RESEARCH, REFERENDUM, LITIGATION, AND LEGISLATION
PICKING THE LOCKS ON THE DOORS OF PERCEPTION

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About me

Columbia College, Columbia University, New York, NY; B.A. (Political Science), 1995
Senior paper: “How Treatment Got Lost: Law Enforcement and Prevention in U.S. Drug Control”

Benjamin N. Cardozo School of Law, J.D., 2000

1994: co-founded direct action psychedelic legalization group focusing on ibogaine

2008: organized the first public discussion of racial disproportion in arrests for simple cannabis possession, eventual basis for New York State cannabis legalization

2010: first articulated the concept of “psychedelic law” as a unique area of study

2018: wrote Psychedelic Markets of the Future, a proposed deconstruction of psychedelic policy reform; assisted the Decriminalize Denver campaign in obtaining Denver Board of Elections approval of the text of the ballot initiative that decriminalized psilocybin mushrooms in Denver in May 2019

What are “psychedelics”?

Imprecise designation of various psychoactive substances: generally refers to lysergic acid diethylamide, psilocybin, DMT, mescaline, ibogaine, and bufotenine.
Colloquially includes MDMA and ketamine, although both differ in their action and effects from the ”classic psychedelics.”

Difficulty in formulating term to describe them:
Officially still “hallucinogens” in the federal and state controlled substance acts.
“Psychedelic” coined by Dr. Humphry Osmond in 1957; one among many candidates.
From Greek; means approximately “mind-manifesting.”
“Entheogen,” meaning approximately “generating God within” is popular among certain constituencies.

Categorically different from other psychoactive substances in their subjective effects:
Michael Pollan’s book *How to Change Your Mind*, Michael Pollan 2018 uses the term “ineffable” to describe a psychedelic experience.
Can be disorienting and challenge prior conceptions of self and relationships with others.

PROPOSITIONS

Psychedelics are unique in that they fuse medicine and religion/spirituality: to be reductionist, they are essentially medications that often work by inducing mystical – or at least spiritual (perception of the sacred, feeling of connected to the universe) – experiences. They thus constitute a perplexing and possibly unique fusion of science and religion: they challenge the "medicine/sacrament dichotomy."

They can be characterized as "cognitive technologies" with extremely powerful effects, that may result, in personality change and behavioral change: but that's their promised value. They originally caught the attention of the US government in the 1950s as potential weapons of war to disorient enemy soldiers or for use in brainwashing prisoners of war; there is a hidden history of nonsensual experimentation on human subjects (MK-Ultra). When they escaped the laboratories following use during research, they fueled a cultural revolution that articulated an alternative societal value system whose effects are still felt.

Now they are being promoted as hot new biotech investments, and billions of dollars are pouring into the medical market, the incentive of which is to promote sales and maintain and increase market share for the benefit of for-profit pharmaceutical companies and investors.
The consequences of mass use of psychedelics (a scenario for which there is no precedent), whether marketed by for-profit interests for use under medical supervision, made available in ceremonial practice, or in a retail market, are unknown.

PROPOSITIONS, cont’d

At the same, there is a limited degree of access to certain psychedelics under Constitutional Free Exercise rights.

There is also a rapidly-growing movement to remove criminal penalties for actions involving psychedelics under state or local law, and otherwise facilitate access through a state licensed delivery system.

These changes are not happening in a political vacuum.

Drug policy reform has to a large extent been redefined as an element in the struggle for racial and economic justice, and all legal reform in drug policy, including psychedelic law reform, is viewed in the context of social equity.

PROPOSITIONS, cont'd

Likewise, research is not taking place in a vacuum.

It is taking place in the context of increasing ideological polarization, but psychedelic research receives unusual bipartisanship (trans-ideological) support: advocacy by veterans for access to psychedelics is the public image of psychedelics and has made expedited access a priority for conservative political elements who have not traditionally favored drug policy reform.

It is also taking place in the context of the longstanding, well-evolved psychedelic-using population, which, as referenced above, is the mover of the legislative reform advocacy sweeping local and state governments. That movement is suffused with an anti-commercialization ethos and is often suspicious of, if not hostile to, clinical research which it perceives as an adjunct to the hegemony of the medical market.

PROPOSITIONS, cont'd

<u>One way of understanding the significance of clinical research</u>

Everything affects everything: there is a feedback relationship between research and policy change.

Efforts to expand access immediately under local and state law—outside the scope of FDA-sanctioned research—consistently rely on the published results of clinical research as support.

Markets do not sit still—they react to everything. Cannabis legalization in New York led to an eruption of unlicensed retail venues in New York City. Psilocybin mushrooms are now being sold openly in certain venues, perhaps corresponding to the media characterization of psilocybin mushrooms as "the new cannabis."

PROPOSITIONS, cont'd

The present moment is the result of political reform advocacy (in which I include the efforts of advocates to restart clinical research for almost forty years) *by the drug-using population itself*.

The users are the only ones with direct knowledge and understanding of psychedelics.

Their perspectives on safety and efficacy are necessarily "anecdotal." One key question therefore is whether and, if so, how anecdotal evidence will be recognized in formulating safety and efficacy standards under federal law.

PROPOSITIONS, cont'd

Reports of relatively high efficacy and relatively low risk profiles of psychedelic substances emanating from clinical research may contribute to the hype, both in terms of investment in the pharmaceutical sector and in terms of activity in the illegal market as interest grows among people seeking relief or new experiences.

The open question is what will be the effect of clinical research outside the experimental setting.

History

Examples of use outside of Western biomedicine

- Carvings of mushrooms in North Africa 7000-8000 B.C.E.
- Eleusinian Mysteries in Ancient Greece
- Psilocybin mushrooms in Central America and Mexico before arrival of Europeans
- Iboga in Gabon
- Ayahuasca in South America

Awareness of psychedelics in European and European-derived societies

- Long “amnesia”: association of psychedelic or “dissociative” substances with witchcraft in medieval Europe; suppression by Church
- Suppression of mushroom use in Mexico by Spanish
- 1864 – French become aware of indigenous use of iboga root bark
- 1887 – identification of mescaline, present in peyote cactus in southwest United States
- 1943 – synthesis of lysergic acid diethylamide (LSD) by Albert Hofmann in Switzerland; derived from ergot (rye fungus); unintentional discovery of psychedelic effects
- 1955 - R. Gordon Wasson participates in psychoactive mushroom ceremony in Mexico; Life Magazine publishes his article about the experience; Dr. Hofmann subsequently identifies psilocybin as psychoactive substance

LSD as “wonder drug”

- Thousands of administrations of psychedelic substances by researchers and physicians in 1950s. “Wonder drug”: academic papers published on LSD
- Model psychosis, breakthrough therapy – **but first a proposed mind control drug/weapon (CIA’s MK-ULTRA program)**
- See https://www.trippingly.net/lsd-studies for a sample of articles in the 1950s and 1960s mainstream media about psychedelics as medicine.

Movement to federal prohibition

- 1963 – departure of Timothy Leary and Richard Alpert from Harvard University in connection with notoriety of their psychedelic use and experimentation
- 1965 federal Drug Abuse Control Amendments of 1965 (P.L. 89-75) to the Food, Drug, and Cosmetic Act restricted manufacture, compounding, processing, sale, delivery, or other disposition of “depressants” and “stimulants,” the latter of which included any substance which the Department of Health, Education, and Welfare found to have a potential for abuse “because of its…hallucinogenic effect,” to restricted categories of persons: e.g. pharmaceutical companies, wholesale distributors, physicians and researchers.
- By late 1960s widespread non-medical use led to backlash against psychedelics and designation as public health threat.
- 1970 Controlled Substances Act created federal Schedules I-V. 21 U.S.C. 812
- LSD, psilocybin, DMT, ibogaine, mescaline placed in most restrictive category, Schedule I (alongside cannabis).
- Research declined precipitously.
- Last research in humans ended in 1978.
- Dr. Rick Doblin, in his Ph.D. thesis at the Harvard Kennedy School of Government, describes an unwritten FDA policy of keeping in limbo applications to research into therapeutic use of psychedelics.

The better-known psychedelic substances in Schedule I:

- 21 C.F.R. 1308 (d)
- (11) MDMA
- (17) bufotenine
- (19) DMT
- (21) ibogaine
- (22) LSD
- (23) “Marihuana” A/K/A cannabis
- (24) mescaline
- (26) peyote
- (29) psilocybin
- (30) psilocyn

Possibly immense portion of U.S. population with lifetime use, increase in use among young adults

Estimate of 32 million Americans who have used a psychedelic substances (excluding cannabis) as of 2010.

Terence Krebs and Johanssen. “Over 30 million psychedelic users in the United States.” PubMed Central, March 28, 2023.

Reported increase in use of psychedelics other than LSD by youth among young adults aged 19–30 years.

Katherine M. Keyes and Megan E. Patrick. “Hallucinogen use among young adults ages 19–30 in the United States: Changes from 2018 to 2021.” Addiction, June 7, 2023.

The “psychedelic renaissance”

- Gradual resumption of clinical research beginning in 1990 with DMT.
- Current “psychedelic renaissance”: worldwide explosion in research, publication of medical journal articles, coverage in popular media, proliferation of small pharmaceutical companies dedicated to bringing patented psychedelic substances into the market as adjuncts to psychedelic-assisted therapy, millions of investment dollars pouring in – “the new cannabis”
- Psychedelics are a hot new biotech sector
- See investment advisory websites such as:

  Psychedelic Finance (psychedelicfinance.com)

  Psychedelic Stock Watch (psychedelicstockwatch.com)

Religious freedom to use psychedelics begins under federal law

- Enactment of the American Indian Religious Freedom Act in 1978 – the use, possession, or transportation of peyote by an Indian for bona fide traditional ceremonial purposes in connection with the practice of a traditional Indian religion.
- Protects the Native American Church, a syncretic religion established in the 1890s that uses the peyote cactus (prohibited at 21 C.F.R. 1308(d)(26) in ceremonies.

Peyote prohibition triggers the Religious Freedom Restoration Act

- In Oregon v. Smith, 494 U.S. 872 (1990), the Oregon Department of Human Resources denied unemployment benefit members to two members of the Native American Church, substance abuse treatment providers, who were discharged for use of peyote.

- The Court upholds the denial of benefits on the grounds that the Free Exercise Clause does not bars application of a neutral, generally-applicable law to religiously-motivated action.

Peyote prohibition triggers RFRA, cont'd

Congress reacts by passing the Religious Freedom Restoration Act.

42 U.S.C. §2000bb–1(b).

RFRA prohibits the Federal Government from substantially burdening a person's exercise of religion, even if the burden results from a rule of general applicability except when the Government can demonstrate that application of the burden to the person (1) furthers a compelling government interest; and (2) is the least restrictive means of furthering that interest.

Selective exemption of ayahuasca from the Controlled Substances Act under RFRA

O Centro Espirita Beneficente Uniao do Vegetal (UDV) is a Brazil-based syncretic religion that incorporates consumption of ayahuasca, a brew derived from two rainforest plants that contains DMT, which is prohibited at 21 C.F.R. § 1308(d)(19)

In Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418 (2006), U. S. Customs inspectors seized a shipment of ayahuasca to the U.S. branch of the UDV and threatened prosecution. The Court affirmed an order in UDV's favor enjoining application of the Controlled Substances Act to the UDV's sacramental use under RFRA.

In 2009 the DEA issues guidelines for petitioning for waivers from application of the CSA based on RFRA

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-5)(EO-DEA-007)(Version2)RFRA_Guidance_(Final)_11-20-2020.pdf

The guidelines provide guidance to persons seeking exemptions from application of the Controlled Substances Act to the party's activity on the grounds that it "would (1) be a substantial burden on (2) his/her sincere (3) religious exercise."

The petition should provide detailed information about, among other things,

> (1) the nature of the religion {e.g., its history, belief system, structure, practice, membership policies, rituals, holidays, organization, leadership, etc.);
>
> (2) each specific religious practice that involves the manufacture, distribution, dispensing, importation, exportation, use or possession of a controlled substance;
>
> (3) the specific controlled substance that the party wishes to use; and
>
> (4) the amounts, conditions, and locations of its anticipated manufacture, distribution, dispensing, importation, exportation, use or possession.

Puts the DEA, a federal police agency, in the business of determining what qualifies as a "religion" for the purposes of waiving application of a criminal statute to religious practice.

Local and state psychedelic law reform ballot initiatives and action by local and state elected officials

DENVER

On May 7, 2019, Denver voters pass Initiated Ordinance 301.

1. Enforcement of laws imposing criminal penalties for the personal use and personal possession [defined to include “propagation,” i.e. cultivation] of psilocybin mushrooms shall be the lowest law enforcement priority in the City and County of Denver.
2. Prohibits all officers and employees of the City from using any city funds or resources to assist in enforcement of laws imposing criminal penalties for personal use and personal possession of psilocybin mushrooms by adults.
3. 3. Requires the Mayor to appoint an 11-person “Psilocybin Mushroom Policy Review Panel” to assess and report on the effects of the new law.

Local and state psychedelic law reform ballot initiatives and action by local and state elected officials, cont'd

While psychedelics are **not** "the new cannabis," the movement towards psychedelic law change largely tracks the movement that achieved change in cannabis law:

- Local initiatives 'deprioritize' psychedelic law violations and defund enforcement actions by local government employees
- State law (Oregon only, the first law to pass) creates 'medical' access

However, some California activists seek to pass an initiative that will legalize a general adult use "tax and regulate" commercial retail market

Local and state psychedelic law reform ballot initiatives and action by local and state elected officials, cont'd

Key consideration:

- As with cannabis, decriminalizing use and possession by individuals - the "demand side" of the market – is relatively easy.
  This is the basic approach of local law change.
- More difficult is changing the status of the supply side of the market: manufacturers, wholesalers, distributors, retailers (whether pharmacists, treatment providers, or retailers), which presumably must happen under state law.
- However, (a) the Denver initiative ordinance includes "propagation" of psilocybin within the scope of "personal possession" and (b) the Decriminalize Nature Oakland advocacy group has proposed an ordinance that would permit cultivation and administration of "Entheogenic Plants" by a "Facilitator" recognized by the City.

Decriminalize Nature movement

OAKLAND

On June 4, 2019, the Oakland City Council passed a resolution authored by an advocacy group called Decriminalize Nature which decriminalized the possession and use of naturally-occurring psychedelic substances as a category.

As opposed to the Denver approach of focusing on a specific substance, the resolution covers a category of matter called “Entheogenic Plants.”

Entheogenic Plants are defined as “plants and natural sources…such as mushrooms, cacti, iboga containing plants and/or extracted combinations of plants similar to Ayahuasca; and limited to those containing the following types of compounds: indole amines, tryptamines, phenethylamines.”

Decriminalize Nature movement, cont'd

The Decriminalize Nature movement explicitly invokes sacred character of naturally-occurring psychedelic substances, millennia-old traditions of religious use, and spiritual growth from use of Entheogenic Plants.

It also expresses opposition to the role of for-profit corporations in "plant based healing and psychedelic medicine spaces," i.e., what might be characterized as an anti-capitalist or anti-commodification position, and focuses on Entheogenic Plants as a means of addressing trauma caused by racism. DN chapters have opposed state-level reform in Oregon and Colorado

<u>However</u>, the DN resolution relies heavily on published research results. (See Resolution at 9-14.)

Other local jurisdictions

Decriminalize Nature chapters opened in cities around the United States;

Local jurisdictions, including Ann Arbor, Berkeley, several localities around Boston, Minneapolis, Santa Cruz, San Francisco, Seattle, and the District of Columbia, have decriminalized or deprioritized law enforcement in some way as to certain psychedelics.
Activists have operated under the DN imprimatur (presented the DN resolution); others are independent.

State-level reform models

Licensed psychedelic-assisted therapy system

Oregon Psilocybin Services Initiative (Oregon Measure 109)

Passed on November 3, 2020 with 56% of the vote

- https://ballotpedia.org/Oregon_Measure_109,_Psilocybin_Mushroom_Services_Program_Initiative_(2020) (accessed November 23, 2020)
- Creates a clinic model for onsite consumption of “psilocybin products”
- Distant family relationship to a state medical cannabis system with licensure/prior approval of all participants:

➢ “manufacturer”

➢ “psilocybin service center operator”

➢ “psilocybin services facilitator”

➢ testing laboratory

State-level reform models, cont'd

Oregon Measure 109, cont'd

- Places regulatory authority in Oregon Health Authority
- Grants extensive discretion to OHA in formulating the particulars of the entire system through regulation, e.g., qualifications to be a manufacturer, requirements for "psilocybin products," qualifications to operate a psilocybin services center, form of "psilocybin services" modalities (explicitly provides for three stages: Preparation Session, Administration Session, Integration Session), and qualifications to be psilocybin services facilitator.
- Can be construed as attempting to main low barriers for entry into the market, e.g., by including in the statute minimum requirements for licensure other than standard good character requirements, 2-year residency requirement, and age minimum.

State-level reform models, cont'd

Oregon Measure 109, cont'd

According to news reports, psilocybin administration began in licensed services center this summer.

State-level reform models, cont'd

Research or study group only

Connecticut – enacted 2021
Directs Department of Mental Health and Addiction Services to convene a working group "to study the health benefits of psilocybin. Such study shall include, but need not be limited to, an examination of whether the use of psilocybin by a person under the direction of a health care provider may be beneficial to the person's physical or mental well- being." Working group delivered its report in February 2022, essentially recommending that the state attempt to support clinical research and attempt to obtain FDA approval for a "compassionate use" program.

Shortly afterwards, legislation was passed that directed the Department of Mental Health and Addiction Services to establish a psychedelic-assisted therapy pilot program, to be administered by a medical school in the state, that will provide "qualified patients" with MDMA-assisted or psilocybin-assisted therapy as part of a research program approved by the FDA.
A psilocybin decriminalization bill followed shortly thereafter….

State-level reform models, cont'd

Research or study group only, cont'd

Texas - enacted 2021
Directs Health and Human Services Commission in collaboration with Baylor College of Medicine and in partnership with a military veterans hospital or a medical center that provides medical care to veterans, shall conduct a study on the efficacy of using alternative therapies, including the use of 3,4-methylenedioxymethamphetamine (MDMA), psilocybin, and ketamine, in the treatment of veterans who suffer from post-traumatic stress disorder

State-level reform models, cont'd

Research or study group only, cont'd

Maryland - enacted 2022

- Creates fund to support research into studying the use of alternative therapies for veterans with post–traumatic stress disorder and traumatic brain injuries and providing cost–free access to alternative therapies for **veterans** with post–traumatic stress disorder and traumatic brain injuries

- Directs Department of Health to report to the legislature "any findings regarding the efficacy of alternative therapies as treatment for post–traumatic stress disorder and traumatic brain injuries; and recommendations on budgetary, legislative, or regulatory changes to expand access to alternative therapies for veterans with post–traumatic stress disorder and traumatic brain injuries. [NOT FOUND AS OF 9/11/23]

State-level reform models, cont'd

<u>Decriminalization of personal use, cultivation, and sharing, PLUS licensed psychedelic-assisted therapy system</u>

COLORADO
Natural Medicines Act – voter initiative, passed November 2022

Two parts:
(1) Creates the "regulated natural medicine access program," which includes licensure for a facilitator and a healing center - equivalent to the Oregon model.
Establishes "the Natural Medicine Advisory Board"

(Note: for the purposes of statute, "natural medicines" mean only psilocybin and psilocyn until June 2026, at which point the Department of Health may add one or more of the other enumerated substances to the list of "natural medicines.")

State-level reform: models, cont'd

Excerpt from Legislative Declaration:

The voters of the State of Colorado find and declare that:
(a) Colorado's current approach to mental health has failed to fulfill its promise. Coloradans deserve more tools to address mental health issues, including approaches such as natural medicines that are grounded in treatment, recovery, health, and wellness rather than criminalization, stigma, suffering, and punishment.

(b) Coloradans are experiencing problematic mental health issues, including but not limited to suicidality, addiction, depression, and anxiety.

(c) An extensive and growing body of research is advancing to support the efficacy of natural medicines combined with psychotherapy as treatment for depression, anxiety, substance use disorders, end-of-life distress, and other conditions.

(d) The federal government will take years to act and Coloradans deserve the right to access natural medicines now.

State-level reform: models, cont'd

Research-related provisions:

Tasks the Board with making recommendations to the state as to matters, including, as relevant :

- **research related to the efficacy and regulation of natural medicine, including recommendations related to product safety, harm reduction, and cultural responsibility;**
- the proper content of training programs, educational and experiential requirements, and qualifications for facilitators;
- affordable, equitable, ethical, and culturally responsible access to natural medicine and requirements to ensure the regulated natural medicine access program is equitable and inclusive;
- appropriate regulatory considerations for each natural medicine;
- the addition of natural medicines to the regulated natural medicine access program…based on available medical, psychological, and scientific studies, research, and other information related to the safety and efficacy of each natural medicine;
- requirements for accurate and complete data collection, reporting, and publication of information related to the implementation of this article….

State-level reform: models, cont'd

Research-related provisions, cont'd:

"the Board shall, on an ongoing basis, review and evaluate existing research, studies, and real-world data related to natural medicine and make recommendations to the legislature and other relevant state agencies as to whether natural medicine and associated services should be covered under Health First Colorado or other insurance programs as **a cost effective intervention for various mental health conditions**, including but not limited to end of life anxiety, substance use disorder, alcoholism, depressive disorders, neurological disorders, cluster headaches, and post traumatic stress disorder."

State-level reform: models, cont'd

(2) General decriminalization

Addresses severe community criticism of Oregon Measure 109 for failure to protect legacy market through decriminalization.

The Act decriminalizes:

"possessing, storing, using, processing, transporting, purchasing, obtaining, or ingesting natural medicine for personal use, or giving away natural medicine for personal use without remuneration to a person or persons twenty-one years of age or older";

"growing, cultivating, or processing plants or fungi capable of producing natural medicine for personal use" subject to limitations on controlling access to the production area

State-level reform: models, cont'd

CALIFORNIA (big news)

On September 7 and September 8 of this year, the California Senate and the California Assembly, respectively, passed SB-58, a bill that (a) makes lawful the possession, preparation, obtaining, transfer, as specified, or transportation of, specified quantities of psilocybin, psilocyn, DMT, ibogaine, and mescaline, for "personal use" by and with persons 21 years of age or older, and (b) tasks the California Health and Human Services Agency with convening a working group that will make recommendations to the legislature on "the establishment of a framework governing the therapeutic use of those substances.

Reference to clinical research in the legislative declaration:

"**Clinical research demonstrates the potential use of some psychedelic compounds, in conjunction with therapy, for the treatment of mental health, such as end-of-life anxiety, depression, post-traumatic stress, and substance use disorders**. Observational evidence and traditional uses of psychedelic plants and fungi demonstrate how ceremony and community are utilized to enhance the outcomes and increase the safety of spiritual practice, emotional healing, and responsible personal growth."

Workgroup shall include, among others, "university researchers with expertise in psychedelics" and "research scientists with expertise in clinical studies and drug approval process under the federal Food and Drug Administration."

State-level reform: models, cont'd

The workgroup must study subjects including but not limited to:

- **Research on the safety and efficacy of using each of the controlled substances specified in subdivision (a) in a therapeutic setting for treating post-traumatic stress disorder, depression, anxiety, addiction, and other mental health conditions**.
- Long-term impact of supervised psychedelic or dissociative drug use with seeking and misusing other substances, including alcohol, cannabis, illicit substances, and unregulated psychedelic or dissociative drugs.
- Perceptions of harm of psychedelic or dissociative drugs following enactment of decriminalization both on a personal use and therapeutic use level.
- Impact of different regulatory frameworks on different health outcomes among vulnerable populations, including youth, people with substance use disorders, and minority or disenfranchised groups.
- Regulated use models for the controlled substances specified in subdivision (a) from other jurisdictions.
- Content and scope of educational campaigns that have proven effective in accurate public health approaches regarding use, effect, and risk reduction for the substances specified in subdivision (a), including, but not limited to, public service announcements, educational curricula, appropriate crisis response, and appropriate training for first responders and multiresponders, including law enforcement, emergency medical services, fire service, and unarmed coresponder units.
- Policies for minimizing use-related risks, including information related to appropriate use and impacts of detrimental substance use.
- Appropriate frameworks to govern the therapeutic use of controlled substances, including qualifications and training for therapists or facilitators.

State-level reform: models, cont'd

The workgroup shall develop and report to the legislature policy recommendations regarding, but not limited to, all of the following:

- Development of a statewide program or programs for the training of individuals providing therapeutic psychedelic services in therapeutic settings, including facilitated and supported use settings.
- Development of a statewide credentialing process for individuals providing therapeutic psychedelic services in therapeutic settings, including facilitated or supported use settings.
- The content and scope of educational campaigns and accurate public health approaches regarding use, effect, risk reduction, and safety for mescaline, ibogaine, psilocybin, and psilocin.
- Policies for minimizing use-related risks, including information related to appropriate use and impacts of detrimental substance use.
- Policies for the regulation of [the four substances above], including responsible marketing, product safety, and cultural responsibility.
- Policies for the safe and equitable production, access, use, and delivery of [the four substances above].

State-level reform, models, cont'd

Right to try

Federal right to try law, 21 U.S.C. § 360-bbb et seq., authorizes use of drugs that have gone through FDA Phase I (safety) trials but not received final FDA approval by limited population of patients – sometimes limited to terminal patients. Function of a right to try system requires corresponding state law. Some states exclude Schedule I substances from the scope of drugs that are eligible.

Missouri: 2022 Regular Session HB 249
Deletes provision from Missouri's right to try law that excludes Schedule I substances
Adds text stating that:

> production and distribution of any Schedule I psychedelic drug that qualifies as an investigational drug under…this section by a manufacturer and any dispensation of such drug by a physician or pharmacy for use in accordance with this section shall be considered lawful.

Miscellaneous
Removal from state controlled substances list
Placing psychedelics in a section of the penal law separate from other controlled substances

Some other legal issues

Federal Right to Try litigation and rescheduling petition

AIMS v. Garland, 24 F.4th 1249 (9th Cir. 2022)

Washington State oncologist Sunil Aggarwal sought to provide psilocybin to some of his terminally-ill patients for severe anxiety and depression.
Psilocybin is being investigated in multiple clinical trials and therefore should be eligible for access under Washington's right to try law.

Dr. Aggarwal requested guidance from the DEA as to how to register with the DEA to obtain psilocybin for his patients under the right to try law. DEA responded with a letter stating that it has no give authority to grant a waiver for therapy under the federal Right to Try law because that law does not refer to the CSA.

Dr. Aggarwal and his patients brought a petition challenging what they characterized as a final agency action. The Circuit Court dismissed the petition on the grounds that the DEA response was not a final agency action and therefore the Court had no jurisdiction to review it.

In response, Dr. Aggarwal filed a petition to move psilocybin from Schedule I to Schedule II. [https://emergelawgroup.com/2017/wp-content/uploads/2022/02/Rescheduling-Petition.pdf, last accessed May 26, 2022]

Briefing is complete and oral argument is scheduled for October.

RISKS, KNOWN AND UNKNOWN

Sexual abuse by therapists and other treatment providers/spiritual guides

Undue influence in the context of elder abuse

"A psychedelic therapist allegedly took millions from a Holocaust survivor, highlighting worries about elders taking hallucinogens," Olivia Greenhill, April 21, 2022 https://www.statnews.com/2022/04/21/psychedelic-therapist-allegedly-took-millions-from-holocaust-survivor-highlighting-worries-about-elders-taking-hallucinogens/ [accessed May 26, 2022]

According to the article, daughters of a wealthy, elderly man brought an action against a younger romantic companion who they alleged had unduly influenced him to provide with substantial financial benefits. Sarko v. Dulai, Superior Court, Marin County (FL 2101372).

Defendant is a well-known advocate of psychedelic therapy. The alleged victim, a refugee from the Holocaust and Communist Hungary, supported psychedelic research and took psychedelics with the defendant.

Risks, known and unknown, cont'd

According to the article:

> Clinical trials testing psychedelics involve therapists meeting with patients before, during, and after their psychedelic experience. People who take psychedelics report they create feelings of emotional intimacy, heightening the susceptibility that already exists between patients and health care providers. Moreover, the drugs are being explored as a way to ease patients' anxiety at the end of life. And yet it's unclear whether psychedelic therapists will be required to meet the same licensing standards as other therapists such as psychiatrists and psychologists.
>
> "It's a whole new frightening possibility of elder abuse," Donovan Maust, a geriatric psychiatrist and health services researcher at the Michigan Medicine Department of Psychiatry, said about the risks faced by older people treated with psychedelics.
> ….
> The lawsuit alleges Dulai used drugs including ayahuasca and MDMA to heighten Sarlo's dependence on her, and as Sarlo's health deteriorated, she introduced him to ketamine and supervised an "intensive" dosing regimen. Meanwhile, Sarlo bought her a Porsche and loaned her $1.4 million to purchase a home now worth an estimated $2.3 million for her and her husband in Mill Valley, an affluent city in Marin County, just north of San Francisco. He later forgave the loan, turning it into an outright gift.

The article reports that the action was settled.

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