

## *The Psychedelic Revolution Is Coming. Psychiatry May Never Be the Same.*

Psilocybin and MDMA are poised to be the hottest new therapeutics since Prozac. Universities want in, and so does Wall Street. Some worry a push to loosen access could bring unintended consequences.

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By Andrew Jacobs

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It's been a long, strange trip in the four decades since Rick Doblin, a pioneering psychedelics researcher, dropped his first hit of acid in college and decided to dedicate his life to the healing powers of mind-altering compounds. Even as antidrug campaigns led to the criminalization of Ecstasy, LSD and magic mushrooms, and drove most researchers from the field, Dr. Doblin continued his quixotic crusade with financial help from his parents.

Dr. Doblin's quest to win mainstream acceptance of psychedelics took a significant leap forward on Monday when the journal Nature Medicine published the results of his lab's study on MDMA, the club drug popularly known as Ecstasy and Molly. The study, the first Phase 3 clinical trial conducted with psychedelic-assisted therapy, found that MDMA paired with counseling brought marked relief to patients with severe post-traumatic stress disorder.

The results, coming weeks after a New England Journal of Medicine study that highlighted the benefits of treating depression with psilocybin, the psychoactive ingredient in magic mushrooms, have excited scientists, psychotherapists and entrepreneurs in the rapidly expanding field of psychedelic medicine. They say it is only a matter of time before the Food and Drug Administration grants approval for psychoactive compounds to be used therapeutically — for MDMA as soon as 2023, followed by psilocybin a year or two later.

After decades of demonization and criminalization, psychedelic drugs are on the cusp of entering mainstream psychiatry, with profound implications for a field that in recent decades has seen few pharmacological advancements for the treatment of mental disorders and addiction. The need for new therapeutics has gained greater urgency amid a national epidemic of opioid abuse and suicides.

"Some days I wake up and can't believe how far we've come," said Dr. Doblin, 67, who now oversees the Multidisciplinary Association for Psychedelic Studies, a multimillion dollar research and advocacy empire that employs 130 neuroscientists, pharmacologists and regulatory specialists working to lay the groundwork for the coming psychedelics revolution.

The nation's top universities are racing to set up psychedelic research centers, and investors are pouring millions of dollars into a pack of start-ups. States and cities across the country are beginning to loosen restrictions on the drugs, the first steps in what some hope will lead to the federal decriminalization of psychedelics for therapeutic and even recreational use.

"There's been a sea change in attitudes about what not long ago was considered fringe science," said Michael Pollan, whose best-selling book on psychedelics, "How to Change Your Mind," has helped destigmatize the drugs in the three years since it was published. "Given the mental health crisis in this country, there's great curiosity and hope about psychedelics and a recognition that we need new therapeutic tools."

The question for many is how far — and how fast — the pendulum should swing, and even researchers who champion psychedelic-assisted therapy say the drive to commercialize the drugs combined with a growing movement to liberalize existing prohibitions could prove risky, especially for those with severe psychiatric disorders, and derail the field's slow, methodical return to mainstream acceptance.



The psychedelic researcher Rick Doblin dropped his first hit of acid in college and decided to dedicate his life to the healing powers of mind-altering compounds. Now his research center, MAPS, has raised \$44 million over the past two years. Tony Luong for The New York Times



That's him on the cover: Dr. Doblin holding a September 1985 issue of The Miami Herald magazine. Gretchen Ertl for The New York Times

Dr. Doblin's organization, MAPS, is largely focused on winning approval for drug-assisted therapies and promoting them around the globe, but it is also pushing for

the legalization of psychedelics at the federal level, though with strict licensing requirements for adult recreational use.

Numerous studies have shown that classic psychedelics like LSD and psilocybin are not addictive and cause no organ damage in even high doses. And contrary to popular lore, Ecstasy does not leave holes in users' brains, studies say, nor will a bad acid trip lead to chromosome damage.

But most scientists agree that more research is needed on other possible side effects — like how the drugs might affect those with cardiac problems. And while the steady accumulation of encouraging data has softened the skepticism of prominent scientists, some researchers warn against the headlong embrace of psychedelics without stringent oversight. Although “bad trips” are rare, a handful of anecdotal reports suggest that psychedelics can induce psychosis in those with underlying mental disorders.

Dr. Michael P. Bogenschutz, a professor of psychiatry who runs the four-month-old Center for Psychedelic Medicine at NYU Langone Health, said most of the clinical studies to date had been conducted with relatively small numbers of people who were carefully vetted to screen out those with schizophrenia and other serious mental problems.

That makes it hard to know whether there will be potential adverse reactions if the drugs are taken by millions of people without any guidance or supervision. “I know it sounds silly but, Kids, don't take these at home,” Dr. Bogenschutz said. “I would just encourage everyone to not get ahead of the data.”

### **The Rush to Invest**

Psychedelics are suddenly awash in money.

Dr. Doblin can remember when research funding was nearly impossible to come by. But MAPS is flush now, having raised \$44 million over the past two years.

“I spend a lot of my time saying no to investors,” said Dr. Doblin, whose work has been funded by an unlikely collection of philanthropists, among them Rebekah Mercer, the Republican political donor, and David Bronner, a liberal heir to the liquid soap company Dr. Bronners.

Johns Hopkins, Yale, the University of California, Berkeley, and Mount Sinai Hospital in New York are among the institutions that have recently established psychedelic research divisions or are planning to do so, with financing from private donors.

And scientists are conducting studies on whether psychedelics can be effective in treating everything from depression, autism and opioid addiction to anorexia and the anxieties experienced by the terminally ill.



A Field Trip Health clinic in Manhattan. Calla Kessler for The New York Times





Clients are encouraged to be creative at the Field Trip clinic in Manhattan. Calla Kessler for The New York Times

More than a dozen start-ups have jumped into the fray, and the handful of companies that have gone public are collectively valued at more than \$2 billion. Field Trip Health, a two-year-old Canadian company that trades on the New York Stock Exchange, has raised \$150 million to finance dozens of high-end ketamine clinics in Los Angeles, Chicago, Houston and other cities across North America. Compass Pathways, a Nasdaq-listed health care company that has raised \$240 million, is conducting 22 clinical trials across 10 countries of psilocybin therapy for treatment-resistant depression.

Investors have been encouraged by the changing politics, a shift inspired in part by the nation's accelerating embrace of recreational marijuana and by public weariness over America's endless war on drugs. Last year, Oregon became the first state to legalize the therapeutic use of psilocybin. Denver, Oakland, Calif., and Washington, D.C., have decriminalized the drug, and several states, including California, are mulling similar legislation. Though the drugs remain illegal under federal law, the Justice Department has so far taken a hands-off approach to enforcement, similar to how it has handled recreational marijuana.

Even some Republicans, a group that has traditionally opposed the liberalization of drug laws, are starting to come around. Last month, the former Texas governor Rick Perry, citing the high rates of suicide among war veterans, called on his state's legislators to support a Democratic-sponsored bill that would establish a psilocybin study for patients with PTSD.

"We've had 50 years of government propaganda around these substances, and thanks to the research and a grass-roots movement, that narrative is changing," said Kevin Matthews, a psilocybin advocate who led Denver's successful ballot measure.

#### Decades in the Wilderness

Long before Nancy Reagan warned the nation to just say no to drugs and President Richard Nixon supposedly pronounced Timothy Leary "the most dangerous man in America," researchers like William A. Richards were using psychedelics to help alcoholics go dry and cancer patients cope with end-of-life anxiety.

The drugs were legal, and Dr. Richards, then a psychologist at the Maryland Psychiatric Research Center, was among scores of scientists studying the therapeutic prowess of entheogens, the class of psychoactive substances that humans have used for millennia. Even years later, Dr. Richards and other researchers say, many early volunteers called the psychedelic sessions the most important and meaningful experiences of their lives.

But as the drugs left the lab in the 1960s and were embraced by the counterculture movement, the country's political establishment reacted with alarm. By the time the Drug Enforcement Administration issued its emergency ban on MDMA in 1985, funding for psychedelic research had largely disappeared.

"We were learning so much, and then it all came to an end," said Dr. Richards, 80, and now a researcher at Johns Hopkins University School of Medicine.

These days, the Center for Psychedelic and Consciousness Research at Johns Hopkins, created two years ago with \$17 million in private funding, is studying, among other things, psilocybin for smoking cessation and the treatment of depression associated with Alzheimer's as well as more spiritual explorations involving religious clergy.

"We have to be careful not to overpromise, but these are fantastically interesting compounds with numerous possible uses," said Roland R. Griffiths, the center's founding director and a psychopharmacologist whose 2006 study, on which he is a co-author with Dr. Richards, administered psilocybin to healthy volunteers — one of the first psychedelic studies to win F.D.A. approval in a generation.

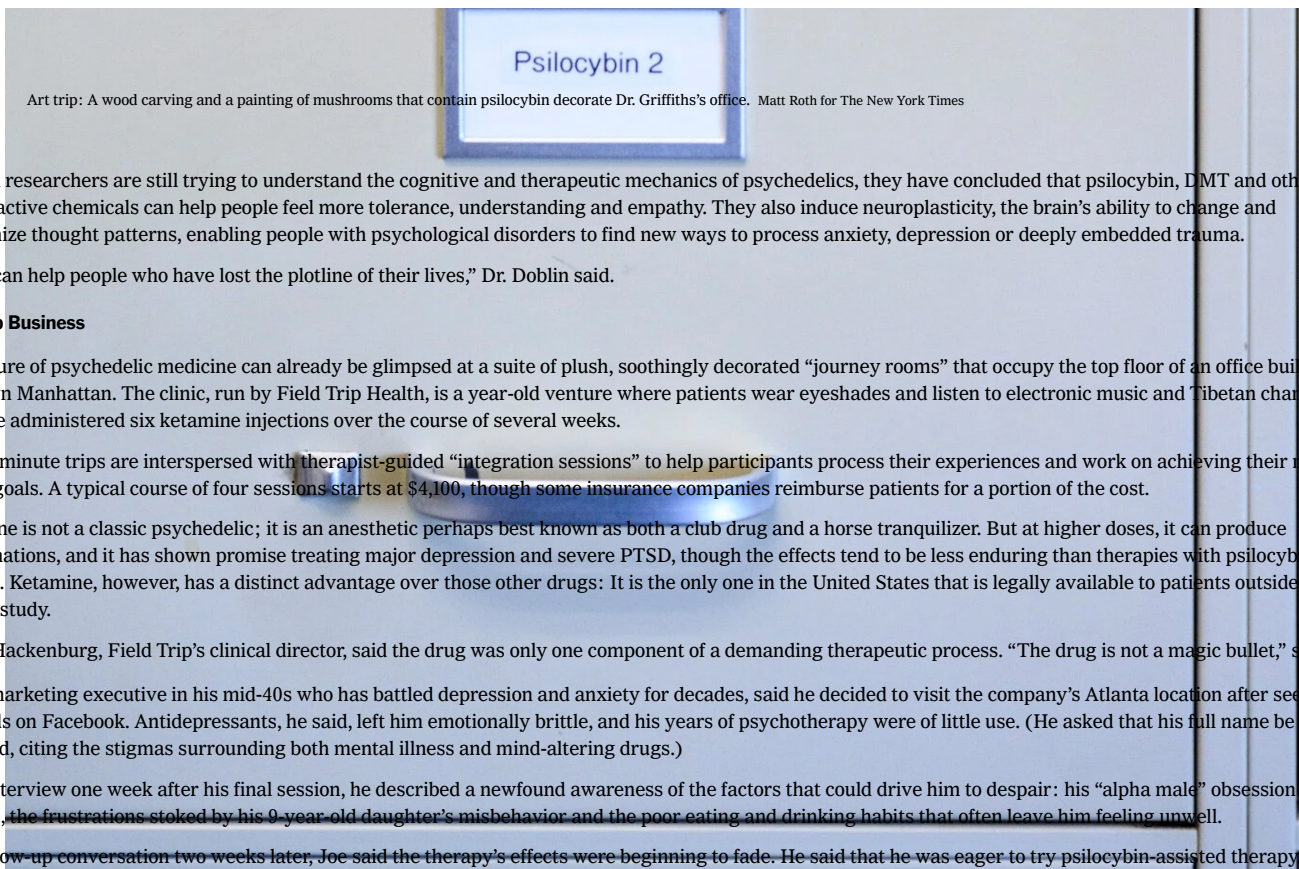




Early pioneers: Dr. William Richards, left, and Dr. Roland R. Griffiths. Matt Roth for The New York Times







Art trip: A wood carving and a painting of mushrooms that contain psilocybin decorate Dr. Griffiths's office. Matt Roth for The New York Times

Though researchers are still trying to understand the cognitive and therapeutic mechanics of psychedelics, they have concluded that psilocybin, DMT and other psychoactive chemicals can help people feel more tolerance, understanding and empathy. They also induce neuroplasticity, the brain's ability to change and reorganize thought patterns, enabling people with psychological disorders to find new ways to process anxiety, depression or deeply embedded trauma.

"They can help people who have lost the plotline of their lives," Dr. Doblin said.

**The Trip Business**

The future of psychedelic medicine can already be glimpsed at a suite of plush, soothingly decorated "journey rooms" that occupy the top floor of an office building in Midtown Manhattan. The clinic, run by Field Trip Health, is a year-old venture where patients wear eyeshades and listen to electronic music and Tibetan chanting, as they are administered six ketamine injections over the course of several weeks.

The 90-minute trips are interspersed with therapist-guided "integration sessions" to help participants process their experiences and work on achieving their mental health goals. A typical course of four sessions starts at \$4,100, though some insurance companies reimburse patients for a portion of the cost.

Ketamine is not a classic psychedelic; it is an anesthetic perhaps best known as both a club drug and a horse tranquilizer. But at higher doses, it can produce hallucinations, and it has shown promise treating major depression and severe PTSD, though the effects tend to be less enduring than therapies with psilocybin or MDMA. Ketamine, however, has a distinct advantage over those other drugs: It is the only one in the United States that is legally available to patients outside a clinical study.

Emily Hackenburg, Field Trip's clinical director, said the drug was only one component of a demanding therapeutic process. "The drug is not a magic bullet," she said.

Joe, a marketing executive in his mid-40s who has battled depression and anxiety for decades, said he decided to visit the company's Atlanta location after seeing one of its ads on Facebook. Antidepressants, he said, left him emotionally brittle, and his years of psychotherapy were of little use. (He asked that his full name be withheld, citing the stigmas surrounding both mental illness and mind-altering drugs.)

In an interview one week after his final session, he described a newfound awareness of the factors that could drive him to despair: his "alpha male" obsession with success, the frustrations stoked by his 9-year-old daughter's misbehavior and the poor eating and drinking habits that often leave him feeling unwell.

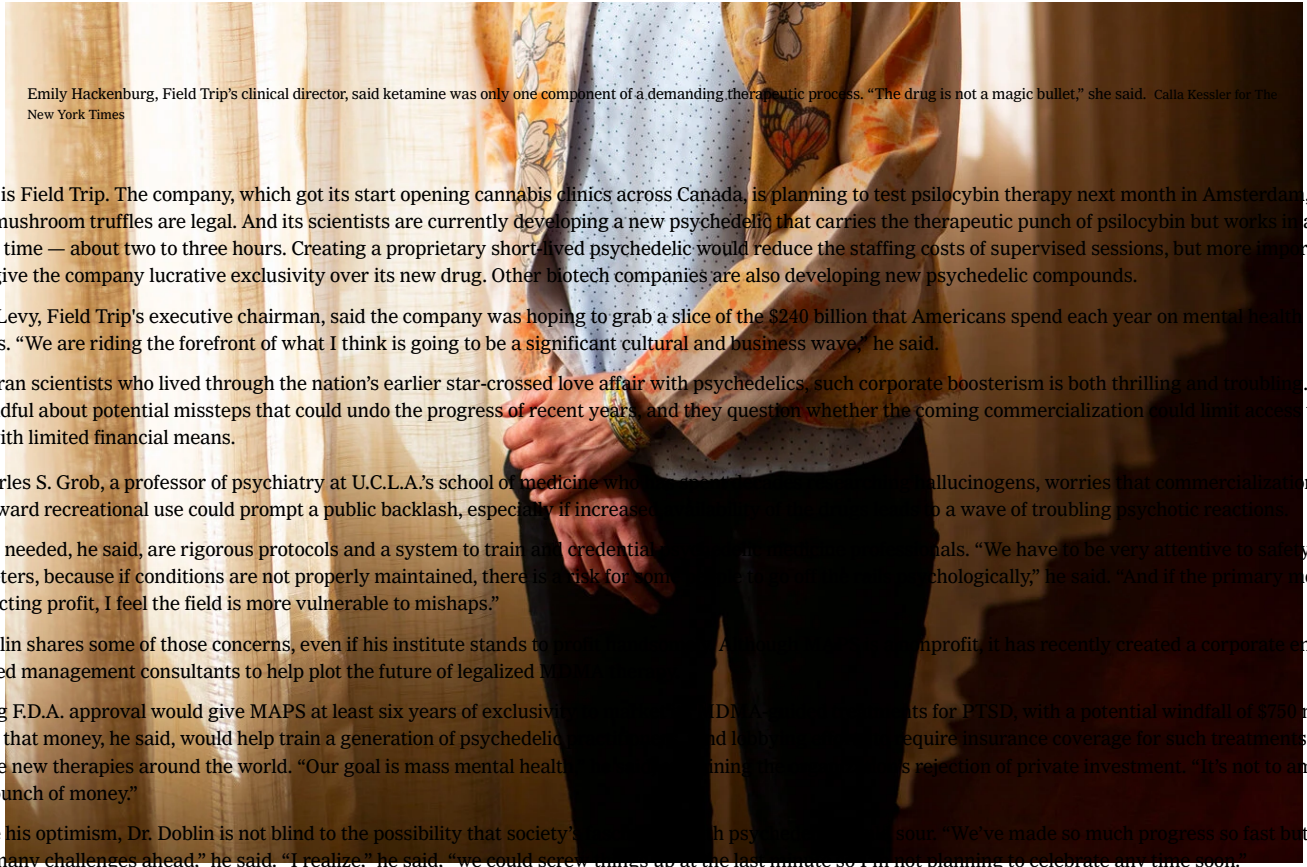
In a follow-up conversation two weeks later, Joe said the therapy's effects were beginning to fade. He said that he was eager to try psilocybin-assisted therapy. "I'm really looking forward to the day when that becomes legal," he said.











Emily Hackenburg, Field Trip's clinical director, said ketamine was only one component of a demanding therapeutic process. "The drug is not a magic bullet," she said. Calla Kessler for The New York Times

So, too, is Field Trip. The company, which got its start opening cannabis clinics across Canada, is planning to test psilocybin therapy next month in Amsterdam, where magic mushroom truffles are legal. And its scientists are currently developing a new psychedelic that carries the therapeutic punch of psilocybin but works in about half the time — about two to three hours. Creating a proprietary short-lived psychedelic would reduce the staffing costs of supervised sessions, but more important, it would give the company lucrative exclusivity over its new drug. Other biotech companies are also developing new psychedelic compounds.

Ronan Levy, Field Trip's executive chairman, said the company was hoping to grab a slice of the \$240 billion that Americans spend each year on mental health services. "We are riding the forefront of what I think is going to be a significant cultural and business wave," he said.

To veteran scientists who lived through the nation's earlier star-crossed love affair with psychedelics, such corporate boosterism is both thrilling and troubling. They are mindful about potential missteps that could undo the progress of recent years, and they question whether the coming commercialization could limit access to those with limited financial means.

Dr. Charles S. Grob, a professor of psychiatry at U.C.L.A.'s school of medicine who has studied the effects of hallucinogens, worries that commercialization and a rush toward recreational use could prompt a public backlash, especially if increased use leads to a wave of troubling psychotic reactions.

What is needed, he said, are rigorous protocols and a system to train and credential therapists and other professionals. "We have to be very attentive to safety parameters, because if conditions are not properly maintained, there is a risk for some people to become psychologically," he said. "And if the primary motivator is extracting profit, I feel the field is more vulnerable to mishaps."

Dr. Doblin shares some of those concerns, even if his institute stands to profit from the new treatments. MAPS, which is a nonprofit, it has recently created a corporate entity and hired management consultants to help plot the future of legalized MDMA.

Winning F.D.A. approval would give MAPS at least six years of exclusivity, and the D.M.A. would receive \$750 million for PTSD, with a potential windfall of \$750 million. Most of that money, he said, would help train a generation of psychedelic therapists and lead to new treatments that require insurance coverage for such treatments and promote new therapies around the world. "Our goal is mass mental health care, not just winning the lottery," he said, rejecting the possibility of private investment. "It's not to amass a whole bunch of money."

Despite his optimism, Dr. Doblin is not blind to the possibility that society's enthusiasm for psychedelics could sour. "We've made so much progress so fast but there are so many challenges ahead," he said. "I realize," he said, "we could screw things up at the last minute so I'm not planning to celebrate any time soon."