SUBMISSION TO THE AUSTRALIAN GOVERNMENT PRODUCTIVITY COMMISSION MENTAL HEALTH INQUIRY

EXECUTIVE SUMMARY

The mismanagement, misinformation, misdiagnosis and culpable behaviour in the mental health industry is causing thousands of deaths in Australia, many suicides, permanent disability, relationship breakdowns, gambling problems and increased unemployment.

Many of these problems are directly attributed to the psychotropic drugs that are being legally prescribed by general practitioners and psychiatrists for classified 'mental health conditions' that are described erroneously and numerously in the *Diagnostic and Statistical Manual of Mental Health* (DSM).

The underlying assumption that there is a chemical imbalance in the brain of a person who is suffering emotional stress is a complete fraud. It has never been proven. There is no test to prove a chemical imbalance in the brain of a person suffering from emotional stress (often erroneously labelled a "mental health condition") before a person is prescribed. That's why when a patient goes to their doctor or psychiatrist with an emotional challenge they are given no tests. Tests are not given, because they do not exist. The questionnaires devised to diagnose a mental health condition are vague, inaccurate and fraudulently devised by the pharmaceutical industry.

There are 10 million opioid prescriptions written in Australia per year and 36 million psychotropic drug prescriptions.

We have a psychotropic drug **prescribing** epidemic, not an epidemic of mental illness.

STOP PRESS:

Antidepressants and psychotropic drugs are now being prescribed off-label instead of opioids for pain relief – which will result in even more suicide deaths.

The days of "asking your doctor" are over.

Doctors either haven't got a clue, or they are culpable. Which one is it?

Doctors themselves have higher suicide rates than the general public (210% higher in the case of female doctors).

75% of doctors are taking psychotropic drugs themselves.

Psychotropic drugs have the side effect of increased mental illness, increased suicide rates, increased depersonalisation, serotonin toxicity, brain damage and long term permanent disability and unemployment. (See full list in A5.)

The mental health industry is diagnosing and prescribing emotional stress <u>symptoms</u> as mental health conditions, and ignoring the <u>underlying problems</u> that cause emotional challenges.

This huge and costly industry (that it has now become), includes charitable organisations and foundations, mental health hospitals, detoxification/withdrawal centres, advertising industry, university research centres etc.

The mental health industry is negligent, corrupt and culpable.

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Even common sense questions that 1 in 6 Australians who are taking psychotropic drugs could all be mentally ill.

The marketing tells us that there are many people who have a mental health condition which is yet to be diagnosed.

The mental health system is over-diagnosing and overprescribing for the industry's profit (including the pharmaceutical companies and our local general practitioners and psychiatrists).

Australia cannot afford to allow this system to continue, with its immediate costs, the costs of future disabilities, unemployment and serious permanent side effects that are attributed directly to the psychotropic drugs that are being prescribed in ever increasing numbers.

The side effects of psychotropic drugs are serious and numerous. They include increased suicide rates (up to 670 percent higher rates – yes you read that right), permanent brain damage, permanent sexual dysfunction, early death, increased compulsive behaviour such as gambling, increased violence even homicide, birth defects, tardive dyskinesia, serotonin toxicity etc. (See A5.)

One example of our failure from a productivity point of view, revealed in the *One Plus One* interview with Deputy Commissioner of the NSW Health Commission, Fay Jackson, is that in Australia only 10 percent of schizophrenics are employed, whereas 90 percent of schizophrenics in Italy are employed. Many people who have taken mental health medications for long periods die in their 50s, gain weight and are marginalised.

Australia's biomedical mental health model is absolutely failing.

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THE GOOD NEWS: INTERNATIONAL LEADERS WE CAN WORK WITH

The good news is that there are solutions and international leaders who have the answers, already working internationally to help solve the significant problems.

- 1. Open Dialogue The world's most successful, standard psychiatric service in Western Lapland, Finland.
- 2. Dr Jaakko Seikkula. Open Dialogue leader.
- 3. Robert Whitaker Author, researcher, collaborator and leading advocate. https://www.MadInAmerica.com
- 4. Professor Peter Gøtzsche. Co-founder of Cochrane and the Institute for Scientific Freedom. World leading expert on bias in clinical trials and international speaker against the overdiagnosis and over-medicating practices in mental health.
- 5. Professor David Healy. International key witness in legal cases (e.g. Dolin vs GSK), founder of www.rxisk.org, co-author of 'Restoring Study 329' published in the British Medical Journal, expert on the corruption of clinical trials and drug approval processes.
- 6. Professor Heather Ashton. Benzodiazepine expert, www.benzo.org.uk, The Ashton Manual.
- 7. Dr. Ann Blake-Tracy. International Coalition for Drug Awareness, author, FDA contributor, and has been tracking the direct connection between psychotropic drugs and violence (including mass shootings) for over 25 years.
- 8. Dr Peter Breggin. Key witness at the US Congressional investigation into increased suicides in the US military. Author, veteran psychiatrist who has actively educated on the dangers of psychotropic drugs for decades.
- 9. Professor Irving Kirsch. Associate Director of the Program in Placebo Studies at the Harvard Medical School and antidepressants expert.
- 10. Professor Jon Jureidini, Australian child psychiatrist at the Women's and Children's Hospital, Adelaide where he works with ill and disabled children and their families. He heads the University of Adelaide's: Critical and Ethical Mental Health (CEMH) research group within the Robinson Research Institute, and the Paediatric Mental Health Training Unit. Co-author of Restoring Study 329 (on paroxetine). British Medical Journal. https://www.bmj.com/content/351/bmj.h4320
- 11. Sue Dengate. Founder of the *Food Intolerance Network* which for decades has investigated and documented the direct relationship between food additives and chemicals and emotional challenges such as (but not limited to) depression-like-symptoms, ADHD-like behaviour and oppositional defiance behaviour. These are not mental health conditions but the result of poor food regulation policy in Australia, and poor education on nutrition.

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KEY RECOMMENDATIONS

- **1.** The Finnish "Open Dialogue" method to be established in Australia as a priority, completely independent of all other psychological and mental health organisations because of the potential for their efforts to be stifled and manipulated in a corrupted environment.
- 2. Criminal action should be taken against this industry and its leading players because of:
 - the deaths, permanent disabilities, financial loss and other harms that are being done to Australians by the pharmaceutical drugs that are now prescribed to 1 in 6 Australians,
 - the manipulation of clinical trial data for financial benefit,
 - the culpable off-label prescribing of pharmaceuticals exposing children, pregnant women and the elderly to increased risk, disability, even death,
 - the huge cost to Australia of subsidising these harmful pharmaceuticals through the Pharmaceutical Benefits Scheme,
 - the huge cost to Australia of increasing and future disability payments being paid as a result of the mismanagement of emotional challenges,
 - the huge cost to Australia of increasing unemployment benefits paid to 'treated mental health sufferers' who are proven in longitudinal studies to fare worse over time than 'untreated groups',
 - the huge cost to our medical care and insurance systems caused by incorrectly treating emotional problems and causing the many side effects from suicide, homicide, aggression, brain damage and birth defects to increased falls in the elderly,
 - the mounting social costs caused by psychotropic medications that include (but are not limited to) increasing gambling, increased alcohol use, relationship breakdowns, family violence, divorce, dependency,
 - careless and serious misinformation within government bodies and government funded bodies including the Therapeutic Goods Administration and leading charities/foundations,
 - the pervasive promotion of mental health in the media, with subsequent damage done by encouraging people into a system that is broken and harmful.
- 3. Access the knowledge from the experts listed in "The Good News: International Leaders we Can Work With" and set up a <u>totally independent body</u> to completely revise the treatments of emotional problems/mental health in Australia.
- 4. Retrain doctors, psychiatrists and mental health professionals on the side effects of psychotropic drugs and sleeping pills so they are fully aware of the harms that are being done by over-diagnosing mental health problems and overprescribing these medications.
- 5. Activate an army of over 50's mothers and fathers as counsellors/mentors/coaches for people under 30 who are experiencing emotional challenges.

Talk therapies are evidence based. It is proven that having a support system around people with emotional challenges is more valuable than pharmaceutical intervention.

Counselling, mentoring and coaching should begin at the earliest indication of an emotional problem and/or emotional symptom, such as children not being able to sleep properly, becoming anxious, displaying obsessive characteristics, becoming overly inward thinking, etc.

These interventions should occur *before* the pharmaceutical interventions occur, and should be independent of the medical profession until recommendation 4 above is fully implemented.

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- 14.3% of the population are over the age of 65, with only 17% of men and 10% of women participating in the workforce. What these figures do not show is that many citizens over the age of 50 are underemployed and/or employed in 'any job' not necessarily a rewarding and stimulating one. Too many qualified and highly qualified older Australians are employed in part time, casual and temporary work in the lower end of the wages classifications. Older Australians are employed in gardening, cleaning, clerical and administration rather than engineering, IT, project management, academia, research and development, etc. This is a shocking waste of talent and mentorship that directly effects Australia's productivity and GDP.
- 6. Fully review the activities of the Therapeutic Good Administration (TGA). The TGA is approving drugs and procedures that are not clinically sound and allowing blatant and common off-label prescribing that cause massive harms to Australians and the Australian economy. Their failures include (but are not limited to) the approval of pharmaceuticals that cause harm, suicides and death; the continued abolition of natural therapies which have a superior evidence base in the area of mental health; the allowance of off-label prescribing which makes a mockery of drug approval processes; and the approval of 'energy drinks' as therapeutic goods when they adversely affect sleep (and therefore mental health). The marketers of energy drinks have been successfully sued in the US for false advertising. The Therapeutic Goods Administration takes no action against doctors and psychiatrists who prescribe mental health and sleeping medications off-label (where there is no evidence to support such prescribing) - this is apparently outside their purpose 'to protect public health and safety'. Why do the Australian public even fund an organisation with such a poor level of governance? After this review, medical associations, charities, doctors, psychiatrists, the Australian Medical Association, Beyond Blue, Headspace, Black Dog Institute, schools, the media, etc. should be required to reflect the policies to ensure the improved health of Australians, including the abolition of off-label prescribing.
- 7. **Review food labelling laws** to ensure that consumers can choose food items based on full and factual disclosure of the contents of the food and their adverse side effects. There are many citizens being diagnosed with a sleep and/or mental health condition who are simply intolerant or allergic to food additives, colourings and flavourings associated with behavioural problems, emotional challenges, lack of sleep and sleep disturbance, depression, anxiety and other symptoms.

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ADDRESSING THE TERMS OF REFERENCE

This submission addresses the following four terms of reference, but is not limited to these alone.

SECTION A. Examine the effectiveness of current programs and initiatives across all jurisdictions to improve mental health, suicide prevention and participation, including by governments, employers and professional groups;

SECTION B. Assess whether the current investment in mental health is delivering value for money and the best outcomes for individuals, their families, society and the economy;

SECTION C. International Experts. Draw on domestic and international policies and experience, where appropriate; and

SECTION D. Develop a framework to measure and report the outcomes of mental health policies and investment on participation, productivity and growth over the long term.

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SECTION A. EXAMINE THE EFFECTIVENESS OF CURRENT PROGRAMS AND INITIATIVES ACROSS ALL JURISDICTIONS TO IMPROVE MENTAL HEALTH, SUICIDE PREVENTION AND PARTICIPATION, INCLUDING BY GOVERNMENTS, EMPLOYERS AND PROFESSIONAL GROUPS.

The effectiveness of current programs and initiatives to improve mental health and suicide prevention is significantly hampered by:

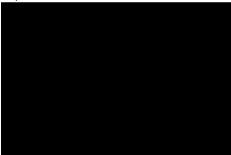
A1. The Erroneous and Significant Assumptions made by Mental Health and Medical Professionals based on unproven science and scientific hypotheses.

The promotion and continuation of the "chemical imbalance in the brain" hypothesis that was discredited before the turn of the century should be outlawed. The chemical imbalance hypothesis plays into the hands of the damaging pharmaceuticals that are now prescribed to approximately 1 in 6 Australians, including off-label prescribing to approximately 50,000 Australian children, including children less than 7 years old.

A.1.1. There is no scientific basis for the mental health classifications listed and described in the Diagnostic and Statistical Manual of Mental Disorders III (DSM III).

"No biological markers have been identified", the DSM III was established by a committee who voted the contents of the DSM III after discussion, and subsequent DSMs have continued the flaws.

Source: Dr James Davies, The Origins of the DSM, Council for Evidence-based Psychiatry, September 30, 2015.



https://youtu.be/6JPgpasgueQ

A.1.2. When a doctor or psychiatrist makes a mental health diagnosis in a clinical setting it is based on opinion rather than any scientific fact or test.

No tests are available that support mental health diagnoses. They are based on opinion, not scientific evidence.

Between 80 and 90 percent of psychotropic/mental health drugs are prescribed by general practitioners.

If you go to your doctor in Australia with insomnia you will be prescribed in 95.2 percent of cases. (Source: BEACH, Bettering the Evaluation and Care of Health, program between April 2006 and March 2008)

A2. The focus on treating the symptoms of "mental health" and not the underlying issues that present as "mental health problems" is a continuing and culpable failure of the mental health system in Australia and internationally.

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By not conducting a full interview during the first doctor's consultation for emotional and sleep issues, the medical profession is causing more harm than good.

The many, legitimate reasons for emotional challenges are being ignored.

They include the side effects of pharmaceutical drugs (including antidepressants and acne medications – to name a couple), grief, physical abuse, sexual abuse, food intolerances to food additives, chemicals and colourings, being bullied at school, parental pressure at school, violent relationships, alcohol and drug abuse, lack of sleep due to environmental factors, exam stress, hormonal changes, snoring partners, stressful workplaces, unethical workplaces, narcissistic bosses, financial stress, huge mortgages and many more.

A legally prescribed pharmaceutical drug will not make any of these issues better – in fact, they are known to worsen these outcomes.

A3. Lack of investigation and support for the underlying problems that present as "mental health conditions" or more precisely emotional, social and health challenges that could be addressed through normal lifestyle changes.

Pharmaceutical non-solutions are the medical professions preferred treatment for emotional problems.

In fact, emotional problems are being diagnosed as "mental health conditions" when they are not mental health conditions but rather emotional, social and health challenges that could be addressed through normal lifestyle changes (including exercise and dietary review), family review (violence, neglect, sexual abuse, unemployment, homelessness, etc.), a full pharmaceutical and other drug side effects review, health inquiries and social review.

During the first consultation with a medical professional when someone presents with emotional problems (described as "anxiety", "OCD", "depression" etc. – often because these are the terms being continually promoted in the media) the following activities should take place:

- A full investigation into the underlying issue that is presenting itself as the *symptom* of an emotional problem
- Detailed questioning on exercise, diet, medications presently prescribed (and their known side effects), inappropriate diet, recreational and other drugs, sleeping patterns,
- Detailed questioning on family and work relationships, partnership issues, family struggles, family support, neglect, unemployment, poverty etc.,
- Questions about when the problem started, if they can remember. Efforts to uncover
 conversations on family violence and sexual abuse, issues from childhood not being talked
 about, even the question "do you not want to talk about this?" can be revealing and
 appropriate,
- Questions about what solutions they may have found in the past that might work, and discussions on whether they could amend those previous solutions for their present situation,
- Questions about whether someone has recently died (including pets), whether they (or their partner) lost their job, whether they have just had a relationship breakdown, whether their caring responsibilities for a family member are too hard to deal with, etc.,
- Questions on whether the person has recently had a major operation, heart attack, the side effects of operations etc., and

• Questions on food intolerances, allergies, chemical intolerances, VOC intolerances, etc.

These are just a few examples of what the **underlying issues** might be, none of them necessarily a "mental health diagnosis" – most of them definitely NOT mental health problems.

Certainly some problems are emotional challenges, and sometimes significant emotional challenges.

1 in 6 Australians do not have a mental health problem, even though 1 in 6 Australians have been prescribed with dependence forming and potentially harmful psychotropic drugs.

Additionally, it is declared weekly (sometimes daily) in the media that people with mental health conditions are not being diagnosed adequately and early enough.

A4. Medical professionals' overdiagnosis and overprescribing practices in clinical settings.

Source: Mental Health: Overdiagnosed and Overmedicated. Professor Peter Gøtzsche. 2015.



https://youtu.be/ZMhsPnoIdy4

A5. Lack of knowledge of the significant and damaging side effects of sleep and mental health medications by medical professionals and patients.

Either doctors and psychiatrists:

- do not know the extent of the side effects of psychotropic drugs, and/or
- they ignore the TGA's pharmaceutical product information for the drugs they prescribe (especially prescribing to children under 18 years of age and particularly when prescribing to children under 7 years of age), and/or
- they culpably prescribe without informed consent.

I believe there should be criminal action taken for many of the oversights being made in the medical profession, especially when a prescription leads to suicide, permanent brain damage, permanent sexual dysfunction, birth defects in babies, violent behaviour (with subsequent criminal records), compulsive gambling that results in financial ruin, marriage breakdowns/divorce, aggression, homicide, permanent neurological damage, suicide because of the unbearable withdrawal symptoms, etc.

And there should be criminal action taken against companies and organisations (including charities, the TGA and government sponsored organisations) that promote the use of these pharmaceuticals without full disclosure of the side effects of the drugs (including dependency) and therefore hindering informed consent.

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There should be criminal action taken against doctors who prescribe medications off label to their patients – such as to children under the age of 18 years, pregnant mothers, children under the age of 7 years and the elderly.

The side effects of psychotropic drugs include, but are not limited to:

- i) Increased risk of suicide, even double the risk of suicide. (I've seen evidence of 670% increases too.)
- ii) Increased risk of suicidal ideation (suicidal thoughts).
- iii) Akathisia, which can result in violence, suicide and homicide.
- iv) Violence.
- v) Increased aggression.
- vi) Suicide and murder combined.
- vii) Sexual dysfunction.
- viii) Permanent sexual dysfunction. Also PSSD (Post SSRI Sexual Dysfunction).
- ix) Increased interest in consuming alcohol.
- x) Visual problems on SSRIs.
- xi) "Antidepressant use during the third trimester has been associated occasionally with a transient neonatal withdrawal-like syndrome characterized by jitteriness, self-limiting respiratory difficulties, and problems with feeding."
- xii) Antipsychotics May Boost Respiratory Failure Risk in patients with Chronic Obstructive Pulmonary Disease (COPD).
- xiii) Genetic Predisposition to more severe adverse reactions because of increased pharmaceutical toxic reactions, which requires testing for cytochrome markers before prescription to avoid some side effects. These cytochrome tests do not routinely happen in Australia. In fact they are rare.
- xiv) The drugs CAUSE chemical imbalances in the brain that were not there previously.
- xv) Dependence. It is very difficult to taper off these drugs, and dangerous. Most general practitioners and psychiatrists are totally unaware of how to do this correctly and safely. In fact, the withdrawal symptoms are so bad that some people take their own lives. And the withdrawal symptoms are often used as proof that the "drugs are working" which is false.
- xvi) Birth defects in babies born to mothers that are taking antidepressants. (One in six babies in America is born to a mother who has taken antidepressants while pregnant, in fact antidepressants are the most commonly prescribed medications to pregnant women.) Risk of birth defects can persist for months or perhaps longer after stopping an antidepressant. Birth defects and challenges include dependence, preterm births, autism, increased risk of miscarriage, babies having trouble breathing, persistent pulmonary hypertension of the newborn (PPHN) and neonatal seizures.

Here is what our government funded Beyond Blue website says in its Perinatal Mental Health National Action Plan 2008-2010:

"Antidepressants in pregnancy are as effective and necessary as for any other depressive episode, as evidenced by the rate of relapse in pregnant women discontinuing medication prior to conception". A potentially fatal piece of information, and a *more than* confusing statement given what we know about these drugs' dependency.

And the definition of insanity: Allowing women to access their superannuation for IVF treatment PROVIDED THEY HAVE A MENTAL HEALTH CONDITION. What could possibly go wrong?

xvii) Increased risk of falls in older people, followed by death for one in 28 of them.

xviii) Adverse effects on general health outcomes and mood disorders.

A study conducted by the World Health Organisation in fifteen cities around the world to assess the value of screening for depression did not support the view that failure to recognize depression has serious adverse consequences. "The group that suffered most from "continued depression" were the patients treated with an antidepressant."

xix) Adverse outcomes for people diagnosed and treated for major depression in the areas of "Cessation of Role Function" and "Became Incapacitated".

"A US National Institute of Mental Health (NIMH) investigation showed that at the end of six years the treated patients were much more likely to have stopped functioning in their usual societal roles (approximately 32% "Cessation of Role Function" in the treated group, compared with about 9% in the untreated group). And the treated group were much more likely to have become incapacitated (about 8% in the treated group compared with about 1-2 percent in the untreated group)."

"In the United States, the percentage of working-age Americans who said in health surveys that they were disabled by depression tripled during the 1990s."

xx) Shortened Life Span

xxi) Tardive Dyskinesia - a difficult to treat and often incurable neurological disorder resulting in involuntary, repetitive body movements. "Tardive" means that they have a slow or belated onset, and can be the result of long term (usually at least 3 months duration) or high dose use of antipsychotic drugs. Many of these people find themselves unemployed.

xxii) "Virtually wreck the part of the brain called the basal ganglia"

Source: Dr Peter Breggin. Psychiatric Drugs are More Dangerous than you Ever Imagined.



https://youtu.be/luKsQaj0hzs

xxiii) Significantly higher risk of claiming disability pensions and unemployment pensions.

xxiv) Significantly higher risk of ceasing to function in their usual societal roles and have become incapacitated.

xxv) Significantly poorer outcomes of schizophrenia patients who are on antipsychotic medications.

xxvi) Tardive Dysphoria. Absence of feeling/can't get excited about anything after using the drugs.

xxvii) Increased vulnerability to relapse.

xxviii) Increased possibility of unemployment in the longer term.

xxix) Increased possibility of receiving a disability pension/being disabled in the longer term xxx) Insomnia

xxxi) Increased possibility of self-harm.

xxxii) Head shocks, brain zaps.

xxxiii) Serotonin toxicity.

xxxiv) Neurotoxicity (e.g. toxic encephalopathy)

xxxv) May be depressogenic agents over the long term - Professor Irving Kirsch, Harvard University.

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xxxvi) Compensatory adaptation – causing more irreversible brain damage.

xxxvii) Increase in compulsive behaviour including gambling and sexual activity (not necessarily with their normal partner). The increase in gambling is particularly worrying with children now playing online games that are encouraging them to gamble through loot boxes and the like – which will be worsened if they are taking medications that increase compulsive behaviours.

https://theconversation.com/gambling-loot-boxes-in-video-games-could-be-conditioning-children-107667

xviii) REM sleep disorder. Very serious where violence is involved.

Other side effects that should be investigated and costed by the Productivity Commission include: increased breast and ovarian cancer risk, weight gain – including huge weight gain (even after ceasing medication), increased risk of stroke, bladder and urinary problems, gender dysmorphia, mental turmoil, mammoplasia (growing breasts), galactorrhea (milky nipple discharge), personality drained away, brain cell damage, weakened bones, becoming introverted, feeling terrible, increased risk of dementia, increased apathy, impaired memory, increased blood pressure, increased heart disease, etc.

The Side Effects and Harms of using Benzodiazepines/Sleeping Pills:

Sleeping problems can be an early warning signal that an underlying issue needs investigation.

Sleeping problems are often associated with emotional issues and mental health problems, and are certainly a side effect of psychotropic drugs and a withdrawal symptom of psychotropic and sleep medications.

As stated previously, if you present to your doctor in Australia with insomnia you will be prescribed a sleeping pill in 95.2% of cases.

Sleeping pills never solve the underlying problem, and in many cases are the start of the escalation of the problem.

"The Benzodiazepine Medical Disaster" with Emeritus Professors Heather Ashton and Malcolm Lader OBE:



https://vimeo.com/188181193

The side effects and adverse effects include:

i). Sleeping Pills will never address the underlying problem that lies beneath the sleep disorder.

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Insomnia is always a symptom of something else. The only way to cure insomnia is to cure the underlying problem that is causing insomnia.

ii). Sleeping pills mask the symptom(s) of insomnia and sleep disorders.

Taking sleeping pills makes it more difficult to diagnose what the underlying problem is; and they can be the start of the *escalation* of the problem. (e.g. the 'patient' could now end up being dependent on these drugs, when actually all they needed was for their diet to change.)

iii). Sleeping Pills cause dependence/addiction.

There is quite a debate at the moment about saying a drug is addictive or dependent. The experts are now promoting the use of 'dependence' over the word 'addictive' because the word addictive is associated with inappropriate acquisition and use of drugs. (The fact that many people use benzodiazepines to commit suicide is not part of this paper's discussion.)

However it is accepted that sleeping pills are addictive/dependence forming whether they are used exactly as prescribed or not.

The terms make little difference to the people who are struggling to withdraw from their dependence.

iv). One of the side effects when you try to come off sleeping pills is rebound insomnia.

Sometimes the rebound insomnia is presented as proof that the pills were "working", and you need to go back on them – when it is just the 'rebound insomnia' side effect that is presenting.

- v). Sleeping pills have a variety of symptoms and side-effects:
- Grogginess in the morning
- Headache
- Pain in the limbs, back and neck, teeth and jaw
- Stiffness in the limbs, back and jaw
- Paresthesia/paraesthesiae (stabbing pins and needles in the limbs and face)
- Dizziness
- Tinnitus
- Hypersensitivity to sound, light, touch and taste
- Muscle pain and twitches
- Tremor
- Fits and seizures
- Drowsiness
- Nausea
- Myalgia
- Dyspepsia
- Hallucinations
- Anxiety
- Disorientation
- Drugged feeling
- Fatigue
- Lethargy
- Poor memory and concentration
- Peculiar or bitter taste

- Dry mouth
- Changes in certain hormone levels, including testosterone and prolactin. These changes could lead to sexual side effects, including decreased libido, milk-like nipple discharge, fertility problems
- Nausea
- Vomiting
- Abdominal pain, diarrhoea and constipation
- Blurred vision
- Insomnia and nightmares
- Agoraphobia and other phobias
- Panic attacks and palpitations.
- vi). Sleeping Pills have a half-life.

The length of time of the half-life is variable between different benzodiazepine medications, varies between individuals and varies with age. Figures for half-lives have been shown as 2 hours to 200 hours.

Most people do NOT understand the idea of a half-life, and do not realize that taking a sleeping pill night after night can have a dangerous cumulative effect.

- vii). Stilnox, which has a shorter half-life, was the most complained about medication to the Australian Medicines Event Line run by the National Prescribing Service and Brisbane's Mater Hospital between September 2007 and February 2009.
- viii). "Sleeping tablets usually make sleep problems worse, not better, in the long term." (Source NPS.)
- ix). In spite of the previous National Prescribing Service recommending people investigate all possible avenues before using sleeping pills, the actual prescribing behaviour of medical practitioners in Australia shows a wide variance from those recommendations.

Here is what is ACTUALLY happening in Australia:

- For new cases of insomnia being reported 81.7 percent were prescribed medications.
- Generally 95.2 percent were prescribed medications.
- x). Viewed as a group, sleeping pills will reduce the time it takes to fall asleep by 12.8 minutes compared with fake pills. (Source New York Times, Stephanie Saul.)
- xi). Viewed as a group, sleeping pills increase your sleep time by 11.4 minutes. (Source, as above)
- xii). Sleeping pills have been blamed for some bizarre behaviours.

The following weird and bizarre behaviours (parasomnias) have been connected to the use of sleeping pills.

- Sleepwalking,
- Sleep-eating and cooking,
- Making phone calls,
- Having sex while not fully awake,
- Behaving abnormally,
- Driving while asleep.

Often, people do not remember these events.

In March 2007 in Sydney it was reported that an Australian federal health watchdog was to review the safety of a certain sleeping pill following the death of a man who had, allegedly, fallen to his death from his 12th floor unit after having taken Stilnox.

xiii). Some sleeping pills are associated with increased risk of depression.

"Data for 5535 patients randomized to a hypnotic and for 2318 randomized to placebo were compiled. The incidence of depression was 2.0% among participants randomized to hypnotics as compared to 0.9% among those randomized in parallel to placebo (p < 0.002)."

"Modern hypnotics were associated with an increased incidence of depression in data released by the FDA. This suggests that when there is a risk of depression, hypnotics may be contra-indicated."

xiv). Sleeping pills have been associated with a four-fold risk of death and increased rates of cancer for people taking large amounts per year.

Receiving hypnotic prescriptions was associated with greater than threefold increased hazards of death even when prescribed less than 18 pills per year.

xv). Some sleeping pills can change your perception of your sleep, for perceived benefits.

"Most sleeping pills work on the same brain receptors as drugs to treat anxiety. By reducing anxiety, the pills may make people worry less about not going to sleep. So they feel better."

xvi). Most sleep medications affect people's memories, called "anterograde amnesia"

"Another theory about the discrepancy between measured sleep and perceived sleep involves a condition called anterograde amnesia. While under the influence of most sleep medications, people have trouble forming memories. When they wake up, they may simply forget they had trouble sleeping."

xvii). Patients are demanding them of doctors.

Doctors are concerned that patients are demanding they prescribe sleeping pills, and indicate that if they do not prescribe them, they will seek out prescriptions from other sources.

Dependence is a side effect of sleeping pills.

xviii). Dependence is a side effect of sleeping pills: they have withdrawal symptoms - some are severe including suicidal ideation and suicide.

The reported withdrawal symptoms include:

- Suicide,
- "Persistent withdrawal syndrome", which means that you can have withdrawal symptoms that last for years, even permanent damage where you do not recover from the symptom,
- anxiety,
- unusual dreams,
- sweating,
- shakiness,
- fatigue,
- rebound insomnia,

- · unusual depressed or anxious mood,
- stomach cramps,
- vomiting,
- sweating,
- fatigue, and/or
- irritability.

xix). Sleeping pills have been linked to sleep driving, impaired driving, sleep walking and other dangerous behaviours.

One sleeping pill, Ambien (US brand name, Stilnox is the Australian brand name), ranks among the top 10 drugs found in the bloodstreams of impaired drivers, according to some US state toxicology labs.

"The behaviour can include driving in the wrong direction or slamming into light poles or parked vehicles, as well as seeming oblivious to the arresting officers, according to a presentation last month at a meeting of forensic scientists".

"People get up, they take their car keys and they go drive. As you might imagine, that might be potentially dangerous to the patient and others as well".

Zolpidem/Stilnox now has a black box warning in Australia because of its association with sleep walking, sleep driving and bizarre behaviours. The warning includes a caution with other central nervous system depressant drugs: that they should not be taken with alcohol, and its use should be limited to maximum four weeks under close medical supervision.

In my opinion this medication should be taken off the market because adequate warnings are not being given by medical professionals, the side effects are not adequately reported on government and government subsidized sites and generally people are not aware of the possibly fatal consequences.

xx). Sleeping pills are respiratory depressants and can exacerbate sleep apnoea and related illnesses.

Sleeping pills should not be used if you have sleep apnoea.

Sleeping pills, like alcohol, might prevent the necessary momentary arousals necessary to resume breathing in sleep apnoea sufferers.

xxi). Sleeping pills have been associated with increased fall and fracture rates in elderly people.

Please refer to the information on falls in people over 65 years of age in the side effects of antidepressants section below.

Falls in elderly patients are often followed by death within 12 months.

xxii). Sleeping pills may help you fall asleep, but will not help you get all the way to stage 5 sleep.

Stage 5 sleep is described by some as the rapid eye movement sleep (REM sleep) that occurs just before waking up at the end of a normal and beneficial night's sleep.

"To feel fully rested, you need to spend a lot of time in Stage 5. This stage is also known as REM sleep and it's where dreaming and deep sleep occur."

xxiii). While some sleeping pills prolong the time in slow wave sleep and reduce the time spent in REM While some sleeping pills prolong the time in slow wave sleep and reduce the time spent in REM (see above), other sleeping pills (such as benzodiazepines) inhibit the time spent in SWS and cause sleepers to have lighter sleep generally – or sleep spent in the higher brain wave patterns – such as REM.

SWS is associated with healing your body; bone and muscle growth; tissue restoration; protein synthesis; carbohydrate and fat metabolism (including cholesterol); decreasing stress, anxiety and the susceptibility to illness; the production of milk in new mothers, etc. Meanwhile our brains and the firing rate of neurons drops dramatically, and other activities that look like pruning mental deadwood and clearing your mind are carried out, and declarative memory is strengthened.

xxiv). Completed Suicide.

The association between benzodiazepine use and attempted suicide is especially high for non-antidepressant users, for the young, and for males.

There have been 2158 reported cases of completed suicide for Zolpidem users alone, recorded by the Rxisk.org website.

"You can be suicidal on a benzodiazepine alone." (Source: Professor Heather Ashton, www.benzo.org.uk)

xxv). Significant Lowering of Minimum Oxygen Levels.

Benzodiazepines significantly lowered minimum oxygen levels during the night when compared with placebo.

xxvi). In 2012 the Therapeutic Goods Administration announced that it was considering a proposal to reclassify all benzodiazepines from Schedule 4 to Schedule 8, making them controlled drugs and effectively prohibiting most GPs from being able to prescribe them without specific authority.

Seventy public pre-meeting submissions were received; among them was an unfavourable submission from the Australian Medical Association (AMA), stating that the rescheduling "would have added significantly to the administrative burden on GPs and hospital staff".

Interesting that the AMA thinks that doctors' administration workload is more important than the health of Australians.

The end result of this initiative was that only the Alprazolam class of benzodiazepines was moved to schedule 8, but the other benzodiazepines remain at Schedule 4 in Australia.

xxvii). Akathisia is a frequent and common adverse effect of treatment with antipsychotic (neuroleptic) drugs, including benzodiazepines, and in the withdrawal or tapering phase of use.

According to Wikipedia, the term 'akathisia' was coined by the Czech neuro-psychiatrist Ladislav Haskovec (1866–1944), who described the phenomenon in 1901.

Yet most people have no idea what the term means, and very few doctors mention it as a side effect of the medications they are prescribing.

Akathisia predisposes suicide and homicide in some users.

xxviii). Congenital Abnormalities/birth defects.

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One study suggested higher risk of oral cleft, the floppy infant syndrome, dependence in babies, or marked neonatal withdrawal symptoms when using benzodiazepines during pregnancy.

An increased risk of congenital malformations in humans has been suggested with use of some benzodiazepines. Withdrawal syndrome has been described in neonates whose mothers took benzodiazepines during pregnancy. Withdrawal symptoms such as intrauterine growth retardation, tremors, irritability, hypertonicity, diarrhoea/vomiting, and vigorous sucking have been described. Floppy infant syndrome, which presents as hypotonia, lethargy, and sucking difficulties, has also been reported with the use of certain benzodiazepines, such as diazepam or lorazepam.

Benzodiazepines are in "FDA Pregnancy Category D" which recommends against their use during pregnancy.

Yet Australian doctors prescribe them during pregnancy.

xxix). Overdose deaths and poisonings using benzodiazepines.

The Victorian Drug Overdose Register showed that Diazepam (which is a benzodiazepine) was the drug that caused or contributed to the highest number of overdose deaths in 2014 (the year before the findings were brought down).

According to the Drug Poisonings in England, NHS 2014 list there were 15,385 poisonings attributed to benzodiazepines, the next on the poisonings list was heroin (2,450) following by cocaine (2,306) poisonings.

There were 374 deaths in England and Wales in 2014 (an increase of 8 percent on the previous year and the largest since recording began). Benzodiazepine death numbers lagged death by heroin and morphine (952) and methadone (394).

xxx). Doctor Shopping of Benzodiazepines

There are inadequate checks and balances to ensure that addicted benzodiazepine users do not and cannot 'doctor shop' to ensure supply of these drugs they want.

The inquest into the deaths of Christopher Salib, Nathan Attard and Shamsad Akhtar by the State Coroner's Court of New South Wales recommended a raft of measures in June 2015, including that benzodiazepines be moved to schedule 8 of the Poisons Schedule, that the state develop an online real time registration and monitoring system of all schedule 8 prescriptions, imposing a restriction on general practitioners to look into prescription histories before prescribing, continued education to pharmacists on prescription shopping and drug dependence case studies, clinical guidelines be developed around prescribing these drugs, the Royal Australian College of General Practitioners develop a clinical governance framework for schedule 8 medicines and that they pursue collaboration with the National Coronial Information System (NCIS) and database to share information on deaths linked to prescription medication, that general practitioners attend a unit of skills training related to opioids and benzodiazepines, all medical prescribers to be registered under the Prescription Shopping Program, and to establish local forums for multidisciplinary professionals to discuss pharmaceutical shopping, etc.

xxxi). Genetic Predisposition for more Severe Adverse Reactions.

Some genetic types can render the medications toxic through an inability to metabolise the medications. These patients have a significantly higher risk of problems with these prescribed drugs because of their genetic metabolisms.

This means increased risk of suicide, for example.

Many experts believe that before these dangerous medications are prescribed genetic testing (of Cytochrome P450 for example) for the ability to metabolise these drugs should be undertaken to ensure that the toxic reactions (that bring on suicide, for example) are minimised.

Poor metabolisers, which include a higher percentage of eastern Europeans, have, on average, a 4-fold higher exposure to the reference drug than homozygous extensive metabolisers (EMs). Heterozygous EMs have, on average, a 2-fold higher drug exposure than their homozygous EM counterparts.

There are very few experts in Australia who have sufficient knowledge of this problem, and it is costing lives.

This information should be included on the TGA website and government sponsored websites and in the necessary sleep training to medical professionals so that drugs are not given without informed consent.

xxxii). 50 percent increased risk of Alzheimer's disease.

xxxiii). Difficulty Walking.

Professor Heather Ashton reported in the British Medical Journal in 1984 that "all patients complained of difficulty walking. This appeared to result from a combination of sensory disturbance, muscle weakness, pain and stiffness".

xxxiv). REM sleep disorder. Sometimes involving violent acts.

A6. Off-label prescribing of psychotropic drugs including benzodiazepines.

Off-label prescribing is the practice of prescribing pharmaceutical drugs to patients when those drugs have not been approved by the TGA (and included in the Product Information):

- For that purpose or patient group. E.g. Thalidomide was approved as an antidepressant, but was being prescribed off-label by doctors for morning sickness. I have personally seen antidepressants prescribed for muscle twinge after a less than successful medical operation. I am also aware that they are being prescribed for pain management.
- For that age group. E.g. The current Prozac Product Information statement, downloaded from the TGA website clearly states on page 17 "Children and Adolescents (<18 years) While clinical studies have been conducted in children and adolescents, the use of PROZAC is not recommended in this population." The current Aropax (paroxetine) Product Information statement states "Children and Adolescents (<18 years) paroxetine is not indicated for use in children or adolescents aged <18 years. Controlled clinical studies in children and adolescents with major depressive disorder failed to demonstrate efficacy, and do not support the use of paroxetine in the treatment of depression in this population. The safety and efficacy of paroxetine in children aged < 7 years has not been studied."

Yet in 2014 100,000 prescriptions were written for children in Australia for anti-psychotic drugs. (Sources: https://www.abc.net.au/news/2014-11-16/anti-psychotics-over-prescribed-australian-children-experts-say/5892822).

CCHR figures, obtained from the government, show 16,570 individual children in the group 16 years and younger, and 17,581 young adults in the 17-21 age group were taking anti-psychotic drugs in in the calendar year 2015. (Source: http://cchr.org.au/wp-content/uploads/2016/08/Numbers-on-Antipsychotics-30-May-2016.pdf).

The numbers of individuals in these age groups who were taking antidepressants for the calendar year 2015 are: 02-06 years old = 1459, 7-11 years old = 9,716, 12-16 years old = 37877, and 17-21 years old = 116,138. (Source: http://cchr.org.au/wp-content/uploads/2016/08/Numbers-on-Antidepressants-30-May-2016.pdf)

The medical profession, National Prescribing Service and the Therapeutic Goods Administration all agree that off-label prescribing is common and unavoidable.

But is it ethical? Are patients being told, in every case, that the prescription is being given off-label? Is informed consent achieved?

What are the legal and/or professional ramifications for off-label prescribing, even if it results in death? I can see no laws that cover this.

A7. Off-label prescribing of pharmaceutical drugs should be illegal.

The promotion of off-label prescribing by **drug companies** is illegal, but off-label prescribing by **medical professionals** is absolutely legal.

There have been notable cases where pharmaceutical companies have been proven guilty of promoting off-label use of drugs and fined large amounts of money. Click this link to view some examples:

https://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals?fbclid=IwAR2jyqfksDwDcml_R4lhttps://violationtracker.goodjobsfirst.org/industry/pharmaceuticals.goodjobsfirst.org/industry/pharmaceuticals.goodjobsfirst.org/industry/pharmaceuticals.goodjobsfirst.org/industry/pharmaceuticals.goodjobsfirst.org/industry/pharmaceuticals.goodjobsfirst.org/industry/pharmaceuticals.goodjobsfirst.org/industry/pharmace

My contacts with the Therapeutic Goods Administration (TGA) in Australia 2019 resulted in the following interactions:

- The person I spoke to did not know what off-label prescribing was,
- The second person I spoke to said that off-label prescribing had nothing to do with the Therapeutic Goods Administration, that they did not regulate off-label prescribing. They did not know who to report off-label prescribing breaches to. They referred me to the NPS Medicinewise for more information. NPS Medicinewise claims to be an independent, evidence-based organisation while making the following statements:

"While many people experience a bad night's sleep from time to time, a sleeping problem may become an issue for you if it continues for several nights or weeks. Thankfully, there are several techniques that can help you to sleep better — sleeping pills aren't the only solution." (https://www.nps.org.au/consumers/how-to-sleep-right, Accessed April 1, 2019.)

(In case you didn't get that, dependence forming sleeping pills never address the underlying issue behind why people can't sleep. Ever.)

The TGA should NOT be referring the public to the NPS Medicinewise website to find out information about pharmaceutical drugs.

The Australian Medical Association has this statement on its website, apparently following the Fluvax flu vaccine being given to dozens of children younger than five years despite a TGA ban on its use for younger children because of a heightened risk of seizures:

The off-label use of medicines has come to attention in recent days after it was revealed that dozens of children younger than five years were given the Fluvax vaccine despite a TGA ban on its use for younger children because of a heightened risk of seizures. https://ama.com.au/ausmed/lots-consider-going-label

In Guiding Principles for the quality use of off-label medicines, the Council said that, "in determining the appropriateness of using a medicine off-label, there should be sufficient evidence to support its efficacious and safe use, and an overall favourable harm:benefit ratio for the intended clinical use and population".

AMA President Dr Hambleton told ABC radio many medicines were "routinely" used by doctors off-label, but the use of Fluvax on young children was not condoned by the Association.

"If you give a product that's off-label and, in this particular case, it was off-label, you do accept and take on all the responsibility for the benefits and the risks of giving that particular product," Dr Hambleton said. "And there are many products that we routinely use off-label. This particular one the AMA wouldn't support, the College of GPs wouldn't support and, certainly, the TGA doesn't support its use."

It has also been revealed that some doctors are prescribing acne treatment Diane 35 as a contraceptive pill, even though it is linked to the formation of blood clots.

It is fanciful to think that a doctor or psychiatrist could make a call according to the above statements when they have no access to the raw data of the relevant clinical trials (the TGA never did either, and neither did the ghost writer of the clinical trial report in most cases). Refer professor David Healy's TED talk in "The Clinical Trial Process is a Sham" below.

In fact it sometimes takes a huge fraud case, in another country, for the judge to make a ruling to open up the raw data of a clinical trial for inspection because of such a fraud.

GSK was found guilty of both fraud and marketing Paxil/paroxetine (antidepressant) to under age citizens via the medical profession in 2012, and agreed to pay a \$ 3 billion fine. It was the largest healthcare fraud settlement in US history, reported by SBS in Australia (https://www.sbs.com.au/news/glaxosmithkline-fined-3bn-in-us-drug-fraud-scandal) but to my knowledge has made no difference to the actual prescribing patterns in Australia. In fact, worldwide, the sales of Paxil increased by 3 percent the year after this case.

Source: https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report

The Clinical Trial Process is a Sham

After this significant case, the raw data of the clinical trial for Paxil was released by order.

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One resultant important paper "Restoring Study 329: Efficacy and Harms of paroxetine and imipramine in treatment of major depression in adolescence" was published in the British Medical Journal September 2015 by world leading investigators including Australians Professor Jon Jureidini and Melissa Rayen.

So let's hear from Professor David Healy, who worked with this group on the clinical trial process: "Making Medicines Safer for All of Us". Professor David Healy, TEDxAberystwyth.



https://youtu.be/vpTqei5hZ3g

This landmark case is just one example of the deception that goes behind clinical trials.

To think that our local general practitioner or psychiatrist would have any idea of the complexity of the clinical trial raw data and results is a large stretch of the imagination.

And to think that his decision would be superior to the results found, in say, "Restoring Study 329" published in the BMJ is well, insane.

Laws have been established to halt the promotion of off-label prescribing to medical practitioners by pharmaceutical companies.

However no laws have been established to stop <u>doctors and/or psychiatrists</u> from prescribing off-label.

Off-label prescribing by medical professionals is legal in Australia, and should not be.

And it is done in most cases without informed consent.

Furthermore, my efforts to establish from the Therapeutic Goods Administration how off-label prescribing is treated resulted in comments to the effect that it is no business of theirs. One example of off-label prescribing in Australia is the off-label prescribing of certain antidepressants to children 18 years and younger with no clinical support. Additionally, the evidence that these drugs can double the suicide rate (and perhaps more) seems to make no difference to the increasing prescription rates of these drugs to Australian children and the "early intervention" activities of groups like Headspace. Whenever the suicide discussion comes up in the media, it appears that early intervention and early diagnosis is the solution, when in actual fact this should be illegal, because in Australia a diagnosis is followed by medication in a very high percentage of cases.

Just yesterday, April 2, 2019, there was an additional \$ 461 million given to the Mental Health industry in the Australian budget, including for the opening of 30 new Headspace centres, which target youth. I shudder to think of the numbers of lives that will be adversely, even fatally affected by such an initiative.

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Why are Pharmaceutical Companies held to a greater Ethical and Moral Standard than our Therapeutic Goods Administration, Australian Medical Association, Clinical Governance Bodies, Charitable Organisations and Medical Professionals?

We need to revise our scientific, ethical and moral governance of all these bodies without delay.

A8. <u>Early intervention and early recognition of depression does not improve outcomes</u>. Evidence reported by the World Health Organisation after their study of 15 cities around the world failed to support the view that failure to recognise depression has serious adverse side effects.

In fact, contrary to the study's expected results, of the 740 people identified as depressed in the study it was the 484 who weren't exposed to psychotropic mediations (whether diagnosed for not) that had the best outcomes. "The group that suffered most from "continued depression" were the patients treated with an antidepressant." Source: Whitaker, Robert Anatomy of an Epidemic: Magic Bullets, Psychiatric Drugs, and the Astonishing Rise of Mental Illness in America. Page 165.

A9. There is a <u>lack of informed consent</u> in clinical settings that prove that decisions are made by patients without full information being provided by medical professionals about the drugs they are about to ingest, their side effects, the off-label prescribing, their withdrawal symptoms and the difficulties experienced while withdrawing.

Informed consent is an expectation of our society when dealing with medical professionals, and should continue to be an expectation.

Unfortunately informed consent is no longer guaranteed, and has been under threat for some time.

A10. The Diagnostic and Statistical Manual for Mental Health (DSM) is not a scientifically based document. The inclusions and information were decided on by opinion and voting – not on scientific evidence, chemical testing, blood testing, brain scans or any other method that would support the inclusion of many 'mental health conditions' listed in the DSM. All efforts to provide scientific evidence to support the DSM inclusions and conditions have failed.

See video embedded on the last page of this submission. Dr James Davies: The Origins of the DSM. https://youtu.be/6JPgpasgueQ

A11. <u>Inadequate and incorrect information on government websites</u>, including on government funded websites (Beyond Blue, Headspace etc.), NSW State Library's drug information resource. https://druginfo.sl.nsw.gov.au/drugs-z-drugs/benzodiazepines

Incorrect and irresponsible information that can lead to death, suicide and permanent disability exists on government websites, government funded charities and other respected online resources.

Here are some examples:

- Both BeyondBlue and Headspace (among others) declare that antidepressants are not drugs
 of dependence. It is now well known that withdrawal from antidepressants is both
 challenging and potentially dangerous. The oft expressed view that it takes about 2 weeks to
 withdraw from these medications has become such a thorn in the side of sufferers that the
 hashtag #2weeks was born. See "Lets Talk Withdrawal" in Section C International Experts.
- No website that I can see lists all the side effects of antidepressants and psychotropic drugs. There are so many side effects it would be obvious if there was a full list given. The sorts of

side effects that are not listed correctly are permanent sexual dysfunction, serotonin toxicity, difficulty walking, permanent brain damage, anorgasmia, relationship breakdown, increased compulsive behaviour (including gambling and compulsive sexual behaviour with new partners), double the suicide rate (there are figures that show 670% increases in suicide rates – but not where they should be showing), babies born dependent to these drugs, underdeveloped babies, akathisia leading to violence and homicide, etc. (See fuller list in section A5 above.)

- The Therapeutic Goods Administration makes no effort to explain off-label prescribing to the visitor so that they can decide whether their doctor has indeed prescribed a medication off-label that might result in harm, even permanent disability and death. If patients were required to be told by their doctor when they were being prescribed off-label they may take a more proactive approach to their own medications and take more responsibility for their own health outcomes. Furthermore, when you ring the TGA they may or may not even know what off-label is and therefore cannot explain it to you when you question them.
- The New South Wales State Library's list of side effects is inadequate (see the link above).
- There is no information that shows that your doctor swapping medications, adding medications, sharply withdrawing you from medications etc. could be very damaging, even fatal. A significant proportion of people have serious adverse effects while they are withdrawing from psychotropic medications some of these permanent effects are serious, some are unbearable. Some withdrawal effects are so unbearable that people take their own lives. There are over 20 hidden Facebook pages that help people slowly taper from psychotropic medications. Some people take years to withdraw, some never achieve the goal, some take their own lives because the challenges are too great during the withdrawal process. Some participants are there because they withdrew too quickly, are damaged and looking for solutions.

This is not an exhaustive list, but it certainly demonstrates that these organisations and government bodies are grossly negligent in the information they are providing.

Lack of information prohibits informed consent.

A12. The <u>increasing and inappropriate power of the pharmaceutical industry</u> in the mental health industry, including its financial and other incentives given to medical professionals, doctors, psychiatrists, clinical studies, university boards, key academics, politicians, foundations and charities and the media.

Doctors, psychiatrists, industry leaders, politicians, government instrumentalities, educational institutions, research institutes, and charities are all susceptible to bias when there are financial incentives provided.

And the pharma lobby is one of the most powerful lobby groups in the world.

See A14 below.

A13. The <u>languaging around mental health</u>, disguised as an effort to de-stigmatise mental health problems, has created a new problem where what might actually be 'emotional challenges' or 'side effects of medications', 'lack of exercise', 'lack of resilience', 'effects of violence' have morphed into mental health diagnoses.

This change in languaging played directly into the hands of the pharmaceutical industry, which is a significant part of the problem.

Other languaging problems include 'treatment resistant depression' which actually means 'pharmaceutical treatment resistant depression' in most of the references. The pharmaceuticals do NOT cure mental health problems, and to talk about 'treatment resistant depression' is a reasonably sophisticated expression that generally refers to 'pharmaceutically treated depression', which we know from the evidence is not working, and can be harmful, even deadly.

A14. <u>Undeclared and complicated conflicts of interest</u> in the medical and mental health fields which adversely affect mental health outcomes for Australia.

"Only 15% of guidelines on the National Health and Medical Research Council (NHMRC) portal from the most prolific developers have published conflict of interest (COI) statements, and fewer detail the process used to manage conflicts."

https://www.mja.com.au/journal/2011/195/8/conflict-interest-guidelines-clinical-guidelines

Australian clinical governance bodies are failing.

A15. No <u>federal health ombudsman</u> exists where reports can be made of harmful and fraudulent mental health activities.

A16. No <u>whistleblower protection</u> exists in Australia. This enables the continued degradation of the health of Australians, and the harassment of leaders in the medical field who speak out.

A17. Significant promotion of incorrect mental health strategies by the media, stifling proper debate in the media. The real mental health story is being supressed. Media releases are being ignored and when visiting world experts like Robert Whitaker speak in Australia there is no coverage of the story on television or radio.

A18. <u>Political lobbyists for the pharmaceutical industry</u> and their placement into key national and state positions of power, including royal commissions.

A19. A <u>lack of continued research</u> into the underlying issues that result in emotional stress and potential mental health issues. See C12, *The Great Porn Experiment*, TEDxGlasgow, Gary Wilson.

A20. The continued degradation and defamation of natural remedies in Australian health, when we know from the evidence that most deaths and harms are iatrogenic. In fact iatrogenic harms are the third leading cause of death globally.

Talk therapies (of the sort you might experience during a natural therapies consultation), on the other hand, are evidence based. This is a corruption issue, and exists right through our medical, insurance, educational, and parliamentary systems. "Alternative" and natural remedies do not make money for publicly listed companies, and have very little power in the "economy of health".

The most recent diminished list of natural/alternative items listed on health insurance has resulted in an increase in insurance bills. A very interesting development, and one that indicates quite a bit to the informed. If natural therapies are so useless, premiums should have reduced recently when they were taken off insurance listings, not increased.

Natural and cost effective treatments such as exercise; food free of adverse food additives, chemicals and colourings; walks in nature; counselling; friends; wholesome work environments, positive sleep hygiene etc. are being ignored.

A21. There is a total lack of <u>community health services</u>, and funding for <u>preventive medicine</u> is approximately 4 percent of the medical budget.

Community education on sleep and lifestyle – PREVENTATIVE MEDICINE – is effectively unavailable. I have looked for it for months, and have been 'closed out' from my investigations by so-called clinical governance leaders.

Councils and other local organisations used to play a part in preventative medicine, but there has been a movement towards cost cutting within government - resulted in our health being 'owned by profit centres' i.e. pharmaceutical companies, medical professionals, testing processes, device selling, etc.

There are no preventative health initiatives for the prevention of mental health problems, such as natural sleep training, lifestyle and sleep centres, counselling opportunities separated from pharmaceutical drug options, training on the side effects of medications and supplements, the benefit of exercise – these are generally left up to the media to deliver, which is an unacceptable situation.

And the media has vested interests to deliver value for their advertisers, including "tailored" content.

A22. Blaming the victim instead of finding the perpetrators. In many cases of serious emotional damage there are perpetrators involved, whether they are violent family members, sexual predators, bullies, manipulators, etc.

Our present system drugs the victim when they go to their doctor or psychiatrist without bringing perpetrators to justice.

By neglecting to establish the underlying reason why the mental health symptom exists, our present system treats the victim, not the perpetrator.

There are cases where the perpetrator should be in jail, sued, taken to court and punished — but our medical process treats the symptom, not the cause.

Perpetrators are allowed to continue their criminal and harmful activities.

A23. Australia cannot afford to pay the future disability and unemployment benefits to citizens harmed by psychotropic drugs. The nation already suffers significant financial stress as a result of the significant and culpable mismanagement of 'mental health', but with 1 in 6 Australians now prescribed psychotropic drugs the bills haven't even started coming in.

Outcomes are not improving *because our present model of pharmaceutical intervention* is failing. But there are very few people willing to make this statement and ruin their career.

A study conducted by the World Health Organisation in 15 cities around the world to assess the value of screening for depression did not support the view that failure to recognise depression has serious adverse consequences. In fact, contrary to the study's expected results, of the 740 people identified as depressed in the study it was the 484 who weren't exposed to psychotropic medications (whether diagnosed or not) that had the best outcomes. "The group that suffered most from continued depression" were the patients treated with an antidepressant." (Source: Robert

Whitaker's Anatomy of an Epidemic: Magic Bullets, Psychiatric Drugs, and the astonishing Rise of Mental Illness in America. Page 165.)

A24. Longitudinal studies have shown that in large population samples the "treated for mental health" group fare worse than the "untreated for mental health" group.

Source: Robert Whitaker, Mental Health in Crisis conference, Sydney February, 2018 and www.MadInAmerica.com. Refer Robert Whitaker presentations in Section C, International Experts.

A25. Talk therapies, psychotherapy and counselling are evidence based. In many cases they are not being used at all, and when they are they have generally been delegated as "add-ons" not the main event – after having been prescribed a medication.

Source: https://youtu.be/ZMhsPnoIdy4 See full Video in Section C, International Experts.

A26. The pharmaceutical industry is running mental health in Australia, and is failing significantly.

About 1 in 6 Australians are taking psychotropic drugs, and the figure is increasing at an alarming rate.

"The proportion that experiences a disturbing side-effect has been estimated at between 50 and 70 per cent, and participants in our study reported on average between six and seven medication side-effects.

"It is difficult for an outsider to appreciate what this means to individual consumers, and how it impacts on their self-image and ability to cope."

Source:

https://medicalxpress.com/news/2015-02-antipsychotic-meds-prompt-zombie-like-state.html?fbclid=IwAR3Sq1AgsNkOVeNLqeyQtpUdgK7sTfUvirEhifMBVXDMvhqsaUwVRuJnRd8

A27. Tens of thousands of Australians now need to be safely withdrawn from psychotropic medications including benzodiazepines and we do not have the resources to do this.

The cost of establishing detoxification centres, rehabilitation centres and proper counselling to help people safely and slowly taper from these drugs of dependence will be prohibitive: but it must commence now.

Significant and permanent harms are being done when doctors recommend/prescribe and/or patients swap, cold turkey, increase, decrease or change their medications.

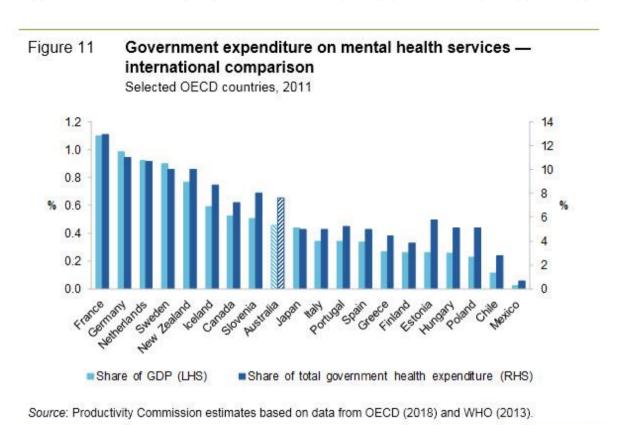
Unfortunately, with the available misinformation from such 'leaders' as Beyond Blue and Headspace that antidepressants are not dependence forming the prescribing patterns continue unchecked.

Significant harms and deaths are being caused by these organisations through misinformation and misinformed activities.

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SECTION B. ASSESS WHETHER THE CURRENT INVESTMENT IN MENTAL HEALTH IS DELIVERING VALUE FOR MONEY AND THE BEST OUTCOMES FOR INDIVIDUALS, THEIR FAMILIES, SOCIETY AND THE ECONOMY.

B1. GOVERNMENT EXPENDITURE ON MENTAL HEALTH SERVICES - INTERNATIONAL COMPARISON.



The above figure 11 from page 35 of the Productivity Commission Issues Paper shows Finland as having the third lowest share of total government health expenditure on mental health services. (See below.)

Finland has the most successful mental health programs in the world, particularly the Open Dialogue program in Western Lapland.

Open Dialogue has been developed over 30 years. Their tracking of patient outcomes are the best in the world.

Dr. Jaako Seikkula has begun training in Sydney Australia, but unfortunately there appears to be inadequate advertising, funding and support for international best practice to be rolled out around Australian immediately.

For more information:

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https://www.youtube.com/watch?v=Oq5qtc90VHI http://open-dialogue.net/

Italy, who's costs are lower than Australia's, set a precedent in 2000 for banning Electro Convulsive Treatment (ECT, previously known as electroshock therapy) for children, pregnant women and the elderly in 2000, with further reduction since.

B2. WHY HAS OUR MENTAL HEALTH BUDGET AND EXPENDITURE EXPANDED OVER THE LAST 30 YEARS, SHOWING INCREASED MENTAL HEALTH PROBLEMS AS THE PHARMACEUTICAL MODEL HAS EXPANDED?

I think the answers are very obvious - but just to recap:

- Mental health problems are not related to chemical imbalances in the brain,
- The 'pharmaceutical solution', based on a biomedical model, increases mental health problems, creates chemical imbalances in the brain and causes dependency,
- Longitudinal studies prove that the 'treated for mental health' groups perform worse than 'untreated for mental health' groups,
- Early detection of mental health, as is commonly advertised in our media, is not resulting in better outcomes. There is no empirical evidence that supports this premise. And off-label prescribing to children is rampant.
- While we continue to medicate and not address the underlying issues that present as the SYMPTOM of emotional challenges, we do not solve any problems, but create worse ones, including drug dependence, brain damage, long term unemployment, birth defects etc.
- We are erroneously labelling people with emotional challenges as having a mental health condition, giving that mental health condition a name (such as ADHD, anxiety, OCD and depression), medicating that person, and then, in many cases leaving them to their own devices without adequate social and personal support, counselling, social connections, a job, somewhere to live and food to eat (in some cases), a safe home without violence, health solutions etc. How could this possibly be a solution to emotional problems? Additionally we are often telling sufferers that they will remain on their medications for life, which provides no hope for them generally, and in some cases puts them over the edge.
- We are allowing the perpetrators, if that is the situation, to remain free and continue their abuse, violence, manipulation and nasty behaviours unchecked.
- Our society is clueless to this situation many families abandoning their family members when they show signs of aggression, brain damage etc. which can be the side effects of the drugs they have been legally prescribed and their reactions are not their fault.
- Doctors and psychiatrists do not actually know the extent of the harm they are causing, if they do, they should be in jail. If they are ignorant of the harm they are causing they need to be correctly trained. That training should NOT be performed by the pharmaceutical

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- companies and their associated entities and pharmaceutical representatives whether or not the association is declared.
- Off-label prescribing to over 50,000 children in Australia should be deemed illegal, as well as
 prescribing to pregnant women and the elderly. The off-label prescribing to children under 7
 is unbelievable, considering the absence of studies that even remotely support such
 prescribing practices, and the total lack of long term studies that, no doubt, will show
 significant damage.
- Not all clinical trial results are published. We have a broken system of drug approval in Australia, and the TGA is negligent like the other drug approval bodies around the world in relation to psychotropic drugs including sleeping pills.
- There are human rights abuses occurring in mental health institutions, with informed consent not being achieved, and restraint occurring against the wishes of patients and their parents/guardians/carers. Hopefully there will be other submissions made from experts in this area.
- The situation in mental hospitals, jails, orphanages, children's homes, institutions and the like needs to be investigated fully with appropriate action taken. The exposure is likely to be much higher there, and that would be unacceptable.

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SECTION C. INTERNATIONAL EXPERTS. DRAW ON DOMESTIC AND INTERNATIONAL POLICIES AND EXPERIENCE, WHERE APPROPRIATE.

International Experts, International Ground-breaking Legal Cases, Testaments to the US Congress, TED Talks, etc.:

C1. The Bio-Medical Model based on a Chemical Imbalance in the Brain is not supported by Evidence.

Professor Peter Gøtzsche.

Mental Health: Overdiagnosed and Overmedicated.



https://youtu.be/ZMhsPnoIdy4

"Over half a million people die each year in the US and UK because of psychiatric drugs."

Wikipedia: https://en.wikipedia.org/wiki/Peter C. G%C3%B8tzsche

C2. Robert Whitaker's longitudinal studies prove that the 'treated mental health' groups have worse outcomes than the 'untreated mental health' groups.

Are Antidepressants Depressergenic Over the Long Term?

The mental health treatment outcomes include (but are not limited to) an increase in disability and increased unemployment. He also demonstrates that some mental health drug effects such as sexual dysfunction are not reversible, talks about birth defects and foetal development (autism), tardive dysphoria (absence of feelings), increased vulnerability to relapse, Post SSRI Sexual Dysfunction (PSSD), serotonin compensatory adaptation and the inability of dopamine receptors to normalise.



https://youtu.be/TEpjyKCPTEE

World Health Organisation quote: "depression is now the leading cause of disability worldwide."

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Wikipedia:

https://en.wikipedia.org/wiki/Robert Whitaker (author) https://en.wikipedia.org/wiki/Anatomy of an Epidemic

https://www.facebook.com/madinamerica/

https://www.facebook.com/madinamericacontinuingeducation/

C3. Significant Flaws in the Clinical Trail Process and the Medical Approval Processes Internationally.

Professor David Healy.

TED Aberystwyth: Making Medicines Safer for All of Us.



https://youtu.be/vpTqei5hZ3g

Wikipedia: https://en.wikipedia.org/wiki/David_Healy_(psychiatrist)

https://www.facebook.com/david.healy.7773

https://www.rxisk.org https://study329.org/ Key witness in Dolin vs GSK Presenter at FDA Hearings

C4. Psychotropic Drugs Increase the Suicide Rate.

This information also supported by the information in videos C1 and C2 above.

Dr Peter Breggin

Presentation to the US Congressional Committee: US House Committee on Veterans Affairs: *Antidepressants and Suicide*.



https://youtu.be/SBJfZtB 3cc

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Wikipedia: https://en.wikipedia.org/wiki/Peter Breggin

C5. Psychotropic Drugs do Not Perform Better than Placebo, and have Significant Side Effects.

Professor Irving Kirsch.

Harvard University.

"In the future there will come a point when the prescription of antidepressants that we currently use will be regarded the way we now regard blood-letting: how could doctors have done this?"

Q&A: Antidepressants Risks and Advices.



https://youtu.be/NuyHi7ljWF4

Mad In America Podcast Episode 14 Dr Irving Kirsch: The Placebo Effect and What It tells Us About Antidepressant efficacy



https://youtu.be/naxZsTEegB8

C6. Open Dialogue -the most successful Mental Health System in the World - Finland.

Dr. Jaakko Seikkula

Open Dialogue with Families (Jaakko Seikkula)



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https://youtu.be/Oq5qtc90VHI

C7. Open Dialogue. Documentary Film on the Western Lapland Open Dialogue Project. 74-minute documentary film on *Open Dialogue*.



https://youtu.be/HDVhZHJagfQ

C8. DSM III was Decided at Meetings with Voting Processes, Not Scientific Evidence.

Dr James Davies.

Council for Evidence-based Psychiatry. The Origin of the DSM.



https://youtu.be/6JPgpasgueQ

C9. GlaxoSmithKline to Plead Guilty and Pay \$ 3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data.

(Largest Health Care Fraud Settlement in U.S. History.)

Part of this case was the indirect marketing of Paxil to children under 18 years of age - off-label.

Direct prescribing to children under 18 years old is being done by doctors in Australia today.

https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report

"Paxil: In the criminal information, the government alleges that, from April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric (sic.) use. The United States alleges that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy. At the same time, the United

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States alleges, GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended. Since 2004, Paxil, like other antidepressants, included on its label a "black box warning" stating that antidepressants may increase the risk of suicidal thinking and behavior (sic) in short-term studies in patients under age 18. GSK agreed to plead guilty to misbranding Paxil in that its labeling (sic.) was false and misleading regarding the use of Paxil for patients under 18."

C10. Dolin vs GSK.

\$ 3 million damages was awarded to Wendy Dolin, wife of Stewart Dolin after he uncharacteristically committed suicide after taking a generic version of Paxil.

During this case it was revealed that 22 deaths had occurred during the clinical trials, but they were not reported.

Full trial transcripts available here:

https://www.baumhedlundlaw.com/prescription-drugs/paxil-injuries/gsk-paxil-trial-transcripts/

Increased suicide rates do not only apply to children.

This high profile case helped prove this point, but we heard nothing about it in the Australian media, and none of the TGA drug specifications changed after this case was decided. The case continues.

C11. Before Australians are prescribed Psychotropic Drugs (including sleeping pills) we should test if they might have an increased possibility of a Toxic Reaction. An increased chance of a toxic reactions is associated with increased suicide rates and other adverse reactions.

There are genetic predispositions to toxic reactions to certain pharmaceuticals. If a person has such genetics, their chance of suicide and other adverse reactions increases. It is extremely rare that these genetic tests are occurring in Australia, and there is much to learn about this technology can reduce suicide.

Dr Yolande Lucire

Forensic Psychiatrist.

Adverse Reactions to Psychiatric Drugs: Yolande Lucire MBBS, Peter Breggin MD.



https://youtu.be/IEoSs6Yo0DA

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C12. TEDxGlasgow. The Great Porn Experiment

Gary Wilson, connecting porn with depressive thoughts (not supported by clinical trials).

A thought provoker on why our clinical trials and discussions are so limited and insular.



https://youtu.be/wSF82AwSDiU

C13. Dr. Ann Blake-Tracy

Author who has followed the connection between SSRIs and violence and murder for over 2 decades.

https://www.SSRIStories.org

C14. James Moore, Let's Talk Withdrawal Podcasts.

https://www.facebook.com/groups/LetsTalkWithdrawal/

C15. Brent Wisner and Michael Baum of Baum, Hedlund, Aristei, Goldman attorneys.

Dolin vs GSK law suit.

https://www.baumhedlundlaw.com/prescription-drugs/paxil-injuries/gsk-paxil-trial-transcripts/

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SECTION D. DEVELOP A FRAMEWORK TO MEASURE AND REPORT THE OUTCOMES OF MENTAL HEALTH POLICIES AND INVESTMENT ON PARTICIPATION, PRODUCTIVITY AND GROWTH OVER THE LONG TERM.

D1. DOCUMENT AND MONITOR ALL OFF-LABEL PRESCRIBING OF PSYCHOTROPIC DRUGS BY DOCTORS AND PSYCHISTRISTS.

On March 7, 2019 I rang the TGA to obtain a list of all the medications that can be prescribed to children 18 years and younger, so that I could establish if certain medications being given to children of friends of mine were being prescribed off-label.

The person I spoke to did not know what off-label prescribing was until I explained it to them.

As stated elsewhere in this report it is NOT illegal for doctors to prescribe medications off-label.

So what is the point of having a drug approval process in the first place?

What is the point of conducting clinical trials if the doctors can prescribe any drug for whatever purpose to whoever they like? Like Thalidomide for morning sickness, acne medications as contraceptives, antidepressants for pain?

The system is a sham.

D.1.1. It should be illegal for doctors, psychiatrists and any other health professionals to prescribe a pharmaceutical or procedure off-label.

What is the point of having drug approval processes, even the TGA, if doctors and other health professionals can ignore the results of reported clinical trials and prescribing recommendations and put the health and safety of their patients at risk, at their own discretion?

D.1.2 The TGA should have a very precise and downloadable list of off-label prescribing breaches so that the general public can access and check the information and prescribing practices of their general practitioners and psychiatrist.

(It is clear that general practitioners and psychiatrists are not telling their patients when they are prescribing medications for a purpose that they were not intended to be prescribed for. Such as thalidomide for morning sickness.)

D2. UPON THE SUICIDE DEATH OF ANY PERSON IN AUSTRALIA A FORENSIC REPORT SHOULD BE SUBMITTED TO SHOW WHAT DRUGS THE PERSON WAS TAKING AT THE TIME OF THEIR SUICIDE, THEIR GENETIC VULNERABILITY MARKERS, AND THE DETAILED HISTORY OF THE PSYCHOTROPIC DRUG PRESCRIPTIONS.

This forensic testing of what drugs were in the blood at the time of death, and their genetic markers, should be done in a timely manner so that the evidence is not lost, and should be part of normal policing procedures.

Following the death, and forensic reporting, the investigation should then continue at the office of the general practitioner who is in charge of that person's health and wellbeing.

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Doctors are responsible for the drugs they prescribe to their patients, and the results that are achieved – both good and bad.

It should be fully documented:

- What pharmaceuticals were being prescribed and in the system of the person who has just taken their life,
- What pharmaceuticals were being tapered, increased, swapped or changed in any way leading up to the suicide death of the person in question,
- Whether genetic predisposition to toxic reaction testing (CYP450 etc.) was undertaken by the medical practitioner before the prescribing of the psychotropic drugs,
- Whether polypharmacy was a factor in the death of the patient (one doctor or several),
- This results of this thorough testing should be documented at a centralised coronary database, available for review at a later date by this Productivity Commission and the TGA.

This is particularly relevant in the case of a suicide death of a child, as I expect that off-label prescribing with be a factor in this, and we will learn the exact extent of the problem.

D3. AS ABOVE FOR INSTANCES OF VIOLENCE AND HOMOCIDE.

UPON THE MURDER, OR MURDER/SUICIDE DEATH OF ANY PERSON IN AUSTRALIA A FORENSIC REPORT SHOULD BE SUBMITTED TO SHOW WHAT DRUGS THE PERSON WAS TAKING AT THE TIME OF THE MURDER OR MURDER/SUICIDE, THEIR GENETIC VULNERABILITY MARKERS, AND THE DETAILED HISTORY OF THEIR PSYCHOTROPIC DRUG PRESCRIPTIONS.

This forensic testing of what drugs were in the blood at the time of death, and their genetic markers, should be done in a timely manner so that the evidence is not lost, and should be part of normal policing procedures.

Following the death, and forensic reporting, the investigation should then continue at the office of the general practitioner who is in charge of that person's health and wellbeing.

Doctors are responsible for the drugs they prescribe to their patients, and the results that are achieved – both good and bad.

It should be fully documented:

- What pharmaceuticals were being prescribed and in the system of the person who has just taken someone's life, and/or their own life,
- What pharmaceuticals were being tapered, increased, swapped or changed in any way leading up to the suicide death of the person in question,
- Whether genetic predisposition to toxic reaction testing (CYP450 etc.) was undertaken by the medical practitioner before the prescribing of the psychotropic drugs,
- Whether polypharmacy was a factor in the death of a citizen and/or the patient (one doctor or several),
- This results of this thorough testing should be documented at a centralised coronary database, available for review at a later date by this Productivity Commission and the TGA.

There is an international trend towards violent crimes, but the media is supressing the link between suicide and violence and psychotropic drugs.

We know this link exists, but doctors and psychiatrists are either not aware of the link, or they continue prescribing knowing the link.

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Informed consent is not achieved while the general public is unaware of the proven link between psychotropic drugs and violence, suicide, even homicide.

In America the link is often put down to guns.

Because Australia has more stringent laws on gun ownership these shooting incidents are less common, of course.

In Australia I increasingly see the use of knives, drowning and high rise incidents as the method of death

This disclosure needs to be made and understood for Australia to move forward in our treatment of mental health patients.

D4. OPEN DIALOGUE SHOULD BE INTRODUCED, FULLY FUNDED AND ROLLED OUT ACROSS AUSTRALIA, BY FINLAND'S EXPERTS OF OPEN DIALOGUE, INCLUDING DR. JAAKO SEIKKULA.

Open Dialogue should be given their own totally independent health care department, fully funded by the federal and state governments.

I believe there are already moves to silence this powerful and most successful mental health modality.

D5. DRUG TAPERING PROCEDURES, AND SPECIAL TAPERING REHABILITATION CENTRES

It is clear that Australia has no idea about the dangers of tapering and changing psychotropic medications.

The only places I can see that are reliable are online help groups, none of them Australian – and all independent of the Australian government health system.

Severe and permanent side effects (including suicide, homicide, brain damage, REM sleep disorder etc) are the side effects of incorrectly tapering from psychotropic drugs including sleeping pills and benzodiazepines.

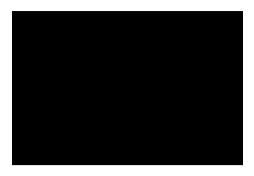
With 1 in 6 Australians now taking these psychotropic drugs, we absolutely do not have the facilities or the knowledge to correctly taper people off these drugs before they become permanently damaged, disabled and many unemployed.

Swapping, changing, adding to, decreasing, cold turkey – these can all have catastrophic effects if not done correctly. Sometimes people simply cannot come off these drugs completely because it is too painful for them.

D6. THE PRODUCTIVITY COMMISSION SHOULD CONDUCT A FULL INVESTIGATION INTO HOW THE UNPROVEN BIOMEDICAL MODEL BECAME AUSTRALIA'S "GOLD STANDARD" FOR MENTAL HEALTH.

The biomedical model is a fraud, and the medications that come with it are causing severe and common problems.

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Mental Health – Overdiagnosed and Overmedicated. Professor Peter Gøtzsche. Accessed January 16, 2019.

https://youtu.be/ZMhsPnoIdy4

D7. THE PRODUCTIVITY COMMISSION SHOULD CONDUCT A FULL INVESTIGATION INTO THE FLAWED, HARMFUL, EVEN DEADLY DRUG APPROVAL PROCESS USED BY THE TGA WHICH IS RESPONSIBLE FOR ALLOWING DRUGS, MEDICAL DEVICES AND PROCEDURES, AND OTHER HEALTH PRODUCTS TO BE APPROVED FOR USE IN AUSTRALIA – EVEN IF THEY CAUSE HARM AND DEATH.

This flawed process is not uniquely Australian, but that provides no excuse.



Making Medicines Safer for All of Us. Professor David Healy. https://youtu.be/vpTqei5hZ3g Accessed January 16, 2019.

D8. THE PRODUCTIVITY COMMISSION SHOULD CONDUCT A FULL INVESTIGATION INTO WHY THE MENTAL HEALTH AND MEDICAL PROFESSIONALS TREAT THE <u>SYMPTOMS</u> OF EMOTIONAL CHALLENGES, AND IGNORE THE <u>UNDERLYING CAUSES</u> THAT PRESENT AS EMOTIONAL DIFFICULTIES/MENTAL HEALTH CHALLENGES.

The underlying causes of emotional/mental health conditions include divorce, abuse, bullying at school, school and parental pressure to achieve high marks, lack of sleep, poverty, a health condition (not a mental health condition), sexual abuse, bad diet, lack of exercise, divorce, employment termination, food additives and colourings that affect behaviour, etc. This is a long list... but these matters are not discussed in a 6-10 minute consultation with a doctor.

Importantly, if there is a perpetrator, such as a sexual predator or bully, the perpetrator continues, and the situation is not resolved. We are blaming the victims by drugging them with harmful drugs, and the predators continue to harm.

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D9. A FULL INVESTIGATYION SHOULD BE IMPLEMENTED INTO THE LONGITUDINAL STUDIES THAT PROVE THAT OVER THE LONG TERM THE 'TREATED FOR MENTAL HEALTH' PATIENT GROUPS HAVE POORER RESULTS THAT THE 'UNTREATED FOR MENTAL HEALTH' GROUPS.

Robert Whitaker is the world expert on this topic (and others), and should be fully consulted in this matter.

Here is Robert Whitaker speaking in Westminster at The All-Party Parliamentary Group for Prescribed Drug Dependence on 11 May 2016 to discuss evidence of the link between the rise in disability claimants and the record level of antidepressant prescribing:



D10. A FULL INVESTIGATION SHOULD BE IMPLEMENTED TO ENSURE THAT THE THERAPEUTIC GOODS ADMINISTRATION (TGA), BEYOND BLUE, HEADSPACE, LIFELINE, BLACK DOG INSTITUTE, SANE, BRAIN AND MIND CENTRE AND ALL OTHER GOVERNMENT FUNDED HEALTH GROUPS AND UNIVERSITIES CORRECTLY REPORT EVERY SIDE EFFECT OF PSYCHOTROPIC MEDICATIONS INCLUDING INCREASED RATES OF SUICIDE, INCREASED RATES OF VIOLENCE AND HOMICIDE, PERMANENT BRAIN DAMAGE, BIRTH DEFECTS, ETC, INCLUDING SIDE EFFECTS THAT HAVE BEEN REPORTED, WHERE A CONCLUSION HAS NOT BEEN REACHED BECAUSE OF LACK OF GOVERNMENT FUNDING TO PURSUE A STUDY.

These side effects should be easy to find, downloadable and clear. E.g. Beyond Blue does recognize that antidepressants double the suicide risk in children, but it is very hard to find this information on their website, and it is not stated clearly.

e.g. Although I can see on the Beyond Blue website (*Antidepression Medication Factsheet BL/0125 12/16* December 2016) that: "There is concern that a small percentage of young people up to the age of 24 years taking Selective Serotonin Reuptake Inhibitors (SSRIs) for the treatment of depression may experience an increase in suicidal thoughts and behaviour. Research shows the risk to be roughly 4 per cent compared to 2 per cent for those taking a placebo (dummy pill)." But I cannot see this information on the TGA website – effectively warning people that SSRIs can **double the risk of suicide** for people under 24 years old. (And I'll make a note here to say that increased suicidality is not limited to this age group.)

Another example of misinformation is the claim on the Beyond Blue's *Antidepression Medication Factsheet* BL/0125 03/18 (still valid today on their website) that antidepressants are not drugs of dependence/addiction. The 'factsheet' states:

"People often want to stop taking antidepressants quickly because they are concerned they are addictive. This may be because they confuse them with sedatives, a group of medications that are used to help a person feel relaxed and, in some cases, fall/stay asleep. Sedatives are designed to be used only for a short time. If used for long periods of time, sedatives may cause withdrawal insomnia and anxiety and be needed in higher

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doses in order for them to have the same effect. Sedatives may be craved and become addictive. **This is not the case with antidepressants."** (Author's bolded emphasis.)

How is this statement justified given the research and shocking problems people have getting off these drugs (including REM sleep disorder, suicide, etc.)? I am personally aware of at least 30 secret Facebook groups where people go to get help and support to come off these drugs (because they cannot find the answers to these problems from their doctor – this is a common and dangerous problem).

Beyond Blue has received over \$ 100 million in government funding – it should have its facts correct. This information is not only incorrect, but dangerous.

D11. A FULL AND THOROUGH INVESTIGATIO SHOULD BE CONDUCTED INTO WHY IT IS LEGAL FOR DOCTORS TO PRESCRIBE MEDICATIONS TO PATIENTS WITHOUT **INFORMED CONSENT**. AND THIS INVESTIGATION SHOULD INCLUDE TRAINING DOCTORS ON EXACTLY WHAT IS REQUIRED IN ORDER TO ACHIEVE INFORMED CONSENT ON ANTIDEPRESSANTS AND SLEEPING PILLS.

If you go to your doctor with 'insomnia' you will be prescribed a medication in an alarming 95.2 percent of cases, during a normal consultation. Furthermore over 80 percent of psychotropic drugs are prescribed by a general practitioner. In Australia you do not even have to be referred to a psychiatrist to be diagnosed with ADHD, bipolar disorder or the full range of mental health conditions. And you can come away with an incorrect and damaging diagnosed mental health condition, and a potentially dangerous drug prescription for a drug of dependency.

In the more extreme cases, you, the patient could take your own life by suiciding within the first week. That includes children.

This system is outrageous and I believe should be regarded as criminal behaviour.

It is well known that the doctors and psychiatrists do not fully explain the side effects of these drugs to patients. Many do not even know the list of side effects of these medications, and they are being grossly negligent by performing these prescribing routines.

D12. A FULL AND THOROUGH INVESTIGATION SHOULD BE CONDUCTED INTO WHY IT IS LEGAL FOR DOCTORS AND PSYCHIATRISTS TO PRESCRIBE OFF-LABEL, TO THE DETRIMENT OF THEIR PATIENTS.

It is illegal for pharmaceutical companies to promote off label uses of their drugs as proven by the US government's \$ 3 billion fine to GSK for promoting the use of Paxil to children under the age of 18 years.

https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report

However actually prescribing to these children is legal in Australia.

Off-label prescribing of drugs is very common in Australia, and includes prescribing these drugs to children (as young as infants, even babies), prescribing these drugs for other purposes (such as physical pain etc.).

How is this allowed to continue? It should be a criminal offence.

Doctors should be fully trained on what off-label prescribing is, as they clearly have no idea.

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Their off-label prescribing habits make a mockery of the TGA approval process.

Why have a drug approval process if the doctors then proceed to prescribe drugs however they like?

(Recently I had a colleague prescribed an antidepressant for muscle twinge after an unsuccessful hand operation. It is difficult to believe that this sort of negligent behaviour is legal. Thankfully her ethical pharmacist alerted her to exactly what the medication was, explaining that it had serious side effects – so that she ended up not taking the medication. Others would not be so lucky. There are many other examples of off-label and bizarre prescribing practices. Doctors seem to think that if a drug has been approved, it is approved for anything! And of course, they are incentivised to prescribe. This case could also be an example of the growing trend to prescribe antidepressants for pain.)

D13. AN INVESTIGATION SHOULD BE MADE INTO WHY AUSTRALIA HAS NEVER ESTABLISHED A FEDERAL HEALTH OMBUDSMAN WHERE MEMBERS FO THE PUBLIC, AND ANYONE ELSE, COULD MAKE COMPLAINTS ABOUT MEDICAL PROFESSIONALS, PSYCHIATRISTS, THE UNREPORTED SIDE EFFECTS OF MEDICATIONS, CRUELTY EXPERIENCED IN HOSPITALS AND MENTAL HEALTH INSTITUTIONS, TGA PROFESSIONAL BREACHES, INAPPROPRIATE CONDUCT BY CHARITIES AND FOUNDATONS, INCORRECT INFORMATION BEING PROMOTED BY GOVERNMENT FUNDED ORGANISATIONS, SCHOOL INTERVENTIONS INTO MENTAL HEALTH THAT INCLUDE THE ENCOURAGEMENT OF OFF-LABEL PRESCRIBING OF PSYCHOTROPIC DRUGS TO CHILDREN, ETC.

Why are the Australian Government, state and federal ministers, universities, government bodies (such as the TGA), funded charities/foundations (Beyond Blue, Headspace, etc.) so ignorant and incompetent (and/or corrupted) that leadership and best practice is severely lacking until someone calls a Royal Commission, or the Productivity Commission conducts a special inquiry?

Whenever I have contacted state and federal health and mental health ministers to complain about the inadequacies of the system I am told variously and condescendingly by the ministers' offices that "the doctors are looking after that" or that "Australia has world's best practice systems and methodologies" — which is clearly not true.

While no-one is there to collect complaints, log breaches of the law, or listen to ideas and suggestions, report culpable doctors or psychiatrists, review off-label prescribing etc., the system continues unchecked.

There are hundreds, perhaps thousands of health care professionals with 'clinical governance' positions, what are they doing? Who are they reporting to?

Why is the general public called on to report on breaches and inadequacies of the health and mental health systems?

Things are very bad!

D14. THE PRODUCTIVITY COMMISSION SHOULD STUDY AND INTRODUCE THE MOST SUCCESSFUL FINNISH "OPEN DIAGLOGUE" MENTAL HEALTH METHODOLOGY INTO AUSTRALIA WITHOUT DELAY, INDEPENDENT OF ALL OTHER BODIES.

Open Dialogue is world renowned as a hugely successful early intervention methodology in mental health and psychosis cases in Western Lapland, Finland.

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Their research over 15 years of interventions in Finland is the most exceptional in the world, and shows the greatest success in longitudinal studies.

This should be immediately rolled out across Australia.

I am ONLY if favour of early intervention IF EARLY INTERVENTION IS PERFORMED BY APPROVED AND TRAINED "OPEN DIALOGUE" PROFESSIONALS.

(Australia's present early intervention processes are beyond lacking, and result in pharmaceutical interventions in far too many school children, including off-label prescribing to children less than 18 years old.)

D15. THERE SHOULD BE A FULL INVESTIGATION INTO THE SUPRESSION OF FACTUAL INFORMATION, SUBMISSIONS AND STUDIES THAT WOULD INFORM AUSTRALIAN CITIZENS ABOUT THE HARMS BEING DONE BY PSYCHIATRIC DRUGS, PSYCHOTROPIC DRUGS, ECT, MENTAL HEALTH HOSPITALIZATION AND OTHER FORCED TREAMENTS, INCLUDING BY THEIR DOCTORS, PSYCHIATRISTS, CHARITIES AND FOUNDATIONS, MENTAL HEALTH HOSPITALS, GOVERNMENT RUN WEBSITES (SUCH AS THE TGA THROUGH MISINFORMATION AND INCOMPLETE INFORMATION).

Australia 'seems to be' concerned about our growing suicide rate, but does NOT seem to want to know that the pharmaceutical drugs/psychotropic drugs/SSRIs etc. are DIRECTLY CONTRIBUING TO THE INCREASE IN SUICIDE, both in adults and in children.

Furthermore, not only are psychotropic drugs directly increasing suicide rates, but also family violence, homicide, aggressive behaviour, etc. Refer to the side effects listed in section A5 above.

D16. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE THE SUPRESSION OF MENTAL HEALTH AND SLEEP HEALTH INFORMATION AT STATE AND FEDERAL LEVEL AND IN THE MEDIA.

Important information about self harm, suicide, violence and other side effects of mental health mediations are being supressed from the public.

Although we know that suicide, self harm and violence are the side effects of sleeping pills and/or psychotropic drugs the information is seldom provided in media reports of these instances. The Australian public should be fully informed when a violent act hits the news when a person is newly taking psychotropic drugs, tapering from the drugs, swapping psychotropic drugs, etc. The public, and many health professionals, have yet to make this connection, even though the evidence has been available for decades.

Will all submissions to this mental health Productivity Commission inquiry which IMPORTANTLY mention self-harm suicide, homicide etc. be similarly supressed?

The public needs to know when legally prescribed drugs can cause a patient to be violent, self-harm, murder and/or suicide. And the public needs to know when doctors take it upon themselves to prescribe these dangerous drugs to children, off-label, that we know can double the risk of suicide.

Every workplace in Australia should be aware of the risks associated with violence, suicide, self-harm, aggression etc. that are associated with psychotropic drugs. At the moment this risk appears to be connected to staff members' "mental health conditions" but never the drugs they are legally prescribed.

D17. THE PRODUCTIVITY COMMISSION SHOULD INCLUDE A FULL INVESTIGATION INTO THE PROVEN CONNECTION BETWEEN PSYCHOTROPIC DRUGS AND INCREASED INCIDENTS OF SUICIDE, VIOLENCE, HOMICIDE AKATHISIA AND DOMESTIC VIOLENCE. ACTS OF TERRORISMS SHOULD ALSO BE INCLUDED IN THIS INVESTIGATION TO ESTABLISH WHAT DRUGS THESE PERPETRATORS ARE TAKING, OR TAPERING FROM WHEN THESE VIOLENT ACTS HAPPEN.

This connection, already proven in internationally recognised studies, could be reinforced by compulsory forensic blood testing of all suspects in violence cases, including the forensic blood testing of murder/suicide perpetrators. These blood tests should be kept in a national register documenting the link between drugs and violence, suicide, self-harm, homicide and domestic violence, even terrorists.

At the moment, when a mother, for example, kills her 3 children it is erroneously attributed "the mother's mental health condition". This is not enough information. Generally a 'mental health condition' would not push a mother to kill her 3 children — it is so extreme as to involve psychotropic drugs or ICE for example. There is more to investigate in these cases.

In actual fact, the reports and news should clearly document the legally prescribed drugs the person is taking, and show the list of side effects associated with such a drug.

The public needs to be informed – at the moment they have no idea. Everything is blamed on a 'mental health condition' which is a misleading conclusion at best.

Adverse violent behaviour is attributed to the medications, to the medications when people are newly taking the medications, after prolonged use via serotonin toxicity, as a withdrawal effect when the person is reducing or changing their medications, when tapering the dependent medication too quickly, or tapering too fast, etc.

In view of this information it is clear that the **websites that deny psychotropic drugs are drugs of dependence** – are potentially culpable for people having no idea when they find themselves in grave difficulty, commit homicide, suicide etc.

Furthermore, it is not atypical, that when mental health patients show these extreme symptoms their medications are INCREASED or SWAPPED by their doctors/psychiatrists, increasing the risk of deadly side effects. (Additionally it is well documented that when mental health patients present at a hospital because they are feeling very unwell, they often have their medications increased.)

Hospitalisation does not have long term advantages, but I'm unaware of the exact studies that prove this. I believe that Open Dialogue may have the research to prove hospitalization reduces the chance of good outcomes for emotionally challenged patients.

D18. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE THE SIDE EFFECTS OF FOOD ADDITIVES, CHEMICALS AND COLOURINGS IN OUR PROCESSED FOODS TO ESTABLISH AND DOCUMENT THE REACTIONS THAT APPEAR TO BE, BUT ARE NOT, MENTAL HEALTH CONDITIONS.

There are over 40 food additives and colourings etc. that affect behaviours in both children and adults, including reactions such as anxiety, night terrors, insomnia, oppositional defiance, aggressive behaviours, depression, continual crying as babies, etc.

In these cases putting the child on pharmaceutical medications will not solve the problem, but will probably make it worse – and ignore the underlying issue of the intolerance and allergy to particular food additives/colourings/chemicals.

Sue Dengate of the Food Intolerance Network, with over 25 years of expertise in this area, should be consulted and made an integral part of this investigation. http://www.fedup.com.au

D19. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE THE SIDE EFFECTS OF ALL MEDICATIONS THAT INCLUDE SYMPTOMS AND BEHAVOURS *THAT APPEAR TO BE* MENTAL HEALTH/EMOTIONAL PROBLEMS.

There are many prescriptions and non-prescription drugs that have side effects which include what appear to be mental health conditions. The side effects include depression, anxiety, restless sleep, insomnia, etc.

Furthermore, our present drug approval processes do not take into account drugs contraindications which can occur when people take more than one drug at a time – which is increasingly common.

Some apparently mental health conditions can simply be side effects of a medication that patients are already taking (including, ironically, antidepressants and psychotropic drugs).

These drugs include the contraceptive pill, psychotropic drugs, antihypertensives, stimulants, cardiovascular drugs, bronchodilators, decongestants, flu and cold medications, CNS stimulants, cold remedies, steroids, respiratory medications, diuretics, antihypertensives, slimming tablets, hormones, painkillers, cough syrups, etc.

Medical professionals are NOT looking at all the underlying issues that present as the symptoms of emotional issues/mental health conditions, and often prescribe ANOTHER medication on top of the offending medications, which makes the problem worse, not better.

D20. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE AND FACILITATE TRAINING TO MEDICAL PROFESIONALS AND PSYCHIATRISTS ON INFORMED CONSENT.

Medications are being prescribed, and patients taking the medications WITHOUT INFORMED CONSENT.

This should be regarded as criminal negligence, knowing the serious, even deadly side effects, of psychotropic drugs.

D21. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE THE TRAINING REQUIRED FOR DOCTORS, PSYCHIATRISTS AND ALL MEDICAL PROFESSIONALS THAT ARE PRESCRIBING PSYCHOTROPIC DRUGS AND WORKING IN MENTAL HEALTH HOSPITALS SO THAT THEY ARE AWARE OF THE INTERNATIONAL DEVELOPMENTS, WORLD'S BEST PRACTICE, AND INFORMATION THAT APPEARS TO HAVE NOT REACHED AUSTRALIA, NOR AUSTRALIA'S MENTAL HEALTH LEADERS.

D22. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE ALL PRESCRIBING AND PROMOTIONAL INCENTIVES GIVEN TO DOCTORS, MEDICAL PROFESSIONALS, FOUNDATIONS AND CHARITIES, PSYCHIATRISTS, UNIVERSITIES, MEDICAL LITERATURE, THE TGA, ETC.

This should include public organisations being provided information and research results from pharmaceutical companies, and organisations with a vested interest, financial and/or otherwise.

And it should include politicians incentivized to make certain policy changes – during and after their political careers.

D23. The PRODUCTIVITY COMMISSION SHOULD FULLY INVESTIGATE THE DRUG MEFLOQUINE, THE ANTI-MARLARIAL DRUG THAT HAS BEEN GIVEN TO THE AUSTRALIAN DEFENCE FORCES PERSONNEL, WHICH HAS SEVERE SIDE EFFECTS — THAT APPEAR TO BE MENTAL HEALTH CONDITIONS OR PTSD — BUT IN ACTUAL FACT ARE SIDE EFFECTS OF THIS MEDICATION.

Members of our armed forces employees are wrongly being diagnosed with PTSD when they should be being treated for the severe side effects of Mefloquine.

Mefloquine is toxic and should be taken off the market until a full and thorough investigation has been conducted into the very harmful side effects that can ruin people's lives, and cause them to commit suicide.

D24. DOCTORS, PSYCHIATRISTS, NURSES AND ALL MEDICAL STAFF SHOULD BE TRAINED ON THE SHORTCOMINGS OF DRUG APPROVAL PROCESSES.

Medical personnel are far too confident in their prescribing behaviours, given the undisclosed, secretive, and sometimes fraudulent approval processes of pharmaceutical drugs.

See Professor David Healy's TED talk below (D33) that explains hidden raw data, ghost writers, side effect non-disclosures, even fraud.

D25. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE THE INFLUENCE OF PHARMACEUTICAL ADVERTISING AND FOUNDATION/CHARITY MENTIONS ON MEDIA NEWS STORIES AND DISCLOSURE OF INFORMATION.

Over the last few years I have noticed absolute silence in Australia on major developments in the sleep and mental health space that go unreported in the media.

Here are four examples in the last couple of years that went unnoticed in the Australian media, the Mental Health Ministers' media releases, on the Beyond Blue website, on Headspace websites, mental health stories, etc:

- World class experts visiting Australia speaking against the pharmaceutical model and biomedical approached to mental health, such as Professor Peter Gøtzsche and Robert Whitaker were ignored in February 2018 when they presented leading edge information at the Mental Health in Crisis Conference in Sydney. https://www.mentalhealthcrisis.co/sydney
- Publication of the world renowned Restoring Study 329, published in the British Medical Journal and including Australian authors Professor Jon Jureidini and Melissa Raven, published September 2015. https://www.bmj.com/content/351/bmj.h4320
- 3. Presentations given by the Finnish experts from the most successful mental health process in the world "Open Dialogue", Dr Jaakko Seikula and Dr Pekka Borchers speaking in Sydney December 2018. There should have been thousands of attendees. http://www.mentalhealthcarersnsw.org/events/open-dialogue-research-seminar/
- 4. Dolin vs GSK, where \$ 3 million was awarded in damages to Wendy Dolin after the suicide death of her husband Stewart Dolin who was taking a generic version of the antidepressant Paxil at the time. Proving a connection to suicide to people of all ages, not just children. Full

transcripts available here: https://www.baumhedlundlaw.com/prescription-drugs/paxil-injuries/gsk-paxil-trial-transcripts/

D25. THE PRODUCTIVITY COMMISSION SHOULD FULLY INVESTIGATE WHY THE PEAK FOUNDATIONS AND CHARITIES IN AUSTRALIA, SUPPORTED BY HUNDREDS OF MILLIONS OF DOLLARS OF TAX PAYER'S GRANTS, SUCH AS HEADSPACE AND BEYOND BLUE, DO NOT HAVE CORRECT INFORMATION ON THEIR WEBSITES. E.G. BOTH THESE WEBSITES CLAIM THAT PSYCHOTROPIC DRUGS ARE NOT DEPENDENCE FORMING.

Their misinformation is not limited to this area.

And their misinformation is negligent and culpable.

D26. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE AND IMPLEMENT A TRAINING STRATEGY AROUND EDUCATING MEDICAL PROFESSIONALS, HUMAN RESOURCES PERSONNEL AND THE PUBLIC ON AKATHISIA, A POTENTIALLY DANGEROUS AND VIOLENT SIDE EFFECT OF PSYCHOTROPIC DRUGS.

Akathisia is a side effect of psychotropic medications and can be the forerunner of suicide, homicide, violence, and self-harm. Everyone in the public should know how to recognise it, and what to do about it.



What is Akathisia? MISSD Organisation. Accessed January 16, 2019. MISSD, started by Wendy Dolin after the suicide death of her husband Stewart Dolin, see Dolin vs GSK in other sections of this submission.

D27. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE POSSIBLE RULINGS ON COMPULSORY BLOOD TESTS OF ALL PATIENTS BEFORE THEY ARE GIVEN PSYCHOTROPIC MEDICATIONS, LOOKING TO AVOID TOXIC REACTIONS TO THE DRUGS BECAUSE OF GENETIC PREDISPOSITIONS TO ADVERSE REACTIONS

Some genetic types are predisposed to toxic reactions to psychotropic medications, resulting in increased rates of suicide, homicide, etc. It should be regarded as negligent to prescribe psychotropic drugs to people who have a genetic predisposition to adverse reactions to these drugs without testing for cytochrome CYP450/CYP2C19 inhibitors etc. Please refer to Dr Yolande Lucire's YouTube video on this topic.

D28. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE THE INTRODUCTION OF PROMPT AND APPROPRIATE FORENSIC BLOOD TESTING OF PEOPLE COMMITTING VIOLENT CRIMES, IMMEDIATELY AFTER THE VIOLENT ACT OR DEATH, TO ESTABLISH THE PRESENCE OF PSYCHOTROPIC DRUGS IN THE BLOOD STREAM OF THESE PEOPLE.

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This is already an established link, but the media and Australia's reporting systems are not making the connection public.

Is this information being supressed?

D29. THE *DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS* (DSM) IS TO BE FULLY INVESTIGATED BY THE PRODUCTIVITY COMMISSION.

The DSM is approaching, and possibly has already become, a pharmaceutical drug and ECT marketing tool.

e.g. in 1980: In the Psychiatric Disorder list DSM-111: it was acceptable after a death to grieve for 2 years.

In 1994: In Psychiatric Disorder DSM-IV: it was acceptable to grieve for only 2 months before you were considered to be mentally ill.

In 2013: Psychiatric Disorder DSM-V: You are considered to be mentally ill if you grieve for more than 2 weeks.

This is preposterous.

All other conditions and mental illness diagnoses should be thoroughly investigated as the medical profession and psychiatrists are simply 'selling sickness' to the masses, prescribing harmful medications and increasing both the rate of physical and mental harm, drug dependence, unemployment and disability pensions.

Council for Evidence Based Psychiatry.

https://www.youtube.com/channel/UC8eIK8kuf7tht1gV1HApH0g

http://cepuk.org/moreharmthangood/

Dr James Davies: The Origins of the DSM



https://youtu.be/6JPgpasgueQ

D30. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE THE INADEQUATE WARNINGS AROUND PSYCHOTROPIC DRUGS.

By your doctor at the time of diagnosis and prescribing (there is NO informed consent), on the drug labels, on the information sheets contained within the drug packages, by the pharmacist at the time of fulfilling the prescription, on the generic versions of the drugs as well.

Generic versions of the drugs should have the same warnings and legal redress as the originally branded medications, such as Paxil.

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D31. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE INTERNATIONAL TRENDS IN MOVING LEGAL LIABILITY AWAY FROM THE PHARMACEUTICAL COMPANY PRODUCING AND PROFITING FROM THE DRUG, ON TO THE STATE, SO AUSTRALIA IS FULLY AWARE OF THIS POTENTIAL CHANGE.

There appears to be some moves towards blaming the TGA/FDA for drug exposure – especially in the case of generic versions of approved drugs - where pharmaceutical companies might take NO responsibility for harms caused by generic versions of drugs.

Refer to the most recent case following the Dolin vs GSK case in the US, here https://cookcountyrecord.com/stories/511687361-widow-asks-scotus-to-toss-gsk-s-win-in-lawsuit-over-paxil-labeling-lawyer-s-suicide?fbclid=lwAR2MzIDPt3ojQthHAzb2az7p1wINceBgLNZecc6OMnKD1anAbYZa2KEhwSA

Already in the US liability has been moved from the vaccine manufacturers to the government (i.e. American citizens) through the passing of the National Vaccine Injury Compensation Act 1986.

The health and pharmaceutical lobby groups know this is a very large commercial advantage to themselves, and I believe there are now moves to complete their *shift of liability* in all areas of health to the government and other groups (such as the FDA/TGA) etc., so they can continue their culpable behaviours without being brought to ethical or financial justice.

This recommendation highlights the absolute importance of the TGA knowing it's exact legal liability in relation to drug approval.

And the Productivity Commission might investigate the role of the Trans Pacific Partnership (TPP) in future exposures relating to drug approvals, generic versions of drugs and their side effects. Who is looking at this potential problem?

D32. THE PRODUCTIVITY COMMISSION SHOULD DO A FULL COSTING OF THE ECONOMIC DAMAGE ALREADY BEING DONE TO THE ECONOMY AS A RESULT OF THE INAPPROPRIATE, COSTLY AND UNSUCCESSFUL BIOMEDICAL MODEL AND HOW IT WILL DEVELOP OVER THE NEXT 40 YEARS.

We cannot afford to continue with the biomedical model, as those treated with pharmaceutical drugs have worse outcomes over time than the untreated groups.

This problem is already manifesting in Australia, today.

The pharmaceutical lobby group would have us believe that by not treating mental illness with pharmaceutical drugs, and by not intervening early, we are going to have a huge problem down the road.

This costing could be achieved with the help of Professor Peter Gøtzsche and Robert Whitaker.

The EXACT OPPOSITE is what is happening, and the evidence is in.



Robert Whitaker speaks at the All-Party Parliamentary Group for Prescribed Drug Dependence, Westminster May 2016.

"Rising Prescriptions, Rising Mental Health Disability: Is there a Link? Robert Whitaker.

D33. AUSTRALIA SHOULD LOOK INTERNATIONALLY FOR EXPERT ADVICE.

The Productivity Commission should actively pursue world renowned international experts to input into this study. They include: Professor Peter Gotzsche, Professor David Healy, Dr Peter Breggin, Dr Irwin Kirsch, Dr Jaako Seikkula, Robert Whitaker and Dr Ann Blake-Tracy.

It is clear that the Australian experts, and our leading 'charities and foundations' such as Headspace and Beyond Blue (and their founders, and executives) are failing us: they do not reflect international best practice and evidence in this field.

The so-called Australian experts support the **unproven biomedical hypothesis/model** and as such should be disqualified from the discussions.

When the biomedical model experts promote 'early intervention' it is usually directed at an early DIAGNOSIS and subsequent MEDICATION.

"Early intervention" in Australia equates to early pharmaceutical prescribing and poorer outcomes.

The very few experts in the non-biomedical model in Australia are being ignored, professionally disadvantaged and in some cases harassed.

Additionally many are afraid to voice their opinions because of professional and personal discrimination.

Professor Peter Gotzsche



Dr. Peter Gøtzsche exposes Big Pharma as Organized Crime. https://youtu.be/dozpAshvtsA

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Professor David Healy



Professor David Healy speaking at PAST Wales Senedd Awareness Day, December 11, 2018 - Part 1 December 2018.



Professor David Healy. Making Medicines Safer for All of Us. TEDxAberystwyth. https://youtu.be/vpTqei5hZ3g

Dr Irwin Kirsch.

Irving Kirsch, the Harvard University psychologist responsible for the most thorough analysis of the effectiveness of SSRIs, says that: 'In the future, there will come a point when the prescription of antidepressants that we currently use will be regarded the way we now regard blood-letting: how could doctors have done this?'.



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Robert Whitaker



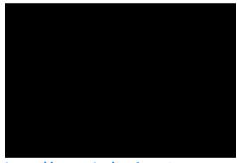
https://youtu.be/dozpAshvtsA

Author of "Anatomy of an Epidemic: Magic Bullets, Psychiatric Drugs, and the Astonishing Rise of Mental Illness in America. Broadway Paperbacks, 2010.

Longitudinal meta-analyses prove that the treated mental health groups perform worse than the untreated groups. Additionally, there is no evidence to support early detection of a mental health condition: this fact also supported by the World Health Organisation.

https://www.MadInAmerica.com

Dr. Peter Breggin



https://youtu.be/SBJfZtB_3cc

Peter R. Breggin, MD - Antidepressants & Suicide. Congressional Testimony before the Veterans' Affairs Committee of the U.S. House of Representatives on February 24, 2010

75% of young doctors are on psychotropic drugs:

https://breggin.com/alert-20-75percent-of-young-docs-on-psyche-drugs/

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[&]quot;They are causing a huge amount of misery, loss of quality of life, loss of love life,"

[&]quot;These drugs are devastating to people." Dr Peter Breggin.

Ann Blake-Tracy – Violence, suicide and homicide as side effects of psychotropic drugs, and how to withdraw (very slowly) from these drugs of dependence.



Ann Blake-Tracy speaking at an FDA hearing. https://youtu.be/w1p4DWTj2Bw

Dr Jaako Seikkula - Open Dialogue



https://youtu.be/Oq5qtc90VHI

"Open dialogue with families increase resources for avoiding unnecessary medication and improve the outcome in psychotic crises" Published Feb 10, 2017. Similar presentation to the one Dr Jaako Seikkula presented at Sydney University late 2017.

D34. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE THE DANGERS OF PSYCHOTROPIC DRUG WITHDRAWAL. THIS INVESTIGATION SHOULD INCLUDE THE COSTS AND ROLL OUT OF APPROPRIATE WITHDRAWAL CENTRES ACROSS THE COUNTRY TO FACILITATE THE HUGE JOB OF ALLOWING WITHDRAWAL FROM MEDICATIONS FOR THE APPROXIMATELY 1 IN 6 AUSTRALIANS WHO ARE ALREADY TAKING THESE DEPENDENCE-FORMING MEDICATIONS.

As stated by Professor Peter Gøtzsche in Sydney February 2016 we simply do NOT have the facilities to help people withdraw from psychotropic drugs in Australia.

It is a very slow and difficult withdrawal process, many people find themselves in dire situations when withdrawing. Cold turkey withdrawal is NEVER recommended (which includes dangerous swapping, adding and changing medications).

Dr Ann Blake-Tracy is an international expert on this topic. Another source of quality information is Let's Talk Withdrawal with James Moore http://www.letstalkwithdrawal.com/

D35. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE THE LACK OF ACCESS TO THE RAW DATA BEHIND THE CLINICAL TRIALS THAT LEAD TO APPROVAL OF PSYCHOTROPIC DRUGS AND THE

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HUGE NUMBER OF UNPUBLISHEDD CLINICAL TRIALS IN THE MENTAL HEALTH AREA – PRESUMABLY BECAUSE THE RESULTS OF THOSE TRIALS WERE UNFAVOURABLE.

Restoring Study 329 is a particularly ground-breaking study, because it is so rare that a court will require the raw data of clinical trials be made available for inspection.

This was a rare viewing into the fraud and misrepresentation that occurred during the Study 329 clinical trial.

Refer to the TEDxAberystwyth presentation by Professor David Healy *Making Medicines Safer for All of Us* to gauge the enormity of the problem. https://youtu.be/vpTqei5hZ3g

D36. THE PRODUCTIVITY COMMISSION SHOULD CALL FOR CONTRIBUTIONS AND INVESTIGATE THE FORCED PSYCHIATRIC TREATMENTS, PSUYCHIATRIC ABUSES, HUMAN RIGHTS VIOLATIONS AND PEOPLE BEING LOCKED UP AGAINST THEIR WILL, UNAUTHORISED E.C.T. (ELECTROSHOCK TREATMENT) ETC. – AND THE COSTS OF THESE ACTIVITIES TO THE AUSTRALIAN ECONOMY.

D37. THE PRODUCTIVITY COMMISSION SHOULD CALL FOR CONTRIBUTIONS AND INVESTIGATE THE "PHARMACEUTICAL TREATMENT" OF PEOPLE IN AGED CARE FACILITIES, JAILS, MENTAL HEALTH INSTITUTIONS AND DETENTION CENTRES AND THE COSTS OF THESE ACTIVITIES TO THE AUSTRALIAN ECONOMY.

D38. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE THE SUCCESSFUL BANNING OF ECT IN ITALY, AND THE POSITIVE RESULTS THAT HAVE BEEN EXPERIENCED IN THAT COUNTRY AFTER ECT WAS ABOLISHED.

The cost/benefits of similarly banning ECT in Australia should be investigated.

D39. THE PRODUCTIVITY COMMISSION SHOULD INVESTIGATE WHY THERE IS A SIGNIFICANT DEFICIT IN NON-PHARMACEUTICAL TALK THERAPIES AND NON-PHARMACEUTICAL COUNSELLING WHEN THIS METHOD OF DEALING WITH MENTAL HEALH ISSUES IS EVIDENCE BASED.

Experts believe that social interaction and friendships can be vital to emotional recovery, and we appear to be doing the opposite by prescribing medications with a side effect of depersonalisation.

There is growing pressure being mounted on all natural and talk therapies, which is inappropriate, as the pharmaceutical model is doing far more damage than any counselling and talk therapy methodology could ever achieve.