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Australian Psychiatrist Sues State Of Victoria For Denying MDMA Treatment For Ailing Patient

by **David Carpenter**
(https://www.benzinga.com/user/798673)
November 17, 2021 2:01 pm

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The Australian state of Victoria **faces a seminal lawsuit** that seeks to make **MDMA available for severe mental illness.**

Attempting to secure permission to treat a gravely ill patient using MDMA (universally known as the street drug ecstasy), psychiatrist **Dr. Eli Kotler** initiated legal action against the Victorian Department of Health after his application for treatment was denied.

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Stefan Tulloch, acting chief officer of medicines and poisons regulation at the Department of Health, told Dr. Kotler in a letter that was released by ABC Australia, that "There is insufficient data to establish the safety and efficacy ... with regards to safe use of a

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Schedule 9 poison in clinical practice."

In Australia, **Schedule 9 drugs and poisons** are considered substances and preparations that may be legally used only for research purposes. The sale, distribution, use and manufacture of such substances without a permit is strictly prohibited by law.

The case in Australia comes at a time when **clinical trials employing therapies using MDMA-assisted therapy**—specifically to treat severe post-traumatic stress disorder (PTSD)—are seeing **remarkably successful outcomes** in the U.S., Canada and Israel.

Funded by the **Multidisciplinary Association for Psychedelic Studies** (MAPS) and conducted by the Food and Drug Administration, **trials are currently in Phase III** (<https://www.benzinga.com/markets/cannabis/20/08/17015922/maps-and-the-road-to-fda-approval-for-mdma>) and demonstrating that two months after the trial, 67% of the MDMA-assisted group no longer suffers from PTSD. In fact, results are so positive that the **FDA granted treatments** (<https://www.benzinga.com/markets/cannabis/20/05/16096339/mdma-assisted-therapy-for-ptsd-likely-to-get-fda-approval-by-2022>). "breakthrough therapy status," a designation given only when preliminary clinical evidence indicates that a drug may demonstrate substantial improvement over available therapies.

Dr. Kotler Goes To Court

"The patient is quite unwell and has a range of mental health issues where it's believed that MDMA would be safe and efficacious to use therapeutically," Kotler's attorney Greg Barns explained to the court, adding that his team would be welcoming experts from California and the UK to make their case in favor of using MDMA to treat mental trauma.

Over the course of the past year, the Therapeutic Goods Administration (TGA), the body that regulates medications in Australia, has been weighing the downgrading of MDMA and making it a controlled drug. Being placed in the **Schedule 8 controlled drugs category**, which includes hydrocodone, ketamine and codeine, would allow MDMA to be used for medical treatment under strict conditions. A decision on that matter is projected for early 2022.

Dr. Kotler's case has likewise been adjourned until next year, which could coincide with a change in scheduling for MDMA by the TGA.

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The Week In Cannabis: Stocks Down, Republican Legalization Bill, Germany, Uruguay, Earnings, New ETF And More

Below is a recap of the main news related to the cannabis industry and markets for the week of November 15, 2021. [Contents](#)

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