PRESCRIBED DEATHS

LIFE IN THE KILLING ZONE

PATRICK O'CONNOR

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Prescribed Deaths – Life in the Killing Zone

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Warning

Do not stop taking a prescribed medication without discussing it with your doctor. Information can also be obtained by calling the NPS Medicines Line on 1300 633 424 or the Adverse Medicines Events Line on 1300 134 237 for advice. If you need support for any medical concern, including mental health matters, please contact your doctor. Lifeline also provides a 24 hour support service on 13 11 14 or www.lifeline.org.au

ABOUT THE AUTHOR – PATRICK O'CONNOR

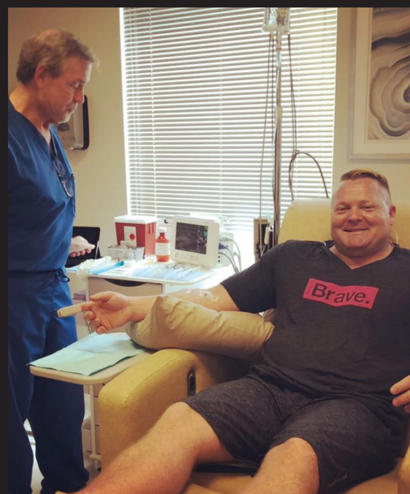
UN. New York – 2019

My name is Patrick O'Connor. Like a million other Australians, I live with severe mental illness. And like most of those people – my people – I also live with other debilitating chronic illnesses.

In 2016, I reached the end of the line when it came to medical treatments in Australia. Based on my condition, statistically I only had three years to live. My physical conditions were destroying my body, my mental illness was torturing me with extreme psychological distress, and the prescribed medication – well, that was killing me too.

I honestly couldn't see myself lasting another 12 months, and I shouldn't have.

BECOMING TREATMENT RESISTANT



Ketamine Research Institute, Florida, USA – 2018

Many of the dangerous PBS medications described in this report have been prescribed to me. These medications shorten lives, threaten lives, and can be used to end lives. I know, I have experienced all three.

My life expectancy was comparable to living with a terminal illness, yet I was told that there were no treatments left to try. Doctors described my conditions as 'treatment resistant' – but I felt that the doctors in Australia were the ones being resistant to trying new treatments. Faced with the reality that my doctors could offer nothing to save my life, I made the decision to save myself.

I researched new advancements in medicine and continually came to the same outcome: I needed to go to the USA. While I had experienced a negative view of the US healthcare system by many Australian doctors, to me, it offered the best chance at life.

For four years, I travelled to the US every few months for treatments that were not available in Australia.

While not everything worked, I could still see how the treatments were helping others. Many treatments did (and still do) work for me and saved my life – as well as thousands of others in the US every day.

EXPLORING OPTIONS

To find the right medical pathway for me, I knocked on the doors of countless medical specialists across America. The whole time, I was tormented with the realisation that unless I could bring these treatments to Australia, my people would continue to suffer and die prematurely. That is what led to this report.

I wrote this report during my battle, not at the end of it. I wanted to provide information to save lives, just in case I wasn't successful in saving my own. I needed to make sure what you are about to read didn't die if I died.

I am proud, very proud, that I have been able to play a role in bringing some of the treatments from the US to Australia. A second report will follow this one to explain that journey.

FORMING THE KILLING ZONE

Severe mental illness is pure evil. It seeks to destroy everything you love, and when it has done that, it comes back to take your life. It's a slow death, torturous and horrific. It impacts everyone around you, it has no mercy or compassion and even after it has taken lives it continues to bring pain to family and friends. You cannot co-exist with evil – it has to be killed and that has always been my goal.

Yale University, School of Medicine, USA – 2019

Before you read the report there is something deeply personal that I want to share with you. In short, I should be dead. Several years ago, I went through a period when I wasn't winning. I was suffering on an unimaginable level and I lost my battle. I simply wanted the suffering to end, so I consumed a large quantity of my medication. It was the worst day of my life, but not my last. The next morning, I woke up in my hotel room. Written on the note pad beside my bed were three words: 'The Killing Zone'. I knew what that meant and what I had to do.

Something happened that night in the period when my body was processing a prescription medication cocktail that should have ended my life. In my heart, I believe that the thousands of 'my people' who lost their battles, sent me back to tell our story. That day I opened my laptop and I started to write this report.

A friend once told me that "depression costs people, people"; for me it cost me the women I loved. There was never any fault, and I always knew this was a battle I had to fight alone. They all loved and supported me, yet losing their smiles from my world made me fight harder to stop the same thing happening to others.

I make no apologies for anything contained in this report. I have written this in the same way that I have lived the last eight years – fighting for change and for a better life.

REMEMBERING THOSE WE HAVE LOST

On one of my visits to the US I visited a cemetery in a region heavily impacted by the Opioid Crisis. Hundreds of thousands of vulnerable people died after seeking help from their doctors, without receiving warning of the risks of the medications prescribed.

While there, I had a brief conversation with a couple about this report. They asked me to publish the names of those who need to be made accountable, no matter the consequences. I hesitated to commit, but they pointed to the recent graves and said, "It's the only way to stop families having to put names here". It was a deeply moving day for me.

I have fulfilled the promise. The report is finished but the fight for change is only just getting started.

Patrick O'Connor

EXECUTIVE SUMMARY

The greatest barrier to improving the lives of millions of Australians with mental illness is not the illness itself, it is the medications prescribed by our doctors. This report unravels a myriad of systemic issues, and lays bare a healthcare system that is causing more suffering and deaths than the illness it treats. There are multiple safety failures in the medication prescribed to treat mental illness and pain conditions (conditions commonly suffered together). By exposing the indefensible failure to uphold our human right to safe healthcare and the resulting loss of life, this report aims to force urgent changes in the way these conditions are treated.

Severe mental illness rarely exists as a single condition and sufferers typically deal with multiple chronic illnesses. To attempt to improve our afflictions we are managed by multiple doctors, using complex medication prescriptions combined with other treatments. From diagnosis to unconscionable exposure to premature death – this is the reality of Australia's response to mental illness.

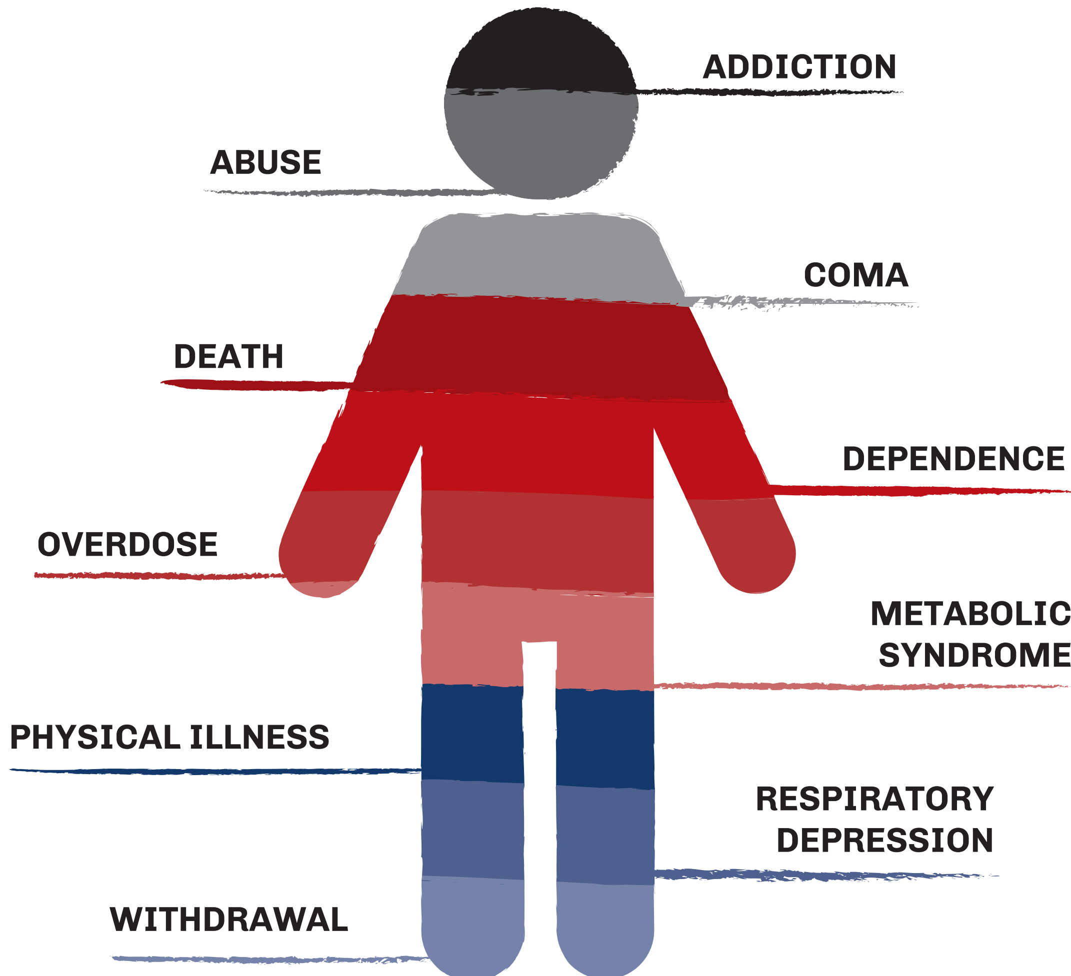
This report is written from the perspective of people who live with severe mental illness. The author has personally experienced treatments in both the Australian and the US mental healthcare systems. Using those experiences, we provide a deeper understanding of what life is like with mental illness, the issues that are not being addressed, and some recommendations to start saving lives today.

Arguably the greatest barrier to fixing many of these systemic problems is getting people in positions of responsibility to acknowledge publicly that the failures exist. This report aims to call attention to how dire the situation really is in this country.

Prescribed Deaths – Life in The Killing Zone provides frightening insights into our endless struggle to survive. Thankfully, there is a path to saving lives, and it starts here.

OUR PHARMACEUTICAL COCKTAIL

Medications used as frontline treatments for mental health in Australia include opioids, benzodiazepines, antidepressants and antipsychotics. The life-threatening risks of these medications include:



Due to these high risks, most of these medications are classed as scheduled poisons. Their use is controlled and it is illegal to possess them without a prescription. The risks of these medications, such as addiction, begin from the **first dose** and they are present even when being used as prescribed for a short period of time. Australia places second in the world for prescription drug addiction (the US is first).

On one hand, these drugs are deemed medications for treatment, but due to the dangerous side effects, they are also classed as dangerous poisons. When these medications happen to be used together, the risks multiply – particularly the risk of death. Yet lethal combinations of these medications are prescribed to treat millions of vulnerable people with mental illness and pain conditions in Australia, with the numbers growing each year.

THE HUMAN COST

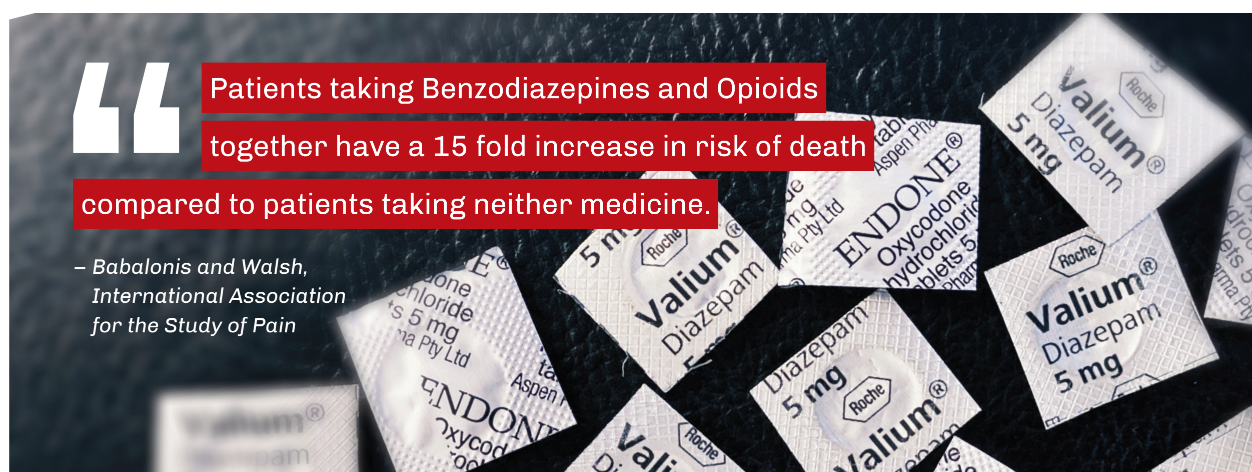
Tragically these medications are also the leading cause of overdose deaths and hospitalisations in Australia. People are dying as a result of the medication that was prescribed to treat them; the greatest failure a healthcare system can make. Drug overdose deaths kill more Australians each year than car accidents, with prescription medications being the most common drug present. The victims are most commonly people who are taking medications that are prescribed by their own doctor, for diagnosed mental illness and pain conditions, with medications dispensed by their usual pharmacist. The number of deaths has trebled since 2007 and it continues to rise each year.

In 2017 the Australian Bureau of Statistics (ABS) Director of Health and Vital Statistics, James Eynstone-Hinkins, said drug deaths were **most commonly associated with benzodiazepines and oxycodone**, noting that, “These are both prescription drugs which are used to manage anxiety and pain respectively”.

ABS statistics also tell us that three million people use opioids each year and six million prescriptions are dispensed for benzodiazepines. Between 2001–2017, all opioids deaths totalled 13,269 and benzodiazepines caused 8,061 deaths.

The risks of prescription medication also pose a significant non-fatal impact. There are 250,000 Australians hospitalised each year, with another 400,000 presenting to emergency departments. As with fatalities, the medications identified in people’s bodies are opioids, benzodiazepines, antidepressants and antipsychotics.

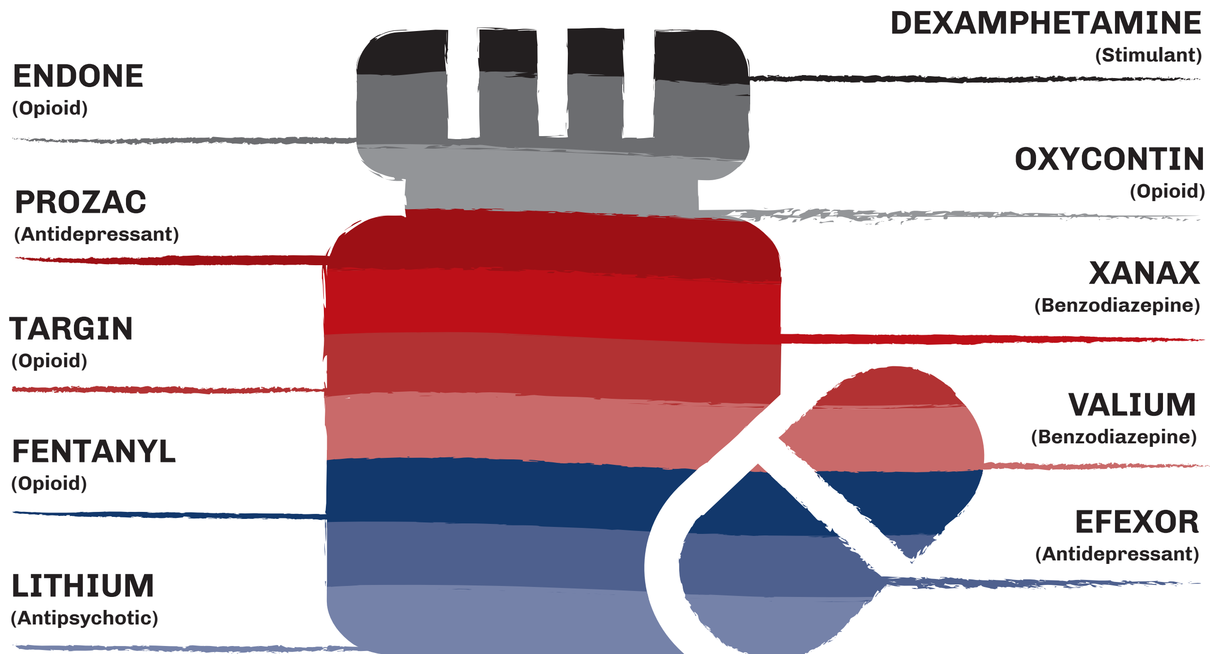
NSW Health estimates that there may be 750,000 Australians currently dependent on pharmaceutical opiates. Monash University claim 50,000 new people become long-term users of dispensed pain killers each year, putting them at risk of addiction. The prescribing practises of our doctors puts these lethal poisons in our hands, but the consumer warnings are just as deadly.



> “Patients taking Benzodiazepines and Opioids together have a 15 fold increase in risk of death compared to patients taking neither medicine.
>
> *– Babalonis and Walsh, International Association for the Study of Pain*

CONSUMER MEDICATION WARNINGS

This report has undertaken a detailed assessment of 10 medications prescribed in Australia through the Pharmaceutical Benefits Scheme (PBS). The analysis shows that pharmaceutical companies have been producing consumer medication information (CMI) documents that **deliberately include misleading, inaccurate and incomplete information on the life-threatening risks of taking these medications for over 20 years**. These risks include addiction, overdose, coma and death. For the 10 medications analysed, we identified 46 instances where the warnings represent breaches of the *Therapeutic Goods Act 1989*.



This is a sample of the most deadly prescription medications in Australia. These are the treatments prescribed to our most vulnerable people, yet the pharmaceutical companies have ensured they have not been warned of life-threatening risks. The CMIs provide very little information to the person on their exposure to these risks and how to avoid them. For example:

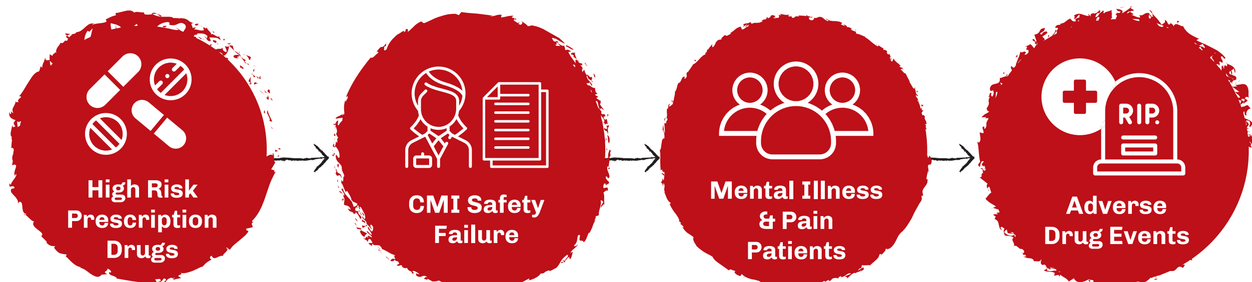
- Valium and Endone are controlled drugs due to the high risk of addiction, yet neither CMI mentions the risk of addiction once.
- Xanax, the benzodiazepine classified as the most dangerous due to the number of deaths recorded, contains no warning on the risk of death.
- OxyContin is responsible for the US opioid epidemic, where deliberately misleading information attributed to the deaths of hundreds of thousands of Americans. This misleading information is present in Australian CMIs.
- The Endone CMI describes the side effect of consuming alcohol whilst taking the medication as dizziness. In a separate document provided to doctors, the side effects listed include profound sedation, coma and death.
- The lethal toxicity of Lithium is dangerous even at prescribed levels, yet the CMI states the opposite.
- The combination of opioid and benzodiazepine medications is the leading cause of overdose deaths, yet none of the CMIs mention the risk of death when these drugs are prescribed together.

> ... these are all very dangerous drugs, reading these Australian warnings, I am very disturbed that patients haven't been warned up front, they haven't been warned adequately, and they haven't been warned enough.
>
> *– Dr Lori Calabrese (US psychiatrist and medication expert)*

When CMI versions from earlier years were analysed, the number of critical warning failures is two to three times greater. Arguably many of these are so incomplete that they do not meet the legal requirement to be classified as a CMI. We asked two leading US medication experts to provide their opinions on the warnings identified in our analysis. Both doctors noted that these side effects have been well known for decades and are clearly explained in US consumer warnings written by the *same companies* – and this presents a real risk to the safety of consumers.

Even for the 'weaker', commonly prescribed codeine opioids like Panadeine Forte, the CMI does not contain a single mention of the risk of death, addiction, dependence, tolerance, withdrawal or abuse. In comparison, the document provided to doctors for Panadeine Forte discloses the risk of death nine times.

This report shows that the **exact risks not disclosed are directly or indirectly linked to the majority of Australia's adverse drug events and deaths**. The cause and effect cannot be any clearer and the people affected are vulnerable people who are prescribed these medications.



INFORMED CONSENT

The rights of vulnerable people – in fact, all people – to safe healthcare is enshrined in the Universal Declaration of Human Rights, the Australian Charter of Healthcare Rights, and the Convention on the Rights of Persons with Disabilities. It is a legal requirement that medical treatment, including taking medication, can only commence after we give our informed consent. For the consent to be valid, it has to be informed, meaning that we have been provided with all the information about potential risks of taking the medication. This includes when multiple medications are prescribed.

The law provides us with the right to full disclosure of all risks – there is no discretion, even for risks that might be deemed rare in occurrence. Our CMI analysis is emphatic in demonstrating dangerous risks have not been disclosed for the most commonly prescribed medications for people with mental illness and pain conditions. Millions of people have given consent, without being informed, and hence their consent is not legally valid. You simply cannot assess a risk that you don't know about. You cannot follow safety advice if it has never been given to you. The resulting impact on human life has been physical illness, dangerous side effects and for many, death. Prescribing medication without informed consent is criminal. It exposes the system to medical negligence claims and it is an unequivocal breach of our fundamental human right to safe healthcare.

These Australian documents are woefully inadequate, they do not give a person the multiple life-threatening risks of these medications. This doesn't provide them with an understanding of the risks to give **informed consent**.

– Dr Craig Allen (US medical expert)

Global studies have shown that at least one third of people do not get any improvement at all from mental health medications. Benzodiazepines are not recommended to be used for more than a few weeks. Opioids are recommended to be prescribed at the lowest dose, for the shortest period of time. It is impossible to see how the benefits outweigh the risks, especially if the risks are not being acknowledged.

THE HEALTH CARE SYSTEM FAILURE

Medication is the most widely used medical treatment for mental health and pain in Australia. It is funded by the PBS, which is controlled by the Australian Government. Medication is prescribed by doctors and dispensed by pharmacists. It is regulated by the Therapeutic Goods Administration (TGA) and medication safety is also addressed by multiple other government departments. The ABS regularly reports on adverse medication events, including deaths. We have multiple organisations responsible for implementing the national mental health strategy. We also have countless independent mental health organisations and charities. Medication safety goes further than the pharmaceutical companies and the contents of the CMIs; it is the responsibility of all areas of the health care system.

Hence, how has an entire health care system failed to identify and correct the largest systemic failure of consumer health care rights in the last 50 years? Especially considering the resulting deaths are reported every year.

By examining the role of each area in this tragic failure, we uncover multiple systemic issues:

- **DOCTORS** – Mental health treatment is largely managed by General Practitioners (GPs). Mental illness diagnosis is based on self-reported symptoms, with significant potential for human error, misdiagnosis and unnecessary exposure to the wrong medication/s. It is estimated as many as 50% of diagnoses for depression may be incorrect. As with the CMIs, details of many medication risks have not been provided to GPs. For instance, a guideline for GPs on the prescribing of benzodiazepines made no mention of the risk of death. Over the 12-year period it was in use, 84 million prescriptions were dispensed,

and 4,459 people died from adverse side effects caused by benzodiazepines. Examining the time poor process by which GPs make a diagnosis, select medication for treatment, explain the risks and obtain informed consent, raises questions as to how the consent could possibly be valid.

> ... some GPs lack knowledge and skills in mental health and require considerably more training in identifying risks, diagnosing conditions, assessing and recognising the physical health consequences of prescribed treatments, and connecting patients with other services (such as online mental health services and allied health services).

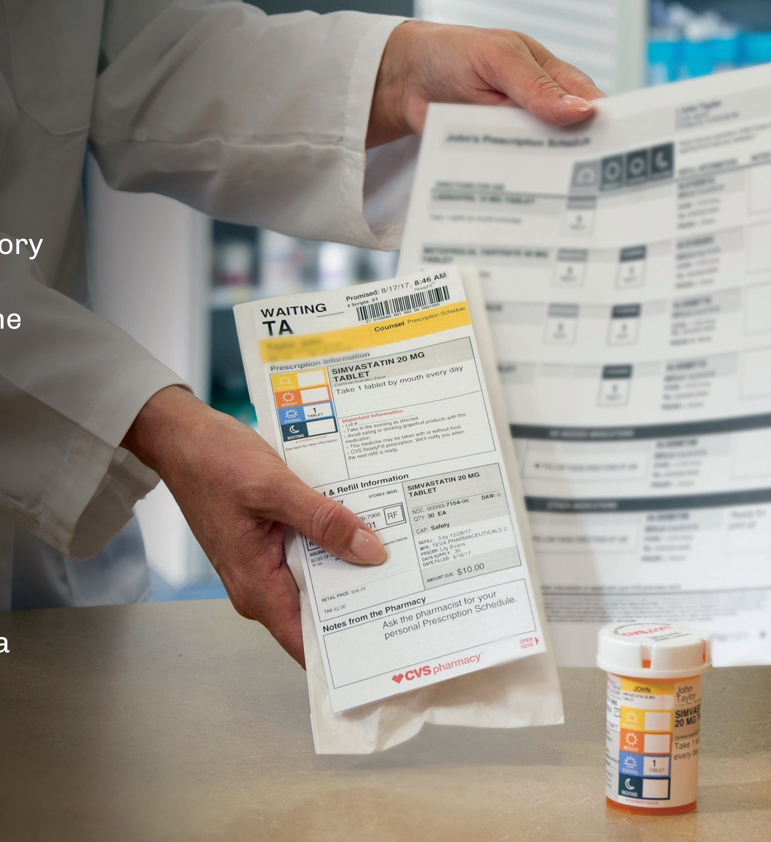
– Productivity Commission report into Mental Health 2019

– **PHARMACISTS –** The stewards of medication safety, pharmacists are remunerated significantly by the PBS for providing medication to Australians. They have an ethical and legal responsibility to deliver the highest level of medication safety to vulnerable people. The code of ethics for pharmacists requires them to ensure patients have information to make an informed decision on medication treatments. The code also requires pharmacists to ensure the information is relevant, and up to date. Pharmacists are responsible for dispensing the CMI leaflets, as part of consumer consultations to ensure safe medication use, and so have failed to identify and address the lack of warnings in the CMIs. A patient may have multiple doctors, but they generally have only one pharmacist. As such, pharmacists have visibility and access to information on a person's multiple prescriptions, as they are the chemist physically dispensing them. Pharmacists have also failed to ensure that vulnerable people with multiple prescriptions have been warned of the dangerous side effects of these combinations, even though they have software to automatically assess these risks.

There is no legal requirement for a doctor or pharmacist to give a person a CMI when medication is prescribed or dispensed. This is the case even for medication that is strictly controlled due to high risks, for medication that a person has never taken before, when a person is cognitively impaired, and even when **new dangerous warnings are added to a CMI**. A CMI is not even a mandatory provision when the side effects of the medication include sedation, confusion and memory loss, which are common with mental health medications. It is left to the person to ask for the information, or left to the discretion of a doctor or pharmacist. Multiple studies show that CMIs are rarely provided, and pharmacists have resisted any changes to the laws.

> Pharmacy Guild of Australia spokesman Greg Turnbull said the organisation supported "maximum patient empowerment and health literacy" but that making the issuing of a CMI mandatory "for every one of the 300 million-plus PBS scripts per year might not be the best solution".

When it comes to medication safety, this is actually the only solution. It is difficult to understand how consumers can reach a position of 'maximum patient empowerment and health literacy' without the information to read.



In comparison, the provision of consumer warnings with every prescription are mandatory in the US. In an interview with a pharmacist in Connecticut for this report, when asked why he agreed with this process he replied:

> Because the cost of a human life is worth more than the cost of a piece of a paper.

If only the Pharmaceutical Society of Australia (PSA) and the Pharmacy Guild of Australia felt that way too.

Real world experience of pharmacy consultations has been included in this report to show that information that is misleading and inaccurate is commonly provided to vulnerable people, including advice that could increase the risk of death to the consumer. The transcripts of the discussions with 15 pharmacists are simply horrifying.

> If you'd had some Endone and some Valium and two or three beers, you'd be like, 'No, I'm home for the night', because they've all got a sedating thing. I should write it down.

– Pharmacist

> You would have exactly what I have if you Google it up. Type in the name and read, that's exactly what I would give you.

– Pharmacist

> If you overdose, then – let me check. So the [inaudible] I mentioned it may lead to respiratory depression, constipation problem.

– Pharmacist

The PBS even allocates additional fees to be paid to pharmacists for the dispensing of dangerous medications that are scheduled poisons, like opioids and benzodiazepines.

- **THERAPEUTIC GOODS ADMINISTRATION (TGA) –** The TGA regulates consumer warning documents in Australia. In 2019 they admitted that the CMI for opioids do not contain warnings for the dangerous risks identified in this report. Each risk not appropriately disclosed is a breach of the *Therapeutic Goods Act 1989*, however the TGA opted to take no action, other than to request the pharmaceutical companies update the CMIs. Remember, 13,269 lives have been due lost to opioid use between 2001–2017 in Australia, yet the TGA takes **no legal action against the pharmaceutical companies who knowingly misled consumers**, with fatal consequences. Nor did the TGA investigate how broad this issue is or how it came to happen in the first place. The TGA's actions on CMI disclosure are woeful and fail to urgently address the issues. Troublingly they also have made no recommendations to ensure it doesn't happen again.

  Belatedly, some changes to opioid CMIs are slowly taking place. Finally, warnings relating to coma, overdose, addiction, abuse and death are being added. The TGA stated that the "improvements to information for prescribers and patients [are to] encourage best-practice prescribing and help consumers to be better informed about the potential risks and how to mitigate them". Consumers can only give informed consent to taking medication if they have been fully informed. The changes now being made by the TGA are an emphatic admission of the opioid risks that consumers have not been provided within the CMIs for decades.

  And alarmingly, the pharmacists we spoke to were unaware of the recently updated CMIs, and therefore, the critical warnings remain unknown to those filling or re-filling their prescriptions.

GOVERNMENT RESPONSE

When taking action on overdose deaths, the Australian Government goes to great lengths to blame the victims for the situation, even their own deaths. They enforce this narrative of prescription medication 'misuse and abuse' and 'victim blaming' in government policy. It provides a neat cause and effect link that all prescription medication deaths are caused by abuse and misuse, without any serious examination of other alternative reasons for these adverse events. The increase in deaths from prescription medication has increased with the growing prescribing of these medications. Why has there not been more investigation into how vulnerable people became addicted in the first place?

The government endorses the CMI as the information source for accurate medication safety and side effects, including prescription medication interactions. Approving these medications for the PBS provides a further endorsement in the minds of vulnerable people – given the PBS subsidises the cost, it makes the medication more accessible to us. The failure to ensure that vulnerable people are provided with accurate information is not only a breach of our right to safe health care, it also means that the government has full culpability for the resulting health issues we have suffered.

A CMI leaflet gives you information on how to use your medicine safely and properly. For example, it tells you:

- *how to take the medicine*
- *why it may have been prescribed for you*
- *potential side effects*
- *other medicines it may interact with*

There is a significant difference between 'how to take the medicine' instructions and warnings of the 'potential side effects' of taking a medication. Advising to not consume alcohol whilst taking the medication, is a how to take instruction. Advising that the consumption of alcohol with the medication can result in respiratory depression, coma or death, is an explanation of potential side effects. The CMI analysis shows that the focus is on how to use instructions and whilst this is important, it does not provide the information on the potential risks to enable a person to give informed consent.

The role of government is to protect the most vulnerable in our society. The thousands of people who have died and suffered at the hands of medication prescribed to them, without warning them of the risks, deserve a better response than to be blamed for their own deaths. It seems completely lost on all areas of health care that our cognitive ability is diminished due to the conditions we suffer and the medications we are prescribed. When it comes to medication safety, it is easy to see how this tragedy has unfolded.

The Australian healthcare system prescribes lethal poisons as treatments, without telling people the risks that can kill them. Please take a moment to read that again.

This report documents the government response to issues relating to medication safety attributed to doctors, pharmacists and pharmaceutical companies. In these instances, no link is made between the failures and the deaths. The issues are downplayed and handled with soft touch responses, like general warning letters. Overall, the government's response to the range of issues is disjointed, ignoring systemic issues in health care and lacking urgency given the severity of the problems. The introduction of a Real Time Prescription Monitoring (RTPM) system again focuses on the concept of victim blaming, using 'doctor shopping' as the primary reason for such a system. Despite the importance placed on the RTPM by government, it still hasn't been implemented nationally and is years overdue.

This report has also reviewed the recommendations of multiple government mental health plans and inquiries. The recurring outcome is that not only are the issues reported on mental health medication safety deliberately ignored, there is also very little being done to progress new treatments being introduced into Australia. In responding to the draft recommendations of the Productivity Commission report into Mental Health, the Pharmaceutical Society of Australia National President said:

Unfortunately, what the draft report seems to overlook is the need for improved medicine safety practices and strategies for people with mental ill health and across mental health services.

We need to ensure we are using medicine as effectively as possible in the treatment of mental ill-health. For this reason, PSA does not think it is possible to look at mental health care without considering the safe and quality use of medicines…

These organisations have also largely ignored the global recognition of the risks of medications and programs to reduce these deaths. The submissions to government from the lead mental health organisations, Beyond Blue, Black Dog Institute and Orygen/Headspace also ignore this issue. The consumer information they produce does not adequately explain the risks. These mental health organisations encourage Australians to seek treatment, so they have a responsibility to make sure the treatment they get is safe and people are informed of the risks.

Despite all the evidence, Australia still refuses to acknowledge and address the issues, urgently adopt safer medicine treatments, or even to warn consumers.

And why is it that a number of the organisations mentioned in this report have significant, and long-term, lobbying power with government? How is this regulated?

THE US AND AUSTRALIAN OPIOID CRISIS

A comparison of the well-documented US Opioid Crisis with trends in Australia's opioid deaths uncovered some brutally obvious consistencies. The same pharmaceutical companies, selling the same medications, withheld the same dangerous consumer warnings – the outcome is thousands of fatal and non-fatal events over the last 20 years. The only difference between the US and Australia is that the US has taken legal action against those companies, whilst in Australia they continue to enjoy the full support of government. In the last 12 months the companies referred to in this report have been forced to pay over USD $14 billion in compensation for the adverse drug events of the medications we analysed. In Australia they haven't paid a cent.

The architect of the US Opioid Crisis, Purdue Pharma, has filed for bankruptcy. Their Australian operation, Mundipharma, which sells OxyContin and Targin, is being sold to finance the compensation settlement to the American people. Purdue is also providing medication to prevent opioid overdoses for free as part of the settlement. Purdue do not provide the same medication for free in Australia; Mundipharma sell it at full price to the PBS.

Well, we don't want to end up in the place that the United States is in where opioids are a national crisis. Here, we are in a much better position…

– Greg Hunt, transcript of Tyabb Doorstop, 23 June 2018

Tragically the 13,269 people who died from opioid use, are certainly not in a better position.

It's time to call this what it is: Australia's very own overdose crisis. And make no mistake; it's a crisis that is getting worse.

– John Ryan, Chief Executive Officer of drug policy organisation, Penington Institute

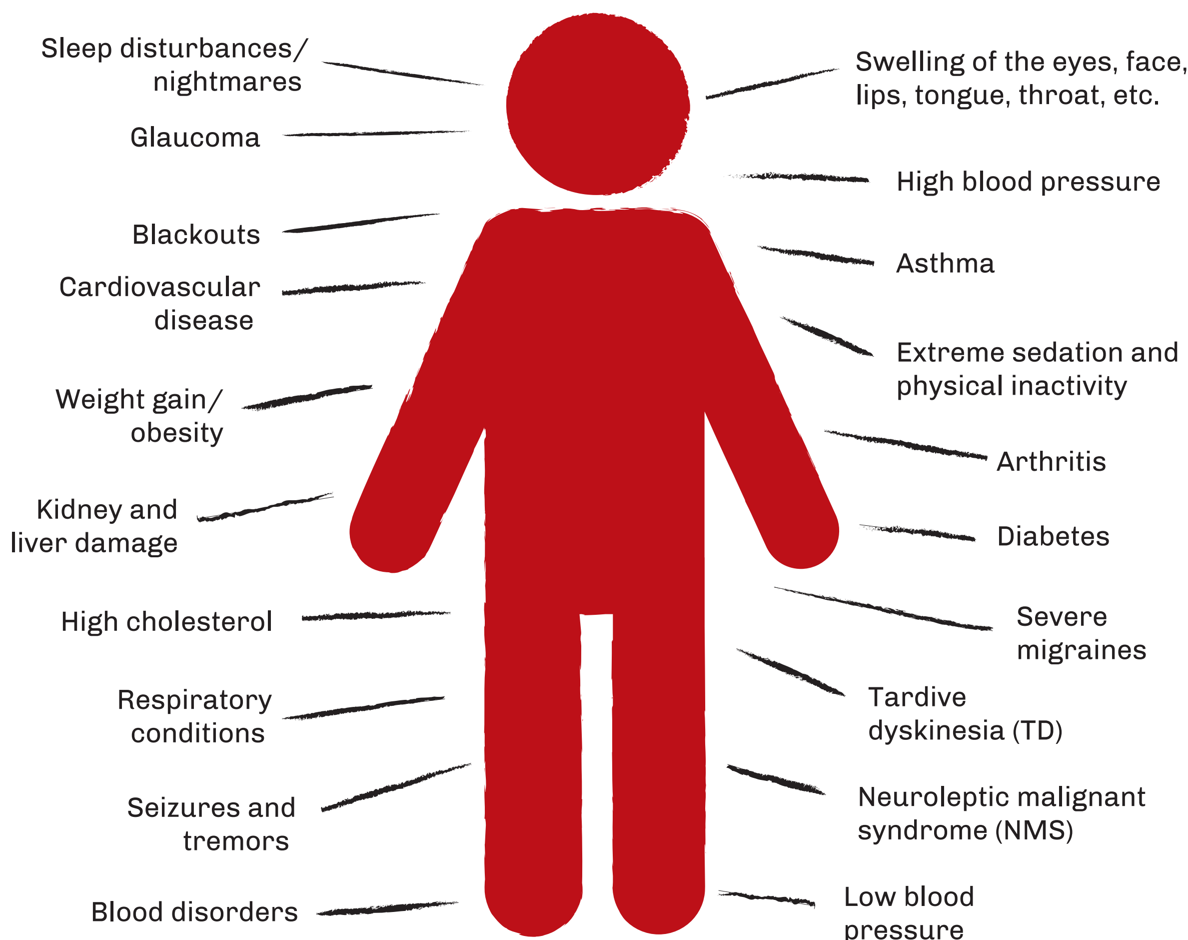
The legal action in the US has been successful based on the lack of consumer warnings that were provided about life-threatening risks. The exact same situation exists in Australia and it is time similar compensation is made payable to the victims.

SEVERE MENTAL ILLNESS – LIFE IN THE KILLING ZONE

...people with mental illness typically live between 10 and 32 years less than the general population.

– The Royal Australian and New Zealand College of Psychiatrists (RANZCP)

At least 800,000 Australians suffer from severe mental illness. Many also suffer from other physical conditions like chronic pain and even multiple mental illnesses. One million Australians suffer from both anxiety and depression. In addition to the life-threatening risks already mentioned, the medication prescribed also has many side effects that are described as life shortening; they are the main reason we live 10–32 years less than expected. **The medication prescribed for mental illness actually causes so much damage to our bodies that it shortens our lives. In trying to save people from suicide, we die prematurely due to physical illnesses**. Some of the side effects include:



This is one of the facts actually not disputed by the health care system; the physical damage from side effects has been known for decades. The Australian Government's National Mental Health Commission (NMHC) *2012 National Report Card on Mental Health and Suicide Prevention* confers:

> *"The finding regarding antipsychotic medications is most concerning. Most Australians may not know treatments with prescribed psychiatric drugs may lead to worse physical health. There are increased risks for some specific treatments such as antipsychotics and for those with underlying vulnerabilities such as diabetes. This can mean that the antipsychotic medications that are prescribed to manage severe mental illnesses such as schizophrenia, contribute to the risk of having severe physical illnesses. The decision for people to take medications to improve their mental health, is made often with the knowledge that their physical health and quality of life will suffer."*

People with lived experience will disagree that we have ever been made aware of these risks, and the CMIs provide no information on the trade-off we have made with our mortality.

Unlike other chronic illnesses like cancer, severe mental illness is not an illness that a person is expected to be cured from. Improving to a position of being in remission is rarely achieved or even discussed. We exist, we don't live. Our quality of life is poor and hope for a better life is all many have to hold on to. Unfortunately, hope can only last so long for many of us. The suicide rate among people with a mental illness is at least seven times higher than the general population. It is one of the main causes of our premature deaths.

In addition to the life-threatening and life-shortening risks, the lethal nature of our medications exposes us to risks that are described as life-ending. Prescription medication overdose is a common method of suicide. The same medications prescribed to vulnerable people with mental health and pain conditions are also toxic enough to be used as a means of suicide death, and sadly, they are being used for this purpose.

The statistics from the last 20 years show that opioids, benzodiazepines, antidepressants, and antipsychotics are not only the most common drugs present in accidental drug deaths, but they are also the same medications used in suicide attempts and deaths. Horrifyingly, in some instances, the very medication prescribed to treat the *risk* of suicide is used as a method of poisoning in suicide. Distressingly the increase in prescriptions of these medications to young Australians has resulted in an increase in their deliberate self-poisoning using these medications.

> The risk of a person dying by suicide increases if they have access to lethal means of death, like a firearm. Suicide prevention experts classify the medications in this report as lethal means of death, comparable to having a loaded gun in the home. Prescribing medication that can cause death, actually increases the risk of suicide to people with mental illness. No CMI explains this or provides any strategies to reduce this risk.

> "Reducing access to lethal means in the home, such as firearms and medication, can determine whether a person at risk for suicide lives or dies.
>
> *– Suicide Prevention Resource Center (US)*

The medication given to mentally ill people provides us with a method for taking our own lives, funded by the PBS, right in our own homes. How can deadly medications be legally prescribed and PBS-funded, with almost no consumer warnings to help patients and their families protect against the use of these drugs in suicides? Is there a greater failing of any society, or a greater breach of our human rights, than when a health care system deliberately provides vulnerable people with a deadly means of ending their suffering, funded by taxpayers?

The architects of Australia's adult and youth mental health system argue that it is more dangerous to not use these medications to treat mental illness than to use them, which is a view not universally agreed. What is beyond dispute is that all the risks of using medications must be provided to obtain informed consent. This report has found no evidence of any written consumer information in which this occurs.

The tragedy of prescription medications being used in suicides is also not mentioned in our national suicide prevention plans or reports. The World Health Organization (WHO) recommends that national plans have specific objectives to *reduce the number of suicides as a result of overdose of medications*. It seems this doesn't apply to Australia.

The statistics prove that you do not live a long time with severe mental illness. The greater the number and severity of medical conditions, the greater the suffering, the greater the struggle to regain good health and the greater risk of suicide. That is why many of us describe life with severe mental illness as living in The Killing Zone.

> Although psychological strategies are the first-line of treatment, antidepressants and other drugs form an important part of the care provided. But only about half of patients have a positive response from their first medication prescription, and the response diminishes with subsequent alternatives. Current approaches of trialling different medications may result in prolonged episodes of depression, which impacts on quality of life and may increase the risk of suicide.

– Greg Hunt in a statement about pharmacogenomic testing

PRESCRIBED HOPE – A CHANCE FOR LIFE

There is hope for those in The Killing Zone. Several new medications are now available and many more are in the final stages of regulatory approval overseas.

The National Institute of Mental Health (NIMH) is the lead US federal agency for research on mental disorders. With an annual budget of USD $2 billion, it is the largest mental health research centre in the world. They have been the driving force behind a number of medications now in use or in trial stage. Ketamine, administered via an IV drip, is described as having strong, rapid antidepressant effects within hours, even for people who have not responded to previous medications. A nasal spray ketamine version called Spravato was recently launched, as was the first medication for postpartum depression called Brexanolone. Global trials of Psilocybin and MDMA are yielding incredible results in depression treatment, with notable organisations involved including Yale University, John Hopkins University and the Imperial College of London.

Medical cannabis has proven globally to be a life-saving treatment to enable a better quality of life for people with chronic pain and mental illness. Whilst it is available in Australia, the regulatory process and lack of PBS subsidy makes it out of reach to most people.

Unfortunately, the Productivity Commission and NMHC are silent on these new treatments. They are not mentioned in recent reports or recommendations at all. Despite the lobbying of many with lived experience and mental health groups, accessibility of these treatments is far from imminent.

Incredibly, the lead reason given for not embracing these new medications is a belief that they will expose Australians to dangerous side effects. Not only is this position in contrast to their actions on protecting Australians from the dangers of existing medications, it also ignores the current global evidence that these new treatments are actually safer and more effective. So why are they so reluctant to change?

TIME FOR ACCOUNTABILITY

As disgraceful as the actions of the pharmaceutical industry are, vulnerable people have actually never met them. They don't treat patients, they don't diagnose conditions, they don't prescribe medication, they don't dispense medication, they don't review the patient's conditions regularly, they don't know what other medication the patients are taking or even their stage of recovery. Producing a medication with dangerous side effects and an equally dangerous CMI in itself doesn't kill anyone. For that to happen, it has to get in the hands of a patient and there are a lot of critical failures that occur to make that happen.

Many failures have also occurred in response to our prescription medication crisis; that list is even greater.

The RANZCP acknowledges the adverse side effects of mental health medications and the shorter life expectancy they contribute to. However, the *attitude* of psychiatrists in Australia to this matter has long been seen as a barrier to acknowledging the required changes to the prescribing practices of psychiatrists. The RANZCP in a media release (which has since been deleted) said:

> *"Psychiatrists are highly trained medical professionals with expertise in managing both physical and mental health. The prescription of antidepressant or antipsychotic medications is something that a psychiatrist only ever does in partnership with the patient and after due consideration of the risks and benefits."*

The patients of psychiatrists in this country do not share this view. We have been demanding new treatments to kill our mental illnesses because the ones we have now just kill us. These medications are the responsibility of the RANZCP and there is a lot that they need to explain and change.

The Black Dog Institute, Beyond Blue and Orygen/Headspace have received billions in taxpayer funding, yet no independent review of the investment has ever been released. These organisations refer to themselves repeatedly as 'world leading', 'world class' in delivering 'evidence based treatments', yet the real world results tell a different story. The use of medications like fluoxetine (Prozac) in Headspace clinics demands further examination, considering the rise in youth self-harm using fluoxetine and the fact that Orygen/Headspace published guidelines on its use and the lack of warnings in the CMIs.

These organisations have the most noble causes at their heart, but good intentions don't save lives; good medicine does. Encouraging people to talk, to seek help, and to help others, is not a treatment. The frustration of many people with lived experience with these organisations is that we have provided them with decades of stories on the failure of safe medication prescription. Despite this, we are still prescribed ineffective treatments, with horrendous side effects, reduced life expectancy, and no alignment with international human rights. Reviewing the online forum of these organisations shows a litany of messages dating back over years that are cries for help.

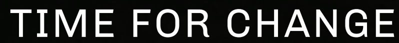
Many doctors and many psychiatrists – not one talked about side-effects or interactions with other medications.

– online forum Beyond Blue (2013)

These organisations might not be the appropriate areas to implement the changes, but they absolutely have the obligation to fight for us until someone else does. It is not just lived experience that has been dismissed, but also the numerous reports provided by medication safety audits.

Studies undertaken in the community have shown that people with mental illness who receive a collaborative medicines review have between four and seven medication-related problems per person, including problems with adverse drug reactions and drug interactions.

– Australian Commission on Safety and Quality in Health Care



TIME FOR CHANGE

When medication works it is life saving and there are many people who benefit greatly from existing drugs. When it doesn't, and this is the majority of instances, it impacts the ability for people to engage in other forms of mental health recovery. How are people expected to have any benefit when our medications leave us sedated mentally and debilitated physically? How can we exercise, when we are unable to walk without feeling physically ill from dizziness? How can we undertake therapy when we are so sedated we can barely stay awake? How can we maintain employment with significant cognitive impairment?

The best pathway to new treatments in all areas of mental health is to force national debate about the failures of the current health care model. We have no hope of a better life when government refuses to acknowledge and remedy the reasons why our life expectancy is 32 years shorter than it should be. We need a broad and all-encompassing Royal Commission into all areas of medication safety. Many aspects of this report demand criminal investigation. Thousands of lives have been lost. It is too easy to say that the system failed these people; **each person who died has a name**. Each person deserved better care from their doctors and those doctors have names. Each person deserved better care from their pharmacists and they have names too. The government officials who failed in their duty of care are easy to identify, as are the pharmaceutical brands they were prescribed.

The government's job is to save vulnerable people from disease and death. Saving vulnerable people from mental illness is no different to saving vulnerable people from COVID-19. Today, COVID-19 has no vaccine and no cure, and neither does mental illness. At the date of publication, COVID-19 has taken 102 Australian lives, and based on previous ABS reports, suicide will have taken over 1500 in the same time period.

Like cancer, the best way to stop mental illnesses is to treat it as soon as the symptoms appear. It is widely commented that people are slow to seek help for mental health conditions. The reason is attributed to a perceived stigma of these conditions. We have a different view. **People are not afraid of seeking help, they are afraid of the help they are going to get.** At all stages of a mental health illness, we need, expect and demand a level of intense focus to save our lives – with the same level of urgency that would be applied for a cancer diagnosis or a coronavirus pandemic. There is no other alternative.

The most important measure of success is actually not the lives that are saved from suicide, it is the quality of the life everyone who is afflicted gets to live. The health care system needs to be judged against delivering this outcome. There is no chance of achieving 'zero suicide' unless people are given a life worth living. More Australians will start talking when they can see a mental health system that saves lives, not reduces the quality and duration of them. Most importantly when this happens, and only then, can we finally start to win this war.

ABOUT THE REPORT

Prescribed Deaths – Life in the Killing Zone offers a detailed, holistic and wide-ranging assessment of the Australian mental health care sector. The report contains honest opinions and critical examinations of the end-to-end treatment experience for those living with severe mental illness. These conclusions are backed by multiple research references from reputable sources.

The research and findings provide an integration of lived experience, detailed investigations, expert opinions, and matters of public health concern.

The author of this report, Patrick O'Connor, has been an advocate for reform in mental illness support services over many years. As a person with lived experience of the issues facing millions of Australians, public interest is at the forefront of the author's intent.

All statements made in the report are presented as critical examinations of the topic. There is no malice intended and the strength of language used in the report is designed to maximise the education and awareness of critical safety failures, with the goal to warn other Australians.

By investigating government policy and legislation, the report provides a link between systemic healthcare failures and the legal implications of these failures. The author provides these assessments **as a complaint to multiple organisations** with the responsibility to uphold these legal standards.

The author has no conflicts to disclose at the time of publication. The preparation of the entire report, all travel and associated costs have been funded by the author. No government or third-party funds or donations have been received nor requested. Further to this, donations post-release will not be accepted.

The author would also like to strongly note that the report has been produced for no commercial benefit. The report will be made available electronically at no cost. Access will not be limited and will be provided on an ongoing full access commitment. Any costs to obtain the report will only be incurred if hard copy materials are requested through a publication organisation.

Any potential litigation or claims for compensation by people with lived experience against organisations assessed in this report, will have no financial interest to the author or any entity the author is associated with. **This is a lived experience report, provided for free for the primary purpose of bringing urgent attention to physical risks that Australians are exposed to every day, without warning.**

All interviewees provided their time and opinion at no cost. They neither requested nor were offered any remuneration for their services. Their personal disclosures can be obtained from their organisational websites.

All recorded interviews were undertaken whilst asking questions for the sole purpose of obtaining medication safety information. No information was requested that did not relate directly to the topics examined in this report. Any information that has not been included relates to personal information that does not meet the purpose of the report and would breach the commitment to confidentiality.

Prior to publication of this report, the author has on multiple occasions provided, or attempted to provide, the information in this report to organisations including the National Mental Health Commission (NMHC), Australian Government Department of Treasury, Australian Government Department of Health, Beyond Blue, Orygen/Headspace, and the Black Dog Institute. Feedback has been provided to individual pharmacies around Australia on multiple occasions, with no evidence of changed dispensing practices. The universal lack of any interest in understanding the information provided or offered to these organisations has necessitated the publication of this report. While the author attempted to warn numerous parties in the Australian healthcare system, he failed to obtain any engagement from these parties.

Further reports are in production and are expected to be published after a period of public feedback following release of this report. Any modifications to this report will be included in the document available on the author's website at www.prescribeddeaths.com.au