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Big Brother Cancels Trip, Court Says Not So Fast My Friend

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A few weeks ago, the Ninth Circuit Court of Appeals in *Aggarwal v. U.S. DEA* directed the U.S. Drug Enforcement Agency (DEA) to reconsider its decision not to transfer psilocybin from Schedule I to Schedule II.

Since at least 2021, Dr. Sunil Aggarwal has been working to legally obtain psilocybin for terminally ill cancer patients undergoing end-of-life care. Because psilocybin is a Schedule I drug under the Controlled Substance Act (CSA), obtaining the drug to treat his patients was "practically and legally difficult" according to his lawyers. Aggarwal turned to the DEA, petitioning the agency to transfer psilocybin from Schedule I to Schedule II. The DEA denied the petition in a four-sentence letter. Aggarwal then looked to the Ninth Circuit.

The Ninth Circuit sided with Aggarwal, at least for now and at least in part. The court held that the "DEA failed to provide sufficient analysis to allow its path to be reasonably discerned" and "failed to clearly indicate that it ha[d] considered the potential problem identified in the petition." More specifically, the Ninth Circuit noted that the DEA failed to define "currently accepted medical use with severe restrictions," which was the applicable standard for rescheduling on which Aggarwal relied. The court directed the DEA to clarify or reevaluate its position.

So, what does this mean?

Rescheduling Psilocybin

The Ninth Circuit's opinion does not change the legal status of psilocybin. Hope springs eternal, and the psychedelic industry may take this as a nod from the Ninth Circuit that psilocybin is on the fast track to being rescheduled. But the limitations of the court's decision can't be dismissed. The Ninth Circuit's order did not tell the DEA what decision to reach. And the chance for the DEA to reconsider (and rewrite) its determination could certainly result in a more robust denial from the DEA – one that would be more defensible by critics of rescheduling.

It, however, certainly keeps the petition to reschedule alive. So, yes, we're telling you there's a chance.

Given that our modest blog began as an update exclusively on the cannabis plant, we would be remiss not to direct you to our posts on recent efforts by the Biden administration to consider the rescheduling or de-scheduling of cannabis. If the psychedelic industry can learn anything from the cannabis industry, it's that the implications of rescheduling could be huge but that the trip can be long.

The DEA's Five-Part Test – Will It Hold Up?

Since the 90s, the DEA has utilized a five-part test for determining whether a drug has a "currently accepted medical use" and should be rescheduled pursuant to 21 U.S.C. § 812(b)(2)(B). Under the test, a drug is considered to have a "currently acceptable medical use" if it meets five elements:

1. The drug's chemistry is known and reproducible;
2. There are adequate safety studies;
3. There are adequate and well-controlled studies proving efficacy;
4. The drug is accepted by qualified experts; and
5. The scientific evidence is widely available.

(Though it would be fair of you to do so, *Budding Trends* readers shouldn't confuse the DEA's five-part test with the eight-part test utilized by the U.S. Department of Health and Human Services (HHS)).

One could infer from the DEA's denial letter that its position is that a drug must meet the five-part test to be rescheduled, but as noted by the Ninth Circuit, the DEA didn't explicitly say so. And the DEA's position on that remains to be seen.

The Ninth Circuit in *Aggarwal* made clear that it was not deciding whether the DEA's five-part test is a lawful interpretation of 21 U.S.C. 812(b)(2)(B). We expect that proponents of change will challenge the test in the coming months and years, and the Ninth Circuit's decision seems to invite new challengers to do so.

Whose Line Is It Anyway? DEA Points to the FDA; Court Points Back to the DEA

Maybe the DEA is sick of always being the one to break up the party. The one thing that was abundantly clear in the DEA's denial of Aggarwal's petition was that the DEA was pointing the finger at the FDA. Specifically, the DEA's position was that a prerequisite to transferring a substance from Schedule I to Schedule II "is for the [FDA] to determine that a substance has a currently accepted medical use in treatment in the United States." The Ninth Circuit wasn't convinced and certainly didn't bite at the chance to let the DEA shift the blame or the burden. The Ninth Circuit made it clear that the DEA cannot defer to the FDA and its lack of movement. The court's decision said the DEA's reasoning was contrary to 21 U.S.C. § 812(b)(2)(B), "which sets as a prerequisite to transfer to schedule II *either* a currently accepted medical use in treatment in the United States *or* a currently accepted medical use with severe restrictions."

In other words, absent movement by the FDA to determine that psilocybin has a "currently accepted medical use in treatment in the United States," the DEA is going to have to make its own decision. It's going to have to consider and assess whether psilocybin has a "currently accepted use *with severe restrictions*." This is a distinct question from what the FDA may answer – whether psilocybin

has “a currently accepted medical use *in treatment in the United States*.”

What’s Next?

Research regarding the medicinal use of psilocybin — and other psychedelics — is on the rise. And many studies seem to be seeing positive results for the industry.

On at least two occasions in recent years, the FDA has designated psilocybin therapy as a “breakthrough therapy.” According to the FDA, a designation of a drug as “breakthrough therapy” is “designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint.”

Results from a study recently published by Johns Hopkins and Ohio State “support the potential for psilocybin to produce lasting improvements in mental health symptoms and general wellbeing.” According to the study, its “results indicate broad therapeutic potential of psilocybin to produce lasting improvements in mental health symptoms related to anxiety, depression, and substance misuse.”

In another recent study led by “a research team from institutions including Yale, Johns Hopkins, NYU Langone, and San Francisco Veterans Affairs Medical Center and published in the Journal of the American Medical Association,” “outcomes reveal that psilocybin was well-tolerated and elicited fast, solid, and long lasting efficacy results” for treating adults with major depressive disorder.

Given what appear to be positive outcomes, we certainly expect there to be continued increases in funding into such studies – both from private and public sources. In the first part of this year, for example, the National Institute on Drug Abuse announced new funding opportunities for studies with a focus on the use of psychedelics to treat substance use disorders and allocated $1.5 million for such studies.

As more medical professionals come to believe there are serious medicinal benefits to the use of psychedelics like psilocybin, we think the pressure will only increase on the government to consider rescheduling.

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The Ninth Circuit’s refusal to accept the DEA’s out-of-hand dismissal of a petition to reschedule psilocybin is yet another step in what appears to be faster and faster footsteps towards the future. What that future holds is yet to be determined – though we will monitor closely – but whatever the future is it promises to be quite a ride.

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