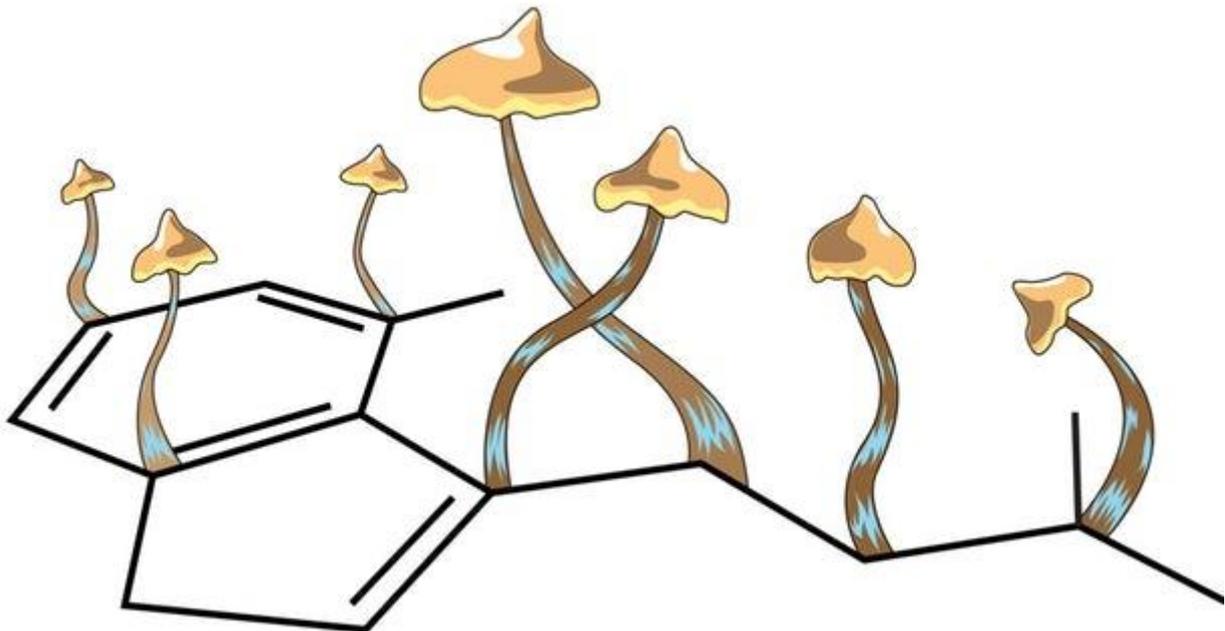


Psychedelic psilocybin therapy for depression granted Breakthrough Therapy status by FDA



[Rich Haridy](#)



Granting of Breakthrough Therapy status allows the FDA to expedite research and review of psilocybin-based treatments to move them into clinical use sooner

In an extraordinary step forward for the psychedelic drug research community, the US Food and Drug Administration (FDA) has just given psilocybin therapy for treatment-resistant depression a Breakthrough Therapy designation. This classification suggests the treatment has demonstrated significant potential in early clinical evidence, allowing the FDA to assist and expedite subsequent development and review processes.

The FDA's Breakthrough Therapy designation was created in 2012 as a way of presenting a faster pathway to approval for drugs that display treatment advantages over current options for serious or life-threatening conditions. While not all Breakthrough Therapy treatments may ultimately prove efficacious and make it to market, the designation is generally a positive thumbs-up from the FDA that it's potentially useful and should be expedited.

The specific designation in this instance is directed at a phase IIb trial currently underway across Europe and North America. The research is investigating the optimal dose range for psilocybin in regards to severe treatment-resistant depression. Prior research has found that one to two doses of the psychedelic agent, administered in controlled settings, can markedly reduce a person's depressive symptoms. The safety of these treatments has also been established through earlier research.

The multi-center clinical trial now underway is being run by life sciences company COMPASS Pathways and expands on [decades of work by researchers](#) around the world who toiled to push this previously taboo drug into the light of legitimate medical research. Robin Carhart-Harris, head of the Psychedelic Research Group at Imperial College London, has been working for several years to establish the efficacy of psilocybin treatment for depression, and notes that this new FDA designation is a positive sign for the future of psychedelic drug therapy.

"The Breakthrough Therapy designation is a strong endorsement for the potential of psilocybin therapy," says Carhart-Harris. "We look forward to learning more as further clinical studies are carried out, by our team at Imperial College as well as in COMPASS's multi-center trial."

One of the interesting looming implications of psilocybin's acceleration towards legitimate medical use is that if it passes phase III clinical trials the FDA will be forced to change its restrictive Schedule 1 control. Schedule 1 is the most restrictive category of drug control in the United States, essentially establishing the substance as highly addictive and having no medical benefit. This kind of oppressive classification limits the breadth of research into potential beneficial uses for specific drugs.

Marijuana has been the drug under the most scrutiny in recent times regarding its strict scheduling. Following the [landmark approval of Epidiolex](#), the first ever medicine approved in the United States from a marijuana-derived compound, the FDA was challenged to reschedule marijuana, or at the very least cannabidiol (CBD), the primary compound derived from the plant. Ultimately the FDA refused to drop either marijuana or CBD from its restrictive Schedule 1 classification, instead [contorting itself](#) to limit the rescheduling to Epidiolex specifically and not anything broader.

This psilocybin therapy, on the other hand, poses a more complicated scenario for the FDA, and other relevant United States authorities. Much like the pathway being forged with [MDMA for PTSD](#), the demonstrable clinical benefits of the substance make it impossible to keep it restricted to Schedule 1, especially if it successfully moves through phase III clinical trials.

Researchers working with psilocybin from Johns Hopkins recently [penned a comprehensive article](#) suggesting the drug needs to be rescheduled down to Schedule IV. The article outlined a raft of evidence highlighting the potential therapeutic benefits of the drug, as well as its proven low rates of abuse, and demonstrable lack of physical dependence potential.

"We should be clear that psilocybin is not without risks of harm, which are greater in recreational than medical settings," [says Matthew Johnson](#) from Johns Hopkins, "but

relatively speaking, looking at other drugs both legal and illegal, it comes off as being the least harmful in different surveys and across different countries."

This latest step from the FDA, to offer psilocybin a Breakthrough Therapy designation, is a quietly extraordinary move from the federal agency, implicitly suggesting this previously stigmatized drug may have beneficial clinical uses. And, if all continues along the same path, within the next five years a significant psychedelic drug, that has been restricted for decades, may become more available for clinicians and medical researchers to work with.