

Mind Medicine Australia's

Submission to The Royal Commission into Victoria's Mental Health System



MIND MEDICINE A U S T R A L I A

5th July 2019

"...My hope is that we will engage in mature, evidence-based discussions about how best to fund and deploy psychedelic-assisted psychotherapies to augment existing approaches to the treatment of mental illness. I hope that governments will have the courage to put the welfare of their citizens ahead of their fear of controversy – and that our politicians will deploy their considerable skills and positions of influence to nurture a balanced and objective understanding amongst the public."

– Dr Simon Longstaff AO, Leading Australian Ethicist
and Executive Director of The Ethics Centre



MIND MEDICINE
A U S T R A L I A

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5th July 2019

The Commissioners
The Royal Commission into Victoria's Mental Health System

Dear Commissioners

We live in one of the wealthiest countries and we have one of the best medical systems in the world. Yet despite the high calibre of our medical practitioners and institutions, and the enormous associated system costs, we also have one of the highest rates of mental illness in the world, and the situation appears to be getting worse. Simply doing more of the same, or making only incremental changes to the current system, is not going to solve this problem and relieve the suffering of so many Victorians.

To create positive change, we have to broaden the tools available to our medical practitioners and qualified therapists in this area.

Psychedelic-assisted treatments offer enormous potential in providing a very meaningful alternative to current modalities. This approach has already been given 'Breakthrough Therapy' designation by the Food and Drug Administration in the United States, and we have seen positive research trials taking place at many of the most prestigious universities in the world. Yet Australia will only be starting its first clinical psychedelic trial – conducted by PRISM and St Vincent's Hospital and part-funded by Mind Medicine Australia – later this year.

We are delighted to be able to brief you on the exciting potential of psychedelic-assisted psychotherapy for relieving the distress experienced by far too many sufferers of mental illness in Victoria, and to suggest tangible opportunities for the State of Victoria to become a world-leader in this exciting area.

We are, of course, available to answer any questions that you have, and we would be delighted to arrange for local and overseas experts in this field to be available to you.

Yours faithfully,

Peter Hunt AM
Chair

Tania de Jong AM
Deputy Chair

Dr Paul Liknaitzky
Executive Officer

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Introduction

Despite significant international investment and positive research outcomes for psychedelic treatments of mental illness (with 'Breakthrough Therapy' designation granted by the US Food and Drug Administration in the United States for both psilocybin- and MDMA-assisted treatments), Australia has barely participated in this highly prospective area of medicine. Esteemed researchers from leading universities such as Johns Hopkins, Harvard, Imperial College London, UCLA, and Yale have conducted well-controlled psychedelic treatment trials with remarkable results. Psilocybin-assisted psychotherapy for the treatment of depression and MDMA-assisted psychotherapy for the treatment of PTSD look set to become prescribable treatments in overseas jurisdictions as early as 2021, subject to positive Phase 3 trial results. In Australia, we have 39 universities, a large variety of brain and mind Institutes, Centres of Excellence in mental health, and numerous targeted psychiatric research facilities; we have some of the best mental health researchers in the world; and yet we are only just about to start our first psychedelic trial.

Mind Medicine Australia is proposing that a *Centre of Excellence in Psychedelic Medicine* be established in Victoria. This would be developed through a consortium with representation from universities, other relevant research establishments, industry, and Government and provide leadership, best practice development, research, information, and medical training in psychedelic-assisted treatments for mental illnesses, subject always to ongoing trial results and relevant regulatory approvals. The aim would be to develop a new modality for the treatment of mental illness which could offer substantial relief and support to a large number of people who have not found successful treatments in this State, and make Victoria a world-leader in this area.

We are also proposing that specific trials be conducted in this State, and seek support for the development of best practice therapist training courses to prepare for the potential implementation of this new paradigm.

A recent example of a world-leader in this area is the Centre for Psychedelic Research at Imperial College in London: <https://www.imperial.ac.uk/department-of-medicine/research/brain-sciences/psychiatry/psychedelics/> (please view the short video at this site for more information).

In this submission, we focus on the substantial impact that psychedelic-assisted therapies could have in the treatment of depression and PTSD. Also, we note that trials are being conducted or planned overseas to apply psychedelic therapy to other indications, such as addiction and anxiety disorders.

For the purposes of this submission, we use the term psychedelic-assisted therapy to refer to both psilocybin- and MDMA-assisted psychotherapy.

"There continues to be substantial untreated morbidity for many people with mental health problems; we urgently need to explore new treatment paradigms, and the promise of psychedelic medicines in terms of alleviation of suffering cannot be under-estimated."

– Prof David Castle, Psychiatrist at St Vincent's Hospital and the University of Melbourne

Mind Medicine Australia

Mind Medicine Australia (MMA) seeks to establish safe and effective psychedelic-assisted treatments for mental illness in Australia. As a registered charity (DGR-1 status), we seek to raise awareness through education, and support clinical research and development towards safe, regulatory-approved and evidence-based psychedelic-assisted therapies in this country. We provide a science-based nexus between medical practitioners, academia, government, regulatory bodies, philanthropists and other partners.

It is important to note that we do not advocate for non-clinical use of psychedelics or any other prohibited substances, nor do we advocate for any change to the law regarding non-clinical use.

The broad organisational approach of MMA can be found in Attachment 2, and our Frequently Asked Questions about MMA and about psychedelic-assisted therapy can be found in Attachment 3.

MMA's Board, Management team, Ambassadors, and Advisory Panel members consist of leading practitioners in the applied treatment of mental illness, psychedelic medical research, health strategy, ethics, and other relevant fields from both Australia and overseas, including:

- **Applied treatment of mental illness:** Professor David Castle (Professor of Psychiatry at The University of Melbourne); Dr Ben Sessa (adult and adolescent psychiatrist based in the UK, lead of psychedelic medical research team); Dr Nigel Strauss (practising psychiatrist).

- **Psychedelic medical research:** Professor David Nutt (Head of Neuropsychopharmacology at Imperial College London and lead on multiple clinical psychedelic trials); Dr Rick Doblin (Founder of the Multidisciplinary Association of Psychedelic Studies in the US, which is sponsoring the FDA-approved Phase 3 trials for MDMA therapy for PTSD); Professor Roland Griffiths (Research psychologist at the John Hopkins University School of Medicine, and leads on multiple clinical psychedelic trials); Dr Martin Williams (President of Psychedelic Research In Science and Medicine, Australia), Professor Jayashri Kulkarni (Professor of Psychiatry at The Alfred and Monash University); and Dr Robin Carhart-Harris (Director of the Centre for Psychedelic Research at Imperial College London).
- **Health Strategy:** Professor Jane Burns (Chair of the Centre for Mental Health at Swinburne University)
- **Ethics:** Dr Simon Longstaff AO (Executive Director of the Ethics Centre, and one of Australia's leading ethics practitioners).
- **Therapist Training:** Sean O'Carroll (Psychotherapist and psychotherapy course designer) and Dr Paul Liknaitzky (Research psychologist and Executive Officer of MMA).
- **Business and the Social Sector:** Peter Hunt AM (Investment Banker, Engaged Philanthropist, co-founder of MMA), Tania de Jong (Founder of Creative Universe, Creativity Australia, Creative Innovation Global, co-founder of MMA), and Monojit Ray (CEO and founder of ConnectAlex).

A full list of MMA's Board, Ambassadors, Advisory Panel Members, and Management Team can be found in Attachment 4.

Mind Medicine Australia's Purpose is to reduce mental ill-health in Australia. To achieve this, our Aims are to:

1. **Accelerate** the scientific exploration of psychedelic-assisted treatments for mental ill-health, and – *subject to adequate evidence* – regulatory approval, clinical training, and implementation.
2. **Develop and promote regulated best practice** in clinical psychedelic-assisted treatments for mental ill-health to enhance safety and effectiveness.
3. **Maximise accessibility** of psychedelic-assisted treatments for mental ill-health within medical centres of excellence, *subject to regulatory approval*.

For further detail about MMA's Approach and Principles, please see Attachment 1.

Terms of reference

This submission addresses the following Royal Commission into Victoria's Mental Health System (Royal Commission) terms of reference:

1. *How to most effectively prevent mental illness and suicide, and support people to recover from mental illness, early in life, early in illness and early in episode, through Victoria's mental health system, and in close partnership with other services.*
2. *How to deliver the best mental health outcomes and improve access to and the navigation of Victoria's mental health system for people of all ages, including through:*
 1. *best practice treatment and care models that are safe and person-centred;*
6. *Any other matters necessary to satisfactorily resolve the matters set out in paragraphs 1-5.*

Submission

Mind Medicine Australia submits that the Royal Commission recommend that the State of Victoria become a leader in the field of psychedelic-assisted treatment for mental illness through actively supporting:

1. The establishment of a *Centre of Excellence in Psychedelic Medicine* that positions Victoria as a global leader in the research and development of psychedelic assisted therapy for the treatment of mental illnesses.
2. Targeted randomised controlled trials testing the safety and long-term efficacy of psychedelic-assisted therapy in the person-centred treatment of depression and PTSD.
3. The establishment of Australia's first Psychedelic Therapist Training program.

The aim would be to position Victoria as a leader in the development and application of an alternative modality for the treatment of mental illness which could offer relief and support to a large number of people suffering from mental illness in this State.

MMA believes that it is crucial for the Victorian Government to be part of a funding consortium for these projects. MMA will contribute and seek philanthropic funding and support from other relevant stakeholders as part of this initiative.

Also, MMA would invite the opportunity to appear before the Royal Commission regarding this submission, and to make available expert witnesses to respond to Commissioners' questions regarding the safety and efficacy of psychedelic therapy.

A world-leading Centre of Excellence

The Centre of Excellence in Psychedelic Medicine, built on collaborative efforts, would bring together a consortium of Victorian leadership in clinical and research excellence, positioned on a world stage alongside other leading Research and Development centres across the United States, United Kingdom, and Europe. The *Centre* would be a world-leader in the exploration and development of psychedelic-assisted treatment, an approach that looks set to have a major impact on mental health treatment in the coming few years.

Victoria is uniquely positioned to take a leadership role in establishing a state-of-the-art *Centre of Excellence in Psychedelic Medicine*: the first clinical psychedelic trial is set to take place within Victoria this year; Mind Medicine Australia has established strong relationships internationally with experts and organisations at the forefront of psychedelic research and practice; a number of Victorian universities can support hospital-based trials and have experience with human-testing of Schedule 9 substances; and Victoria boasts the most extensive range of world-class research institutions in Australia, along with its exemplary clinical network. Consequently, it is the ideal Australian State to lead the development, understanding and application of psychedelic therapy in this country.

This would be trailblazing in Australia, and put Victoria on the global map for the development of psychedelic therapies to treat depression and PTSD.

Clinical Research Trials

Among the most prospective of psychedelic treatments, psilocybin-assisted psychotherapy for depression and MDMA-assisted psychotherapy for PTSD have achieved 'Breakthrough Therapy' designation from the FDA in the United States and are entering the final phase of clinical testing prior to their registration as prescribable medicines [see below for further detail].

Shockingly, one in seven Australians will experience depression in their lifetimesⁱ and one in 13 will experience PTSD.ⁱⁱ Current treatment options, including

pharmacotherapy and psychotherapy, help about 50% of sufferers, and often with nasty side effects and/or large economic and time burdens. And, in spite of a sustained global effort to understand and treat these mental illnesses, prevalence rates show that we are losing the battle. Novel and effective treatment options are needed if we are to have a substantial impact on mental health treatment. We therefore believe that Government, philanthropists and medical researchers need to support clinical trials that leverage off overseas work and focus on the development and evaluation of safe and effective outcomes in the Australian context.

Local clinical trials would use and refine best practice, comparing psychedelic-assisted psychotherapy to currently available combined pharmacotherapy and psychotherapy, and to a placebo with psychotherapy.

The approach we recommend will enable assessment of the long-term safety and efficacy for Australian patients in Australian conditions. Moreover, these trials would offer an opportunity to develop and test a viable service delivery framework, prepare clinicians, and afford a smooth transition to future service provision subject to regulatory approval.

Therapist Training Program

In order to adequately prepare for the availability of psychedelic-assisted therapies in Australia, qualified clinicians will require additional knowledge, skills, and experience in order to safely and successfully facilitate this treatment. Given the impressive early clinical evidence to date, and the near-term regulatory changes predicted in the US and EU subject to forthcoming data, an Australian therapist training program will play a major part in responsibly preparing the Australian context for likely regulatory changes in the coming years.

This first in Australia Therapist Training program will leverage off existing programs developed by our collaborators overseas, including the Multidisciplinary Association for Psychedelic Studies (MAPS) and the California Institute of Integral Studies (CIIS). Content for the training program will also be shaped to suit Australian applications and draw on local expertise.

The proposed program will incorporate theoretical, practical, and experiential modes of training, and will focus on all three stages of psychedelic-assisted psychotherapy: preparation, psychedelic session, and integration.

“Australia currently lags behind the international research and development community (Johns Hopkins, Imperial College London, Harvard, Stanford) in understanding the role that psychedelic medicine might play in the treatment of mental illness. A growing evidence base regarding psychedelic medicine and the importance of providing choice to consumers to access ‘the right care at the right time’ warrants careful consideration of the role that psychedelic medicine might play in supporting holistic mental health care in Australia.”

– Prof Jane Burns, Professor of Social Innovation,
Swinburne University

The need for new treatments for depression and PTSD

The Letters Patent establishing the Royal Commission state that:

Each year, one in five people in Victoria experience some form of mental illness.

Despite the number of people who experience mental illness in Victoria, only about half receive treatment.

Many people seeking help from Victoria’s mental health system...are not able to get the treatment and supports they need. For too many Victorians, the care they receive is far too late, when their mental health has deteriorated to the point of a serious crisis.

Mental health services are under significant pressure.

Every person living with mental illness deserves high quality care and treatment, so that every Victorian can have the opportunity to experience their best mental health, remain well and live a full life.

Depression is one of the most common mental illnesses in Australia. An estimated 5.8% of Australians (i.e. around 123,000 people) experience a major depressive episode in any year, while 30% of men and 40% of women will experience Major Depressive Disorder in their lifetime. Those suffering from severe and persistent depressive disorders live approximately 15 years less than other Victorians.ⁱⁱⁱ

Australia has one of the highest rates of antidepressant use (the most prevalent of which are the selective serotonin reuptake inhibitors; SSRIs). However, mounting evidence shows that these medications are substantially less effective than previously thought.^{iv} The effectiveness of commonly employed psychotherapies for

depression is modest too, and over-estimated.^v While better results are achieved using combined psychotherapy and pharmacotherapy, a high proportion of sufferers still do not respond, and the associated costs, high patient burden, and medication side-effects limit the ability for this approach to have substantial and sustained outcomes.

In fact, only 40 to 60% of depressed individuals respond to current pharmacotherapies or psychotherapies^{vi} (effect sizes of $d = 0.2$ are typical for high quality studies and meta-analyses), with the majority experiencing ongoing symptoms that fall below diagnostic thresholds, and between 50% and 80% relapse after treatment stops^{vii,viii,ix,x}. In addition, psychotherapy is often associated with high economic costs, and chemical therapies are usually associated with considerable side-effects.

Another debilitating disorder, Post-traumatic stress disorder (PTSD) will affect one in 13 Australians in their lifetimes.^{xi} Rates of PTSD among victims of sexual assault, childhood trauma, and veterans are as high as 50%.^{xii} More Australian soldiers commit suicide than have died in recent conflicts. PTSD commonly arises following exposure to traumatic events, and is often co-morbid with other disorders and illness, such as anxiety, depression, obesity, hypertension, and immune dysfunction.^{xiii}

PTSD is notoriously hard to treat, with current pharmacotherapy achieving relief from symptoms in about 20-30% of sufferers.^{xiv} For psychotherapy, PTSD sufferers exhibit very low retention rates, with around 30% of patients completing treatment. Therapeutic efficacy in PTSD may be limited by risks of re-traumatisation and substantial psychological discomfort associated with therapy.^{xv} Current treatments are ineffective for up to 50% of PTSD patients enrolled in clinical trials.^{xvi}

In addition to the devastating effect on quality of life, high rates of unresolved depression and PTSD produce a significant and ongoing economic burden on the healthcare system, and the economy more broadly: in 2017-18, working age Australians with a mental or behavioural illness were nearly twice as likely to be unemployed or not in the labour force as those without mental illness.

In spite of a vast global effort to understand and treat depression and PTSD, little appreciable advance in treatment outcomes has been made over the last 30 years, and treatment options remain inadequate. In this context of high prevalence, debilitating cost to human life and society, and inadequate treatment outcomes following decades of global research, *novel* and *effective* approaches are urgently needed. A substantial proportion of individuals diagnosed with depression or PTSD do not achieve remission following multiple treatment attempts. Variations on current treatment options, notwithstanding some positive advances, have not stemmed the tide.

Safety and effectiveness of psychedelic-assisted therapy

The last 15 years have seen a resurgence in psychedelic-assisted treatments for mental illness. Evidence is mounting for the safety and efficacy of psilocybin-assisted psychotherapy for depression, anxiety and addiction, and for MDMA-assisted psychotherapy in the treatment of Post-Traumatic Stress Disorder. A number of well-controlled Phase 2 trials that have shown excellent safety and remarkable treatment effect sizes. Indeed, many mental health experts are now paying close attention to this resurging field, in the hope that psychedelic-assisted psychotherapy may offer breakthroughs in mental health treatment.

Larger multi-site Phase 2b and Phase 3 clinical trials have commenced or are set to commence over the next year. Results from the preceding Phase 2 clinical trials have been so compelling that the Food and Drug Administration (FDA) in the United States recently designated both psilocybin- and MDMA-assisted psychotherapies as 'Breakthrough Therapies', expediting their transition to prescription medicines subject to positive outcomes within current trials. This designation highlights the FDA's anticipation that these therapies may offer substantial advantage over current treatments. If the results confirm these treatments are effective, MDMA-assisted treatment of PTSD may become prescribable as early as 2021, with psilocybin-assisted treatments for depression soon thereafter. Also, MDMA-assisted psychotherapy has recently been approved for advanced access (Compassionate Use) in Israel for patients who have not improved with available approaches. A similar program (Expanded Access) is pending approval in the USA.

Should the Commissioners wish to speak with the leads on currently active Phase 3 trials overseas, MMA would be happy to organise this. Also, please see statements attached from Dr Rick Doblin and Professor David Nutt, both actively leading this work (see Attachment 5).

Indeed, the resurgence in interest is palpable. About one hundred psychedelic research trials have recently been completed or are currently active. In many cases, the results have been remarkable in terms of the strength, speed, and the enduring nature of the treatment effect. Reductions in psychopathology symptoms within the modern trials have been substantially larger than what is typically found for other effective treatments, with statistically significant Cohen's *d* values ranging from 0.8 to 3.1, (i.e. a 'large effect')^{xvii}.

Preliminary and currently active trials are investigating additional applications, for example for obsessive-compulsive disorder, social anxiety associated with autism, and neurodegenerative disorders.

Overall across the clinical psilocybin trials for depression and anxiety, impressive and sustained improvements were found: about 80% of participants reported enduring positive effects six months after one psilocybin treatment session (longer follow-up data forthcoming). For example, in the well-controlled study at Johns Hopkins using psilocybin-assisted psychotherapy, 51 terminally-ill patients experiencing symptoms of depression and anxiety received one high-dose and one low-dose (i.e. “active placebo”) psilocybin session: following the high-dose session, 60% reported a drop in depression symptoms into the normal range, with sustained and further improved outcomes 6 months later (71% reporting remission into normal range).^{xviii}

As Prof David Nutt, Head of Neuropsychopharmacology at Imperial College states, *“The effect sizes of these psilocybin interventions are high, often greater in magnitude than those produced by other medicinal and psychological approaches. On the basis of these results there is a strong need to conduct further studies to confirm these present findings and establish the utility of psilocybin therapy in other countries and in other indications. If these are positive then I believe psilocybin will rapidly become an accepted treatment for mental illness.”* [See Attachment 5 for further detail].

Over the past decade, the Multidisciplinary Association for Psychedelic Studies (MAPS) completed six Phase 2 trials testing MDMA-assisted psychotherapy for the treatment of PTSD. Participants were 105 individuals with extremely severe PTSD ratings, an average duration of 18 years of PTSD, and multiple failed treatment attempts. These participants underwent a treatment program that included preparatory and follow-up psychotherapy sessions, along with two or three supervised MDMA (or placebo) sessions. The data across these trials was collated, showing that overall 54% of participants in the MDMA condition no longer met diagnostic criteria for PTSD, compared with 23% in the placebo group. It was also found that patients treated with MDMA-assisted therapy continued to improve, as observed in subsequent follow-ups a year later. These results are all the more remarkable given the severe and previously intractable nature of the diagnosis among most of these participants.

MDMA was well tolerated with only minor side effects reported in some cases. Over the 6 studies, 105 participants received MDMA without Serious Adverse Events. As Dr Rick Doblin, Director of MAPS, states, *“...psychedelics have been plagued by an incomplete and often inaccurate understanding of their risks and benefits. Extensive research since the 1950s, and in particular over the last two decades, shows that when done responsibly, psychedelic-assisted therapy and/or interventions are safe*

for humans and effective for the treatment of certain mental illnesses, including anxiety disorders, substance use disorders, and depression.” [See Attachment 5 for further detail].

As a result of the highly promising results, US-based MAPS is currently commencing a large multi-site international Phase 3 trial testing MDMA-assisted treatment for PTSD, and UK-based Compass Pathways is conducting a large multi-site Phase 2b and Phase 3 trial testing psilocybin-assisted treatment for depression.

In Australia, no research into the therapeutic benefits of psychedelics has yet been conducted.

The first Australian psychedelic trial will commence in September 2019, using psilocybin-assisted psychotherapy to treat severe anxiety and depression in 30 terminally-ill patients. This trial was developed and spearheaded by Psychedelic Research In Science and Medicine (PRISM), in collaboration with St Vincent’s Hospital in Melbourne. The trial will be conducted within the palliative care unit at St Vincent’s, and is part-funded by MMA.

Historical Context

It may be useful to place contemporary therapeutic research into an historical perspective.

Through the 1950s and 1960s, extensive studies of the psychotherapeutic effects of psychedelics were conducted in several countries. Over 1000 peer-reviewed clinical papers detailing the use of psychedelic compounds, involving over 40,000 participants, were published by the mid-60s.

The widespread and unregulated non-clinical use of hallucinogenic drugs through the 1960s caused concern in the US. This was a time when many young people were seeking more liberalised lives away from the conformity of the post war years. When coupled with the politics of a growing youth anti-Vietnam War protest movement, concern turned to prohibition. In 1971, the administration of US President Richard Nixon classified all psychedelics as prohibited substances.

Through international treaties, that prohibition was adopted in Australia, the UK, Europe, and many other countries. At that point, medical research ceased due to the nebulous legal framework and the increasing stigma associated with research that previously had been regarded as paradigm-changing. Classical psychedelics and MDMA remain categorised as Schedule 9 in Australia. Accordingly, administration and use of psychedelic substances within Australia are broadly prohibited by the

scheduling legislation, and importation and medical research are subject to the grant of appropriate licenses.

However, political motivations were central to the prohibition and scheduling of classical psychedelics as substances with no known medical benefit and high abuse potential (both not supported by the science). Decades later, John Ehrlichman (senior aide to Nixon) described the deliberate efforts of the Nixon White House to associate the anti-war left with psychotropic substance use in order to disrupt their efforts. In his words, *“Did we know we were lying about the drugs? Of course we did”*.

Since the early 2000s, there has been a steadily growing resurgence in research into this highly promising approach. To note, this research is being conducted by esteemed experts within highly regarded institutions such as UCLA, Johns Hopkins University School of Medicine, New York University, University of Zurich, and the Centre for Psychedelic Research within the Faculty of Medicine at Imperial College London. Research groups, including the Multidisciplinary Association for Psychedelic Studies (MAPS), the Heffter Research Institute, and the Beckley Foundation have built on the foundations set down half a century ago and, with the aid of modern brain imaging technology, we are now able to gain insights into how psychedelics influence the brain and how neuronal firing patterns are associated with clinical outcomes.

“Early stage clinical research has shown that when delivered safely and professionally, psychedelic therapy holds great promise for treating some very serious mental health conditions.”

– Dr Robin Carhart-Harris, Head of the Imperial Centre for Psychedelic Research, Imperial College London

What is psychedelic-assisted psychotherapy?

Psychedelic-assisted psychotherapy typically involves psychotherapy alongside the ingestion of a classical psychedelic such as psilocybin, or the compound MDMA. Three distinct phases of therapy have been described: preparation; active psychedelic session; and integration. The therapeutic context of this approach is essential for both safety and effectiveness. Approaches to preparation include practical aspects, patient symptoms and expectations, non-avoidance training, and the development of a therapeutic alliance. In clinical trials, therapy occurs in co-therapy teams. Participants will typically attend several psychotherapy sessions with the therapists, who will facilitate and provide support during their psychedelic session(s).

During the psychedelic session, 'set' and 'setting' are considered paramount. 'Set' refers to mind-set (e.g., expectations, mood, associations); 'setting' refers to the context in which the session takes place (e.g., comfort and aesthetic quality of the room, interpersonal context, medically safe environment). While many modern clinical trials occur within hospitals or research institutes, the session rooms are decorated in a way that is inviting and comfortable. The participant may sit or lie on a couch, they are often encouraged to wear eyeshades and listen to music compiled to help guide the experience. The active dose session will typically last about 6-8 hours. The therapeutic approach during psychedelic sessions is non-directive: attentive, with minimal direct inquiry, supporting the participant's emerging process. Trial protocols typically include between one and three psychedelic sessions.

Immediately after the psychedelic session and over the following weeks, a process of integration is facilitated by the therapists. During these integrative sessions, the participant can process, make sense of, and give meaningful expression to their psychedelic experience and any changes it has precipitated. The central aim is in sustaining the positive changes produced through the psychedelic sessions.

In clinical psychedelic sessions, classical psychedelics like psilocybin frequently produce profound personal or existential insights, feelings of empathy and self-compassion, and a sense of connection or unity with other people and the world in general. Research shows that these characteristics are correlated to therapeutic outcomes. The majority of patients report that their psychedelic experiences were among the most meaningful experiences of their lives. Classical psychedelics may help alleviate depressive, anxious, and addictive disorders by allowing the brain and mind to 'break out' of suboptimal, rigid styles of thinking, feeling, and behaving. Psychedelics temporarily create a labile brain state by de-coupling large-scale brain networks and increase connectivity between novel neural networks within the brain. These changes may help shift patients out of pathological patterns of habitual thought.

With respect to PTSD treatment, MDMA-assisted therapy has been found to increase feelings of safety and self-acceptance whilst decreasing fear and defensiveness, allowing patients to revisit traumatic memories and to address them. All memories are encoded by the brain with the emotional tone of the experience, which is re-encoded each time the memory is recalled. A key challenge for treating PTSD is that reactivating traumatic memories can induce fearful responses, increasing the risk of re-traumatisation. MDMA allows a substantial increase in a patient's ability to tolerate traumatic memories, and these memories are subsequently associated with an entirely different emotional state of ease and acceptance. In the words of [REDACTED], a participant in a clinical MDMA trial for PTSD, *"The effect this treatment has had on my life has been nothing*

short of a miracle. Following my final treatment and integration sessions, I noticed my PTSD was almost entirely gone... Over the next 6 months, my suicidal ideation slowed and then stopped... I now lead a full and rich life... I am better today than I was before I left for Iraq.” [See Attachment 5 for further detail].



A psilocybin-assisted therapy session, Johns Hopkins University

Need for further research and development in Australia

Psychedelic-assisted therapies have shown strong early clinical results, and considerable international research is being conducted and planned to ensure appropriate levels of safety and to optimise clinical efficacy. Large multi-site international Phase 3 trials of both psilocybin and MDMA are already underway or set to commence in the next year. In line with standard medical research practice, these trials are essential to determine whether the promising results seen to date in the smaller Phase 2 trials will hold up in larger and more realistic clinical settings.

While classical psychedelics pose only negligible risks in terms of toxicity and potential for dependence, psychological risks need to be better understood and mitigated. To date, research trials have done well to select appropriate participants and conduct trials in such a way as to ensure impressive levels of safety; for example, potential participants who have, or are at risk of, psychotic or personality disorders have been excluded due to risk of exacerbating their condition. However, in order to offer these therapies to a much larger proportion of the population, more

work is needed to understand the psychological risks and how to maintain the currently low levels of adverse events.

Various theories have been put forward to explain why psychedelic-assisted therapies may be clinically effective, although none have been directly tested. More research into the therapeutic mechanisms of these approaches is essential in order to optimise the effective aspects while reducing any unhelpful aspects of the therapy, to understand why some people do not respond clinically, and to determine what works best for different mental health indications.

The impressive efficacy of psychedelic psychotherapy observed so far in the treatment of mood disorders suggests that it will be a viable and economical alternative to current first-line treatments, including psychotherapeutic approaches such as Cognitive Behavioural Therapy (CBT), and pharmacotherapeutic interventions such as antidepressant medications. The cost of psychedelic psychotherapy is likely to be cheaper than the cost of established treatment options. As the psychedelic drugs used are essentially generic medicines, and hence available at low cost, the primary costs associated with psychedelic psychotherapy are represented by therapist time, the total requirement for which is somewhat less than that associated with CBT and other psychotherapies. On the other hand, psychedelic psychotherapy typically involves a very small number of drug-assisted therapy sessions – usually only one or two – whereas pharmacotherapeutic treatments typically require daily administration of medicines for months, years, or even the rest of a patient's life.

We submit that it is critical for Australian medical science to be active in this highly prospective and emerging approach to the treatment of mental illness. While the Australian population generally experiences comparable prevalence and similar types of mental illness to those of other Western countries, there are undoubtedly particular aspects of the Australian experience that would necessitate the optimisation of therapeutic approaches to meet local needs. Equally important, acceptance of psychedelic psychotherapy by the Australian medical practitioner community is likely to be substantially strengthened after its effectiveness and safety have been established in the local context. In the words of Dr Rick Doblin, Director of the Multidisciplinary Association for Psychedelic Studies (MAPS): *“Further research into the safety and efficacy of psychedelic therapy is needed. MAPS supports and encourages the Victorian and Australian governments to research the medical and therapeutic potential of psychedelic substances.”*

Conversely, foregoing the opportunity will mean that Australia will continue to fall behind the USA, the UK, Canada, Europe, and Israel in mental health research and treatment. Based on the increasingly well-founded prediction by many in the field that psychedelic psychotherapies will be approved for a range of mental health conditions in those countries in the next few years, it can be anticipated that patient

awareness and consequent demand will drive Australia in the same direction; however, a lack of focus locally will almost certainly lead to unreasonable delays in approval by regulatory authorities and adoption by the Australian medical community.

Indeed, we are seeing a surge of interest around the world, and large investments in further exploration of psychedelic-assisted research and therapy. This is an historic moment in mental health research and treatment. And it is time for Australia – led by the State of Victoria – to join in this exploration and implement the best solutions to ensure these therapies can be made accessible to all. We owe it to every person suffering with mental illness and their families to not be held hostage by historical prejudices, and to identify the best solutions available to alleviate the increasing suffering in our community.

“I would like to see psychedelics ... re-established as medicine... it's so important that we tell the truth about these drugs, because if we don't, we are losing an enormous amount of therapeutic potential”

– Professor David Nutt (speaking with Lynne Malcolm on All in the Mind, 2019)

Further Information and Contacts

For further information, please contact:

Dr Paul Liknaitzky

Executive Officer, Mind Medicine Australia



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MIND MEDICINE
A U S T R A L I A

PURPOSE, AIMS, APPROACH, PRINCIPLES

Version: 20190705

Purpose: Reduce mental ill-health in Australia

Aims:

1. **Accelerate** the scientific exploration of psychedelic-assisted treatments for mental ill-health, and – *subject to adequate evidence* – regulatory approval, clinical training, and implementation.
2. **Develop and promote regulated best practice** in clinical psychedelic-assisted treatments for mental ill-health to enhance safety and effectiveness.
3. **Maximise accessibility** of psychedelic-assisted treatments for mental ill-health within medical centres of excellence, *subject to regulatory approval*.

Approach:

1. **Expand support** for evidence-based psychedelic-assisted therapies for mental ill-health.
2. **Educate** public and key stakeholders (e.g. medical associations, universities, representatives of veterans and first responders, regulatory bodies, etc.) on clinical research (in terms of benefits, risks, clinical approaches, therapeutic mechanisms) and the implications of unique aspects of psychedelic therapies.
3. **Guide regulatory change** through policy discussions and engagement with law-makers, policy-makers and regulators.
4. **Ensure implementation feasibility** through partnerships and the development of policies for reliable procurement, importation, and storage of medicines, and clinical training certification, referrals, site development, and rebates.
5. **Post-graduate clinical training** development, certification, and delivery.
6. **Provide financial support** for clinical and sociological research studies that align with Aims.
7. **Raise funds** for all MMA operations, including: informing government policy development, clinical training, research, and future treatment centres.

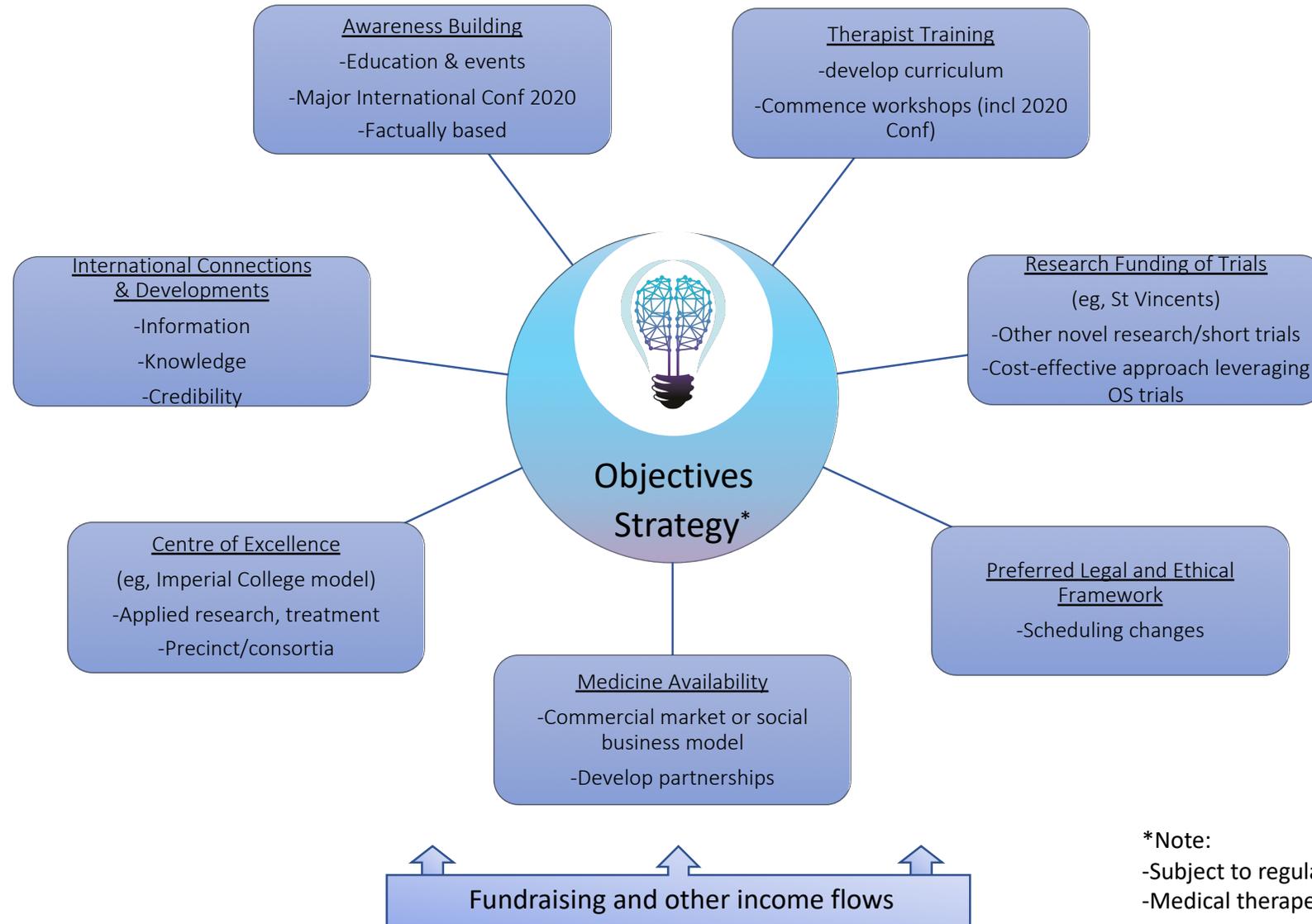
Principles:

1. **In service:** we put the common good above private or commercial gain; we support and collaborate with organisations who share our Aims and Principles.
2. **Ethical and responsible:** we report and discuss risks and safety considerations, and always act responsibly with patient safety as a top priority; we are transparent in our dealings with everyone, and respectful of differences; we support service provision only by appropriately qualified clinical professionals with certified psychedelic therapy training. We do not advocate for the use of psychedelic treatments prior to adequate scientific support; we do not condone any illegal activity in psychedelic use; we do not associate with individuals operating outside the law.
3. **Intellectual integrity:** we report information truthfully, reliably, and objectively, without omission or distortion, including weak or adverse results, methodological limitations, research gaps, and potential limitations of this clinical approach; our view of the role of psychedelic treatments is not dogmatic or fervent, but is driven by scientific evidence.
4. **Clinical and scientific:** we are solely focused on evidence-based clinical applications, and support rigorous scientific research; we do not advocate for non-clinical use or changes in the law with respect to non-clinical use.
5. **Consultative and outcome driven:** we consult and work with experts and seek professional advice to ensure ethical and leading-edge practice (e.g. medical fraternity, academics, clinical trainers, regulators, etc); our approach is respectful and professional; our contribution and engagement are based on leading scientific evidence, clinical practice, and the regulatory framework; we are driven to deliver on our Aims, towards improvements in mental ill-health in Australia.
6. **Best practice in Governance:** we respect the governance principles of leading organisations and institute a best practice framework.

Attachment 2



Broad Overview – an Applied Organisation



*Note:

- Subject to regulatory approval
- Medical therapeutic focus (not recreational)



Frequently Asked Questions

Questions about Mind Medicine Australia

What is Mind Medicine Australia?

Mind Medicine Australia is a registered charity working towards establishing regulatory-approved and evidence-based psychedelic-assisted therapies for mental illness in Australia.

Why was Mind Medicine Australia launched?

Mind Medicine Australia was established to support further investigation to enhance the effectiveness and safety of psychedelic-assisted therapies, and to reduce unnecessary delays in implementing this approach within Australia. One in five Australians are currently suffering from a mental illness. One in two Australians will be affected by a mental illness in their lifetime. Australia is experiencing a growing mental health crisis that current treatment options are unable to adequately address. While available mental health treatments can be effective, about half of all patients do not respond. Therefore, we need to support the most effective and innovative treatments to address this unmet need. Over the past decade, psilocybin- and MDMA-assisted psychotherapies have demonstrated remarkably promising clinical results in overseas trials. Mind Medicine Australia believes Australia should join the global effort to investigate and optimise these treatment approaches for mental illness. [Read more about the state of mental health here.](#)

Why psychedelic-assisted psychotherapy?

In major international trials, psychedelic-assisted psychotherapies have shown impressive outcomes in treating a range of mental illnesses with greater effectiveness than standard treatments, and with an excellent safety profile. Australia is currently behind the US, UK, Canada, Israel and Europe when it comes to research and regulatory support for these promising treatments. [Read a literature review by our Scientific Officer here.](#)

What do you hope to achieve?

Mind Medicine Australia acts as a nexus between clinicians, academia, government, regulators, philanthropists, and patients, working in close consultation and partnership with relevant experts and organisations. Subject to the results from Phase 3 clinical trials currently underway overseas, we are preparing to assist the health care system for possible regulatory changes in Australia, by supporting clinical research, and developing a clinical implementation framework and therapist



training protocols. We are also educating and engaging relevant stakeholder groups and the general public, to increase awareness, and to drive best-practice.

What is Mind Medicine Australia's Therapist Training program?

Knowledge, training, and certification will be essential to ensure best practice for a novel therapeutic approach that is currently largely unfamiliar to the Australian mental health service sector. Therefore, in partnership with leading organisations overseas and locally, we are establishing an evidence-based therapist training program.

What are MMA's plans for research?

Mind Medicine Australia supports research that investigates the benefits, mechanisms, and risks of psychedelic-assisted psychotherapy. We are particularly interested in novel research protocols that expand on research conducted by major universities overseas, and that seek to answer key questions to enhance clinical effectiveness and safety.

What policy change is MMA advocating for?

We advocate for evidence-based policy that supports research into the therapeutic use of psychedelics alongside psychotherapy. We are not advocating for recreational or other non-clinical use of psychedelics. Nor do we advocate any changes to the law with respect to non-clinical uses. Subject to positive results from Phase 3 clinical trials (the final stage clinical trials before regulatory approval), which are commencing overseas, we will advocate for the development and availability of psychedelic-assisted psychotherapy within a limited number of designated clinical centres in Australia.

How can I assist MMA to achieve its goals?

We are a small organisation doing big things. We rely on support from our partners and the community. You can help to support research and the development of psychedelic-assisted psychotherapy by:

- donating money or skills;
- connecting us with people and organisations within the medical fraternity, academia, government, regulatory agencies, philanthropy, and other relevant sectors;
- sharing the evidence for this treatment approach and contributing to mature and open conversations about such matters.



Questions about psychedelics

What are psychedelics?

Psychedelics are chemical compounds which temporarily create changes in brain function including shifts in perception, thinking, and feeling, producing an 'altered state of consciousness'. The 'classical psychedelics' include substances like psilocybin (found in a variety of mushrooms), ayahuasca, mescaline, lysergic acid diethylamide (LSD), and dimethyltryptamine (DMT). Although not a classical psychedelic, MDMA is often included in this category due to some similarities in its effects and clinical applications. Classical psychedelics appear to produce many of their effects through the activation of a specific Serotonin receptor (5HT_{2A}) in the brain. The word psychedelic, coined by British psychiatrist Humphry Osmond, means 'mind revealing'.

What is psychedelic-assisted psychotherapy?

Psychedelic-assisted therapy involves certain approaches to 'talk-therapy' alongside the ingestion of a psychedelic compound such as psilocybin, or MDMA. Researchers and clinicians often describe three distinct therapy phases that take place over several days: preparation, the psychedelic experience, and integration. Importantly, the non-psychedelic elements of this approach are essential for both effectiveness and safety.

For how long have psychedelics been in use?

Historians and anthropologists have found that psychedelic agents have been utilised for thousands of years and in various contexts, from the medicinal to the ritualistic. The historical use of psychedelics in the West traces back to Ancient Greece's Eleusinian Mysteries, a ritualised initiation rite involving what anthropologists believe was a psychedelic drink. MDMA was first synthesised in 1912 by the German pharmaceutical company Merck, and LSD was first synthesised in 1938 by the Swiss chemist Albert Hofmann at Sandoz Laboratories. Sandoz also isolated psilocybin for the first time in 1957. In the 1950s, psychedelic-assisted psychotherapy was regarded by a large proportion of psychiatry as the next big breakthrough for treating mental illness, and was used for a range of conditions in tens of thousands of patients. Thousands of research papers were published on psychedelic therapy between 1950-1972. These documented their application as treatments for depression, anxiety, post-traumatic stress disorder (PTSD), and alcohol dependence.

Why were these substances scheduled alongside drugs like heroin and crack cocaine? How did they get such a bad name?

Psychedelics were scheduled for predominantly political reasons. These centred on former US President Nixon's 'War on Drugs', which was used to suppress the anti-Vietnam war movement. Classical psychedelics and MDMA are currently Schedule 9 drugs in Australia (Schedule 1 in the USA). This category is reserved for substances considered by regulators to be without medical value, and with high abuse potential. Extensive research has shown that psychedelics do not meet either of



these criteria. In addition to unjustified scheduling that has had a global impact through various international treaties, government funding and ethics committee support for research was completely stopped. Given that psychedelic-assisted psychotherapy was establishing itself through the 1950s and 1960s as the ‘next big thing’ in psychiatry, this censoring of inquiry into such a promising line of research is unprecedented in the modern world. Former US officials within the Nixon administration have since admitted that their scheduling of psychedelics and certain other compounds was an attempt to suppress parts of society that posed a challenge to their world-view and political agenda.

What is the evidence for their effectiveness?

Internationally, there has been a resurgence of research into psychedelics at universities such as Harvard, Johns Hopkins, New York University, Stanford, Imperial College London, and the University of Zurich. Several well-controlled clinical trials have yielded promising results. The new data show that psychedelic-assisted psychotherapy frequently leads to remission from certain mental illnesses within a few doses, when administered with proper psychotherapeutic support before, during and after treatments. The proportion of participants who show positive clinical improvements, and the degree to which they improve, are substantially higher than clinical outcomes associated with currently available treatments. [Read a literature review by our Scientific Officer here.](#)

Are there advantages to psychedelic therapies over available treatments?

Research over the past decade shows that with psychedelic-assisted psychotherapy, patients frequently experience reductions in symptoms within a few sessions, with little in the way of side-effects. This is a striking difference from traditional pharmacotherapy, such as anti-depressants, where patients take medication daily for months, years, or indefinitely, and typically experience unpleasant or problematic side effects.

In terms of ‘talk therapy’, the time and financial commitment for ongoing mental health treatment can be a barrier for many. More critically, only about half of patients respond to common drug and talk therapies in use today, with a majority of responders continuing to experience sub-diagnostic symptoms during treatment, and high relapse rates.

Psychedelic-assisted therapies have achieved substantially better clinical outcomes than the available talk therapies and drug therapies, with far fewer ‘therapeutic doses’ required to achieve robust outcomes. Also, they are generally free from the unpleasant or problematic side effects. Further work is needed to investigate how and to what degree clinical outcomes can be sustained following psychedelic-assisted psychotherapy; yet the longer-term data from early studies suggest the outcomes might be sustained longer than available treatments, with avenues to explore further sustaining the change.

How effective are psychedelics compared with current treatments?

Current drug and talk therapies for depression and anxiety work in 40-60% of cases, with high rates of sub-diagnostic symptoms and relapse. In a trial involving participants who had failed to respond



to several different drug and talk therapies, psilocybin-assisted psychotherapy substantially reduced depressive symptoms in over 65% of these 'treatment-resistant' patients.

In a trial using psilocybin-assisted-therapy for smoking cessation, 80% of patients had quit smoking six months after the therapeutic sessions, and after one year, that figure was still at 67%. Typically, the current "gold-standard" smoking cessation treatments with similarly addicted participants can hope to achieve around a 20% quit rate at follow-up.

PTSD is notoriously hard to treat, with current anti-depressant pharmacotherapy achieving relief from symptoms in about 20% of sufferers. In recent trials, MDMA-assisted psychotherapy led to remission from PTSD in over 75% of patients who had not previously responded to standard treatments. These trials have informed the current Phase 3 clinical trials, and the FDA's decision to designate MDMA as a "Breakthrough Therapy", expediting research and the transition to prescription medicine.

How do psychedelics work?

A number of theories have been put forward to account for the therapeutic effects of psychedelics. The most prominent theories are based on recent brain imaging data. One way in which classical psychedelics may help with issues like depressive, addictive, and obsessive disorders is by allowing the brain and mind to 'break out' of repetitive and rigid styles of thinking, feeling, and behaving. Psychedelics temporarily alter activity and increase connectivity between novel neural networks within the brain, potentially breaking patients out of pathological patterns of thought and habit.

What do psychedelics do?

In a therapeutic setting, psychedelics frequently produce profound personal or existential insights, feelings of empathy and self-compassion, and a sense of connection or unity with other people, things, and the world in general. Research shows that these characteristics are correlated to therapeutic outcomes and that patients regard these experiences among the most meaningful of their lives. In clinical settings, psychedelic-assisted-psychotherapy creates a fertile ground for change and for restoring patient agency.

What do brain imaging studies tell us about psychedelics?

Brain imaging studies have opened a window into the mechanisms of psychedelic-assisted therapy and the study of consciousness itself. Psychedelics reduce the activity of a 'hub' structure in the brain called the Default Mode Network (DMN). The DMN is associated with rumination about the past, daydreaming and autobiography - our 'self-story', which can become distorted and overactive in mental illness. By temporarily decreasing the activity of the DMN, psychedelics appear to enable communication among more diverse brain regions, and possibly facilitate an opportunity to break free from dysfunctional beliefs and mental 'ruts'.

How does MDMA work?

MDMA is known for increasing feelings of trust and compassion whilst decreasing fear and defensiveness, which makes it easier for patients to be able to revisit their traumatic memories



without debilitating anxiety, and to address them in various ways. MDMA-assisted psychotherapy increases a sense of safety and self-compassion, allowing patients to revisit traumatic memories without producing re-traumatisation.

Is MDMA the same thing as the street drug Ecstasy?

MDMA is not the same as "Ecstasy". Substances sold on the street may contain MDMA, but frequently also contain unknown adulterants. In clinical studies, pure MDMA has been shown to be safe for human consumption when taken a limited number of times in moderate doses.

How safe are these medicines/therapies?

The risk profile of psychedelics is excellent, with negligible physiological toxicity or abuse potential, and little in the way of side-effects for eligible participants (e.g., people at risk of psychosis, or with cardiac issues, are typically not eligible). The psychological risks need to be better understood and mitigated. To date, modern research trials have done well to select appropriate participants and conduct trials in such a way as to produce impressive levels of safety. While the therapy can be challenging and bring up difficult experiences, these may be crucial to the therapeutic process, and the majority of participants rate the experience as among the top five most important of their lives.

I've heard that psychedelics can induce psychosis or can result in frightening experiences

While psychedelics are powerful substances, and can produce challenging experiences without appropriate support, there is no evidence that psychedelic use is linked to either mental illness or negative health outcomes. A meta-analysis published in the premier journal *Nature* found no link between psychedelic use (not within a clinical context) and psychosis across a cohort of 135,000 people. The researchers found that individuals who had taken psychedelics were not at increased risk of developing 11 indicators of mental-health problems, including: schizophrenia, psychosis, depression, anxiety disorders and suicide attempts. In addition, it was found that lifetime psychedelic use was associated with decreased suicide risk and improved wellbeing. For patients with psychosis risk or other unstable personality issues, psychedelic-assisted psychotherapy may be ineffective or involve complications, and is not recommended – although further research is needed to determine the degree to which safety concerns are warranted. As a matter of caution, patients with these conditions are typically excluded from clinical trials of psychedelic-assisted psychotherapy.

Which mental illnesses are helped by psychedelics - based on recent studies?

So far, psilocybin-assisted psychotherapy has shown great promise in the treatment of depression, anxiety, and addiction in well-controlled Phase 2 clinical trials, with some evidence for successfully treating Obsessive Compulsive Disorder. MDMA-assisted psychotherapy has been successfully used to treat PTSD; early clinical data also suggests application for social anxiety in autistic adults.



What other conditions could psychedelics assist with?

It has been suggested that psychedelics are most helpful in conditions characterised by rigid thoughts and behaviours such as depression, anxiety, addiction, OCD, and eating disorders. Recently, the Psychedelic Research Centre at Imperial College has suggested investigating psychedelics for use in 'disorders of consciousness' including acquired brain injury, vegetative states and minimally conscious states. MDMA was originally used in couples' therapy and for conflict resolution, for which it offers great promise.

When will this therapy be available?

Psilocybin and MDMA have been granted 'Breakthrough Therapy' status by the US Food and Drug Administration (FDA), expediting their transition to prescription medicines subject to positive outcomes within current trials. Critical data are expected to be released within the next year from Phase 2b and Phase 3 trials for psilocybin and MDMA respectively. If these confirm the treatments to be effective, MDMA for the treatment of PTSD may become available as early as 2021 in the US and psilocybin for the treatment of depression within the next five years in some countries. MDMA has recently been approved for advanced access (Compassionate Use) in Israel for patients who do not have other treatment options. Likewise, MDMA is pending approval for a similar program (Expanded Access) in the USA.

What research is there still to do?

While psychedelic-assisted therapies have shown some strong clinical results, considerable research is still required to confirm the benefits, ensure best practice and optimise clinical effectiveness. Several large multi-site international 'Phase 3' trials of both psilocybin and MDMA will determine whether the promising results seen to date will hold up in larger and more realistic clinical settings.

While classical psychedelics pose negligible toxicity or dependence risks, psychological risks need to be better understood and mitigated. To date, research trials have done well to select appropriate participants and conduct trials in such a way as to produce impressive levels of safety. However, in order to offer these therapies to a much larger proportion of the population, more work is needed to understand psychological risks and how to maintain the currently low levels of adverse events.

More research into the 'therapeutic mechanisms' of this approach is essential in order to optimise the effective aspects of the therapy, to understand why some people do not respond clinically, to determine what works best for different mental health conditions, and to prolong the positive change.



MIND MEDICINE A U S T R A L I A

OUR PEOPLE

AMBASSADORS

Dr Rick Doblin (USA)

Founder and Executive Director, Multidisciplinary Association for Psychedelic Studies (MAPS)

Rick Doblin, Ph.D. received his doctorate in Public Policy from Harvard's Kennedy School of Government, where he wrote his dissertation on the regulation of the medical uses of psychedelics and marijuana and his Master's thesis on a survey of oncologists about smoked marijuana vs. the oral THC pill in nausea control for cancer patients. His professional goal is to help develop legal contexts for the beneficial uses of psychedelics and marijuana, primarily as prescription medicines but also for personal growth for otherwise healthy people, and eventually to become a legally licensed psychedelic therapist. He founded MAPS in 1986, and currently resides in Boston with his wife and empty rooms from three children who are all in college or recently graduated.

Professor David Nutt (UK)

Head of Neuropsychopharmacology at Imperial College London

Renowned researcher, policy advisor and author, Professor David Nutt, is currently Head of Neuropsychopharmacology at Imperial College London. Under the leadership of Professor Nutt, the Psychedelic Research Group at Imperial College is one of the world's foremost psychedelic research laboratories, publishing landmark research on psychedelic therapies and neuroimaging studies of the psychedelic state. Professor Nutt has also held many leadership positions in both UK and European academic, scientific and clinical organisations, including presidencies of: the European Brain Council, the British Neuroscience Association, the British Association of Psychopharmacology, the European College of Neuropsychopharmacology. He was previously Chair of the UK Advisory Council on the Misuse of Drugs.

Professor Roland Griffiths (USA)

Professor of Psychiatry and Behavioral Sciences at the Johns Hopkins University School of Medicine.

Roland Griffiths, Ph.D., is Professor in the Departments of Psychiatry and Neurosciences at the Johns Hopkins University School of Medicine. His principal research focus in both clinical and pre-clinical laboratories has been on the behavioural and subjective effects of mood-altering drugs. His research has been largely supported by grants from the National Institute on Health and he is author of 380 journal articles and book chapters. He has been a consultant to the National Institutes of Health, to numerous pharmaceutical companies in the development of new psychotropic drugs, and as a member of the Expert Advisory Panel on Drug Dependence for the World Health Organization. He has conducted extensive research with sedative-hypnotics, caffeine, and novel mood-altering drugs. In 1999 he initiated a research program investigating the effects of the classic psychedelic psilocybin that includes studies in psychedelic naive and experienced volunteers, in beginning and long-term meditators, and in religious leaders. Therapeutic studies with psilocybin include treatment of psychological distress in cancer patients, treatment of cigarette smoking cessation, and psilocybin treatment of major depression. Drug interaction studies and brain imaging studies (fMRI and PET) are examining pharmacological and neural mechanisms of action.

Dr Ben Sessa (UK)

Psychiatrist, Researcher & Writer

Dr Ben Sessa trained at UCL, London, graduating in Medicine in 1997. He works clinically as an adult and adolescent psychiatrist, and academically in Bristol and Imperial College London University, with an interest in the developmental trajectory from child maltreatment to adult mental health disorders. In the last ten years Ben has been a study doctor and a test subject administering and receiving legal doses of pure LSD, psilocybin, MDMA, DMT and Ketamine. He is currently conducting the world's first clinical study using MDMA to treat addiction. Ben is the co-founder and past President of the UK's premier psychedelic research conference, Breaking Convention. He has published dozens of peer reviewed papers on psychedelics and is the Author of several textbooks, including the influential book 'The Psychedelic Renaissance'.

BOARD OF DIRECTORS

Peter Hunt AM

Co-founder Mind Medicine Australia, Investment Banker & Engaged Philanthropist; Founder, Women's Community Shelters

As an investment banker Peter Hunt AM advised local and multi-national companies and governments in Australia for nearly 35 years. He co-founded and was Executive Chairman of one of Australia's leading investment banking advisory firms, Caliburn Partnership (now called Greenhill Australia) and continued as Chairman of the Firm after its sale to Greenhill Inc. in 2009. Peter was a member of the Advisory Panel of ASIC and chaired the Vincent Fairfax Family Office. Peter is an active philanthropist involved in funding, developing and scaling social sector organisations which seek to create a better and fairer world. He is Chairman of Mind Medicine Australia which he established with his wife, Tania de Jong, in 2018. He founded Women's Community Shelter in 2011 and remains on the Board. He is Chairman of So They Can, Grameen Australia and Grameen Australia Philippines. Peter is a Director of Project Rozana and an Advisory Board member of the Monash Sustainable Development Institute. Peter also acts as a pro bono adviser to Creativity Australia. Peter was made a member of the General Division of the Order of Australia in the Queen's Birthday Honours List in 2010 for services to the philanthropic sector.

Tania de Jong AM

Co-founder Mind Medicine Australia; Founder, Creative Universe, Creativity Australia & Creative Innovation Global

Tania de Jong AM is a trail-blazing Australian soprano, award-winning social entrepreneur, creative innovation catalyst, spiritual journey woman, storyteller and global speaker. Tania is one of Australia's most successful female entrepreneurs and innovators developing 5 businesses and 3 charities over the past 3 decades including Creative Universe, Creativity Australia and With One Voice, Creative Innovation Global, Mind Medicine Australia, Dimension5, MTA Entertainment & Events, Pot-Pourri and The Song Room. She works across the public, private, creative and community sectors. Tania speaks and sings around the world as a soloist and with her group Pot-Pourri releasing ten albums. She is Founder and Executive Producer of future-shaping events series, Creative Innovation Global. She was appointed a Member of the Order of Australia in June 2008 and named one of the 100 Women of Influence and the 100 Australian Most Influential Entrepreneurs in 2018. Tania's TED Talk How Singing Together Changes The Brain has sparked international interest. Tania's mission is to change the world, one voice at a time!

Admiral Chris Barrie AC

Founder and Chair, PTSD-Australia New Zealand

Admiral Chris Barrie commanded all arms of the Defence Force as its Chief (CDF) from 1998 till 2002. After this, Chris worked on strategic leadership as a consultant, teacher and mentor, initially through Oxford University's Strategic Leadership and Stimulus Forum Programs (2002-2011); and as Distinguished Visiting Professor he also taught an elective on Strategic Leadership to senior U.S. military officers at the National Defense University in Washington DC from 2004 till 2010. He is busy now as the founder and Chair of PTSD-Australia New Zealand, whose subsidiary 'FearLess Outreach' is intended to assist an estimated 6 million people in the Australian and New Zealand communities, who live with post-traumatic stress. He is an outspoken commentator on Climate Change and Security using community advocacy to raise awareness of the potential costs of inaction. Chris is also the Australian member of the Global Military Advisory Council on Climate Change (GMACCC), and an adjunct member of the Planetary Security Initiative based in the Hague.

Professor Jane Burns

Chair of Open Arms, Chair of STREAT and Chair of the Centre for Mental Health, Swinburne University

Jane is a health strategist, advising the government, university and social enterprise sector. She is Chair of Open Arms, Chair of STREAT and Chair of the Centre for Mental Health at Swinburne University. She has over twenty years' experience as a C-Suite Executive with high profile organisations, beyondblue: the national depression initiative and reachout.com, and was the founder and CEO of the Young and Well Cooperative Research Centre, raising over \$100M in capital. She is the Founder and Non-Executive Director of InnoWell and a Non-Executive Director with APPLI. She was a Harkness Fellow in Health Care Policy, a VicHealth Fellow in Health Promotion and an NHMRC Fellow in Suicide Prevention. In recognition for her achievements in entrepreneurship she won the category of Social Enterprise for 2015's Australian Financial Review and Westpac Group 100 Women of Influence, and was a Victorian Finalist in the 2017 Telstra Business Women's Awards.

Professor David Castle

Professor of Psychiatry, The University of Melbourne

David Castle is Professor of Psychiatry at The University of Melbourne. He has wide clinical and research interests, encompassing schizophrenia and related disorders, bipolar disorder, OCD spectrum disorders and disorders of body image. He has a longstanding interest in the impact of licit and illicit substances on the brain and body and is actively engaged in programmes addressing the physical health of the mentally ill and the mental health of the physically ill. He has published widely in the scientific literature and is a frequent speaker at scientific meetings. His broader interests include music, literature, theatre and art.

Dr Simon Longstaff AO

Director, the Ethics Centre

Dr Simon Longstaff commenced his work as the first Executive Director of The Ethics Centre in 1991. Simon is a Fellow of CPA Australia and in June 2016, was appointed an Honorary Professor at the Australian National University – based at the National Centre for Indigenous Studies. Formerly serving as the inaugural President of The Australian Association for Professional & Applied Ethics, Simon serves on a number of boards and committees across a broad spectrum of activities. He was formerly a Fellow of the World Economic Forum. Simon's distinguished career includes being named as one of AFR Boss' True Leaders for the 21st century. In 2013 Dr Longstaff was made an officer of the Order of Australia (AO) for "distinguished service to the community through the promotion of ethical standards in governance and business, to improving corporate responsibility, and to philosophy."

Mono Ray

CEO & Founder, ConnectAlex; Non-Executive Director, Kidney Health Australia

Mono Ray is a corporate advisor and former PwC Tax and Legal Partner turned Change Agent. He has advised national and global companies across industries for 30 years on innovations including the privatisation of energy, establishing electronic and foreign banking and many significant deals. With a love of helping people achieve difficult things, he's also the Managing Director and co-founder of ConnectAlex, a platform that gives people ways to build savings faster, and a non-executive director of Kidney Health Australia. Mono served on industry bodies including the Financial Services Council and the Property Council of Australia and the Australian Financial Centre Forum Reference Group. He consulted with state and federal regulators to design policy and legislation. He has a B.Sc. (Neuropsychology), LL.B, LL.M (Investor Protection & Tax), and postgraduate qualifications in business, and is a Solicitor of the High Court of Australia and the NSW Supreme Court. Mono has a passion for driving change for the better in business and society through technology, evolutionary approaches and resetting boundaries.

Luke Mitchell

Director, Murchisons Accounting Firm

Luke Mitchell is a Director of Sydney based accounting firm Murchisons. Luke has over 18 years' experience as an accountant and business advisor and was previously a partner of Crowe Horwath. Luke donates his accounting experience to the non-profit sector, supporting Grameen Australia and Manly Women's Shelter.

ADVISORY PANEL

Dr Robin Carhart-Harris (UK)

Founder, Centre for Psychedelic Research at Imperial College London

Robin Carhart-Harris moved to Imperial College London in 2008 after obtaining a PhD in Psychopharmacology from the University of Bristol and an MA in Psychoanalysis from Brunel University. At Imperial, he has run and overseen brain imaging studies involving LSD, psilocybin, MDMA and DMT, plus a clinical trial of psilocybin for treatment-resistant depression, and a current study comparing psilocybin with escitalopram for major depressive disorder. In 2019, he set-up the Centre for Psychedelic Research at Imperial and he also an honorary position with the University of Oxford. Two of his most influential works include the 'Entropic Brain Hypothesis' and 'REBUS and the anarchic brain'.

Dr Matthew W. Johnson (USA)

Associate Professor at Johns Hopkins School of Medicine

Matthew W. Johnson, Ph.D., Associate Professor at Johns Hopkins, is an expert on psychedelics, other drugs, and addiction. Working with psychedelics for >15 years, he has published >100 papers with 43 on psychedelics. Matt published psychedelic safety guidelines in 2008, helping to resurrect psychedelic research. He published the first research on psychedelic treatment of tobacco addiction in 2014, and the largest study of psilocybin in treating cancer distress in 2016. His recent psilocybin review recommended placement in Schedule-IV upon medical approval. He has personally guided >100 psychedelic sessions. Matt also conducts behavioural economic research on both addiction and sexual risk. He has published studies on nearly all psychoactive drugs classes, and is President of the Psychopharmacology and Substance Abuse Division of the American Psychological Association. Matt has been interviewed by the New York Times, Washington Post, Wall Street Journal, BBC, CNN, Fox Business News, NPR, CBS News, and NBC News.

Professor Avni Sali AM

Founding Director of NIIM, and Member of the Scientific Board of The European Congress for Integrative Medicine

Founding Director of NIIM, and Member of the Scientific Board of The European Congress for Integrative Medicine. He is former Head of Graduate School of Integrative Medicine, Swinburne University and the University of Melbourne Dept of Surgery, Heidelberg Hospital. Often referred to as the 'Founding Father' of Integrative Medicine, Prof Sali has pioneered leading research and education in the field of Integrative Medicine, as well as being a specialist in the clinical treatment of cancer and chronic disease. His integrative medicine books include: Co-authored, 2011 – 'A guide to Evidence-Based Integrative and Complementary Medicine' –

Elsevier Australia, and 2017 'A Clinician's Guide to Integrative Oncology', Springer USA. In 2016 a book about his life was published entitled 'Visionary Man, Visionary Medicine'. In 2016 he received an Order of Australia for "significant service to integrative medicine as an educator, clinician and researcher, and to professional education."

Dr David Caldicott

Adjunct Professor, University of Canberra & Emergency Consultant

David Caldicott is an Irish Emergency Consultant, living and working in Canberra – he holds conjoint academic positions with the University of Canberra, and the Australian National University. David is the co-recipient of an NHMRC Partnership grant as part of the 'Driving Change project'. He is currently the Clinical Lead at the Australian Drug Observatory of The ANU. David has always been 'disruptive'. He wrote and delivered Australia's first medicinal cannabis course, conceived to teach clinicians the science behind the headlines. He also designed and negotiated Australia's first sanctioned 'pill testing' trial in the ACT in 2018. David has an Irishman's interest in influencing politics to effect evidence based policy, and is an expert on illicit drugs for the Australian Science Media Centre.

Professor Jayashri Kulkarni

Professor of Psychiatry, The Alfred and Monash University

Jayashri Kulkarni commenced her appointment as Professor of Psychiatry, The Alfred and Monash University in 2002. She directs a large psychiatric research group, the Monash Alfred Psychiatry Research Centre (MAPrc), with approximately 150 staff and students. The Centre is dedicated to discovering new treatments, new understanding and new services for people with a range of mental illnesses. Jayashri Kulkarni completed her MBBS degree in 1981 at Monash University and worked mainly in Emergency Medicine before deciding to specialise in Psychiatry. She became a Fellow of the Royal Australian and New Zealand College of Psychiatrists in 1989 and was awarded a PhD from Monash University in 1997 for her thesis "Women and Psychosis". Jayashri has pioneered the novel use of estrogen as a treatment for schizophrenia and is internationally acknowledged as a leader in the field of reproductive hormones and their impact on mental health. Jayashri is the President of the International Association of Women's Mental Health, a role she commenced in 2017.

Professor David E. Nichols (USA)

Adjunct Professor of Chemical Biology and Medicinal Chemistry, University of North Carolina, Chapel Hill.

David E. Nichols, PhD is an Adjunct Professor of Chemical Biology and Medicinal Chemistry at the University of North Carolina, Chapel Hill. Previously he held the Robert C. and Charlotte P. Anderson Distinguished Chair in Pharmacology and was

a Distinguished Professor of Medicinal Chemistry and Molecular Pharmacology at the Purdue University College of Pharmacy. He received his B.S. degree in chemistry from the University of Cincinnati in 1969, and the PhD in Medicinal Chemistry from the University of Iowa in 1973, following which he did postdoctoral work in pharmacology at the University of Iowa, College of Medicine. In 2004 he was named the Irwin H. Page Lecturer by the International Society for Serotonin Research and in 2006 he received the first Provost's Outstanding Graduate Mentor award from Purdue University. He has published more than 300 scientific articles, most of which deal with the relationship between molecular structure and biological action.

Sean O'Carroll

Private Practice Psychotherapist

Sean O'Carroll is a psychotherapist in private practice in Melbourne, Australia. He has a background in philosophy, transpersonal psychology, and a number of psychotherapeutic modalities including relational gestalt therapy and creative arts therapy. He has been teaching and training psychotherapists since 2011, and is the director of Wild Mind. His MA research thesis (2014 – 2017) involved a phenomenological exploration into the experience of being alone with nature, and in 2018 he developed and delivered Australia's first tertiary level course in eco-psychotherapy for training therapists. Sean's work under the banner of Wild Mind employs non-ordinary states of consciousness to support health and wholeness. This work is grounded in various state-change technologies including dance/movement, nature-based practices and a variety of other psychotherapeutic processes. Sean does not facilitate psychedelic journeys for legal reasons, but works closely with members of the Melbourne medicine community in a psychotherapeutic capacity, supporting the exploration and integration of psychedelic experiences.

Chris Raine

Founder and CEO, Hello Sunday Morning

Chris Raine is the Founder and CEO of Hello Sunday Morning (HSM) – a non-profit that supports one of the largest communities in the world of people looking to change their relationship with alcohol. Thanks to the support of several corporate foundations (Google, Macquarie Bank, Vodafone and nib) as well as governments across Australia and New Zealand, Hello Sunday Morning provides free access to peer and/or clinical support for any Australian looking to change their relationship with alcohol, in the moment they need it. Chris is a Young Australian of the Year (QLD), a Westpac Social Change Fellow and received a Skoll Scholarship in Social Entrepreneurship to complete his MBA from Oxford University in 2014 (graduating with a Dean's Commendation).

Patrycja Slawuta (USA)

NYC-based researcher and entrepreneur. Founder, SelfHackathon

Patrycja Slawuta (USA) Patrycja Slawuta is a New York City based behavioral scientist. She completed her Masters Degree at the University of Warsaw where here research centered around moral emotions of guilt and shame. Her academic work has been presented at various scientific conferences and published in articles and books on social psychology. After a successful academic career, Patrycja founded SelfHackathon, a boutique consultancy that uses cutting edge scientific research for business innovation. With a network of 50+ scientists and domain experts, SelfHackathon helps high performing individuals, teams and companies hack, rewire and upgrade themselves. Her latest initiative is called PsychTech, the seamless fusion of psychology and technology to enhance and accelerate performance and results. As an expert on the complexity, nonlinearity and the messiness of the human nature, Patrycja lectures globally and works with some of the most exciting and disruptive businesses in the world.

Dr Nigel Strauss

Consultant Psychiatrist with over 40 years' experience

Nigel Strauss has been a Consultant Psychiatrist for over 40 years and is the Medical Director of the Millswyn Clinic in South Yarra, a private outpatient psychiatric facility. He has a special interest in medico-legal psychiatry and is employed as a lecturer by AMA Victoria. He has been a Consultant to Worksafe and TAC. Dr Strauss has a special interest in psychedelic medicines and has trained in the UK to work as a psychedelic therapist. He is an advocate for psychedelic-assisted psychotherapy research in Australia.

Dr Alex Wodak AM

Physician; Director of Australia 21 and President, the Australian Drug Law Reform Foundation

Alex Wodak, a physician, is a Director of Australia 21 and is the President of the Australian Drug Law Reform Foundation. He was Director of the Alcohol and Drug Service, St Vincent's Hospital, Sydney, from 1982 until he retired in 2012. Dr Wodak was the Foundation President of the International Harm Reduction Association (1996-2004) and helped to establish the National Drug and Alcohol Research Centre (1987), the NSW Users AIDS Association (1989), and the Australian Society of HIV Medicine (1989).

MANAGEMENT

Dr Paul Liknaitzky

Executive Officer, Mind Medicine Australia

Paul Liknaitzky is the Executive Officer of Mind Medicine Australia. He also holds Research Fellow appointments at Deakin University and Odyssey House Victoria. Paul has an Honours in Neuroscience and a PhD in Psychology from the University of Melbourne. He has worked on mechanistic experimentation and intervention development within depression and addiction research. The clinical applications and therapeutic mechanisms of psychedelic-assisted treatments are central to Paul's interests. A large part of Paul's doctorate investigated how psychedelic treatments (and other treatments that produce non-ordinary states) are able to alleviate depression. Paul has extensive knowledge of psychedelic research and therapy, and his work includes the development and investigation of best-practice clinical protocols and implementation frameworks that optimize safety, effectiveness, and sustained positive outcomes.

Melissa Warner

Education and Communications Officer, Mind Medicine Australia

An advocate for innovative solution for mental health. Melissa seeks to communicate an evidence-based understanding of mental health, consciousness and psychedelic-assisted therapies. Melissa is a graduate of Neuroscience from the University of Melbourne. Melissa is a member of the management committee of Psychedelic Research in Science & Medicine (PRISM) and co-founder of The Australian Psychedelic Society (APS). Melissa is an experienced scientific communicator through the written and spoken word. Melissa is interested in building next-generation mental health treatment in Australia through clinical research, cultural awareness and professional education. In her role as Education and Communications Officer of Mind Medicine Australia, Melissa harnesses her vision, tenacity, and experience as a scientific communicator to increase awareness of the clinical potential of psychedelic-assisted therapies.

Dr Martin Williams

Scientific Officer, Mind Medicine Australia

Martin Williams, a postdoctoral fellow in Medicinal Chemistry at Monash University, is founding Vice President of Entheogenesis Australis and founding President of Psychedelic Research in Science & Medicine (PRISM). He is also affiliated with Harm Reduction Victoria as a Peer Educator at events and festivals in Victoria. In

these various roles, Dr Williams advocates a mature, open discussion about the use of psychoactive plants and chemicals in societies, past and present, and their (increasingly demonstrated) potential to contribute to a more healthy and harmonious future for humanity. With his fellow members of PRISM, he is working to initiate an Australian contribution to the expanding global field of psychedelic medical research. In partnership with St Vincent's Hospital, PRISM will conduct the first Australian medical trial using psilocybin to ease anxiety and depression for terminally ill patients, supported by Mind Medicine Australia and the Vasudhara Foundation.

Attachment 5



Multidisciplinary Association for Psychedelic Studies
 1115 Mission St. Santa Cruz, CA 95060 USA
 Phone: +1 (831) 429-6362 Fax +1 (831) 429-6370
maps.org | mdmaptsd.org | mdma-autism.org

**Submission by MAPS to the Royal Commission into Victoria's Mental Health System via
 Mind Medicine Australia**

July 1, 2019

To the Royal Commission:

Since 1986, when I founded the [Multidisciplinary Association for Psychedelic Studies](http://maps.org) (MAPS), a non-profit research and educational organization, my life has been focused on understanding the therapeutic potential of psychedelics, including cannabis, as medical treatments for mental healthcare. Through MAPS, I have supported psychedelic research, education, and risk reduction for over thirty years.

MAPS is presently developing MDMA-assisted psychotherapy into a US Food and Drug Administration (FDA)-approved treatment, available by prescription. To that end we have sponsored clinical research into MDMA-assisted psychotherapy as a treatment for post-traumatic stress disorder (PTSD), social anxiety in autistic adults, and for anxiety associated with a terminal illness. Ongoing research is also studying MDMA for eating disorders, couples counseling, and in conjunction with other modalities, including cognitive-behavioral therapy (CBT) and exposure therapy. MAPS is currently conducting Phase III clinical trials and anticipates FDA approval in 2021, with approval from the European Medicines Agency (EMA) likely following soon after.

MAPS has also sponsored or otherwise supported research into the medical value of other psychedelics, including [LSD](http://maps.org), [ibogaine](http://maps.org), and [ayahuasca](http://maps.org).

Much of MAPS' education is focused on the fact that psychedelics have been plagued by an incomplete and often inaccurate understanding of their risks and benefits. Extensive research since the 1950s, and in particular over the last two decades, shows that when done responsibly, psychedelic-assisted therapy and/or interventions are safe for humans and effective for the treatment of certain mental illnesses, including anxiety disorders, substance use disorders, and depression.

For instance, data show that the combined neurobiological effects of MDMA can increase compassion for self and others, reduce defenses and fear of emotional injury, and make unpleasant memories less disturbing while enhancing communication and capacity for introspection. Our research has shown that these effects make MDMA a suitable pharmacological adjunct to enhance psychotherapy for anxiety disorders, such as PTSD, social anxiety in autistic adults, or end-of-life anxiety in terminally ill patients. Other psychedelics can similarly shift one's physiological and psychological experience enough to create a window of time in which people can make lasting change.

**Multidisciplinary Association for Psychedelic Studies**

1115 Mission St. Santa Cruz, CA 95060 USA
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maps.org | mdmaptsd.org | mdma-autism.org

For more specific information about MDMA, I welcome you to review [MAPS' 2017 submission to the US Sentencing Commission](#) or our MDMA [Investigator's Brochure](#) (updated 2018). In addition, attached to this submission is a written testimony from [REDACTED], a US Army and Marine veteran who was diagnosed with PTSD and experienced significant and enduring healing from his MDMA-assisted psychotherapy treatment in MAPS' Phase II clinical trials.

Further research into the safety and efficacy of psychedelic therapy is needed. MAPS supports and encourages the Victorian and Australian governments to research the medical and therapeutic potential of psychedelic substances.

I would be glad to provide additional evidence or testimony directly to the Royal Commission if requested, via phone or video-conference.

Sincerely,

Rick Doblin, PhD



Multidisciplinary Association for Psychedelic Studies
 1115 Mission St. Santa Cruz, CA 95060 USA
 Phone: +1 (831) 429-6362 Fax +1 (831) 429-6370
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Re: *Submission from MAPS (personal testimony) for the Royal Commission into Victoria's Mental Health System via Mind Medicine Australia*

July 1, 2019

To the Royal Commission:

My name is Sergeant [REDACTED] (US Army, Retired). I am a citizen and resident of the United States. I served [REDACTED] in the United States Marine Corps as a [REDACTED] [REDACTED] and I served [REDACTED] in the Army as an [REDACTED]. During my time in service I had the distinct honor of serving with ADF personnel during Operation [REDACTED] and in [REDACTED]. In both circumstances, I witnessed the best of Australia and every ADF member I interacted with showed determination, courage, and valor. It is my ADF brothers and sisters I think of as I write this testimony.

I was deployed to [REDACTED] in [REDACTED]. My base was mortared thousands of times. One of those mortars hit near my location, causing traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD). Within 60 days of my return to the US, I made 5 suicide attempts (others followed).

Prior to my participation in the MAPS trial I had crippling PTSD. The Veterans Administration (VA) Hospitals did their best with other approved treatments, but those were wholly inadequate in my case. I tried CBT, PET, and others. Throughout the treatments I was medicated heavily, at one point taking 42 pills a day, coupled with weekly talk therapy. None of this abated my daily constant suicidal ideation. My last suicide attempt was on [REDACTED] and I was hospitalized for 8 days.

I discovered MAPS and MDMA Assisted Therapy through a VA Intern. I applied and was accepted to the MAPS phase 2 trial. The treatment was unlike anything else I have experienced in my life. For the first time in [REDACTED] years, the therapy actually worked. My therapists asked simple questions and I was able to respond honestly without having a panic attack or any of the usual physiological responses that prevented me from approaching the trauma. I worked through various issues in my three sessions and saw improvement each time.

The effect this treatment has had on my life has been nothing short of a miracle. Following my final treatment and integration sessions, I noticed my PTSD was almost entirely gone (I went from a 95 to a 50 in CAPS-5 Scoring). Over the next 6 months, my suicidal ideation slowed and then stopped. My depression also improved greatly over time. I now lead a full and rich life; I am in the career field I have always wanted to be, and I am able to walk into rooms with 10,000 people without issue. I am better today than I was before I left for [REDACTED].

I took my last dose of MDMA in [REDACTED]. I have had no relapse, even though I had two highly traumatic events in my life in the past 12 months. In both cases (one involved a failed



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drowning rescue attempt), I talked over the phone with my therapist (without MDMA), and within a week I had no issues, as I had properly processed the trauma.

While I understand the stigma surrounding the MDMA molecule, the limited risks associated pale in comparison to the suffering it heals. MDMA-assisted therapy is given in a medical setting with specially trained licensed practitioners. We as a society regularly give exceptionally powerful medications involving surgery and other medical procedures under doctor's supervision; this is no different.

Research into the therapeutic effects of psychedelics has never been properly conducted in the past due to laws banning the research. I was taught that trauma-based mental illnesses were chronic, lifelong disorders: in other words, PTSD was my "new normal". MDMA-assisted therapy has demonstrated that this belief was false, and that mental injuries can be healed just like any other physical injury. We must conduct further research.

I would be honored to provide further written or oral testimony to the Royal Commission as requested.

Sincerely,

████████████████████

Statement to The Royal Commission into Victoria's Mental Health System

June, 2019

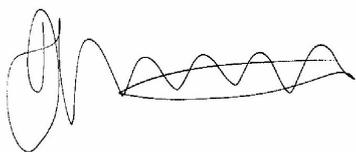
Professor David Nutt DM FRCP FRCPsych FMedSci DLaws
The Edmond J Safra Chair in Neuropsychopharmacology
Head Centre for Neuropsychopharmacology
Imperial College London
Burlington-Danes Building
Hammersmith Hospital
Du Cane Rd
London
W12 0NN



Introduction – my background

- 1) I am psychiatrist and professor of Neuropsychopharmacology at Imperial College London.
- 2) I am a Fellow of the Royal Colleges of Physicians and of Psychiatry and of the Academy of Medical Sciences of the UK. My cv is attached in the appendix below.
- 3) Because of my expertise in drugs of potential abuse I was appointed to chair the UK government Advisory Council on the Misuse of Drugs Technical sub-committee for the assessment of drug harms from 1999-2008. During this period I led the scientific reviews that recommended control of several drugs under the UK 1971 Misuse of Drugs Act.
- 4) In 2004/5 I was the medical lead on the UK government's Foresight committee that provided a 25 year future vision of addiction and brain science.
- 5) I have published over 500 research papers as well as several hundred specialist reviews and over 30 books in this field largely on the effects of drugs on the brain [see cv]. My book on drugs for the general public – Drugs: without the hot air (UIT press) won the Transmission prize for science communication in 2014.
- 6) Several of my research papers relating to drug harms and policy have been extensively cited and have been used to produce evidence-based changes to national drug policies in several countries including the USA, Finland and Sweden. As a result of this work I have been asked to speak on comparative drug harms in a number of important locations including at the UN Office of Drugs and Crime, the Houses of Parliament [UK], the European Commission, and in both the Dutch and New Zealand legislatures.
- 7) For over 25 years I have acted as the editor of the Journal of Psychopharmacology one of the top journals in the world on the effects of drugs and the brain.

- 8) In 2013 I was awarded the Nature/Sense About Science annual John Maddox prize for Standing up for Science by pursuing research of public interest with perseverance and courage.
- 9) My expertise has been recognised with a number of prestigious appointments including my current one as President of the European Brain Council [2013-2017] and previously presidencies of the European College of Neuropsychopharmacology, the British Association of Psychopharmacology and the British Neuroscience Association. I have also served on the MRC Neuroscience board, and for 16 years I held programme grant funding from the MRC for the study of addictions and the effects of drugs on the brain.
- 10) I have conducted scientific research on the brain actions in humans of a wide range of legal and illegal drugs including alcohol, tobacco, heroin, amphetamines, GHB, buprenorphine, antidepressants, benzodiazepines, antipsychotics, methadone, LSD, psilocybin, DMT, cannabis, cannabidiol, ketamine, paracetamol, ibuprofen and caffeine.
- 11) I have been requested by Mind Medicine Australia to comment on the potential use of psychedelics in mental health treatment for the Royal Commission into Victoria's Mental Health System.
- 12) My research group has conducted a series of world-leading studies on the effects of psychedelic drugs in the brain. The drugs studied were psilocybin [magic mushrooms] LSD and DMT.
- 13) From these brain imaging studies we came to the conclusion that these drugs might be useful in the treatment of psychiatric disorders especially depression
- 14) In 2012 we obtained funding from the UK MRC to conduct a study of psilocybin in treatment-resistant depression. This trial proved that a single high [25mg] dose of psilocybin could produce profound and enduring improvements in mood.
- 15) Since then there have been a series of similar studies in patients with other forms of depression, addictions and other mental health problems. Together these confirm a significant benefit from psilocybin
- 16) During these studies there have been no significant adverse effects reported
- 17) The effect sizes of these psilocybin interventions are high, often greater in magnitude than those produced by other medicinal and psychological approaches
- 18) On the basis of these results there is a strong need to conduct further studies to confirm these present findings and establish the utility of psilocybin therapy in other countries and in other indications. If these are positive then I believe psilocybin will rapidly become an accepted treatment for mental illness.
- 19) I can confirm that I am willing to give evidence directly to the Royal Commission if required [e.g. via a skype interview].



Signed Prof David Nutt

Appendix – CV

NAME: David John NUTT

[REDACTED]

PRESENT POSITION:

The Edmond J Safra Chair in Neuropsychopharmacology
 Head Centre for Neuropsychopharmacology
 Division of Brain Sciences
 Dept of Medicine
 Imperial College London
 Burlington-Danes Building
 Hammersmith Hospital
 Du Cane Rd
 London
 W12 0NN

[REDACTED]

Overview

David is currently the Edmund J Safra Professor of Neuropsychopharmacology and Head of the Centre for Neuropsychopharmacology in the Division of Brain Science, Dept of Medicine, Hammersmith Hospital, Imperial College London. He is also visiting professor at the Open University in the UK and Maastricht University in the Netherlands.

After 11+ entry to Bristol Grammar he won an Open Scholarship to Downing College Cambridge, then completed his clinical training at Guy's Hospital London. After a period in neurology to MRCP he moved to Oxford to a research position in psychiatry at the MRC Clinical Pharmacology Unit where he obtained his DM. On completing his psychiatric training in Oxford, he continued there as a lecturer and then later as a Wellcome Senior Fellow in psychiatry. He then spent two years as Chief of the Section of Clinical Science in the National Institute of Alcohol Abuse and Alcoholism in NIH, Bethesda, USA. He returned to England in 1988 to set up the Psychopharmacology Unit in Bristol University, an interdisciplinary research grouping spanning the departments of Psychiatry and Pharmacology before moving to Imperial College London in December 2008 where he leads a similar group with a particular focus on brain imaging especially PET.

He is currently President of the European Brain Council and Chair of the Independent Scientific Committee on Drugs (ISCD) and Past-President of the British Neuroscience Association. In addition, he is a Fellow of the Royal Colleges of Physicians, of Psychiatrists and of the Academy of Medical Sciences. He is also the UK Director of the European Certificate and Masters in Affective Disorders Courses and a member of the International Centre for Science in Drug Policy. He has edited the Journal of Psychopharmacology for over fifteen years and acts as the psychiatry drugs advisor to the British National Formulary. He has published over 450 original research papers, a similar number of reviews and books chapters, eight government reports on drugs and 31 books including one for the general public Drugs without the hot air, which won the Transmission book prize in 2014.

Previously he has been member and Chair of the Advisory Committee on the Misuse of Drugs (ACMD – 1998-2009), President of the British Association of Psychopharmacology

(BAP), President of the European College of Neuropsychopharmacology (ECNP), member of the HEFCE/NHS Senior Lecturer Selection Panel and member of the MRC Neuroscience Board. Other previous national contributions include serving as the medical expert on the Independent Inquiry into the Misuse of Drugs Act (2000 Runciman report), and membership of the Committee on Safety of Medicines, the Committee on NHS drugs and the Ministry of Defence Science Advisory Board. He was the clinical scientific lead on the 2004/5 UK Government Foresight initiative "Brain science, addiction and drugs" that provided a 25-year vision for this area of science and public policy and in 2006 he was Director of Bristol Neuroscience.

He broadcasts widely to the general public both on radio and television; highlights include being a subject for The Life Scientific on BBC radio 4, several BBC Horizon programs and the Channel 4 documentary Ecstasy-live. Additionally, David is much in demand for public affairs programs on therapeutic as well as illicit drugs, their harms and their classification. He also lectures widely to the public as well as to the scientific and medical communities; for instance has presented three times at the Cheltenham Science Festival and several times for Café Scientifiques. In 2010 The Times Eureka science magazine voted him one of the 100 most important figures in British Science, and the only psychiatrist in the list and in 2013 he was awarded the John Maddox Prize from Nature/Sense about Science.

Career Overview

SCHOOL: Bristol Grammar School

UNIVERSITY:

1969 - 1972 Downing College, Cambridge - Open Scholarship

1972 - 1975 Guy's Hospital, London

QUALIFICATIONS:

1972	BA (Cantab)
1975	MB BChir (Cantab)
1977	MRCP (London)
1981	MA, MB, BChir (Oxon) (by Incorporation).
1982	DM (Oxon)
1983	MRCPsych (UK)
1994	FRCPsych (UK)
2002	FMedSci
2002	FRCP
2016	Doctor of Laws honoris causa (Bath university)

GENERAL MEDICAL COUNCIL REGISTRATION 2251774

POSITIONS HELD

1969	Technician, Dr A Rogers, Physiology Dept, Bristol University
1975	House Physician, Guy's Hospital
1976	House Surgeon, Royal Sussex County Hospital, Brighton
1976	Senior House Officer, Dermatology, Guy's Hospital
1977	Senior House Officer, Neurology, St. Mary's Hospital, Paddington
1978	Senior House Officer, Psychiatry, Guy's Hospital
1978-1982	Clinical Scientist in the MRC Unit of Clinical Pharmacology, Radcliffe Infirmary, Oxford (Professor D G Grahame-Smith).
1982-1983	Registrar in Psychiatry on the Oxford Rotational Training Scheme.
1983-1985	Lecturer in Psychiatry, University of Oxford, attached to the Psychopharmacology Research Unit, Littlemore Hospital, Oxford.

1985-1986	Wellcome Senior Fellow in Clinical Science; University Department of Psychiatry, Warneford Hospital, Oxford. Honorary Consultant Psychiatrist.
1986-1988	Fogarty Visiting Scientist NIH and Chief of the Section of Clinical Science, National Institute on Alcohol Abuse and Alcoholism, Bethesda, Maryland.
1988-date	Director, Psychopharmacology Unit, University of Bristol; Senior Research Fellow in Pharmacology and in Mental Health; Honorary Consultant Psychiatrist, United Bristol Healthcare Trust.
1994	Professor of Psychopharmacology, University of Bristol
1996-1997	Head, Division of Psychiatry, University of Bristol
1997-2003	Head of Department of Clinical Medicine
2000-2003	Dean of Clinical Medicine and Dentistry
2003- 2008	Head of the Department of Community Based Medicine
2008- 2016	Edmond J Safra Chair of Neuropsychopharmacology Imperial College London

AWARDS & PRIZES

1969-1975	Saunders Open Scholarship
1969-1975	Christchurch & Bushmills Scholarships
1971	Badminton "Blue"
1972	JCR President Downing College
1972-1975	Clinical Prizes: First Clinical Prize Guys Hospital: Gillespie Prize in Psychiatry Gilbert Prize in Rheumatology Dermatology Prize Beany Prize in Pathology
1972-1975	University "Purple" and Captain of Badminton, London University
1975	Mental Health Trust Essay Competition: "The Significance of Life Changes in the Development of Illness"
1984	Royal College of Psychiatrists Research Prize, Proxime Accessit: "The experimental pharmacology of anxiety: New concepts of benzodiazepine receptor function"
2009	Daily Telegraph Briton of the year – top 25
2009	2 nd (to Banksy) as Bristolian of the year
2010	69 th place in The Times list of 100 most influential figures in UK science
2013	Winner the John Maddox prize for Standing up for Science
2014	The Transmission prize for science communication
2015	The BNA John Wolstencroft lecturer

COLLEGE APPOINTMENT

1983-1988	Research Fellow in Medical Sciences, Corpus Christi College, Oxford
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LEARNED SOCIETIES by examination or election

	Royal College of Physicians
	Royal College of Psychiatrists
	President British Association for Psychopharmacology – President - 2000-2002 (BAP)
	President European College of Neuro-Psychopharmacology (ECNP) – President 2007-2010
	President British Neuroscience Association 2011-2013
	President - European Brain Council 2013-2017

Editor: Journal of Psychopharmacology since 1989
Drug Science, Policy and Law since 2013

OTHER UNIVERSITY AWARDS

Visiting Professor University of Maastricht	2004-date
Visiting Professor Imperial College University of London	2006 -2011
Visiting Professor University of Otago, New Zealand	2004-2008
Raine visiting professor, University of Western Australia	2006
Visiting Professor The Open University UK	2014

GOVERNMENT RESPONSIBILITIES

Home office

Chair: Advisory Council on the Misuse of Drugs	2008 -2009
Chair of Technical Committee, ACMD	2000-2008
Cross departmental research group	2008
Home Office Scientific Advisory Committee	2008

Science and technology/ DTI/OSI

Scientific Lead DTI Foresight Program “Brain Science Addiction and Drugs” 2003-2005

Dept of health

Advisory Committee on NHS Drugs	1995-2000
British National Formulary (BNF) Adviser	2000-date
Committee on Safety of Medicines	2000-2005

Ministry of Defence

Consultant	1990 - 2004
Member Defence Sciences Advisory Council - DSAC	2005- 2007

Parliamentary evidence

To House of Lords committee on cannabis	2000
Home Affairs committee on drugs	2004
Evidence to the Select Committee on Science and Technology; Scientific Advice, Risk and Evidence:	2006
Cocaine and related drugs	2009
Home affairs Select Committee review of the drug laws	2012

Advisor to Swedish government review on drug alcohol and tobacco research 2011-2012
EU scientific committee for Month of the Brain 2013 2012-2013

Charitable work

Founder and current Chair DrugScience.org.uk (formerly ISCD) 2010 - on
Founder/Chair London Joint Working Group on Drug Abuse and Hepatitis C 2009 - 2014

Refereeing for grants and fellowships: MRC, BBSRC, ESRC, Wellcome Trust, The Netherlands MRC, NIHR, INSERM, German-Israel research fund, NIH

SUPERVISION OF RESEARCH STUDENTS: 40 students to PhD or MD degrees

Reports and books

Drugs and the Law: Report of the Independent Inquiry into the Misuse of Drugs Act 1971. Members of Inquiry: Viscountess Runciman (Chairman), A Chesney, R Fortson, J Hamilton PQPM, S Jenkins, A Maynard, L G Murray, DJ Nutt, D O'Connor QPM, G Pearson, I Wardle, B Williams, A Zera. Report published in 2000.

Advisory Council on the Misuse of Drugs (2002) The Classification of Cannabis under the Misuse of Drugs Act 1971. London: Home Office.

Nutt DJ and Nash J 2002 Cannabis- an update. Home Office publications
http://www.drugs.gov.uk/ReportsandPublications/Communities/1034165905/Cannabis_update_1999to2002.pdf

Nutt DJ and Williams T 2004 Ketamine – an update
<http://www.drugs.gov.uk/ReportsandPublications>

Williams T and Nutt DJ 2005 – Khat (qat): assessment of risk to the individual and communities in the UK – Home Office on-line publication <http://drugs.homeoffice.gov.uk>

Rawlins M et al 2005 Further considerations of the classification of cannabis under the Misuse of Drugs Act 1971

Rawlins M et al 2008 Cannabis; classification and public health. Home Office on line publication <http://drugs.homeoffice.gov.uk/publication-search/acmd/acmd-cannabis-report-2008>

Nutt DJ et al (2009) MDMA (ecstasy): A review of its harms and classification under Misuse of Drugs Act 1971 <http://drugs.homeoffice.gov.uk/publication-search/acmd/acmd-MDMA-report-2009>

EMCDDA monograph 2009. Addiction neurobiology: ethical and social implications
<http://www.emcdda.europa.eu/publications/monographs/neurobiology>
 ISBN 978-92-9168-347-5 doi: 10.2810/48676

ISCD publication 2011. A minimum data set for the control of new drugs
<http://drugscience.org.uk/minimumdataset.html>

WHO pre-review on cannabis 2016
<http://www.drugscience.org.uk/legislation/whocannabis>

Books

1. Sarter M., Nutt DJ., Lister, RG. (1994) Inverse agonists. John Wiley and Sons 1-304; i-x
2. Nutt, DJ & Mendelson, WB. (1995) Hypnotics and Anxiolytics. Baillière's Clinical Psychiatry. Ed. Byres, C. Baillière's Tindall Ltd, London 1-509; i-ix
3. Nutt, DJ., Bell CJ., Potokar J. (1997) Depression, Anxiety and mixed Conditions. Martin Dunitz Publishers, London 1-72
4. Nutt, DJ., Ballenger, JC., Lépine, JP. (1998) Panic disorder: clinical diagnosis and treatment. Martin Dunitz Publishers, London 1-237, i-ix
5. Nutt, DJ., Argyropoulos, S., Forshall, S. (1998) Generalized anxiety disorder: diagnosis, treatment and its relationship to other anxiety disorders. Martin Dunitz Publishers, London, pp: 1-97
6. Shiloh, R., Nutt, DJ., Weizman, A. (1999) Atlas of Psychiatric Pharmacotherapy. Martin Dunitz Publishers, London 1-235, i-ix. ISBN 1-85317-630-3
7. Briley, M & Nutt, DJ. (2000) Milestones in Drug Therapy: Anxiolytics. Birkhäuser Verlag, Basel, Switzerland 1-181, i-ix. ISBN 3-7643-6032-1
8. Nutt, DJ., Davidson, J., Zohar, J. (2000) Post traumatic stress disorder: diagnosis, management and treatment. Martin Dunitz Publishers, London 1-260, ISBN 1-85317-926-4 second edition 2008
9. Nutt, DJ., Hood, SE., Argyropoulos, SV (2000) Clinician's manual on anxiety disorder and comorbid depression. Science Press, London 1-56. ISBN 1-85873-397-9
10. Griez, E.J.L., Faravelli, C., Nutt, DJ., Zohar, J. (2001) Anxiety disorders: an introduction to clinical management and research. John Wiley & Sons Ltd, Sussex 1-380, i-xxii. ISBN 0-471-97873-6

11. Nutt, DJ., Bell, C., Masterson, C., Short, C. (2001) Mood and anxiety disorders in children and adolescents. Martin Dunitz Limited, London 1-110, i-viii. ISBN 1-85317-924-8
12. Nutt DJ, Feeney A, Argyropoulos S. (2002) Anxiety disorders comorbid with depression: panic disorder and agoraphobia. Martin Dunitz Limited, London 1-111. ISBN 1-84184-049-1
13. Nutt DJ, Rickels K, Davidson J. (2002) Generalised Anxiety Disorder: Symptomatology, Pathogenesis and Management. Martin Dunitz Limited, London. i-xii, 1-204. ISBN 1-84184-131-5
14. Nutt, DJ & Ballenger, JC. (2003) Anxiety disorders. Blackwell Science Limited, Oxford. I-xii, 1-542. ISBN 0-632-05938-9.
15. Kennedy SH, Lam RW, Nutt DJ, Thase ME. (2004) Treating depression effectively: applying clinical guidelines. Martin Dunitz Limited, London. 1-154. ISBN 1-84184-328-8
16. Doble A, Martin IL, Nutt DJ. (2004) Calming the brain: benzodiazepines and related drugs from laboratory to clinic. Martin Dunitz Limited, London. i-vi, 1-185. ISBN 1-84184-05201.
17. Nutt DJ, Robbins TW, Stimson, GV Ince M and Jackson. A (2006) Drugs and the Future: Brain Science, Addiction and Society. Elsevier. ISBN 0-12-370624-6
18. Shiloh, R., Weizman, A Nutt, DJ. (2007) Atlas of Psychiatric Pharmacotherapy. Martin Dunitz Publishers, London 1-235, i-ix. ISBN 1-85317-630-3. 2006
19. Monti JM, Pandi-Perumal SR, Jacobs B, Nutt DJ (2007) Serotonin and sleep; molecular functional and clinical aspects Birkhauser-Verlag Boston
20. Kennedy SH, Lam RW, Nutt DJ, Thase ME - 2nd edition (2007) Treating depression effectively: applying clinical guidelines. Martin Dunitz Limited, London. 1-154. ISBN 1-84184-328-8
21. Nutt, DJ, Stein M, Zohar, J. Post traumatic stress disorder: diagnosis, management and treatment. 2nd edition second edition in preparation for 2008 Taylor Francis
22. Blanchard RJ, Blanchard DC, Greibel G, and Nutt DJ (2008) Handbook of Fear and Anxiety. New York: Elsevier, 2008. 517 pp. ISBN 978-0-444-53065-3
23. Latt N, Conigrave KM, Marshall J, Nutt DJ, Saunders JB (2008) Addiction: Oxford Specialist Handbook. Oxford UK
24. Wilson SJ and Nutt DJ (2008) Sleep Disorders; Oxford Psychiatry Library - reprinted 2013
- 25 Robbins TR, Everitt B, Nutt DJ (2008) The Neurobiology of Addiction – New Vistas. Philosophical Transcriptions of the Royal Society
26. Pariante CM, Ness R, Nutt DJ, Murray R, Wolpert L (2009) Treating depression: a translational approach
27. Robbins TR, Everitt B, Nutt DJ (2010) The Neurobiology of Addiction – New Vistas OUP
28. Nutt DJ; Drugs: without the hot air (2012) UIT press ISBN 13: 9781906860165
29. Nutt DJ and Nestor L (2013) Drug Addiction OUP
30. Drug and alcohol policy in Europe – the ALICE RAP report. OUP [in press]

Publications

500 + original research papers

more than 500 reviews, book chapters and other outputs