

Legal Status of Psychedelic Drugs and Research Involving Possible Medical Uses

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Issue

Describe (1) the legal status of psychedelic drugs and (2) research involving the possible medical and therapeutic uses of these drugs, specifically for mental health treatment.

Summary

Several psychedelic drugs, such as psilocybin (psychedelic mushrooms) and MDMA (ecstasy), are also Schedule I controlled substances under federal law, subject to various criminal penalties. Schedule I substances, the strictest designation, are generally those with the highest potential for abuse and no approved medical use.

In Connecticut, psilocybin and MDMA are both listed as Schedule I controlled substances. State law does not specifically provide for the approved medical use for these substances.

Proposed legislation in New York advocated removing psilocybin from the list of Schedule I substances. A similar bill was proposed in Iowa, along with additional legislation that would allow for the medical use of certain psychedelics if approved by the state pharmacy board. Several municipalities, including Denver, have decriminalized the possession of psilocybin. Both Oregon and Washington D.C. have approved ballot measures involving psilocybin. Oregon decriminalized the supervised use of psilocybin with a licensed professional in a therapeutic setting, and Washington D.C. decriminalized psilocybin.

There are several universities studying the medical and therapeutic uses of psychedelic substances. Emory University is studying the effects of MDMA on Post-Traumatic Stress Disorder. Researchers at Johns Hopkins University are investigating how psilocybin can assist smokers struggling to quit and patients with Alzheimer's Disease, anorexia nervosa, and major depressive disorder. New York University, UConn, and Yale University are also conducting similar studies.

A few of these universities received assistance from the Multidisciplinary Association for Psychedelic Studies. This organization works to raise awareness of the medical uses of psychedelics and assists scientists with funding, research, and obtaining federal regulatory approval for clinical trials.

Legal Status of Psychedelic Drugs

Federal Law

Under <u>federal law</u>, several psychedelic drugs, such as psilocybin and MDMA, are Schedule I controlled substances, subject to various criminal penalties.

Researchers must obtain approval from the federal Drug Enforcement Administration (DEA) if they are seeking to conduct studies of Schedule I controlled substances not currently approved for medical use. In 2018, the DEA <u>announced</u> that it had taken certain steps to streamline the approval process (see the "Medical Research and Treatment" section below for examples of such research).

Connecticut Law

In Connecticut, psychedelic drugs and other hallucinogenic substances are controlled substances. State law defines "hallucinogenic substances" as "psychodysleptic substances, other than cannabis-type substances, that assert a confusional or disorganizing effect upon mental processes or behavior and mimic acute psychotic disturbances" (<u>CGS § 21a-240(23)</u>).

In Connecticut, controlled substances are listed in Department of Consumer Protection (DCP) regulations (<u>Conn. Agencies Reg., §§ 21a-243-7 to 21a-243-11</u>). For example, psilocybin and MDMA are both listed as Schedule I controlled substances. State law does not specifically provide for any approved medical uses for psychedelic drugs.

We searched Connecticut legislation since 2000 and did not find any bills that would decriminalize these drugs or provide for approved medical uses. As with other illegal drugs, possession of these drugs is generally a misdemeanor and sale of them is a felony under state law.

Other Jurisdictions

Oregon. On the November 3, 2020, ballot voters approved <u>Oregon Measure 109, Psilocybin</u> <u>Mushroom Services Program Initiative (2020)</u>. This ballot initiative authorizes the Oregon Health Authority to create a program to permit licensed service providers to administer psilocybinproducing mushroom and fungi products to individuals age 21 or older.

Washington, D.C. There was also an initiative on the ballot in Washington, D.C. on November 3, 2020, to decriminalize the cultivation and possession of "entheogenic plants and fungi" (<u>Initiative</u> <u>81, the Entheogenic Plants and Fungus Measure (2020)</u>). The measure, which was approved, requires police to treat the non-commercial cultivation, distribution, possession, and use of entheogenic plants and fungi among the lowest law enforcement priorities. It defines "entheogenic plants and fungi" as species of plants and fungi that contain ibogaine, dimethyltryptamine, mescaline, psilocybin, or psilocyn.

Legislative Proposals. Other states have had legislative proposals to decriminalize psilocybin or MDMA. For example:

- Earlier this year, a legislator in New York introduced a bill that would remove psilocybin from the list of Schedule I controlled substances (<u>A 10299</u>).
- Last year, a legislator in lowa introduced a similar bill (<u>HF 248</u>). He also introduced another bill that would allow the medical use of psilocybin, MDMA, and another specific psychedelic substance when used under rules approved by the state pharmacy board (<u>HF 249</u>).

Municipal Initiatives

Across the country, a few municipalities have effectively decriminalized the possession of psilocybin, including Ann Arbor, Michigan; Denver, Colorado; Oakland, California; and Santa Cruz, California. Denver was the first to do so, by a ballot initiative in mid-2019.

The Denver <u>initiative</u>:

- 1. prohibits the city from spending resources to impose criminal penalties for the personal possession and use of psilocybin mushrooms by persons age 21 and older,
- 2. makes such possession and use the city's lowest law-enforcement priority, and
- 3. establishes a policy review panel to assess and report on the initiative's effects.

According to <u>news reports</u>, the policy review panel met for the first time in February 2020.

Medical Research and Treatment

Emory University

Emory University's Department of Psychiatry and Behavioral Sciences is studying the effect of MDMA on the startle response, which is a symptom of Post-Traumatic Stress Disorder. Researchers will analyze participants response to startle tests, which include measuring eye-blink response to loud sounds and brief blasts of air directed at their throat, after receiving MDMA or a placebo.

Johns Hopkins University

A research group at Johns Hopkins University was the first in the country to obtain regulatory approval to conduct research with psychedelics in healthy volunteers.

Researchers have been studying the impacts of psilocybin on longtime smokers who were previously unsuccessful with quitting since 2014, when a study found that 12 out of 15 chronic smokers were able to successfully quit for at least six months after receiving two to three doses of psilocybin in combination with cognitive behavioral therapy. The researchers cautioned that their results were not an endorsement of personal drug use for smoking cessation; rather, they were specific to controlled administration in a treatment program involving cognitive behavioral therapy.

Johns Hopkins researchers are currently conducting the following studies on:

- 1. <u>psilocybin and smoking cessation</u> to measure the treatment's effect on the patient's mood and smoking, along with the use of questionnaires, interviews, MRI scans, and biological measures of smoking;
- 2. psilocybin and major depression disorder (temporarily suspended due to COVID-19);
- 3. <u>psilocybin and Alzheimer's Disease</u> to examine the impact of psilocybin on depression in people with Mild Cognitive Impairment or early Alzheimer's Disease; and
- 4. <u>psilocybin and anorexia nervosa</u> to examine the psychological effects of psilocybin on patients with anorexia nervosa.

In 2019 the university launched a new center focused on research involving psychedelic drugs. The Johns Hopkins Center for Psychedelic and Consciousness Research is a privately funded research group focusing on how psychedelics affect behavior, mood, and biological markers of health, among other things. Previous studies included evaluating the therapeutic effects of psychedelics on addiction and distress caused by life-threatening diseases, and future studies include determining the effectiveness of psilocybin as a new therapy for post-treatment Lyme disease.

In a 2020 <u>study</u>, researchers discovered that psilocybin may be even more effective in treating patients suffering from major depression than had been previously found. Researchers conducted a study of 24 people who experienced symptoms of depression for approximately two years prior to enrolling. It was reported that 54% of participants no longer qualified as being depressed four weeks post-treatment. Researchers will continue to follow participants for a year after the study.

New York University (NYU)

<u>NYU's Department of Psychiatry at Langone Health</u> offers both clinical services and research programs that focus on schizophrenia, trauma, and addiction, among others.

In 2016, NYU researchers conducted a double-blind, placebo-controlled <u>study</u> involving cancer patients experiencing anxiety and depression as a result of their cancer diagnoses (Johns Hopkins University also conducted a similar study and released results concurrently with NYU). It was reported that a majority of the 29 patients suffering from cancer-related anxiety or depression found considerable relief for up to six months from a single large dose of psilocybin. Study participants also received counseling.

The department currently has at least two open clinical research studies involving psychedelics. Researchers are <u>comparing</u> the effectiveness of psilocybin to Diphenhydramine (Benadryl) in the treatment of alcohol dependence and <u>studying</u> the effects of a single dose of psilocybin compared to an active placebo in trial participants with Major Depressive Disorder (MDD) who are otherwise medically healthy.

UConn

In 2018, UConn Health began a <u>phase 3 FDA trial</u> testing the treatment of post-traumatic stress disorder (PTSD) through MDMA-assisted psychotherapy. The trial was intended to focus on people from communities of color who have PTSD and who have experienced racial violence, harassment, or discrimination. UConn Health was one of 12 test sites in the country participating in this trial.

The study <u>concluded</u> after the pilot stage and researchers were unable to further collect data due to certain obstacles, including the loss of a Drug Enforcement Administration-licensed psychiatrist required to administer MDMA due to its classification as a Schedule I substance.

Yale University

In 2016 Yale established the <u>Yale Psychedelic Science Group</u> within the Yale Department of Psychiatry to examine the connection between the therapeutic aspects of psychedelic substances and psychiatry.

In November 2019 the Department of Psychiatry began a <u>study</u> to evaluate the potential efficacy of a single 25 mg oral dose of psilocybin for MDD compared to the active placebo in otherwise medically healthy individuals.

Additionally, the university recently launched a <u>study</u> to investigate the effects of oral psilocybin in posttraumatic headache. Randomized study subjects will receive a placebo, low dose psilocybin, or high dose psilocybin and keep a headache diary throughout the treatment process to document frequency and intensity of their headaches. Another <u>study</u> in progress is investigating the behavioral effects of MDMA on patients with PTSD. Randomized study subjects will receive a placebo or a single 1.5 mg dose or MDMA. Researchers will measure the effects of MDMA on certain outcomes, including changes in PTSD symptoms, depression symptoms, personality traits, and mental states.

Multidisciplinary Association for Psychedelic Studies

The <u>Multidisciplinary Association for Psychedelic Studies</u> (MAPS) is a nonprofit research and educational organization focused on raising awareness about the medical, legal, and cultural ways in which people potentially could benefit from using psychedelics and marijuana. MAPS assists scientists with designing and funding studies, and obtaining approval from government regulatory agencies, including the FDA and the DEA, to conduct research using Schedule I substances. MAPS's current priority is funding clinical trials of MDMA-assisted psychotherapy for the treatment of PTSD and studying whether it can heal psychological and emotional damage caused by traumas including sexual assault, war, and violent crime. (MAPS organized UConn's trial on MDMA-assisted psychotherapy for PTSD treatment.) MAPS is also studying MDMA-assisted psychotherapy for autistic adults with social anxiety and for people with anxiety related to life-threatening illnesses.

MAPS has sponsored clinical trials of (1) LSD-assisted psychotherapy for people with anxiety and (2) medical marijuana for PTSD in war veterans. MAPS has also sponsored observational studies for ibogaine therapy and ayahuasca-assisted treatment for drug addiction. More information on MAPS research is available <u>here</u>.

Hyperlinks

Johns Hopkins University: "<u>Alzheimer's Study</u>." Center for Psychedelic & Consciousness Research, 2020.

Johns Hopkins University: "<u>Anorexia Study</u>." *Center for Psychedelic & Consciousness Research*, 2020.

Johns Hopkins University: "<u>Depression Study</u>." Center for Psychedelic & Consciousness Research, 2020.

Johns Hopkins University: "<u>Magic Mushrooms' Help Longtime Smokers Quit</u>." September 2014.

Johns Hopkins University: "<u>Psychedelic Treatment with Psilocybin Relieves Major Depression, Study</u> <u>Shows</u>." Johns Hopkins Medicine Newsroom, November 4, 2020.

New York University: "<u>Single Dose of Hallucinogenic Drug Psilocybin Relieves Anxiety & Depression</u> in Patients with Advanced Cancer." *NYU Langone News*, December 4, 2016.

Psychedelic Times: "<u>Pioneering UConn MDMA Research Focused on People of Color Ends Early:</u> <u>What Are the Next Steps for Equity in Treatment</u>?" December 20, 2018.

University of Connecticut: "<u>MDMA Opens Door for PTSD Patients to Work Through Trauma</u>." *UConn Today*, May 15, 2018.

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