
Professional Certificate in Psychedelic-assisted Psychotherapy

Legal and Policy Issues in Psychedelic Therapy

Psychedelic therapy is a rapidly growing field that involves the use of psychedelic substances, such as psilocybin, ayahuasca, and LSD, in a therapeutic context. This type of therapy has shown promise in treating a variety of mental health conditions, including depression, anxiety, and PTSD. However, the use of psychedelics in therapy also raises a number of legal and policy issues. In this explanation, we will explore some of the key terms and vocabulary related to legal and policy issues in psychedelic therapy.

Psychedelics: Psychedelics are a class of psychoactive substances that produce altered states of consciousness, often characterized by changes in perception, mood, and cognition. Some common psychedelics include psilocybin (found in certain species of mushrooms), LSD, DMT (found in ayahuasca), and mescaline (found in peyote).

Therapy: Therapy refers to the treatment of mental or psychological disorders through the use of psychological techniques and methods. In the context of psychedelic therapy, this typically involves the use of psychedelic substances in conjunction with talk therapy or other therapeutic interventions.

Decriminalization: Decriminalization refers to the reduction or elimination of criminal penalties for the possession or use of a substance. In the context of psychedelics, decriminalization means that the possession and use of these substances would not be a criminal offense, but it would still be regulated and potentially subject to civil penalties.

Legalization: Legalization refers to the full legalization of a substance, allowing for its production, distribution, and use in a regulated manner. In the context of psychedelics, legalization would mean that these substances could be legally produced, distributed, and used for both medical and non-medical purposes.

Medicalization: Medicalization refers to the process of defining a behavior or condition as a medical issue, and treating it with medical interventions. In the context of psychedelics, medicalization would mean that these substances would only be available for use in a medical context, and would be subject to the same regulations as other prescription medications.

Double blind studies: Double blind studies are a type of research design in which neither the participants nor the researchers know who is in the control group and who is in the experimental group. This is done to reduce bias and ensure that the results are due to the independent variable (in this case, the psychedelic substance) and not other factors.

Controlled substances: Controlled substances are drugs that are regulated by the government due to their potential for abuse and dependence. In the United States, the Controlled Substances Act (CSA) categorizes

drugs into five schedules based on their potential for abuse and accepted medical use. Psychedelics are currently classified as Schedule I controlled substances, meaning they have a high potential for abuse and no accepted medical use.

FDA approval: The Food and Drug Administration (FDA) is the agency responsible for regulating food, drugs, and medical devices in the United States. FDA approval is required for a drug to be legally marketed and sold in the United States. Currently, no psychedelic substance has received FDA approval for use as a medicine.

Right to try: Right to try laws allow terminally ill patients to access experimental treatments that have not yet received FDA approval. These laws vary by state, but generally allow patients to use investigational drugs, biologics, and devices if they have exhausted all other treatment options and are unable to participate in a clinical trial.

Expanded access: Expanded access, also known as compassionate use, is a process by which the FDA allows patients with serious or life-threatening conditions to access investigational drugs, biologics, and devices outside of a clinical trial. This process is typically used when a patient is unable to participate in a clinical trial and has exhausted all other treatment options.

Good manufacturing practices (GMP): Good manufacturing practices (GMP) are regulations that govern the production, testing, and distribution of pharmaceutical products. GMP regulations ensure that products are consistently produced and controlled according to quality standards.

Informed consent: Informed consent is the process of providing patients with information about the potential risks and benefits of a treatment, and obtaining their consent to proceed. In the context of psychedelic therapy, informed consent would include information about the potential risks and benefits of the psychedelic substance, as well as any potential side effects or complications.

Drug development: Drug development is the process of bringing a new drug or treatment from the initial discovery phase through clinical trials and FDA approval. This process can take several years and cost millions of dollars.

Clinical trials: Clinical trials are research studies that test the safety and efficacy of new drugs or treatments. Clinical trials are typically conducted in three phases: Phase I tests the safety of the drug in a small group of healthy volunteers; Phase II tests the efficacy of the drug in a larger group of patients with the condition being treated; and Phase III tests the safety and efficacy of the drug in a large group of patients in a real-world setting.

Placebo: A placebo is a substance or treatment that has no therapeutic effect. Placebos are often used in clinical trials to compare the effects of a new drug or treatment to the effects of no treatment.

Randomization: Randomization is the process of assigning participants in a clinical trial to either the

experimental group (which receives the new drug or treatment) or the control group (which receives a placebo or standard of care) at random. This helps to ensure that any differences between the two groups are due to the independent variable (the new drug or treatment) and not other factors.

Blinding: Blinding is the process of keeping participants, researchers, and/or evaluators unaware of which group a participant has been assigned to in a clinical trial. This helps to reduce bias and ensure that the results are due to the independent variable and not other factors.

Schedule I controlled substances: Schedule I controlled substances are drugs that have a high potential for abuse and no accepted medical use. Psychedelics, such as LSD, psilocybin, and DMT, are currently classified as Schedule I controlled substances in the United States.

Research exemption: A research exemption allows researchers to possess and use Schedule I controlled substances for research purposes. In the United States, researchers must apply for a research exemption from the Drug Enforcement Administration (DEA) in order to conduct research with Schedule I controlled substances.

Compassionate use: Compassionate use, also known as expanded access, is a process by which the FDA allows patients with serious or life-threatening conditions to access investigational drugs, biologics, and devices outside of a clinical trial.

Right to try: Right to try laws allow terminally ill patients to access experimental treatments that have not yet received FDA approval.

Good clinical practice (GCP): Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. GCP regulations ensure that clinical trials are conducted in a way that protects the rights and safety of participants.

Investigational new drug (IND): An investigational new drug (IND) is a drug that has not yet been approved for use by the FDA, but is being tested in clinical trials. In order to conduct clinical trials with an IND, researchers must submit an IND application to the FDA.

New Drug Application (NDA): A New Drug Application (NDA) is a formal application to the FDA to request approval to market a new drug. The NDA must include data from clinical trials, as well as information about the drug's chemistry, manufacturing, and controls.

Fast track designation: Fast track designation is a process by which the FDA expedites the review of drugs that treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs.

Breakthrough therapy designation: Breakthrough therapy designation is a process by which the FDA expedites the review of drugs that demonstrate substantial improvement over existing therapies for serious or life-threatening conditions.

Accelerated approval: Accelerated approval is a process by which the FDA approves a drug for marketing based on surrogate endpoints, or markers that are believed to predict clinical benefit. This process is used when there is a serious or life-threatening condition and no available