MIND MEDICINE
AUSTRALIA

Mind Medicine Australia's Critique of the Article by Stephen Bright and Martin Williams titled "Will Australia legalise ecstasy and magic mushrooms to treat mental illness? Here's why it's still too soon." The article appeared in The Conversation on 25th January 2021

See: https://www.theconversation.com/will-australia-legalise-ecstasy-and-magic-mushrooms-to-treat-mental-illness-heres-why-its-still-too-soon-150448

The authors, Stephen Bright and Martin Williams, are two of the three directors of Psychedelic Research in Science and Medicine (or PRISM for short). PRISM was set up as a charity about 10 years ago to promote psychedelic research in Australia. The organisation had an influential role in promoting the current research trial being run by St Vincent's Hospital in Melbourne on the use of psilocybin-assisted therapy for depression and anxiety associated with a terminal diagnosis.

Mind Medicine Australia (MMA) was one of the leading funders of PRISM in relation to the development of the St Vincent's trial. MMA cut its funding to PRISM in October last year because of PRISM's lack of accountability for the funds which we had given to them and for its failure to report back to us regularly as a major donor.

We have an enormous number of people in Australia suffering from treatment-resistant depression and treatment-resistant post-traumatic stress disorder (PTSD). Despite the large amount of research to date confirming the safety and efficacy of these therapies and their huge potential in Australia to reduce unnecessary suffering the authors have used a series of poorly researched arguments in an apparent effort to restrict access to these therapies and promote their research agendas.

The authors actually had input into MMA's psilocybin rescheduling application and at no stage did they argue against the veracity of the science and the data supporting the rescheduling of these medicines.

The article contains a significant number of errors and misleading statements.

The article is reproduced below in italics with MMA's comments on highlighted statements in the text appearing in normal type and within blue boxed shading.

"While the public focus remains on COVID vaccines, the Therapeutic Goods Administration (TGA) continues to evaluate a range of proposals around the provision of medical treatments in Australia.

*The regulatory body is **currently considering whether psychiatrists should be allowed to prescribe MDMA and psilocybin to treat mental illness**. The TGA will announce its interim decision on February 3, and will make a final ruling on April 22."*

This statement is misleading because psychiatrists can already prescribe these medicines under Australia's Special Access Scheme-B on a case-by-case basis. The problem with the Schedule 9 listings is that some Australian States still have legislative barriers to access. MMA has already helped 10 psychiatrists with their TGA submissions and the TGA has given approvals to each one of these psychiatrists within 2 days of receipt. The practical effect of a successful rescheduling depends upon the controls placed on the use of these medicines, as Schedule 8 controlled medicines, by the TGA's expert panel. In our applications we suggested that only psychiatrists or specialist addiction physicians should be able to prescribe these medicines as part of therapy.

"Psychedelic drugs for the treatment of mental illness represent a promising area. And any new treatment which could help people suffering — particularly in the wake of the pandemic — may seem like a good thing.
But until Australia engages in further research into the therapeutic potential of these drugs, we believe it's too soon to make them available as medicines."

This is a strange argument because the TGA has already made it clear to us that they are happy to rely on overseas research for the safety and efficacy of these medicines. The authors are well aware (but don't mention) that both medicines already have breakthrough therapy designation from the FDA in the United States; that MDMA therapy for PTSD is already in the second stage of Phase 3 trials and psilocybin is in Phase 2b trials. In each case, as per our rescheduling applications, there is lots of evidence that these medicines can be used safely as an adjunct to therapy in medically controlled environments.

The above statement also ignores the fact that access to these medicines can already be approved through regulatory controlled expanded access schemes in the US, Canada, Israel and Switzerland as well as Australia under the Special Access Scheme. In light of all of the overseas research it would be fascinating to see the authors explain to an Australian who is suffering from treatment-resistant PTSD or treatment-resistant Depression (and who may be potentially suicidal) that they shouldn't be able to access these therapies because research from around the World at some of the leading institutions globally is simply not good enough because the research hasn't yet been done in Australia!

"The application

Increasing research evidence suggests MDMA, commonly known as ecstasy, could be an effective adjunct to psychotherapy for people with post-traumatic stress disorder (PTSD).

Meanwhile, clinical trials of psilocybin, the psychoactive component of magic mushrooms, show it could assist psychotherapy in the treatment of anxiety and depression, addiction, and a range of other mood disorders.

On this basis, in July 2020, an organisation called Mind Medicine Australia made an application to the TGA requesting MDMA and psilocybin be classified as Schedule 8 controlled medicines."

Our applications have been publicly available on our website for nearly 6 months. What the authors fail to point out is that our applications for these medicines to be rescheduled as part of therapy to Schedule 8 is limited to the prescriber being a psychiatrist or specialist addiction physician and the medicines only being used in medically controlled environments. In other words, the medicines have to be combined with psychotherapy and can never be taken home by the patient. They also fail to point out that the two applications were supported by over 80 leading psychiatrists, pharmacologists, psychologists, researchers and other scientists from Australia and around the World and that MMA has an outstanding and highly credentialed Board, Ambassadors and Advisory Panel.

"MDMA and psilocybin are currently classified as Schedule 9 prohibited drugs. Other examples of Schedule 9 drugs include heroin and methamphetamine."

Methamphetamine is actually a schedule 8 controlled medicine. Comparing psilocybin and MDMA with heroin and methamphetamines is ridiculous. Both heroin and methamphetamines are used as recreational drugs and MMA is not arguing for the legalisation of recreational psilocybin and recreational MDMA. In any event, please see here a link to work done by leading academics comparing the relatively low risks in the recreational area associated with MDMA and psilocybin compared to heroin and methamphetamines- https://journals.sagepub.com/doi/10.1177/0269881119841569. Note that MMA is only talking about these medicines being used in medically controlled environments and there have been no adverse events with these medicines either in overseas trials or through Expanded Access programs.

"As Schedule 8 controlled medicines, MDMA and psilocybin would sit alongside drugs like dexamphetamine, morphine and some forms of medical cannabis. Some of these and other Schedule 8 drugs such as ketamine and cocaine are used recreationally."

We are not sure what point the authors are trying to make here. Morphine (Schedule 8) is chemically very similar to heroin (Scheduled 9) and both are addictive. The medical system accepts the risks of morphine in medically controlled environments because of its benefits in terms of pain relief. Neither psilocybin nor MDMA are addictive and our application only deals with the use of these medicines in medically controlled environments (so very similar to morphine but much less dangerous).

"If the TGA reclassifies MDMA and psilocybin, Australia would be the first country in the world to recognise these drugs as legitimate medicines."

Not sure what to make of this statement given that the TGA has already recognised psilocybin and MDMA as medicines through approvals given under the Special Access Scheme and this is mirrored by the expanded access scheme approvals that have been given in the US, Canada, Israel and Switzerland. They are also widely used as medicines in Holland and parts of South America.

"Is Australia ready?

Early research suggesting psychedelics had therapeutic potential lapsed after 1971, when the drugs were made illegal around the world. But it resumed early in the 2000s, manifesting into an international renaissance in psychedelic science.

Australia was a little later to get involved than some countries, but in the past 18 months we've succeeded in initiating clinical research locally.

Edith Cowan University, Monash University, the University of Melbourne, and St Vincent's hospitals in Melbourne and Sydney all have research on psychedelic-assisted therapies either in the pipeline or already underway. The trial at St Vincent's hospital in Melbourne is the first to have started recruiting participants.

These trials aim both to contribute to the research happening globally, and to demonstrate that Australia has the regulatory processes, people and infrastructure to provide these treatments safely and effectively."

The obvious question here is who do we need to demonstrate this to and why? The current St Vincent's trial for end-of-life anxiety and depression associated with a terminal illness has already been done on two occasions overseas - at NYU and Johns Hopkins. The trial isn't pushing the research envelope very much and is taking years to complete. The proposed Edith Cowan trial is small and is unlikely to have any bearing on the global research landscape. The Monash trial is much more interesting because it focuses on a mental illness (general anxiety disorder) that hasn't to date been a focus of major research anywhere in the World.

"But we're not there yet

There are three key reasons why Australia is not yet ready for MDMA and psilocybin to be rescheduled as medicines by the TGA.

1. No accredited training

Australia has very few health-care professionals trained to provide psychedelic-assisted psychotherapy. These drugs produce powerful changes in consciousness that could lead to psychological harm, rather than healing, when given to unsuitable patients, or by health-care workers without the necessary training."

This is precisely why the protocols to date have involved psychiatrists screening out patients with psychosis. The authors are also well aware that MMA has a psychedelic-assisted therapist course (the first intake starts next Saturday). If you look at our website https://cpat.mindmedicineaustralia.org/ you will see that the Course Faculty includes some of the leading researchers and trainers in these therapies globally and the first intake of 50 includes very credentialed people – namely psychiatrists, psychologists, GPs, mental health nurses, social workers, occupational therapists, addiction physicians, and other therapists working in the mental health sector with significant therapy experience. With 100 health practitioners going through the course this year and plans to substantially increase the intake next year, Australia will be able to build up a significant base of trained therapists (and frankly a much larger number and in a much shorter timeframe than those involved in trials).

"2. Prohibitive costs Medical cannabis is only legally available in pharmaceutical formulations — the actual plant is not available as a medicine. This makes medical cannabis expensive. Only 3.9% of Australians using cannabis for medical reasons access it legally. We expect pharmaceutical-grade MDMA and psilocybin will also be expensive to access."

This argument is nonsense - the TGA shouldn't reschedule these medicines as part of therapy because the medicines could be expensive! Try telling people in pain getting relief from medical cannabis that they shouldn't be allowed to get medical cannabis from their doctors because it's too expensive even though they are willing to pay the price! The paragraph is also wrong. MMA has a supply contract in place to import GMP medical grade psilocybin and GMP medical grade MDMA from a medical supplier in North America subject to the necessary regulatory approvals. The cost per dose (including import costs and delivery charges to the clinic where the medicine is to be used) will be a small component of the overall cost of their therapies (3 dosed sessions are required). As a medicine it's much cheaper than medical cannabis because you only need to take it 2-3 times. The psychotherapy that goes with the medicine is where the larger cost is. However, even then the overall cost will be much lower than a lifetime of mental illness and associated medications, treatments and loss of quality of life, or inpatient TMS (a modality increasingly used for treatment-resistant depression).

"3. Going underground

Like medical cannabis, we're concerned that lack of access and prohibitive costs will mean more people will access existing unregulated MDMA and psilocybin treatment services. This puts people at risk, since there's no quality control of either the drugs or the therapists.

Should these issues arise, our efforts over recent years to finally establish psychedelic medicine in Australia could be undone."

This paragraph is actually a strong argument in favour of rescheduling. Given the increasing publicity associated with positive trial results, safety data and high remission rates from overseas, *the likelihood* is that many more people will seek to access underground therapy if these therapies aren't made part of our medical system as soon as possible.

"What will the TGA decide?

Given these concerns, we believe it's highly unlikely the TGA will decide to reschedule MDMA and psilocybin as medicines at this stage.

And while emerging evidence is continuing to suggest these drugs can be effective adjuncts to psychotherapy, we believe the application was made without sufficient regard to the universally accepted process of new drug approval.

We need to see Phase 3 clinical trials completed before any informed decisions can be made (the trials in Australia have not yet reached Phase 3). This approval process is important so we know the drugs are effective and safe, including understanding any side effects."

This paragraph confuses the process of getting a medicine listed on the TGA register with the scheduling of a medicine under the Poisons Standard. There are many examples of substances being rescheduled in the Poisons Standard without being registered on the TGA register. For example ibogaine is in Schedule 4 and different variations of medicinal cannabis are now in Schedules 3, 4 and 8 of the Poisons Standard. There have also been many detailed studies done on the safety and efficacy of using medicinal psilocybin and medicinal MDMA as part of therapy (the main ones are listed in our rescheduling applications).

"By way of comparison, we know Pfizer wouldn't apply for TGA approval for a new antidepressant before completing Phase 3 research. Even the COVID-19 vaccines Pfizer, AstraZeneca and Moderna are fast-tracking internationally have been required to complete stringent, widely scrutinised Phase 3 trials."

The analogy with antidepressant isn't a good one given their low effect size and nasty side effects in many patients. See: https://medium.com/@pbfitzgerald/the-challenges-of-depression-treatment-in-2020-. The other point to make is that pharmaceutical companies like Pfizer have shown no interest to date in psychedelic medicine simply because they can't patent the pure form of psilocybin or MDMA which is being used in these therapies. In addition, these medicines as an adjunct to therapy (unlike antidepressants) are only used 2 - 3 times rather than for years/decades, so aren't very attractive to a traditional pharmaceutical company.

The comparison to COVID vaccine trials is also disingenuous. The proposed medical use of psilocybin and MDMA is as part of clinical therapy. Unlike the COVID vaccines there are decades of data on their low toxicity and effectiveness when used in this way. This is very different than a new kind of vaccine that seeks to trick the body's defensive system into believing that its being infected by a new and dangerous disease that it hasn't experienced before.

"Where to from here?

Current and future Australian research in this space will offer a crucial pathway for therapists to learn how to provide psychedelic-assisted psychotherapy. This is an important step before Australia is ready for MDMA and psilocybin to be approved as medicines.

Moving forward, we anticipate Australian health-care professional registration boards will come to acknowledge psychedelic-assisted psychotherapy as a speciality area of training and will need to develop accredited training programs to meet the demand for appropriately qualified therapists.

Notably, none of the current research into psychedelic-assisted treatments for mental illness in Australia is receiving government funding. Government support will be important to extend this research beyond the early-phase trials, and ultimately will be crucial for the widespread rollout of this treatment.

Finally, to ensure equitable access, psychedelic-assisted therapies will need to be embedded within the public health-care system and supported by the Pharmaceutical Benefits Scheme.

Our submission to the TGA, along with others, will be made public on February 3, when the TGA announces its interim decision on the rescheduling of psilocybin and MDMA."

These comments all revolve around the need for more research before these therapies can be accessed by patients in need, particularly the comments about wanting more research funds from Government. All medicines (whether already registered or not) can benefit from more research. However, the approach of the authors would unnecessarily delay people that are suffering from treatment-resistant depression and treatment-resistant PTSD from being given access to these therapies for many years into the future despite the strong safety and efficacy data that supports them.