Right-to-Try: Legal Battle With DEA Continues

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The Case of Right-to-Try Psilocybin: The Battle Between Dr. Sunil Aggarwal and the DEA Continues

Anyone who has been close to a person with a life-threatening illness understands the anguish that such a diagnosis can carry. While there is pain on a physical level, there is often also mental and emotional suffering, as death, in modern American culture, essentially remains a taboo topic that can evoke terror.

For those living with advanced illnesses, these death-related fears can outweigh preoccupations about physical pain or the deterioration of the body. Doctors have an arsenal of drugs they can prescribe to manage physical symptoms. However, treatments or interventions that can effectively address existential crises are few. Psilocybin is a psychedelic substance that has long been used throughout history to ease acceptance around the transition to death; in recent years, numerous clinical studies have demonstrated that psilocybin can bring immediate, significant, and sustained relief from end-of-life anxiety.

The 2018 passage of the Right to Try Act, a federal law intended to enable people with life-threatening illnesses access to investigational drugs that have progressed beyond Phase I clinical trials, appeared to create a legal avenue for such individuals to access otherwise off-limit treatments, such as psilocybin.

However, there's a catch.

Just under two years ago, Dr. Sunil Aggarwal, a palliative care physician and co-founder of the Advanced Integrative Medical Science Institute (AIMS) in Seattle, attempted to access psilocybin under this law for two cancer patients suffering from debilitating anxiety and depression. In order to gain access to the psychedelic, he had to obtain permission from the Drug Enforcement Agency (DEA), because psilocybin is categorized as a Schedule I drug.

Schedule I drugs are classed as drugs with no currently accepted medical use and a high potential for abuse — despite the fact that numerous clinical trials have indicated diverse therapeutic applications for psilocybin. The substance has additionally been found to be safe and have a low risk of addiction (with some researchers even proposing that the psychedelic could be used to treat substance use disorders).

Receiving DEA permission should have been straightforward for Aggarwal and his patients.

There are now Phase III clinical trials of psilocybin underway, the utility of the psychedelic in addressing end-of-life anxiety is becoming well-established in the literature, and there is nothing in federal law that excludes scheduled drugs from the Right-to-Try Act. However, the Agency denied Aggarwal's request.

In response, Aggarwal with his legal team led by Kathryn Tucker, Director of Advocacy for the National Psychedelics Association, filed suit in federal court. The initial case, AIMS I, was dismissed on the grounds that the DEA's denial had not been sufficiently final to enable a judicial review–in other words, the case was overturned on a legal technicality.

Aggarwal's legal team subsequently requested a 'final agency action', waiving or exempting them from DEA's registration requirements so they could enable access to psilocybin under Right to Try. They also filed a petition to reschedule psilocybin from Schedule I to Schedule II.

"In August, 2022, the DEA issued a final determination denying waiver or exemption of registration requirements for RTT access," said Tucker. Soon after, on September 23, 2022, the DEA issued a letter denying the psilocybin rescheduling petition on the grounds that the FDA had not approved psilocybin, asserting that this "requires" that it remain on Schedule I.

The legal team is now pursuing appeal of both the final denial for access under RTT(AIMS II) and the rescheduling denial (AIMS III).

"A favorable outcome in the rescheduling litigation, leading to rescheduling of psilocybin off of Schedule I, would remove the barrier to Right-to-Try access," explained Tucker.

"We believe this case is a strong vehicle, indeed THE vehicle, to overturn the DEA's application of an erroneous test to rescheduling petitions, which has foiled multiple efforts to reschedule cannabis."

Aggarwal's legal team are mounting the case that psilocybin does not meet criteria to be classed as a Schedule I drug as it has currently accepted medical use with severe restrictions, has been granted breakthrough status by the FDA and is considered an "eligible investigational drug" according to Right to Try law.

"Ample research, clinical experience, and surveillance shows that psilocybin has a low potential for abuse when compared with other drugs in Schedules I and II."

"The original placement of psilocybin is widely understood to be the result of a substantial overestimation of the risk of harm and abuse potential, not rigorous science. Accordingly, psilocybin belongs on Schedule II or lower."

Aggarwal also believes the rescheduling of psilocybin would be a gamechanger for physicians and researchers.

“Rescheduling from Schedule I to Schedule II would allow doctors to prescribe psilocybin as part of empirical treatment trials such as Right to Try and would ease restrictions on research,” says Aggarwal. “This will help to relieve suffering and distress and advance knowledge and understanding.”

AIMS II will be stayed to allow the rescheduling appeal to be resolved first, as its resolution may provide access pursuant to RTT. Legal briefing for the case will take place in early January 2023, with amicus briefing due one week later. Amicus means support from individuals or groups who are not party to the petition, but have a strong interest in the matter being contested. Tucker expects the amicus participation to be robust. The DEA will then file their responsive brief in February. Following this, a hearing before a three-judge panel of the Ninth Circuit Court of Appeal will be set and a decision will then follow.

“A success on the rescheduling petition would eliminate the barrier to Right to Try access,” said Tucker. “Doctors can prescribe or administer Schedule II drugs–something they cannot do with Schedule I substances. And, of course, another huge benefit of rescheduling would be easier access for researchers.”

Tucker also points out that recent events regarding drug scheduling matters at a national level may also influence the outcome of the petition.

For example, President Biden’s directive issued in October 2022 orders that the Attorney General and the Secretary of Health and Human Services, “initiate the administrative process to review expeditiously how marijuana is scheduled under federal law”, with potentially significant ramifications for the upcoming case. Similarly, last week, Sen. Cory Booker and Rand Paul filed a bill that would require the Drug Enforcement Administration (DEA) to reschedule breakthrough therapies such as psilocybin and MDMA from Schedule I to II and remove research barriers for strictly controlled substances.

In the meantime, however, Aggarwal’s case has been gathering momentum on numerous fronts. In May, a protest outside DEA headquarters saw several protestors arrested, including one of Dr. Aggarwal’s patients. In July 2022, congressional lawmakers filed companion bills to clarify that “Right to Try” laws allow patients with life-threatening conditions access to Schedule I drugs, including psychedelics such as psilocybin and MDMA.

More recently in September, the DEA declined a FOIA request on behalf of Aggarwal and his lawyers for access to internal records from 2022 discussing the reclassification of psilocybin. The DEA told Aggarwal that their request had been classified as one of commercial interest, and that the agency would not review records unless they paid $11,740 in fees. Tucker and her co-counsel refuted this claim as federal Right to Try laws would prevent Aggarwal from profiting from obtaining the drug under Right to Try (though he could still request standard medical services fees for providing services or care). It’s possible that the coming months will see even more developments unfold in the lead-up to the hearing at the Ninth Circuit Court of Appeal.

However, Aggarwal believes that the fact the struggle is ongoing symbolizes a wider systemic failure.

“I am dismayed at the level of ignorance, delay, and nonchalance with which our pleas for psilocybin access for the Right to Try palliative care purposes for my patients with advanced cancer were met by the Biden Department of Justice and the DEA”, says Aggarwal.

“This is despite our having the backing of so many state Attorney Generals, law professors, bioethicists, leading medical experts, the ACLU, the Cato Institute, and others. It has further deepened my resolve that the entire prohibitionist drug control system in this country deeply undermines public health and human rights, including the right to palliative care and the right to try promising treatments when you have a life-threatening illness.”

Nonetheless both Tucker and Aggarwal remain steadfast in their resolve to see patients able to access psilocybin treatment in the near future.

“All of these efforts drive toward the goal of opening access as soon as possible for those with life-threatening conditions,” says Tucker