

Excerpts From Our Rescheduling Applications For Psilocybin and MDMA

MEDICAL PRACTITIONERS

- 1. "From the research literature, I understand that psilocybin is increasingly identified as a useful substance, the controlled administration of which can effectively reduce intractable symptoms in terms of severity, frequency and duration. Of particular note is the generally short-term treatment protocols associated with psilocybin-assisted psychotherapy." Tim Golding, Clinical Psychologist
- 2. "All the psychotropic medications we currently use have high toxicity, really horrendous side effect profiles, multiple drug interactions as well as horrible dependence and withdrawals. I have seen this multiple times with many patients. People with mental health conditions do not need to keep suffering, we have the opportunity to do something meaningful and impactful here and now. We need to make this change for the betterment of others, and we need to act now so we can ensure the improvement of people's lives. The time to act for change is now." Bavly Nasralla, Clinical Pharmacist
- 3. "Sadly, as a GP working primarily in mental health, it is evident that effective treatment modalities are scarce, with current medications often resulting in limited or unreliable improvements in patient outcomes especially in the realms of PTSD which is alarmingly widespread and often under-reported. Additionally, many patients with severe treatment resistant depression or anxiety often end up on lifelong medications such as SSRI's or SNRIs that offer limited improvement and a range of significant side effects such as weight gain or loss of libido." Mark Melek, General Practitioner
- 4. "Current first line therapies for post-traumatic stress disorder have limited efficacy, with pharmacological treatments usually requiring costly and potentially side-effect prone daily use. Only 20-30% of PTSD sufferers fully respond to pharmacotherapy. Tragically, many of these patients are former soldiers and emergency responders who have spent their lives serving our nation" Jesse Schnall, Junior Medical Doctor
- 5. "With respect to PTSD, the morbidity levels for sufferers are significant and extend into their family and social networks. In addition to the horrific internal experiences lived through daily, the difficulty an individual faces in returning to the work force or completing everyday tasks, previously taken for granted, is noteworthy. Suicide amongst this population is unfortunately too common. Family members are at an increased risk of mental health problems themselves. With respect to PTSD, the morbidity levels for sufferers are significant and extend into their family and social networks. In addition to the horrific internal experiences lived through daily, the difficulty an individual faces in returning to the work force or completing everyday tasks, previously taken for granted, is noteworthy. Suicide amongst this population is unfortunately too common. Family members are at an increased risk of mental health problems themselves. New, evidence based treatments are needed now. MDMA has been researched extensively, the pharmacological profile is well understood and the risks are known to be minimal when treatment occurs within a clinical setting." Rob Wainwright, registered pharmacist and psychologist

- 6. "There is considerable evidence that both psilocybin and MDMA have significant potential in the treatment of psychiatric disorders, especially in augmenting psychotherapy in trauma-based disorders. Trauma is the foundational cause of a whole suite of psychiatric disorders." Tanveer Ahmed, Psychiatrist
- 7. "In a medically facilitated environment, Psilocybin is a very safe compound to use. It does not produce dependency at its established therapeutic dose, nor at any dose. Further its addictive properties (both psychological dependence and psychological dependence) is far lower than current drugs on the market." Dr Harsumeet Sandhu, Medical Officer
- 8. "The use of these substances is already prevalent in our community and increasingly patients are seeking them out without the safety which comes from effective regulation, including drug quality, reducing stigma and facilitating open communication with clinicians, ensuring appropriate use and setting, minimising direct and indirect risks, improved research and understanding, and much more. "—Dr Ksenia Goureeve GP- and Stephen Bunce
- 9. "Psilocybin has been afforded "Breakthrough Drug Status" by the US FDA. This designation is provided to fast-track medicines that show substantial promise in the treatment of serious or life-threatening conditions. Psilocybin is already being prescribed in the USA, Europe and Israel for certain specified psychiatric problems under expanded access schemes. At present, psilocybin is classified as a prohibited substance in Australia, making its use for treatment of serious psychiatric conditions impossible." Dr Roberto D'Angelo Psychiatrist
- 10. "Psilocybin when used with proper protocols in a medically controlled environment can provide high remission rates for the key classes of mental illness mentioned above when compared to current treatments (such as antidepressants and conventional therapy). Treatment is brief: only 2 to 3 dosed sessions are required, in contrast to a permanent or long-term use of pharmaceutical substances such as antidepressants. Psilocybin has minimal side effects, again in contrast to pharmaceuticals such as antidepressants." R Gerrand Psychiatrist
- 11. "As a trained telephone counsellor with Lifeline, I hear first-hand the suffering many Australians living with mental illness are going through. The mental health system can fail them and traditional medications often provide additional burden and little benefit. Many Australians are unnecessarily suffering mental illness their whole lives when it could be cured with psilocybin assisted therapies" Nicole Chapman Counsellor
- 12. "Currently, more than 264 million people of all ages suffer from depression and it is the leading cause of disability worldwide. Mental illness not only affects the individual and their functioning, but it has major consequences on their ability to work and therefore the economy. The estimated annual cost to the Australian economy due to mental illness is \$180 billion." Dr Nicola Santarossa General

Practitioner

- 13. "High remission rates being achieved for people having access psilocybin based therapies in overseas trials. These medicines have been shown to be safe and non-addictive when used in a medically controlled environment. These therapies only require two to three sessions with the medicines in contrast to pharmaceuticals like anti-depressants which can create lifetime dependence." Dr Navin Doloswala General Practitioner
- 14. "My professional observations make me believe that medicinal use of Psilocybin and MDMA holds enormous healing potential for treating substance abuse, trauma and mental illness by motivating individuals to seek improved health and live functional and meaningful lives." Dr Mark Porter Psychologist
- 15. "In clinical trials, patients who show clinically significant outcomes report that the most 'salient' acute effect of psilocybin is a distinct shift in the quality of their consciousness (Watts et al, 2017). These changes may help shift patients out of pathological patterns of belief and make it easier to revise old beliefs and create new ones about the self (Carhart-Harris & Friston, 2019). These mechanisms underlie psilocybin's ability to alleviate depressive, anxious, and addictive disorders by allowing the brain and mind to 'break out' of maladaptive, fixed styles of thinking, feeling, and behaving." Dr Mark Melek General Practitioner
- 16. "Having training in several specific models of evidence-based psychological therapy, I understand how extraordinary these research-based treatment outcomes are. It is essential that these medicines are reclassified into a category that can allow them to be prescribed by a psychiatrist to be utilised in a clinically controlled therapeutic setting. Below is some more specific information about these medicines and their extraordinary potential for mental health treatment: Phase 2 trials have illustrated significant efficacy for psilocybin-assisted therapy in cases of depression, end-of-life distress and alcohol addiction, showing that treatment groups significantly improved outcomes compared to controls (Schenberg, 2018)
 - There is promising evidence that psilocybin-assisted therapy may help with OCD, anorexia and other difficult to treat disorders of "over-control" (Johnson & Griffiths, 2017)
 - Trials to date have shown that psilocybin-assisted therapy can lead to remission in 60-80% of cases of anxiety and depression, whereas current existing treatments lead to remission in a maximum of 35-42% of cases
 - Psilocybin had been shown to be safe, non-toxic and anti-addictive (Passie, 2008)" – Mark Baxter - Psychologist
- 17. "Mind Medicine Australia's application to amend and reschedule the possession and use of Psilocybin for the treatment of mental health conditions is being put forward for consideration before the Therapeutic Goods Administration for the purpose of increasing positive outcomes in Australian patients who have not responded well to traditional therapeutic modalities and authorised medication options. The use of

restricted psychoactive substances in treating patients diagnosed with psychiatric disorders is a growing movement in the world. This therapeutic approach is being led by licensed medical practitioners and credentialed health professionals who seek to improve the emotional wellness of patients with the objective of achieving long-lasting results (while being mindful of all due safety precautions and considerations)." – Dr Lana Lubimoff - psychiatrist

- 18. "Psychedelic Assisted Psychotherapy with psilocybin is a safe, effective treatment with low short-term risk and very few, if any, ongoing adverse effects. It is a safer, more effective treatment modality than many of the medications I currently prescribe. The initial application lodged by Mind Medicine Australia summarises the understood risks and benefits. 60-80% remission rates for anxiety and depression (compared to 35-42% of current available treatments) cannot be ignored! Psilocybin is not addictive and the potential for abuse is low, especially within the proposed parameters of use. (Note psilocybin is ranked amongst the lowest risk in analysis of relative drug harms even before allowing for a controlled environment.)" Joe Howe
- 19. "I have personally had three patients complete suicide in the past 5 months. All three patients were fully treated with the best available treatments including antidepressant therapy, psychotherapy, and intensive case management. It is frustrating and heart-breaking to have complete treatment failure in the majority of my patients with the best currently available therapies. I currently have another patient suffering end of life anxiety after a diagnosis of rapidly progressing motor neurone disease. She has requested psilocybin-assisted psychotherapy as she has tried every other available treatment without any relief of her symptoms. The evidence favouring the use of psilocybin to assist with end of life anxiety also appears very promising and there appear to be no side effects." Jessica Hickmott Psychiatrist
- 20. "Psilocybin is novel in mechanism, working at a biological level to realign the neurological pathways that contribute to depressive and anxious states. This is a game-changing discovery in a field that has seen almost no novel-acting therapies in the past three decades." Dr Jesse Schnall Junior General Doctor
- 21. "Because of the evidence within my own practice, I was encouraged to further investigate and have since read extremely compelling evidence around this medicine and its use for depression and anxiety. The results I have witnessed over the past couple of years have me very excited by this medicine as the benefits have been sustained and have freed the patients for our therapy to be of much more use. Importantly, it has saved years of time. It does seem that the work achieved in one day with psilocybin can be equated with several years of psychotherapy." Deborah Coulthard psychoanalytic psychologist
- 22. "The most complex patients I see engage in regular therapy for years. For many, suboptimal early life relationships and experiences have resulted in deeply ingrained belief systems which consider the patient to be unlovable, unworthy, and a source of shame. These "self-stories" are embedded within the Default Mode Network, a large-

scale brain network which is highly active in rumination and self-criticism, and highly impervious to reason and re-framing. Traditional therapy can be beneficial, however the enormous commitment of time and finances required to begin to "re-story" these belief systems can be a challenge and is often an exclusory factor." – Caroline Dale - Clinical Psychologist

- 23. "I was struck by the innovation of a treatment that simultaneously focussed on both mind and brain. I was impressed by the caution being shown by researchers and the quality of the institutions that were taking the lead. The safety and side effect profile of both substances, given a well-selected population group and the proper clinical environment, was extremely reassuring, as was the evidence that they are not addictive (which does not mean they cannot be abused as can many medications). Most surprisingly I found the efficacy with respect to treatment resistant depression, anxiety and PTSD absolutely remarkable." Dr Andrew Roberts Psychiatrist
- 24. "Furthermore, if Psilocybin treatment was accessible to the general public through a specialised trained practitioner, this would have incredible and such beneficial results for mental health treatment outcomes; this is clearly evident in areas where people are able to access these treatments, such as the United States where the Food and Drug Administration have Psilocybin assisted therapies as Breakthrough Therapy Designation, as well as Switzerland and Israel. It is an inequitable disservice to the Australian population to not be given access to what could be defined as lifechanging treatment, in comparison to the evidence found in anti-depressants that can lead to life-long dependence." Adrienne Moore drug and alcohol- Mental health practitioner
- 25. "PTSD is common in Australia. There are a proportion of PTSD sufferers for whom the standard of care in the treatment of their PTSD has failed. Those people are left with burdensome symptoms, many are disabled and those with treatment resistant PTSD are at risk for suicide. Self-evidently, available treatments have little to offer the treatment resistant. I submit that the proposal to rescheduling MDMA to Schedule 8 would enable appropriately qualified practitioners to alleviating suffering and disability in those with treatment resistant PTSD at low risk. This would be good for those with treatment resistant PTSD." Al Griskaitis Psychiatrist
- 26. "I am a psychiatrist with an interest in the treatment of post-traumatic stress disorder (PTSD). I receive referrals from other psychiatrists as well as GPs and psychologists when they have patients with PTSD who are difficult to treat. I can often help them but frequently cannot. I am strongly in favour of MDMA being rescheduled to Schedule 8 of the Poisons Standard, for the following reasons; There is still a significant need for innovation and new treatments for PTSD in Australia. MDMA assisted psychotherapy is such a treatment and one that I am keen to add to my therapeutic repertoire, as high remission are rates being achieved for people having access to these therapies in overseas trials. MDMA has been shown to be safe and non-addictive when used in a medically controlled environment and MDMA assisted psychotherapy only requires two to three sessions with the MDMA in contrast to pharmaceuticals like anti-depressants which often require lifelong administration. When used properly, MDMA has minimal adverse side effects.

MDMA assisted psychotherapy is not long-term therapy and avoids the high cost and long-term commitment to the therapeutic process of some other modes of therapy." – Eoin Wilson, Consultant Psychiatrist

- 27. "MDMA-assisted psychotherapy, in contrast, is effective, with two thirds of recipients in a recent phase two clinical trial no longer meeting the criteria for a PTSD diagnosis. Remarkably, these benefits are long-lasting, persisting 12 months after only two to three sessions of treatment. MDMA is novel in mechanism, allowing victims of trauma to safely work through their experiences with in a therapeutic setting without being paralysed by fear and shame. This is a potentially field-changing treatment, enhancing the potential of PTSD psychotherapy. Most importantly, MDMA-assisted psychotherapy is safe, with few recorded serious adverse effects when administered in controlled settings. Instances of abuse, addiction, diversion and physical harm are extremely rare. Already, MDMA-assisted psychotherapy has been awarded breakthrough therapy designation by the Food and Drug Administration in the United States, fast-tracking it through the US regulatory process." Jesse Schnall Junior Medical Doctor
- 28. "Our field continues to search for more effective treatments which are safe and which could be accessed by the large segment of our community who struggle with mental illness. There have been no significant advances or new approaches to the treatment of mental illness for many decades. New antidepressants and psychotropics are released on a regular basis, however none has been shown to be more effective than older drugs already available. Psychedelic-assisted psychotherapy is a completely new approach to treating mental illness which is currently undergoing an explosion of interest and research around the world. The available studies to date suggest that this treatment is very safe and also highly effective, promising substantially higher response rates than any existing treatments. These medicines appear to be rapidly effective, requiring only 2-3 doses to achieve remission in up to 70% of patients. They have also been shown to be extremely safe and non-addictive when used in a medically controlled environment." Dr Roberto D'Angelo, Psychiatrist and Psychoanalysis
- 29. "I am a doctor that has only been working in the health industry for a short time. Yet even in this short time I have seen the tremendous toll that mental health has on individuals, families, society and on the hospital system. I have seen and dealt with many patients who have been tried on multitude of compounds for their depressive disorders, each compound with its benefits and side effects. Some have been successful in managing their illness, but many more, not so successful. It is for the thousands of our fellow brothers and sisters, parents and grandparents, patients and doctors alike, that we deserve to give them a fighting chance of living a peaceful life, a life free from mental illness the granting of this proposal is a small but an important step in achieving that." Dr Harsumeet Sandhu, Junior Medical Officer

- 30. MDMA appears to have a unique mechanism of action, which makes it particularly valuable for PTSD and it is strongly suspected that it may equally valuable for other anxiety disorders such obsessive-compulsive disorder (OCD) and social anxiety disorder. For the treatment of war veterans for example, or Australians who have experienced natural disasters or domestic violence, the evidence points to MDMA-assisted psychotherapy being a particularly efficacious treatment: indeed it appears that MDMA-assisted psychotherapy it may be rather more efficacious than existing treatments. Furthermore, the fact that MDMA now has "breakthrough therapy designation" with the FDA in the United States and has moved on to Phase 3 trials attests to its treatment potential." James Bennet, Clinical Psychologist
- 31. "The recommended medical treatments for people suffering from PTSD show a 20-30% response and only 50% of people respond to any treatment (medications and talking therapies) but with very low rates of remission. This is in contrast to the research results from studies using MDMA in a therapeutic milieu where as few as 3 treatment sessions with the medication can successfully treat between 60-80% of suffers to the point that they no longer meet the criteria for the diagnosis. When calculating the risks and benefits of reclassifying MDMA from a Schedule 9 prohibited substance to a Schedule 8 controlled substance the evidence from the research is clear that when used in a regulated and systematic way, it has a wonderful potential to benefit those people who have had no success in using all the available treatments and continue to experience profound suffering day to day from mental illness." Anthony Kelly, Credentialed Mental Health Nurse
- 32. "Over the years in my practice I have worked with several clients who on their own volition sought out MDMA medicine as they had heard about the promising transformation possible. Having worked with these particular clients prior to them seeking out the MDMA medicine and then working with them after the event to support their integration of the experience, I can confidently say that the transformation I have witnessed in my client's mental health state was remarkable: changes I would normally only expect after a much greater duration of psychotherapy. It was as though the non-ordinary state accessed through the MDMA gave rise to a new and expansive perspective within the client thus restoring hope, possibility and a greater capacity to work with the new information gained Witnessing my clients overcome the anxiety, depression and trauma they were experiencing, as well as following the global research in Psychedelic medicines for treatment of mental health, has convinced me of the importance for ongoing research to continue and greater access to the MDMA medicine within a safe clinical setting made available. I am heartened by the positive outcomes of the trials worldwide that have shown the efficacy and curative nature of MDMA medicine. Most important to me, is that MDMA is non-toxic, non-addictive and often effective after only 2 to 3 doses in conjunction with psychotherapy.."- Jeorge Chambers, university-trained counsellor, psychotherapist, art therapist
- 33. "As a psychologist of 16 years treating people for a range of clinical conditions, I am compelled to support these proposed amendments. My work has involved many

years of supporting recovery for people diagnosed with PTSD and with depression. In that time we have not seen any significant new developments in the mental health field. The research in MDMA-assisted psychotherapy for PTSD and psilocybin-assisted therapy for depression is showing very promising treatment outcomes. The novel aspects of these research outcomes show that: In the case of PTSD, full remission from very long-term treatment resistant PTSD is not only possible but statistically likely with the help of MDMA as an adjunct medicine to a therapeutic intervention and the treatment process for each is economical, with 2-3 medicine assisted sessions combined with some pre-preparation and post-integration sessions. This is much more cost effective and compassionate than years of daily medication use and/or psychological therapy, with poorer outcomes." — Mark Baxter, psychologist

RESEARCHERS

- 1. "The scientific journal Addictions reports the toxicity of psilocybin and magic mushrooms to be very low [2]. The lethal dose of psilocybin is extrapolated to 6g in humans. This is 300x the typical therapeutic dose of 20mg. Just imagine consuming 300x the usual cup of coffee, dose of Panadol, pint of beer, or even a daily multivitamin." Victor Chiruta
- 2. "A review on the harm potential of psilocybin-containing magic mushrooms published in the scientific journal Regulatory Toxicology and Pharmacology, found only two deaths due to direct overdosing internationally since 1960 [5]. For comparison, the Australian Bureau of Statistics (ABS) reported 276 deaths from antidepressants and 663 deaths from anti-anxiety medication during 2016 in Australia alone [6]." Victor Chiruta
- 3. "Current controlled medicines buprenorphine, methadone, fentanyl, cannabis, ketamine, amphetamine; prescription medicines anabolic steroids, benzodiazepines; and unscheduled drugs tobacco and alcohol, all ranked as causing more harm to the user and more harm to others when compared to psilocybin-containing magic mushrooms." Victor Chiruta
- 4. "Now we're seeing the emergence of a completely new way of tackling this deepening crisis that is showing remarkable results globally with remissions up to 80% in 120 current and recent trials after just 2-3 medicinal doses of psilocybin or MDMA combined with psychotherapy. And we are seeing increasing remissions up to a year after these treatments as evidenced in the MAPS Phase 2 trials supervised by the FDA." Tania de Jong
- 5. "The TGA can note that psilocybin is already being used by medical practitioners as part of expanded access schemes in the United States, Switzerland and Israel and that psilocybin assisted therapy for end of life distress and anxiety has been approved on a case by case basis in Canada." Prof Rob Moodie
- 6. "There is a broad range of studies highlighting the efficacy of psilocybin-assisted psychotherapy for the treatment of a range of conditions, some of which I have, such as treatment-resistant depression, obsessive-compulsive disorder (OCD), and anxiety disorder" Emsee
- 7. "Psilocybin is considered safe, non-toxic, and non-addictive (Ross et al., 2016). There has been no evidence of any physiological harm in animal, clinical, or epidemiological studies (Johnson, 2008). Two large-scale studies have found that psilocybin use may reduce the risks of serious mental health disorders or suicidality (Hendricks et al., 2018). The risks often associated with psilocybin use occur with polydrug use and disorientation resulting in physical injuries and are significantly diminished in controlled medical settings. In a controlled setting with thorough screening, I believe psilocybin has great potential in combatting the mental health crisis and reducing recidivism in Australian correctional centres. As a therapist providing psychological-based rehabilitation and reintegration programs for incarcerated adult men, I have

- seen the impacts of mental health disorders on substance abuse, criminogenic behaviours, and reoffending." Lloyd Riman
- 8. "Research shows that when medically supervised Psilocybin-assisted therapy is properly administrated by registered healthcare professionals to appropriately screened patients diagnosed with clinical depression in a controlled medical environment, such treatment is invariably safe (and perhaps safer than traditional treatment options for patients with medication resistant depression)." Lana Lubimoff
- 9. "Psychedelic experiences are a curious phenomena, the nature being that of a mystical or spiritual encounter that is often described as a realisation of oneness and connectedness to the world, resulting in lasting feelings of compassion towards one self and others as well as the predominant emotion of self-love (Watts et al. 2017). These experiences are usually accompanied by hallucinations that seem to reflect a visual representation of the subconscious mind, allowing access to parts of the mind that we might have never got the opportunity to explore overwise. This type of experience opens the door for a temporary dissolution of the ego." Karina Foster
- 10. "If further clinical research indicates that these results are typical we may be able to change the current paradigm of how we treat consumers experiencing mental distress, especially depression. We may go from treating people in an acute setting where they need frequent monitoring for side effects to a more community based setting where people have access to psilocybin therapy sessions as required, say one session every 5 weeks or so. To get to this place, psilocybin needs to lose it's 'scary illegal drug' stigma and be seen as the helpful substance that it is. The first step towards that happening is rescheduling." Justin Somerville
- 11. "Studies such as, The Australian Drugs Harms Ranking Study (Nutt D et al.), have shown alcohol, a legal drug, to be one of the most destructive drugs to self and others. Psilocybin has been shown to be at the opposite end of the spectrum causing minimal harm to self and others. The potential benefits of re-scheduling psilocybin clearly outweighs the risks. The rescheduling of psilocybin to schedule 8 means it is would not be freely available and it's prescription and use would be highly regulated. It would provide access to researchers and people living with psychiatric illnesses a safer and more efficient alternative to the current treatments available. Being under schedule 8 regulations and embedded within a structured therapeutic program reduces the abuse potential of the medicine." Elspeth Watson
- 12. "The evidence from trials conducted at universities around the world is very compelling. MDMA has been shown to significantly reduce PTSD which is incredible given there is little to no other options for PTSD sufferers. I believe that for survivors of trauma, be it war veterans, rape or sexual abuse victims, witnesses to horrific accidents or murders or any other form of severe trauma, this medicine could be absolutely life saving. Given the safety and non addictive nature of MDMA when taken in a clinically controlled setting, it is devastating that this medicine isn't already accessible to people experiencing such deep suffering, trauma and debilitating mental health issues." Annie Davies

PATIENTS

- 1. "I found some powdered mushrooms and began to take them progressively over the evening, amounting to a reasonably large dose, in the research of hindsight. I not only enjoyed myself immensely, laughing more than I had done in years, but as if by magic, for the next week I was a new person. Or rather, my old self. The depression had disappeared and was replaced with a zest for life, enthusiasm for socialising and a general appreciation of the world in which we live. There was also a resilience instilled in my psyche where I was able to better navigate stressful situations and have a quicker recalibration time after such issues were addressed." William Hancock patient with lived experience
- 2. "Being born Jewish and having lost many of my relatives in the Holocaust, I've lived with inter generational trauma for as long as I can remember. I was never really aware of what exactly was holding me back until I experienced supervised psilocybin treatments in the Netherlands. Since then I have been able to release and heal much of this trauma and also washed away lifetimes of collective trauma that we all carry along with us. I feel a deeper sense of identity, greater insight, compassion and connection. This has helped me to be more authentic and vulnerable in my relationships and has improved my productivity and creativity. It's like all these missing parts of myself have been found. I am more integrated and much calmer." Tania de Jong Founder of MMA and lived experience
- 3. "Thank you for accepting my thoughts and experiences. If it wasn't for psilocybin medicine, used therapeutical in the United States I would be still stuck taking painful depression medication will woeful side effects, and can now be present and conscious and authentically loving to my grandchildren what a gift. And I've had no cravings at all, as it is totally non addictive, it's been 18 months since I had the medicine and I'm still feeling terrific." Tom Maher lived experience
- 4. "In my case, conventional treatments over a number of years have resulted in a greatly reduced quality of life and long-term dependence on prescription medication, as well as significant monetary costs and damage to my professional carrier, all without resolving the health conditions that have led to such treatments. Over the last two years I desperately explored alternatives to the conventional treatments and have identified psylocibin as the most promising medication for my condition." Terry Catipovski patient lived experience
- 5. "I was never really aware of what exactly was holding me back until I experienced supervised psilocybin treatments in the Netherlands. Since then I have been able to release and heal much of this trauma and also washed away lifetimes of collective trauma that we all carry along with us. I feel a deeper sense of identity, greater insight, compassion and connection. This has helped me to be more authentic and vulnerable in my relationships and has improved my productivity and creativity. It's like all these missing parts of myself have been found. I am more integrated and much calmer." Tania de Jong Founder of MMA and lived experience

- 6. "I have experienced first-hand the side effects and addictive qualities of currently available SSRI and Benzodiazepines which were prescribed to me from a very young age. These medications require long term use and once stopped; the symptoms always return. On the other hand, Psilocybin is a non-addictive substance and in fact, can help facilitate remission for people with alcohol and tobacco addiction (Burdick & amp; Adinoff 2013, p. 291). Psilocybin requires minimal sessions with a trained psychiatrist and has shown to have lasting effects after the treatment has concluded (Hendricks et al. 2015, p. 282), opposed to a potential lifetime taking SSRIs. Psilocybin had been shown to be safe, non-toxic, and anti-addictive (Passie, 2008)". Phoebe Morwood Mental health Practitioner
- 7. "I have had my own personal struggle with treatment-resistant depression for over two years and have experienced firsthand the displeasure of trialling twelve currently approved treatments, many of which have worsened my condition in the form of extra pyramidal side effects, kidney damage and cognitive impairment. I can only dream of what my life could have looked like if psilocybin was approved when I was in dire need of life-saving treatment." Dr Nicola Santarossa General Practitioner
- 8. "I have been seeking counselling assistance with dealing with childhood trauma (I lost my father when I was 15) and also have been going through a marriage breakup. While counselling services have been positive, they do not delve deep enough to address these issues that are having an affect on my ongoing mental health. Counselling has been a useful stopgap however unresolved issues still remain and seem to be out of reach of these conventional approaches. I have also been, thankfully, able to avoid major pharmaceutical intervention as I firmly do not believe that these lead to positive outcomes and can lead to lifetime dependency." Dr Davin Doloswala General Practitioner with lived experience
- 9. "Five years ago one of my close friends, Matthew Stutsel (a successful former KPMG and Freehills partner), killed himself as a result of mental illness. He went off his medication. I wonder if he would still be alive today if his mental illness was treated with psilocybin or MDMA." Mono Ray Businessman with lived experience
- 10. "My childhood abuse was re-triggered into PTSD in mid-2013 when 6 months of workplace bullying culminated in me having to leave my last job. Since then, my PTSD symptoms have gotten gradually worse, with impaired cognitive function, increasingly volatile emotional dysregulation and sleeplessness from triggering thoughts and memories, physical endurance and energy limits, severed relationships, fear, anger, hopelessness, anxiety, depression, and suicidal ideation." Emsee Patient
- 11. "Approximately 10 years ago, I suddenly remembered and realised the truth about my childhood. As I recognised it's devastating impact on my life, and grieved for the life I might have had, I made myself a promise. I promised God and myself that I would only kill myself after I had tried everything to heal. I'm still trying." Emsee Patient with lived experience

- 12. "There are so many of us suffering in silence, thrown away by society. I think it is unacceptable that people like me who for 50 years have been through so much cannot access a treatment that can place it in remission. Overseas trails report high remission rates. If I had money I could travel overseas for this life changing therapy but unfortunately, I do not. Instead, I am forced to endure an unbearable existence because of all the abuse emotional, physical and sexual that I have suffered throughout my life. Despite three university qualifications, I am now an unemployable isolated recluse and my health continues to decline. If I cannot heal, I know I am tracking toward homelessness where more horror awaits." Lucy Keating Patient
- 13. "I want to work. I exercise, I don't drink or smoke and eat well and have read many "Self- Help" books but it has not been enough. Unfortunately, Affirmations, writing, singing, drawing and all the self-care practices I have tried have not healed me. Nor have the professional resources I purchased from overseas. If I was healthier, I would be able to continue to house myself and not need to access a Centrelink allowance. My situation is all the more dire because I do not have family to provide support. There is no other option left for me. This is literally a matter of life and death for me." Lucy Keating Patient with lived experience
- 14. "My recent medical treatment from the current SSRI antidepressants and anti anxiety medications (benzodiazapines) available completely incapacitated my ability to function normally both mentally and physically. Four years of treatment led to a much worse condition. Heavily addicted, weening off benzodiazapines (clonozepam) (40mg daily) for five months and then having to detox for the following 20 months, was the most excruciating, unrelenting physical and mental pain I have or will ever endure. The mental, physical and emotional traumatic suffering felt every single minute during this period is absolutely ineffable to describe. My body continues to feel to the tortuous side effects these drugs had on me to this very day. The current treatment provided by our health system, I believe diminished my condition considerably and ultimately failed me." Joe Cooper Patient
- 15. "On a trip to Mexico years ago, I was put in touch with a sharman who faciliated a personal high dose psilocybin therapy session to specifically treat internal tumoil and subconciously repressed childhood trauma. The parameters surrounding this session represented the classic 'set and setting' model. It was a safe, comfortable, warm enviroment, complete with eyeshades, specific native music, a trusted healer and the ancient wise elders, the mushrooms containing psilocybin. During that single, eight hour high dose session, I was able to internally confront, process and resolve deep seated very specific childhood trauma. I was also able to internally identify the major events, short comings and causes over my life that have contributed to developing such damaging mental afflictions. Having this type of immeidate insight allowed me to correct negative behavior and empowered me to the point that I realised I am so much more powerful than the sum of what happened to me. I have never felt such an appreciation of not only being alive but to realise I'm an integral part of everything that has ever existed in this universe. The overwhelming feeling of the deepest sense of the worlds love, the undeniable connection to nature, my spirit, my deceased

family members, was purely exhilarating beyond human comprehension." – Joe Cooper - Patient with lived experience

16. "In 2002, at the age of 23 I went from being a functioning, happy & Depth Street, and the world and how it works overnight. Since that day I have been living in solitary confinement within my own mind. It's relentless mental torture without a break. Countless medications, Psychiatrists, and Monash trials of Ketamine and TMS, have had no effect. Until now.

Earlier this year I was given mushrooms to try and assist. Not clinically, but through a friend who heard of the benefits for depression. Before becoming depressed, I had never taken drugs, never smoked and never even had alcohol. I was hesitant about psychedelics because the thought of tripping' never appealed to me. But I swallowed 2 grams.

- a. WOW!!! WOW!! and WOW!!!!
- b. Within in an hour I completely came back into existence. I felt connected again to my body and mind. I was no longer a walking corpse but instead was re-discovering freedom again. It was the experience of being able to see, to smell, to taste and hear the world in the way it should be. The calmness within my soul combined with the electricity of life felt enormous in comprehension. My brain was functioning normally again for the first time in 18 years." Jerry Gigez Patient with lived experience
- 17. "I have interest in this issue because through my own journey I was looking for a holistic, alternative to the mainstream medical path and seeking a spiritual path due to the type of Depression I had. To set it free I had to have a change in mindset and seek out a journey of personal growth. I believe the Depression that I was treated for was based on the theory that every type of depression is treated the same. I am a highly sensitive, deep thinker/feeler, and unusually perceptive, and believe what I had was existential depression that was not diagnosed. I had to turn to other people's opinions and experiences to gain an insight into the type of depression I was dealing with." Jenny Davidson Patient with lived experience
- 18. "Since that first encounter with psilocybin I have used it alone in a private settings, after careful self preparation, and with a strong purpose of self-examination. As a classical musician, one is performing on an unprecedentedly high level year after year, demanding a degree of physical and mental skill and focus that is expected only of elite athletes albeit in their cases the career span is much shorter. The rigour of this life very regularly leads to self-doubt, severe performance anxiety, burn-out and self-harm. I have encountered many colleagues resorting to heavy abuse of substances such as alcohol and nicotine in fact I would say this is even normalised behaviour. The heavy physical, mental and emotional toll of these substances on the user, their families and ultimately on musical careers cannot be under-estimated. However, these harmful, strongly habit-forming products are legal and readily available, whereas psilocybin, a non-toxic and non-addictive substance, has been demonised in Australia since the 1970s, for reasons far more to do with politics and stigma imported from the U.S. Additionally "magic mushrooms", as they used to be

- sold in the Netherlands, received unfairly bad press after several tourist deaths." Jane Gower classical musician patient
- 19. "Since the age of 15 Kate has seen a series of psychiatrists, in close consultation with her GP, and been prescribed a range of SSRI/SRNI anti-depressants and other adjunct drugs such as Topiramate, Epilim, Seroquel and Valium to manage her mental health. She has undergone psychotherapy, CBT and DBT with a number of psychologists and other therapists and Transcranial Magnetic Stimulation (TMS) as an inpatient at a Sydney private hospital. Kate has had three multi-week hospital admissions to treat extreme periods of depression and three times over the years she has attempted suicide, twice resulting in acute hospital admissions and once in transportation to ICU by ambulance." Guy Freeland patient with lived experience
- 20. "My daughter is only 16 and between her age and the age of my 22 you eldest we have too many stories of suicide and severe mental illness. This tragedy is becoming more than an epidermic and we know that it is spiralling out of control. I am experiencing myself the great difficulties of accessing medical support and appropriate care for my daughter. I am an educated and well-resourced individual and can only imagine how dreadful the situation is for many people in a far less advantageous situation than I am. And I am struggling badly. I have seen the extent of the medical support available to my mother over the years and to my daughter over the past four years and the thought of us only being able to rely on the current medication available is extremely frightening. There is a desperate need for innovation and expansion of the available treatment for mental illness in Australia." Bridget O'Hare patient in support of family member
- 21. "On a more personal level, I suffered severe clinical depression and suicidality in 2011. I sought out a GP and was prescribed an anti-depressant, but it did not assist me or improve my situation, and shortly after I almost took my own life. Having gained the experience and knowledge I have now, I wish I had been given the opportunity to have psilocybin assisted therapy to help me through my depression. I am lucky, I survived, many others will not if we do not act, this therapy can save lives and there is no real reason, besides historical impacts on society, to not legalise these therapies now. If we do not, many people will continue to suffer or die." Bavly Nasralla Pharmacist lived expereince
- 22. "As someone who suffers from mental health issues, it pains me greatly to see the rest of the world moving forward, while Australia lags behind yet again. I am forced to suffer while reading about the near miraculous effects of these substances for other people in my position." Alexander Murdoch patient
- 23. "I have suffered depression since early childhood and I am now 64. I live alone, divorced and have almost no family contact. My most recent relationship was over 10 years ago. Increasing rates of depression and anxiety must be having a debilitating effect on productivity in this country. Easing restrictions on psychedelics for therapeutic use may address that problem. I would like to think my final years can be

- more bearable. There is a history of depression in my family, including my mother who committed suicide in 1985. She went through the full gammit of treatments including ECT (shock treatment)." Geoff Harrison patient with lived experience
- 24. "I live in Townsville and have numerous mates who served in the Australia Army and who now either hold Department of Veterans Affairs gold cards or are classified totally and permanently incapacitated either wholly or significantly due to psychological trauma during their service. In point of fact there are 2 individuals that if I do not hear from them for a couple of weeks, I become deeply concerned that they have found the struggle too much to bear like so many of their contemporaries. I see the quality of life they have with their existing psychiatric treatments, the weight gain, being numbed out of their brain, trying this one and that one often in the vain hope of finding an effective treatment. These men were formerly fit and capable men with purpose in their lives and a desire to serve. They do not have quality of life, they in fact barely exist. Given the efficacy that has been established I cannot help but think that these friends of mine that I care deeply for may have vastly different lives were they able to access treatment with MDMA. Potentially regaining a level of quality to their lives free from an ongoing need for overwhelmingly ineffective medication and their terrible side-effects." – Glenn Lynch - patient with lived experience
- 25. "My partner experienced her trauma prior to our partnership forming however throughout our time together I have witnessed consistent, proactive, sustained and dogged efforts by my partner to heal her trauma though various, currently "standard" methodologies and medicines. These being; Eye Movement Desensitization and Reprocessing (EMDR), Cognitive Behavioural Therapy (CBT), Antidepressants, & Antipsychotics. Whilst there is sometimes small positive changes to my partners C-PTSD symptoms with the above treatments, the overriding and overwhelming feedback from my partner (and from myself observing and living alongside her) is that the above psychotherapy treatments are extremely triggering for her, this then places her into overwhelm/dissociation and makes her feel retraumatised. The net sum effect of this process is a reduced desire to continue with these therapies as it makes her feel as if she is reliving her trauma's with each new "treatment" and places her on a terrifying "hamster wheel" of wanting healing but having to re-live the trauma again and again. I strongly pledge my support behind the rescheduling of MDMA to Schedule 8 and hope that the timeline to do so is expedited so as to give people like my partner (and many others Australia wide) an opportunity at accessing easily and cost effectively another tool in the fight to heal Complex PTSD." – Henry Ledingham - in support of partner with lived experience
- 26. "My life is agonising. Despite proactively seeking help to treat my Complex Post Traumatic Stress Disorder, I have been unable to find the help I need. I have spent decades and decades reaching out. Yet again, two separate GPS in Private Practice recently advised me that Mental Health Referrals are "Closed" and a unicorn easier find than a Therapist skilled in C-PSTD. I remain shocked at how inadequate these professions are in dealing with people like me. From my constant search for tools to heal, I am aware of huge breakthrough treatments that Psilocybin and MDMA

provide with just a few treatments. Sufferers like me desperately need to be able to access such therapies in Australia. In fact, so called "Talk Therapy' re traumatised me and made me infinitely worse and left me coping with the fall out alone and even more damaged. Nor did prescribed medication help. Yet an effective and non-addictive option is available. We should be able to access it. My situation is all the more dire because I do not have family to provide support. There is no other option left for me. This is literally a matter of life and death for me." – Lucy Keating - patient with lived experience

- 27. "Within my extended family, I have four young people suffering from chronic mental health issues for the last fifteen years- two in Australia and two abroad- and all of them are outstandingly intelligent professionals. I am only presenting to you my personal story of an unending search for an effective treatment. I state this with great disappointment that the government regulations responsible for denying an existing effective treatment that is available and could improve the mental health of millions of Australians, restore quality of life of many millions, reduce billions of dollars of economic cost, and save many lives who feel suicidal and unfortunately many end up ending their lives." Mohinder Gulati in support of family with lived experience
- 28. "I am a 56-year old woman with treatment-resistant chronic Complex PTSD. I've had symptoms all my life. These health issues can be traced to the bullying I endured from my brother between the ages of 5 to 18 years. Verbal, emotional, physical, spiritual and social abuse were the background of daily life for me. My parents minimised it, and dismissed my complaints by criticising my perspective and feelings. As a result, I have not met the academic and career potential that my 130+ IQ would indicate. I have not felt worthy of a good love partner, nor capable enough to have children. So I have been mostly single, and childless. Approximately 10 years ago, I suddenly remembered and realised the truth about my childhood. As I recognised it's devastating impact on my life, and grieved for the life I might have had, I made myself a promise. I promised God and myself that I would only kill myself after I had tried everything to heal. I'm still trying. The only comfort I have when faced with the realistic fear that I may never heal well enough to earn a decent living and have fulfilling relationships, is that I can end my life whenever I want. When my money runs out, when all hope of healing is gone, and my life becomes unbearable, there will be no other option. But what a cruel waste of talent. I might have been a research psychologist, contributing to the greater good while expressing my values and abilities in meaningful work. imagine Australia's social fabric and economy if most of the Australians who've been abused could heal, and so work, relate, and contribute constructively to our nation's overall well-being! Imagine how Australia could benefit if the sensitive, intuitive, talented, intelligent people who were bullied for being different, were healed and operating close to their potential! PLEASE reschedule MDMA to Schedule 8 of the Poisons Standard, so I and other Australians have a better chance to heal from our trauma." – Anonymous - lived experience
- 29. "I have a condition known as PTSD and from what I have been told and researched, it is in the severe end of the spectrum. It manifests as severely resistant depression,

chronic anxiety and panic attacks and has sculpted my life since the traumatic period in my childhood. After trying several different types of prescription medication to no avail, I began researching other types of ways to manage my overwhelming sadness with life. A lot of the stimulus with finding a solution to my problems lay with an underlying option of seriously considering suicide. After a friend took her own life due to similar symptoms, I began to research my own case in earnest, in the hope that I would not only fix myself, but find a way to help others out of a similar predicament. It is a travesty that our civilisation has the technological advancements and developments that we do, and yet continues to lose lives to suicide while potentially having the solutions scheduled at a level that are inaccessible to patients in need. The last great frontier is not space, but our minds. Inner peace, not outer space is where the human race will find its solutions. I have been in therapy with my psychologist on and off for nearly twenty years. We have worked through many different aspects of my case. I have come to understand that for me to heal my mental state, I needed to address what happened as a child, rather than push it away, as I did as an eight year old. The problem lies in the retraumatisation of my mental state through the addressing of the issues. This can potentially lead to creating more problems, not resolving them. I read about how MDMA can act as a buffer zone in these situations and, if used in a controlled and supervised environment with a qualified individual in conjunction with Cognitive Behavioural Therapy can make relatively comfortable inroads into the issue and assist greatly, if not making it entirely possible, in resolving them. I had come up against a wall in my developmental inner work with a particularly difficult situation from my childhood. I was stuck and looking for solutions. After researching the use of MDMA in conjunction with CBT as best I could, given limited resources and restrictions to information, I was at a loss. And so, feeling like a criminal, I found some MDMA and a Cognitive Behavioural Therapist and proceeded to initiate one session with this medicine. I can affirm that even one session in this environment was a great success, in that it allowed me to look at the trauma objectively and begin to work with it on a level that afforded me some respite and still allowed me to confront the issues involved. I only had one session like this. I feel like a couple more would do the trick to healing this particular issue and allowing me greater freedom and personal happiness. Unfortunately I could not continue, due to legal, supply and support issues. I feel I would benefit greatly from two or three more similar sessions in a framework that both supported and guided this healing, without leaving me feeling like a criminal and helpless as to where to go and how to do it. I wholeheartedly support the rescheduling of MDMA from schedule 8 to schedule 7 in that we may begin to work with this molecule in a controlled and safe environment while being able to vouch for the quality of the manufacturing and the knowledge of the dosage levels and potential negative side effects."- William Hancock - patient with lived experience

30. "I believe I would benefit greatly from a rescheduling of MDMA, as in my current state I am just bounced between ineffective and expensive anti- depressants, anti-anxiety medications, Benzodiazepines, and finally being told by doctors and therapists "Just breathe." "Just exercise." I am actively trying to get better, but I believe as long as I am restricted to the ineffective state of Australian mental health care, I will be forced to live like this." — Alexander Murdoch - lived experience

OTHER

- "Mental health statistics in Australia and globally support the proposition that current treatments are woefully inadequate. There has been no effective innovation, no effective alternatives developed for many decades in regard to anti-depressants and PTSD. The pharmaceutical industry vacated the innovation space long ago." – Andrew Robb, Chairman of the Robb Group
- 2. "The benefits are for people with treatment resistant PTSD- including first responders, war veterans and people who have experienced extensive trauma, including sexual, in childhood. PTSD is typically a chronic illness with high rates of psychiatric and medical comorbidity, disability, suffering, drug abuse and suicide. Existing treatment for PTSD include both psychotherapies and pharmacotherapy. Medications have some, but limited efficacy. Psychotherapy, including cognitive behavioural therapy, (particular prolonged exposure and cognitive processing therapy), Eye Movement Sensitisation and Reprocessing (EMDR) and psychodynamic therapy, are expensive and difficult to access in the community. Not all psychologists and psychiatrists are trained to deliver treatment for complex trauma, and the therapies are lengthy and time consuming, falling out of reach of access for the many people who can only afford 10 or so sessions under a Mental Health Care Plan. In addition, there is the risk of re-traumatising patients, when they recall painful, shameful and long avoided memories of trauma." Justine Thompson
- 3. "Mental health treatment in Australia is in a critical state. A large portion of the population either has struggled with or will experience a chronic mental illness in their life. If not them, someone close to them will. People are having their lives wasted by remaining stuck in self- defeating and destructive psychological states and through a burden of unnecessary suffering (potentially to the point of suicide). Economically, the annual cost to the country of all of this is estimated at \$180 billion. Current treatment is barely adequate. It is usually either lengthy and expensive therapy, and/or pharmaceuticals that are often not much more effective than a placebo, require lifelong dependence, and produce horrible side- effects. We are in desperate need of treatment that is safe, affordable and works and we already have it but cannot access it." Luke McInerney, psychology student
- 4. "Currently, Israel's Ministry of Health has approved using MDMA to treat patients suffering from PTSD in four Israeli hospitals. Over 10 percent of the Israeli population experiences PTSD. The results are promising. Of the 105 people who have taken MDMA in a clinical setting so far, 68% report they are not suffering from PTSD 12 months after their therapy ended. We believe that the growing body of science is providing significant and substantive indications as to the efficacy to both MDMA and psilocybin as modalities for the treatment of PTSD and mental trauma. The growing number of Australians struggling with mental health issues and specifically with trauma related mental health challenges deserve to know that mental health clinicians in Australia have ready access to MDMA and psilocybin for patient treatment." Ronald Samuel Finkel, President of Hadssah Charity Limited (HCL)

- 5. "Rescheduling psilocybin will more successfully enable its research by removing excessive cost and regulatory barriers associated with a schedule 9 designation." Thomas Zane Velican
- 6. "We know that they can heal hundreds of millions of people suffering with mental illnesses globally when provided in supervised settings with trained practitioners." Tania de Jong Founder of MMA
- 7. "We owe it to the unbearable suffering, wherever it is found, to set aside any preconceptions and stigma and bring an open mind to the approaches that work. We have lost 50 years of progress due to the political and non-scientific censorship of these medicines. Our society and humanity cannot afford to wait any longer." Tania de Jong Founder of MMA
- 8. "It is for the thousands of our fellow brothers and sisters, parents and grandparents, patients and doctors alike, that we deserve to give them a fighting chance of living a peaceful life, a life free from mental illness the granting of this proposal is a small but an important step in achieving that." Harsumeet Sandhu
- 9. "Psilocybin has been shown to be safe and non-addictive when used in a medically controlled environment and achieves high remission rates for people having access to it in overseas trials." Rob Moodie professor
- 10. "As rates of depression and anxiety continue to increase in Australia, medical professionals and the general public both recognise an urgent need for more effective methods of treatment. Mental illness burdens our economy and impinges on the broader functioning of society." Oliver Zambon
- 11. "People with mental health issues come from all walks of life. Untreatable post-traumatic stress disorders ("PTSD"), untreatable depression and conditions like alcohol addiction may affect, first responders, the terminally ill or, our service men and women. They could be doctors, nurses, health workers, blue or white-collar workers, mums and dads, the ordinary person or the billionaire. The point is, like COVID 19, mental health illness does not discriminate." Mono Ray
- 12. "My interest is only to have it available for the members of my extended family under medical supervision and I shall bear all the costs which would be insignificant compared to 15 years of lost potential of these wonderful and intelligent young professionals." Mohinder Gulati on behalf of family members
- 13. "Substances classed as schedule 9 are described as being 'of no therapeutic benefit, highly dangerous, and highly addictive'. Not only does psilocybin not have these characteristics; it actually has the complete opposite qualities. When administered appropriately, it is of profoundly therapeutic benefit, non-toxic, and physiologically incapable of being addictive." Luke McInerney psychology student

- 14. "Too often have I heard and seen stories about people trying to get the help they desperately need and want and being discouraged at the last step because of the daunting and overwhelming commitment long term therapy can bring, with financial and time management stresses that would make it next to impossible for many to commit for an extended period of time. If we can make this process not only shorter and more palatable but also more accessible for those who really need it, I can only see it as a benefit for us as a Nation." Luke Beauchamp lived experience
- 15. "The before mentioned application, combined with other evidence, clearly demonstrates that there is a real and urgent need (especially now in the Sars-Cov-2 environment) for new medicines, such as psylocibin, to undergo further clinical evaluation for a range of conditions. These conditions include severe depression (including end of life depression and anxiety), treatment-resistant depression, anxiety disorders, addiction, anorexia nervosa, body-dysmorphic disorder, cluster and migraine headaches, OCD (obsessive compulsive disorder). All of which, in controlled environments with controlled therapy including psilocybin, have been shown to be beneficial to the extent of remission with an acceptable risk profile. With regards to risk profile, the use of psilocybin to date within Australia (utilising the Special Access Scheme) and overseas demonstrates a satisfactory risk-benefit profile with an acceptable toxicology profile at the proposed doses provided by MMA in their submission." Karl Herz pharmacist
- 16. "The Victorian mental health system is unable to cope with the demand for treatment and treatment options are limited. On a daily basis I work with people discharged, due to bed pressure and re-current hospital admissions. These are often due to compliance issues with medication or treatment resistance. When listening to people's stories, medication compliance is often related to the devastating side effects that impact their quality of life, such as weight gain, decreased libido, memory issues & amp; drowsiness. Patient's must be monitored during admission when medication changes are made due to serious side effects such as Serotonin Syndrome, Neuroleptic Malignant Syndrome (NMS) which affects blood pressure and heart rate as well as Extrapyramidal Side Effects (EPSE) the symptoms include muscle spasms (eye rolling, neck twisting, inability to swallow), pseudo-parkinsonism symptoms, inner restlessness and abnormal movements such as tongue protrusion, lip smacking and thrusting. I have worked with a number of patients with permanent hyperpigmentation, which turns their skin, a metallic blue colour and is irreversible." Elspeth Watson Clinical Social Worker
- 17. "Rescheduling will help reduce the stigma currently associated with psychedelics. For example, once the community understands their prohibition was not based on any scientific or medical rationale but was politically motivated by a disgraced President of the United States (President Nixon), then safe treatment paradigms will be accepted. The failure of our system to recognise that these substances can be used effectively as medicines in a medically controlled environment is detrimental to the

- 18. "Psychedelic substances like psilocybin have been made illegal and pilloried as being damaging to individuals and communities. Looking back at the context of history it appears there was an agenda to demonise these substances which eventually became the social consensus. This has shut a door on the potential benefits of use of these substances for the last 5 decades and excluded their use for people who are suffering debilitating mental illness" Anthony Kelly Registered nurse
- 19. "The results achieved for people accessing Psilocybin in overseas trials is extremely compelling, across a broad range of mental health issues. Research at Universities such as John Hopkins, Harvard and The University of California (amongst many others) show significant reductions in depression, distress, grief, anxiety, alcohol and tobacco dependency (to name a few) in clinical trials. Psilocybin is safe, non-addictive and only requires two to three sessions with a therapist (as opposed to other pharmaceutical medicines such as antidepressants which can lead to lifetime dependence), meaning we could be saving not only individuals, but also our health system (for example rehab centres, mental health clinics, suicide services) millions of dollars. And that doesn't even factor in the lives that we could be saving." Annie Davis
- 20. "The failure to draw a distinction between the recreational use of psilocybin and the medicinal use of the drug has resulted in over 50 lost years for sufferers of depression, 50 years during which this drug could have worked wonders for many people cursed with the disability of depression, given the remarkable results of clinical trials in recent years in the United States, the UK and Israel." Andrew Rob-Doctor and psychiatrist
- 21. "Given recent precedence with medicinal cannabis, in regard to legislative and regulatory influence, the decision for the TGA to reschedule CBD and THC has proven to be the lynchpin to state and territory policy consideration. Given the TGA's powerful and unique position to set the policy reform agenda across Australian jurisdictions, it is my hope that they will embrace their role in policy leadership and enable this new hope for mental healthcare in Australia." Thomas Zane Velican MMA team member
- 22. "I believe it can assist in weaning me off the SSRI antidepressant medication I have been taking for around 15 years. While the medication has served a purpose and has been great in helping to stabilize my mood and limiting the effects of my underlying depression, it is only covering up the problem and my ultimate goal is to be able to exist medication free. I have also noticed over the years that its effectiveness has waned." Timothy Young patient lived experience
- 23. "There have been no significant advances or new approaches to the treatment of mental illness for many decades. New antidepressants and psychotropics are released on a regular basis, however none has been shown to be more effective than older drugs already available." Dr Roberto D'Angelo psychiatrist

- 24. "Psychedelic-assisted psychotherapy promises to offer a superior treatment for these treatment-resistant individuals. It also promises to offer a rapid response and potential cure without the need for lifelong medication or psychological treatment which can often go on for many years. It offers these patients the potential to be relieved of the substantial personal suffering they experience, and a chance to rebuild their lives and careers." Dr Roberto D'Angelo psychiatrist
- 25. "The therapeutic use of psilocybin only requires two to three sessions under strict control in contrast to pharmacotherapies such as anti-depressants which can create lifetime dependence, with a host of attendant side effects, let alone the inordinate cost to the PBS." Rob Moodie professor
- 26. "Treatment is brief: only 2 to 3 dosed sessions are required, in contrast to a permanent or long-term use of pharmaceutical substances such as antidepressants. Psilocybin has minimal side effects, again in contrast to pharmaceuticals such as antidepressants." R Gerrand Psychiatrist
- 27. "Close to half of Australia's population will suffer a mental illness of some sort within their lifetime. The current pharmaceutical treatments available have poor efficacy and tolerability and come at great expense when taken for long periods of time which is necessary in an attempt to achieve the desired effect. The side effects are in numerous and not only impact the individual with impaired cognition which further affect the individual's capacity to work, but their relationships in the form of sexual dysfunction. Metabolic side effects are of grave concern and contribute to the burden of disease. These resulting physical illnesses, including Type 2 Diabetes, then place the individual at greater risk for heart attack and stroke. This then becomes a burden not just on the individual but on the entire healthcare system. In comparison, psilocybin when used under the proposed clinical conditions, has very few side effects and minimal long-term consequences." Dr Nicola Santarossa General Practitioner
- 28. "Additionally, many patients with severe treatment resistant depression or anxiety often end up on lifelong medications such as SSRI's or SNRIs that offer limited improvement and a range of significant side effects such as weight gain or loss of libido." Dr Mark Melek General practitioner
- 29. "On the other hand, Mainstream anti-depressants create a life-long dependency this proves that they don't fix the root of the problem, they simply repress it with terrible side-effects, unlike psilocybin where in almost all cases of controlled setting, negative side-effects subside by the end of the session, with patients stating that upon reflection, the confrontation to fear/anxiety was part of the healing process." Karina Foster -
- 30. "Antidepressants and antipsychotics, in combination with benzodiazepines, are the current options for psychiatrists when prescribing medication for acute mental distress. All of these medications have known side effects from mild things such as headaches, nausea, and dizziness, to more severe things such as metabolic changes

causing diabetes, cardiac complications, extrapyramidal side effects, addiction, increased suicidal ideation, and in some cases, death. The current system sees people initially taking medication for their mental distress. Over time they begin seeking help for their physical health which are often due to complications and side effects from the original prescribed medication." – Justin Somerville

- 31. "Many consumers are diligently taking their prescribed medications daily yet are still becoming acutely unwell. This shows that the current medications, while they may work for periods of time, do not 'cure' mental illness. They merely treat some of the symptoms some of the time. It is common practice for a psychiatrist to change a persons medication whilst they are in the inpatient unit as it has been deemed not to be effective or strong enough. The person is told that the new medication may take up to 6 weeks to make an improvement in their mood (in the case of antidepressants) and they will most likely be discharged long before those 6 weeks have elapsed. Often consumers stop taking medication before there are any positive changes in their mood due to unwanted or dangerous side effects, and their treatment regime is then changed to an alternate antidepressant. This leads to more time in hospital for monitoring and more time elapsing before they experience positive change." Justin Somerville psychiatris nurse
- 32. "I see the adverse effects of antidepressants (SSRIs, SNRIs) and stronger psychoactive medicines (especially the antipsychotics sometimes used in treatment resistant depression/anxiety/PTSD) on a daily basis hypertension, tachycardia, weight gain/metabolic syndrome, sexual dysfunction, excessive sweating and headaches being among the most common." Dr Jo Howe General Practitioner
- 33. "While counselling and psychotherapy has had positive outcomes for many, it often needs long-term commitment, necessitating multiple interventions which is expensive for both the individual and the community. Underfunding, under resourcing and limited sessions available to a person deems it inaccessible to many. The current medications that are widely prescribed such as anti-depressant medications have failed to give the change promised and with the considerable negative and dangerous side effects often being understated." Jeorge Chambers university-trained counsellor, psychotherapist, art therapist
- 34. "I am currently working in a remote Aboriginal Community where I have had to bear witness to the repercussions of suicide and serious mental health illness in people of all ages. I know these issues are not isolated to the area I am working in as I, myself have experienced mental illness and have seen many friends and family members suffer in the same way. The rate and severity of mental health issues in Australia only seems to be getting worse as the COVID-19 pandemic goes on." Phoebe Morwood Mental health practitioner