

**SECOND GENERATION  
ANTIDEPRESSANTS: ARE THEY  
CURES OR KILLERS?**

**EXAMINING**

**THE SCIENTIFIC EVIDENCE**

**THAT ANTIDEPRESSANTS**

**INDUCE SUICIDE**

**Yolande Lucire  
PhD, MB BS DPM FRANZCP  
Forensic Psychiatrist**

Poster from 40th RANZCP CONFERENCE, Sydney,  
May 2005.

**While the FDA faces lawsuits for failing to protect the public, and is squirming out of its arrangement to fast track drug approvals at the expense of safety**

**IN AUSTRALIA**

**Health Minister Tony Abbott, at a Pfizer-sponsored post budget meeting on 11 May 2005, at the Sydney Opera House has announced a plan to make the TGA 'self funding' presumably as the FDA was, paid by Pharma to licence their drugs**

**IN THE USA**

**New law aims to distance the FDA from the drug industry** *Jeanne Lenzer New York BMJ 2005;330:1106 (14 May), doi:10.1136/bmj.330.7500.1106-a*

**Legislation aimed at ending the close relationship between the US Food and Drug Administration and the drug industry was introduced last week.**

The 1993 US Supreme Court Decision in **Daubert v. Merrell Dow Pharmaceuticals** altered the criteria by which scientific testimony is admitted as evidence in court.

The unanimous ruling states that the criterion of the scientific status of a theory is that it can be tested, refuted and falsified.

Scientific method is based on generating a null hypothesis, suggesting something does not exist, then trying to find evidence that it does

The unicorn does not exist. The prisoner is not guilty. These are respectively good science and good law

Disproving the negative differentiates science from other forms of inquiry

William Daubert, et ux., etc., et al., Petitioners v. Merrell Dow Pharmaceuticals, Inc. Supreme Court of the USA, June 28, 1993.

The following is Daubert-competent Evidence, science that has passes 6 Daubert Hearings.

that SSRIs (and other antidepressants) cause:

Completed suicide  
Suicidal Ideation  
Suicidal Acts

Two numbers are important

**RELATIVE RISK RR (of suicide)**

and

**SUICIDE RATE /100,000**

And the confidence interval (CI)

**Australian courts demand scientific evidence and often use a Daubert criterion to exclude junk science and opinion evidence.**

## **DAUBERT COMPETENT SCIENCE DEMANDS**

1. Testability. 2. Peer review and publication:  
3. Known or potential error rate: 4. Standards controlling operation: 5. General acceptance:

### **GENERAL ACCEPTANCE:**

1. **TEXTBOOKS**; Kaplan and Saddock; 1980... "A manifestation of drug sensitivity, it may be confused with psychotic agitation and incorrectly treated by increasing the dose of offending medication. The symptom subsides promptly when the offending medication is discontinued and replaced by another one better tolerated by the patient."

2. **DSM IV from 1994, AND DSM IV TR** where SSRI-induced akathisia (as well as the better known neuroleptic induced akathisia) appears at DSM IV TR 333.99

3. **The US FDA Public Health Advisory March 22, 2004** Subject: Worsening Depression And Suicidality In Patients Being Treated With Antidepressant Medications

4. **Pharmaceutical company prescribing information (PI)** for all relevant Second generation and combinations **with other drugs similarly metabolised.**

5. **MIMS** information about metabolic pathways for these drugs and **interactions**, and prescribing guidelines and interactions.

6. **Courts in the United States.** Six Daubert hearings

7. **Supreme Courts in NSW (R v Hawkins)** and Western Australia (R v B)

8. NSW Coroners Court on evidence from Dr Bill Barclay (V. Crane)

9. **The Hon Professor Emeritus, Peter Baume AO, Sentinel Events Committee,** NSW Health has evaluated this information and has taken it up with ADRAC, which gets conflicting advice from the RANZCP.

At the same time, reservations, 'we are not convinced' have been expressed by Dr Bill Lyndon, Chairman, Committee for Psychotropic Drugs and other Physical Treatments, RANZCP which has advised that the issue of SSRI suicide remains a 'controversy'

A **Relative Risk, RR**, is the difference in the rate of SUICIDE\*

between SSRI-TREATED PATIENTS and those treated with a TCA, or with sugar pills or not treated at all.

\*or its precursors, thinking of it trying to do it,

If a medicine saves some patients from committing suicide, the RR between that medicine and no treatment should be less than 1.

Tricyclics halved the number of suicides in a seriously (biologically) depressed 'hospital' population of the 1960s.

The RR of treated v untreated was generally 0.5,

they halved the risk, halved suicide rates

If the Relative Risk equals 1.0, the risk in treated individuals is the **same** as the risk in untreated ones.

If a vaccination program had a RR of 1, it would be not be of any use and it would be cancelled.

If the relative risk is more than 1.0, the risk in the treated is greater than in untreated patents.

There is a belief that SSRIs stop some patients from being suicidal,

and we know that some people do well on them.

As we are trying to prevent suicide, an RR of 1 would be ominous.

**Any problem that exists needs to be identified and confronted.**

**And controlled.**

Exposure to asbestos is **legally** deemed contributory to cancer although the RR is only 1.2 which is 20% higher. Asbestos was never expected to PREVENT cancer, 29% more. **AN RR OF 2 IS FIVE TIMES MORE THAN THAT.**

**Endorsement by prominent opinion leaders is not evidence admissible in courtrooms.**

**•NHMRC Level Type of evidence**

**I** A systematic review of all relevant randomized controlled trials.

**II** At least one properly designed randomized controlled trial.

**III-1** Well-designed pseudo-randomised controlled trials (alternate allocation or some other method).

**III-2** Comparative studies with concurrent controls and allocation not randomized

•(cohort studies), case control studies, or interrupted time series with a control group.

**III-3** Comparative studies with historical control, two or more single-arm studies, or

•interrupted time series without a parallel control group.

**IV** Case series, either post-test or pre-test and post-test.

**All levels evidence for causality of suicide by SSRIs can be found in many areas of research**

**1. CLINICAL PSYCHIATRY**

Observations and mechanisms  
Challenge - De-challenge - Re-challenge  
experiments (4)

Studies of NEW suicidal ideation, (Fava)(4)

**2. SUICIDE EPIDEMIOLOGY (3)**

**3. SUICIDES BY PRESCRIBED DRUG**

JICK,UK (3)

DSRU (3)

DONOVAN (3)

**4. POPULATION STUDIES (level I)**

PRIMARY CARE

HEALY AND BOARDMAN( level 3)

**5 HEALTHY VOLUNTEER STUDIES (I)**

**6. RANDOM CONTROL TRIALS (2)**

(RCTs) at the FDA (and paediatric trials at FDA) level (I)

(7) Ronald Maris Daubert (level I)

The scientifically acceptable, Daubert competent evidence overwhelmingly supports a relative risk of suicide by SSRI users of greater than 2, and sometimes as high as 8 or 10.

**“Suicide and Neuropsychiatry Adverse Effects of SSRI Medications:Methodological Issues”**Scientific Symposium  
October 4, **2002**. **RONALD WM. MARIS, PH.D.**

Distinguished Professor Emeritus, [Maris@sc.edu](mailto:Maris@sc.edu), 803-777-6870, [www.suicideexpert.com](http://www.suicideexpert.com)

**ABSTRACT:** This paper critically examines several methodological issues growing largely out of *Daubert*, pertinent to the question of whether or not SSRI medications can be said scientifically to cause suicide ideation, suicide attempts, and/or completed suicide

The cases versus the controls normally should have a relative risk (RR) or odds ratio of 2.0 or higher other reliable methodologies.

For example, **Donovan et al, 2000**, studied 2776 deliberate self-harm (DSH) cases over 24 months. In this study paroxetine (an SSRI) had a RR of DSH of **1.9** versus Tofranil (imipramine) and a RR of **4.0** versus the tricyclic (TCA) Elavil (amitriptyline) (**The RR for Prozac was 6.6**).

In a related study of another selective serotonin reuptake inhibitor (SSRI), **Jick et al., 1995**, found that Prozac (fluoxetine) had a RR for suicide of **2.1** versus Dothiepin.

**Fava and Rosenbaum, 1991**, found the RR of emergent *de novo* suicide ideation was **2.7 in fluoxetine users** versus the non-flouxetine users (Cf., Mann and Kapur, 1991; Mann, 2000).

**Healy (2002)** finds RRs ranging from **2.4** (suicidal acts) for the SSRIs v. placebo, from **4.3** (completed suicides for all SSRIs) to **10.0** for fluoxetine (Cf., Healy, 2001)

## CLINICAL PSYCHIATRY 1988

### SUICIDAL ACTS

2 of 26 depressed patients overdosed in the first 2 weeks when Prozac was increased quickly.

**7.6% is an extremely high rate.**

**M. Muijen, et al., A Comparative Clinical Trial of Fluoxetine, Mianserin, and Placebo in Depressed Outpatients, Acta Psychiatrica Scandinavica, Vol. 78 (1988), pgs. 384-390.**

A drug company-funded properly designed trial whose results Eli Lilly tried to suppress.)

**CLINICAL PSYCHIATRY 1990 Teicher  
Glod and Cole**  
first reported the phenomenon 15 years ago!

**Six patients developed intense, violent suicidal preoccupation after 2-7 weeks on Prozac which persisted 3 days to 3 months after Prozac was stopped.**

**None had ever experienced a similar state.**

Drug companies try to dismiss this as 'anecdotal' and said

**"It's the disease not the drug, doctor"**

There are now scores of such reports, and few psychiatrists have not seen this happen

**American Journal of Psychiatry. Teicher Glod and Cole 147(2):207-10, 1990 Feb.**

## **CLINICAL PSYCHIATRY 1991 SUICIDAL THINKING**

**Fava and Rosenbaum** found **suicidal thinking developed** in patients who had **never** been suicidal before, more on Prozac than on other drugs.

Prozac v TCAs = **RR = 2.7**  
Scores of reports

There are many Challenge-Dechallenge-Re-challenge studies.

Suicidality starts on drug,

clears up when it is stopped and

Reappears on re-exposure, even to another SSRI.

- Most challenge de-challenge re-challenge is done accidentally

Fava, M. & Rosenbaum, J. 1991. Suicide and 3 fluoxetine. Journal of Clinical Psychiatry, 52-5

### **SUICIDE EPIDEMIOLOGY: JICK *et al.***

Against concerns that Britain's most popular TCA antidepressant, Prothiaden, was dangerously toxic in overdose and was being labeled as a 'dirty drug by SSRI mfrs.

Jick examined

172,598 persons and 1.2 million scripts for 10 antidepressants, old and new, general practice patients 143 had committed suicide.

**SSRI overdoses are not fatal, other than Efexor XR.I. SSRI suicides tend to be violent: hanging, drowning, shooting, jumping, stabbing or cutting, dying on a railway, burning, electrocution, or deliberate road accidents.**

Jick S, Dean AD, Jick H (1995). **Antidepressants and suicide.** *British Medical Journal* 310: 215-218

### **SUICIDE EPIDEMIOLOGY : JICK *et al.***

**Prothiaden turned out to be the safest as only 14% of suicides involved antidepressant overdose.**

#### **RR of SUICIDE**

<b>Prozac v all TCAs</b>	<b>RR =</b>	<b>6.6</b>
<b>Prozac v Tofranil</b>	<b>RR =</b>	<b>1.9</b>
<b>Prozac v Amitriptyline</b>	<b>RR =</b>	<b>4.0</b>
<b>Prozac v Prothiaden</b>	<b>RR =</b>	<b>2.1</b>
<b>Prozac v Lofepamine</b>	<b>RR =</b>	<b>4.04</b>

**SUICIDE EPIDEMIOLOGY** The Jicks were embarrassed and suggested that 'selected' patients may have been given Prozac, which had a high suicide rate attached in 1995.

In a follow up study of suicide epidemiology, JAMA June 21, 2004, Aropax came out the worst, so the Jicks who had never seen a patient accounted for this by suggesting that more seriously depressed might have been given Aropax, in 2004.

**Suicides on Antidepressants in Primary Care in the United Kingdom:  
Jick *et al.***

<b>Drug</b>	<b>Suicide Rate/ 100,000 Patients</b>	<b>Absolute Suicide Numbers</b>
<b>Dothiepin</b>	70 (C.I. 53 Š 91)	52 Suicides in 74,340 Pts
<b>Lofepamine</b>	26 (C.I. 8 Š 61)	4 Suicides in 15,177 Pts
<b>Amitriptyline</b>	60 (C.I. 41 Š 84)	29 Suicides in 48,580 Pts
<b>Clomipramine</b>	80 (C.I. 38 Š 144)	9 Suicides in 11,239 Pts
<b>Imipramine</b>	47 (C.I. 20 Š 90)	7 Suicides in 15,009 Pts
<b>Doxepin</b>	69 (C.I. 17 Š 180)	3 Suicides in 4,329 Pts
<b>Flupenthixol</b>	78 (C.I. 43 Š 129)	13 Suicides in 16,599 Pts
<b>Trazodone</b>	99 (C.I. 31 Š 230)	4 Suicides in 4,049 Pts
<b>Mianserin</b>	166 (C.I. 86 Š 285)	11 Suicides in 6,609 Pts
<b>Fluoxetine</b>	93	11 Suicides in 11,860 Pts
<b>Total excluding Fluoxetine</b>		<b>132 Suicides per 195,931 Patients</b>
		<b>Fluoxetine 67 Suicides per 100,000 Patients</b>

**COMPLETED SUICIDES,  
DONOVAN *et al.***

again sought to establish the safety of SSRIs against TCAs which were toxic in overdose.

**Examined 222 COMPLETED  
SUICIDES, and the medicines  
they had been taking,**

**and found**

**SSRIs v TCA                      RR= 2**

Donovan S, Kelleher MJ, Lambourn J, Foster R. The occurrence of suicide following the prescription of antidepressant drugs. *Arch Suic Res.* 1999; 5: 181-192

**SUICIDAL ACTS: DONOVAN *et al.***

At the same DONOVAN looked at 2776 acts of DELIBERATE SELF HARM in 1954 persons presenting to emergency

and what they were taking

**Aropax v Tryptanol (TCA) RR = 4.0**

**Prozac v Tryptanol (TCA) RR = 6.6**

**Zoloft v Tryptanol (TCA) RR = 4.9**

**Aropax v Tofranil (TCA) RR = 1.9**

**All SSRI v Tofranil (TCA) RR = 5.5**

Donovan S, Clayton A, Beeharry M, Jones S, Kirk C, Waters K, Gardner D, Faulding J, Madely R. Deliberate self-harm and antidepressant drugs. Investigation of a possible link. *Brit J Psychiatry.* 2000; 177: 551-556

**SUICIDE EPIDEMIOLOGY: Boardman and Healy**

What is normal? Boardman and Healy investigated 475,000 citizens over 5 years

counting all the mood disorders in all the private practices and

suicide rates for these disorders

**PRIMARY CARE SUICIDE RATES UNTREATED**

All mental disorders  $\leq$  **27-67/100,000**.

This suggests hormesis: that a little of a toxin, stress, actually protects from the consequences of a lot of it.

•# this makes Sweden an unsuitable country to cite decrease in suicides since SSRIs came in.'

•Boardman AP, Healy D. Madeley. Suicide risk in primary care primary affective disorders. *European Psychiatry*. 2001; 16: 400-405.

**PRIMARY CARE SUICIDE RATES UNTREATED**

Minor mental disorders, untreated, have a lower rate of suicide than the 'healthy population. And people with minor mental disorders are getting SSRIs

These figures fit in with other primary care suicide statistics

Holland	<b>30/100,000#</b>
Sweden	<b>0/100,000</b>
Antedating SSRIs Simon, von Korff	<b>30/100,000</b>

Highest possible UK rate consistent with National Suicide Rate is **67/100,000**

•Boardman and Healy

**Drug Safety Research Unit Studies of SSRIs & Mirtazapine in Primary Care in the United Kingdom**

A set of post-marketing surveillance studies have been carried out in primary care in the United Kingdom by the Drug Safety Research Unit (DSRU) on all of the major SSRIs.

These studies recorded 120 suicides in over 44,000 patients being treated in primary care in Britain.

The DSRU methodology has since been applied to mirtazapine, where there have been 13 suicides reported from a population of 13,554 patients. The figures for SSRIs permits the comparisons.

**Drug Safety Research Unit Studies of SSRIs & Mirtazapine in Primary Care in the United Kingdom.**

<b>Drug</b>	<b>No. Patients</b>	<b>No. Suicides</b>	<b>Suicides/ 100,000 Patients</b>
Fluoxetine	12692	31	244 (C.I. 168-340)
Sertraline	12734	22	173 (C.I. 110-255)
Seroxat/Paxil	13741	37	269 (C.I. 192-365)
Fluvoxamine	10983	20	183 (C.I. 114-274)
<b>Total SSRIs</b>	<b>50150</b>	<b>110</b>	<b>219/100,000</b>
Mirtazapine	13,554	13	96 (C.I. 53-158)

**Source: ANTIDEPRESSANTS AND SUICIDE BRIEFING PAPER 2004, JUNE 20<sup>TH</sup> HEALY**

## FROM THE MORGUES

**SUICIDE EPIDEMIOLOGY :DRUG SAFETY RESEARCH UNIT, UK, follows up drugs in the community (50,000 pop.)**

looked at completed suicides and what medicines they had been prescribed.

Suicide rate on SSRIs =	<b>219</b> /100,000.
Prozac	<b>244</b> /100,000
Aropax	<b>269</b> /100,000
Luvox	<b>183</b> /100,000

## HEALTHY VOLUNTEERS

Healy: 2 of 20 healthy volunteers ( his staff) became suicidal on Zoloft.

At least 3 healthy volunteers have committed suicide in SSRI Trials:

19 year old Traci Johnston committed suicide on February 7th 2004 in a trial for incontinence, not mental disorder, of Eli Lilly's new Serotonin drug - duloxetine, aborting the trial. Hers was one of 7 suicides in 4124 subjects.

Duloxetine was still licensed, with a 'black box warning' in the USA.

The question of suicide in normals has come to the fore with news that a 19-year old girl, Traci Johnson, in one of Lilly's healthy volunteer trials of duloxetine committed suicide on February 7<sup>th</sup> 2004. At least one further volunteer in the Paxil/Seroxat program of trials in the 1980s committed suicide. There may have been others. From FDA's point of view are these and all the other testimonies presented at the February 2<sup>nd</sup> hearings simply anecdotal deaths? (David Healy questions to the FDA. Social Audit website).

**RANDOM CONTROLLED TRIALS  
(RCTs)  
SUICIDES AND SUICIDAL ACTS**

2003, Khan et al. looked at  
BLIND CLINICAL TRIALS from 1986-90

Presented to the US Federal Drug  
Administration, in late 1980s to get 9  
Serotonin ANTIDEPRESSANTS licensed.

They were tested  
against  
comparators (usually TCAs) and sugar  
pills.

There seemed to be no difference between placebo, the  
old and the new antidepressants.

Kahn found 77 suicides in 48,277 participants in  
SSRI trials.

That's a lot.

Am J Psychiatry. 2003 Apr;160(4):790-2

**RANDOM CONTROLLED TRIALS**  
'Samples of Convenience'

'Biologically depressed patients  
carrying suicide risk were excluded  
from these trials.

SSRIs were aimed at general  
practice patients under stress, with  
minor disorders were found for  
clinical trials.

The Valium using population of the  
1970s

Suicidal patients and borderlines were  
actively filtered out.

**RANDOM CONTROLLED TRIALS  
(RCTs) SUICIDES AND SUICIDAL ACTS  
SECOND GENERATION  
ANTIDEPRESSANTS**

2003, Khan looked at Blind Clinical Trials from 1986-90 presented to the US Federal Drug Administration, in late 1980s to get 9 ANTIDEPRESSANTS licensed.

They were tested against comparators (usually TCAs) and sugar pills.

There seemed to be no difference between placebo, the old and the new antidepressants.

**Kahn found 77 suicides in 48,277 participants in SSRI trials.**

Re-analyzing the Kahn data as outlined above it is clear that there have been approximately 180 suicides per 100,000 exposures to antidepressants compared with a figure of 68 per 100,000 exposures to placebo – an excess of 100 per 100,000 exposures to active treatment.

*Am J Psychiatry.* 2003 Apr;160(4):790-2.

**CLINICAL TRIALS FOR SECOND  
GENERATION PSYCHIATRIC DRUGS**

Khan then reviewed 71,604 participants in FDA clinical trials treated with antipsychotics, SSRIs and anticonvulsants.

**He found a rate of 757 suicides for every 100,000 participant year or 715 per 100,000 participants.**

**That is 68 time the population rate, enormous.**

**Kahn's research further revealed that nearly 4% of drug-trial participants attempted suicide the following year. 4000/100,000**

That suggested that these drugs may affect people for a while after they are stopped.

*Khan, A., Khan, S., Kolts, R., & Brown, W. (2003). Suicide rates in clinical trials of SSRIs, other antidepressants, and placebo: analysis of FDA reports. Am J Psychiatry, 160(4), 790-792*

15

In September of 2003, Healy and Whittaker re-evaluated the same, original FDA studies.

They published a watershed paper in September 2003.

**Antidepressants and  
suicide:  
risk–benefit conundrums  
David Healy, MD; Chris  
Whitaker, MSc**

Healy — Department of Psychological Medicine,  
University of Wales College of Medicine, Hergest  
Unit; Whitaker —  
Department of Informatics, University of Wales Bangor, Bangor,  
United Kingdom.

*J Psychiatry Neurosci* 2003;28(5):331-7

**ABSTRACT:** There has been a long-standing controversy about the possibility that selective serotonin reuptake inhibitor (SSRI) antidepressants might induce suicidality in some patients.

To shed light on this issue, this paper reviews available randomised controlled trials (RCTs), meta-analyses of clinical trials and epidemiological studies that have been undertaken to investigate the issue further. The original clinical studies raising concerns about SSRIs and suicide induction produced evidence of a dose-dependent link on a challenge-dechallenge and rechallenge basis between SSRIs and both agitation and suicidality. Meta-analyses conducted around this time indicated that SSRIs may reduce suicidal ideation in some patients. These same RCTs, however, revealed an excess of suicidal acts on active treatments compared with placebo, with an odds ratio of 2.4 (95% confidence interval 1.6–3.7). This excess of suicidal acts also appears in epidemiological studies.

**The data reviewed here make it difficult to sustain a null hypothesis that SSRIs do not cause problems in some individuals.** Further studies or further access to data are indicated to establish the characteristics of patients who may be most at risk.

**Incidence of Suicides and Suicide Attempts in  
Antidepressant Trials Submitted to FDA**

<b>Investigational Drug</b>	<b>Patient No</b>	<b>Suicide No</b>	<b>Suicide Attempt No</b>	<b>Suicides &amp; Attempts as a % of Patient No</b>
<b>Sertraline</b>	2,053	2	7	0.44%
Active comparator	595	0	1	0.17%
Placebo	786	0	2	0.25%
Placebo Washout		0	3	
<b>Paroxetine</b>	2,963	5	40	1.52%
Active comparator	1,151	3	12	1.30%
Placebo	554	0	3	0.54%
Placebo Washout		2	2	
<b>Nefazodone</b>	3,496	9	12	0.60%
Active comparator	958	0	6	0.63%
Placebo	875	0	1	0.11%
<b>Mirtazapine</b>	2,425	8	29	1.53%
Active comparator	977	2	5	0.72%
Placebo	494	0	3	0.61%
<b>Bupropion</b>	1,942	3	----	
Placebo	370	0	----	
<b>Citalopram</b>	4,168	8	91	2.38%
Placebo	691	1	10	1.59%
<b>Fluoxetine</b>	1,427	1	12	0.91%
Placebo	370	0	0	0.00%
Placebo Washout		1	0	
<b>Venlafaxine</b>	3,082	7	36	1.40%
Placebo	739	1	2	0.41%
<b>All New Drugs</b>	21,556	43	232	1.28%
<b>All SSRIs</b>	13,693	23	186	1.53%
Total Placebo	4,879	2	21	0.47%

Healy and Whittaker's conclusion was modest:

**It is no longer possible to support the null hypothesis that SSRIs do not cause suicide**

**The null hypothesis has been falsified.**

Any way you look at available information, clinical settings, emergency rooms, morgues, clinical trials,

SSRIs as a general cause of suicide would pass the scientific standard of proof.

The disclosure that the FDA knew all along and did not inform prescribers and consumers led to congressional hearings into the FDA and a House of Commons Inquiry in UK. The BMJ issued warnings on February 5 2004.

FDA on March 23

Most manufacturers put on Websites on May 3, 2004. Only in USA.. Prescriber information is different in USA.

FDA Talk Paper March 22, 2004

**FDA Issues Public Health Advisory on Cautions for Use of Antidepressants in Adults and Children**

FDA Public Health Advisory March 22, 2004

**Subject: WORSENING DEPRESSION AND SUICIDALITY IN PATIENTS BEING TREATED WITH ANTIDEPRESSANT MEDICATIONS**

- The drugs that are the focus of this new Warning are: Prozac (fluoxetine); Zoloft (sertraline); Paxil (paroxetine); Luvox (fluvoxamine); Celexa (citalopram); Lexapro (escitalopram); Wellbutrin (bupropion); Effexor (venlafaxine); Serzone (nefazodone); and Remeron (mirtazapine).

- Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and non-psychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, and the other symptoms described above, as well as the emergence of suicidality, and to report

- The drug manufacturers promote the medicalisation of stress subsidize psychiatrists, journals, conferences.

Encourage moral entrepreneurs of health who

talk about cases of 'depression' undiagnosed, and so untreated

John Merson calls this phenomenon 'epistemic capture': the control of knowledge by vested interests.

- 200/100,000 represents 1 death in 500 people treated with SSRIs in primary care.

68/100,000 v 200/100,000

A least 100 suicides per 100,000 over treatment with other drugs or non treatment.

By 2003, over 28 million people had started Prozac since its launch in 1988.

- 6,664,960 prescriptions for SSRI written 2003 by Australian doctors.  
Twelve times the annual number studied by Donovan

40% of first prescriptions remain unfinished, because of side effects.

PBS spends \$160 million a year on SSRIs.

Cui Bono? Who benefits? Doctors PhaRMAs or patients?

- **No warnings or advisories have been issued in in Australia. ADRAC takes counsel fro the RANZCP which Is 'not convinced.'**
- **Unlike smallpox, depression has not been disappeared since a cure became available**

**Potentially fatal complications of any treatment**

**might be acceptable if the treated population were small, dangerously ill, at high risk**

**the availability of a remedy has increased the diagnosis of depression a thousandfold. and lethal side effects have increased by the same multiplier.**

- **1 in 500**  
**too rare for clinicians to see.**

**They need advice from suicide epidemiologists and statisticians.**

**Opinion evidence is not admissible. 'We are not convinced' and ad hominem arguments do not get admitted as evidence.**

**1 in 500**  
**is well above Rogers and Whittaker's,**  
**1 in 14,000**  
**and demands a duty to warn of a catastrophic side effect.**

- Someone has that duty.

Who will tell the prescribing doctor? The manufacturers have not done so in Australia.

The Therapeutic Goods Administration has not issued warnings.  
Cites advice from RANZCP.

- The Federal Drug Administration in USA argues that its role is licensing drugs, not protecting the public.

Psychiatrists, clinicians, are 'not convinced'.

- All Truth passes through Three Stages: First, it is Ridiculed...

Second, it is Violently Opposed...

Third, it is Accepted as being Self-Evident.

Arthur Schopenhauer (1778-1860)