

# **INTENTIONAL SELF-HARM AND SUICIDAL BEHAVIOUR IN CHILDREN**



SUBMISSION TO THE CHILDREN'S COMMISSIONER FROM THE  
AUSTRALIAN NATIONAL OFFICE OF THE INTERNATIONAL ORGANISATION  
THE CITIZENS COMMISSION ON HUMAN RIGHTS

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1. The Citizens Commission on Human Rights 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. There are hundreds of chapters in 34 countries around the world. In Australia CCHR is known as the Citizens Committee on Human Rights.
2. The main task of CCHR has been to reform mental health and preserve individuals' 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 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.
3. Recently CCHR has been conducting education campaigns to protect children from the trauma of restraint, the harm of electroshock (ECT) and psychosurgery in various states of Australia where Mental Health Acts are 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> Currently no Australian state bans the use of ECT on children.

In 2011, WA issued a draft Mental Health Bill which proposed to allow children of any age, 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 be 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 Draft Bill. In addition the age at which a child could consent to electroshock and psychosurgery was lifted to over 14 years. CCHR, other concerned groups and professionals continued to educate the public and late last year the psychosurgery ban was lifted again to under 16. The new WA Mental Health Act has passed the Legislative Assembly with these changes and is currently with the Legislative Council.

4. 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.
5. While CCHR does not provide medical or legal advice, it works closely with and supports medical doctors and medical practice. Medical drugs are essential for treating and curing disease but the same cannot be said of psychiatric drugs which can seriously adversely affect children as this submission will outline.

# INTRODUCTION

6. Many people think that psychiatric disorders, such as depression, 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. To have them think the problems their child is experiencing is the result of a “chemical imbalance in the brain,” requiring mind-altering medication, is false and potentially very harmful, especially since there is no test to prove the child has a chemical imbalance of the brain and many of the subsequent drugs prescribed are well documented to cause harm, including suicidal thoughts and suicidal behaviour.
7. This does not mean that serious emotional difficulties do not exist, 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 is the issue under question.
8. The Australian Government have not 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.<sup>2</sup>
9. Australia and other countries have issued warnings that antidepressants can cause suicidal ideation and behaviour. Side-effects reported to Australia’s drug regulatory agency evidenced in the Therapeutic Goods Administration Database of Adverse Events Notifications also contain ample evidence that antidepressants, antipsychotics and ADHD drugs are linked to self-harm, suicidal behaviour and suicide in children.
10. As early as 1995, nine Australian psychiatrists reported that patients had slashed themselves or become pre-occupied with violence while taking SSRIs “I didn’t want to die, I just felt like tearing my flesh to pieces,” one patient told psychiatrists.<sup>3</sup>
11. Psychiatrist Peter Breggin says that adverse drug reactions to SSRIs range from mild agitation to manic depression, agitated depression, obsessive preoccupations that are alien or uncharacteristic of the individual and akathisia (inability to remain still or motionless). In addition, “Each of these reactions can worsen the individual’s mental condition and can result in suicidality, violence and other forms of extreme abnormal behaviour.”<sup>4</sup>
12. In 2005, there were 8 published and 16 unpublished randomised controlled trials of newer antidepressants in children. None of the unpublished and only half the published studies show any advantage over placebo on the pre-specified primary outcomes. Only one-third of all published measures (all of these physician-rated rather than self-or parent-rated) favour drug over placebo. Australian psychiatrist Dr. Jureidini said, “...we have poor evidence of efficacy, small but significant increases in suicide risk, and significant, probably underestimated, adverse events. The evidence therefore shows us that antidepressants are not demonstrably ‘better than nothing’ and may be worse.” Further he stated, “Such prescribing, based on faith or hope that antidepressants may actually be better than the evidence indicates, risks contravening the injunction to ‘first do no harm.’”<sup>5</sup>
13. In 2008, during a US law suit it was revealed that GlaxoSmithKline knew as early as 1989 that the antidepressant Paxil increased suicidal behaviour in patients by more than 8-fold compared to patients who received placebo, but did not inform health care professionals by letter until May 2006. In too many

cases psychiatrists and pharmaceutical companies have used difficulties experienced by children and adults to their advantage, promoting powerful drugs as a “solution” for vulnerable children and adults which has led to dire and sometimes fatal consequences.<sup>6</sup>

14. In April 2013 it was announced that Eli Lilly had settled a long-running wrongful death lawsuit filed by parents of a South Dakota boy who committed suicide four weeks after taking the antidepressant Cymbalta (duloxetine). Terms were not disclosed by the court. There have also been cases confidentially settled in the US where Eli Lilly was sued for failure to divulge suicidal inclinations linked to Prozac.<sup>7</sup>
15. Last October Australian Federal Member of Parliament, Alannah McTiernan said that she believed that the Australian Government was leaving itself open to legal action if continuing reports of side-effects are ignored for the ADHD drug Strattera after it was revealed there had been 28 reports of suicidal thoughts in children, some as young as 7. “There are question marks about the way it got onto the Pharmaceutical Benefits Scheme,” she said.<sup>8</sup>
16. Despite claims from psychiatrists that their drugs actually *prevent* suicide, one National Survey of Mental Health and Wellbeing found that more than 73% of people who reported making a suicide attempt had used mental health services in the previous 12 months.
17. The cause of the problem for each and every child can vary and finding the actual cause of the problem and rectifying that will lead to many more children recovering and leading happier and healthier lives. 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 disappear.
18. The Children’s Commissioner is commended for looking into how prescribing of psychiatric drugs contributes to the rates of suicide and self-harm in Australian children.<sup>9</sup>

## SUBMISSION

### **The Diagnosis of Psychiatric Disorders which Leads to Prescription for Psychiatric Drugs Known to Cause Self-Harm and Suicide**

19. While mainstream physical medicine deals with diseases such as malaria, bronchitis and hepatitis that have exact, identifiable physical causes, psychiatry deals with disorders. Disorders are names given to undesirable feelings and behaviour but 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.

20. Science is the systematically arranged knowledge of the material world which has been gathered in a four step process:

1. Observation of phenomena
2. Collection of data
3. Creation of a hypothesis or theory by inductive reasoning and
4. 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.

21. 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>10</sup>
22. While feelings of depression are very real, there are no scientific tests to diagnose depression as a medical illness. *The Diagnostic and Statistical Manual of Mental Disorders DSM-IV-TR* (DSM) used by psychiatry in Australia to "diagnose" disorders is not based on science. This is a fact that is not known by all those who are doing their best to assist parents and children and those responsible for the funding of mental health services for children. In the section on depression of the DSM on page 352 it states, "No laboratory findings that are diagnostic of Major Depressive Disorder have been identified." Similar wording appears under Bipolar Disorder (on page 384).
23. There are also no tests to prove a child has ADHD which once a child is diagnosed with, they could be prescribed the non-stimulant drug Strattera (atomoxetine, an antidepressant with warnings for suicidal behaviour). The DSM entry for ADHD states "There are no laboratory tests, neurological assessments or attentional assessments that have been established as diagnostic in the clinical assessment of Attention Deficit/Hyperactivity Disorder."<sup>11</sup>
24. Australian psychiatrist George Halasz said with regards to ADHD, "First there is no blood test; second, there is no X-ray; third there is no brain scan to diagnose ADHD."<sup>12</sup>
25. "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," says John Read, senior lecturer in psychology, Auckland University, New Zealand.<sup>13</sup>
26. Psychiatrist, David Kaiser says, "...modern psychiatry has yet to convincingly prove the genetic/biologic cause of any single mental illness...Patients[have]been diagnosed with 'chemical imbalances' despite the fact that no test exists to support such a claim, and...there is no real conception of what a correct chemical imbalance would look like."<sup>14</sup>

27. 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 about near "epidemic" rates of mental illness. Along with this comes the demand for more funds. After World War II, one in 20 were said to be mentally ill. Yet rather than reduce this rate as one would expect would be occurring if psychiatry were working and providing effective treatment, psychiatry now says one in five is mentally ill and half of us in Australia will experience mental ill health during our lifetime. This statement is without any scientific evidence.

## **Australian and International Drug Warnings for Suicide and Self-harm**

28. There have been at least 37 drug regulatory agency warnings from 11 countries to warn that antidepressants can cause suicide/risks/attempts and 8 warnings for self-harm. To put a child onto these drugs for something that cannot be scientifically proven to exist and without a thorough investigation to locate the cause of the problem can be potentially fatal for the child and cause great tragedy for the child and family as the many drug warnings indicate.
29. In 2004 the United States drug regulatory agency the Food and Drug Administration conducted a comprehensive review of all the available published and unpublished controlled clinical trials of antidepressants in children and adolescents. They found that about 4 percent of those taking SSRIs experienced suicidal thinking or behaviour, including actual suicide attempts which was twice the rate of those taking placebo, or sugar pills.<sup>15</sup>
30. In response to this review, the United States drug regulatory agency the Food and Drug Administration (FDA) ordered the strongest warning that can be placed on a drug, — a "Black Box Warning" for the risk of suicide in children and adolescents who take SSRI antidepressants. The latest version of this Black Box Warning includes the following text, "Suicidality and Antidepressant Drugs: Antidepressants increase the risk compared to placebo of suicidal thinking and behaviour (suicidality) in children, adolescents, and young adults in short term studies of major depressive disorder (MDD) and other psychiatric conditions."<sup>16</sup>
31. Australia does not have this Boxed Warning for antidepressants and despite considering one in the past, it has not eventuated. The only antidepressant with a boxed warning related to suicide in Australia is for the failed antidepressant atomoxetine, which is used as a non-stimulant ADHD drug.
32. In April 2010, **a Harvard study was published in *Pediatrics*, the first long-term study of antidepressants causing suicide in youths. They found that while the risk of suicide did not vary among users of different antidepressants, however cumulatively they found five times the suicide rate compared to the general population.** Furthermore this study followed 20,906 children aged 10 to 18 years in British Columbia prescribed an antidepressant over a nine-year period. In the first year of use, there were 266 attempted suicides. The study concluded that the decision by the US Food and Drug Administration to include all antidepressants in the black box warning regarding potential for increased suicidality was supported by this study.<sup>18</sup>
33. Below are a selection of international and Australian drug warnings relating to suicide:

**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>19</sup> Wyeth issued the same warning to doctors in New Zealand<sup>20</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>21</sup>

**October 2004:** The US Food and Drug Administration (FDA) ordered pharmaceutical companies to add a “black box” to SSRI antidepressant packaging, warning that the drugs could cause suicidal thoughts and actions in children and teenagers.<sup>22</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>23</sup>

**August 2005:** The Australian Therapeutic Goods Administration published Adverse Drug Reaction Bulletin reporting evidence supporting an association between SSRI use and new onset suicidality in adults and children. 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.

**See Appendix 1**

**March 2006:** The TGA ordered a Boxed Warning (the most serious type of warning) for the risk of suicidal thoughts and behaviours be put onto the non-stimulant ADHD drug Strattera, (atomoxetine, an antidepressant).<sup>24</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. 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>25</sup>

34. In addition to drug warnings, the Australian Product Information (PI—which doctors, pharmacists and other health professional’s use) for ADHD drugs lists suicide as a potential side-effect. The PI for Ritalin (methylphenidate) for example lists the possibility of suicide as an adverse reaction (including completed suicide) and states that adverse events since market introduction include suicide, suicide attempt and suicidal ideation.<sup>26</sup>
35. Alarming any 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”. It is called a “Boxed Warning” because this warning is placed in a text box within the PI. The information is placed within the CMI but not in the exact same words and **not** within a box.
36. Therefore parents do not always know that the strongest warning that can be issued for a drug in Australia has been placed on the drug proposed for their child. It is left to the parent to independently research the drug further themselves on the internet or in a library and locate the relevant PI for the drug. They can 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.

37. Even the CMI is not always given to a consumer each and every time they fill a prescription for a psychiatric drug. This is despite the fact that pharmacists are paid 10 cents per prescription by the Government to distribute the CMI. Not all psychiatric drugs in Australia have information within the packet from the maker. In many cases these above situations prevents parents from being fully informed at time of prescribing or filling a prescription and so being unaware that their child needs to be monitored for suicide. Coupled with the fact that not all psychiatrists inform their patients of all warnings and potential side-effects for the drug, parents are not always able to give fully informed consent for any psychiatric drug proposed as treatment for their child.

## **Adverse Drug Reactions Reported to Therapeutic Goods Administration in Australian**

38. Experts say that overall it is thought that less than 1% of Adverse Drug Reactions are reported in Australia and many more go undetected. The FDA in the US also estimates that only 1% of all serious adverse events are reported to it. This illustrates that the numbers of side-effects reported for self-harm and suicidality in children can only be the tip of the iceberg.<sup>27 28</sup>
39. 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 parents, those who work with children and public. For example the Public Case Details contain such information as:
- A 16 year old girl “made 2 suicide attempts since starting drug [Lovan], nil previous.” Under treatment it states, “Drug ceased.”
  - A 9 year old boy on the antidepressant Lovan 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 and information contained on the Public Case Detail report included, “Depression, crying, saying he wants to kill himself. Tried to run in front on 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 eg 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.”



To view the above adverse reactions and further samples of Public Case Details for suicide, suicidality and self-harm. **See Appendix 2**

40. 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 antidepressants including a break-up of the type of reaction as well as request this data specifically for children. To obtain these figures now, one has to generate a report for each drug on the TGA website and add the various types of reactions together for each drug—an onerous task.
41. CCHR has generated the statistics for the numbers of reported adverse reactions from the TGA website in relation to suicide and self-harm (as of February 2014—the latest statistics). These figures show that there have been nearly 1,100 adverse reactions reported for suicide and self-harm linked to antidepressants, antipsychotics and ADHD drugs. With around 1% of adverse drug reactions reported, the real figure could be up to 110,000 adverse drug reactions. With 30 children aged between 10 and 19 reported as attempting suicide while on an antidepressant by mid-2011, the real number of suicide attempts by children can only be alarmingly high.
42. Below are the statistics. The second column contains the numbers of reactions for children obtained from the TGA in mid-2011. If the Children’s Commissioner has not already requested a Medicine Summary with the numbers of reactions specifically for children to the present date, it would be well worth requesting this from the TGA.

- **ANTIDEPRESSANTS:**

<b>Reactions for all Ages by 2014</b>	<b>Reactions for children by mid-2011</b>
1. Suicidal ideation: 305	(21 were children aged between 10 & 19)
2. Suicide attempt: 231	(30 were children aged between 10 & 19)
3. Completed suicides: 51	(2 were children aged between 10 & 19)
4. Suicidal behaviour: 15	(3 were children aged between 10 & 19)
5. Suicidal depression: 2	
6. Intentional self-harm: 25	(4 were children aged between 10 & 19)
7. Self-injurious behaviour: 19	(8 were children aged between 10 & 19)
8. Self-injurious ideation: 16	(1 was a child aged between 10 & 19) <sup>29</sup>
<b>Total: 664</b>	<b>Total: 69</b>

- **ANTIPSYCHOTICS:**

<b>Reactions for all Ages by 2014</b>	<b>Reactions for children by mid-2011</b>
1. Suicidal ideation: 136	(3 were children aged 10 to 19) (3 were children under 9)
2. Suicide attempt: 117	(9 were children aged 10 to 19)
3. Completed suicide: 52	

4. Suicidal behaviour: 8
5. Suicidal depression: 2
6. Intentional self-harm: 11 (2 were children aged 10 to 19)  
(1 was child under 9)
7. Self-injurious behaviour: 12 (3 were children aged 10 to 19)  
(1 was child under 9)
8. Self-injurious ideation: 3

**Total: 341**

**Total: 22**

- **ADHD DRUGS:**

1. Suicidal ideation: 51
2. Suicide attempt: 9
3. Completed suicide: 3 (includes suicide of 9 year old)
4. Suicidal behaviour: 2
5. Intentional self-harm: 6
6. Self-injurious behaviour: 7
7. Self-injurious ideation: 2

**Total: 80**

## Withdrawal from Antidepressants

43. Psychiatrists say that antidepressants are not addictive but this is not true. Withdrawal Syndrome can occur when a psychiatric drug is reduced, ceased or when switching to another psychiatric drug. Parents and patients are not always told about withdrawal syndrome or that they should not just stop taking a psychiatric drug without medical assistance which can have severe consequences. Depression and anxiety are common symptoms when withdrawing and the depression can be worse than the original depression an antidepressant was prescribed to treat in the first place. Consequently patients are often told that the withdrawal symptoms are a return of the "mental illness" and medication is resumed.
44. Withdrawal side effects have long been known about. In 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>30</sup>
45. In 1996, the National Preferred Medicines Center 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>31</sup>

46. In January 2001 *Australian Prescriber* published an article on ceasing antidepressants written by a Victorian psychiatrist and Victorian researchers. They wrote, "Discontinuation reactions may have physical or psychological symptoms, which appear after stopping or reducing the dose of medication... These are distinct from symptoms of depression..." The article also covered that discontinuation effects are also common after withdrawal of MAOIs (a class of antidepressant) and the effects include, paranoid delusions, aggressiveness, hallucinations, depression and **suicidality**.<sup>32</sup>
47. In August 2005, the TGA published an Adverse Drug Reactions Bulletin reporting a review of SSRIs which found evidence supporting an association between SSRI use and "new onset of suicidality" 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>33</sup>
48. By February 2014, adverse reactions for withdrawal syndrome and withdrawal convulsions reported to the TGA for antidepressants and antipsychotics were 1,059 (for all ages).

## Off Label Prescribing

49. Despite the fact that no antidepressant is registered for the treatment of depression in Australia for children under 18, they are still prescribed and funded on the Pharmaceutical Benefits Scheme by the Federal Government- a situation which defies logic, that the Government would fund drugs for which they have themselves not registered for a particular use. It is of even greater concern when these drugs can cause suicidal behaviour and self-harm. A search of the Pharmaceutical Benefits Scheme used by doctors for Efexor and Zoloft for example, provides the information that they have a "Restricted Benefit" which says it is for "major depressive disorders." No mention is made of the fact these drugs are not registered for use in depression in children under 18 which can only be leading to more off label prescribing of these potentially harmful drugs to children when they should not be prescribed.
50. In 2008 when it was revealed that nearly 4,000 Australian children under 10 were prescribed an antidepressant (500 of those aged 1 to 5), psychiatrist Professor Gordon Parker said, "When the particular drugs are considered, the risk of significant side-effects – let alone their efficacy – is of key concern. It strikes me that there would be wisdom in having the doctors justify such prescriptions to determine whether there are any justifiable reasons for such surprising data."<sup>34</sup>
51. Figures obtained from the Department of Health by CCHR for 2009/10, show that there were a staggering 26,605 children under the age of 16 who were prescribed an antidepressant on the Pharmaceutical Benefits Scheme. Astoundingly, 1,264 of those were aged between 2 and 6 years.
52. No-one is currently taking responsibility for the off label prescribing of antidepressants or other psychiatric drugs to children. This was evidenced when the Parliamentary Secretary for Health asked the TGA to investigate if there were any methods for reining in inappropriate prescribing regarding the use of Ritalin in pre-schoolers against manufacturer's advice. The Parliamentary Secretary for Health then said 2 days later that state Medical Boards were the best place to investigate patient concerns on prescribing. In response the NSW Medical Board said they "...would only act where prescribing went against recommendations by doctor's professional bodies."<sup>35</sup>

53. In 2011, when traces of antidepressants which are linked to suicide in children, were found during post mortems of 2 Qld teenagers who hung themselves within weeks of each other, Pfizer's response was that neither venlafaxine (Efexor) nor Zoloft should be prescribed to teenagers and that they would immediately alert the TGA about the deaths. Ultimately nothing is ever done to protect children in this area, with leading authorities saying it is not their responsibility.<sup>36</sup>
54. 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 N.S.W. it would still be legal. If specific psychiatric drugs are not registered for a specific use they should not be able to be used outside the specific registered use by law.

## **Numbers of Australian Children on Psychiatric Drugs**

55. A Freedom of Information request in 2012 showed that prescriptions for antipsychotics given to Australian children had doubled in 5 years and antidepressant prescriptions had also risen, bucking international trends to reduce the use of the drugs after they were linked to children developing suicidal thoughts. In the US after the FDA issued a warning about the risk of suicide in children and teenagers taking antidepressants, there was a 58% drop in the use of the drugs.<sup>37</sup>
56. With the potential for psychiatric drugs to cause serious harm to children, it is vital that Australia authorities know how many of its children are on a psychiatric drug and that these statistics are published, completely transparent and monitored. These figures are vital to compare the increasing rate of suicide and self-harm in children with the escalation of prescribing of psychiatric drugs. These figures are not currently published by age, state and drug, effectively hiding what is going on. Obtaining them now costs thousands of dollars (previously the Department of Health would provide them at no charge when requested). It should not be a question of even requesting the information; the statistics should be published yearly as should prescription numbers by age, state and drug.

## **Conflicts of Interest**

57. Conflicts of interest between psychiatrists and pharmaceutical companies is an area which drives up the use of antidepressants and other psychiatric drugs. This area should be closely looked into when a psychiatrist or organisation says that antidepressants should be prescribed to children when the government has not registered their use for depression in children under 18 and even the manufacturers say they should not be prescribed to children under 18 for depression.
58. Conflicts of interest were very much evidenced in the re-write drafting of Australia's ADHD Guidelines which initially recommended that for moderate to severe ADHD, drugs be used as a first line treatment for children. The Chair of the Committee of the re-write of the Guidelines had been an advisor to Novartis who make Ritalin and also Eli Lilly who make the ADHD drug Strattera, an obvious conflict of interest which once exposed in media resulted him in resigning as Chair though he remained on the Committee. Further, 7 other Committee members had connections to pharmaceutical companies including 2 others who had served on advisory committees for makers of ADHD drugs.

59. The Guidelines heavily promoted ADHD drugs while at the same time saying that sugar did not affect a child's behaviour and that unharmed solutions which have worked for many parents such as elimination or restrictive diets may be of little or no benefit. These Guidelines have still not been finalised by the National Health and Medical Research Council after many years due to conflicts of interest involved in the process. Specifically, more than 70 of the studies cited as references to support the recommendations in the ADHD Guidelines involved a Harvard University psychiatrist (Dr Joseph Beirderman) who was under U.S. Congressional investigation for his undeclared financial ties to drug companies that paid him US\$1.6 million during a seven-year period.
60. "Psychiatry's statistics are grossly exaggerated says Melissa Raven, a lecturer in public health at Flinders University in Australia stating that the promotion of depression is "disease mongering" aimed at protecting a multi-million dollar yearly market.<sup>38</sup>
61. The authors of the first comprehensive analysis of long-term trends in Australian psychotropics prescribing since 1987 found that prescribing had increased 58% between 2000 and 2011. They concluded, "The increasing reliance on psychotropic medications...generated considerable controversy, especially given current concerns about the influence of the pharmaceutical industry on treatment practices and the absence of an improvement in the mental health of Australians."<sup>39</sup>
62. The Royal Australian and New Zealand College of Psychiatrists (RANZCP) received at least \$757,000 between 2006 and 2010 just for sponsorship and exhibitor fees for their conferences from pharmaceutical companies. RANZCP do not publish the total amount of funds they receive from pharmaceutical companies.
63. 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 who were advising the Minister for Mental Health on reforming mental health in Australia in 2011.<sup>40</sup> Professor Hickie has served on the professional advisory boards convened by 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, Professor Hickie further declared he had received travel support from Servier and Astra Zeneca and in the area of paid educational seminars/resources declared the involvement of 4 drug companies.<sup>41</sup>
64. Professor McGorry has received unrestricted research grants from Janssen-Cilag, Eli Lilly, Bristol Myer Squibb, Astra-Zeneca, Pfizer and Novartis. He has acted as a paid consultant for, and has received speakers fees and travel reimbursement from all or most of these companies.<sup>42</sup>

## **Informed Consent**

65. It is of major concern that parents and those who care for children are not adequately informed about the treatment and "disorder" they will be subject to. Parents and guardians should be factually informed about the side-effects of any proposed treatments including psychiatric drugs so they can make a fully informed choice regarding any treatment proposed.

66. The NSW Bureau of Health Information released very concerning information in 2013 after a survey of 1,028 mental health patients who were asked about the quality of their care. Only 30% of those surveyed said they were completely informed about the side-effects of the drugs given to them and a staggering 55% said they felt they couldn't refuse medicine or treatment.<sup>43</sup>
67. Unless educated, parents can be swayed into accepting that taking a mind altering antidepressant is the only way to resolve their child's emotional upheaval. Also of major concern is that anyone on an SSRI is meant to be monitored for the emergence of suicidality and self-harm thoughts and behaviour. If parents and family members are not told this and do not receive the Consumer Medicine Information as previously stated above, then they can't monitor their child or family member or know themselves, that SSRIs can cause suicide.
68. Parents should also be informed that withdrawal symptoms include anxiety, agitation and aggression and that withdrawal can also cause suicidal thoughts.
69. For fully informed consent to be obtained parents must be given information including the fact that there is controversy surrounding the "disorder/s and treatments," the specific nature of the psychiatric drugs and their side-effects and the alternative treatments that are available for the depression or problems they are experiencing.
70. In this way informed consent will actually become a reality and funds should be expended in this area to protect children and indeed the general public.

## **Alternatives to psychiatric drugs and providing real help**

71. 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."
72. An article in the *New England Journal of Medicine* on adolescent depression stated, "Medical illness should be ruled out in patients with depression. For example, anaemia, mononucleosis, hypothyroidism or hyperthyroidism, inflammatory bowel disease and collagen vascular disease may cause symptoms that overlap with depression."<sup>44</sup>
73. 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>45</sup>
74. There are many causes of mental distress which have been known about for a very long time. Researchers Richard Hall and Michael Popkin list 21 medical conditions that can cause anxiety, 12 conditions that can cause depression, 56 conditions that can cause mental disturbance in general, and 40 types of drugs that can create "psychiatric symptoms."

75. In 1967 they wrote, "The most common *medically induced* psychiatric symptoms are apathy, anxiety, visual hallucinations, mood and personality changes, dementia, depression, delusional thinking, sleep disorders (frequent or early morning awakening), poor concentration, changed speech patterns, tachycardia [rapid heartbeat], nocturia [excessive urination at night], tremulousness [shaking or trembling] and confusion.
76. The late Dr. Carl C. Pfeiffer, M.D., a researcher with a doctorate in chemistry, discovered that depression, as well as many mental and behavioural disturbances often result from either vitamin or mineral deficiencies, or possibly mineral imbalances, something prescription drugs are known to contribute to.<sup>46</sup>
77. Dr. David W. Tanton, Ph.D., author and founder and research director for the Soaring Heights Longevity Research Center, states that eating foods that create allergies or sensitivities can easily affect moods. Hypoglycemia (abnormally low level of blood sugar), hypothyroid (insufficient thyroid gland), or adrenal fatigue, as well as the use of many prescription and over-the-counter medications could easily contribute to feelings of depression.<sup>47</sup>
78. The above are just some of the possible causes of a child's problem and they indicate how vital it is for a thorough investigation to be done. The source of the problem needs to be found for each child. If the child is being sexually abused or bullied, has problems at home or school, like the above possible causes of problems, a psychiatric drug will never solve any of these problems.

## Summary and Recommendations

79. The numbers of children who are suffering suicidality, suicide and self-harm as a result of being wrongly and unnecessarily prescribed antidepressants is continuing to increase. There is ample evidence that psychiatric drugs do contribute to suicide and self-harm in children. Further deaths and incidents of self-harm can be reduced by implementing the following:
  - i. A Boxed Warning for the risk of suicide must be placed onto antidepressants like the US has. In addition, all Boxed Warnings should be on the packet of the drug so parents are easily able to be more fully informed.
  - ii. The Federal Government must take responsibility to protect children and ban the off label prescribing of antidepressants for children under 18. If not the rates of suicide and self-harm will only continue to increase.
  - iii. For every child (and adult) suicide, autopsy's need to include tests for the presence of psychoactive drugs. Subsequent Coroner's reports need to indicate the presence of a psychoactive 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.
  - iv. Each child death resulting from psychiatric drug related causes, should be investigated for criminal culpability.

- v. Medical Boards investigating cases of negligence or misconduct involving prescription practices that lead to the death of a child should be required by law to report these to the police for criminal investigation. The same should apply to Coronial Inquiries.
- vi. Statistics on the numbers of children on psychiatric by drug, age and state need to be published once a year automatically so they can be compared with increased suicide and self-harm rates.
- vii. The Therapeutic Goods Administration's Database of Adverse Events Notifications, needs to include the ability to generate reports which are a summary of the total numbers of different types of adverse reactions including suicide and self-harm as well as the ability to generate these types of summaries specifically for children. If the numbers of children on these drugs is known and the numbers of adverse drug reactions linked to these drugs is also easily known, then the statistics can be compared, monitored and appropriate action taken to protect children.
- viii. Funding does need to be spent on ensuring that doctors, hospitals etc report any drug complications from the use of any psychiatric drug to the Therapeutic Goods Administration. Funds should be specifically allocated to inform both parents and the general public of the fact that they can report adverse reactions to any psychiatric drug.
- ix. Funding needs to be spent on information sheets for dispensing from doctors, chemists, hospitals, etc relaying the advantages and disadvantages, the side-effects and known risks of the antidepressants and other psychiatric drugs being proposed to parents for their child as well as alternative treatments.
- x. For children who are unwell and need care, hospitals/wards need to be turned into places of proper care based on scientific medicine where children can obtain proper care and return home as happy and healthy children.
- xi. The government and those who care for children who experience problems should not rely on the psychiatric intervention called the DSM. We ask that when any policies are made or when funding is obtained to assist children that the idea of undertaking searching and competent, non-psychiatric physical examinations to discount any underlying, physical condition as the cause of the child's mental condition, before any child is "diagnosed," is considered. This simple expedient would save countless children from being falsely labelled and treated as mentally ill through the use of the DSM. This is not only sound financial judgement, it is sound mental health as well.
- xii. Funding should only be given to those mental health services that have been held accountable and are producing results. 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. Accountability means providing a full break up of EXACTLY what the funds are for, proven results previously obtained in helping children. This is extremely important considering the actual number of government and non-government mental health organisations receiving funding.



# APPENDIX 1

Prepared by the Adverse Drug Reactions Advisory Committee (ADRAC). Members of ADRAC are Associate Professor Duncan Topliss (Chair), Dr Vicki Kotsirilos, Professor David Isaacs, Dr Cecillie Lander, Professor John McNeil, Associate Professor Peter Pillans, Dr Simone Strasser, Dr Dana Wainwright

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# AUSTRALIAN ADVERSE DRUG REACTIONS BULLETIN

Volume 24, Number 4, August 2005

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- ☆ Suicidality with SSRIs: adults and children
  - ☆ Ezetimibe and muscle disorders
  - ☆ Pathological gambling with cabergoline
  - ☆ Reporting problems with products other than medicines
- 

Please report **all** suspected reactions to these **Drugs of Current Interest**

Aripiprazole (Abilify)  
Atomoxetine (Strattera)  
Ezetimibe (Ezetrol)  
Fenofibrate (Lipidil)  
Iron sucrose (Venofer)

Levetiracetam (Keppra)  
Pimecrolimus (Elidel)  
Reboxetine (Edronax)  
Teriparatide (Fortéo)

## 1. Suicidality with SSRIs: adults and children

In 2004, ADRAC published a statement on the use of SSRI antidepressants\* in children and adolescents, in view of evidence that use of these agents in these age groups was associated with an increased risk of suicidality, including suicidal ideation, suicide attempts and self-harm events.<sup>1</sup>

SSRIs are not registered for the treatment of depression in those less than 18 years of age, and neither are any other antidepressants.

Recently, ADRAC conducted a review of the evidence of suicidal thoughts and behaviour associated with the use of SSRIs in adults. The Committee concluded that, in most adult patients, SSRIs in the treatment of depression are beneficial or cause no harm. However, it was noted that individual case reports, including some describing dechallenge and rechallenge, support an association between SSRI use and new onset suicidality.<sup>2,3</sup> When this syndrome occurred it tended to develop soon after introduction of an SSRI, or an increase in the dose and to be associated with akathisia, agitation, nervousness and anxiety. The effect often persisted with continuing treatment. Similar symptoms can follow withdrawal of the SSRI.

Despite evidence of the infrequent occurrence of suicidal thoughts and behaviour with SSRIs, a recent large case control study by Jick et al found that prescription of fluoxetine or paroxetine, both SSRIs, was not associated with suicidal behaviour more frequently than prescription of the tricyclic antidepressant (TCA), dothiepin.<sup>4</sup> Participants were all first-time users of antidepressants and individuals at high risk of suicidality were excluded.

The Jick study included 17 suicides, and these occurred much more frequently in the first 9 days after starting antidepressants than later in the treatment period. This increased risk of suicide early in therapy may occur because the antidepressant has not yet taken effect, because the medication was begun when the depression was at its worst, or because of an activation effect of the medication.

A meta-analysis of 702 randomised controlled trials found an association between treatment with an SSRI and suicide attempt when compared with placebo, but in common with the Jick study, when TCAs were the comparator no difference in

frequency was found.<sup>5</sup> There was no difference between SSRIs and placebo for fatal suicide attempts.

Increased prescribing of antidepressants in Australia during 1991-2000 was associated with decreasing suicide rates, with the trend being most apparent in older age groups.<sup>6</sup> These results do not demonstrate a causal relationship, but the authors suggest the trend may be indicative of improved overall management of depression, including treatment at the primary care level, use of psychosocial intervention and prescribing of SSRIs (first available in the early 1990s). The SSRIs have brought many advantages, including once daily administration, lower rates of key adverse reactions, and safety in overdose.

Because of the risk of suicidal ideation and behaviour in both adults and children being treated for major depression and other psychiatric disorders, the TGA has recently required the sponsors of antidepressants, including the SSRIs, to update their Australian product information with appropriate warnings. The warnings provide the following advice:

- Worsening of depressive symptoms and emergence of suicidality may occur with treated or untreated depressive illness;
- Patients should be closely monitored for suicidality in the first weeks of treatment, and if there is a change in dose (up or down);
- Consideration should be given to changing or discontinuing therapy if worsening of symptoms persists or emergence of suicidality occurs with treatment;
- Patients and caregivers should be advised to monitor for worsening illness, suicidal or self-harm-related thoughts and behaviour and advised to seek medical assistance immediately should these occur.

\* The SSRI antidepressants included are citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline, and the related medicine, venlafaxine.

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# **APPENDIX 2**



# THERAPEUTIC GOODS ADMINISTRATION

## Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:  
 Auscap, EROCAP, FLUOXETINE HYDROCHLORIDE, Fluohexal, GenRx Fluoxetine, LOVAN, PROZAC, PROZAC LIQUID, ZACTIN

### Report Detail

**Case Number:** 223112      **Seq:** 1      **Gender:** F  
**Reported:** 14/11/2006      **Weight:** 0.00  
**Hospitalisation:** Admitted to hospital      **Age:** 16  
**Onset Date:** 21/08/2006      **DOB:** 12/07/1990  
**Outcome:** Not yet recovered      **Causality:** Causality possible

### Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life	Patient made 2 suicide attempts since starting drug, nil previous.	Drug ceased.

### Medicine Details:

<b>LOVAN (Suspected)</b>	<b>Reason:</b> Depression
20.0 Milligram	Daily
<b>Batch:</b>	<b>Started:</b> 19/08/2006 <b>Stopped:</b> 23/08/2006

### Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

### Additional Information:

1st time on SSRI.

# Public Case Detail

Cases Count: 1411

Case Number : 233350

Data Entry Date : 13/09/2007

State :

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 9Y

DOB :

Causality : Causality possible

## Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Self injurious behaviour		has grabbed a blunt knife on 5 occasions and attempted to cut himself	
Suicidal ideation		he talks often of wanting to die	

### Medicine details :

Lovan (Suspected)	Reason :		
	20 Milligram	1 time	Oral
Batch :	Started : 15/09/2006	Stopped :	0
Risperidone (Suspected)	Reason :		
			Oral
Batch :	Started :	Stopped :	0

# Public Case Detail

**Case Number : 74228**

**Data Entry Date :** 20/11/1991

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Not yet recovered

**Gender :** M

**Weight (kg) :** 23

**Age :** 7Y

**DOB :**

**Causality :** Causality possible

**Information:** Depression, crying, saying he wants to kill himself. tried to run in front of cars. threatened to jump off roof.

## Reaction :

**Preferred Term**

**Severity**

**Report Description**

**Treatment**

Depression

Psychotic disorder

Suicide attempt

## Medicine details :

**RITALIN (Suspected)**

**Reason :** Behavior disorders of childhood

Tablet

20 Milligram

Daily

Oral

**Batch :**

**Started :** 14/07/1991

**Stopped :** 04/11/1991



# Public Case Detail

Cases Count: 1411

## Case Number : 245182

Data Entry Date : 07/10/2008  
 State :  
 Hospitalisation : Hospitalisation prolonged  
 Onset Date : 01/03/2007  
 Outcome : 01/03/2008  
 Recovered

Gender : F  
 Weight (kg) : 0  
 Age : 16Y  
 DOB :  
 Causality : Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Headache	Caused or prolonged inpatient hospitalisation		
Neurological symptom	Caused or prolonged inpatient hospitalisation	Patient experienced excessive bleeding, psychosis, high blood pressure, severe diarrhoea, sweating, tremors, violent, aggressive and suicide attempt, serotonin syndrome.	Ceased Zoloft, ceased Prozac
Psychotic disorder	Caused or prolonged inpatient hospitalisation		
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		
Aggression	Caused or prolonged inpatient hospitalisation		
Suicidal behaviour	Caused or prolonged inpatient hospitalisation	Patient experienced excessive bleeding, psychosis, high blood pressure, severe diarrhoea, sweating, tremors, violent, aggressive and suicidal behaviour, serotonin syndrome.	Ceased Zoloft
Hypertension	Caused or prolonged inpatient hospitalisation		
Central nervous system lesion	Caused or prolonged inpatient hospitalisation		
Suicide attempt	Caused or prolonged inpatient hospitalisation		



# Public Case Detail

Cases Count: 76

**Case Number : 211934**

**Data Entry Date : 23/09/2005**

**Hospitalisation :** Required a visit to the doctor

**Onset Date :**

**Outcome :** 15/08/2005

Recovered

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 30/07/1993

**Causality :** Causality probable

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Decreased appetite		Patient experienced anorexia, weight loss, fidgeting, compulsive behaviour eg. ripping fingers and toe nails out, cutting and picking clothing and anger outburst.	Strattera stopped.
Aggression			
Obsessive-compulsive disorder			
Restlessness			
Weight decreased			

**Medicine details :**

<b>Strattera (Suspected)</b>	<b>Reason :</b>
Capsule	60 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 15/12/2004 <b>Stopped :</b> 15/08/2005

# Public Case Detail

Cases Count: 1411

## Case Number : 245680

Data Entry Date : 21/10/2008  
State :  
Hospitalisation : Admitted to hospital  
Onset Date :  
Outcome :  
Recovered

Gender : M  
Weight (kg) : 86.8  
Age : 14Y  
DOB :  
Causality : Causality probable

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	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 four days of ceasing Fluoxetine.	Observation and containment in hospital.

#### Medicine details :

Fluoxetine Hydrochloride (Suspected) Reason : Depression  
20 Milligram Daily  
Batch : Started : 11/09/2008 Stopped : 12/09/2008



# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

## Report Detail

Case Number: 230966 Seq: 1

Reported: 16/07/2007

Gender: F

Weight: 58.00

### Hospitalisation:

Age: 14

Onset Date: 18/02/2007

DOB: 02/05/1992

Outcome: Recovered

19/02/2007

Causality: Causality probable

## Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	Recent suicidal ideation in patient with no past history.	

## Medicine Details:

<b>SERTRALINE HYDROCHLORIDE (Suspected)</b>	<b>reason:</b>
Tablet	50.0 Milligram Daily Oral
<b>Batch:</b>	<b>Started:</b> 05/02/2007 <b>Stopped:</b>

## Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

## Additional Information:



## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:  
CELAPRAM,CIPRAMIL,CITALOPRAM HYDROBROMIDE,Chem Mart Citalopram,Ciazil,GenRx Citalopram,TALOHEXAL,Talam

### Report Detail

**Case Number:** 223170      **Seq:** 1      **Gender:** M  
**Reported:** 15/11/2006      **Weight:** 0.00  
**Hospitalisation:** Admitted to hospital      **Age:** 15  
**Onset Date:** 19/09/2006      **DOB:** 12/09/1991  
**Outcome:** Not yet recovered      **Causality:** Causality possible

### Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	Attempted suicide by gassing himself in sisters car. Increased superficial laceration/cutting of arms and face.	Medication ceased, he was admitted to inpatient unit for ongoing monitoring of mental state
Self mutilation	Caused or prolonged inpatient hospitalisation		

### Medicine Details:

<b>CITALOPRAM HYDROBROMIDE (Suspected)</b>		<b>Reason:</b> Depression	
Tablet	10.0 Milligram	Daily	Oral
<b>Batch:</b>	<b>Started:</b> 12/09/2006	<b>Stopped:</b> 20/09/2006	0

### Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

### Additional Information:



# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

## Report Detail

Case Number: 169388 Seq: 1

Reported: 03/10/2001

Hospitalisation: Admitted to hospital

Onset Date: 17/05/1999

Outcome: Death, maybe drug

Gender: F

Weight:

Age: 15Y

DOB:

Causality: Causality possible

## Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Patient was hospitalised. date of death 22.5.1999.

## Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
	0.5 Dose Unspecified Daily
Batch:	Started: 14/05/1999 Stopped: 21/05/1999

## Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

## Additional Information:



# Public Case Detail

**Case Number : 237114**

**Data Entry Date : 21/01/2008**

**Hospitalisation :** Required a visit to the doctor

**Onset Date :** 01/03/2007

**Outcome :** 15/11/2007

Recovered

**Gender :** M

**Weight (kg) :** 29

**Age :**

**DOB :** 18/11/1997

**Causality :** Causality probable

**Information:** ADHD/ASD with no medication able to be taken.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Anorexia		Patient experienced loss of appetite, insomnia, skin sores, (scratching of skin sores), head banging on walls, psychosis, violent self harming behaviour with rages lasting up to 1 hour.	Medications ceased.
Aggression			
Head banging			
Insomnia			
Self injurious behaviour			
Skin lesion			

## Medicine details :

**Concerta (Suspected)** Reason : Behavior disorders of childhod

Tablet 18 Milligram Daily Oral

**Batch :** **Started :** 01/03/2007 **Stopped :** 31/10/2007



# Public Case Detail

**Case Number : 229120**

**Data Entry Date :** 30/05/2007

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 11Y

**DOB :**

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		The patient took Strattera for the treatment of ADHD to complement Ritalin, under the influence of which he became suicidal and depressed.	Ceased medication.
Depression			
Drug ineffective			

**Medicine details :**

<b>RITALIN (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhod
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>
<b>Strattera (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhod
Capsule	Oral
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>





# Public Case Detail

**Case Number : 212597**

**Data Entry Date :** 17/10/2005

**Hospitalisation :**

**Onset Date :** 15/02/2005

**Outcome :**

Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 11Y

**DOB :**

**Causality :** Causality probable

## Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Patient experienced suicidal ideation.	

### Medicine details :

<b>Strattera (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhood		
Capsule	25 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/02/2005	<b>Stopped :</b> 15/05/2005	



# Public Case Detail

**Case Number : 212705**

**Data Entry Date :** 19/10/2005

**Hospitalisation :**

**Onset Date :** 30/05/2004

**Outcome :**

Not yet recovered

**Gender :** M

**Weight (kg) :** 25

**Age :** 8Y

**DOB :**

**Causality :** Causality possible

**Information:** History: High protein, low carbohydrate diet.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Depressed mood		Patient experienced sadness and hit his head against a wall (purposely). He has had thoughts of suicide- stating that he wants to kill himself.	
Self injurious behaviour			
Suicidal ideation			

## Medicine details :

<b>Strattera (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhod
Capsule	20 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 27/05/2004 <b>Stopped :</b> Continuing

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- <sup>10</sup> Margaret Hagen, Ph.D., *Whores of the Court, The Fraud of Psychiatric Testimony and the Rape of American Justice*, 1997, p.42
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