

## Do dying people have a 'right to try' magic mushrooms? 9th Circuit weighs case

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Do dying patients have a "right to try" illegal drugs such as psilocybin and MDMA if they might alleviate end-of-life suffering from anxiety and depression?



That question is now before one of the nation's highest courts, with a Seattle-based palliative care physician appealing a U.S. Drug Enforcement Administration decision barring him from prescribing psilocybin to his late-stage cancer patients.

Dr. Sunil Aggarwal says he has a right to prescribe psilocybin—the hallucinogenic compound in "magic mushrooms"—under state and federal "right to try" laws, which give terminal patients access to experimental drug therapies before they are approved by the U.S. Food and Drug Administration. More than 40 states, including Washington and California, have such laws in place, and Congress passed a federal version in 2018.

"I have patients who want to try psilocybin-assisted therapy for existential distress," Aggarwal said in an interview with The Times. "And there are lots of studies that support that."

The DEA has denied Aggarwal's request, arguing that therapeutic use of psilocybin remains banned—even for terminal patients—under the Controlled Substances Act of 1970, which lists the drug as a "Schedule I" narcotic with no recognized medical use. The agency said Aggarwal could only work with the drug if he received a license to do so as a researcher, not as a regular part of his palliative care practice.

The case is one of two Aggarwal now has pending before the 9th Circuit, each pitting the DEA's law enforcement authority against state powers to regulate medicine. In the second case, Aggarwal is asking the DEA to simply reschedule psilocybin, making it available for therapy—not just research.

Physicians and medical experts across the country are closely watching the "right to try" case, and eight states and the District of Columbia have weighed in directly in support of Aggarwal.



In February, the state coalition filed a brief that accused the DEA of reaching far beyond its law enforcement role of preventing the illegal diversion of powerful narcotics. They said the DEA's assertion that the Controlled Substances Act trumps state right-to-try laws represented a "threat to state sovereignty."

"If accepted, DEA's interpretation would ratify federal involvement in some of the most wrenching decisions a person can make, based on the most 'attenuated' relationship to any conceivable federal interest," Washington Deputy Solicitor General Peter Gonick wrote on behalf of the coalition.

Gonick said there is no reason to believe that allowing psilocybin to be given to terminal patients under doctor supervision "will substantially affect any interstate market in such substances or otherwise contribute to illicit use, even in the aggregate."

The same issue will soon arise with other drugs, Gonick said, most notably with MDMA—commonly known as ecstasy or molly—which is being studied as a treatment for anxiety in terminal patients.

Joining Washington and D.C. are Delaware, Illinois, Michigan, Minnesota, Nevada, Oregon and Pennsylvania. State officials and the DEA both declined to comment on the case.

California is not part of the coalition, and California Attorney General Rob Bonta's office did not respond to a request for comment on where California stands on the litigation.

Gov. Gavin Newsom vetoed a bill last year that would have decriminalized psilocybin and other natural psychedelics, and a more recent effort to put decriminalization on state ballots failed. However, advocates continue to push for state approval of therapeutic treatments



using the drug.

Aggarwal's case lands at a pivotal moment for medical research into psychedelics and other mind-altering substances. Clinical trials have increasingly suggested efficacy in treating depression, anxiety and trauma-related disorders. With psilocybin, "micro-dosing" has come into vogue as a way to mildly alter or improve one's mental state without inducing hallucinations or intense effects.

Use of the drugs has been on the rise, raising some concerns about unintended consequences.

Aggarwal, a University of Washington faculty member, leader in hospice and palliative medicine nationally and co-director of the Advanced Integrative Medical Science Institute, said he just wants to give his <u>dying</u> <u>patients</u> the best possible care in the safest possible way—which isn't happening right now.

Aggarwal said he has seen it again and again: A terminal patient desperately wants to enjoy their last days with loved ones, but is overwhelmed by "debilitating" anxiety and depression associated with their diagnosis.

"When you are being told that you have an <u>incurable disease</u>, that all we can do is extend your lifespan for a certain amount of time but there is no cure, the psycho-spiritual toll that places on somebody's mind is very high," he said.

Some of his patients have told him that they are already taking psilocybin that they've sourced illegally, which is concerning. Dosage and purity of street drugs are impossible to know, Aggarwal said, and his patients are taking them in uncontrolled settings without proper medical guidance—which studies have shown presents more risk of a bad



reaction than when given in a clinical setting.

Right now, all Aggarwal can do in such situations is offer his patients "harm reduction strategies," he said, "but I don't think that's good enough."

In his brief to the 9th Circuit, Aggarwal notes that psilocybin "has shown enormous promise in early <u>clinical trials</u> in relieving debilitating anxiety and depression suffered by terminally ill patients," has been given "breakthrough" status as a promising medical therapy by the FDA, and is in the final phase of clinical trials before approval.

It has shown promise not only in addressing direct symptoms of anxiety and depression related to terminal illness, he said, but can also help patients make clearer and sometimes better decisions about the rest of their treatment plan.

"Getting that kind of relief could change how you actually face cancer itself and what kinds of treatments you accept or don't accept," he said.

However, when he began looking into obtaining the drug under the "right to try" framework a few years ago, it became clear no manufacturer would supply him without DEA approval.

Since setting up a true research project for accessing the drug for his patients would be too costly and time-consuming, especially for his patients, he said, he asked that the DEA either make clear that no special registration or waiver was necessary for him to prescribe <u>psilocybin</u> under "right to try" law, or that it provide him a waiver.

It refused to do either.

"Unfortunately we feel like we are dealing with a situation where the



government is restricting things for their own bureaucratic reasons," Aggarwal said, "and not for sick and dying patients."

Kathryn Tucker, director of advocacy at the National Psychedelics Association and one of Aggarwal's attorneys, said she hopes the 9th Circuit will issue a strong opinion telling the DEA that it is "way out of its lane."

"The DEA has interposed itself to nullify the operation of duly enacted state and federal law, and the result is that dying patients suffering from anxiety and depression in the face of death continue to suffer when they could be getting relief," Tucker said. "It's heartbreaking."

Courts, including the U.S. Supreme Court, have shown deference to doctors over law enforcement in other recent cases to do with prescribing medicine, including powerful opioids. The DEA is preparing to reclassify marijuana as a less dangerous drug with recognized medical uses.

David Olson, director of the UC Davis Institute of Psychedelics and Neurotherapeutics, said Aggarwal's case raises "super interesting" questions in a burgeoning field of medicine that holds tremendous promise.

Evidence suggests psychedelic drugs not only provide patients with potential spiritual and existential peace and acceptance in the face of challenging terminal diagnoses, but can help to physically repair neural circuits in the brain tied to depression—which raises astounding prospects.

"How we think, how we feel, how we behave really comes down to the totality of the circuits in your brain," Olson said.



Olson believes it is just a matter of time before such drugs are approved as therapeutic medicines by the FDA. However, the process of getting to that point is unpredictable, with no clear timeline, he said—which is why Aggarwal's case for his dying patients is so compelling.

"As a society we spend a lot of time trying to help people live well, but we also should be helping people to die well," Olson said. "It's sad if someone has to go through that kind of anxiety and terror without any kind of release."

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