



Antidepressants & Children Marketing a Contagion

*“At his best, man is the noblest of all animals;
separated from law and justice he is the
worst” .*

Aristotle

Agenda

- What are antidepressants?
- Legal Actions from USA.
- Statistics on Mental Health and Anti-Depressant use in Australia.
- Zoloft & Children.
- Zoloft & Suicide.
- The Law.
 - *Statute of Limitations 1969*, see also mirrored provisions in *ACL s87*.
 - *Australian Consumer Law 2011 (Cth)*
 - *Fair Trading Act 1987 (NSW)*



What are antidepressants?

- An antidepressant is a psychiatric medication used to alleviate mood disorders, such as major depression and dysthymia and anxiety disorders such as social anxiety disorder.
- The new class of antidepressants known as Selective Serotonin Reuptake Inhibitors (**SSRIs**) which include Prozac, **Zoloft** and paroxetine, also known as Aropax, Paxil, Seroxat) were viewed as relatively harmless when they came on the market in the 1980s. However, starting in 1992, a number of SSRIs have been linked to a condition called akathisia. Unpublished data suggests that up to one patient in four may suffer from this condition.
- A review of all studies ever submitted to the U.S. Food and Drug Administration (FDA) of 12 anti-depressants, published and unpublished, was submitted to the FDA in 2004. In the published literature, anti-depressants had 94% success in treating depression. In the withheld literature, they had below 50% success. Combined, all studies showed 51% efficacy- only two points better than that of placebo. This increased the apparent efficacy of different anti-depressants from between 11% to 69% over placebo.^[1]

- *[1] Turner EH, Matthews AM, Linardatos E, Tell RA, Rosenthal R (January 2008). 358 (3): 252–60 Selective publication of antidepressant trials and its influence on apparent efficacy . New England. Journal. Medicine.*

Snapshot of Legal Actions from USA.

- A summary of these actions including civil and criminal actions regarding settlements of \$1 million in the past 20 years are included below:
 - “Of the 165 settlements comprising \$19.8 billion in penalties during this 20 year interval, 73% of settlements (212) and 75% of the penalties (\$14.8 Billion) have occurred in the past five years”.
 - 4 Companies of which Pfizer was one accounted for more than 53% (\$10.5 billion) of all financial penalties imposed over the past decade.
 - In the past it was the defence industry who was the largest defrauder of Tax payer coffers, however, the Pharmaceutical industry has greatly overtaken them. The Pharmaceutical industry leads all industries in this area of fraud.
 - *Currently Australia does not have a specific provision relating to Qui Tam actions, however, the idea has been canvassed in previous senate inquiries. Any actions in future Pharmaceutical litigation should seek to establish Qui Tam laws in Australia to prevent Tax payer frauds. Essentially the aim of this Act will be to prosecute fraud against the Government and Tax payers.[A]*
 - *Sammy Almashat, Charles Preston, Timothy Waterman, Sidney Wolf. ‘Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010 - (16 December 2010), 2.*

Statistics of Anti-Depressant Use in Australia

- A 1995 Study suggested that Tricyclic antidepressants are not more effective than Placebo in children and adolescents.^[2]
- In 2006-07 Medical practitioners provided 183.4 million PBS/RPBS subsidised prescriptions for medications, of which 20.6 million (11.2%) were for mental related medications. This is equivalent to 990 mental health related prescriptions per 1000 population.^[3]
- It is noted that 45,145 patients aged less than 15 years of age were issued mental health related prescriptions with a total number of prescriptions totalling 228,272.^[4]
- Approximately \$5.3 Billion was spent on Mental Health Services nationally in (Australia). In 2008-09 over 21 million mental health related prescriptions with 51% representing anti-psychotics and 41% representing antidepressant sales. These costs were largely paid for by the (Pharmaceutical benefit Scheme – PBS) who is funded by the Tax-payer.
- Federal government health department data has revealed that prescribing rates of “controversial” drugs in children aged 2 to 6 has risen from 852 in 2007-8 to 1264 in 2009-10.^[5]

- [2] P, Hazell, D, O’Connell, D, Heathcote; J, Robertson, D, Henry (1995) 310:897-907 ‘Efficacy of tricyclic drugs in treating child and adolescent depression: a meta analysis, British Medical Journal.
- [3] Mental Health Related Prescriptions [Tab 38 – p119].
- [4] Ibid, [Tab 38 – p 125].
- [5] Elissa Doherty and Marianne Betts (May 30, 2011) ‘Alarm as more kids on Anti-depressants’. Herald Sun. [Tab 47]

Zoloft & Children

- Studies demonstrating the adverse effects of SSRIs on children had become a part of Scientific knowledge in the early **1990's** with numerous studies from different sources. [7]
- In a heavily redacted document obtained from the TGA regarding the approval of Zoloft dating back to 1993, the Product information (PI) for Zoloft states that **“Safety and Effectiveness in children has not been established”**. **The Drug was still approved for use on Australian Children.**
- In 1993 (Zoloft Product Information) Woman of child bearing potential were advised that they should use contraception. (*Does this indicate that Pfizer Knew of the effects, or suspected the adverse effects of Zoloft on child births back then?*)
- **According to Peter R Breggin (Expert) issues relating SSRI induced violence and suicidal behaviour also involves children and young adults. It is noted in this journal that adverse events tend to present themselves more frequently and severely in this segment, providing for a magnified view of the same or similar effects that the drugs cause in adults.** [8]
- It was not until **2004** that the Food and Drug Administration (FDA) and Therapeutic Drug Administration (TGA) in **2005** released warnings to the public regarding the Risks of suicide in Children and adolescents from SSRI's.
- 132,582 Patients aged 15-24 representing 777,763 prescriptions were issued. It is unclear from the information provided exactly what drugs these scripts represented in terms of their brand.

• [7] [Tab 50] Peter Breggin 'Suicidality, Violence and Mania caused by Selective serotonin reuptake inhibitors (SSRIs): A review and analysis'. (2003/2004) 16, 40.

• [8] Ibid.

Zoloft & Suicide - Donovan - Case Study

- As early as 1990 the alarm was raised by a Harvard Psychiatrist Martin Tiecher that after 2-7 weeks on Prozac six patients developed Intense, **violent suicidal preoccupation**, which persisted 3 days to 3 months after the medications were ceased.
- Donovan conducted a study of 2776 consecutive cases of Self-Harm age 17 and older seen in an emergency unit in a Derbyshire Hospital over a period of 2 years in 1995 - 1996.
- Of the 2776 persons reviewed, **307** had taken an antidepressant **30** days prior to self-harm.
- The relative incidence rate of deliberate Self-Harm (DSH) per **10,000** prescriptions was **Fluoxetine (19.8) Sertraline (14.8), Paroxetine (12.1)**.^[6]
- These numbers are alarming when compared to the standard set in *Roger v Whitaker (1992)* 175 CLR 479 where **1** in **14000** was held to provide a Duty to disclose of risks.

^[6] S. Donovan, A Clayton, M. Beehary, S. Jones, C Kirk, K. Waters, D. Gardner, J. Faulding and R. Madeley . ' Deliberate Self harm and antidepressant drugs: Investigation of Possible Link (2000) 551-556, *British Journal of Psychiatry* Vol 177.

Relevant Laws & Issues

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Daubert Scientific Standard and Law.



“NO RATIONAL ARGUMENT WILL HAVE A RATIONAL EFFECT ON A MAN WHO DOES NOT WANT TO ADOPT A RATIONAL ATTITUDE.”

- KARL POPPER

History Daubert Hearings

- Prior to Daubert the standard was based on the Frye decision.
- Frye dealt with a systolic blood pressure deception test, a "*crude precursor*" to the polygraph.
- In a 1923 case, *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), the D.C. Circuit held that evidence could be admitted in court only if "***the thing from which the deduction is made***" is "***sufficiently established to have gained general acceptance in the particular field in which it belongs.***"
- In 1923, this blood pressure test was not widely accepted among scientists, and so the Frye court ruled it could not be used in court. Over the years, scholars disputed the proper scope and application of the Frye test.
- This principle is similar to the Civil Liability Act 2002 (NSW) s5(1).

Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993)

- Daubert is a United States Supreme Court case determining the standard for admitting expert testimony in federal courts. The Daubert Court held that the enactment of the Federal Rules of Evidence implicitly overturned the Frye standard; the standard that the Court articulated is referred to as the Daubert standard.
- Essentially the principles enunciated in Daubert allowed for Judges to be gatekeepers for the admissibility of evidence.
- For example - To say a “Unicorn does not exist” stands until a Unicorn is sighted.^[10]
- Previous inquiries into SSRIs inducing suicide has passed six Daubert hearings in the United States of America. The United States Courts concluded that the Science behind SSRI induced Suicides and the problems that lead to the manifestation of these and other adverse reactions is **“Sound”**.

• [10] Yoalnde Lucire ‘New Drugs, New Problems’ (2005), 4-5. Vol 37:1, 9-25. *Australian Journal of Forensic Sciences*.

Civil Liability Act 2002 (NSW)

- **CIVIL LIABILITY ACT 2002 - SECT 50**
- *Standard of care for professionals*
- **50 Standard of care for professionals**
- **Frye in CLA.**
- (1) A person practicing a profession ("a professional") does not incur a liability in negligence arising from the provision of a professional service if it is established that the professional acted in a manner that (at the time the service was provided) was widely accepted in Australia by peer professional opinion as competent professional practice.
- **Possible Daubert Arguments in CLA**
- (2) However, peer professional opinion cannot be relied on for the purposes of this section if the court considers that the opinion is irrational.
- (3) The fact that there are differing peer professional opinions widely accepted in Australia concerning a matter does not prevent any one or more (or all) of those opinions being relied on for the purposes of this section.
- (4) Peer professional opinion does not have to be universally accepted to be considered widely accepted.

Civil Liabilities Act 2002 (NSW) & Daubert Standard

- The *Civil Liabilities Act 2002 (NSW) (CLA)* seems to be a mixture of the Frye Rule and Daubert standards.
- The CLA – Frye Rule is mirrored in s50(1).
- The CLA – Daubert Standards seem to be mirrored in s50(2);(3) & (4).
- What is unclear is the extent to which the Frye Rule maintains its dominance in Australian Law. That is, are Australian Courts prepared to challenge the dominance of Frye.

Limitations Act 1969 (NSW)

Limitations, Discovery and Long Stop
Period.

Statute of Limitations

- **The Relevant law is – *Limitations Act 1969 (NSW)*.**
- **LIMITATION ACT 1969 - SECT 50C**
- **Limitation period for personal injury actions**
- **50C Limitation period for personal injury actions**

- (1) An action on a cause of action to which this Division applies is not maintainable if brought after the expiration of a limitation period of whichever of the following periods is the first to expire:
 - **(a) the "3 year post discoverability limitation period", which is the period of 3 years running from and including the date on which the cause of action is discoverable by the plaintiff,**
 - **(b) the "12 year long-stop limitation period", which is the period of 12 years running from the time of the act or omission alleged to have resulted in the injury or death with which the claim is concerned.**
 - **Note: The 12 year long-stop limitation period can be extended by a court under Division 4 of Part 3.**
 - **Case Law suggests that a person discovers the injury at the point they are made aware of the action. This can occur through a number of processes: (1) Doctors Report, (2) Expert report, (3) A Lawyer indicating that a cause of action is available.**
 - **Even where correspondence occurs between plaintiff and Lawyer, the discovery time does not begin until the Lawyer provides Plaintiff with Prospects of Success. (*Morrison-Baker*) Case.**