2019 Submission - Royal Commission into Victoria's Mental Health System

Organisation Name: Sleepless No More

SUB.1000.0001.1077

1. What are your suggestions to improve the Victorian community's understanding of mental illness and reduce stigma and discrimination?

Australia is unfortunately a country with pervasive Incorrect Information, Lack of Information, Unsubstantiated Information and Out of Date Information about mental health, emotional health and the underlying reasons for emotional challenges.

The reason people do not understand emotional challenges, being promoted as "mental illness", is that they are not being given full and correct, up to date and relevant information.

The Australian public is being given information which is coming from the 'mental health industry' not information that reduces mental health problems. The information is industry driven. "Follow the money" is a phrase very relevant in this field.

People need to be given correct information that empowers them and ensures that they continue to be emotionally resilient.

The information being promoted, marketed as 'de-stigmatising mental health' has resulted in people incorrectly self-diagnosing and presenting to their medical professionals asking for help with their anxiety (mental health problem), depression (mental health problem), bipolar (mental health problem), etc.

Examples of information and mental health developments I do not see mentioned or promoted in Australia as part of making Australians emotionally resilient, and therefore not diagnosed and medicated as mentally ill:

• The flaws in the clinical trial process, and how to check the strategies being promoted by health care professionals, the government, doctors and psychiatrists.

Making Medicines Safer for All of Us. Professor David Healy. December 2018.



https://youtu.be/vpTqei5hZ3g

 International legal cases that prove that clinical trial results have been fraudulently manipulated.

2012. GlaxoSmithKline ordered to pay fine of \$ 3 billion to resolve fraud allegations and failure to report safety data.

Part of the findings were for "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."

This drug is being prescribed off-label to Australian children 7 years after this fine was imposed – in Australia it is "business as usual" as 100,000 children less than 18 years old are being prescribed antidepressant medications off-label – with no positive evidence to support this prescribing behaviour (and a significant amount of negative evidence).

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

Restoring Study 329: Efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence, 2015. https://www.bmj.com/content/351/bmj.h4320

Minimal publicity in Australia following this ground-breaking study published in the British Medical Journal, even with a number of Australians involved in this historic research.

• International legal case Dolin vs GSK proving the connection between antidepressant medications and adult suicide. Suicide risk is increased for both children and adults: this information is not recognized in Australia's Product Information statements, approved by drug companies and the TGA.

Product Information statements for these drugs in Australia recognize an increased suicide risk for younger people only.

\$ 3 million dollars awarded to Wendy Dolin, wife of Stewart Dolin who committed suicide by throwing himself in front of a train. During this ground-breaking case it was shown that 22 people had died during the Paxil clinical trial, with all the 22 deaths remaining unreported until 'Restoring Study 329' was published in the British Medical Journal.

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

Paxil/paroxetine product information showed no risk beyond the age of 24 and other relevant information.

This payment of \$ 3 million has since been overturned by the US Supreme Court, not because the connection was not established, but the court argued that the responsibility for damages did not rest with the pharmaceutical company.

How does our TGA fare in not telling Australians about this suicide risk? Not well.

This potentially life-saving information should be disclosed on the outside of all medical packaging, in the Product Information statements, in the Consumer Medicines Information (CMI), in all government funded mental health websites (Headspace, Beyond Blue etc), and all charity websites, and any other website that can be seen by the public.

May 2019. Antidepressants are now recognized in the United Kingdom as drugs of dependence, with NICE moving to change their product information around this class of drugs.
 https://cepuk.org/2019/05/30/royal-college-psychiatrists-call-update-nice-antidepressant-guidelines-following-cep-campaign/

There has been no murmur in Australia about this new development. No public declarations to protect the 3 million Australians who are taking these drugs, no withdrawal warnings, no new initiatives to establish withdrawal centres and withdrawal training programs for these vulnerable people.

• International experts should be featured broadly in Australia, in the Australian media, on the

TGA website and documentation, and on government funded mental health foundations/charities such as Beyond Blue, Headspace, Batyr, and many others.

Professor Peter Gøtzsche's presentation in Australia 2015 *Overdiagnosed and Overmedicated* is one example.



https://youtu.be/ZMhsPnoIdy4

 Of the Top Ten Legal Drugs Linked to Violence 8 of them are psychotropic drugs: antidepressants, benzodiazepines and ADHD medications.

Szalavitz, Maia, *Top Ten Legal Drugs Linked to Violence*, Time Magazine, July 1, 2011. http://healthland.time.com/2011/01/07/top-ten-legal-drugs-linked-to-violence/#ixzz1AiJRKLhO

1A. A Complete Review of all Government Documentation that promotes the unproved, outdated and erroneous concept that mental illness is related to, caused by, or a function of "chemical imbalances in the brain" and corrected.

In spite of rigorous efforts, over decades, to prove such a connection exists, this unproved theory was finally disproven before the end of the last century.

This myth continues to underpin many approaches to mental health treatment in Australia and internationally – most obvious in the overprescribing of psychotropic drugs which can be fatal, harmful, dependence forming and disabling.

The reason no testing exists to demonstrate, quantify, explain or distinguish mental health problems is because there is no such test. The hypothesis is unproven.

Over 3 million Australians are now taking antidepressants.

Over 100,000 children are being prescribed psychotropic drugs off-label. There is no proof that psychotropic drugs work for children, in fact they double the suicide rate of children (at least, there are higher figures) and cause significant harms for many.

1B. Mental Illness is the Symptom, not the Underlying Cause.

In every case of emotional and mental hurt there is an underlying cause.

Our mental health system has failed profoundly at addressing the *underlying causes* of emotional stress and emotional symptoms, instead unsuccessfully dealing with the *symptoms*.

Underlying issues that are being ignored and/or badly addressed by our mental health system include, but are not limited to: bullying at school, physical and sexual abuse in the family, food additives and chemicals, lack of sleep, neglect, financial stress and unemployment, grief, the experiences of war, trauma and shock, etc.

One *underlying issue* that is being wrongly diagnosed as a "mental health illness" is the side effects of legally prescribed medications – known as 'prescripticide' – see Question 3 for a listing of over 500 legally prescribed medications that are associated with both suicide and depression. These drugs that are associated with suicide and depression include antidepressants, sleeping pills, SSRIs, SNRIs and benzodiazepines. All these drugs are commonly prescribed FOR depression and mental health problems, and these drugs are ASSOCIATED WITH depression and mental health issues. CAUSATION has also been established. Furthermore – all these drugs are now recognised as DRUGS OF DEPENDENCE.

However SSRIs have not been recognized as drugs of dependence in Australia – yet another flaw in our very flawed mental health system.

SSRIs have been known to be dependence forming/addictive and to have significant withdrawal effects for decades. Only recently has the debate moved from academic and commercial arguments around the definitions of 'dependence', addiction, etc. to move towards education and damage control for users of these drugs. Recently the Royal College of Psychiatrists in the United Kingdom has moved to require NICE to change its guidelines to reflect the difficulties experienced by people attempting to withdraw from mental health medications. Source: Campaigning Persuades Royal College of Psychiatrists to Change its Position on Antidepressant Withdrawal. Council for Evidence Based Psychiatry. May 30, 2019.

https://cepuk.org/2019/05/30/royal-college-psychiatrists-call-update-nice-antidepressant-guidelines-following-cep-campaign/

Here are some very simple, completely cost effective solutions to "mental health problems" that are not being addressed: (I could add about 50 others to this list.)

- Not allowing children to start school at too young an age. Children who are too young for their class at school are often diagnosed with "ADHD", a diagnosis that has no scientific base only subjective.
- Financial counselling and employment programs for people who cannot find a job and cannot keep up with their mortgages and are diagnosed as "being depressed".
- Children who are demonstrating behavioural difficulties such as oppositional defiance or the inability to sleep should be recommended the FAILSAFE diet (or similar) to identify any food additives, colourings or chemicals to which they may have intolerance, thereby solving the underlying issue that is causing their behavioural and sleeping problems.
- Counselling should be the first recommendation by doctors in all instances of emotional upheaval without medications. Medications complicate the process of counselling. Sometimes the person has even committed suicide because of the pharmaceutical drugs before counselling is even started.

We need a smart and fully functioning Emotional Health, Community Health and Preventative Health Minister to champion the early stages of health problems in the community before issues become actual health problems wherever possible.

This minister would also be responsible for food labelling laws, especially reviewing the food additives, flavourings, colourings and chemicals that relate to mood and behavioural problems including depression, oppositional defiance, inability to concentrate, and physical reactions to food additives and chemicals.

1C. A Complete Review of Mental Health Terminologies should be Conducted.

Many emotional challenges encountered through normal living are now being classified as mental health diagnoses.

Additionally, many health challenges which have an emotional response are also being diagnosed as mental

health problems.

They include, but are not limited to:

- children who are the victims of domestic and sexual violence. Battered and beaten, no wonder they have emotional responses.
- withdrawal from medications, including mental health medications (which sometimes, erroneously, is used as proof that the drugs are working!)
- depression is the side effects of over 500 medications (see further information in this submission)
- insomnia and chronic insomnia has a direct effect on emotions, resilience, mood, and perceptions,
- food intolerances give rise to emotional responses, and are often incorrectly diagnosed as mental health problems, etc.

By classifying emotional challenges as mental health problems the sufferer is DISEMPOWERED, OVERDIAGNOSED, OVERMEDICATED, and the problems continue to get worse.

Furthermore, where a perpetrator is involved, medicating the victim is *blaming the victim*, and in many cases, because the correct counselling is not given BEFORE medications, the *perpetrators go free, unpunished and still at large to reoffend*.

1D. A Complete Review of the Product Information statements, Side Effects of Mental Health Drugs, Mental Health Charity websites, TGA statements etc. should be undertaken, independently of pharmaceutical interests.

At the moment the information published by the Therapeutic Goods Administration, Product Information, Consumer Medicines Information and government funded organisations such as Beyond Blue and Headspace is incorrect, out of date, and/or inconclusive.

Peer review, international court cases, Cochrane, international reviews of clinical trials (such as Restoring Study 329), documentaries, and international developments should all be used to update the knowledge of everyday Australians.

"Mental health" and the adverse effects of diagnoses and mental health drugs now effects every family in Australia.

e.g. The current Product Information statement for Aropax/(paroxetine) in the *Discontinuation of Treatment* section (page 11) contains the statement "The occurrence of discontinuation symptoms is not the same as the drug being addictive or dependence producing as with a substance of abuse."

There have been various 'academic' attempts to distinguish between the words "addictive" and "dependence forming" including arguments put forward by drug company leaders such as in the BBC News Panorama, *The Secrets of Seroxat*, aired on BBC October 1, 2002: (again, this is not new news..)



https://youtu.be/Z043efODoug

This hair-splitting over terminology is costing lives, possibly many lives, as people who think these drugs are not addictive/dependence forming cold turkey off these drugs with serious and fatal consequences. Permanent disability is one side effect of coming off these drugs too quickly, as attested by thousands of people now in withdrawal help groups and hidden social media platforms, etc.

In view of the recent turn around in the UK with NICE guidelines about to change, we have no excuse to be dragging the chain on this issue.

NONE of these recommended tapering sites is run by the Australian government, by any of the 'leading' mental health groups, or by Australia's TGA. At the moment, the only groups I can recommend are all based outside Australia.

It is a shocking and deadly state of affairs.

1E. Misinformation.

Misinformation is common in all areas of mental health.

Misinformation, lies, understatements, omissions and all varieties of potentially dangerous confusion exist in government information, Therapeutic Goods Administration, Product Information statements, Consumer Medicines Information, "respected" websites and charities such as Beyond Blue and Headspace, internet forums such as Beyond Blue, Food Standards Australia and New Zealand, and many other organizations.

No wonder doctors and psychiatrists don't seem to have a clue.

(Here's the choice: they either don't have a clue, or they have a clue and they are culpable. Take your pick.)

Headspace

Here is Headspace's information on deaths attributed to SSRI prescription taken from their *Evidence Summary:* Using SSRI Antidepressants and Other Newer Antidepressants to Treat Depression in Young People: What are the issues and what is the evidence? Version 2, updated December 2012. Still current and downloaded June 19, 2019 (Version 2 Updated 2012): https://headspace.org.au/assets/Uploads/Resource-library/Health-professionals/ssri-v2-pdf.pdf

- "No deaths have been reported that are attributed to SSRI prescription."
 - So the 22 suicide deaths that occurred during ONE clinical trial of paxil that went
 unreported in the clinical trial findings and were later exposed in the ground-breaking US
 court case Dolin vs GSK is not a reason for Headspace to update their 'Evidence Summary'
 since 2012? (See Plaintiff's Exhibit 347 https://www.baumhedlundlaw.com/prescriptiondrugs/paxil-injuries/paxil-trial-exhibits/)
 - 2. BBC One Panorama "A Prescription for Murder" July 26, 2017. Another reason to update their "Evidence Summary"? https://www.bbc.co.uk/programmes/b08zjyp1
 - SSRI Stories, Antidepressant Nightmares. https://ssristories.org/ and https://www.ssristories.net/

SSRI Stories is a collection of over 6,000 stories that have appeared in the media (newspapers, TV, scientific journals) in which prescription drugs were mentioned and in which the drugs may be linked to a variety of adverse outcomes including violence.

Interestingly SSRI Stories was started by Rosie Meysenburg who had a bad reaction to

Prozac in 1992. (She was prescribed Prozac by her doctor off-label for smoking cessation – see the fuller story here: https://davidhealy.org/the-story-of-ssri-stories/)

This is NOT new news. These stories have been documented for decades, but apparently Headspace is not aware of them.

This "Evidence Summary" provides information on suicide, but does NOT list the array of side effects
that are known to be associated with SSRI antidepressants and documented in the Product
Information documentation from the TGA. The Evidence Summary is unacceptable.

No mention of increased violence, akathesia, sexual dysfunction, dependence, discontinuance syndrome, withdrawal effects, homicide, insomnia, permanent sexual dysfunction, decreased appetite, depersonalisation, serotonin syndrome/toxicity, agitation, confusion, tardive dyskinesia and many other known side effects.

Headspace and Beyond Blue receive eye-watering amounts of funding from the Australian Government, and innumerable free mentions in the media (including during the news), they should get their facts right, at the very least.

Beyond Blue

Has similar problems with its "Factsheet" and other information. Refer to question 11 for a fuller report.

Headspace and Beyond Blue receive eye-watering amounts of funding from the Australian Government, and innumerable free mentions in the media (including during the news), they should get their facts right, at the very least.

Australian Food Standards Dangerous Misinformation

Here is one example of the *difference in information* being presented by a Government instrumentality (Food Standards) and a privately run research and education forum on ADD/ADHD and food additives.

MSG (monosodium glutamate) is one of about 50 food additives and colourings that the Royal Prince Alfred Hospital Allergy Clinic and Australia's Food Intolerance Network has identified as being associated with 'ADHD-type behaviours'.

Here is the commentary on how food additives affect some children, resulting in "ADHD type symptoms" (which many wrongly interpret as ADHD or ADD):

From Australia's Food Intolerance Network website www.fedup.com.au

About ADD/ADHD: https://www.fedup.com.au/fedup-newsletters/2000/failsaf18-may-2000

"Many thanks to paediatrician Dr Velencia Soutter, an allergy associate physician at Royal Prince Alfred Hospital Allergy Clinic. Dr Soutter confirmed on TV what we parents already know: "at least one third are substantially better with the diet, one third are significantly better and there's a group where the parents say 'well, they are better but the diet wasn't worth the effort'. So it's not the answer for everyone with behaviour problems. But if it is, it makes a big difference and certainly for many of them it's a blessing when it comes to avoiding medication"."

Here is the information presented by Australia's Food Standards Website (www.foodstandards.gov.au): "Is MSG Safe?"

"Is MSG Safe?" According to the Food Standards Website:

"A small number of people may experience a mild hypersensitivity-type reaction to large amounts of MSG when

eaten in a single meal. Reactions vary from person to person but may include headaches, numbness/tingling, flushing, muscle tightness, and general weakness. These reactions normally pass quickly and do not produce any long-lasting effects."

MSG in Food. Food Standards Australia New Zealand. October 2017. http://www.foodstandards.gov.au/consumer/additives/msg/Pages/default.aspx

The problem with this simplistic statement from Food Standards Australia is that a child who is having a behavioural reaction to MSG (as one example of many) might be wrongly diagnosed by their doctor as having ADHD and medicated with ADHD medications. A more extreme case might be that the doctor diagnoses this child with a mental health disorder, and prescribes a mental health drug that doubles their chances of suicide – and that child actually takes their own life – because of the medication (a known and listed side effect).

Correct information in the age of 'increasing diagnoses of mental health conditions' and 'prescribing dangerous drugs' has become a life and death situation.

1F. Independent Training of Medical Professionals to reflect Peer Reviewed Data, International Litigation and Known Side Effects of Mental Health Medications and Interventions.

As part of their personal development and other training medical professionals are receiving training directly or indirectly from pharmaceutical companies. This is simply a conflict of interest.

Exactly what were the processes, training and actions that lead to 100,000 Australian children being prescribed mental health medications off-label?

Why have 100,000 children been prescribed mental health medications that double their suicide risk and are known drugs of dependence?

Why are over 3 million Australians taking antidepressant medications with the known side effects of suicide, permanent sexual dysfunction, brain damage, increased rates of unemployment, increased numbers of falls in the elderly, increased risk of dementia, increased violence and homicide, serotonin toxicity, dependence, akathisia, obesity... the list goes on and on.

1G. Australia needs a complete review of the Pharmaceutical Benefits Scheme to establish which drugs are still evidence based, which should be moved to Schedule 8 etc.

The Four Corners "Wasted" program illustrated that about 95 percent of the listed items on the Medical Benefits Scheme list are NOT EVIDENCE BASED.

How many of the drugs on the Pharmaceutical Benefits Scheme are NOT EVIDENCE BASED?

Why does it take Four Corners to investigate what should have been investigated by the TGA decades ago?

And why has the TGA not acted to this day to review the Pharmaceutical Benefits Scheme in light of the latest medical evidence, suicide rates, alarming INCREASE in mental health problems, meta-analyses and pharmaceutical reviews?

1H. Australians need to Learn to NOT Trust their Doctors.

A sad state of affairs, but while doctors continue to prescribe off-label and inappropriately, while not addressing the underlying issue that is causing the emotional challenge/mental health problem we continue to have problems.

It is too late when your child commits suicide to find out that the drug that the doctor gave them can increase

their suicide rate... and that you trusted their opinion.

These problems are occurring all around the world with ALL of the 30 or so serious side effects of these potentially dangerous medications.

If doctors don't improve their game very quickly, they will find themselves looking for new careers.

Being a doctor is already not the career that most doctors thought it was going to be. They have higher than average suicide rates themselves, with female doctors having over double the suicide rate of their patients. Are they the right people to be getting mental health assessments from?

Please refer to my detailed answer submitted in Question 11.

2. What is already working well and what can be done better to prevent mental illness and to support people to get early treatment and support?

Please refer to my detailed answer submitted in Question 11.

2.1 Early mental health treatment is not supported by evidence, nor is it supported by the World Health Organisation.

Perhaps it's because we are so seriously bad at it.

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.

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 the 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.)

2.2 Prescribing medications to children under the age of 18 years is off-label prescribing.

Why don't our leading mental health experts, doctors and psychiatrist read the <u>Product Information</u> statements on these drugs?

Or do they read them and ignore them by culpably prescribing psychotropic drugs to over 100,000 Australian children.

The Product Information statement for Paroxetine (for example) clearly states in PRECAUTIONS:

"Children and Adolescents (<18 years)

Paroxetine (used as an example) is not indicated for use in children or adolescents ages < 18 years."

All the information is there in the Product Information, including that they double the suicide rate in children less than 18 years old.

It seems doctors, psychiatrists, parents and patients just can't be bothered to read it, or to take any notice of it.

2.3 Off-label prescribed, described as 'routine' by the AMA, should be made illegal.

Why bother having a TGA if doctors and psychiatrists can prescribe <u>however they like</u> after a drug or procedure has been approved for use?

"there are many products that we routinely use off-label."

AMA President Dr Hambleton, February 2014. Lots to consider in going off-label Australian Medical Association. Feb 14, 2014. https://ama.com.au/ausmed/lots-consider-going-label

Even the AMA has challenges with off-label prescribing by doctors. It appears that since prescribing off-label is "routine" doctors no longer know the difference between just *any old off-label prescribing* behaviour or a *serious off-label behaviour*.

And is their ACTUALLY any difference? My argument is that there is **no difference** – if it is off-label it is off-label. e.g. the off-label prescribing of antidepressants to a child can double their risk of suicide (and more), is that doubled risk not important enough for a doctor of psychiatrist to NOT prescribe off-label?

The off-label prescribing of Thalidomide was one of the earliest cases of how this practice is a sham, but we appear to have learned nothing since the 1960s in relation to off-label prescribing.

The risks of drugs being incorrectly approved is great enough (demonstrated by Thalidomide and Vioxx for example), let alone allowing off-label prescribing after they have been approved.

How often do doctors know that they are prescribing a drug off-label?

Do medical professionals inform their patients when they are prescribing off-label?

Is informed consent ever gained?

Doctors, psychiatrists and the AMA should be held to account.

I recommend that off-label prescribing should be illegal.

Medical professionals have proven that they are incapable of putting the interest of their patients first when they prescribe off-label.

2.4 Monitoring and Reporting Side Effects of Approved Medications is Inadequate.

It is well accepted that part of the ongoing health of the nation requires doctors to observe and report the side effect of medications so that the health of Australians improves.

This process is clearly not happening properly.

When adverse drug effects are experienced by people with a mental health challenge they are routinely having their medications changed, swapped, stopped, increased, added to etc., rather than having the drug reported as being ineffectual, causing adverse effects (such as akathisia or suicidal ideation, or increased violence), or making the problem worse. Changing, swapping and adding to medications is known to be very dangerous, sometimes fatal. In many cases doctors and psychiatrists go into 'damage control' blaming the patient, changing the diagnosis, or even bullying the patient who is 'known to have a mental health problem'. Internationally there are many support sites on the internet that demonstrate exactly that - many are hidden because of the harassment and harm that has been caused by these medications, and trolls that visit these pages. Examples of websites that assists people with some of these problems are:

https://www.madinamerica.com/drug-withdrawal-resources/ - Psychiatric Drug Withdrawal Resources https://rxisk.org/ - Independent Drug Safety website

http://www.letstalkwithdrawal.com/ - Established for people to slowly taper from their mental health medications to avoid suicide, permanent damage and adverse side effects

www.SSRIstories.net - Help with drug withdrawal

www.SSRIStories.org – Focused on violent behaviours and SSRIs, including mass shootings and family homicides

3. What is already working well and what can be done better to prevent suicide?

Suicide should be renamed "Prescripticide"

Suicide is the side effect of 500 drugs routinely prescribed by doctors and psychiatrists and medical professionals.

https://rxisk.org/500-drugs-that-cause-depression-and-suicide-aka-akathisia/

Rabin, Roni Caryn, Common Drugs May be Contributing to Depression, New York Times June 13, 2018.

https://www.nytimes.com/2018/06/13/well/prescription-drugs-depression-suicide.html?fbclid=IwAR0MrYjY2WEU2fXWeasZOfuIeuVFULmoISN_baMj_CzVUsMTgAQ1E_i0R-M

List of Medications with Potential Depression Adverse Effects Identified for Inclusion in Study (N=203)a

A. SuicidalSymptoms (n=103)°

- 1. Analgesics (Acetaminophen/Tramadol, Hydropmorphone, Tapentadol, Tramadol)
- 2. Anticonvulsants (Carbamazepine, Clonazepam, Diazepam, Ethosuximide, Gabapentin, Lamotrigine, Levetiracetam, Lorazepam, Methouximide, Oxcarbazepine, Phenytoin, Pregabalin, Topiramate, Valproic Acid, Zonisamide)
- 3. Antidepressants (Amitriptyline, Amitriptyline/Chlordiazepoxide, Amitriptyline/Perphenazine, Bupropion, Citalo pram, Clomipramine, Desipramine, Desvenlafaxine, Doxepin, Duloxetine, Escitalopram, Fluoxetine, Fluoxetine/Olan zapine, Fluoxamine, Imipramine, Milnacipran, Mirtazapine, Nefazodone, Nortriptyline, Paroxetine, Phenelzine, Protriptyline, Selegiline, Sertraline, Trazodone, Venlafaxine, Vilazodone)
- 4. Anxiolytics, Hypnotics, and Sedatives (Alprazolam, Butabarbital, Chlordiazepoxide, Clonazepam, Clorazepate, Diazepam, Doxepin, Eszopiclone, Flurazepam, Pentobarbital, Ramelteon, Triazolam, Zaleplon, Zolpidem)
- 5. Gastrointestinal Agents (Metoclopramide)
- 6.Hormones/HormoneModifiers(Finasteride1,Leuprolide,Levonorgestrel,Oxandrolonez, Progesterone)
- 7. Respiratory Agents (Montelukast, Ribavirin, Roflumilast, Zafirlukastg)
- 8. Other Therapeutic Classes

(Acamprosate, Amantadine, Armodafinil, Aripiprazole, Asenapine, Atomoxetine, Carbidopa/Entacapone/Levodopa, Carbidopa/Levodopa, Ciprofloxacin, Dapsone, Efavirenz, Efavirenz/Emtricitabine/Tenofovir, lloperidone, Interferon Beta-

- 1a,InterferonBeta-
- 1b, Isotretino in, Luras idone, Memantine, Mefloquine, Methylphenidate, Modafinil, Moxifloxacin, Naltrexone, Natalizumab, Olanzapine, Ofloxacin, Peginterferon Alfa-
- 2a, Quetiapine, Raltegravir, Risperidone 4, Rivastigmine 5, Sibutramine, Tetrabenazine, Varenicline)

B.Depressive(Non-Suicidal)Symptoms(n=100)°

- 1. An algesics (Cyclobenza prine, Fentanyl, Acetamin ophen/Hydrocodone, Ibuprofen, Indomethacin, Morphine, Nabumetone, Oxycodone)
- 2. Antihypertensives (Atenolol, Atenolol/Chlorthalidone, Betaxolol, Bendroflumethiazide/Nadolol, Brimonidine, Brimonidine/Timolol, Dorzolamide/Timolol, Enalapril, Hydrochlorothiazide/Metoprolol, Hydrocodone, Metoprolol, Nisoldipine, Quinapril, Telmisartan, Timolol, Trandolapril)
- 3. Corticos teroids (Betamethasone, Cortisone, Dexamethasone, Methyl prednisolone, Prednisolone, Prednisolone, Prednisolone, Triamcinolone)
- 4. Gastrointestinal Agents (Atropine/Diphenoxylate, Cimetidine, Dexlansoprazole, Esome prazole, Famotidine, Omeprazole, Ranitidine)

5Hormones/HormoneModifiers(Anastrozole,Bicalutamide,Cabergoline,ConjugatedEstrogens,ConjugatedEstrogens/Medroxyprogesterone,Desogestrel/EthinylEstradiol,Dienogest/Estradiol,Drospirenone/EthinylEstradiol,Drospirenone/EthinylEstradiol/Levomefolate,EsterifiedEstrogens,EsterifiedEstrogens/Methyltestosterone,Estradiol,Estradiol/Norethindrone,Estropipate,EthinylEstradiol/Ethynodiol,EthinylEstradiol/Etonogestrel,EthinylEstradiol/Norgestrel,EthinylEstrad

6.RespiratoryAgents(Cetirizine)

7.OtherTherapeuticClasses(Abacavir/Lamivudine,Acebutolol,

Acitretin, Amphetamine/Detroamphetamine, Baclofen, Benzphetamine, Cinacalcet, Clonidine, Cyclosporine, Dantro lene, Dexmethylphenidate, Donepezil, Dronabinol, Emtricitabine, Erlotinib, Flecainide, Fluphenazine 7, Galantamine, Haloperidol, Maraviroc, Methyldopa, Metolazone, Metronidazole, Oxybutynins, Phentermineg, Pimozide, Prazosin, Propafenone, Propranolol, Rasagiline, Rotigotine, Sorafenib, Tizanidine)

.°°.".°'.aMicromedexsymptomslistedundertheadverseeffectssection:depression,depressivedisorder,suicide,suic idalthoughts,suicidalideation,andsuicidalbehavior.Medicationswerenotexcludediftheyhadamaniasideeffect.

b Micromed exsymptoms listed under the Adverse Effects section: suicide, suicidal thoughts, suicidal ideation, and suicidal behavior.

cMicromedex symptoms listed under the Adverse Effects section were considered ``nonsuicide'' if they did not specify a suicide side effect. These included depression and depressive disorder.

1Depressionadverseeffectincludedonlabel.Suicideadverseeffectcitedinpost-

mark eting article: Irwig, M.S. (2012). Depressive symptoms and suicidal thoughts among former users of finasteride with persistents exual side effects. The Journal of clinical psychiatry, 73 (9), 1220-

1223.[https://www.ncbi.nlm.nih.gov/pubmed/22939118]

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Please refer to all other sections of this submission and my detailed report submitted in Question 11.

- 4. What makes it hard for people to experience good mental health and what can be done to improve this? This may include how people find, access and experience mental health treatment and support and how services link with each other.
- 1. We are treating the symptom, not the cause.

Most mental health problems that are diagnosed have a legitimate reason for existing, they are not mental health problems and most certainly do NOT require a prescription for a potentially dangerous, addictive and possibly fatal drug.

2. Incorrect Information, Misleading Information, Culpable Information.

See question 1 above.

- 3. Total lack of facilities to help people with the underlying causes of problems that present as 'emotional problems' and 'mental health issues'.
- 4. No proper education, including of doctors.
- 5. A broken medical system where doctors are given about 10-20 minutes to 'solve' complex issues.
- 6. The commercialization of health in Australia. It is no longer evidence based, it is financially driven.

The Four Corners Wasted program illustrated that about 95 percent of the listed items on the Medical Benefits Scheme list are NOT EVIDENCE BASED. How many of the drugs on the Pharmaceutical Benefits Scheme are NOT EVIDENCE BASED?

Why does it take *Four Corners* to investigate what should have been investigated by the TGA decades ago?

And why has the TGA not acted to this day to review the Pharmaceutical Benefits Scheme in light of the latest medical evidence, meta-analyses and pharmaceutical reviews?

7. Psychotropic Drugs are Drugs of Dependence.

We are constantly hearing of the huge dependence problem Australians have with prescribed opioids.

What we are NOT hearing about is that the dependence problems are far greater in NUMBER with psychotropic drugs than with opioids.

10 million opioid prescriptions are written in Australia every year.

36 million psychotropic drug prescriptions are being written in Australia every year...

AND there is a growing trend to prescribe psychotropic drugs off-label for pain in response to the opioid changes.

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5. What are the drivers behind some communities in Victoria experiencing poorer mental health outcomes and what needs to be done to address this?

Please refer to my detailed paper submitted in Question 11.

Poorer mental health outcomes are experienced because of a severely broken system, and a system that is *not* based on evidence.

Professor Peter Gøtzsche has travelled to Australia twice in the last few years to explain some of the problems.

His presentation *Overdiagnosed and Overmedicated* should be compulsory viewing *before* anyone takes a mental health medication.

I have personally heard stories from a number of people who were harmed by ONE tablet of various legally prescribed mental health drugs!



https://youtu.be/ZMhsPnoIdy4 Here is how clinical trials can be "trumped up" from psychiatrist and international expert Professor David Making Medicines Safer for All of US, TEDx Aberystwyth, December 2018. https://youtu.be/vpTqei5hZ3g 6. What are the needs of family members and carers and what can be done better to support them? We need to address the underlying issues, not the symptoms. We need to introduce "Open Dialogue" now. Please refer to my detailed answer submitted in Question 11.

7. What can be done to attract, retain and better support the mental health workforce, including peer support workers?

Please refer to my detailed answer submitted in Question 11.

The most successful mental health program in the world is the "Open Dialogue" system from Western Lapland, Finland.

People like working in successful systems, with excellent results, not broken, expensive ones that are seeing *increasing* numbers of people diagnosed as having mental health problems, and messages that many people are undiagnosed!

Trailer: OPEN DIALOGUE. Alternative Finnish Approach to Healing Psychosis. March 2011.



https://youtu.be/aBjIvnRFja4

This cost effective and hugely successful *Open Dialogue* model should be rolled out in Australia immediately.

Already seminars have started in Sydney over the last few years, but it has not been correctly advertised and promoted, with very few people having even heard of it.

Open Dialogue should be introduced as a completely independent system in Australia, *independent of all other mental health programs*, so that the success is not impaired and the results can be correctly monitored, documented and celebrated.

Open Dialogue is a training that can be given to nurses, which is cost effective and will improve the morale of nurses in Australia at the same time.

There will probably be push back from psychiatrists, another reason I am recommending that *Open Dialogue* be given autonomy to roll-out independently.

There are vested interests that would not like this system to succeed in Australia.

8. What are the opportunities in the Victorian community for people living with mental illness to improve their social and economic participation, and what needs to be done to realise these opportunities?

Australia needs to follow the lead of the Royal College of Psychiatrists and update our TGA guidelines and product information statements to reflect that antidepressants are drugs of dependence.

We have 3 million Australians potentially dependent on psychotropic medications, which is a national disaster caused by the medical profession, and clinical governance personnel.

https://cepuk.org/2019/05/30/royal-college-psychiatrists-call-update-nice-antidepressant-guidelines-following-cep-campaign/

Recommendations:

- Australia should publicly announce in the media that antidepressants are now recognised internationally as drugs of dependence.
- Australia should, at the same time, provide warnings to Australian citizens of the dangers of quick tapering, medication changes, cold turkey withdrawals, etc., so that this new information does not result in a national catastrophe.
- Australians should be made very aware that the withdrawal effects from these medication might appear to be their mental health problem coming back – but that withdrawal effects include mental health challenges, the side effects of the medications (reoccurring at the time of withdrawal) etc.
- The medical bodies and medical professionals should all undergo training immediately to enable them to deal with the new information and practices.
- The Australian government, through the TGA, the AMA, and other medical bodies should immediately research the successful, world leading information provided by groups such as Mad in America, Let's Talk Withdrawal etc., so that they get the most up to date information from the best withdrawal centres and trainings.
- Australia needs to immediately establish knowledgeable withdrawal programs and centres to help the 3 million Australians (including 100,000 children) who wish to withdraw from these drugs of dependence.

We have a VERY serious situation that has developed over decades because of clinical governance negligence in many areas of Australia's health services.

This situation needs to be reversed as a matter of grave urgency.

Please refer to my detailed answer submitted in Question 11.

9. Thinking about what Victoria's mental health system should ideally look like, tell us what areas and reform ideas you would like the Royal Commission to prioritise for change?

A. Abolish the bio-medical model and start addressing the underlying issues that present as emotional and mental health issues.

The biomedical model was disproved before the end of the last century, yet we continue to promote and use this model that is causing death, dependence and harm.

B. Introduce "Open Dialogue" from Finland immediately.

C. Upon every suicide death in Australia and every violent act and/or death and every public shooting and violent act including homicide/suicide forensic blood tests should be taken immediately and reported in the death certificates, as well as the full history of psychiatric drug administration, tapering, prescriptions swapping, increasing and decreasing for Australia to know the full extent and the proven relationship between psychotropic drugs and suicide, violence, akathesia and homicide. These are all known side effects of these drugs.

We need to quantify and document it, and take appropriate legal action to prevent it.

D. Establish withdrawal centres specifically for slow tapering of psychotropic drugs, copying world's best practice sites such as *Mad In America*.

Rehab centres are known to cause harm because they do not correctly and slowly taper people from these drugs.

Some people take years to withdraw successfully from these harmful drugs, some take even 7-8 years, some are never successful because it is very difficult for them (or they take their own life).

E. A full review of all the side effects of these drugs, and an order to update the Product Information, Consumer Medicines Information (CMI), medical professional's training, mental health charities website and 'factsheets', Lifeline policies, etc.

There is far too much incorrect and dangerous information in 'respected sites' in Australia.

F. Off-label prescribing of drugs should be made illegal immediately.

The efficacy of SSRIs for people under the age of 18 years, have NEVER BEEN PROVEN, yet there are now 100,000 children taking these medications.

A full investigation should be held into the doctors and psychiatrists who continue to prescribe psychotropic drugs to children under the age of 18 years.

Included in this review should be a review of prescribing these medications to pregnant women and older people with their increased risk of falls.

And all other off-label prescribing should also be investigated, e.g. antidepressants used as pain relief, etc.

G. Procedures should be drawn up for medical professionals to know how to obtain 'informed consent' when prescribing psychotropic medications including sleeping pills and benzodiazepines.

H. All sleeping pills should be moved to Schedule 8.

I. All antidepressants should be moved to Schedule 8. With 3 million Australians already taking these drugs we have a national emergency, we do not want to make this problem even bigger.

J. When babies are born with dependencies and birth defects the antidepressant and psychotropic drug histories should be shown on the death certificate, and documented so that the extent of the problem of using mental health drugs during pregnancy is document and can be studied. At the moment most of these problems are not even recognised, let alone warned about.

Pregnant women are prescribed at the same rate as non-pregnant people – it is a human rights issue.

K. A list of all the possible underlying reasons that could present as emotional challenges/mental health conditions should be compiling – from someone's dog dying, to bullying, sexual assault, side effects of medications, recreational drugs, lack of sleep, work stress, job loss, unemployment, poverty, financial stress, menopausal symptoms, there could be hundreds of them – and this list be used to investigate fully the underlying problems that people have BEFORE they are diagnosed with a mental health problem and prescribed potentially harmful and dependence-forming medications.

L. The DSM should be totally reviewed, giving particular attention to any listed diagnoses that are not backed up by empirical evidence - and abolishing all items that are subjective diagnoses and/or unable to test.

All DSM listings since DSM III have been included by committee vote and other unscientific and potentially fraudulent methodologies. This is a sham.

The Origins of the DSM, Dr. James Davies, CEP UK, September 2015.



https://youtu.be/6JPgpasgueQ

M. There should be a full inquiry into the complete failure of our Clinical Governance in Australia.

According to the Medical Journal of Australia 2011 "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 detailed the processes used to manage conflicts". https://www.mja.com.au/journal/2011/195/8/conflict-interest-guidelines-clinical-guidelines

Mental health in Australia is part of these culpable oversights and unprofessional behaviours.

Hundreds of millions of dollars have been received by leading mental health researchers, mental health charities, mental health foundations, mental health university professors, university departments dealing with mental health, etc. – from governments, pharmaceutical companies and other vested interests – in a

variety of forms including money, time, contributions, etc.

Very little of this activity and financing is visible on the internet or declared so that the public can review exactly what conflicts of interest exist, who is likely to be most influenced, and how our mental health system is structured and financed.

Australia's medical field appears to be very corrupt.

O. Establish a more effective system of reporting adverse drug reactions in Australia. The present system of relying and trusting doctors and medical professionals to report adverse drug reactions is clearly not working, when the TGA has inadequate Product Information and Consumer Medicines Information statements.

At present the best website in the world that I can see for adverse drug reactions is www.rxisk.org, which is not Australian.

Please refer to my detailed answer submitted in Question 11.

10). What can be done now to prepare for changes to Victoria's mental health	system	and
	support improvements to last?		

See question 9 above and my detailed answer submitted in Question 11.

11. Is there anything else you would like to share with the Royal Commission?

All academic references available on request.

SUBMISSION TO THE VICTORIAN GOVERNMENT ROYAL COMMISSION INTO MENTAL HEALTH

At the moment I believe the terms of reference is perfectly set up for the pharmaceutical lobby group and the pharmaceutical industry. Changes need to be made to the terms of reference to improve mental health outcomes for the Australian population.

The theory that mental health problems are caused by 'chemical imbalances in the brain' is still totally unproven, and is a fraudulent hypothesis promoted by the pharmaceutical industry and vested interests in Australia and around the world.

The drugs being prescribed for mental health problems include psychotropic drugs and benzodiazepines which are permanently disabling members of the public, increasing suicide rates, increasing violence and other very adverse drug side effects, including dependence.

All academic and peer reviewed references are available on request.

1. The Royal Commission should conduct a full investigation into the unproven hypothesis of 'a chemical imbalance in the brain' of a person with a mental health problem.

The biomedical model is a fraud.



https://youtu.be/ZMhsPnoIdy4

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

2. The Royal Commission to 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.



https://youtu.be/vpTqei5hZ3g

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

3. The Royal Commission to conduct a full investigation into why the mental health and medical professionals treat the SYMPTOMS of emotional challenges, and ignore the UNDERLYING CAUSES that present as mental health/emotional difficulties.

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.

4. A full investigation should be implemented into the longitudinal studies that prove that over the longer term the TREATED WITH PHARMACEUTICALS mental health patient groups have POORER RESULTS than the UNTREATED WITH PHARMACEUTICALS groups.

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:



https://youtu.be/vejVt1fNYQk

5. A full investigation should be implemented to ensure that the Therapeutic Goods Administration (TGA), Beyond Blue, Headspace, Lifeline, Black Dog Institute, 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 the conclusion has not been reached because of lack of funding for the study etc.

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 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 suicide)? 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.

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

- i) Increased risk of suicide, even double the risk of suicide.
- ii) Increased risk of suicidal ideation (suicidal thoughts).
- iii) Akathisia, which can result in violence, suicide, homicide.
- iv) Violence.
- v) Increased aggression.
- vi) Suicide and murder combined.
- vii) Sexual dysfunction.
- viii) Permanent 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, which requires testing for cytochrome markers before prescription to avoid some side effects. These cytochrome tests do not routinely happen in Australia.
- 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.

As a matter of interest 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 this drug's dependency.

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

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.

Other side effects that should be investigated by the government include: increased unemployment, increasing disability pensions, increased breast and ovarian cancer risk, weight gain even after ceasing medication, increased risk of stroke, bladder and urinary problems, gender dysmorphia, self-harm, mental turmoil, mammoplasia (growing breasts), galactorrhea (milky nipple discharge), personality drained away, huge weight gain, brain cell damage, weakened bones, insomnia, becoming introverted, head shocks, 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:

As most people with a mental health issue present to their doctor at some stage with a sleeping problem, and are prescribed a drug in 95.2 percent of cases it is important to know that sleeping pills are not the solution to the problem and can, in many cases, be the start of the escalation of the problem.

The side effects and adverse effects include:

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

- iv). One of the side effects when you try to come off sleeping pills is rebound insomnia.
- When you come off them you can get rebound insomnia, which makes some people think 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."
- 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.
- xi). Viewed as a group, sleeping pills increase your sleep time by 11.4 minutes.
- 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 12^{th} 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.

"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 appose 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."

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. (See Resources below.)

Akathisia predisposes suicide and homicide in some users.

xxviii). Congenital Abnormalities/birth defects.

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".

6. A full and thorough investigation should be conducted into why it is legal for doctors to prescribe medications to patients without informed consent.

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.

7. A full and thorough investigation should be conducted into why it is legal for doctors to prescribe off-label.

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?

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

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?

8. An investigation should be made into why Australia has never established a Federal Health Ombudsman where members of 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 health charities and foundations, 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.

Australia increasingly seems to be "governed by Royal Commissions".

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 that leadership and best practice is severely lacking until someone calls a Royal Commission!

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.

9. The Royal Commission should include a full investigation into the implementation in Australia of the most successful Finnish Open Dialogue mental health methodology in the world.

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

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 IN 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.)

10. There should be a full investigation into the suppression 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 treatments, 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 'mental health' pharmaceutical drugs/psychotropic drugs 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 point 5 above.

11. The Royal Commission should include a full investigation into the proven connection between psychotropic drugs and increased incidents of suicide, violence, homicide, akathesia, domestic violence etc.

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.

At the moment, when a mother, for example, kills her 3 children it is erroneously attributed "the mother's mental health condition".

In actual fact, it should be clearly documented as a side effect of the psychotropic medications she was legally prescribed by her medical professional. This 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.

12. The Royal Commission should investigate why off-label prescribing by doctors, psychiatrists, medical professionals, nurses etc. is not illegal, with a view to making off-label prescribing a criminal offence.

Off-label prescribing makes the work done by the TGA irrelevant.

e.g. If off-label prescribing was illegal it would have greatly reduced the incidence of phocomelia in babies born of mothers who took thalidomide while they were pregnant. Thalidomide was originally approved for depression, never for morning sickness. Doctors took it upon themselves to prescribe thalidomide off-label to pregnant mothers for morning sickness, with disastrous effects.

It is illegal for pharmaceutical companies to promote or market the off-label use of drugs, demonstrated by the \$ 3 billion fine to GlaxoSmithKline for promoting the use of the antidepressants Paxil, Wellbutrin and Avandia to children under 18 years of age.

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

But it is NOT ILLEGAL for doctors and psychiatrists to prescribe young children with these exact drugs.

This should be a criminal offence.

(Most 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.)

13. The Royal 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. http://www.fedup.com.au

14. The Royal Commission should investigate the side effects of all medications that include symptoms and behaviours 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.

15. The Royal Commission should investigate and facilitate training to medical professionals 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.

- 16. The Royal Commission should investigate the training required for doctors, psychiatrists and all medical professionals that are prescribing psychotropic drugs and working in mental hospitals so that they are aware of the international developments and information that appears to have not reached Australia, nor Australia's mental health leaders.
- 17. The Royal 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.

18. The Royal Commission should fully investigate the drug Mefloquine, the anti-malarial drug that is being given to the Australian Defence Forces personnel, which has severe side effects – that APPEAR TO BE MENTAL HEALTH CONDITIONS or PTSD.

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.

19. 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 that explains hidden raw data, ghost writers, side effect non-disclosures, even fraud.

20. The Royal 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:

- 1. 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. Full transcripts available here: https://www.baumhedlundlaw.com/prescription-drugs/paxil-injuries/gsk-paxil-trial-transcripts/
- 5. The UK recognises antidepressants as drugs of dependence, late May 2019.
- 21. The Royal Commission should fully investigate why the peak foundations and charities in Australia, supported by hundreds of millions of dollars in government grants, such as HeadSpace and Beyond Blue do NOT have correct information on their websites such as statements that psychotropic drugs are NOT dependence forming.
- 22. The Royal Commission should investigate and implement a training strategy around educating medical professionals, HR personnel and the public on akathesia, a potentially dangerous 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.



https://youtu.be/x86aCDtvbT0

What is Akathisia? MISSD Organisation. Accessed January 16, 2019.

23. The Royal 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.

24. The Royal Commission should investigate the introduction of prompt and appropriate forensic blood testing of people committing violent crimes immediately after death to establish once and for all the presence of psychotropic drugs in the blood streams of these people.

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?

25. The *Diagnostic and Statistical Manual of Mental Disorders (DSM)* is to be fully investigated by the Royal 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.

26. The Royal 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.

27. The Royal 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. Refer to the most recent case following the Dolin vs GSK case in the US, here <a href="https://cookcountyrecord.com/stories/511687361-widow-asks-scotus-to-toss-gsk-s-win-in-lawsuit-over-paxil-labeling-lawyer-s-suicide?fbclid=IwAR2MzIDPt3ojQthHAzb2az7p1wINceBgLNZecc6OMnKD1anAbYZa2KEhwSA

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.

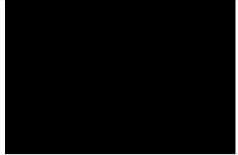
28. The Royal Commission should do a full costing of the economic damage already being done to the economy as a result of the inappropriate, costly and unsuccessful biomedical model and how it will develop over the next 40 years.

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.

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



https://youtu.be/vejVt1fNYQk

Robert Whitaker, *Rising Prescriptions, Rising Disability, Is there a Link. Westminster All-Party Parliamentary Group APPG, Westminster.* Published on May 27, 2016

29. Australia (including the state of Victoria) should look internationally for expert advice in this Royal Commission.

The Royal 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.

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

Professor David Healy



https://youtu.be/4fZD2kb_LYM

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

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?'.



https://youtu.be/naxZsTEegB8

Mad in America Podcast with Prof. Irwin Kirsch

Robert Whitaker



https://youtu.be/5VBXWdhabuQ

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

"They are causing a huge amount of misery, loss of quality of life, loss of love life,"

"These drugs are devastating to people." Dr Peter Breggin.

75% of young doctors are on psychotropic drugs:

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

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



https://youtu.be/w1p4DWTj2Bw

Ann Blake-Tracy speaking at an FDA hearing.

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 one I attended at Sydney University late 2017 by Dr Jaako Seikkula.

30. The Royal Commission should investigate the DANGERS of psychotropic drug withdrawal. Including the costs and roll out of appropriate withdrawal centres across the state to facilitate the huge job of allowing withdrawal from medications for the approximately 1 in 6 Victorians who are already taking these dependence forming medications.

As stated by Professor Peter Gotzche in Sydney February 2016 we simply do NOT have the facilities to help people withdraw from these 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.

31. The Royal Commission should investigate the international moves towards pharmaceutical companies taking NO responsibility for harms caused by generic versions of their drugs.

This has been highlighted in the recent developments following the Dolin vs GSK case.

32. The Royal Commission should investigate the lack of access to the raw data behind the clinical trials approving psychotropic drugs and the huge number of unpublished 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.

- 33. The Royal Commission should call for contributions and investigate the forced psychiatric treatments, psychiatric abuses, human rights violations and people being locked up against their will.
- 34. The Royal Commission should call for contributions and investigate the "pharmaceutical treatment" of people in aged care facilities, jails, mental health institutions and detention centres.
- 35. The Royal Commission should investigate the successful banning of ECT by Italy, and the positive results that have resulted in that country after ECT was abolished.
- 36. The Royal 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 health issues IS EVIDENCE BASED.

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.

Privacy acknowledgement I understand that the Royal Commission works with the assistance of its advisers and service providers. I agree that personal

information about me and provided by me will be handled as described on the Privacy Page.
⊠ Yes □ No