



WHAT A LONG,  
STRANGE TRIP  
IT'S BEEN.  
PSYCHEDELICS,  
THANKFULLY,  
GO MAINSTREAM.

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ORIGINAL ARTWORK  
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If it seems like everyone you know has been taking psychedelics this past year, it's because, well, they have been.

Mushrooms and LSD (and all their friends) are having a moment. But even if those in your inner circle aren't tripping right after your regular Friday Teams call yet, you need only look to the glut of new research, cries for regulatory repeal and the billions (yes, with a B) invested globally to see that a psychedelic revolution is indeed underway.

But why now? So goes the answer to many big questions in 2021: these are unprecedented times.

Approaching the two-year anniversary of lockdowns, economic uncertainty and ever-changing public health restrictions, we find ourselves in a global mental health crisis. Researchers fear aftershocks will be felt long after the pandemic has subsided. And with treatments like antidepressants – that some say don't work well already – the search is on for novel solutions to persistent problems.

Enter psychedelics. The focus of over 260 clinical trials, novel clinics, retreats and beloved by a growing wave of microdosers, the drugs are showing promise to heal a variety of ailments.

"These aren't just meds that treat symptoms or numb someone out, they're more geared at getting to the root underlying causes, and in some cases, even going for the cure, which is a rare and beautiful thing in mental health," said Novamind Chief Scientific Officer Reid Robison.

## RESEARCH REVOLUTION

In the research community, psychedelics are now considered the biggest innovation in mental healthcare since the introduction of antidepressants in 1987. They're being studied to treat a myriad of health problems, from PTSD and treatment-resistant depression to anorexia and substance abuse disorder.

A recent phase two study from Imperial College London suggests two doses of psilocybin (combined with therapy) is as effective at

treating severe depression as a common prescription antidepressant.

And new evidence suggests MDMA could cure post-traumatic stress disorder. Results of a 2021 phase three study by the Multidisciplinary Association of Psychedelic Studies (MAPS) showed that following treatment and therapy, nearly two-thirds of participants no longer qualified for a diagnosis of PTSD.

This mounting body of evidence supports theories that psychedelics, combined with psychotherapy, could replace some traditional pharmaceuticals and recover billions in associated healthcare and societal costs.

## HISTORY REPEATING

In Canada, psychedelics are classified as controlled substances. Legislation stipulates only 'licensed dealers,' researchers and persons granted 'Section 56 exemption' are legally allowed to possess psychedelics.

Ketamine, a dissociative anesthetic with powerful psychedelic properties, was approved in Canada for treatment-resistant depression in 2020. The next evolution in legal access to psychedelics may come in the form of regulatory revision for psilocybin—similar to Canada's medical cannabis regulations.

Vancouver-based non-profit TheraPsil advocates for terminally ill patients seeking psilocybin to help them cope with end-of-life anxiety. To date, TheraPsil has helped over 60 Canadian patients and therapists receive Section 56 exemptions, allowing them to legally use and possess psilocybin.

But the group believes the current approvals system does little to address the need and infringes on patients' Charter rights.

In August, TheraPsil drafted a proposed framework for medical psilocybin, dubbed the Access to Psilocybin for Medical Purposes Regulations (APMPR).

Sound familiar? The framework, a revision to the Controlled Drugs and Substances Act, resembles Canada's 2016 medical cannabis

regulations, the Access to Cannabis for Medical Purposes Regulations (ACMPR). The psilocybin-tweaked APMPR guidelines stipulate packaging, labelling, production and physician authorization to use psilocybin.

## A GROWING INDUSTRY

While clinical trials are, traditionally, an agonizingly long process in biotech, the FDA has granted 'breakthrough designation' to a handful of promising trials, including COMPASS Pathways' and the Usona Institute's study of psilocybin for depression.

This fast-tracked FDA support ensures the clinical development approvals process is swift and efficient. The furthest along in the approvals race is MAPS, whose Phase 3 trials were granted breakthrough designation in 2017. The U.S. non-profit anticipates approval of its MDMA-assisted psychotherapy for PTSD by 2023.

Today, more than 40 psychedelic companies are publicly traded, valued at an estimated \$10 billion globally, according to the Psychedelics as Medicine Report: Third Edition.

The report, which examines the sector through a lens of commerce, science and regulation, suggests Canada is becoming a global psychedelics hub. Canada's history of adopting novel healthcare policies, early psilocybin medical exemptions and relatively progressive drug policies suggest it is the most fertile ground for domestic regulatory repeal.

The biggest push is around regulating the drugs as adjuncts to psychotherapy. Therapist-guided psychedelic treatment includes dosing of a drug (be it ketamine, psilocybin, MDMA or similar), careful tuning of 'set' (the patient's intention of outcome, or mindset) and 'setting' (a safe, supportive physical environment). Patients are typically treated post-trip in follow-up 'integration' sessions, intended to unpack their experience and apply any learnings to their lives.

"Having done over 200 clinical trials in psychiatry, I have never seen anything as effective as psychedelic medicines at treating



even severe depression, PTSD and other conditions,” Robison told KIND.

With corporate offices in Toronto and treatment and research sites in the U.S., Novamind currently works with patients in ketamine clinics and is conducting a study which aims to address trauma faced by frontline pandemic healthcare workers.

“It’s been an extremely difficult year for so many people, but there is something of a silver lining coming out of the stress, trauma and difficulty we’ve gone through together. It seems like out of necessity, we’ve begun to get serious about our mental health and band together in ways that will have lasting positive impact, even when the pandemic is done.”

### TRIPPING OUTSIDE THE LINES

Outside clinical settings, many are currently using illicitly-sourced psychedelics. From underground therapy to pure recreational use, psychedelics are becoming popular with people who aren’t card-carrying psychonauts, notably, microdosing.

The functional form of consumption (roughly 1/10th or lower of a typical dose, usually LSD or psilocybin), is often ‘sub-perceptual’, absent those classic psychedelic changes in vision or hearing.

Microdosing is more subtle in effect with a shorter duration, and it’s lower commitment for those who don’t necessarily want to breach the stratosphere, says Peter Reitano, founder of Gwella.

The Toronto-based company offer products and content that enable people to use psychedelics safely and effectively - they’re masters of the microdose.

“We want people to get better results out of them, outside of this very prescriptive medical lane. People should be able to use psychedelics for whatever reason they want,” Reitano says.

Though many first-person reports suggest microdosing is beneficial for improving mood, creativity and concentration, little supporting scientific evidence currently exists. While the benefits of full dosing and ‘heroic dosing’ (+5 grams of psilocybin or equivalent) have become understood in the scientific community, the efficacy of microdosing remains a subject of debate.

Telling evidence has begun to emerge, however. In October, a group of researchers released findings of one of the first clinical LSD microdose studies on cognitive processing in healthy adults. The study concluded that low doses of LSD may provide therapeutic and behavioural benefit – no

blast-off psychedelic experience required.

### A LOOK AHEAD

Following states like Oregon, decriminalization efforts are underway in Vancouver and Toronto, where civic consensus favours harm reduction over penalties.

A national regulatory approach of responsible production and distribution is light years better than prohibition, says Wood.

“We have a choice. We can just keep saying, ‘No, never, human hands can’t touch this unless it’s in a clinical trial,’ or,” says TheraPsil legal counsel David Wood, “We can reflect on whether an approach similar to cannabis could work.” ♦

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