practice their faiths."

Spirituality vs. Religion

What is the bright-line?

Religion is found sufficiently where beliefs are in the believer's "own scheme of things, religious" and with conviction.

US v. Seeger (1965)

When is individual use "religious"?

What communal use is (or is not) religious exercise?

Compelling Interests of Government

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1. **Risk to Participants in Use of Controlled Substance**
   - Scientific evidence of safe use;
   - And screening participants for contraindications of health and substances, and religious intent
2. **Risk of Diversion of Substance**
   - Religious intent of participants;
   - Securely storing sacrament;
   - Recordkeeping;
   - Strictly limited access.

Same diversion prevention protocol of DEA licensees.

Individualized Analysis for Religious-Based Exemption

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To deny a religious-based exemption claim or defense, "[B]eyond broadly formulated interests justifying the general applicability of government mandates… State needed 'so show with more particularity how its admittedly strong interest . . . would be adversely affected by granting an exemption.'"

-- O C*entro*

Must establish the "[a]sserted harm of granting **specific exemptions** to **particular religious claimant…**"

Precedent guides future cases, doesn't create exemptions for churches automatically

Religious-Based Exemption:
Gonzales v. O Centro Espírita Beneficente União do Vegetal

- U.S. Supreme Court granted UDV exemption to use ayahuasca as sacrament (2006)
- Unanimously affirmed that seizure of their sacrament and threats of prosecution constituted substantial burden
- “Because the [UDV’s and U.S. Government’s] evidence on health risks and diversion was equally balanced, the Government had failed to demonstrate a compelling interest justifying the substantial burden on the UDV.”
- Court prohibited the government from burdening the religious practice with ayahuasca by any church of the UDV in the United States.

Religious-Based Exemption:
Church of the Holy Light of the Queen v. Mukasey

- U.S. District Court found government failed to show that its interests justified prohibiting the Daime tea outright. Granted a broad injunction.
- On appeal, the U.S. Court of Appeals Ninth Circuit sent the case back to district court to narrow the scope of the injunction. The final decision legalized Santo Daime's use of ayahuasca and prohibited the government from outright banning the church's importation of Daime tea for ceremonies. (2009)
- Evidence of harm extrapolated from unrelated studies provided by government.
- No evidence of viable market of ayahuasca.

[T]he very reason Congress enacted RFRA was to respond to a decision denying a claimed right to sacramental use of a controlled substance. The Government has not shown that granting the UDV an exemption would cause the kind of administrative harm [for the DEA] recognized as a compelling interest…

O *Centro* (2006)

DEA Guidance: Religious Based Exemption Petitions

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In response to *O Centro*, the DEA established an "interim" petition process in 2009, for religious organizations to petition for an exemption from the Controlled Substances Act.

Petitioners must submit a petition detailing:

- Information demonstrating sincere religious exercise
- Specific controlled substance and usage parameters

Petitioners must agree to cease religious exercise with sacrament until petition is determined.

In 2024: U.S. Gov't Accountability Off. published a report: Drug Control: DEA Should Improve Its Religious Exemptions Petition Process for Psilocybin (Mushrooms) and Other Controlled Substances, GAO-24-106630 (May 2024). The Department of Justice agreed with these recommendations.

Current Religious Based Exemptions

All religious-based exemptions are granted to ayahuasca churches:

- O Centro: US Supreme Court in 2006
- Holy Light of the Queen: Ninth Circuit in 2009
- Church of Eagle and Condor: Settlement in 2024
- Church of the Celestial Heart: Settlement in 2025
- Church of Gaia: Petition granted in 2025

Any church without an explicit exemption has the ability to file a claim and legal defensibility for the constitutional right to religious exercise, but is not operating legally.

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Thank you!