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Psilocybin Right-To-Try Petition To Get 9th Circ. Hearing

By **Sam Reisman**

Law360 (August 16, 2024, 12:04 PM EDT) -- A Ninth Circuit panel will hear oral arguments Monday in an appeal brought by a Seattle doctor seeking to administer psilocybin to terminal cancer patients under state and federal right-to-try laws.

The hearing marks the culmination of a **multiyear battle** by a Seattle-based physician to assert terminally ill patients' right to use psilocybin, which has shown efficacy in treating major depression in clinical trials, but remains a Schedule I drug under federal law. Schedule I is the category for drugs with no accepted medical use and a high potential for abuse.

Petitioner Dr. Sunil Aggarwal and the clinic he co-founded, Advanced Integrative Medical Science Institute, or AIMS, allege that the Drug Enforcement Administration's summary refusal to approve proposals to treat patients with psilocybin was arbitrary and capricious.

In court documents, Aggarwal and AIMS have asserted that federal drug enforcers rebuffed all entreaties to lawfully access and dispense psilocybin in accordance with both the Controlled Substances Act, or CSA, and state and federal right-to-try, or RTT, laws without providing a compelling reason.

"If DEA wants to disclaim authority to grant Dr. Aggarwal access to psilocybin under the CSA and RTT, it must provide a reasoned explanation for how that decision comports with the CSA and the agency's own precedent," petitioners said in their brief.

Right-to-try laws have been enacted in a majority of states and at the federal level to allow terminally ill patients to access investigational drugs not yet approved by the U.S. Food and Drug Administration.

In response, the federal government has argued that Aggarwal and his clinic misunderstand the interactions between the federal Right to Try Act, the CSA and the federal Food, Drug, and Cosmetic Act, saying that while RTT amends the FDCA, it doesn't affect the CSA at all.

U.S. Department of Justice attorneys have told the court that the federal Right to Try Act only allows physicians to dispense Schedule I substances if they are part of government-approved research, and that while that law exempts such treatment from specific requirements under the FDCA, it doesn't mention or change the restrictions of the CSA.

"The CSA and the FDCA (which the Right to Try Act amends) are separate regulatory schemes with separate requirements and restrictions," the DEA argued in its brief. "Nothing in the Right to Try Act changes that. A doctor who wishes to dispense drugs that are also controlled substances must comply with both."

In a related case, a Ninth Circuit panel in **October** ordered the DEA to clarify why it believes psilocybin should remain a Schedule I substance after the agency cursorily rejected Aggarwal's petition to move psilocybin to Schedule II — the tier for drugs that have an accepted medical use with severe restrictions.

In the current appeal, AIMS and Aggarwal accused the DEA of a similar oversight, saying the agency effectively violated administrative law by rejecting multiple proposals that would permit physician-

administered use of psilocybin without addressing the arguments presented.

Specifically, Aggarwal told the circuit court that the DEA's refusals to accommodate his requests contradicted the agency's own precedents, public health and safety considerations, and established law.

"For the same reasons this court remanded DEA's inadequate denial letter in [the prior case] less than four months ago, it must remand DEA's final decision in this case, as well," the petitioners' brief states. "The [Administrative Procedure Act] obligates administrative agencies to provide reasoned explanations when they deny the petitions like the one Dr. Aggarwal presented here."

Kathryn L. Tucker of the National Psychedelics Association, one of the attorneys representing Aggarwal and AIMS, **told Law360 earlier this year** that the protracted legal wrangling caused by the DEA's denials had obstructed dying patients' access to a drug that their doctors believed would give them relief from anxiety and depression.

"Right to Try is intended to allow dying patients access to promising investigational drugs recognizing they do not have time to wait for the slow process of new drug approval to wend to completion," Tucker said.

A spokesperson for the DEA did not immediately respond to a request for comment Thursday.

Aggarwal and AIMS are represented by Shane Pennington of Porter Wright Morris & Arthur LLP, Kathryn L. Tucker of the National Psychedelics Association, Matthew C. Zorn of Yetter Coleman LLP, and James F. Williams, Andrew J. Kline, Thomas J. Tobin, Holly Martinez, Caleb Bacos and Mason Y. Ji of Perkins Coie LLP.

The DEA is represented by Brian M. Boynton, Mark B. Stern and Thomas Pulham of the U.S. Department of Justice's Civil Division.

The case is Advanced Integrative Medical Science Institute et al. v. U.S. Drug Enforcement Administration, case number 22-1568, in the U.S. Court of Appeals for the Ninth Circuit.

--Additional reporting by Mike Curley. Editing by Amy French.
