



SUBMISSION TO THE PRODUCTIVITY  
COMMISSION FROM THE AUSTRALIAN  
NATIONAL OFFICE OF THE  
INTERNATIONAL ORGANISATION,  
THE CITIZENS COMMISSION ON  
HUMAN RIGHTS

5 April 2019

# Index of Contents

BACKGROUND OF THE CITIZENS COMMISSION ON HUMAN RIGHTS	3
INTRODUCTION	5
SUBMISSION	7
The Diagnosis of Psychiatric Disorders which Leads to Prescription for Psychotropic Drugs and Psychiatric Treatments for Entire Populations	7
Australian Psychotropic Drug Warnings	9
Suicides & Deaths Linked to Psychotropic Drugs	10
All Available Adverse Drug Reactions Reported to Therapeutic Goods Administration in Australia to be Made Publicly Available	12
Withdrawal from Psychotropic Drugs	13
Numbers of Australians on Psychotropic Drugs	14
Electroshock (ECT)	15
Restraint	17
Conflicts of Interest	19
Accountability	22
Alternatives, Informed Consent: Providing Real Help	24
SUMMARY OF RECOMMENDATIONS	25
Appendix 1 - Australian Psychotropic Drug Warnings	28

# BACKGROUND OF THE CITIZENS COMMISSION ON HUMAN RIGHTS

The Citizens Commission on Human Rights is a non-profit organisation which was established in 1969 by the Church of Scientology and the late Dr Thomas Szasz, Professor of Psychiatry, as an independent body to investigate and expose psychiatric violations of human rights and to clean up the field of mental healing. CCHR offers a free public service to those who have been harmed in the psychiatric industry and it is an international organisation with headquarters in Los Angeles.

The main task of CCHR has been to reform mental health and preserve individual's rights in line with the *Universal Declaration of Human Rights*. In Australia CCHR was instrumental in uncovering and bringing to the attention of NSW authorities the lethal drug and electroshock (ECT) practice known as "Deep Sleep Treatment" used at Chelmsford Private Psychiatric Hospital. And it helped achieve the NSW Royal Commission into Deep Sleep Treatment in 1988 and the Queensland government inquiry into the psychiatric ward, Ward 10B, at Townsville Hospital in 1990.

More recently CCHR conducted education campaigns to protect children from the trauma of restraint, the harm of electroshock and psychosurgery in various states of Australia where mental health acts were under review. The World Health Organisation has stated, "There are no indications for the use of ECT in minors, and hence this should be prohibited by legislation." <sup>1</sup>

This included in W.A. where a draft Mental Health Bill proposed to allow children of any age, to be able to consent to sterilisation if a psychiatrist determined they had the "capacity to consent." No further consent was needed from anyone including parents or a Tribunal. The Bill also proposed to allow for children aged 12 to be able to consent to electroshock and psychosurgery — again if the child was considered to have the capacity to consent as determined by a psychiatrist with a Tribunal giving final approval. No parental consent would have been needed at any stage and a clause in the bill allowed for parents to be excluded from the Tribunal hearing. CCHR launched an education campaign to inform parents and the general public including placing half page ads in the main and community newspapers, bulk mailings and many other actions.

As a result, there was worldwide condemnation on these issues, with over 1,000 submissions received by the WA Mental Health Commission. Not only was the proposal to allow children to consent to sterilisation dropped, but sterilisation was completely removed from *the Mental Health Act*. In addition, the age at which a child could consent to electroshock and psychosurgery was lifted to over 14 years. CCHR continued to educate the public and the psychosurgery ban was then lifted again to under 16 years. The new act with these changes was implemented on 30<sup>th</sup> November 2015.

Internationally CCHR is responsible for many hundreds of reforms gained through testimony before legislative hearings, its own public inquiries into psychiatric abuse and its work with the media, law enforcement and public officials.

While CCHR does not provide medical or legal advice, it works closely with and supports medical doctors and medical practice. Medical drugs and scientific tests are essential for treating and curing disease but the same cannot be said of psychotropic drugs and treatment which can seriously adversely affect vulnerable children and adults.

# INTRODUCTION

1. CCHR applauds the Productivity Commission for its inquiry into mental health. An investigation into accountability and spending is very much welcomed.
2. We are constantly reminded in the media of abuse of the mentally ill, the massive drugging of them, mistreatment in psychiatric hospitals and even preventable deaths in a system that has shown itself incapable of resolving the issues, despite billions more being doled out. An incredible \$9.1 billion was spent on mental health in 2016/17, with state and territory governments accounting for 62% of this. For the 31.8% increase in spending in the previous six years (\$6.9 billion in 2010/11 to \$9.1 billion in 2016/17), one would expect the result to be children and adults leading happier and healthier lives and a decline in the numbers of people needing assistance, but this is not the case.<sup>2</sup>
3. How psychiatry “diagnoses” someone affects not only the person, their family and friends but also the money spent by both Federal and State Governments. If the diagnosis is not scientific and the treatments not proven to work, then the result can be devastating for those involved and money is wasted.
4. Psychiatry’s main “diagnosis manual” used in Australia the *Diagnostic and Statistical Manual of Mental Disorders* itself states there are no scientific tests. As of 25 March 2019, Medicare Benefits Schedule is still using DSM-IV and the Pharmaceutical Benefits Scheme uses DSM-5. Examples in the DSM manuals include:

**DSM-IV for Schizophrenia:** “No laboratory findings have been identified that are diagnosis of schizophrenia” (p.305).

**DSM-IV for ADHD:** “No laboratory tests, neurological assessments or attentional assessments have been established as diagnostic in the clinical assessment of Attention Deficit/Hyperactivity Disorder” (pp. 88,89)

**DSM-5 for ADHD:** “No biological marker is diagnostic for ADHD” (p.61)

**DSM-5 for schizophrenia:** “Currently there are no radiological, laboratory or psychometric tests for the disorder” (p.101).

This means that unlike in normal medicine a “diagnosis” is completely subjective with no scientific basis to justify the prescribed treatment. More and more money is spent as the real cause of the person’s problem is not found and rectified, the person suffers unnecessarily and in some cases they die.

5. Despite the above, many think that psychiatric disorders, such as ADHD or schizophrenia, are the same as medical diseases or illnesses. However, this is very misleading for someone, especially a parent whose child is experiencing great difficulties, for those who care for children and adults who desperately need help and those who decide where funding should be spent. To have them think the problems people are experiencing is the result of a “chemical imbalance in the brain,” requiring mind-altering medication, is false and potentially very harmful. Especially harmful since

there is no test to prove anyone has a chemical imbalance of the brain, no tests for any psychiatric diagnosis and many of the subsequent drugs prescribed are well documented to cause harm, including suicidal thoughts and suicidal behaviour. If there were a test for a chemical imbalance, then everyone would be given one who is having problems.

6. University of Adelaide psychiatry professor Dr. Jon Jureidini has referred to such use of diagnostic labels to explain people's predicaments as "unexplanations."<sup>3</sup>
7. This does not mean that serious emotional difficulties do not exist, that sometimes these can be severe, that people's hopes cannot be shattered or that their methods of coping with this cannot fail. How we deal with this and provide compassionate, effective help to vulnerable Australian's is the issue under question.
8. There are humane and safe proven methods of assisting children and adults including proper medical care that are also cost effective.
9. The cause of the problem for each and every child can vary. Finding the actual cause of the problem and rectifying that will lead to many more children and adults recovering and leading happier and healthier lives.
10. Studies have proven that an undiagnosed medical condition can manifest as "psychiatric symptoms". Medical doctors who take the time to conduct a thorough physical examination of someone exhibiting signs of what psychiatrists say are "mental disorders", will often find undiagnosed, untreated physical conditions. Once the medical condition is treated, the mental symptoms can disappear.

# SUBMISSION

## The Diagnosis of Psychiatric Disorders which Leads to Prescription for Psychotropic Drugs and Psychiatric Treatments for Entire Populations

11. While mainstream medicine deals with diseases such as malaria, bronchitis, hepatitis and heart disease all which have exact, identifiable physical causes, psychiatry deals with “disorders”. Disorders are names given to undesirable feelings and behaviour for which no exact physical causes have been isolated. These mental disorders are frequently referred to as “illnesses” or “diseases” but they are not the same thing. This difference sets psychiatry far apart from the usual practice of medicine.
12. Science is the systematically arranged knowledge of the material world which has been gathered in a four-step process:
  - a. Observation of phenomena
  - b. Collection of data
  - c. Creation of a hypothesis or theory by inductive reasoning and
  - d. Testing of the hypothesis by repeated observation and controlled experiments.

And it should be workable and invariably right for the body of knowledge in which it operates.

13. Boston University Lecturer, Margaret Hagen, PH.D. puts it this way: “The findings discovered through the observation in one laboratory must be replicable in another laboratory. Data measured and gathered by one instrument, must be the same as data gathered by another similar instrument. And thus, the objectivity comes not from an individual practitioner but from a system that demands consistent and repeatable results.”<sup>4</sup>
14. While feelings of depression are absolutely very real and those experiencing depression need help to rectify the cause of their depression, there are actually no scientific tests to diagnose depression as a medical illness. As previously mentioned, The *Diagnostic and Statistical Manual of Mental Disorders* (DSM) is the main manual used by psychiatry in Australia to “diagnose” disorders and it proves the unscientific nature of a psychiatric diagnosis including depression.

**DSM–IV:** States in the section on depression, “No laboratory findings that are diagnostic of Major Depressive Disorder have been identified” (p.352)

**DSM–IV:** Under Bipolar Disorder it states, “There appears to be no laboratory features that are diagnostic of Bipolar 1 Disorder or that distinguish Major

Depressive Episodes found in Bipolar 1 Disorder from those in Major Depressive Disorder or Bi Polar II Disorder” (p. 384).

**DSM-5:** States the following for major depressive disorder, “No laboratory test has yielded results of sufficient sensitivity and specificity to be used as a diagnostic tool for this disorder” (p.165).

15. **“There are no objective tests in psychiatry — no X-ray, laboratory, or exam finding that says definitively that someone does or does not have a mental disorder.” “I mean, you just can’t define it.” — Allen Frances psychiatrist and former DSM-IV Task Force Chairman** <sup>5</sup>
16. **“Unlike physical illness, we can’t rely on blood tests, brain scans or other biological tests. As a consequence of this lack of diagnostic accuracy, our field relies purely on observation.** “— Bernard Baune, Professor & Head of Psychiatry at University of Adelaide <sup>6</sup>
17. **“There are no laboratory tests, such as blood tests or scans, to determine if you have ADHD.”** — Royal Australian and New Zealand College of Psychiatrists <sup>7</sup>
18. **“Making lists of behaviours, applying medical-sounding labels to people who engage in them, then using the presence of those behaviours to prove they have the illness in question is scientifically meaningless. It tells us nothing about causes or solutions. It does, however, create the reassuring feeling that something medical is going on,”** — John Read, former senior lecturer in psychology, Auckland University, New Zealand. <sup>8</sup>
19. Based on the DSM, which is usually the source for surveys which come up with the figures of the numbers of “mentally ill people,” statistics are touted as near “epidemic” rates of mental illness. Along with this comes the demand for more funds. After World War II, 1 in 20 were said to be mentally ill. Yet rather than reduce this rate as one would expect would be occurring if psychiatry and its treatments were working and providing effective treatment, psychiatry now says one in five is mentally ill and that half of all Australian’s will experience mental ill health during our lifetime.
26. When the very science behind something is wrong, no amount of money thrown at it will improve the system.

**RECOMMENDATION:** That the Productivity Commission should recommend that government, criminal, educational, judicial and other social agencies not rely on the DSM and recommend that no legislation should use this as a basis for determining mental state, competency, educational standard or rights of any individual.



# Australian Psychotropic Drug Warnings

20. There have now been 67 psychotropic drug warnings issued by Australia's drug regulatory agency, the Therapeutic Goods Administration (TGA) since 1995. Thirty-one of these since 1 Jan 2010. [See Appendix 1 for a full list and references of all the Australian warnings]
21. These warnings include to warn of the risk of the risk of hallucinations, increased blood pressure, agitation, akathisia (inability to remain motionless), aggression, life threatening heart problems, addiction, suicidal ideation and possible death.
22. **Alarmingly “Boxed Warnings” in Australia are not on the packaging of the drug and are not on the “Consumer Medicine Information” (CMI) which is given to the consumer when they fill a prescription. The Boxed Warning is only on the “Product Information” (PI) used by doctors to prescribe.**
23. **The TGA also do not list out “Boxed Warnings” for drugs on their website.** Therefore, parents and adults do not always know that the strongest warning that can be issued for a drug in Australia has been placed on the drug proposed. It is left to the parent/adult to independently research the drug further themselves on the internet or in a library and locate the relevant PI for the drug. They could also ask their doctor or pharmacist for a PI or ask them if the drug has a Boxed Warning, but **only** if they are aware of these boxed warnings, many are not.
24. Even the CMI is not always given to a consumer each and every time they fill a prescription for a psychotropic drug. Not all psychotropic drugs in Australia have information within the packet. In many cases these above situations prevent parents/adults from being fully informed at time of prescribing or filling a prescription and so being unaware that they, their family member or child needs to be monitored for suicide if on particular psychotropic drugs. Coupled with the fact that not all psychiatrists inform their patients of all warnings and potential side-effects for the drug, parents and adults are not always able to give fully informed consent for any psychotropic drug proposed as treatment for their child.

## **RECOMMENDATIONS:** That the Productivity Commission Recommends:

- A. As the general public are not aware that they can report side effects, funds need to be re-allocated to fully educate the public that they can report side effects and how to do so. In this way the true picture of the extent of the damage caused by these drugs will be known.
- B. Funding needs to be reallocated to ensure that doctors, hospitals etc., report any drug complications from the use of any psychotropic drug to the Therapeutic Goods Administration.
- C. Consumers must be given information on the psychotropic drug at time of prescribing. CMI's need to be changed so that they include information on any “boxed warnings” the psychotropic drug may have and the TGA needs to list boxed warnings in one location on their website.

## Suicides & Deaths Linked to Psychotropic Drugs

25. It is not that everyone who takes a psychotropic drug will try to commit suicide, but clearly some do, as has been warned by drug regulatory agencies across the world, including the TGA in Australia and as adverse drug reactions reported to the TGA expose. The fact that psychotropic drugs are linked to suicide has been known about for decades and largely ignored by the psychiatric profession.
26. Experts say that only between 1 and 10% of side effects are reported in Australia. The Food and Drug Administration in the US also estimates that only 1% of all serious adverse events are reported to it. <sup>9</sup> This illustrates that the numbers of side effects reported can only be the tip of the iceberg.
27. **An inspection of the TGA's adverse drug reaction database reveals that as of 3<sup>rd</sup> January 2019 there have been the following reported linked to antidepressants:**
- **25,607 adverse drug reaction reports (ADRs)**
  - **15,153 of these were "single suspected" ADRs (person was on only one drug)**
  - **593 deaths**
  - **140 completed suicides (including 7 children under 18)**
  - **606 reports of suicidal ideation**
  - **326 suicide attempts**
  - **20 reports of suicidal behaviour** <sup>10</sup>
- If 140 people suicided after eating food with harmful chemicals, that product would be pulled from the market.
28. As far as antipsychotics are concerned, they too can cause suicidal behaviour and death. Antipsychotics can cause tardive dyskinesia and akathisia. The inability to sit still and involuntary repetitive body movements is extremely distressing for a person and has been associated with suicidal thoughts and behaviour. <sup>11</sup>
29. **TGA database reveals as at 3<sup>rd</sup> January 2019, the following for antipsychotics:**
- **25,607 adverse drug reaction reports**
  - **18,031 of these were "single suspected" ADRs (person was on only one drug)**
  - **1,114 deaths (692 or 62% of these deaths are linked to clozapine)**
  - **105 completed suicides**
  - **199 suicide attempts**
  - **228 reports of suicidal ideation**
  - **22 reports of suicidal behaviour** <sup>12</sup>
30. ADHD drugs are also linked to suicidal behaviour, especially atomoxetine (Strattera which is an antidepressant). The TGA database reveals the following for ADHD drugs as of 3<sup>rd</sup> Jan 2019:

- **671 adverse drug reaction reports**
- **535 of these were “single suspected” ADRs (person was on only one drug)**
- **9 deaths, including 5 while deaths linked to methylphenidate**
- **4 completed suicides including the suicide of a 9-year-old on Strattera**
- **11 suicide attempts**
- **68 reports of suicidal ideation**

31. Below is a selection of international and Australian drug warnings relating to suicide with antidepressants and ADHD drugs:

**June 2018:** The TGA issued a Medicines Safety Update to warn and remind health professionals to effectively communicate to patients and carers the risk of neuropsychiatric side effects (including agitation, aggressive behaviour or hostility, depression, insomnia, irritability, hallucinations, suicidal thinking and behaviour) with antidepressants, atomoxetine (Strattera, an ADHD drug and antidepressant) and the antidepressant Zyban used in smoking cessation.<sup>13</sup>

**December 2016:** The TGA issued a Medicines Safety Update covering the increased risk of suicidal thinking and behaviour with antidepressants, particular SSRI's.<sup>14</sup>

**December 2013:** The TGA issued a Medicine Safety Update warning again of the risk of suicidality in children with the non-stimulant ADHD drug atomoxetine (Strattera, an antidepressant) after the suicide of a 9-year-old on the drug.<sup>15</sup>

**March 2006:** The TGA ordered a Boxed Warning (the most serious type of warning) for the risk of suicidal thoughts and behaviours is placed onto the non-stimulant ADHD drug atomoxetine, (Strattera, an antidepressant).<sup>16</sup>

**August 2005:** The Australian Therapeutic Goods Administration published an Adverse Drug Reaction Bulletin reporting evidence supporting an association between SSRI use and new onset suicidality in adults. It usually developed shortly after commencing the drugs or after increase in dosage that could cause akathisia, agitation, nervousness and anxiety. Similar symptoms could also occur during withdrawal.<sup>17</sup>

**December 2004:** The Australian Therapeutic Goods Administration (TGA) issued an Adverse Drug Reaction Bulletin recommending caution in prescribing SSRI's to children and adolescents citing a recent study involving Prozac that showed an increase in suicide, self-harm, aggression and violence.<sup>18</sup>

**October 2004:** The US Food and Drug Administration (FDA) ordered pharmaceutical companies to add a “black box” warning to SSRI antidepressant packaging, warning that the drugs could cause suicidal thoughts and actions in children and teenagers.<sup>19</sup> Australia does not have a boxed warning for suicide with antidepressants and should.

**August 2003:** Wyeth Pharmaceuticals, the makers of the antidepressant Efexor issued a warning to US doctors that Efexor could cause hostility, suicidal ideation and self harm in patients under the age of 18.<sup>20</sup> Wyeth issued the same warning to doctors in

New Zealand<sup>21</sup> and in September they issued a similar warning to doctors in Canada telling them Efexor had been linked with possible suicidal thinking in children.<sup>22</sup>

**RECOMMENDATIONS:** That the Productivity Commission should recommend:

A. For every child and adult suicide, autopsies need to include tests for the presence of psychotropic drugs.

B. Subsequent Coroner's reports need to indicate the presence of a psychotropic drug at time of suicide (by methods other than drug poisoning). This will then give a true picture of the harm these drugs actually cause in children and adults.

C. Each child and adult death resulting from psychotropic drug related causes should be investigated for criminal culpability.

## All Available Adverse Drug Reactions Reported to Therapeutic Goods Administration in Australia to be Made Publicly Available

32. CCHR has on several occasions requested the "Public Case Details" reports (PCD) for antidepressants, antipsychotics and ADHD drugs in Australia from the TGA. The Public Case Detail reports contain additional information that is not available on the TGA's Database of Adverse Event Notifications (DAEN) currently on their website. The PCDs are no longer being made available to the public. The additional information on the PCDs includes information about the side effect and any treatment that resulted from the side effect, key information which should be available to the public so they can make fully informed choices. For example, the Public Case Details contain such information as:

- A 16-year-old girl "made 2 suicide attempts since starting drug [Lovon], nil previous." Under treatment it states, "Drug ceased."
- A 9-year-old boy on the antidepressant Lovon and antipsychotic Risperidone reactions were, "Self injurious behaviour and suicidal ideation." Additional information stated, "Has grabbed a blunt knife on 5 occasions and attempted to cut himself. He often talks of wanting to die."
- A 7-year-old boy on Ritalin attempted suicide. Information contained on the Public Case Detail report included, "Depression, crying, saying he wants to kill himself. Tried to run in front of cars, threatened to jump off roof."
- A 16-year-old girl on 2 antidepressants, Prozac and Zoloft, "Experienced excessive bleeding, psychosis, high blood pressure, severe diarrhoea, sweating, tremors, violent, aggressive and suicidal behaviour." Under "treatment" it stated that both the Prozac and Zoloft were ceased.
- A 12-year-old girl on the ADHD drug Strattera's report said, "Patient experienced anorexia, weight loss, fidgeting, compulsive behaviour, e.g. ripping finger and toe nails out, cutting and picking clothing and anger outburst. Strattera stopped."

- A report for a 14-year-old on the antidepressant fluoxetine states, “Severely increased suicidal ideation in two days with high level of intent and plan to jump in front of train. Previously no suicidal ideation and settled spontaneously within 4 days of ceasing fluoxetine.”

All the Public Case Details above and that CCHR Australia has requested and been given by the TGA can be viewed on the CCHR Australia website on this link: <http://cchr.org.au/side-effects>. Please see about half way down the page for instructions on how to view the side effects.

33. Additionally, the TGA no longer provide “Medicine Summaries” for classes of drugs. Previously it was possible to request a summary of exactly how many reports the TGA have received for all classes of psychotropic drugs including a break-down of the type of reaction. The information could also be requested specifically for children. To obtain these figures now, one has to generate a report for each drug on the TGA website and manually add the various reactions together for each drug — an onerous task that very few do and subsequently this information remains hidden from the public.

**RECOMMENDATION:** That the Productivity Commission recommends that the TGA Public Case Details and full summaries of ADRs by class of drug need to be made publically available for full transparency and to enable fully informed consent by the public.

## Withdrawal from Psychotropic Drugs

34. Psychiatrists say that psychotropic drugs are not addictive, but this is not correct, and this is certainly not what is reported to CCHR by those it assists. Withdrawal Syndrome can occur when a psychotropic drug is reduced, ceased or when the patient is switching to another psychotropic drug. Parents and patients are not always told about withdrawal syndrome and not told that no one should stop any psychotropic drug without the advice and assistance of a competent medical doctor.
35. Depression and anxiety are common symptoms when withdrawing and the depression can be worse than the original depression an antidepressant was prescribed to treat for in the first place. Consequently, patients are often told that the withdrawal symptoms are a return of the “mental illness” and the drug is resumed when in fact it is withdrawal syndrome and they need medical assistance to wean off correctly. If patients are not aware of withdrawal syndrome, this can also increase suicidal behaviour as they do not know they could be experiencing withdrawal side effects.
36. As early as 1980, a literature review found that precaution should be taken when terminating therapy with stimulants and tricyclic antidepressants due to numerous reports of rebound phenomena.<sup>23</sup>
37. Then in 1996, the National Preferred Medicines Centre Inc. in New Zealand, issued a report on “Acute drug withdrawal”, saying that withdrawal from psychoactive drugs can

cause 1) rebound effects that exacerbate previous symptoms of a “disease,” and 2) new symptoms unrelated to the condition that had not been previously experienced by the patient. Antidepressants can create “agitation, severe depression, hallucinations, aggressiveness, hypomania [abnormal excitement] and akathisia [severe restlessness causing violent behaviour].”<sup>24</sup>

38. The *Journal of Psychotherapy and Psychosomatics* published a report in September 2012 about persistent post-withdrawal effects which began six weeks after cessation of taking SSRI antidepressants. Researchers reviewed self-reported adverse events between February and September 2010 and found post- withdrawal symptoms “may last several months to years.” Symptoms included disturbed mood, persistent insomnia, emotional lability, irritability, depression, impaired concentration and memory and poor stress tolerance.<sup>25</sup>
39. There have been 8 psychotropic drug warnings issued by the TGA to warn of withdrawal syndrome including in neonates whose mothers took antidepressants during pregnancy.
40. By 4 January 2019, adverse reactions for withdrawal syndrome reported to the TGA for antidepressants and antipsychotics had reached 1,172 (for all ages). Again, as only between 1 and 10% of side effects being reported, the numbers can only be much higher. <sup>26</sup>

**RECOMMENDATION:** That the Productivity Commission recommends that money be re-directed to educate the public on withdrawal syndrome and the need to not stop any psychotropic drug without the advice and assistance of a competent medical doctor.

## Numbers of Australian’s on Psychotropic Drugs

41. According to the Australian Institute of Health and Welfare, there were 35,742,606 psychotropic drug prescriptions written in 2016/17 on the PBS/RPBS both subsidised and under co-payment (the latest figures available), nearly a 15% increase since 2012/13.
42. This represents over 4 million Australians including 110,697 children under 15 years of age. The breakup of numbers of people on them by class of drug is below:
- Antidepressants:** 2,936,769  
**Psychostimulants and nootropics:** 160,295  
**Hypnotics and sedatives:** 764,772  
**Antipsychotics:** 460,783 <sup>27</sup>
43. Statistics for the numbers on psychotropic drugs by age breakup, drug and state are not published. effectively hiding what is going on. These statistics were previously

available free to anyone if requested. CCHR would do so and then publish them for the public. But since 2014, CCHR has requested the figures twice and to obtain them had to pay \$3,458 in 2014 and in 2016 the cost was \$4,834.71 to the Department of Human Services (DOHS).<sup>28</sup>

44. The Australian Government have not authorised or registered SSRI antidepressants or indeed any antidepressant for the treatment of depression in those less than 18 years of age, yet they are being prescribed in ever increasing numbers, with the latest figures from the DOHS indicating there are over 100,000 children on antidepressants.<sup>29</sup>
45. These figures should not even have to be requested let alone paid thousands of dollars for. This lack of transparency is contributing to the lack of accountability.

**RECOMMENDATION:** That the Productivity Commission recommends that statistics on the numbers of children and adults by age breakup, drug and state are made transparent, accurate, published annually and monitored.

## Electroshock (ECT)

46. Electroshock is the application of hundreds of volts of electricity to the brain. It can cause severe and permanent memory loss, brain damage, suicide, cardiovascular complications, intellectual impairment and even death. Many are no longer able to work after electroshock due to severe memory loss.
47. The WA Chief Psychiatrist's ECT Guidelines recommended ECT form, states: "In some people, memory loss may be severe and can even be permanent."<sup>30</sup>
48. Psychiatry admits it still doesn't know how ECT "works," a fact easily discovered when researched for. The Victorian former Deputy Chief Psychiatrist Professor Kuruvilla George wrote in an ECT article, "How does ECT work? This is the million-dollar question and the first thing to state is that no one is certain."<sup>31</sup>
49. Psychiatrist's attempts at explaining how ECT works include such statements as, "It is believed...", "it has been suggested...", and "One theory suggests..." A heart surgeon couldn't claim he doesn't know how the heart works but has dozens of theories—and no scientific fact—about why a coronary bypass operation should be performed. He would be sued for malpractice if he did so.
50. Psychologist Dr. John Breeding says, "It is prima-facie common sense obvious that ECT causes brain damage. After all the rest of medicine, as well as the building trades, do their best to prevent people from being hurt or killed by electrical shock. People with epilepsy are given anticonvulsant drugs to prevent seizures because they are known to cause brain damage."<sup>32</sup>

51. A major proponent of ECT, psychiatrist Harold A. Sackeim, when addressing the regularity of patients complaining about memory loss, stated, “As a field, we have more readily acknowledged the possibility of death due to ECT than the possibility of profound memory loss, despite the fact that adverse effects on cognition [consciousness] are by far ECT’s most common side effects.”<sup>33</sup>
52. In June 2011, it was reported that patients in NSW had been anaesthetised for more than 2 days to undergo court ordered ECT. Psychiatrist Jonathan Philips said he was concerned that such treatment could be the start of the “slippery slope” for even more radical treatment. Anaesthetising someone for 2 days to administer electroshock has parallels to Chelmsford Hospital in NSW, where deep sleep treatment (patients were put into a drug induced coma and given electroshock) was administered.<sup>34</sup>
53. A 2010 study involving a literature review of ECT studies on the efficacy of ECT concluded there is no evidence at all that it prevents suicide. It also found that there have been significant new findings confirming that brain damage, in the form of memory dysfunction, is common, persistent and significant and that it is related to ECT rather than depression. Further it stated, “The continued use of ECT therefore represents a failure to introduce the ideals of evidence-based medicine into psychiatry.”<sup>35</sup>
54. The United Nations Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment in 2013 reported to the United Nations on abuse in health care settings. Mr Juan Mendez stated, “*States should impose an absolute ban on all forced and non-consensual medical interventions against persons with disabilities, including the non-consensual administration of psychosurgery, electroshock and mind-altering drugs, for both long and short-term application.*”<sup>36</sup>
55. W.A. bans the use of electroshock on children under 14 and A.C.T. bans its use on children under 12.<sup>37</sup> Sicily and Slovenia have banned electroshock completely and there are other bans and restrictions around the world.<sup>38</sup>
56. In 2005 the World Health Organization stated, “There are no indications for the use of ECT on minors, and hence this should be prohibited through legislation.”<sup>39</sup>
57. Electroshock given in private facilities is not always required to be reported by law including in NSW and Victoria as their mental health acts do not require it to be reported. It can be given against a person’s will if they are involuntarily detained and, in some states, legal representation is not available.
58. There were 35,489 Medicare funded electroshock “treatments” in 2017/18, a 21% increase since 2012/13.<sup>40</sup>
59. For those who are given it, it is torture. One Victorian woman who was forced to undergo electroshock said she has had security guards wheel her down to the treatment room holding her down so she didn’t escape. “I felt like I was being wheeled down to the gas chamber really,” she said. She would even eat from a stash of food to avoid the general anaesthetic and when staff found her food, she resorted to eating grass to avoid the electroshock.<sup>41</sup>



60. In 2016 Victorian Legal Aid lawyer Chris Povey said there were serious human rights implications posed by compulsory treatment orders, particularly electroshock orders, "It's hugely concerning that we are forcing people to accept ECT and hundreds are missing out on legal representation."<sup>42</sup>
61. In 2018 the Victorian coroner ruled that the death of a Melbourne grandfather who attempted suicide and later whose life support system was turned off, was a preventable death. He was submitted to more than 200 electroshocks and the coroner found that there was no evidence the electroshock would provide any relief and it had become largely experimental.<sup>43</sup>
62. In November 2018 Justice Bell of the Supreme Court of Victoria ruled that the orders forcing two Victorian patients to undergo electroshock were made in breach of their human rights. He said, "A person does not lack the capacity to give informed consent simply by making a decision that others consider to be unwise according to their individual values and situation."<sup>44</sup>
63. Electroshock never addresses the cause of a child or adult's problem, offers no cure, has severe side effects and increases costs to both federal and state budgets when those who are given it cannot return to work or require continual care.

**RECOMMENDATION:** That the Productivity Commission recommend that each state and territory to ban electroshock for all ages in their mental health acts.

## Restraint

64. While it is excellent that mechanical restraint and seclusion rates are coming down, all forms of restraint and seclusion need to be completely eliminated and made illegal in psychiatric wards.
65. The use of physical restraint is **not** coming down and the use of chemical restraint (the use of psychotropic drugs to subdue and control behaviour) is not reported. Restraint can and does cause death in Australia.
66. The use of both restraint and seclusion has a deep and lasting impact on an already fragile and vulnerable child or adult, leading to longer stays in hospital due to distress and not only do they not help, they are increasing costs.
67. ***"There is a lack of evidence internationally to support seclusion and restraint in mental health services. There is strong agreement that it is a human rights issue, that it has no therapeutic value, that it has resulted in emotional and physical harm..."*** — Former Australian National Mental Health Commissioner, the late Ms Jackie Crowe.<sup>45</sup>

68. The United Nations Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment in 2013 stated:

***“The mandate has previously declared that there can be no therapeutic justification for the use of solitary confinement and prolonged restraint of persons with disabilities in psychiatric institutions; both prolonged seclusion and restraint constitute torture and ill-treatment. In my 2012 report (A/66/88) I addressed the issue of solitary confinement and stated that its imposition, of any duration, on persons with mental disabilities is cruel, inhuman or degrading treatment.”*** – Mr Juan E Mendez.<sup>46</sup>

69. A NSW Health Policy Directive states, ***“There have been instances both in Australia and internationally in which young apparently healthy people have died suddenly while held in physical/manual restraint. Resuscitation attempts in these circumstances have rarely been successful. Most deaths have been attributed to positional asphyxia or cardiac arrest. While some deaths involved apparent pressure to the neck, thorax or abdomen, the inappropriate application of restraint does not always appear to be a factor.”***<sup>47</sup>

70. Deaths reported in Australia from restraint include:

- An involuntarily detained patient at Graylands hospital in Western Australia repeatedly told staff restraining him to let him go and said, “You are going to kill me,” moments before he slumped to the ground and died. A post mortem found significant bruising on his neck and that death was consistent with cardiac arrhythmia during restraint.<sup>48</sup>
- Dr Minh Le Cong who works for the Royal Flying Doctor Service in Queensland, in a 2017 article in *Medical Journal of Australia InSight*, detailed specifics of 4 of the many restraint deaths that have occurred in Australia. Two of the deaths were linked to the excessive use of the benzodiazepine midazolam as a chemical restraint. The third person who died was given the antipsychotic olanzapine and then midazolam. The fourth person was physically restrained and given midazolam.<sup>49</sup>
- Former Austin Hospital Director of Mental Health Dr Richard Newton said he would estimate one death in circumstances involving restraint, forced sedation and seclusion each year in Victoria alone.<sup>50</sup>

71. A 2017 NSW review of restraint and seclusion in mental health facilities report states,

***“It is not unusual for staff to raise concerns that staff and consumer safety will be compromised if seclusion and/ or restraint are reduced, but this concern is not supported by the weight of evidence.”***<sup>51</sup>

72. The Australian Institute of Health and Welfare (AIHW) now publish restraint rates and numbers of times they were used on their website. While this is a major improvement towards transparency, they only report mechanical (devices such as belts, straps) and

physical restraint (hands on immobilisation such as holding a person down to forcibly administer “treatment.”

73. AIHW’s reporting also only covers the use of restraint in “public sector acute mental health services. It does not include the use of restraint in non-acute wards or its use in private facilities, so the use of restraint can only be much higher.<sup>52</sup>

74. In 2017/18 there were 796 mechanical restraints reported from states and territories in public sector acute facilities and physical restraint was used 16,917 times, a 16% increase in 3 years (14,533 in 2015/16 to 16,917 in 2017/18). CCHR has concerns that mechanical restraint is simply being replaced with physical and chemical restraint in some instances.<sup>53</sup> Note: Queensland did not report the use of physical restraint except for 2017/18 and WA did not report mechanical restraint for any of these years.

75. Seclusion was used 11,315 times in 2017/18 in public sector acute mental health services.<sup>54</sup> The average duration of seclusion for children was 1.3 hours; the average rate for adults was 5.3 hours and for the elderly, 5.2 hours.<sup>55</sup>

76. There are valid ways to calm and work with traumatised people that preclude the need for harsh and inhumane treatment. Often when patients are treated abruptly, harshly and their opinions ignored, they become more fearful and aggressive.

**RECOMMENDATIONS:** That the Productivity Commission recommends the following:

- a. The use of restraint is criminal and it must be made a criminal offence in all state and territory mental health acts if performed on a psychiatric patient or someone allegedly mentally ill.
- b. Reporting of all uses of restraint including chemical must be made mandatory by law in the interests of transparency and accountability
- c. Government funding of any type should not be provided to any facility that uses restraint or seclusion.

## Conflicts of Interest

77. Conflicts of interest between psychiatrists, mental health support groups and pharmaceutical companies is an area which drives up the use of antidepressants and other psychotropic drugs. No-one responsible for advising governments, involved in writing medical guidelines, conducting inquiries or doing anything that affects entire populations with potential conflicts of interest should take part in these activities. They must be excluded.

78. There are concerns that pharmaceutical kickbacks have gone unreported after changes made in 2015 to Australia’s system of self –regulation by Medicines Australia as one study demonstrates:

***“These changes allowed for reduced reporting of spending on food and beverages at events and for sponsored healthcare professionals, with the result that over a third of previously reported industry funding on healthcare professionals is now hidden.***

***“This study demonstrates the limitations of a self-regulatory system, which can be quietly changed in such a way as to reduce overall public reporting of industry funding in the healthcare sector.”*** — Dr. Lisa Parker from the University of Sydney co-author a paper published in the *British Medical Journal Open*.<sup>56</sup>

79. Pharmaceutical funding on free drug samples and funding for research are not reported as they are in the US and UK. Advisory Board meeting funding also needs to be disclosed in Australia.
80. **The Royal Australian and New Zealand College of Psychiatrists (RANZCP):** Their 2017 Annual Report, lists Janssen, Lundbeck, Pfizer, Merck Sharp and Dohme, Servier, Otsuka and Teva Pharma as supporting their activities.<sup>57</sup>
81. **Professor Ian Hickie** received funding from Bristol-Myers Squibb to establish an Australia wide GP training program in depression called SPHERE. The organisers of this training bragged on their website that Pfizer’s funding of this GPs training helped restore their antidepressant, Zoloft, to the number one product in the market in Australia.<sup>58</sup>
82. Prof. Hickie has served on professional advisory boards convened by the drug industry in relation to specific antidepressants made by Bristol Myer Squibb and Eli Lilly. He has led projects funded in part by Bristol Myer Squibb, Pfizer, Eli Lilly, Wyeth and Servier. In 2013, Prof. Hickie has also received travel support from Servier and Astra Zeneca and in the area of paid educational seminars/resources has declared the involvement of 4 drug companies.<sup>59</sup>
83. **Professor Patrick McGorry** has received unrestricted grant funding from drug companies, Janssen-Cilag, Eli Lilly, Bristol-Myers Squibb, AstraZeneca, Pfizer and Novartis. He has acted as a paid consultant for and has received speaker’s fees and travel reimbursement from all or most of these companies. He has also received honoraria for consulting and teaching from Roche, Lundbeck, Janssen-Cilag, Eli Lilly, Pfizer and Astra Zeneca.<sup>60</sup>
84. **Headspace Centres:** Prof. McGorry founded the youth mental health centres “headspace” and he is a well-known advocate of “early intervention” treatment for mental disorders. This involves treating those “at risk” of psychosis, i.e. they don’t have it now but could get it. How non-scientific is this? Essentially it is an arbitrary list of behavioural symptoms, which psychiatrists claim can predict the onset of “psychosis.” Often predicted at age 12-14 years old, psychiatrists can then “treat” the adolescent to “prevent the disorder.” headspace’s “At risk evidence summary” estimates 82% to 90% will **not** go on to develop psychosis within a year of diagnosis. Psychiatrist Allen Frances, who chaired the committee who produced the diagnostic

manual for psychiatry (DSMIV) warned that Prof. McGorry's Early Psychosis Intervention Centres do not have a reliable early diagnosis tool.<sup>61</sup>

85. Despite this and many other warnings, the premise is that youth should still be treated now. Potentially dangerous antipsychotics could be prescribed as part of this "treatment."<sup>62</sup> There are 109 headspace centres around Australia. 15 of these operating based on Prof. McGorry's Orygen Centre's early psychosis model.<sup>63</sup>
86. Prof. McGorry's Orygen Centre currently directly operates 4 of the 27 headspaces in Victoria.<sup>64</sup> Orygen has been funded by drug companies Eli Lilly, AstraZeneca, Janssen-Cilag and Bristol-Myers Squibb.<sup>65</sup>
87. An independent evaluation report released in 2015 of McGorry's headspace centres revealed that of the 26,058 evaluated 12-25-year-olds seen by headspace, only 13% had a "clinically significant improvement," 29% had no change and an unacceptable 24% either declined or significantly worsened. Consultation costs ranged from \$136 to \$1,000 per visit.<sup>66</sup> Despite this between October 2018 and January 2019 the Australian federal government gave \$208 million to headspace.<sup>67</sup>
88. Psychiatrists Professor Ian Hickie and Patrick McGorry both declared they had no conflicts of interest when they were part of the Mental Health Expert Working Group which was advising the Minister for Mental Health on reforming mental health in Australia in 2011.<sup>68</sup> The forms filled out did not stipulate pharmaceutical company funding as a conflict of interest, instead they asked for conflicts that "appear to influence proper consideration or decision making." Nowhere is it more important than at the Federal Government level that Conflicts of Interest Forms are comprehensive.<sup>69</sup>
89. **Psychiatric advocacy groups:** While there are people who genuinely want to help others in these groups, as far as psychiatric advocacy groups are concerned, pharmaceutical funding of these groups raises concern about the influential role this can play in setting health policy.

**"There is no doubt that industry funding can distort the patient voice."** — Dr Ray Moynihan, Bond University Queensland.<sup>70</sup>

***"The way we think about disease is being subtly distorted by ostensibly independent players, including patient advocacy groups, who are largely singing the tunes acceptable to companies seeking to maximise markets for drugs and [medical] devices."*** — Professor Lisa Bero, University of Sydney.<sup>71</sup>

90. A cursory review of several psychiatric advocacy groups reveals the following:

**Australian ADHD Professionals Association (AADPA):** The 2018 president of AADPA (Prof. Mark Belgrove) has previously received a research grant from Eli Lilly, an educational grant from Shire, and has spoken at meetings sponsored by Janssen-Cilag, Shire and Eli Lilly. The 2018 vice president (Prof. David Coghill) has received research support from Shire and Vifor-Pharma, and payment for Advisory Boards/speaking from Shire, Eli Lilly, Janssen-Cilag, Medice and Novartis. Committee

member Roger Paterson has received speaker's fees from Janssen, Eli Lilly, Novartis, Shire and Servier, and is a paid Advisory Board member for Eli Lilly and Shire.<sup>72</sup>

**Mental Illness Fellowship of Australia (MIFA):** MIFA has received funding from Janssen<sup>73</sup>, makers of antipsychotic drugs such as Risperdal.<sup>74</sup> The organisation received \$7400 from Janssen for a 'Parliamentary Friends of Mental Illness' dinner in 2017<sup>75</sup>; \$33,318 for Schizophrenia Awareness week activities, education and awareness events for parliamentarians and participation in a mental health advisory board in 2016,<sup>76</sup> and \$47,394 for a public awareness programs in 2015.<sup>77</sup>

**SANE:** received \$23,000 from Janssen in 2017<sup>78</sup>, \$74,750 in 2016<sup>79</sup> and \$91,900 in 2015. In 2014, the organisation listed AstraZeneca, Eli Lilly and Pfizer as supporters<sup>80</sup>, with Pfizer providing \$30,000 over 2013/2014.<sup>81</sup>

91. Failure to declare conflicts of interest threatens public trust. The integrity of medical guidelines has been shaken with high profile exposure of bias and conflicts, both in Australia and the US, which have brought untouchable bastions of authority into disrepute.
92. Consumers are already highly attuned to conflicts and bias in what is being marketed and sold to them aided by the internet.
93. Authoritative advice loses credibility when the consumer discovers an undisclosed conflict of interest. They value transparency and openness and demand this, in order to make valued decisions.
94. The simplest method to counteract conflicts of interest is to make it mandatory they are disclosed.

**RECOMMENDATIONS:** That the Productivity Commission recommends that:

- a. A federal law is passed so that all monies received or given by pharmaceutical companies are declared publicly including amounts and exactly what the money was used for including research funding.
- b. Criminal fines implemented if this is not adhered to.
- c. Comprehensive "Declaration of Conflicts of Interest" forms to be filled out by everyone involved in the writing of a medical guideline, advising governments, conducting inquiries and other similar actions. These forms must stipulate that present and past pharmaceutical funding is required to be declared.
- d. Anyone with conflicts of interest or potential conflicts of interest be excluded from these activities.

## Accountability

95. For years experts have said there is inadequate or no accountability for the money spent on mental health.<sup>82</sup> Despite the lack of accountability, funding continues to soar, has reached over \$9 billion annually and still the psychiatric system has not improved.

96. Again, the Productivity Commission is commended for its inquiry as its own report, *Productivity Commission's Report on Government Services 2019*, reveals that in 2016/17 results were appalling:

- 14.9% or 14,781 of those who were admitted to psychiatric acute inpatient services were re-admitted to acute wards again within 28 days.<sup>83</sup>
- 40.9% of children aged 0-17 discharged from a psychiatric ward/facility did not significantly improve.
- 44.6% of children aged 0-17 discharged from community care did not significantly improve.
- 62.8% of children aged 0-17 discharged from ongoing community care did not significantly improve.

97. Complaints to the Victorian Mental Health Complaints Commissioner are skyrocketing. They received 1,963 complaints in 2017/18, a 19% increase on the previous year (1,638) and a staggering 96% increase since 2014/15 (999).<sup>84</sup>

98. 860 complaints were received in the areas related to mental health and psychiatry by the NSW Health Care Complaints Commissioner in 2017/18. This is a 34% increase since 2013/14. Of the 860 complaints, 124 were made about psychiatrists.<sup>85</sup>

99. No other industry would be allowed such a poor performance for money invested. In contrast, money given to other areas of medicine shows noticeable progress, such as improving survival rates from cardiovascular disease over the past 20 years.<sup>86</sup>

100. With psychiatry having no real workable humane solutions, a continual cry for more funding and the lack thereof being blamed as the cause of the problem, proven solutions that help and don't harm must be implemented. The existing money must be spent on solutions that do work.

101. There are many medical professionals in Australia who genuinely help children and these should be the people and services that receive funding to assist children with problems. Accountability does not mean that the government is just informed by the mental health service that: "The funds were spent on the development of long-term screening," for example.

102. Accountability means providing a full break up of **exactly** what the funds are for, proven results in helping children and adults. This is extremely important considering the actual number of government and non-government mental health organisations receiving funding.

103. It is not sound economic practice to continue to increase funding where a lack of improvement and ineffective solutions that can harm are forthcoming.

**RECOMMENDATION:** That the Productivity Commission recommends that government funding should only be given to those mental health services that have been held accountable, report their results once a year and are actually producing results.

## Alternatives, Informed Consent: Providing Real Help

104. CCHR has long been an advocate for competent non-psychiatric medical evaluation of people with mental problems. Undiagnosed and untreated physical conditions can manifest as “psychiatric symptoms”.
105. The California Department of Mental Health Medical Evaluation Field Manual states: “Mental health professionals working within a mental health system have a professional and a legal obligation to recognize the presence of physical disease in their patients...physical diseases may cause a patient’s mental disorder [or] may worsen a mental disorder...”<sup>87</sup>
106. In general medicine the standard for informed consent includes communicating the nature of the diagnoses, the purpose of a proposed treatment or procedure, the risks and benefits of the proposed treatment, and informing the patient of alternative treatments, so they can make an informed, educated choice.
107. Psychiatrists routinely do not inform patients of non-drug treatments, nor do they conduct thorough medical examinations to ensure that a person’s problem does not stem from an untreated medical condition that is manifesting as a “psychiatric symptom.”
108. They do not accurately inform patients of the nature of the diagnoses, which would require informing the patient that psychiatric diagnoses are completely subjective (based on behaviours only) and have no scientific/medical validity (no X-rays, brain scans, chemical imbalance tests to prove anyone has a mental disorder).
109. All patients should have what is called a “differential diagnosis.” The doctor obtains a thorough history and conducts a complete physical exam, rules out all the possible problems that might cause a set of symptoms and explains any possible side effects of the recommended treatments.
110. There are numerous alternatives to psychiatric diagnoses and treatment, including standard medical care that does not require a stigmatising and subjective psychiatric label or a mind-altering drug. Governments should endorse and fund non-drug treatments as alternatives to potentially dangerous psychotropic drugs.
111. Children and adults have problems in life, and they need help with their problems. Is a child having problems at school because they need tutoring, has their eyesight and hearing been tested, are they getting enough sleep and exercise as well as eating properly? Are they having problems at home or school with peers or teachers or are they simply high IQ and bored?
112. The cause of the problem can greatly vary from child to child and adult to adult. A thorough investigation is vital. If a child is being abused, bullied or has problems at home, a psychotropic drug, electroshock or forced psychiatric treatment will never solve the problem.



113. For children and adults who are seriously unwell and need care, hospitals/wards need to be turned into places of proper care. They need access to medical assistance and tests, a safe and restful environment where they are not threatened with forced treatment so they can return home as happy and healthy children and adults.

114. This is not only sound financial judgement; it is sound mental health as well.

**RECOMMENDATION:** That the Productivity Commission recommends that when a child or adult presents at a psychiatric hospital or is having problems, they are first given a searching, competent physical check up to discount any underlying, physical condition as the cause of the child or adult's mental condition, before any child or adult is "diagnosed," and treated. If this is done many would not need admitting or treating.

## SUMMARY OF RECOMMENDATIONS

It is the role of Parliament and Government to protect citizens from potentially harmful psychiatric practices and drugs. If governments had not banned Deep Sleep Treatment (where patients were put into a drug induced coma and battered with electroshock) in NSW, it would still be legal and still be killing people.

It is not sound financial policy to keep spending money on psychotropic drugs and treatments that have such great potential to harm.

- 1. Government, criminal, educational, judicial and other social agencies should not rely on the *Diagnostic and Statistical Manual of Mental Disorders (DSM)*. No legislation should use this as a basis for determining mental state, competency, educational standard or rights of any individual.**
- 2. As the general public are not aware that they can report drug side effects, funds need to be re-allocated to fully educate the public that they can report side effects and how to do so. In this way the true picture of the extent of the damage caused by these drugs will be known.**
- 3. Funding needs to be reallocated to ensure that doctors, hospitals etc., report any drug complications from the use of any psychotropic drug to the Therapeutic Goods Administration.**
- 4. Consumers must be given information on the psychotropic drug at time of prescribing. CMI's need to be changed so that they include information on any "boxed warnings" the psychotropic drug may have and the TGA needs to list them all in one place on their website.**
- 5. For every child and adult suicide, autopsies need to include tests for the presence of psychotropic drugs.**

- a) **Subsequent Coroner's reports need to indicate the presence of a psychotropic drug at time of suicide (by methods other than drug poisoning). This will then give a true picture of the harm these drugs actually cause to children and adults.**
  - b) **Each child and adult death resulting from psychotropic drug related causes should be investigated for criminal culpability.**
6. **The Therapeutic Goods Administration "Public Case Details" and full summaries of Adverse drug reaction reports by class of drug need to be made publically available for full transparency and to enable fully informed consent by the public.**
  7. **Money is re-directed to educate the public on withdrawal syndrome and the need to not stop any psychotropic drug without the advice and assistance of a competent medical doctor.**
  8. **Statistics on the numbers of children and adults by age breakup, drug and state are made transparent, accurate, published annually and monitored.**
  9. **Each state and territory is advised to ban electroshock for all ages in their mental health acts.**
  10. **The use of restraint is criminal, and it must be made a criminal offence in all state and territory mental health acts if performed on a psychiatric patient or someone allegedly mentally ill.**
    - a) **Reporting of all uses of restraint including chemical must be made mandatory by law in the interests of transparency and accountability**
    - b) **Government funding of any type should not be provided to any facility that uses restraint or seclusion.**
  11. **To rectify conflicts of interest:**
    - a) **A federal law is passed so that all monies received or given by pharmaceutical companies are declared publicly including amounts and exactly what the money was used for including research funding.**
    - b) **Criminal fines implemented if this is not adhered to.**
    - b) **Comprehensive "Declaration of Conflicts of Interest" forms to be filled out by everyone involved in the writing of a medical guideline, advising governments, conducting inquiries and other similar actions. These forms must stipulate that present and past pharmaceutical funding is required to be declared.**
    - c) **Anyone with conflicts of interest or potential conflicts of interest be excluded from these activities.**

- 12. Government funding should only be given to those mental health services that have been held accountable, report their results once a year and are actually producing results.**
- 13. When a child or adult presents at a psychiatric hospital or is having problems, before any treatment is given, they are first:**
- a) given a searching, competent physical check up to discount any underlying, physical condition as the cause of the child or adult's mental condition.**
  - b) Before any child or adult is "diagnosed," and treated. If this is done many would not need admitting or treating.**

oOOo

## Appendix 1

# Australian Psychotropic Drug Warnings

## 2018

**June** – The TGA issued a Medicines Safety Update to warn and remind health professionals to effectively communicate to patients and carers the risk of neuropsychiatric side effects (including agitation, aggressive behaviour or hostility, depression, insomnia, irritability, hallucinations, suicidal thinking and behaviour) with antidepressants, atomoxetine (Strattera, an ADHD drug and antidepressant) and the antidepressant Zyban used in smoking cessation. Suicidal thinking and behaviour are of serious concern to consumers and generate complaints to the TGA, the warning said. One survey found that just over half of the inpatients and one third of community-based patients reported they did not receive any medicines information. Health professionals are strongly encouraged to provide patients with information on these drugs. The importance of educating patients and their carers about not suddenly stopping these psychotropic drugs due to withdrawal syndrome (worsening of existing symptoms or new not before experienced symptoms) was covered again in this warning.<sup>88</sup>

**June** – A second drug warning was issued in June for the antipsychotic clozapine to warn that clozapine has also been associated with potentially fatal risk of intestinal obstruction, faecal impaction and paralytic ileus (obstruction of the intestine due to paralysis of intestinal muscles). Bowel function and constipation should be closely monitored.<sup>89</sup>

**February** – The TGA warned that the maximum doses for desvenlafaxine (Pristiq) should not be exceeded as prescribing above it can increase side effects. They also warned that dose increases should occur at intervals of not less than 7 days.<sup>90</sup>

## 2017

**October** – The TGA warned in a Medicines Safety Update that lithium toxicity (Quilonum and Lithicarb) can occur close to usual dose. Regular and clinical monitoring is necessary and failure to recognise early signs of toxicity can result in death. As of May 2017, the TGA had received 58 reports linked to lithium toxicity, 2 resulted in death. Early signs include agitation, nausea/vomiting, muscle weakness, diarrhoea, hand tremors, drowsiness. Neurological manifestations and cognitive impairment from lithium toxicity may not be fully reversible.<sup>91</sup>

**February** – The TGA advised in a Medicines Safety Update that the antipsychotic aripiprazole (Abilify and other brands) can cause increased urges particularly for gambling along with the inability to control these urges. Other urges reported included increased sexual urges, compulsive spending and eating and these urges in some cases ceased when the drug was reduced or discontinued.<sup>92</sup>

## 2016

**December** – The TGA issued another Medicines Safety Update covering the increased risk of suicidal thinking and behaviour with antidepressants, particular SSRI's (a class of antidepressants). The TGA stated that several studies have shown that patients and carers have not received enough information about their drugs and the TGA strongly encourages doctors to give their patients the relevant CMI for the antidepressant prescribed. They also warned that antidepressants should never be suddenly stopped and should be reduced gradually [always under a doctor's supervision] to avoid potential discontinuation symptoms (also called withdrawal syndrome- worsening of current symptoms or new never before experienced symptoms) such as nausea, sleep problems, dizziness, irritability, anxiety, numbness and 'electric shock-like' sensations.<sup>93</sup>

## 2015

**August** – The TGA in a Medicines Safety Update advised that they had received 17 reports of cerebrovascular adverse reactions (stroke) for the antipsychotic risperidone (Risperdal). As far as dementia in the elderly is concerned, risperidone is now limited to treatment up to 12 weeks for moderate to severe Alzheimer dementia only. The new PI for risperidone also states that non-drug approaches should be used first.<sup>94</sup>

**April** – The TGA issued a Medicines Safety Update to warn of the risk of liver injury with the use of the antidepressant agomelatine (Valdoxan). The Product Information for agomelatine has been updated to state that it is recommended that liver function tests are done prior to prescribing and before increasing the dose. The TGA also advised that there should be close surveillance of liver function, including liver tests.<sup>95</sup>

## 2014

**October** – A TGA Safety Update advised that in rare cases methylphenidate (Ritalin and Concerta- ADHD drugs) may lead to prolonged and sometimes painful erections. A precaution for this has been added to the Product Information. The TGA also stated that the Product Information for atomoxetine (Strattera- ADHD drug) lists painful or prolonged erection as a potential side-effect.<sup>96</sup>

**October** – The TGA issued a Safety Update to warn of serious cardiovascular adverse events with the antidepressant bupropion (Zyban) used in smoking cessation.<sup>97</sup>

**September** – The TGA in a Safety Alert warned doctors to be alert for serotonin syndrome in people drugs used to treat nausea and vomiting who are also on antidepressants (serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea). In some cases, the TGA said serotonin syndrome can lead to a loss of consciousness, coma

and death. The TGA said doctors should advise patients and caregivers of the risk or serotonin syndrome.<sup>98</sup>

**August** – The TGA completed a safety review of the sleeping drug zolpidem (Stilnox). Subsequently the TGA recommended specific dose rates and warned of next day impairment including drowsiness. They also warned again of potentially dangerous side-effects such as sleep-walking, sleep driving and other bizarre behaviour related to zolpidem.<sup>99</sup>

**February** – The TGA issued a Medicines Safety Update regarding the antipsychotic quetiapine (Seroquel and its generics) because post marketing reports indicated that it can cause QT prolongation (a QT interval is part of the cycle of a heartbeat. A prolongation of the QT interval increases the risk of sudden death from abnormal heart beats). This has occurred not only with overdoses but also with concomitant illness (naturally accompanying or associated illness) and in patients taking other drugs known to cause electrolyte imbalances or increase the QT interval. A new warning in the Product Information (PI) advises that quetiapine treatment in combination with antipsychotics and other drugs known to increase the QT prolongation be avoided, particularly in the elderly. The TGA have received 807 adverse event reports for quetiapine including 2 reports of cardiac arrest.<sup>100</sup>

**February** – The benzodiazepine Alprazolam (Xanax and its generics) was made a Schedule 8 drug placing it in the same category as cocaine, morphine and opium. A Schedule 8 drug is a “controlled drug” meaning its use is restricted to reduce abuse, misuse and physical or psychological dependence.<sup>101</sup>

## 2013

**December** – A Medicines Safety Update issued by the TGA for the antidepressant duloxetine (Cymbalta and generics) to warn it can cause serotonin syndrome (serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea). The TGA has received 21 reports of serotonin syndrome in which duloxetine was the sole suspected drug.<sup>102</sup>

**October** – The TGA issued a Medicine Safety Update concerning the risk of suicidality in children with the non-stimulant ADHD drug atomoxetine (Strattera, an antidepressant) after the suicide of a 9-year-old on the drug. The TGA have received 65 adverse event reports for psychiatric disorders associated with atomoxetine, 45 of these were reports of suicidal ideation with 28 of these for children younger than 18. There were 2 other reports for attempted suicide in children. The TGA advised that anyone prescribed atomoxetine should be monitored for suicidality.<sup>103</sup>

**October** – The ADHD drug lisdexamfetamine (Vyvanse) had a “boxed warning” placed on it to warn that it has the potential for abuse, misuse, dependence or diversion. The boxed warning also states that anyone prescribed the drug should be monitored for abuse and dependency.<sup>104</sup>

## 2012

**June** – A Medicines Safety Update issued by the TGA states that they continue to receive reports of potentially dangerous, complex sleep-related behaviours, amnesia and hallucinations associated with the sleeping tablet zolpidem (Stilnox) use. In 2007, a boxed warning was placed on the drug to warn of bizarre behaviours and despite the media and publicity surrounding this drug, adverse events have persisted at high levels. The Medicines Safety Update instructs that patients should be told of the risks and health professionals are encouraged to report adverse reactions to the TGA. <sup>105</sup>

**February**- The TGA issued a Medicine Safety Update concerning the risk of clinically significant increases in blood pressure and/or heart rate with the use of the non-stimulant ADHD drug Strattera (atomoxetine, an antidepressant). This issue of the Medicine Safety Advisory also warned again the antidepressant citalopram should no longer be used in doses above 40mg as it may be life threatening in higher doses. These follow on from the earlier safety advisories issued in November 2011. <sup>106</sup>

## 2011

**November** – The TGA advised that the antidepressant citalopram (Cipramil, Celapram, Talum, Ciazil, Citalobell, Celica and others with “citalopram” in their name) should no longer be used in doses above 40mg, for some patients no more than 20mg and others with a specific congenital heart condition should not take citalopram. Higher doses may result in life-threatening or fatal arrhythmias in some people. Stopping citalopram suddenly can cause withdrawal symptoms including anxiety, insomnia, emotional instability, headache, diarrhoea, vomiting and palpitations. <sup>107</sup>

**November** – The TGA issued a safety advisory regarding the risk of increased blood pressure and/or heart rate with the use of the non-stimulant ADHD drug atomoxetine (also known as Strattera, an antidepressant). Heart rate and blood pressure should be measured before treatment and monitored during treatment. <sup>108</sup>

**October** – The TGA issued a Medicines Safety Update to inform that the stimulant Modafinil (Modavigil) has had several safety changes and recommendations to the PI as a result of a TGA benefit-risk review after reports of serious skin, psychiatric, nervous system and cardiovascular adverse reports. These changes to the PI include warning that Modafinil has been associated with aggressive and hostile behaviour, suicidal ideation, suicidal-related behaviour, psychosis, mania, depression and ischaemic (reduced blood supply) heart disease in patients with a history of cardiovascular disease. <sup>109</sup>

**August** – The TGA in their Medicines Safety Update said that stress cardiomyopathy (deterioration of the heart muscle) may be an adverse effect of venlafaxine (antidepressant also known as Efexor). <sup>110</sup>

**August** – The TGA issued a Medicines Safety Update to warn that new born infants exposed to antipsychotics during the third trimester of pregnancy may be at risk of extrapyramidal

signs (involuntary movements and muscle rigidity) and/or withdrawal syndrome. Adverse side-effects reported to the TGA for newborns include: breathing difficulties, tremor, agitation and muscle rigidity. All antipsychotics are now classed as pregnancy category C drugs. This means they are in the third most dangerous drug category and suspected of causing harmful effects on the foetus or newborn without causing malformation. These effects may be irreversible. All Product Information for antipsychotics is being updated to include this information.<sup>111</sup>

**April** – The TGA in their Medicines Safety Update Bulletin said that antidepressants appear commonly in suspected reports for drug-induced hyponatraemia (a lower than normal level of sodium in the blood which if severe can cause significant and permanent neurological injury or death). Commonly reported symptoms of hyponatraemia included confusion, Dizziness, dehydration, nausea and vomiting.<sup>112</sup>

**February** – The TGA issued in their Medicines Safety Update Bulletin a warning that if left untreated clozapine (an antipsychotic) induced constipation can lead to serious, potentially fatal complications. Health professionals should inform patients about the risk of constipation with clozapine.<sup>113</sup>

**February** – The TGA in their Medicines Safety Update Bulletin warned of a potential higher death rate amongst women who take tamoxifen for breast cancer and who also use paroxetine (antidepressant). It stated caution should also be taken with other SSRIs (a class of antidepressants).<sup>114</sup>

## 2010

**December** – The TGA in their Medicines Safety Update Bulletin issued a warning for drug-induced acute akathisia (the inability to remain motionless) particularly in patients taking antipsychotics. The inner restlessness and drive to move can result in significant distress.<sup>115</sup>

**December** – The TGA issued in their Medicines Safety Update Bulletin a ‘reminder’ on serotonin syndrome (serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea) to warn that certain drugs including lithium, SSRIs, MAOIs (a class of antidepressant drug) tricyclic antidepressants and SNRIs (a class of antidepressants including Efexor and Cymbalta) can cause serotonin syndrome. Early signs and symptoms can be mild, yet life-threatening. Symptoms include altered mental states – confusion; agitation; restlessness and excitement; as well as physical manifestations such as shivering, flushing, tachycardia (increased heart rate) and hyperthermia (elevated body temperature). Refer also to October 2009 entry above.<sup>116</sup>

**December** – The TGA issued a warning in their Medicines Safety Update Bulletin for lamotrigine (anticonvulsant used for epilepsy and bipolar) causing serious skin reactions which can be potentially fatal. Stevens-Johnson syndrome (a type of life-threatening severe rash) and toxic epidermal necrolysis (where the outer layers of the skin die) can develop



following lamotrigine administration. The warning advises that lamotrigine is discontinued at first sign of rash unless it is obviously not caused by the drug.<sup>117</sup>

**April** - The TGA reported in their Medicines Safety Update Bulletin that their database contained 581 reports of drug induced pancreatitis (inflammation of the pancreas) including 35 for Valproate (an anticonvulsant used for epilepsy and bipolar).<sup>118</sup>

## 2009

**December** – The TGA released the final report of an independent Psychotropic Drug Safety Expert Advisory Panel established in 2008 by the TGA to undertake a scientific review of a series of cases submitted to the TGA by a psychiatrist and an extensive literature review of SSRIs and antipsychotics. Their recommendations included:

- The Product Information (PI) for reboxetine (antidepressant) should include advice about the potential for neonatal side-effects.
- The PI for all SSRIs should warn of the risk of Persistent Pulmonary Hypertension (high blood pressure in the lungs) for newborns.
- Consideration should be given to requiring all PI documents for atypical antipsychotics to recommend glycaemic monitoring regimes (used to monitor blood sugar levels) for those at risk of or those with diabetes.
- That the TGA should review consistency and appropriateness of advice in the PI of all SSRIs concerning monitoring patients at risk of diabetes or with diabetes.
- Consideration should be given to requiring PI documents of SSRIs and SNRIs (a class of antidepressants including Efexor and Cymbalta) to warn of serotonin syndrome during treatment (serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea) during treatment. Treatment with the drug should be discontinued if symptoms of serotonin syndrome occur.
- Consideration should be given that the PI Documents of all SSRIs and SNRIs warn that they should not be used in combination with monoamine oxidase inhibitors (MOIA - a class of antidepressant drug which includes moclobemide). Cases of potentially life-threatening serotonin syndrome have been reported in those on both drugs or those who have recently discontinued an SSRI/SNRI and started on a MAOI.
- They also recommended: There should be a standardized way in which important “drug to drug interaction” information is presented in the PI; The TGA should implement a program where Australian PIs are regularly reviewed for consistency with other international documents throughout the life of the PI for these drugs; The TGA should include items on serotonin syndrome in their upcoming issues of Adverse Drug Reaction Bulletins.<sup>119</sup>

**October** – The TGA issued an Adverse Drug Reactions Bulletin to warn that antidepressants have properties that predispose individuals to suffer adverse effects when switching antidepressants. Serotonin syndrome, a potentially life threatening condition, which occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea is one of the adverse effects of antidepressants and can occur during treatment and during switching particularly in the elderly. <sup>120</sup>

**August** – The TGA issued an Adverse Drug Reactions Bulletin to warn that the antidepressant duloxetine, also known as Cymbalta can cause serotonin syndrome (serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea.) The TGA said they have had 108 reports of suspected adverse reactions for duloxetine from June 2008 to May 2009 including 10 cases of suicidal ideation and 8 cases of agitation. From the evidence the TGA has, they say that serotonin syndrome can occur with duloxetine treatment alone even at normal doses as well as in combination with other drugs known to cause this syndrome. The Product Information for Cymbalta has been updated to include this information. <sup>121</sup>

**April** – The TGA reported in their Adverse Drug Reactions Bulletin some of the serious risks of sodium valproate (approved to treat mania). Specifically, that it is well known to cause foetal malformations and is classified as a Pregnancy Category D drug (drugs that have caused, are suspected to have caused or may be expected to cause an increased incidence of human foetal malformations or irreversible damage). These drugs may also have adverse pharmacological effects. <sup>122</sup>

**February:** A Boxed Warning (the strongest warning) was placed onto the ADHD drug Concerta by the TGA for drug dependence. It warns that chronic abuse of Concerta can lead to a marked tolerance and psychological dependence with varying degrees of abnormal behaviour and frank psychotic episodes can also occur. <sup>123</sup>

## 2008

**December** – The TGA issued an Adverse Drug Reactions Bulletin to warn that the stimulant-like drug, modafinil, can cause serious life-threatening skin reactions and serious psychiatric reactions. The TGA recommends that at the first sign of rash or if patients experience psychiatric symptoms, modafinil should be discontinued and not re-started. <sup>124</sup>

**October** – The TGA reported they had received 307 reports of hyponatraemia (a lower than normal level of sodium in the blood which if severe can cause significant and permanent neurological injury or death) since May 2005. Antidepressants were the suspected cause in 78 of these reports. 101 of the total reports were severe and the most commonly associated drugs for severe hyponatraemia included carbamazepine (anticonvulsant) and the antidepressants, paroxetine (Aropax), venlafaxine (Efexor) and sertraline (Zoloft). Two thirds of the 307 reports received were for patients over the age of 70 and 70% involved women. <sup>125</sup>

**February** – The TGA imposed a Boxed Warning on the sleeping table Stilnox (zolpidem) after 1032 reports of adverse reactions to the drug. The warning instructs that the drug may be associated with potentially dangerous complex sleep related behaviours including sleep walking, sleep driving and other bizarre behaviours. Close medical supervision is needed. <sup>126</sup>

## 2007

**August** – The TGA issued an Adverse Reactions Bulletin about newer antipsychotic agents causing extrapyramidal side-effects - EPS (involuntary movements and muscle rigidity). There had been 70 reports for clozapine and 126 reports for olanzapine (Zyprexa). About one third of patients experiencing EPS had not recovered. <sup>127</sup>

**August** – The TGA's drug adverse reaction database revealed there had been 112 notified adverse reactions reports—in 67 separate cases—for antidepressant use among under 10 year olds. These included convulsions, mania, muscle spasms, hallucinations and insomnia. A further 807 adverse health responses, in 495 cases, had been linked to use by youths aged between 10 and 19 years. The reactions for 10 to 19-year olds include 4 deaths. <sup>128</sup>

**June** – The TGA issued an Adverse Reactions Bulletin stating that a range of cardiac disorders are associated with the use of the antipsychotic drug clozapine. A Boxed Warning alerting prescriber is on the product information. Prescribers should be warned that potentially fatal myocarditis (inflammation of the heart muscle) may develop after commencement of Clozapine. <sup>129</sup>

**June** – The TGA issued an Adverse drug Reactions Bulletin for the antidepressant Mirtazapine (Avanza) stating prescribers need to warn patients of potentially life-threatening neutropenia (condition where a type of white blood cells is low) and agranulocytosis failure of bone marrow to make enough white blood cells). <sup>130</sup>

**April** – The TGA issued an Adverse Reactions Bulletin stating that it appears that all of the atypical antipsychotics can cause neuroleptic malignant syndrome - NMS (abnormally high body temperature causing destruction of tissue which can be potentially fatal). They said they have received 85 reports of NMS for clozapine, 49 reports for olanzapine (Zyprexa), 45 reports for risperidone and there were another 46 reports for other antipsychotics. <sup>131</sup>

**April 5** – The Australian Therapeutic Goods Administration requested that the makers of the sleeping drug Stilnox (zolpidem) strengthen the current warning about mixing the medicine with alcohol. This request comes in the wake of more than 500 complaints about Stilnox including reports of sleepwalkers crashing cars, falling off balconies, smoking, painting and having sex after popping a pill. <sup>132</sup>

**February** – The Australian Therapeutic Goods Administration warned that zolpidem (Stilnox) has had a number of side effect reported, of which "75% of the reports received described one or more neurological or psychiatric reactions, especially visual hallucinations, confusion, depression and amnesia." The Advisory Committee is recommending that people need to be alert to these possible side-effects, and doctors need to warn their patients about it. <sup>133</sup>

## 2006:

**October 18 – The TGA** ordered manufacturers of “ADHD” drugs, Ritalin, Strattera and dexamphetamine to add stronger warnings to their information packaging after receiving 200 adverse reaction reports about the drugs. The TGA had received 123 reports of adverse reactions involving Ritalin, including complaints that it caused headache, nausea, anorexia, somnolence and depression as well as 23 reports about atomoxetine (Strattera), including aggression, and 60 reports about dexamphetamine, including seven of agitation, five of tachycardia (rapid heartbeat) and four reports each of hypertonia (abnormally increased muscle tone causing rigidity), hyperkinesia (involuntary movements occurring continuously) and insomnia.<sup>134</sup>

**March 14 – The TGA** ordered a boxed warning (the most serious type of warning) for the risk of suicidal thoughts and behaviours be put onto Strattera, a non-stimulant drug prescribed for ADHD.<sup>135</sup>

## 2005:

**December – The TGA** issued an Adverse Drug Reactions Bulletin stating that the antipsychotics risperidone, fluphenazine, haloperidol, clozapine, olanzapine, pimozide and thioridazine and the antidepressants amitriptyline, imipramine, clomipramine, dothiepin and doxepin can cause a QT prolongation effect. A QT interval is part of the cycle of a heartbeat. A prolongation of the QT interval increases the risk of sudden death from abnormal heart beats and in this case the TGA said it can lead to a life-threatening tachycardia (increased heart rate).<sup>136</sup>

**September 7 – The TGA** issued an information sheet to health professionals warning that SSRI use—especially Paxil—in early pregnancy could cause congenital heart abnormalities in newborns. It reported that Danish researchers had determined the association in the first trimester of pregnancy. It recommended that patients not suddenly stop taking Paxil because “they may have withdrawal effects that can be severe or life-threatening. Dosage must be tapered off....”<sup>137</sup>

**August – The TGA** published an Adverse Drug Reactions Bulletin reporting a review of SSRIs found evidence supporting an association between SSRI use and “new onset of suicidality” (the likelihood of an individual completing suicide) in *adults*. It usually developed shortly after commencing the drugs or after an increase in dosage that could cause akathisia, (the inability to remain motionless) agitation, nervousness and anxiety. Similar symptoms could also occur during *withdrawal*.<sup>138</sup>

## 2004:

**December – The TGA** published an Adverse Drug Reactions Bulletin recommending that any use of SSRIs in children and adolescents should be carefully monitored for the emergence of suicidal ideation. In a recent study involving Prozac, it said, there was an increase in adverse

psychiatric events (acts and ideation [thoughts] of suicide, self-harm, aggression, violence).<sup>139</sup>

**October** – The TGA ordered a new warning be added to the Product Information for tricyclic antidepressants to warn of the risk of suicide by overdose after high dose presentations that can be obtained by patients have been associated with some patient deaths from overdose.<sup>140</sup>

**June** – The TGA published an Adverse Drug Reactions Bulletin reporting that the latest antipsychotics could increase the risk of diabetes.<sup>141</sup>

**February** – The TGA reported they had received 161 reports of serotonin syndrome. Serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea. It is potentially serious. SSRIs, venlafaxine (Efexor) and tricyclic antidepressants can cause this syndrome. In the majority of reports, the signs and symptoms developed within 24 hours of the addition of another serotonergic agent or an increase in dose of an agent. The TGA said health professionals should note that they can cause this and should inform patients of the risk when serotonergic agents are prescribed.<sup>142</sup>

## 2003:

**October** – The TGA reported that new antidepressants Remeron, Avanza and Mirtazon could cause potential serious reactions such as convulsions, blood clots, anxiety, agitation, blood disorders, nightmares, and hallucinations.<sup>143</sup>

**August** – The TGA reported that the use of SSRIs during or after pregnancy may result in adverse reactions to newborn babies, due to the withdrawal effect following intra-uterine exposure, or a toxic effect from ingestion of an SSRI in breast-milk. The withdrawal effects the baby experienced included agitation, jitteriness, poor feeding, sleepiness/lethargy, gastrointestinal symptoms and hypotonia (deficient muscle tone or tension).<sup>144</sup>

**June** – The TGA reported that as a group, SSRIs account for about one-quarter of all reports of hyponatremia (a lower than normal level of sodium in the blood) received by the Australian Drug Reactions Advisory Committee and are second to diuretics as the group most commonly associated with hyponatraemia. In about two-thirds of cases, full recovery followed withdrawal of the SSRI and fluid restriction. Three cases had a fatal outcome related to hyponatraemia.<sup>145</sup>

## 2001:

**February** – The TGA reported that SSRIs have an association with raised internal pressure within the eye.<sup>146</sup>

## 2000:

**February – The** TGA published an Adverse Drug Reactions Bulletin reporting that psychiatric drugs can cause nightmares and specifically mentioned Prozac, Zoloft, Paxil and Celexa. <sup>147</sup>

## 1999:

**December – The** TGA reported that SSRIs and tricyclic antidepressants can cause constipation. 15 reports have also been received for the antipsychotic clozapine and of these 9 were described as severe. <sup>148</sup>

**August – The** TGA issued an Adverse Reactions Bulletin to warn that olanzapine (Zyprexa) can cause serious problems such as white cell disorders, convulsions and neuroleptic malignant syndrome (abnormally high body temperature causing destruction of tissue). They also said that weight gain and somnolence (excessive sleepiness) were the most commonly reported side-effects. To date they had received 327 suspected adverse reactions to the drug. <sup>149</sup>

## 1998:

**August – The** TGA issued an Adverse Reactions Bulletin on SSRIs such as fluoxetine (Erocap, Lovan, Prozac, Zactin), paroxetine (Aropax) and sertraline (Zoloft) stating they have been associated with bruising and bleeding. <sup>150</sup>

**February – The** TGA issued an Adverse Reactions Bulletin reporting that venlafaxine (Efexor), an antidepressant drug appears to have a greater association with nausea/vomiting/anorexia, headache, increased sweating, syncope (fainting caused by a cardiovascular disorder) and hypertension than the SSRIs. <sup>151</sup>

## 1997:

**November – The** TGA issued an Adverse Drug Reactions Bulletin concerning neonates whose mothers had taken SSRIs throughout their pregnancies and have experienced withdrawal reactions. Reports included a 3-day old baby who developed jitteriness, fever and anorexia. Another baby was treated for rapid breathing and irritability for 2 days after it was born. These reports suggest that adverse reactions to SSRIs can occur in neonates, through either placental or breast milk transfer. <sup>152</sup>

## 1996:

**August – The** TGA issued an Adverse Drug Reactions Bulletin on adverse effects of SSRIs. They said the selective serotonin reuptake inhibitors (SSRIs), fluoxetine (Lovan, Prozac,

Zactin), paroxetine (Aropax) and sertraline (Zoloft) are associated with a variety of adverse effects. They found that 2 of the unusual types of adverse effects were urinary problems and sexual dysfunction.<sup>153</sup>

**February** – The TGA issued an Adverse Drug Reactions Bulletin stating SSRIs have been associated with withdrawal syndrome. The symptoms most commonly reported on withdrawal were dizziness (15 reports) and nausea (10). Anxiety, headache (both 5 reports), agitation, insomnia, increased sweating, tremor and vertigo (4 of each), hallucinations, and depersonalisation (3 of each) were also described. There was a total of 51 different symptoms documented in the reports with a wide range of other neurological and psychiatric symptoms including amnesia, ataxia (unstable gait), blurred vision, confusion, dysarthria (dis-coordination of the speech muscles), delirium, fatigue, hyperacusis (abnormally acute hearing), hypertonia (abnormally increased muscle tone causing rigidity), meningism (spasms of the neck muscles caused by inflammation of the membranes around the brain and spinal cord), mood swings, neurosis, nervousness, nightmares, paraesthesia (abnormal skin sensation e.g. burning sensation in the skin), rigors, sensory disturbance, tinnitus (ringing in the ears), and twitching. There was also a report of a neonatal withdrawal reaction.<sup>154</sup>

## 1995:

**November** – The Australian Therapeutic Goods Administration (TGA) issued an Adverse Drug Reactions Bulletin stating that they had received 109 reports of drug-induced pancreatitis and the most commonly reported drugs in association with this included the antipsychotic clozapine and yet this was not at the time listed as a possibility in the Product Information for the drug.<sup>155</sup>

oOOo

---

<sup>1</sup> WHO Resource Book on Mental Health, Human Rights and Legislation, World Health Organisation, 2005, p. 64.

<sup>2</sup> "Mental Health Services in Australia," AIHW, web report, last updated 22 March 2019. <https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/expenditure-on-mental-health-related-services> : "Health expenditure Australia 2010-11. Health and welfare expenditure series no.47. Cat no. HWE 56. Canberra AIHW. <https://www.aihw.gov.au/getmedia/18a4ccff-416b-4b37-adfc-abe52a0c7083/Mental-health-expenditure-2010-11.pdf.aspx>

<sup>3</sup> "Psychiatric labels and kids: benefits, side effect and confusion," *The Conversation*, 25 October 2012.

<sup>4</sup> Margaret Hagen, Ph.D., *Whores of the Court, The Fraud of Psychiatric Testimony and the Rape of American Justice*, 1997, p.42

<sup>5</sup> Allen J Frances, "Psychiatric Fads and Over diagnosis: Normality is an endangered species," *Psychology Today*, 2 June 2010. <https://www.psychologytoday.com/au/blog/dsm5-in-distress/201006/psychiatricfads-and-overdiagnosis>

<sup>6</sup> Bernhard Baune, "Predicting the future course of psychotic illness," *The Conversation*, 8 October 2014. <http://theconversation.com/predicting-the-future-course-of-psychotic-illness-32423>

<sup>7</sup> "Adult ADHD: Guide for the Public", RANZCP website; <https://www.ranzcp.org/Mental-health-advice/guides-for-the-public/Adult-ADHD-Public.aspx>

<sup>8</sup> John Read, "Feeling Sad? It Doesn't Mean You're Sick," *New Zealand Herald*, 23 June 2004.

<sup>9</sup> "QuarterWatch, Monitoring FDA MedWatch Reports, Anticoagulants the Leading Reported Drug Risk in 2011, 31 May, 2012, New Data from 2011, Quarters 3-4," p.2.

<sup>10</sup> Therapeutic Goods Administration Database of Adverse Event Notifications-Medicines, List of reports generated for each antidepressant, as of 03/01/2019 and added manually. <https://www.tga.gov.au/database-adverse-event-notifications-daen>

<sup>11</sup> Richardson Oghuoteru Tachere, Mandana Modirrousta, "Beyond Anxiety and agitations: A clinical approach to akathisia, *AFP*, The Royal Australasian College of General Practitioners, Vol 46, No 5, May 2017, p. 296. <https://www.racgp.org.au/afp/2017/may/beyond-anxiety-and-agitation-a-clinical-approach-to-akathisia/>

<sup>12</sup> Therapeutic Goods Administration Database of Adverse Event Notifications-Medicines, List of reports generated for each antipsychotic, as of 03/01/2019 and added manually. <https://www.tga.gov.au/database-adverse-event-notifications-daen>

- <sup>13</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, "Medicines associated with a risk of neuropsychiatric adverse events," Volume 9, Number 2, June 2018.
- <sup>14</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, "Antidepressants – Communicating risks and benefits to patients," Volume 7, Number 5, October-December 2016.
- <sup>15</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, "Atomoxetine and suicidality in children and adolescents," Volume 4, Number 5, October 2013.
- <sup>16</sup> "Australian ADHD drug warnings are already in place: TGA," AAP Newswire 22 February 2007.
- <sup>17</sup> "Suicidality with SSRIs: adults and children," The Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol. 24, No. 4, August 2005.
- <sup>18</sup> "Use of antidepressants in children and adolescents," The Australian Therapeutic Goods Administration (TGA) Adverse Drug Reaction Bulletin, Vol 23, No 6, December 2004, p. 22.
- <sup>19</sup> Labelling Change Request Letter for Antidepressant Medications – FDA Letter, 15 October 2004; "FDA orders strong black box warnings on antidepressants used by children, *Associated Press Worldstream*, October 2004.
- <sup>20</sup> "Worsening Depression and Suicidality in Patients Treated with Antidepressant Medications," US Food and Drug Administration Public Health Advisory, 22 March, 2004.
- <sup>21</sup> "New advice on prescribing antidepressants," Media release, Ministry of Health, New Zealand, 21 October 2004.
- <sup>22</sup> Veronique Mandal, "Antidepressant: petition targets Wyeth's Effexor; Users want public to know side-effects," *Windsor Star*, September 12 2003; Sharon Kirkey, "Drugs may make youths suicidal, doctors warned; Number of children on psychiatric drugs soaring," *Windsor Star*, 12 September, 2003.
- <sup>23</sup> G.C. Hodding, M. Jann, I.P. Ackerman, "Drug Withdrawal Syndromes: A Literature Review," *The Western Journal of Medicine*, November 1980.
- <sup>24</sup> "Acute Drug Withdrawal," *PreMec Medicines Information Bulletin*, August, 1996, modified 6 January 1997. Internet URL: <http://www.premec.org.nz/profile.htm>.
- <sup>25</sup> "Patient Online Report of Selective Serotonin Reuptake Inhibitor-Induced Persistent Post-withdrawal Anxiety and Mood Disorders," *Psychotherapy and Psychosomatics*, 19 Jan, 2012 <https://www.karger.com/Article/FullText/341178>
- <sup>26</sup> Therapeutic Goods Administration Database of Adverse Event Notifications-Medicines, List of reports generated for each antipsychotic and antidepressant as of 03/01/2019 and added manually. <https://www.tga.gov.au/database-adverse-event-notifications-daen>
- <sup>27</sup> "Table PBS.2: Patients dispensed with mental health related prescriptions by type of medication prescribed and prescribing practitioner, states and territories, 2016-17," *Mental Health Services in Australia, Mental Health related prescriptions*, Australian Government, Australian Institute of Health and Welfare. Table PBS. 5: "Mental Health-related prescriptions, by type of medication prescribed and prescribing practitioner, 2016-17," *Mental Health Services in Australia, Mental Health related prescriptions*, Australian Government, Australian Institute of Health and Welfare. "Table PBS.7: Mental health-related prescriptions by type of medication prescribed and prescribing practitioner, 2005-06 to 2016-17," *Mental Health Services in Australia, Mental Health related prescriptions*, Australian Government, Australian Institute of Health and Welfare. Download this Excel spreadsheet under the first blue bar graphs on webpage. <https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/mental-health-related-prescriptions/prescriptions>;
- <sup>28</sup> <http://cchr.org.au/wp-content/uploads/2016/08/Evidence-of-Cost.pdf>; <http://cchr.org.au/wp-content/uploads/2016/08/Receipt-for-Payment-of-Statistics.pdf>
- <sup>29</sup> John Ferguson, "100,000 children on pills for depression," *The Australian* 3 April, 2019; "Australian Adverse Drug Reactions Bulletin," Volume 24, Number 4, August 2005, p.14.
- <sup>30</sup> "The ECT Guide: The Chief Psychiatrist's Guidelines for the use of Electroconvulsive Therapy in Western Australia 2006," p.83. ; [https://www.chiefpsychiatrist.wa.gov.au/wp-content/uploads/2015/11/CP\\_ECT\\_Guide\\_2006.pdf](https://www.chiefpsychiatrist.wa.gov.au/wp-content/uploads/2015/11/CP_ECT_Guide_2006.pdf) Accessed 3<sup>rd</sup> April 2019.
- <sup>31</sup> Dr. Kuruvilla George, "Effective ECT," *Australian Doctor*, 5 November 2014.
- <sup>32</sup> Dr. John Breeding, author of *Wildest Colts Make the Best Horses*, "Think They Don't Electroschock People Anymore? Think Again—Even toddlers and pregnant women are being shocked," 24 Jan, 2010.
- <sup>33</sup> "Memory and ECT: From Polarization to Reconciliation," Editorial. *The Journal of ECT*, Vol 16, No.2, 2000, pp.87-96.
- <sup>34</sup> Nicky Philips, "ECT patients under anaesthetic for two days," *Sydney Morning Herald*, 18-19 June 2011, p.7.
- <sup>35</sup> John Reed and Richard Bentall, "The effectiveness of electroconvulsive therapy: A literature review," *Epidemiologiae Psychiatria Sociale*, 19 April, 2010, pp. 333-347.
- <sup>36</sup> Mr. Juan E Méndez, Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, 22nd session of the Human Rights Council Agenda Item 3, 4 March 2013, Geneva.
- <sup>37</sup> *Western Australia Mental Health Act 2014*, S 194, p. 145; *Australian Capital Territory Mental Health Act 2015*, s147, p. 178.
- <sup>38</sup> "Electroschock, Sicily has abolished the practice," *Living In Sicily – Vardag På Sicilien*, 6 October, 2013. <http://livinginsicily.eu/tag/ban/>; Zeljko Spiric, Zvezdana Stojanovic, Radomir Samardzic, Srdjan Milovanovic, Gabor Gazdag & Nadja P. Maric, "Electroconvulsive therapy practice in Serbia today," *Psychiatria Danubina*, 2014; Vol. 26, No. 1, pp 66-69.
- <sup>39</sup> *WHO Resource Book on Mental Health, Human rights and Legislation*, World Health Organisation, 2005, p.64.
- <sup>40</sup> Statistics generated on Medicare Australia website using MBS item codes: 14224 for electroconvulsive therapy and 20104 for anaesthetic, [https://www.medicareaustralia.gov.au/statistics/mbs\\_item.shtml](https://www.medicareaustralia.gov.au/statistics/mbs_item.shtml)
- <sup>41</sup> Sarah Farnsworth, "Hundreds of patients forced to have ECT in Victoria without legal representation," *ABC News*, 21 Nov.2016. <https://www.abc.net.au/news/2016-11-20/patients-forced-to-have-ect-without-legal-representation/8030996>
- <sup>42</sup> Sarah Farnsworth, "Hundreds of patients forced to have ECT in Victoria without legal representation," *ABC News*, 21 Nov.2016. <https://www.abc.net.au/news/2016-11-20/patients-forced-to-have-ect-without-legal-representation/8030996>
- <sup>43</sup> Aisha Dow, "Grandfather forced to undergo ECT before 'preventable death,'" *The Age*, 19 April 2018. <https://www.theage.com.au/national/victoria/grandfather-forced-to-undergo-ect-before-preventable-death-20180418-p4zacy.html>
- <sup>44</sup> "Orders for forced 'shock therapy' breached human rights of schizophrenia patients, court rules," *ABC News*, 1 Nov 2018. <https://www.abc.net.au/news/2018-11-01/human-rights-must-be-upheld-forced-shock-ect-therapy-court-rules/10454750> Supreme Court of Victoria at Melbourne Common Law Division Judicial Review and Appeals List, SCI, 2017 02464, PBU V Mental Health Tribunal and Melbourne Health, NJE V Mental Health Tribunal and Bendigo Health, 1 Nov 2018. <http://aucc.sirsidynix.net.au/Judgments/VSC/2018/T0564.pdf>
- <sup>45</sup> Margaret Scheikowski, AAP, "Call to reform mental health practices," *The Australian*, 29 May 2015.



- <sup>46</sup> UN Human Rights Council, Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, 1 February 2013, A/HRC/22/53
- <sup>47</sup> "Aggression & Restraint in Mental Health Facilities in NSW," NSW Health Policy Directive, next Review Date for this publication is 31 December 2019, (original publication date: Date 26 June 2012), p. 9.
- <sup>48</sup> "Misadventure' as psychiatric patient died," WA Today, 22 Nov.2011 <https://www.watoday.com.au/national/western-australia/misadventure-as-psychiatric-patient-died-20111122-1nsoc.html>
- <sup>49</sup> Minh Le Cong, "Chemical restraint or lethal injection?" MJA InSight, 6 March 2017. <https://www.doctorportal.com.au/mjainsight/2017/8/chemical-restraint-or-lethal-injection/>
- <sup>50</sup> Joel Magarey, "Deaths, injuries, trauma the fallout from psychiatric practices," The Australian, 26 July 2013. <https://www.theaustralian.com.au/news/health-science/deaths-injuries-trauma-the-fallout-from-psychiatric-practices/news-story/1e1be5ae62150c5fa23a8424ddf7ddb?sv=73a16caf5355f8475c6d8b2718e55896;>
- <sup>51</sup> "Review of seclusion, restraint and observation of consumers with a mental illness in NSW Health facilities, December 2017, p.ii.
- <sup>52</sup> "Table RP.5: Restraint rate, public acute sector acute health hospital services, states and territories, 2015-16 to 2018-18, Mental Health Services- Restrictive Practices, Australian Institute of Health and Welfare. Download Excel spreadsheet on this link, see under blue bar graph graphs on webpage to download, <https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/restrictive-practices/restraint>; Glossary of terms: <https://www.aihw.gov.au/reports-data/health-welfare-services/hospitals/glossary>
- <sup>53</sup> "Table RP.5: Restraint rate, public acute sector acute health hospital services, states and territories, 2015-16 to 2018-18, Mental Health Services- Restrictive Practices, Australian Institute of Health and Welfare. Download Excel spreadsheet on this link, see under blue bar graph graphs on webpage to download, <https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/restrictive-practices/restraint>
- <sup>54</sup> "Table RP.2: Seclusion data for public sector acute mental health hospital services, states and territories, 2008-09 to 2017-18, Mental Health Services- Restrictive Practices, Australian Institute of Health and Welfare. Download Excel spreadsheet on this link, see under blue bar graph graphs on webpage to download, <https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/restrictive-practices/restraint>
- <sup>55</sup> "Table RP.3: Seclusion data for public sector acute mental health hospital services by target population, 2008-09 to 2017-18, Mental Health Services- Restrictive Practices, Australian Institute of Health and Welfare. Download Excel spreadsheet on this link, see under blue bar graph graphs on webpage to download, <https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/restrictive-practices/restraint>
- <sup>56</sup> Sean Parnell, "Pharma kickbacks stay under the radar," *The Australian*, 8 Feb 2019. <https://www.theaustralian.com.au/nation/health/pharma-kickbacks-stay-under-the-radar/news-story/347f429bb41df823062c1c81d1882e82?login=1>; "Transparency reporting by pharmaceutical industry in decline," The University of Sydney, 7 February 2019. <https://sydney.edu.au/news-opinion/news/2019/02/07/transparency-reporting-by-pharmaceutical-industry-in-decline.html>
- <sup>57</sup> 2017 Financial Report, The Royal Australian and New Zealand College of Psychiatrists, 17 March 2018, p.8. [https://www.ranzcp.org/files/about\\_us/annual-reports-and-strategy/ranzcp-financial-review-2017.aspx](https://www.ranzcp.org/files/about_us/annual-reports-and-strategy/ranzcp-financial-review-2017.aspx)
- <sup>58</sup> Julie-Anne Davies, "GP jaunts 'boosted' drug sales," *The Australian*, 10 July 2010, p.3. <https://www.theaustralian.com.au/news/health-science/gp-jaunts-boosted-drug-sales/news-story/37e3522ccf14533c143f32424d6109aa>
- <sup>59</sup> Ian Hickie, "Is depression over diagnosed? No," *British Medical Journal*, 18 August 2007; National Mental Health Commission - Register of Interests 6 February 2013.
- <sup>60</sup> Patrick D. McGorry, "Early intervention in psychosis," *The Journal of Nervous and Mental Disease*, May 2015. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4414340/> Patrick D. McGorry, "Is early intervention in the major psychiatric disorders justified? Yes," *British Medical Journal*, 4 Aug. 2008. <https://www.bmj.com/content/337/bmj.a695.full>
- <sup>61</sup> Sue Dunlevy, "Us expert slams Patrick McGorry's psychosis model," *The Weekend Australian*, 14 June 2011.
- <sup>62</sup> "headspace Evidence Summary: Identification of young people at risk of developing psychosis," headspace, pp.2,4. <https://headspace.org.au/assets/Uploads/Evidence-Summary-Identification-of-Young-People-at-Risk-Developing-Psychosis.pdf>; "Australian Clinical Guidelines for Early Psychosis," Orygen, Second edition, updated June 2016. pp 7,52. <https://www.orygen.org.au/Campus/Expert-Network/Resources/Free/Clinical-Practice/Australian-Clinical-Guidelines-for-Early-Psychosis/Australian-Clinical-Guidelines-for-Early-Psychosis.aspx?ext>
- <sup>63</sup> "Youth Early Psychosis Program," headspace website accessed 25 March 2019. <https://headspace.org.au/our-services/hypp/>
- <sup>64</sup> headspace website, "Youth Early Psychosis Program: headspace's Youth Early Psychosis Program supports young people experiencing, or at risk of developing psychosis," accessed 23<sup>rd</sup> March 2019; Orygen website, "Clinical Services," accessed 23<sup>rd</sup> March 2019. <https://www.orygen.org.au/Clinical-Services>
- <sup>65</sup> Clinical Services- Orygen. "Other funding," Orygen Youth Health Research Centre, Orygen web page, accessed 18th February 2012. Please contact CCHR if you would like a copy of this reference.
- <sup>66</sup> "Is headspace making a difference to young people's lives? Final report of the independent evaluation of the headspace program," UNSW, 2015 pp.6,42.
- <sup>67</sup> Naomi Neilson, "Government brings Headspace grants to \$208 million in 3 months," *Third Sector*, 10 Jan 2019. <https://thirdsector.com.au/government-brings-headspace-grants-to-208-million-in-3-months/>
- <sup>68</sup> FOI 231-1011, 4 documents, Department of Health Freedom of Information Disclosure Log 2011-12, entry on Department of Health website is dated 23 September 2011.
- <sup>69</sup> The Department of Health and Ageing, FOI Request 025-1516. <http://www.health.gov.au/internet/main/publishing.nsf/Content/foi-025-1516> Alternatively you can request them from CCHR Australia who does have copies of these documents.
- <sup>70</sup> "Patient advocacy groups should disclose their backers," *6 minutes*, 7 March 2017.
- <sup>71</sup> "Patient advocacy groups should disclose their backers," *6 minutes*, 7 March 2017
- <sup>72</sup> <https://aadpa.com.au/about/board-of-directors/> Accessed 4<sup>th</sup> April 2019.
- <sup>73</sup> Janssen Australia website, <http://www.janssen.com/australia/partnerships/healthcare-organisation-support>
- <sup>74</sup> Janssen Australia website, <http://www.janssen.com/australia/our-medicines>, accessed 17<sup>th</sup> May 2018.
- <sup>75</sup> "Summary of Health Consumer Organisations supported by Medicines Australia Members Companies." For the period: 1 January 2017 – 31 December. 2017. Company: Janssen." <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/06/20180630-HCOSR-R5-Janssen.pdf>

- <sup>76</sup> “Summary of Health Consumer Organisations supported by Medicines Australia Members Companies.” For the period: 1 January 2016 – 31 December 2016. Company: Janssen.” <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2013/06/20170630-HCOSR-R4-RFW-JANSSEN.pdf>
- <sup>77</sup> “Summary of Health Consumer Organisations supported by Medicines Australia Members Companies.” For the period: 1 January 2015 – 31 December 2015. Company: Janssen.” <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2013/06/20160630-HCOSR-R3-RFW-JANSSEN.pdf>
- <sup>78</sup> “Summary of Health Consumer Organisations supported by Medicines Australia Members Companies.” For the period: 1 January 2017 – 31 December 2017. Company: Janssen.” <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/06/20180630-HCOSR-R5-Janssen.pdf>
- <sup>79</sup> “Summary of Health Consumer Organisations supported by Medicines Australia Members Companies.” For the period: 1 January 2016 – 31 December 2016. Company: Janssen.” <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2013/06/20170630-HCOSR-R4-RFW-JANSSEN.pdf>
- <sup>80</sup> Summary of Health Consumer Organisations supported by Medicines Australia Members Companies.” For the period: 1 January 2015 – 31 December 2015. Company: Janssen.” <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2013/06/20160630-HCOSR-R3-RFW-JANSSEN.pdf>
- <sup>81</sup> “Summary of Health Consumer Organisations supported by Medicines Australia Members Companies.” For the period: 1 January 2013 – 31 December 2013. Company: Pfizer Australia.” <http://pfizer.com.au/sites/g/files/g10030496/f/201608/PfizerAustralia%20HealthConsumer%20Organisation%20Support2013forMedicinesAustralia%20FINAL.pdf>
- <sup>82</sup> C. Doran, “Christopher Doran: Valuing mental health,” *Medical Journal of Australia Insight*, 29 July 2013; “Report of the National Review of Mental Health Programs and Services Summary,” Australian Government National Mental Health Commission, 30 November 2014, p.8; *Obsessive Hope Disorder: Reflections on 30 years of mental health reform in Australia and visions for the future*, Synopsis, Key Findings, J. Mendoza, A. Bresnan, S. Rosenberg, A. Alison, Y. Gilbert, P. Long, K. Wilson & J. Hopkins, 2013.
- <sup>83</sup> Mental Health Management, Table 13A.34, Table 13A.62, Part E, Chapter 13, Mental Health Management, *Report on Government Services 2019*, Australian Government, Productivity Commission, 30 Jan 2019. <https://www.pc.gov.au/research/ongoing/report-on-government-services/2019/health/mental-health-management/rogs-2019-part-e-chapter13.pdf>
- <sup>84</sup> “Mental Health Complaints Commissioner, Annual Report 2018,” p. 1; “Mental Health Complaints Commissioner, Annual Report 2017,” p.16; Mental Health Complaints Commissioner, Annual Report 2017,” p.16; Mental Health Complaints Commissioner, Annual Report 2014-15,” p.31; <https://www.mhcc.vic.gov.au/resources/publications>
- <sup>85</sup> *Health Care Complaints Commission 2017-18 Annual Report*, p.164, 165. <http://www.hccc.nsw.gov.au/Publications/Annual-Reports>
- <sup>86</sup> *Cardiovascular disease: most deaths and highest costs, but situation improving*, Australian Institute of Health and Welfare, <https://www.aihw.gov.au/news-media/media-releases/2011/2011-mar/cardiovascular-disease-most-deaths-and-highest-co>
- <sup>87</sup> Lorrin M Koran, *Medical Evaluation Field Manual*, Department of Psychiatry and Behavioural Sciences, Stanford University Medical Centre California, 1991, p.4.
- <sup>88</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Medicines associated with a risk of neuropsychiatric adverse events,” Volume 9, Number 2, June 2018.
- <sup>89</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Clozapine and gastrointestinal effects,” Volume 9, Number 2, June 2018.
- <sup>90</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Desvenlafaxine (Pristiq) recommended dose” Volume 9, Number 1, February-March 2018.
- <sup>91</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Lithium level monitoring and toxicity,” Volume 8, Number 4, August-September 2017.
- <sup>92</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Aripiprazole and impulse control disorders,” Volume 8, Number 1, February 2017.
- <sup>93</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Antidepressants – Communicating risks and benefits to patients,” Volume 7, Number 5, October-December 2016.
- <sup>94</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Risperidone and risk of cerebrovascular adverse events in dementia patients,” Volume 6: Number 4, August 2015.
- <sup>95</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Agomelatine (Valdoxan) – monitoring of liver function,” Volume 6: Number 2, April 2015.
- <sup>96</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Methylphenidate and priapism,” Volume 5: Number 5, October 2014.
- <sup>97</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Bupropion and serious cardiovascular adverse events,” Volume 5: Number 5, October 2014.
- <sup>98</sup> Department of Health and Ageing Therapeutic Goods Administration, Safety Advisory, “Serotonin-blocking medicines used to treat nausea and vomiting,” 22 September 2011; Sunalie Silva, “Watch for serotonin syndrome: TGA,” *Medical Observer*, 23 September 2014.
- <sup>99</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Zolpidem (Stilnox) and next day impairment,” Volume 37: Number 4, August 2014.
- <sup>100</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Quetiapine and QT prolongation,” Volume 5: Number 1, February 2014.
- <sup>101</sup> “Rescheduling of alprazolam to a Schedule 8 drug,” Health alerts, RACGP, 11 December 2013.
- <sup>102</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Duloxetine and serotonin syndrome,” Volume 36: Number 6, December 2013.
- <sup>103</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Atomoxetine and suicidality in children and adolescents,” Volume 4, Number 5, October 2013.
- <sup>104</sup> Australian Public Assessment Report for Lisdexamfetamine dimesilate, Australian Government Department of Health, Therapeutic Goods Administration, October 2013, pages. 6 & 88; Attachment 1 of Australian Public Assessment Report for Lisdexamfetamine dimesilate, Australian Government Department of Health, Therapeutic Goods Administration, October 2013, “Product Information for AusPAR Vyvanse: Lisdexamfetamine; Shire Australia Pty Limited PM-2012-01494-3-1 Date of Finalisation 23 October 2013.
- <sup>105</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, “Zolpidem: continued reporting of abnormal sleep-related events and amnesia,” Volume 35: Number 3, June 2012.

- 
- <sup>106</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update, "Citalopram and QT prolongation- important changes to the dosing recommendations," and "Atomoxetine (Strattera) – risk of increased blood pressure and/or heart rate," Volume 35: Number 1: February 2012.
- <sup>107</sup> Department of Health and Ageing Therapeutic Goods Administration, Safety advisory, "Citalopram and heart problems – changes to recommended doses" 4<sup>th</sup> November 2011.
- <sup>108</sup> Department of Health and Ageing Therapeutic Goods Administration, Safety advisory, "Atomoxetine (Strattera) – risk of increased blood pressure and /or heart rate" 2<sup>nd</sup> November 2011.
- <sup>109</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update "Modafinil (Modavigil) – safety update" Volume 2: Number 5, October 2011.
- <sup>110</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update "Venlafaxine and stress cardiomyopathy," Volume 2, Number 4, August 2011.
- <sup>111</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update "In utero antipsychotic exposure and neonatal extrapyramidal and withdrawal adverse effects" Volume 2, Number 4, August 2011.
- <sup>112</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update "Drug-induced hyponatraemia" Volume 2, Number 2, April 2011.
- <sup>113</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update "Clozapine and severe constipation" Number 1, 2011.
- <sup>114</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update "Drug interaction between tamoxifen and antidepressants" Number 1, 2011.
- <sup>115</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update "Drug Induced Acute Akathisia" Number 6, 2010.
- <sup>116</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update "Serotonin Syndrome" Number 6, 2010.
- <sup>117</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update "Lamotrigine and serious skin reactions" Number 6, 2010.
- <sup>118</sup> Department of Health and Ageing Therapeutic Goods Administration, Medicines Safety Update "Drug Induced Pancreatitis and exenatide (Byetta)" Number 3, 2010
- <sup>119</sup> *Report of the Psychiatric Drug Safety Expert Advisory Panel 2009, "Consolidated Recommendations"*, pp VI to VIII.
- <sup>120</sup> "Washout or tapering when switching antidepressants," Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin, Volume 28, Number 5, October 2009
- <sup>121</sup> "Serotonin syndrome with duloxetine," Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin, Volume 28, Number 4, August 2009.
- <sup>122</sup> "Serious reaction reminders...sodium valproate and foetal malformations," The Australian Therapeutic Goods Administration Adverse Drug Reaction Bulletin, Vol. 28, No. 2, April 2009.
- <sup>123</sup> "Boxed Warning, Contraindications and strengthened Precautions for Methylphenidate," Janssen-Cilag, February 2009.
- <sup>124</sup> Adverse Drug Reactions Advisory Committee, Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin, Vol. 27, No. 6, December 2008.
- <sup>125</sup> "Drug-induced Hyponatraemia," Australian Therapeutic Goods Administration Adverse Drug Reaction Bulletin, Vol. 27, No. 5, October 2008.
- <sup>126</sup> "Zolpidem ("Stilnox") - updated information - February 2008," Australian Therapeutic Goods Administration, February 21, 2008.
- <sup>127</sup> "Atypical antipsychotic agents and extrapyramidal side-effects," Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin, Vol. 26, No. 4, August 2007.
- <sup>128</sup> Therapeutic Goods Administration Summaries 0-9 & 10-19-year olds, Reports run on 16 August 2007.
- <sup>129</sup> "Clozapine and myocarditis," Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin, Vol. 26, No. 3, June 2007.
- <sup>130</sup> "Mirtazapine and blood dyscrasias" Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin, Vol. 26, No. 3, June 2007.
- <sup>131</sup> "Aripiprazole and Neuroleptic Malignant Syndrome," Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin, Vol. 26, No. 2, April 2007.
- <sup>132</sup> "Report of TGA regulatory actions related to zolpidem ("Stilnox")," Therapeutics Goods Administration, April 2007.
- <sup>133</sup> "Zolpidem and bizarre sleep related effects," Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin, Vol. 26, No. 1, February 2007.
- <sup>134</sup> "ADHD drug risks for kids", The Australian, Matthew Franklin, October 18, 2006.
- <sup>135</sup> "Australian ADHD drug warnings are already in place: TGA," AAP Newswire 22 February 2007
- <sup>136</sup> "Medicines and QT prolongation," Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin, Vol. 24, No. 6, December 2005.
- <sup>137</sup> "General information concerning use of SSRI antidepressants in pregnant women" Australian Government, Department of Health and Ageing September 7, 2005.
- <sup>138</sup> "Suicidality with SSRIs: adults and children," The Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol. 24, No. 4, August 2005.
- <sup>139</sup> "Use of SSRI antidepressants in children and adolescents" The Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol. 23, No. 6, August 2004.
- <sup>140</sup> "Warnings for high dose tricyclics antidepressants," The Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol. 23, No. 5, October 2004.
- <sup>141</sup> "Atypical Antipsychotics and Hyperglycemia," Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin, Vol. 23, No. 3, June 2004.
- <sup>142</sup> "Serotonin Syndrome," Australian Therapeutic Goods Administration Adverse Drug Reactions, Vol. 23, No. 1, February 2004.
- <sup>143</sup> "Convulsions and Blood Dyscrasias with Mirtazapine," The Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol. 22, No. 5, October 2003.

- 
- <sup>144</sup> "Maternal SSRI Use and Neonatal Effects," The Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol 22, No. 4, August, 2003.
- <sup>145</sup> "Hyponatraemia with SSRIs," The Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol 22, No. 3 June 2003.
- <sup>146</sup> "SSRIs and increased intraocular pressure," The Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol 20, No. 1, February 2001.
- <sup>147</sup> "Drug-induced nightmares," Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol. 19, No. 1, February 2000.
- <sup>148</sup> "Constipation: It can be severe with clozapine," Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol. 18, No. 4, December 1999.
- <sup>149</sup> "Olanzapine, neutropenia, convulsions and NMS," Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol. 18, No. 3, August 1999.
- <sup>150</sup> "Bruising and bleeding with SSRIs," Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol. 17, No. 3, August 1998.
- <sup>151</sup> "Venlafaxine: not just an SSRI" The Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin, Vol 17, No. 1 February 1998.
- <sup>152</sup> "SSRIs and neonatal disorders..." Therapeutic Goods Administration, Australian Adverse Drug Reactions Bulletin Volume 16, Number 4, November 1997.
- <sup>153</sup> "SSRIs and genitourinary disorders," Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin Volume 15, Number 3, August 1996.
- <sup>154</sup> "SSRIs and withdrawal syndrome" Australian Therapeutic Goods Administration, Adverse Drug Reactions Bulletin Volume 15, Number 1, February 1996.
- <sup>155</sup> "Drug-induced pancreatitis" Australian Therapeutic Goods Administration Adverse Drug Reactions Bulletin Volume 14, Number 4, November 1995.

© 2019 CCHR Australian National Office. All rights reserved. CCHR and the CCHR logo are trademarks and service marks owned by the Citizens Commission on Human Rights.