SAINTS PERSPECTIVES

Things Futuristic

A Psychedelic Medicine performs well against Depression

Regulators are now mulling the results of the late-stage trial

The Economist, Feb 19th 2026

Psilocybin mushrooms stand ready for harvest in a humidified "fruiting chamber" in the basement of a private home.
Photograph: Getty Images

FOR FIVE years biotech startups have been betting that psychedelic substances could be turned into real medicines. One of them may have hit the jackpot. On February 17th Compass Pathways, a British biotech, announced strong results in two late-stage trials showing that a synthetic form of psilocybin—the active compound in magic mushrooms—can rapidly relieve symptoms in patients with treatment-resistant depression (TRD). If America's Food and Drug Administration (FDA) approves the drug, which could happen early next year, it would be the first psychedelic drug to become a fully licensed medicine.

The results are a pivotal achievement for psychedelic medicines. More than 100m people worldwide struggle with depression that does not respond to conventional treatments, and psychedelics have long been touted as having the potential to improve

lives. Proponents claim that those with other mental-health conditions, ranging from anxiety to obsessive compulsive disorder, could also benefit. But amassing good data has proved difficult.

A previous trial of **MDMA**—a drug considered to have minor psychedelic properties—failed to convince regulators. In 2024 the FDA rejected its use for the treatment of post-traumatic stress disorder, owing to concerns over trial design and safety data. Trials of psychedelic drugs are challenging to run, in part because of the difficulty in finding a suitable placebo. It is often obvious who is "tripping", which boosts expectation and can bias the results.

Compass is hoping it has the answer to the FDA's concerns over this issue, which is known as functional unblinding. In the first of its trials, it did the conventional thing: testing whether a single 25mg dose of its synthetic psilocybin, **Comp360**, beat a placebo. In the second trial, participants received two doses, three weeks apart, of either 25mg, 10mg or just 1mg. The 1mg arm was an "active control": too low to have much therapeutic effect, but high enough to make it less obvious to participants which group they were in. By comparing the 1mg with the 25mg, the firm can argue it has addressed the functional-unblinding problem.

Both trials showed that **Comp360** significantly reduced depression. Some participants with TRD responded as soon as the following day, with the benefits from just one or two doses lasting at least 26 weeks. Although full data from the trial have yet to be released, George Goldsmith, the founder of Compass, said the results were an "important step" in accelerating innovation in mental-health treatment. "I see it as very good news for the development of psychedelic therapies," says David Erritzoe, a professor in psychopharmacology and psychiatry at Imperial College London.

Should the FDA reject Compass's approach, it could scupper the entire class of medicines. But there are reasons to be optimistic. **MDMA's** failure also hinged on safety concerns which seem less applicable to psilocybin. Its effects on the heart and the liver seem less worrisome, for one thing, and the potential for patients to either misuse it or become dependent on it is also lower.

Even so, the agency has been unusually turbulent under the current Trump administration. Marty Makary, the FDA's head, put Compass's psilocybin treatment on the agency's list of promising medicines due for accelerated review—something that cuts decision times from a year to as little as a month or two. But when the list was presented to administration officials late last year, they vetoed **Comp360**. It is not known why.

If the drug is eventually approved, **Comp360** will be a welcome addition to the treatment options for serious depression. All the same, it will be neither cheap nor easy to take. Each of the two sessions lasts six to eight hours and a trained professional has to be present throughout. Patients have other obligations, too. They must attend sessions both before and after their treatment to help them make sense of what is often a confusing experience. It is possible that, in time, group-based psilocybin sessions could bring costs down further, but this idea has yet to be properly tested.

For Mr Goldsmith and his co-founder and wife, Ekaterina Malievskaia, a doctor, the potential benefits are not abstract. After watching their son struggle with depression and obsessive-compulsive disorder, they turned to psilocybin for his treatment. Their positive experiences prompted them to start Compass in 2016. If the FDA agrees with their assessment, it would open a forbidden medicine cabinet that has been firmly locked for far too long. ■

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