Dr Yolande Lucire
PhD MBBS DPM Franzp
Forensic & Mecico-legal Psychiatry

Mr. Gary Banks,
Chair,
Impacts of Medical Technology in Australia,
Australian Government Productivity Commission
Locked Bag 2 Collins Street East,
MELBOURNE VIC 8003

Dear Mr. Banks

Re: Impacts of Medical Technology in Australia

Investigate the net impact of advances in overall and individual health technologies on:

Economic, social and health outcomes, including exploring which demographic groups are benefiting from advances in health technology; and

The overall cost effectiveness of healthcare delivery.

I wish to submit information about the epidemic of adverse health outcomes caused about second-generation drugs in psychiatry: antidepressants and antipsychotics and the consequences of pharmacological iatrogenesis.

Psychiatry is not alone. See enclosed paper: New Drugs New Problems.

This view concerning second-generation antidepressants and antipsychotics has international currency. It is orthodox and the subject of United States Food and Drug Authority Public Health Advisories, and American Prescriber Information. Some had belatedly have been incorporated in Australian Prescriber Information, which remains grossly inadequate.

In brief, it is the side effects of the medicines we prescribe, carelessly, for minor disorders that are filling up mental health facilities. The sublethal consequences of these drugs fill hospital wards with suicidal, violent, manic and psychotic patients. This is the side effect profile of the antidepressants and part of serotonergic reactions to antidepressants and dopaminergic reactions to antipsychotics.

Since the first of these drugs Prozac, became available in 1991, there has been an increase of 297 beds in NSW, a trebling of mental heath presentations, increasing violence, trebling of suicides under mental health care and trebling of suicide attempts and prolonging of stays, the last because the efficacy of newer

antipsychotics has been a subject of deception by their makers and by the US FDA.

The acceptance of the fact that antidepressants cause problems in some people, akathisia and suicide, lies in:

1. Textbooks; Kaplan and Saddock: Modern Synopsis of Psychiatry DSM III, 1980… “A manifestation of drug sensitivity [akathisia] may be confused with psychotic agitation and incorrectly treated by increasing thee 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. This body made its decisions on class 1 evidence, as ti was available in the Healy Whittaker analysis of September 2003.

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 preserving guidelines and interactions.

6. Courts in the United States. Six Daubert hearings where side effects such as homicide and suicide have been litigated and settled by the drug companies. 100 homicides have been defended as caused by SSRI-induced akathisia. Supreme Courts in NSW (R v Hawkins) and Western Australia (R v B)

7. The Hon Professor Emeritus, Peter Baume AO, Chair of the Sentinel Events Committee, Tracking Tragedy a report on suicides under health care in NSW Health has evaluated this information and he took it up with ADRAC.

8. Associate Professor Duncan Topliss, Chair, Adverse Drug Reactions Advisory Committee (‘ADRAC’) to Professor Peter Baume, chair, dated 26 October 2004

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, Royal Australian and New Zealand College of Psychiatrists which

appears to have advised everyone who asked that the issue of SSRI suicide remains a ‘controversy’.

Your report on these drugs is consistent with the publications of Professor Ian Hickie. Professor Hickie never mentions the body of evidence concerning suicide and other side effects of antidepressants, including addiction.

Professor Hickie’s connections with and benefits from pharmaceutical companies are a matter of public record and most are available by searching through Google.com. He claims that there is Level 1 evidence that antidepressants ‘work.’ Many leading figures in academe deny that any such evidence exists. The vast majority of those getting these drugs do not suffer from depression, but from anxiety and ‘stress.’ They are promoted for menopause, incontinence and anxiety, none of which carries a suicide risk.

None of Professor Hickie’s publications adverts to the problems caused by these drugs. Even if they affect only one percent of users, when antidepressants are being taken by 4.7% of the population, there are sufficient adverse evens to put heavy demands on mental health services. Serious averse events occur in up to 3.5%of users.

Second Generation Antidepressants

The first question I wish to address is ‘Do antidepressants work?’ I refer you to Peter Medewar’s 1998 paper, which dissects this concern. Already in 1998, there was concern that, among their many side effects, was suicide. Others were mania, psychosis and violence, and homicide and thinking which led up to them.

> Medewar writes: Historians of psychiatry will recall the trajectories of what were, in their times, ‘wonder drugs’ morphine, heroin, cocaine, bromides, barbiturates, meprobamate mandrax benzodiazepines. It took years before their adverse effects were discovered and acknowledged. Each left a residue of addicts and each was expected to cure those left by its predecessor.
>
> Heroin was touted for morphine addiction and cocaine for heroin addiction. Tincture of cocaine was touted, as are new antidepressants as a cure for shyness and timidity, which are not medical conditions, and are medicalised at considerable cost to public health as side effects cause problems for many users.

By 2002, this was well known internationally. See Professor Ronald Maris paper presented in 2002 on suicide epidemiology among those taking new generation antidepressants, commonly but inaccurately known as SSRIs, for Selective Serotonin Reuptake Inhibitors

All of morphine, heroin, cocaine, alcohol, bromides, barbiturates, amphetamines, sedatives, meprobamate and benzodiazepines ‘work’ in the sense that some people feel different on them, and some people like that.

4.7% of the Australian population is taking antidepressants at a cost of over $170 million for the drug alone and one has to ask, if the conditions for which they do are legitimately medical conditions, and should be ‘treated’ by a doctor wearing a metaphorical white coat. They are now being provided for menopause and stress incontinence.

I refer you to my enclosed paper ‘The Ethics of the Solitary Empiricist’ which shows how the Pharmas put about hypotheses of ‘low serotonin’ is a cause for depression and thereby converted human unhappiness into a deficit disease, like diabetes. In any other context, this kind of propaganda would be considered fraud, and subject to fraud legislation. ‘Low Serotonin’ was never more than ‘hypothetical’ and most of the drugs that are advertised in this way affect serotonin at all. This is all PhaRMA propaganda.

The suicidogenic properties of antidepressants were well established by 2002 in the Science Courts of the United States by means of Daubert Hearings. I enclose several summaries of evidence that meets the criterion of Popperian Science.

By September 2003, with the publication of the Healy-Whitaker paper on Risk-Benefit Conundrums (Class 1 evidence), the US Congress commenced hearings into the FDA, because the FDA knew and had failed to inform the public.

The outcome for Antidepressants was the Public Health Advisory of March 22, 2004 and Talk Paper. A similar Advisory had already been published for antidepressants in adolescents, in September of 2003. See Documents.

The RANZCP did not follow suit until April of 2005. Someone has neglected his or her ‘duty to warn.’

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) advised it was ‘not convinced’ by the USFDA Public Health Advisory. It was only on April 5th, 2005, that it passed on the FDA Public Health Advisory concerning adolescents who the FDA had first posted on 27 October 2003 and then twice more before the RANZCP reacted.

With due respect, causation is not a matter of collective opinion but for science.

The lethal side effects of suicide and increased risk of death from Serotonin Syndrome and bleeding are likely to account for the rising rates of death, suicide and suicide attempts of patients under mental health care (I enclose a paper on this: New Drugs New Problems).

I believe that it links to your terms of reference for me to point out that it is the sublethal consequences of these drugs are causing mental health services to demand further funding and hundreds of extra beds. Their benefits have, in my view, been lost.

The ‘Antidepressant Era’ has been a public health disaster, with increasing numbers of newly mentally ill persons increasing, dying, committing suicide and being hospitalised. The tragedy is that the great majority of them did not have a mental illness or any psychiatric history at all before they were given medication for stress and minor disorders. (Unless you can believe that the 4.7% of Australia’s population is ‘depressed’)

The side effect profile of these drugs affects 6-20% of users who are genetically such that they do not have the P450 cytochromes needed to metabolise them. See my Cytochromes paper for a simple explanation of why this is so

Second Generation Antipsychotics

Co-prescribing of incompatible medicines is rife, as is ‘off label’ use of second-generation antipsychotics, Abilify (aripiprazole), Zyprexa (olanzapine), Seroquel (quetiapine), Risperdal (risperidone), Clozaril (clozapine) and Geodon (ziprasidone).

These newer antipsychotics are now subject to a FDA advisory in the elderly as they have a relative risk of death of 1.7 to sugar pills. The magnitude, indeed enormity of this problem can be seen when you review that Vioxx had a risk of something like 1.3 of inducing a heart attack, not a death. These advisories have not been posted by the RANZCP or ADRAC.

If so many older persons have died, one has to ask how many who did not die were admitted to hospital, generated costs with poorly understood iatrogenic conditions.

From working in an admission ward for 8 years, I can advise that the risk of sudden death, bleeding death, does not start at age sixty for antipsychotics, any more than the risk of psychosis (hostility) aggression and suicide stops at eighteen, with antidepressants, as ADRAC seems to have advised.

I can also advise that side effects of these medication form 25-30% of admissions to a rural ward.

The combination of both groups is, in my experience, particularly dangerous, most likely because the neurotoxic anti-psychotic is often prescribed for poorly recognised akathisia that is itself already a symptom of neurotoxicity.

Eli Lilly has deceived the population, as we were deceived about Prozac, which ‘works’ like tincture of cocaine ‘worked.’ Or like amphetamines or barbiturates ‘worked’. But not on the kind of depressive illness that carries suicide risk.

Zyprexa was the most suicidogenic drug in clinical trial history in the FDA trials and the least well tolerated drug judging by drop out rate of nearly 50%

Risperidone was not far behind. Neither Eli Lilly nor Janssen mention in their prescriber information the extraordinary rate of suicide, (1 in 208, or three to six times the norm for schizophrenics on a time adjusted basis nor the sudden deaths nor poor tolerance in the trials presented to the FDA. The FDA trials are available at Lillytrials.com, or at least the information Eli Lilly is prepared to disclose, which does not include suicide attempts.

Washouts from previous medicines were not done in the five FDA schizophrenia trials. Treating doctors are not told it is necessary to do this.

Four papers (Meltzer et al) show that Clozaril reduces suicide risk by 75% over Zyprexa (Olanzapine). These confirm that Olanzapine caused suicide. Suicide on Clozapine is already greater than untreated so this is ominous. It is reminiscent of the trial where Naprosyn was said to protect against heart attacks, whereas it was the drug of interest, Vioxx, causing them.

That Merck has been fined $25,000 for false advertising about Vioxx is an insult to those who suffered from its effects. That amount of money would not pay even a small portion of one person's intensive care after a Vioxx - induced heart attack.

Patients are suing in class actions for Vioxx and overseas there are class actions afoot about antidepressant side effects and deaths and diabetes from Zyprexa.

Perhaps Health Departments Attorneys could be advised to follow Eliot Spitzer's example and sue for costs generated by undisclosed side effects and false advertising.

My Website www.lucire.com.au has some useful links and the papers of mine. I have printed some for you.

The House of Commons Report of April 5, 2005, which deals with 'disease mongering', is available on the Internet. The UK and USA populations are aware of these problems. There is a lack of inquiry and independent scientific examination in Australia.

It is hard not to believe that there is no some kind of conspiracy of silence by Colleges, ADRAC and doctors. The simple explanation I believe it that they do not know that was they are dealing with are side effects, which are well described in documents they do not read or have easy access to.

All Colleges are beneficiaries of Drug Company largesse, which funds conferences and dinners and effectively controls education. The RANZCP has discouraged ADRAC from posting the March 22, 2004 advisories, through a committee, which has done no independent research. All College functions,

educational conferences and much ‘research’ are subsidised by PhaRMAs. Drug companies who generously remunerate travel for ‘opinion leaders’. This poses a challenge to you in evaluation of information.

I enclose some important papers.

Since the diagnosis of ‘depression’ and pharmacological therapies have increased a thousand fold, their lethal and sublethal side effects have increased by the same multiplier.

In the case of modern antidepressants and antipsychotics, we kill more than we save.

I would be happy to attend a hearing with details to submit to examination.

Yours sincerely

Dr. Yolande Lucire
Consultant Psychiatrist

June 11, 2005

Below are deaths suicides. Each is underpinned by 10-20 attempts and many more cases of suicidal thinking and other forms of violence.

If the people in these clinical trials were like my sample in a rural psychiatric ward and in a workers compensation stream, they were hospitalised many times, some up to 13 times before they committed suicide. Many othe6yr psychiatrists do not recognise this problem but I have been a psychiatrist for forty years and this mental condition is new. I recognised something new in 1992 when I saw my first Prozac suicide. I assumed common knowledge but I was mistaken. Suicide attempts have trebled and fill hospital beds and sublethal consequences, serious adverse event occur in up to 3.5% of new antidepressant users and fill the hospitals.

Investigational Drug	Patient No	Suicide No	Suicide Attempt No	Suicides & Attempts as a % of Patient No
Sertraline (Zoloft) Active comparator Placebo Placebo Washout	2,053 595 786	2 0 0 0	7 1 2 3	0.44% 0.17% 0.25%
paroxetine (Aropax)	2,963	5	40	1.52%

Active comparator Placebo Placebo Washout	1151 554	3 0 2	12 3 2	1.30% 0.54%
nefazodone (Serzone) Active comparator Placebo	3,496 958 875	9 0 0	12 6 1	0.60% 0.63% 0.11%
mirtazapine (Avanzar) Active comparator Placebo	2,425 977 494	8 2 0	29 5 3	1.53% 0.72% 0.61%
Bupropion (Zyban) Placebo	1,942 370	3 0	---- ----	
citalopram (Cipramil) Placebo	4,168 691	8 1	91 10	2.38% 1.59%
fluoxetine (Prozac) Placebo Placebo Washout	1,427 370	1 0 1	12 0 0	0.91% 0.00%
venlafaxine (Efexor) Placebo	3082 739	7 1	36 2	1.40% 0.41%
All New Drugs All SSRIs Total Placebo	21,556 13,693 4,879	43 23 2	232 186 21	1.28% 1.53% 0.47%

Healy and Whitaker's conclusion was modest: "It is no longer possible to support the null hypothesis that SSRIs do not cause suicide." Any way you look at available information, clinical settings, emergency rooms, morgues and clinical trials, SSRIs, as a general cause of suicide, would pass the scientific standard of proof.

Antipsychotic Drugs FDA Trials source FDA, David Healy[i]

Drug	Patient No.	Suicides	Suicidal Acts
Risperdal	2607	9	43
Comparator	601	1	5
Placebo	195	0	1
Zyprexa	2500	12	Not disclosed
Comparator	810	1 (2)	Not disclosed
Placebo	236	0 (1)	Not disclosed
Seroquel	2523	1	4
Comparator	426	0	2
Placebo	206	0	0
Sertindole	2194	5	20

Comparator	632	0	2
Placebo	290	0	1
Geodon zisapride	2993	6	Not disclosed
Comparator	951	Not disclosed	Not disclosed
Placebo	424	0	Not disclosed

Chaired by the Hon Emeritus Professor Peter Baume, *Tracking Tragedy* charted the rising numbers of suicides of patients under mental health care.[ii]

Reported suicide deaths of patients in contact with mental health services, and all suicide deaths in NSW 1993-2001[iii]

Year	Suicides in NSW	Suicides in mental health care	Percent of all NSW suicides
1993	676	68	10%
1994	798	72	9%
1995	747	100	13%
1996	811	136	17%
1997	946	166	18%
1998	827	143	17%
1999	846	173	20%
2000	738	156	21%
2001	775	159	21%
2002			
2003		126	

This reveals that, in New South Wales, the number of suicides increased by 99 between 1993 and 2001 and suicides by persons under (state) mental health care accounted for 91 of those, most of increase in numbers in NSW.

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[i] Harris G: Popular Drugs for Dementia Tied to Deaths. *The New York Times*, April 12, 2005.

[ii] *Tracking Tragedy (2003) the Report of the Sentinel Events Committee* http://pandora.nla.gov.au/nla.arc-40156.

[iii] Report of the New South Wales Chief Health Officer 2003-4, Separations for Suicide Attempts http://www.health.nsw.gov.au/public-health/chorep/men/men_suihos_table.htm#table

NEW DRUGS, NEW PROBLEMS

Yolande Lucire

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INTRODUCTION

The Antidepressant Era, from 1988 to the present, may go down in history as a public health disaster. By conservative estimates, the "second generation" of antidepressants, in particular the Selective Serotonin Re-uptake Inhibitors (SSRIs) cause some 400 deaths a year in Australia from induction of suicide. They all have a similar profile for the induction of violence, with the more energising newer ones more heavily implicated. Clinical trials presented to the United States Food and Drug Administration (FDA) and other studies found that they produced a significant risk of suicide. The atypical antipsychotics produce more deaths again from suicide, and cardiovascular events. The drugs of concern are Prozac (fluoxetine), Zoloft (Sertraline), Aropax (paroxetine), Luvox (fluvoxamine), Cipramil (citalopram), Lexapro (escitalopram), Zyban, (bupropion), Efexor (venlafaxine) and Serzone (nefazodone), now withdrawn and others. The antipsychotics include Zyprexa (olanzapine) and Risperdal (risperidone) and some others.

Psychiatric drugs are not alone in causing morbidity. In the United States, the fourth highest cause of death after heart disease, cancer and strokes are the adverse drug reactions. They are responsible for over 105,000 deaths per year and affect many more with their sublethal side effects.[i] If one adds improperly prescribed drugs and those taken incorrectly, adverse drug events (ADEs) become the third highest cause of death. A score of drugs licensed by the FDA in the 1990s have been withdrawn for lethal side effects that were noted in clinical trials but not disclosed to prescribers or patients. The recent withdrawal of Vioxx followed thousands of heart attacks and deaths. It was defended as 'safe' until two weeks before its withdrawal.[ii]

The term PhaRMA comes from the initials of the Pharmaceutical Research and Manufacturers of America. As part of their marketing they promote the medicalisation of stress. They encourage moral entrepreneurs of health who seek to bring all manner of distress into the province of psychiatry. They provide funds to political parties, medical journals and conferences to disseminate the kind of knowledge that suits their purposes, which are commercial and not altruistic. The increasing volume of information about the unintended consequences of the substances they sell brings home the need for a high level inquiry into the inducements offered by "Big PhaRMA" and the corresponding conflicts of interest with the FDA and the Australian regulator, the Therapeutic Goods Administration (TGA). The FDA is the licensing agency, but it states openly that its role is licensing drugs and not protecting the public. The TGA appears to follow the FDA in licensing drugs on the basis of company summaries. Politicians make choices that disregard those of professionals competent to make economic and safety decisions.

Congressional hearings in the United States have revealed the disparity between the knowledge held by PhaRMAs and the information which they disclose in their advertising. New York's Attorney General, Eliot Spitzer, won a settlement of $US430 million against Warner Lambert, a subsidiary of Pfizer Inc. for illegal and deceptive promotions of one of its blockbuster drugs, Neurontin. A score of US State attorneys have followed suit, expecting windfall income for State coffers to recoup some of the healthcare costs generated by the indiscriminate use of these drugs. "It is critically important that physicians and their patients receive fair, balanced and accurate information about prescription drugs and the conditions these medications are approved to treat," Spitzer said. "Marketing strategies that deceptively and illegally promote drugs for unapproved purposes in order to increase a pharmaceutical company's bottom line will be aggressively investigated."[iii]

Spitzer also conducted successful litigation against GlaxoSmithKline for non-disclosure of risk, specifically in the case of Aropax. It has obtained an undertaking by PhaRMAs to place details of clinical trials, even those previously undisclosed, on the internet. These postings on the FDA website have forensic utility to show the extent to which the advertising differs from what was found in clinical trials presented for licensing purposes.[iv]

THE PROBLEM

Completed suicide is the measurable tip of these poorly recognised psychotropic side effects, which have been systematically and deliberately discounted as "the patients' problems." PhaRMAs lose no opportunity to belittle David Healy, who was able through court orders to prise clinical trial statistics out of the FDA, and Peter Breggin, who was the first to bring to public notice the risks of new antidepressants and other medicines used for psychiatric purposes. Breggin defined a *stimulant continuum* beginning with lesser degrees of insomnia, nervousness, anxiety, hyperactivity and irritability, which progresses toward more severe agitation, restlessness, aggression and varying degrees of mania. Mania or manic-like symptoms include disinhibition, grandiosity; sleep disturbances and out-of-control aggressive behaviour. They cycle into depression and suicidality. They can produce a combined state of *stimulation and depression,* an *agitated depression,* with a high risk of suicide and violence. Panic and anxiety are common.

Obsessive preoccupations with aggression, against self or others, are often accompanied by a worsening of any pre-existing depression. Depression and suicidality may appear in persons treated for anxiety or other disorders. A state similar to personality disorder with borderline traits may appear in mature formerly stable persons. Its extreme results from a combination with alcohol and substance abuse, in what seems to be an attempt to relieve the "living hell" that the worst and most dangerous side effect, akathisia, creates. Akathisia may present as a diffuse psychomotor restlessness, which affects the patient's entire body, an increased tenseness, insomnia and a feeling of being very uncomfortable, frequently verbalised, as "I don't feel like myself, weird, strange, not

me." Patients feel they are going mad, in turmoil, and numb as if nothing matters. Embarrassed, they do not confess their impulses. Eliciting them needs careful questioning. These experiences can go on for hours or years, or can be acted on very quickly, in a matter of minutes. Acute akathisia is a psychiatric emergency. Recurrent episodes of hallucinatory delirium along violent or sexual themes with colourful visual, voice and tactile hallucinations may be misdiagnosed as a schizophrenic illness. Sexual craving has been reported.

Akathisia has a strong association with violence, self-harm, suicide and homicide.[v] It is an inner restlessness or jitteriness, accompanied by a subjective as well as objective compulsion to move, abscond, pace or run, or drive long distances in a somewhat dissociated state. Akathisia can lead to suicide because it is intolerable. Preoccupation with unwelcome, obsessively violent thoughts is pathognomonic. First recognised in users of reserpine for high blood pressure, it became prominent in the forensic literature of the 1970s and 1980s as an effect of haloperidol and, later, of flupenthixol.[vi]

The above syndromes often appear in combination with each other. They may recede within days of stopping the medication or persist, requiring hospitalisation and additional treatment over subsequent weeks or months. They occur in individuals with no prior history of violence, suicidality, psychomotor agitation or manic-like symptoms. Some patients cannot easily stop taking these medicines without going into a state of withdrawal. They are, technically, addicted.

No single word describes the problem, but I propose “neurotoxicity spectrum disorder” to describe the manifestations of intoxication with medications said to have serotonergic and/or dopaminergic properties. Professor Perminder Sachdev has proposed a classification of one of these, akathisia. Other than in rare neurological disorders or in the aftermath of epidemics of encephalitis lethargica, akathisia is drug induced, and always iatrogenic.[vii] Acute akathisia may emerge after only two or three doses of an SSRI. It is called tardive akathisia when it develops late in treatment. Withdrawal akathisia is clinically identical and may develop up to three months after stopping the medication. It may be associated with a manic shift as well as rebound depression. It does not get better unless akathisia inducing medications are ceased, and even then, it might take time to recede.

All phases cause serious distress, may compromise the psychiatric status of the patient, may lead to impulsive actions including aggression or self-harm, and may become chronic and resistant to treatment. Reports ascribe to it cases of homicide and suicide. Robert Whittaker wrote about “the madman of our nightmares” who was not a schizophrenic but an akathisiac, having just taken, or taken himself off, prescribed medication.[viii] When treaters do not recognise akathisia as a toxic state and mistake it for schizophrenia, they may prescribe more neurotoxic medications that make it worse. Interactions between drugs from different manufacturers are currently nobody’s responsibility, and this complicates litigation.

Since 1994, SSRI-induced akathisia has been recognised in the Diagnostic and Statistical Manual (DSM IV TR), where it is coded as a movement disorder, but it fits equally well into drug induced psychotic states or with organic brain syndromes. A useful concept is the "akathisia-prone patient" as one who is likely to develop akathisia on tricyclics, lithium, SSRIs, Zyprexa, Risperdal, Solian and Seroquel as well as a variety of other medications. Akathisia accompanies the taking of the medication but it can also occur if the drug is stopped suddenly rather than slowly.

It should not surprise anyone to find that psychotropic drugs have psychiatric side effects, but they are poorly recognised as such, even by psychiatrists, because they occur in the context of treatment for "psychiatric" conditions. Sublethal side effects place heavy demands on Mental Health resources. It is rare to see a person who has been on these medicines for some time who is not also taking co-prescribed tranquillisers of one kind or another.

THE EVIDENCE FOR ANTIDEPRESSANT SUICIDE

Antidepressants form two major groupings, the newer ones described above, and the older ones, tri- and tetracyclics, (TCAs). The latter include Tryptanol (amitriptyline), Anafranil (clomipramine), Tofranil (imipramine), Prothiaden (dothiepin) and Sinequan (doxepin). They have their major effect on a synaptic transmitter, noradrenaline. Mood brighteners are a social phenomenon. These so-called 'antidepressants' act in a variety of ways to increase the levels of serotonin, most of which is in the gut, and not in the brain at all. Despite their name, there is no reliable scientific evidence that serotonin is abnormal in depression, or that SSRIs are, in any way, "specific." Having more serotonin and different neurotransmitters floating around makes for a lot of change, not always for the best.

The possibility that a remedy could have the effect it was supposed to cure was once unthinkable, especially by clinicians, but the history of medicine is full of this type of problem. The alarm was first raised in 1990 by Harvard psychiatrist Martin Teicher. He reported six patients who after 2-7 weeks on Prozac developed intense, violent suicidal preoccupation, which persisted for 3 days to 3 months after the medication was stopped.[xi] None had experienced a similar state in the past. Drug companies dismissed such reports as "anecdotal" and gave, in effect, the reassurance that "It's the disease, not the drug, doctor." Pfizer's Zoloft Litigation Manual is an exhibit from Christopher Pittman's double murder trial, provided to defend their drug in the prosecution for a bizarre Zoloft-induced homicide by a 12-year-old child.[xii] There are now scores of reports of these serious adverse events in patients treated by SSRIs for anxiety, eating disorders, obsessive-compulsive disorder and menstrual problems. Most of these drugs have been banned for children in the UK and USA.

The US Supreme Court decision in *Daubert v. Merrell Dow Pharmaceuticals* (1993) laid the ground for a pre-trial procedure, a Daubert Hearing, by which an expert's testimony could be examined to see if it is "scientific" and admissible, or not, to a trial.[xiii] The scientific status for a theory depends on its ability to be refuted and

falsified. Scientific method involves proposing a null hypothesis, and trying to demonstrate that it is false**.** "The unicorn does not exist" stands until a unicorn is sighted. Disproving the negative is what differentiates science from other forms of inquiry. That SSRIs induce suicide has passed six Daubert Hearings. They conclude that the science behind the revelation of induced suicide, and the problems that lead up to it, is sound.

The (dis)proof of their innocence invokes two numbers: relative risk (RR) and the suicide rate/100,000 patients, or sometimes, patient years (PEYs). Where numbers allow, they are supported by the confidence interval. A relative risk, RR, is how many more times suicide and its precursors, thinking of suicide and suicidal attempts, occur in SSRI-treated patients over and above those treated with tricyclic or sugar pills, or in similar patients in the community who are not treated at all

If a medicine saves some depressed patients from committing suicide, the RR between that medicine and no treatment should be less than one. Tricyclics generally have an RR of 0.5 against no treatment for biological depression, where suicide is a known risk. TCAs halved the number of suicides in this small and well-targeted population, which was at high risk without treatment. TCAs could also induce suicide by energising the depressed, and there is evidence that they are similar to SSRIs in this regard, but the RR was still favourable because careful management could eliminate it. SSRIs are not as effective for the biologically depressed population as are the TCAs. Clinicians will tell you we give as much electroconvulsive therapy as we ever did.

If the relative risk equals 1.0, the risk in treated individuals is the same as the risk in untreated ones. If the relative risk is more than 1.0, the risk in the treated is greater than in the untreated. As the objective is to prevent suicide, an RR of one is ominous. Eli Lilly (Prozac), Pfizer (Zoloft) and GlaxoSmithKline (Aropax) proposed in 1999 that the cut-off point of significance become an RR of 2.0, which is ridiculously high by any standard. David Healy calls this "corporate chutzpah."[xiv] At law, the exposure to asbestos is deemed contributory to cancer even though the RR is around 1.2. Asbestos was never expected to prevent cancer.

The evidence for suicide induction can be found in clinical psychiatry; in observations of new suicidal ideation and in the epidemiology of suicide by prescribed drugs; in challenge-de-challenge-re-challenge studies where suicidality starts on the drug, clears up when it is stopped and reappears on re-exposure, even to another SSRI. This is as good a proof of causality as one can get. The evidence from all these sources, population studies, primary care studies, healthy volunteer studies and random control trials overwhelmingly supports a relative risk of suicide by SSRI users of greater than 2, and sometimes, in the community, as high as 8 or 10. In a company-funded trial, the reporting of which the drug company tried to suppress, two of 26 depressed patients overdosed in the first 2 weeks when Prozac was increased quickly.[xv] Other investigators found suicidal thinking developed in patients who had never been suicidal before, more on Prozac than on other drugs, with Prozac v TCAs having a RR of 2.7.

In 1995, against concerns that Britain's most popular TCA, Prothiaden, was dangerously toxic in overdose and labelled as a "dirty drug" by SSRI manufacturers, Jick *et al.*, epidemiologists, examined 172,598 persons and 1.2 million scripts for 10 antidepressants, old and new, prescribed to general practice patients of whom 143 had committed suicide.[xvi] Prothiaden turned out to be the safest, as only 14% of suicides involved antidepressant overdose. They found a suicide rate on Prozac of 274/100,000 PEYs in the first 30 days of use. This translated to 93/100,000 patients treated. The RR of suicide for Prozac v all TCAs was 6.6, the Prozac v Tofranil RR was 1.9 and the Prozac v Amitriptyline RR was 4.0.

Table 1: Suicides on Antidepressants in Primary Care in the United Kingdom.[xvii]

Drug	Suicide Rate/ 100,000 Patients	Absolute Suicide Numbers
dothiepin	70 (C.I. 53 – 91)	52 Suicides in 74,340 Pts
lofepramine	26 (C.I. 8 – 61)	4 Suicides in 15,177 Pts
amitriptyline	60 (C.I. 41 – 84)	29 Suicides in 48,580 Pts
clomipramine	80 (C.I. 38 – 144)	9 Suicides in 11,239 Pts
imipramine	47 (C.I. 20 – 90)	7 Suicides in 15,009 Pts
doxepin	69 (C.I 17 – 180)	3 Suicides in 4,329 Pts
flupenthixol	78 (C.I. 43 – 129)	13 Suicides in 16,599 Pts
trazodone	99 (C.I. 31 – 230)	4 Suicides in 4,049 Pts
mianserin	166 (C.I. 86 – 285)	11 Suicides in 6,609 Pts
fluoxetine	93	11 Suicides in 11,860 Pts
Total excluding fluoxetine		132 Suicides per 195,931 Patients 67 Suicides per 100,000 Patients

SSRIs are advertised as safe in overdose, but Efexor XR is as lethal in overdose as amitriptyline. SSRI suicides tend to be violent. The patients talk of hanging, drowning, shooting, jumping, stabbing or cutting, lying on a railway line, burning, electrocution or deliberate road accidents. The Drug Safety Research Unit in the UK surveyed medication in a community of 50,000 people, looking at completed suicides and what medicines had been prescribed for them (Table 2). It found a suicide rate on SSRIs of 219/100,000. For Prozac it was 244/100,000, for Aropax it was 269/100,000 and for Luvox it was 183/100,000.[xviii]

Table 2:

Drug	No. Patients	No. Suicides	Suicides/ 100,000 Patients
fluoxetine	12692	31	244 (C.I. 168– 340)
sertraline	12734	22	173 (C.I. 110– 255)
paroxetine	13741	37	269 (C.I.192 – 365)
fluvoxamine	10983	20	183 (C.I. 114– 274)

Total SSRIs	50150	110	219/100,000
mirtazapine	13,554	13	96 (C.I. 53 – 158)

Boardman and Healy investigated 475,000 UK citizens over 5 years, counting all the mood disorders in all the private practices and the suicide rates for these disorders. They found primary care suicide rates for all mental disorders to be in the range of 27-67/100,000.[xix] These figures fitted in with other primary care mood disorder suicide statistics from Holland at 30/100,000 and Sweden, 0/100,000 and the UK at 30/100,000. It would appear that hormesis, protection, had favoured persons with minor mental disorders, who get some support, making them less likely to commit suicide than one might expect. The highest possible suicide rate for mood disorders in the community that is consistent with general suicide rates is 68/100,000.

In 1999, Donovan *et al.* examined 222 completed suicides against their medication and found that the RR of SSRIs v TCAs was two.[xxi] Donovan also studied 2,776 deliberate self-harm (DSH) cases over 24 months. In this study, Aropax, (paroxetine) (an SSRI) had a RR of 1.9 for DSH versus Tofranil (imipramine) and an RR of 4.0 versus Amitriptyline, while the RR for Prozac was 6.6 against all TCAs.[xxii]

In 2001, Khan *et al.* looked at blind clinical trials from 1986-90, all of which had been presented to the US Food and Drug Administration to get SSRIs licensed. Of 48,277 patients who participated in the trials, 77 committed suicide.[xxiii] All the clinical trials for antipsychotics, SSRIs and anticonvulsants (the medicines used for psychiatric problems) involved 71,604 participants. Khan *et al*. uncovered a suicide rate of those involved of 718/100,000, an increase in the rate of suicide for those participating in the SSRI clinical trials of nearly 68% over the rate of suicide in the general public, which is around 11/100,000, in citizens, and around 200/1000,000 in people getting new antidepressants.[xxiv] Although the risk of suicide in untreated 'depression' is constantly promoted by PhaRMAs, only the relatively rare state of 'biological depression' carries a high suicide risk. Four per cent of the SSRI drug-trial participants attempted suicide within the following year, 4000/100,000, leading to the concern that psychiatric drugs may affect metabolism beyond their cessation. Successful suicide lies in a ratio somewhere between 1:10 to 1:20 to attempted suicide. More again become intensely preoccupied with suicide.

The results of random controlled trials (RCTs) provide the justification to have the FDA license a drug. SSRIs were aimed at general practice, so biologically depressed patients and those with borderline personality disorder, all of whom carried a suicide risk, were excluded from these trials. Investigators collected "samples of convenience" that included anxious rather than depressed patients and those under stress with minor disorders. The participants have been described as "the Valium using population of the 1970s." The comparator drugs were mostly TCAs but some were SSRIs as well, generating a fake procedure, rather like comparing a drug to itself.

Not much difference in efficacy was ever found between placebos or old and new medications using the symptom checklist for 'major depression' as it appears in the DSM. Valium had been co-prescribed in the Prozac trials to combat agitation, which occurred in 25%. It may have been the active substance. Many participants had not been able to tolerate even one week's treatment, but the FDA was not fully informed of dropout rates. Healy and Whittaker re-evaluated the original studies. They published a watershed paper in September 2003, naming it "Antidepressants and Suicide: Risk–Benefit Conundrums" (see Table 3).[xxv]

Table 3:

Investigational Drug	Patient No	Suicide No	Suicide Attempt No	Suicides & Attempts as a % of Patient No
sertraline (Zoloft)	2,053	2	7	0.44%
Active comparator	595	0	1	0.17%
Placebo	786	0	2	0.25%
Placebo Washout		0	3	
paroxetine (Aropax)	2,963	5	40	1.52%
Active comparator	1151	3	12	1.30%
Placebo	554	0	3	0.54%
Placebo Washout		2	2	
nefazodone (Serzone)	3,496	9	12	0.60%
Active comparator	958	0	6	0.63%
Placebo	875	0	1	0.11%
mirtazapine (Avanzar)	2,425	8	29	1.53%
Active comparator	977	2	5	0.72%
Placebo	494	0	3	0.61%
Bupropion (Zyban)	1,942	3	----	
Placebo	370	0	----	
citalopram (Cipramil)	4,168	8	91	2.38%
Placebo	691	1	10	1.59%
fluoxetine (Prozac)	1,427	1	12	0.91%
Placebo	370	0	0	0.00%
Placebo Washout		1	0	
venlafaxine (Efexor)	3082	7	36	1.40%
Placebo	739	1	2	0.41%
All New Drugs	21,556	43	232	1.28%
All SSRIs	13,693	23	186	1.53%
Total Placebo	4,879	2	21	0.47%

Whereas Khan had coded as "placebo suicides" those within 2 weeks of stopping an SSRI, Healy and Whittaker recognised these five suicides during withdrawal or washout, and many suicidal acts, as "withdrawal suicides." Khan had counted suicides per number of patient years exposed to the drug, PEYs, whereas Healy and Whittaker

counted suicides per number of patients treated. Healy and Whittaker argued that the risks of SSRIs resembled the risks of space travel, which, mile for mile was the safest form of transport available. But going up and coming down are the danger periods for both. The metaphorical landing and re-entry occurs each time a dose is forgotten, not absorbed, taken with alcohol or if a co-prescribed medicine is added or removed. So users in the community are more likely to be adversely affected than those in clinical trials, who are interviewed about side effects each week. Healy and Whitaker's conclusion was modest: *"It is no longer possible to support the null hypothesis that SSRIs do not cause suicide."* Any way you look at available information, clinical settings, emergency rooms, morgues and clinical trials, SSRIs, as a general cause of suicide, would pass the scientific standard of proof.

David Healy conducted a healthy volunteer study using his staff. Two of 20 became suicidal in a two-week period on Zoloft.[xxvi] Two, possibly three, healthy volunteers have committed suicide in clinical trials for antidepressants. Nineteen-year-old Traci Johnston killed herself in February 2004 in a trial for incontinence of Eli Lilly's new serotonin drug, Duloxetine, aborting the trial, but the drug was licensed in September 2004, carrying a "black box" warning

THE "SECOND GENERATION": "ATYPICAL" ANTIPSYCHOTICS.

More alarming information has emerged from David Healy's evaluation of the clinical trials presented to the FDA of new "atypical" antipsychotic drugs.[xxvii] Because of their high cost ($300+ a month as opposed to $10 a month for haloperidol) they are limited to use for the Special Purpose (SP) of schizophrenia. In practice, they are very frequently prescribed unlawfully for all sorts of problems, with the best of intentions. They are problematic drugs. In the late 1980s, the FDA did not notice that one in 208 or 12 in 2,500 clinical trial subjects with schizophrenia committed suicide during the trials of Zyprexa, but only one on placebo and one on a comparator, most likely haloperidol. The subject numbers were so small that relative risk of suicide on Zyprexa could not be calculated reliably. The overall suicide rate for these trials, on a time-adjusted basis, was two to five times the norm for schizophrenics.

Table 4: Antipsychotic Drugs FDA Trials source FDA, David Healy[xxviii]

Drug	Patient No.	Suicides	Suicidal Acts
Risperdal	2607	9	43
Comparator	601	1	5
Placebo	195	0	1
Zyprexa	2500	12	Not disclosed
Comparator	810	1 (2)	Not disclosed
Placebo	236	0 (1)	Not disclosed
Seroquel	2523	1	4
Comparator	426	0	2
Placebo	206	0	0

Sertindole	2194	5	20
Comparator	632	0	2
Placebo	290	0	1
Geodon zisapride	2993	6	Not disclosed
Comparator	951	Not disclosed	Not disclosed
Placebo	424	0	Not disclosed

The FDA trials and 52 subsequent studies evaluated in 2000, by John Geddes of Oxford University demonstrated no clear evidence that atypical antipsychotics were more effective or better tolerated than conventional antipsychotics.[xxix] Thirty-six, that being one in every 145 clinical trial subjects for Risperdal, Zyprexa, Seroquel, (quietapine) and Sertindole died; most by suicide, yet these deaths are never mentioned in scientific literature or prescriber information. These deaths occurred even though two thirds of Zyprexa, nearly half the Risperdal and 80% of Seroquel subjects did not complete the trials because the drugs were poorly tolerated.[xxx] A rate of 27% akathisia in a trial of Zyprexa 10 mg was balanced by an equally high incidence of akathisia on placebo.[xxxi] This indicated that Eli Lilly either did not know what they were talking about (as akathisia is always a medication-induced phenomenon), or the participants had not fully recovered from whatever they had been taking before entry to the trial. Serious adverse events affected 84 subjects who took Risperdal.

None of this information appears in promotional material. Indeed 47 serious adverse events in 87,000 users of Zyprexa injectable included eight deaths. We are being assured that the deaths are not related to the Zyprexa but, given the number of suicides and deaths associated with the oral preparation, this seems to be improbable. The FDA issued a 'black box' warning about sudden death from the new antipsychotic medications, (including quietepine and ariprazole) but only for the elderly, in spite of evidence that all age groups are adversely affected. [xxxii][xxxiii] Further warnings are expected to advert to the extreme dangers of mixing them with SSRIs. Nor is it the case, as suggested, that Clozaril protects against suicide when compared with Zyprexa. Zyprexa itself is suicidogenic.[xxxiv] This comparison manoeuvre delays their obligation to issue full warnings for all children and adults. The PhaRMAs are stalling again as they did for antidepressants and as Merck did for Vioxx, when they suggested that a high heart attack rate on Vioxx, compared with Naproxen, occurred because the latter was protective. David Healy has pointed out that Zyprexa and Risperdal trials had the highest suicide rates in clinical trial history, but suicide risk does not feature in drug company promotional material. Geodon (ziprasidone) had the same suicide risk as SSRIs, about one in 500.

Only five Zyprexa schizophrenia trials were undertaken, but these generated 234 ghost written articles by prominent "opinion leaders" which were carefully placed in the prestigious journals, dependent for their viability on PhaRMA advertising.[xxxv] None of these publications yielded any picture at all of the risk of suicide or suicidal acts on these drugs, let alone sudden death. "Endorsement Science" had become the means of promotion. The colourful capsules appeared on the cover of Time, in The Washington Times and The New York Times. The "Dopamine Theory of Schizophrenia" was alive and well in these endorsements, although by the time they were published it had no

more scientific validity than the serotonin theory of depression. John Merson calls this phenomenon “epistemic capture,” the control of knowledge by vested interests.[xxxvi]

There is as yet no literature on suicidality when SSRIs and atypicals are used in combination. I have seen a score of cases where SSRIs had been used safely until an atypical was introduced and the patient rapidly became akathisic and suicidal. Both groups of drugs induce akathisia and have many similar side effects. Many medicines are metabolised by the P450 cytochrome system, 1000 enzymes determined by 50 different genes.[xxxvii] Not every person has all the genes and all the enzymes. Genetics of the metabolism, of transporter and neuro-receptor systems, may hold the answer to the mystery of why different people respond differently to the same substances. Some cannot deal with SSRIs at all and react catastrophically to only one or two doses. Enzymes that metabolise them can be carefully "induced" by slowly increasing doses, but they are inhibited by cannabis and some medicines. One can predict that a problem will occur with combined use, but not whether it will be suicide, violence, sedation or psychosis. If too much is given, or is given too quickly, a “traffic jam” occurs and an oversupply of psychoactive metabolites recirculates and acts, unpredictably, on brain receptors.

My guess is that the sublethal effects of medicines that have been introduced in the last 12 years in Australia would account for the increase in violent psychiatric morbidity. Schizophrenia and bipolar rates have not changed for at least a hundred years. Some more neurotoxic psychosis, technically delirium, comes from the use of amphetamines and cannabis, which together with alcohol, and smoking are risk factors for akathisia.

CONSEQUENCES DOWNSTREAM?

A study of psychiatric admissions in 2001 at Yale found that 8% of patients admitted may suffer from SSRI-induced mania or psychosis.[xxxviii] The proportion seems to me more like 25 to 30% from my observation of patients, not those with borderline personality disorder, who presented in a violent state with agitation, suicidal and homicidal thoughts and acts, two or three a week, to a 21-bed rural psychiatric ward where I worked. In two years, involving about 600 admissions, 200 reports were made to the Adverse Drug Reactions Advisory Committee (ADRAC), all when the side effects described above were concurrent with SSRI use, and closely associated with dose changes. This made each hospital admission, by definition, a “serious” ADE. There were also two akathisia suicides, a death from bleeding and a Prozac homicide, all cases where collateral observations made them relatively easy to attribute.

The Bulletin revealed that 400 young mental health patients would commit suicide in 2003.[xxxix] In NSW, the suicide rate in the immediate period after discharge was 100 times the rate for the general population; for patients with depression, it increased to 500 times. Homicides by mentally disordered persons run at three a month in NSW, having nearly doubled from 20 victims in 2000-01 to 36 in 2001-02. In the 1980s, there were only half a dozen a year for forensic psychiatrists like myself to be involved in, out of the 120 or so annual homicides in New South Wales. Dr Bill Barclay reviewed the

perpetrators of nine homicides committed by patients under mental health care. Chaired by the Hon Emeritus Professor Peter Baume, *Tracking Tragedy* charted the rising numbers of suicides of patients under mental health care.[xl]

Table 5: Reported suicide deaths of patients in contact with mental health services, and all suicide deaths in NSW 1993-2001[xli]

Year	Suicides in NSW	Suicides in mental health care	Percent of all NSW suicides
1993	676	68	10%
1994	798	72	9%
1995	747	100	13%
1996	811	136	17%
1997	946	166	18%
1998	827	143	17%
1999	846	173	20%
2000	738	156	21%
2001	775	159	21%

Table 5 reveals that, in New South Wales, the number of suicides increased by 99 between 1993 and 2001 and suicides by persons under (state) mental health care accounted for 91 of those, most of increase in numbers in NSW. A University of Western Australia research team found annual deaths from suicide among mental health patients doubled from 1980 to 1998. In WA, 45% of suicides occurred in people who had used mental health services. The majority had one short contact following a suicide attempt and had committed suicide before receiving any follow-up. Suicide rates were seven times higher in people diagnosed with "mental illness," and the number so diagnosed was increasing as well. The rate of suicide in people with mental illness has been increasing over the period 1990-98, and the increase in that rate almost entirely explains the net increase in the total West Australian suicide rate.[xlii]

In the Australian Capital Territory, between 1996 and 2000, inclusive, 184 citizens died by suicide from a population of 237,798. Of these 101 were categorised as "mentally ill", a rate 11.4 times that of the population[xliii] and similar to that of excessive mortality by suicide in the mentally ill in WA and NSW. In South Australia, mental health presentations to the Accident and Emergency Department of the Flinders Medical Centre requiring Mental Health Care numbered 248 in 1994/1995 (when there were two other hospitals in the region) but had risen to 1,838 in 2002/2003, and that was not counting overdoses.[xliv]

In NSW, 'separations" for suicide attempts which had occasioned hospital admissions trebled from 3,198 in 1989 to 9,586 in 2002, and some hospitals do not report these at all. From 1990 to 2002 antidepressant use had rocketed after the first SSRI, Prozac, was introduced in 1991, Prescriptions for it and the rest rose steadily Australian doctors

wrote 6,664,960 prescriptions for SSRIs in 2003. Forty per cent of first prescriptions remain unfinished, because of side effects. The national suicide rate rose again when atypical antipsychotics were made available, when Risperdal was licensed for use in schizophrenia on the Pharmaceutical Benefits Scheme from 1995, and followed by Zyprexa from early1997. Zyprexa was licensed for bipolar illness in February 2005, as well. I predict a further increase in mental health suicide numbers as doctors co-prescribe it with SSRIs, having first mistaken their "serotonergic" side effect of unstable mood and hallucinations for bipolar disorder.

While it might be expected that mentally ill individuals are at a greater risk of suicide than the population, the increasing numbers of "mentally ill" and increasing numbers of suicides among clients of mental health services year stands as testimony to the fact that psychiatry has got something wrong. Until the error is identified and fixed, and psychiatry has solved the problems internal to it, which appear to be caused by their own remedies, more money for mental health is unlikely to help the situation. For the 300 years when bloodletting was a recommended activity for physicians, the patient, energised by a steroid boost from the shock of losing blood, would feel better but die within days. The physician, happy to be doing something, and gratified by an initial seemingly favourable response, did not look at mortality statistics or ask if he had contributed to early death.

Current priorities promoted to health ministers, State and Federal, focus on 'depression' and its active pharmacological treatment. Since this promotion, increasing numbers of persons have been diagnosed as 'depressed', until 4.7 per cent of the population is on antidepressants.[xlv] The House of Commons report of April 2005 on *the Influence of the Pharmaceutical Industry* expressed concern about the "Defeat Depression Campaign" (1992–1997), run by the Royal College of General Practitioners and the Royal College of Psychiatrists and sponsored by the manufacturers of antidepressants (who provided approximately one-third of the funding.) It targeted doctors as well as patients, in particular to emphasise that these drugs did not cause addiction or dependence. Any definition of dependence uses as a criterion of stopping the drug eliciting untoward effects, which they do and many people are unable to stop, hence are addicted. Witnesses argued that the use of disease awareness campaigns, which in the past have involved conditions including depression, anxiety and obesity, play a major part in the "medicalisation" of our society; in short: "where disease awareness campaigns end and disease mongering begin is a very indistinct line."[xlvi].

THE RESPONSES

PhaRMAs have settled many claims in homicide, suicide and attempted suicide lawsuits, but not enough of them to induce them to give appropriate warnings to users and prescribers in Australia.[xlvii] Over 100 homicides have been defended in various jurisdictions as caused by SSRIs, their perpetrators distinguished by characteristics which make them unlikely candidates for such behaviours. Homicide is followed by suicide in an unusually high proportion of them. Involuntary intoxication leading to dissociation and automatism is raised in the defence of those who offend in this condition.[xlviii]

Transient global amnesia is common. The British Medical Journal issued warnings on February 5 2004, the FDA on March 22, 2004: [xlix]

> Today the Food and Drug Administration (FDA) asked manufacturers of the following antidepressant drugs to include in their labeling a warning statement that recommends close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality. It advises that anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (severe restlessness), hypomania, and mania have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric.
>
> Health care providers should carefully monitor patients receiving antidepressants for possible worsening of depression or suicidality, especially at the beginning of therapy or when the dose either increases or decreases.

Manufacturers in the USA put this information on web sites on May 3, 2004, but they have not amended Australian prescriber information. More than a year later, the TGA has steadfastly refuses to pass on warnings and FDA Public Health Advisories that are available to US citizens, keeping Australian prescribers and consumers in the dark. While SSRI prescribing has fallen overseas along with the share price of the makers, the TGA has posted warnings only about their use in children, in the face of evidence that the problem does not stop on the eighteenth birthday, or on the thirtieth. Marcia Angell MD, former Editor of The New England Journal of Medicine wrote, “Lets face it. The FDA is doing a poor job of ensuring that prescription drugs are safe and effective. It approves drugs that offer only minimal benefit, and then sometimes leaves them on the market long after they've been shown to be dangerous.”[l] The FDA is described as "prone to a culture of secrecy and concealment." The FDA had waived financial disclosure requirements for advisory panel members and excluded any independent authorities in psychopharmacology who have analysed the data and raised the issue of unreported suicides. Ten out of 32 panellists on the FDA had conflicts of interest in that they received income from drug companies as well.

On receipt of the US FDA Advisory, a spokesman for The Royal Australian and New Zealand College of Psychiatrists (RANZCP) issued a media statement saying he was "not convinced.”[li] The RANZCP adopted the position of the American College of Neuropsychopharmacologists task force on SSRIs and suicide. The New York Times called these prominent opinion leaders of American psychiatry a group of “data deprived academic researchers” who “[e]ven so issued a report disputing evidence that [antidepressants] increased suicidal tendencies, only to have the FDA, which had access to all the relevant data, find that the risk was real for some depressed youngsters.[liiliii] The RANZCP has not yet looked at suicide in adults. Sharav reported on 3/3/05, on the website of the Alliance for the Protection of Human Research, ahrp.org, that the American psychiatric establishment continued to operate within a “head in the sand” culture of denial when confronted with compelling evidence showing that their prescribing of antidepressants for children has been misguided.

Both FDA and the TCA have relied on dubious advice, incomplete drug company summaries, and false reassurances about the safety and efficacy of these drugs. The peer reviewed journal reports were based on partial (positive) data, and are, therefore, tainted. Some decisions about purchasing these substances were made under political pressure. Resistance to accepting reality and the failure to use other, non-drug, therapies may put psychiatrists at risk of malpractice suits.[liv]

Doctors are expected to practice evidence-based medicine but they were never taught to differentiate 'evidence' from opinion, endorsement or drug company information. Evidence of the dangers of SSRIs is published and available, but requires evaluation by persons or organizations capable of assessing the evidentiary value of a report or meta-analysis. One can no longer set up another clinical trial to see how many people kill themselves as a consequence of using the drug under testing. It would be impossible to get insurance, ethics approval or informed consent. A participant would have to know that she has a 1 in 500 chance of committing suicide, a one in 70 chance of becoming suicidal, and a 20% risk of a serious adverse effect, and that she runs a significant risk of becoming violent and a small, unquantifiable risk of killing someone. Yet such trials are being proposed for elderly people dying of cancer, to see if Zoloft protects them from getting depressed. With cancer they are likely to develop liver problems and to get co-prescribed medications as well.

Potentially fatal complications of any treatment might be acceptable when the treated population is small, dangerously ill and at high risk. The availability of a supposedly safe 'remedy' has increased by a thousandfold the population that can be medicalised and medicated. Lethal side effects have increased by the same multiplier. It was only after the diagnosis of "depression" was expanded to include anxiety, stress, grief and unhappiness that a huge market for 'antidepressants' emerged.

A side effect, even suicide, when it has a rate of 1 in 500, is too rare for clinicians to see. They need advice from suicide epidemiologists and statisticians: 200/100,000 is the equivalent of one death in 500 people treated with SSRIs. If every single suicide had a "minor mental disorder," the worst figure for suicide in untreated patients with minor disorders in the community is 67/100,000 but is more like 30/100,000 as not everyone who commits suicide has a disorder. An average figure for suicides on SSRIs is 200/100,000. This means that there are more than 100 suicides per 100,000 patients treated with serotonin boosters over treatment with other drugs or non-treatment. Sachdev writes that failing to warn of such profound side effects may attract charges of negligence and failure to get informed consent. One in 500 is well above the risk rate in the precedent set by the High Court in *Rogers v Whittaker*, where it was deemed that a 1 in 14,000 risk demanded a duty to warn of a catastrophic side effect. Someone should have that duty.

The manufacturers have not advised prescribers in Australia. Eli Lilly and Forrest for fluoxetine, marketed as Prozac and Lovan, and Wyeth for Efexor belatedly sent me misspelt faxes, similar in content to the US FDA Public Health Advisories. Not one of my psychiatrist colleagues recalls receiving one of these, but at the suggestion of

Professor Duncan Topliss, Chair of ADRAC, prescribing information in manuals has been very quietly upgraded. (Personal communication). The risk as described in advertising remains incomprehensible to most doctors.

FUTURE ACTION

The lack of clear lines of bureaucratic responsibility and liability for medication side effects and the haphazard nature of data collection by State and Commonwealth agencies are some of the reasons why this epidemic has escaped attention from the various public health regulators. By 2003, over 28 million people had started taking Prozac since its launch in 1988. SSRIs cost the Australian taxpayer some $169 million a year for medication alone, and more has been paid out for treating the problems they have created down the line in morbidity and mortality. Had some of the cost of these drugs gone towards evaluating adverse information as it emerged in medical journals, perhaps hundreds of lives and many hundreds of millions of dollars would have been saved in health care costs.

Since 2003, the FDA has been found repeatedly, along with the National Institute of Health (NIH), to be both incompetent and corrupt.[lv] In view of this lack of reliability, legislative change is needed to ensure that the TGA protects the public interest and is competent scientifically to assess the primary evidence of clinical trials, as opposed to the PhaRMA's spin on them. The charter and responsibilities of the TGA needs to be reviewed to turn it into a different kind of organization, one that is accountable and responsible for the safety of drugs and provides some input into how they are used. It needs to protect the Australian consumers. These responsibilities demand that it be completely independent of the FDA and of political influences that protect the pharmaceutical industry both in Australia and in the United States. Coroners need resources to examine and collate their existing databases. The collection of data should include psychiatric post mortems on a sample of mental health suicides, together with a survey of a sample of patients presenting for psychiatric care at a number of locations.

The Melbourne Age reported on a Victorian psychiatric unit that suffered 13 suicides in 13 months, in 2002-3.[lvi] It has not attracted a coronial inquiry. All the statistics available about relative risk of suicide on these drugs, the rising suicide numbers and rates correlating with increased prescribing, and the increasing number of people requiring psychiatric treatment for their side effects warrant careful public examination. Litigation arising out of these hazards against health departments and doctors could produce another medical indemnity crisis. The problem can be diverted to the source, the PhaRMAs, which collectively have deceived the Commonwealth, taxpayers, patients and prescribers. Not only the companies, but their chief executives and boards, should be held responsible for ensuring the reliability of prescribing information and be held liable for the consequences of having provided prescribers and patients with information which is false or misleading, misrepresented or intentionally withheld.

The Author: Dr Yolande Lucire PhD MBBS DPM FRANZCP is a forensic psychiatrist and medical anthropologist in private practice. She researches and writes about hysteria and moral panics, and is surprised to find a panic worth having that is hard to start. Correspondence to lucire@ozemail.com.au

The Occasion: Plenary session of the New South Wales Chapter of the Academy held on 19th May, 20004 to discuss if second generation antidepressants and SSRIs induced suicide.

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SECOND GENERATION ANTIDEPRESSANTS AND ANTIPSYCHOTICS

MOVING UPSTREAM

Deaths can be quantified, but the sub lethal side effects manifest as PHARMACOLOGICAL IATROGENESIS

Yolande Lucire
PhD, MB BS DPM FRANZCP

Forensic Psychiatrist

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

The NSW Government's Plan for **Mental Health Services**

informs us of **OUR ACHEIVEMENTS**, namely

Since June 2001, an **additional 257 mental health beds have opened**.

By June 2005, an additional 40 beds will have opened.

Does presiding over increasing need for mental health care represent an achievement?

THE INVISIBLE PLAGUE: THE RISE OF MENTAL ILLNESS FROM 1750 TO THE PRESENT. (Rutgers University Press. 2002)

E. Fuller Torrey and Judy Miller ask why insanity , once considerably less than one case per 1000 of population, reached epidemic proportions. 0.68/1000 in 1807 to7.13/1000 in 1961.

SUGGESTED CAUSES INCLUDE
AVAILABILITY OF FACILITIES
ACCUMULATION AND AGED PATIENTS
GENETIC
INDUSTRIAL REVOLUTION AND AND URBANISATION
STRESS
DIET
ALCOHOL
TOXINS
MEDICAL CARE#
INFECTIONS AGENTS
- syphilis
- the polio model the vaccination model
- the pet cat model

#Norman Sartorius suggested the less fit infants survived because of better obstetric care

I pose another causal hypothesis:

IATROGENESIS,

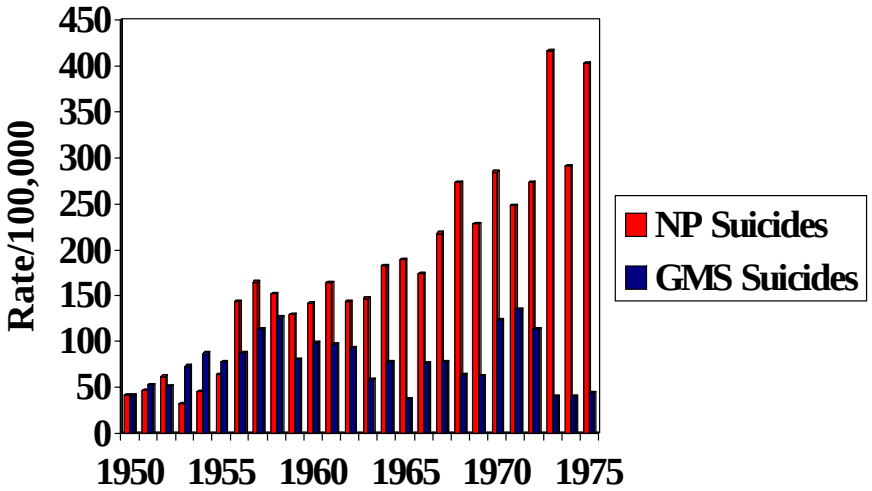
specifically

PHARMACOLOGICAL IATROGENESIS.

Is it possible that the remedies we provide for minor disorders are causing major ones?

What about the alternatives?

SUICIDES IN V.A. HOSPITALS



From these figures it can be seen clearly that the natural rate of suicide in schizophrenia was indistinguishable from that of the rest of the population – see the rates for 1950-1955, when Thorazine was introduced. The best figures today for the natural rate of suicide in schizophrenia suggest that the rate is little different from that of the normal population.

Healy D, Harris M, Tranter R, Gutting P, Austin R, Jones-Edwards G, Roberts AP (in press). Lifetime Suicide Rates in the Course of the Treatment of Schizophrenia in North Wales: Two Cohorts 1875-1924 & 1994-1998. British Journal of Psychiatry.

Psychiatric drugs are not alone in causing morbidity. In the United States, the fourth highest cause of death after heart disease, cancer and strokes are the adverse drug reactions.

ADEs are responsible for over 105,000 deaths per year and affect many more with their sublethal side effects.

If one adds improperly prescribed drugs and those taken incorrectly, adverse drug events (ADEs) become the third highest cause of death.

Recognition of these adverse drug reactions and withdrawal
of the offending substances

can prevent misdiagnosis and potentially severe long term iatrogenic disorders

Lazarou J, Pomeranz BH and Corey PN: Incidence of adverse drug reactions in hospitalised patients: a meta-analysis of prospective studies. JAMA, 279:1200-1205, 1998.Total Recall. Four Corners. ABC. 10 April 2005 on Vioxx.

Akathisia is a subjective desire to be in constant motion.

A manifestation of drug sensitivity, it may be confused with psychotic agitation, and incorrectly treated by increasing the dose of the offending medication.

The symptom subsides when the offending medication is discontinued and replaced by another one, better tolerated by the patient.

Source: Modern Synopsis of Psychiatry lll, Kaplan and Saddock.

1981 edition. And all since.

SSRI-induced akathisia is in the Diagnostic and Statistical Manual (DSM IV TR) at 333.99

Teicher, Glod and Cole (1993) suggested **9 "clinical mechanisms" by which SSRIs can induce or exacerbate suicidal tendencies** by causing the following:

(a) **energizing depressed patients to act on pre-existing suicidal ideation**;

(b) paradoxically **worsening depression**;

(c) inducing **akathisia with associated self-destructive or aggressive impulses;**

(d) inducing **panic attacks**;

(e) switching patients into **manic or mixed states;**

(f) producing **severe insomnia** or interfering with sleep architecture;

(g) inducing an **organic obsessional state;**

(h) producing an organic **personality disorder with borderline features**;

(i)exacerbating or inducing (EEG) or other **neurological disturbances.**

Teicher MH, Glod CA, Cole JO. The emergence of fluoxetine- induced suicidality. Drug Safety 1993;8(3):186-212

International Journal of Risk & Safety in Medicine 16 (2003/2004) 31–4931 IOS Press

Suicidality, violence and mania caused by selective seroton in reuptake inhibitors (SSRIs): A review and analysis *

Peter R. Breggin
101 East State Street, No. 112, Ithaca, NY 14850, USA

Abstract. Evidence from many sources confirms that selective serotonin reuptake inhibitors (SSRIs) commonly cause or exacerbate a wide range of abnormal mental and behavioral conditions. These adverse drug reactions include the following overlapping clinical phenomena: a stimulant profile that ranges from mild agitation to manic psychoses, agitated depression, obsessive preoccupations that are alien or uncharacteristic of the individual, and akathisia. Each of these reactions can worsen the individual's mental condition and can result in suicidality, violence, and other forms of extreme abnormal behavior. Evidence for these reactions is found in clinical reports, controlled clinical trials, and epidemiological studies in children and adults. Recognition of these adverse drug reactions and withdrawal from the offending drugs can prevent misdiagnosis and the worsening of potentially severe iatrogenic disorders. These findings also have forensic application in criminal, malpractice, and product liability cases.

(1) The production of a ***stimulant continuum*** that often begins with lesser degrees of insomnia, nervousness, anxiety, hyperactivity and irritability and then progresses toward more severe agitation, aggression, and varying degrees of mania. **Mania** or manic-like symptoms include **disinhibition, grandiosity, sleep disturbances, and out-of-control aggressive behaviour**, including cycling into depression and suicidality.

(2) The production of a combined state of ***stimulation and depression* – an *agitated depression* –** with a high risk of suicide and violence. Often the overall **depression is markedly worsened**.

(3) The production of ***obsessive preoccupations*** with aggression against self or others, often accompanied by a worsening of any pre-existing depression.

(4) The production of ***akathisia*,** an inner agitation or jitteriness that is usually (but not always) accompanied by an inability to stop moving. It is sometimes described as **psychomotor agitation or restless leg syndrome**.

Those at risk of suicide are agitated,in turmoil, nervous, sleepless, pacing, energized, almost manic, and they reject their obsessive suicidal thoughts as ‘strange’, ‘weird,’‘not me’.

This can go on for weeks or can turn into suicide unpredictably in a matter of minutes.

The traditional suicidogenic triad

1) **akathisia**,

(2) **emotional blunting**, also called psychic numbing **“I cannot feel anything, do not care” and/or**

(3) **psychotic decompensation**

In turmoil, feeling numb as if nothing matters, and feeling one is going mad

•Teicher and Cole, 1993 Healy, Langmaak, and Savage, 1999;

SSRI overdoses are less likely to be fatal, but Efexor XR is as toxic in overdose and amitriptyline..

SSRI suicides tend to be violent:

Akathisiacs are thinking about hanging, drowning, shooting, jumping, stabbing or cutting,
or
dying on a railway,

immolation, burning, electrocution, or deliberate road accidents.

Trying to get police to shoot them, some cut their throats and self mutilate in public, usually using alcohol as well.

I have seen deliberate self harm associated with semi-delirium characterised by violent blood-laden, or sexual abuse hallucinations, coming out of nowhere, sometimes interpreted as “memories’ ‘recovered’ out of the blue.

Sachdev and others report ‘sexual craving”

SECOND GENERATION DRUGS DID NOT PERFORM WELL IN CLINICAL TRIALS

Kahn found 77 suicides in 48,277 participants in SSRI trials.
Khan then reviewed 71,604 participants in FDA clinical trials treated with **ANTIPSYCHOTICS, SSRIs AND ANTICONVULSANTS and** found a rate of 757 suicides/ 100,000 PEYs (participant years) or 715 per 100,000 participants.

That is 68 times 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
Am J Psychiatry. 2003 Apr;160(4):790-2.

The do not do very well in the field either. RR risk of sudden death v sugar pills is 1.7. So:

FDA Talk Paper April 11, 2005

•FDA Issues Public Health Advisory for Antipsychotic Drugs used for Treatment of Behavioral Disorders in Elderly Patients

•The Food and Drug Administration (FDA) today issued a public health advisory to alert health care providers, patients, and patient caregivers to new safety information concerning an unapproved (i.e., "off-label") use of certain drugs called "atypical antipsychotic drugs."

•... have shown a higher death rate associated with their use compared to patients receiving a placebo (sugar pill).

•Today's advisory applies to such antipsychotic drugs as Abilify (aripiprazole), Zyprexa (olanzapine), Seroquel (quetiapine), Risperdal (risperidone), Clozaril (clozapine) and Geodon (ziprasidone). Symbyax

SECOND GENERATION ANTIPSYCHOTICS MAY ALSO BE CULPABLE.

David Healy analysed the FDA trials that got the atypical antipsychotics licensed. The are now publicly available on the FDA website.

The regulator, the FDA, just did not notice, in the late 1980,s that 1 in every 145 subjects that entered the trials for olanzapine, risperidone, and ziprasidone died.

Most, but not all by suicide. Strokes were very common. Coroners have not been told thee is an FDA advisory about sudden death in elderly patients.

Zyprexa (Olanzapine) trials had the highest rate of suicide in clinical trial history. 84, i.e. 1 in 35 - had serious side effects.

Suicide and Suicide Attempts in Clinical Trials of Antipsychotic Agents submitted to the FDA

	Number of Patients	Patient Exposure Years	Number of Suicides	Number of Suicide Attempts
Risperidone	2,607	858	9	43
Comparator	621	71	1	5
Placebo	195	15	0	1
Olanzapine	2,500	1,122	12	N/A
Comparator	810	193	1	N/A
Placebo	236	27	0	N/A
Quetiapine	2,523	1,103	1	4
Comparator	420	52	0	2
Placebo	206	15	0	0
Sertindole	2,194	1,024	5	20
Comparator	632	129	0	2
Placebo	290	27	0	1
Ziprasidone	2993	1189	6	N/A
Comparator	951	383	1	N/A
Placebo	424	82	0	N/A
Total				
New Antipsychotic	12,817	5,296	33	72
Comparator	3,434	828	3	10
Placebo	1,351	166	0	2

Only 5 Zyprexa trials were undertaken to underpin its use in Schizophrenia

50%of enrolled participants did not complete six week trials bec ause of side effects.
1 in 208 committed suicide.

There were 3 Risperdal trials.

50% did not complete.
1 in 250 committed suicide.

Trial 1:160 patients , 6 weeks
50% did not complete
FDA: “equivocal”
Trial 2: 523 patients - 45% did not complete.
FDA:’multiple doses of risperidone compared with a single dose of haloperidol -biased)
Trial 3: 1557 subjects 5 countries

To get psychotic patients for $10-$25,000 each, Borison and Diamond took their schizophrenics off Haloperidol to generate active psychosis, then compared one dose of haloperidol to many of the atypical. They went to jail for ripping off a university.Their work is still cited.

All clincial trials (with strategic information omitted) are now available on FDA website.

12 suicides but no other suicidal acts? Whom are they kidding?

EVERYONE, and very successfully.

Enter: ENDORSEMENT SCIENCE

5 trials of Zyprexa for schizophrenia generated 234 ghost-written articles by prominent opinion leaders and many company summaries.

None of these publications yields a true picture of the drop out rate, side effects or risk of suicide or suicidal acts on Zyprexa.

RISPERDAL and ZYPREXA
were promoted on the cover of Time Magazine, The Post, Washington Times and New York Times.

The Dopamine Theory of Schizophrenia was alive and well in those endorsements.

from David Healy, unpublished.Details from Professor Clive Adams of the Cochrane Centre for Schizophrenia, Leeds, October 2004.

The suicide rate for these trials, on a time-adjusted basis, was two to five times the norm for schizophrenics.

But the literature has already told us, provided you can read it backwards that Zyprexa causes suicide.

Meltzer *et al;.* Clozapine reduces the risk of suicide compared with Zyprexa by 75% .

(Those treated with Clozaril already have a higher suicide rate than untreated.)

ARE WE LOOKING AT ANOTHER VIOXX-STYLE DECEPTION?

Did Merck not tell us that Naprosyn protected against of heart attacks, when compared with Vioxx? When Vioxx caused the hart attacks and they knew!

Which causes? Which protects? Check out the FDA trials.

Meltzer, H.Y., et al., Clozapine treatment for suicidality in schizophrenia: International Suicide Prevention Trial Arch Gen Psychiatry.2003 Jul;60(7):735]. Archives of General Psychiatry, 2003. 60(1): p. 82-91.(5 papers like this)

According to the Mental Health plan, the suicide rate in NSW has declined from 15.1 per 100,000 persons in 1997 to 9.5 per 100,000 persons in 2003, the lowest rate of suicide in Australia.

ARE MENTAL HEALTH SERVICES A ADDING TO OR SUBRTRACTING FROM THIS THIS FALL? Look a the evidence:

PROF RAPHAEL: 2003

About **400** mentally ill patients in Oz under mental health care, **commit suicide each year.**

People fronting at hospital emergency departments for psychiatric treatment has **DOUBLED** in the past decade and presentations are more violent.

. **Various DoH statistics NSW, Victoria, Western**

Mental Health suicide rate 48 hours after discharge, is **100 times** the rate for the general population.For patients with 'depression', it is up to 500 times.

Murders by 'mentally disordered' persons (not in state Mental Health care) are running at three a month, having nearly doubled recently from 20 victims in 2000-'01 to 36 in 2001-'02. (BOSCAR)

Ross Kalucy reports a similar phenomenon at Flinders Medical Centre in South Australia.

Flinders Medical Centre mental health presentations at Emergency Department

1994/1995 it was 248 (double or treble this as it was one of several hospitals then) and in 2002/2003 it was1838 (not counting overdoses)

Source: Kalucy R Thomas D King D Changing Demand for Mental Health Services RANZCP Journal, January February 2005 74-80

WESTERN AUSTRALIA

Annual deaths from suicide among mental health patients doubled from 1980 to 1998.

45% of suicides occurred in people who had used mental health services.

•The majority had one short contact following a suicide attempt and had committed suicide before receiving any follow-up.

Suicide rates were seven times higher in people diagnosed with "mental illness," and the number so diagnosed was increasing as well.

The rate of suicide in people with mental illness has been increasing over the period 1990-98, and the increase in that rate almost entirely explains the net increase in the total West Australian suicide rate.

Coglan R, Lawrence D, Holman, D. A., & Jablenski, A. (2001). Duty to Care:Physical Illness in People with Mental Illness: Department of Public Health and Department of Psychiatry and Behavioral Science, University of Western Australia.

From 1990 to 2002, antidepressant use increased by 352%, to reach 51.5 DDDs/1000/day

In this same period, 1990 and 2002,

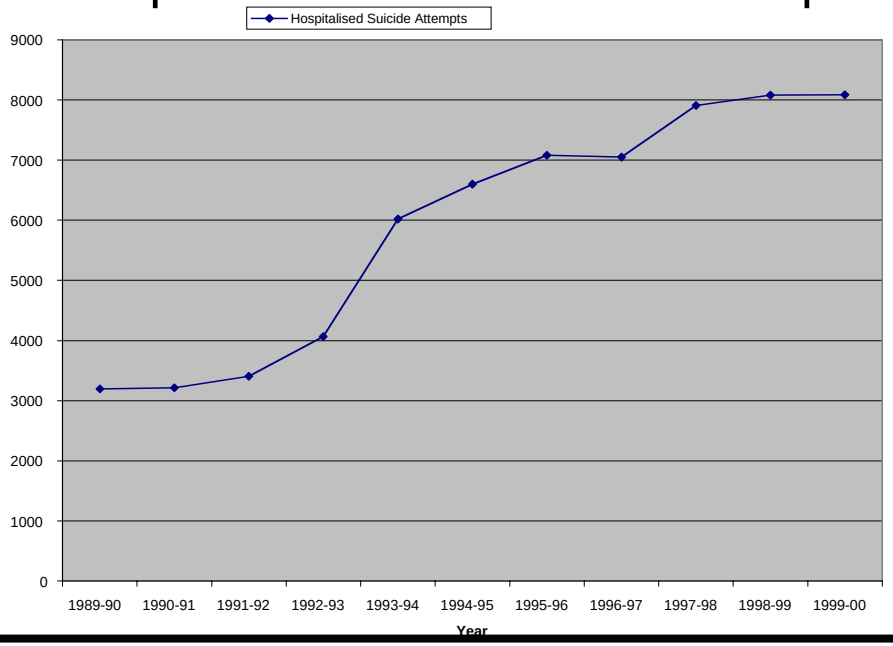
Suicides of persons under Mental Health Care (in NSW alone) increased from 24 to to over 156.

Just about 350%

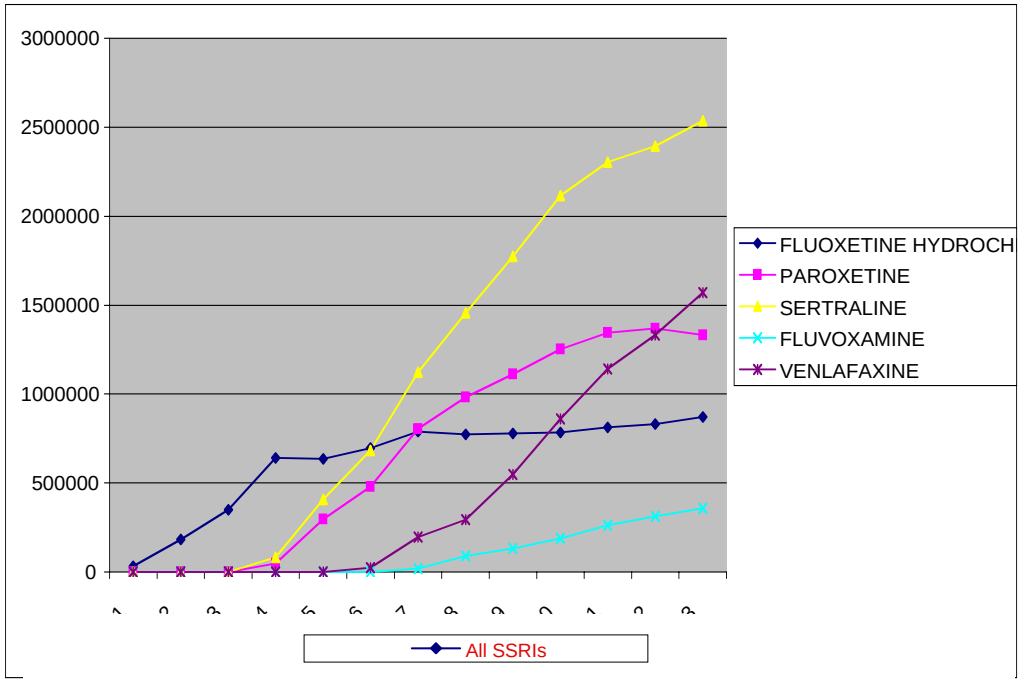
This becomes an empirical question for coroners who will have toxicological results from all of these deaths.

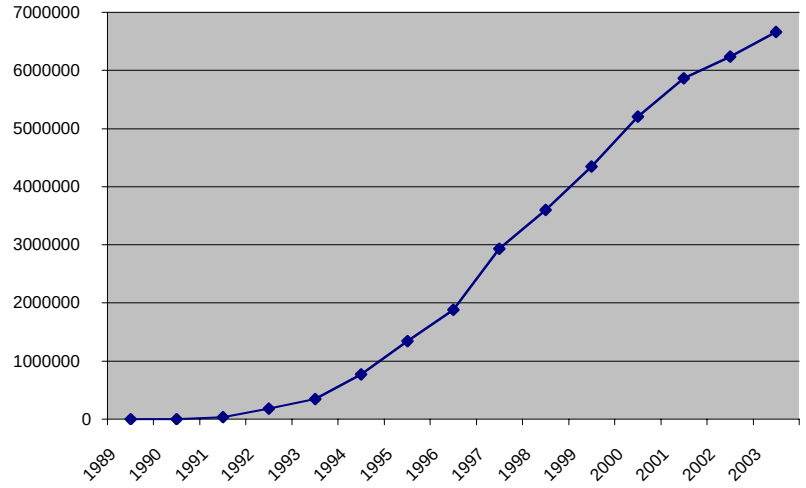
'Separations' for suicide attempts increased from 3211 to 8090 in NSW
from 1989 to 2002.

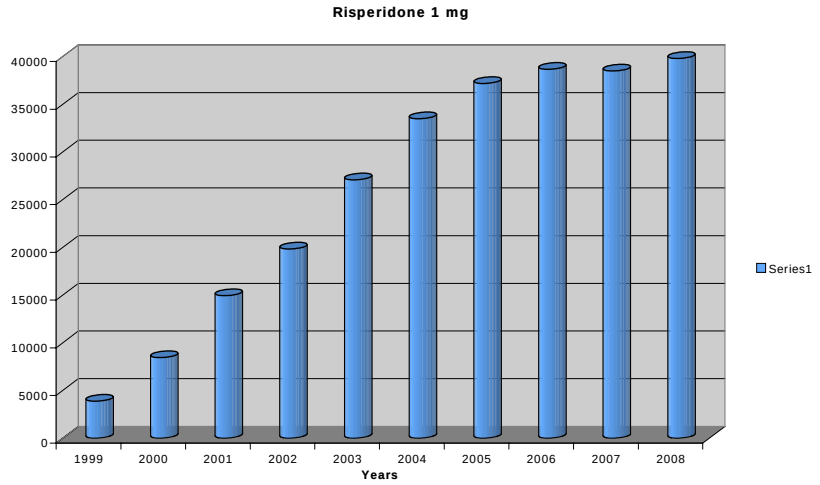
Separations' for suicide attempts

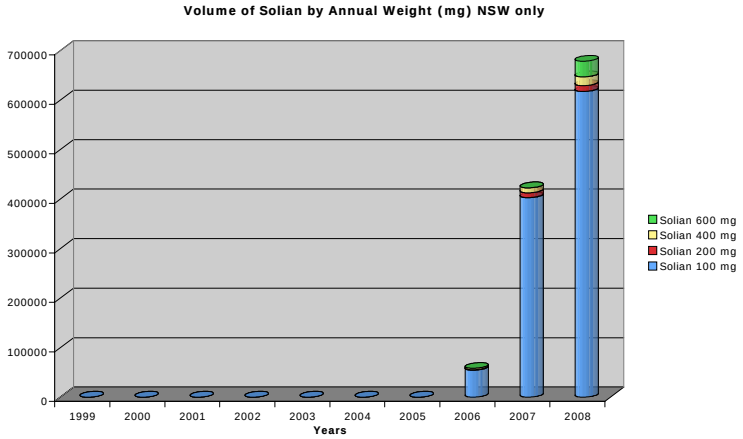


ANTIDEPRESSANT PRESCRIBING

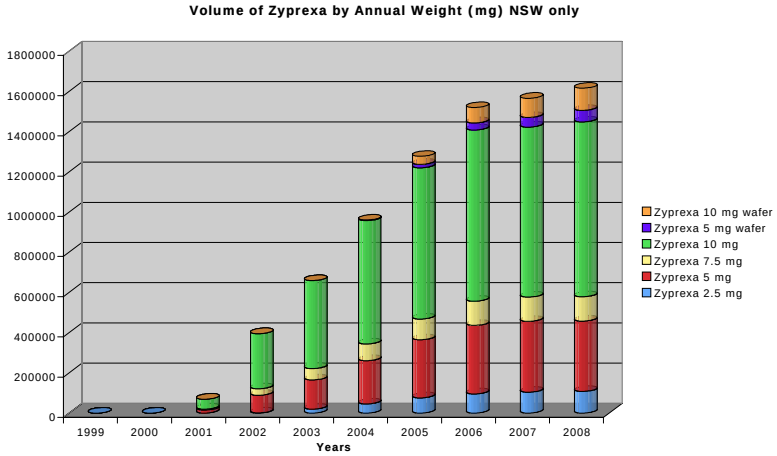




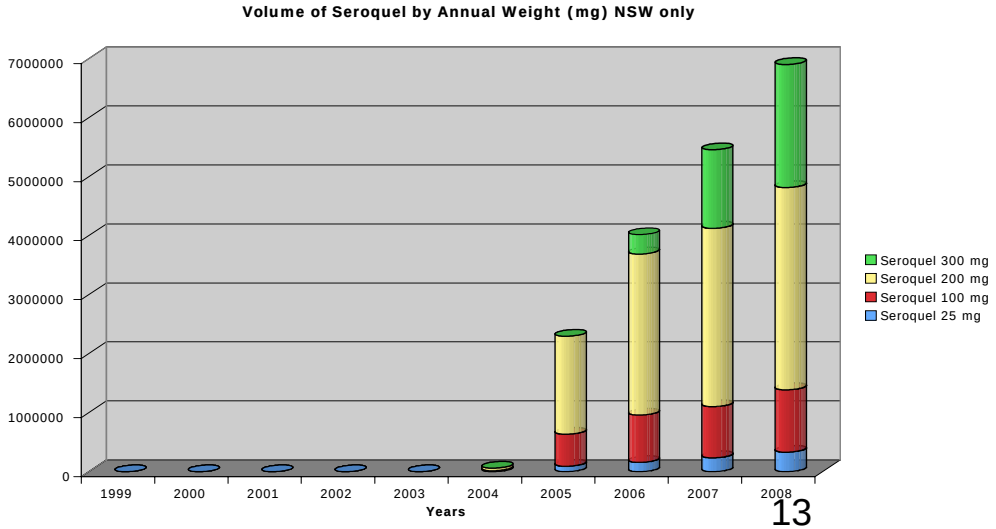




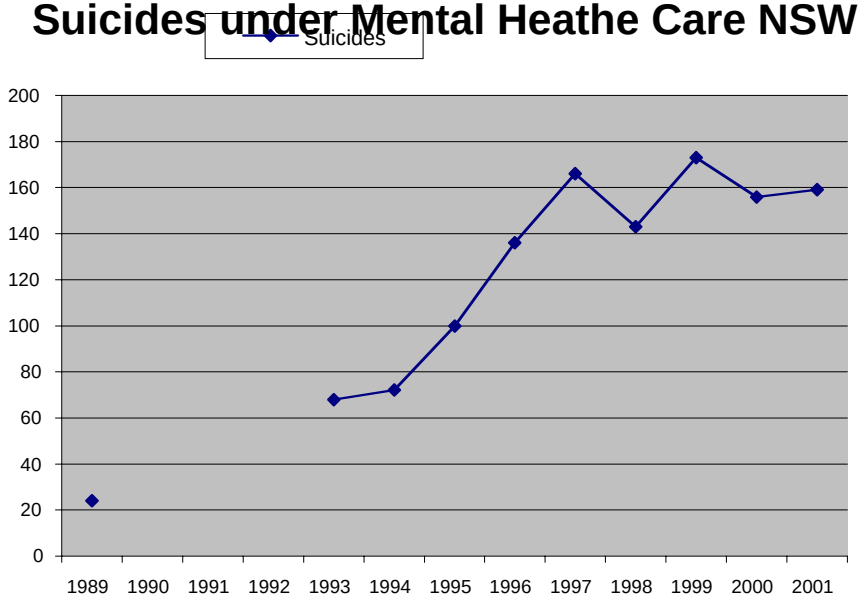
These figures are for NSW. Seroquel was not suicidogenic in FDA trials. It does cause akathisia and withdrawal akathisia in the vulnerable.



These pictures do not tel the ful story.. To understand this one needs to know how many new persons started SSRIs and Atypicals these drugs at any dose and how many came off them. Starting and stopping are danger periods for both. The HIC cannot provide this data.



Suicides under Mental Heathe Care NSW



Graph of Sentinel Events Committee Report. NSW Suicides under Mental Health Care. 1993 to 2002.
As Mental Health Services prescribe andidepressants and antipsychotics, it is unlikely they are contributing to a fall in suicide rates.

- **The Sentinel Events Committee chaired by the Hon. Professor Emeritus Peter Baume AO, charted the rising mental health suicide numbers since 1993. Dr Bill Barclay AM looked at 9 Homicides by patients under Mental Health care.**

- **Tracking Tragedy:Report of NSW Mental Health Sentinel Events Committee**

Year	Suicides in NSW	Suicides in mental health care	Percentfall suicides 9%
1993	676	68	10%
1994	798	72	9%
1995	747	100	13%
1996	811	136	17%
1997	946 rate 15.1/100k	166	18%
1998	827	143	17%
1999	846	173	20%
2000	738	156	21%
2001	775	159	21%
2002	?? rate 0.5/100k		
2003		128	

How common are serious adverse events (hospitalisations) with antidepressants?

A 2001: Yale: 8% of patients admitted **'may suffer'** from SSRI-induced mania or psychosis.

Preda A, MacLean RW, Mazure CM, Bowers MB (2001). Antidepressant associated mania and psychosis resulting in psychiatric admission. J Clinical Psychiatry 62, 30-33

Higher levels of prescribing in OZ and Include **agitation, suicidal and homicidal thoughts and attempts in patients on these drugs,**

It is 2 or 3 admissions a week into 21 beds and this profile accounts for 20 to 30% of admissions.

I charted 600 consecutive discharge summaries for 18 months, and found 150 admissions worth reporting to ADRAC, (not including psychosis or mania) and 42 more in the next 4 months.

I looked for suicidal and homicidal violence and acts, where Second generation antidepressants and atypicals were being used.

The patients whom I assessed (about half of them) had akathisia with the spectrum of side effects described earlier.

All suicidality remitted when the side effects of the antidepressant, atypical or combination of them, were discussed with the patient and carefully withdrawn.

Historians of psychiatry will recall the trajectories of wonder drugs cocaine, bromide, barbiturates, meprobamate mandrax benzodiazepines. It took years before their adverse effects were discovered and acknowledged. Each left a residue of addicts.

They were often on large doses of antidepressants combined with antipsychotics , the latter having been prescribed when antidepressants had caused voice hallucinations or visions.

Suicidal and homicidal ideation were obsessive, intrusive violent and unwelcome. ‘Not me.’ ‘Weird’

They were not the usual suspects, not borderlines, but ordinary people caught up in our gung ho ‘obligation’ to treat a new socially constructed condition labelled ‘depression'
the diagnosis of which has increased a thousandfold since a ‘cure’ became available for it.

Few, if any, had been put on this medicine for serious depression. Many had got worse.
Some had suffered like this for up to nine years, undiagnosed.

Where akathisia is suspected, delirium might coexist,

Is the patient telling you she is ‘seeing things, hearing things’ or constructing a system of delusions around her hallucinations?

The former is recurrent toxic psychosis, which is a delirium,

The latter is schizophrenia.

This is not trivial.

The treatment for schizophrenia induces akathisia in the sensitive.

Amphetamines and cannabis cause akathisia and toxic psychosis which is a delirium.

Drugs do not cause schizophrenia even though their effects mimic it.

Could this patient’s condition be iatrogenic?
Iatrogenic Depression, Mania, OCD,
Panic Disorder, sleep disorder.
Iatrogenic late onset or acute borderline traits?

You have to know the natural history of all of those conditions, at what age they start, and make a fine diagnosis.Akathisia is always iatrogenic.

Who will warn the prescriber? Some manufacturers have now sent misspelt faxes to doctors.

Product inserts have not improved.Others have quietly upgraded information in MIMS.

But who understands akathisia?

The Adverse Drug Reactions Advisory Committee (ADRAC) has not yet passed on the FDA's warnings of March 22, 2004..

But promised me they would, and then say the will not.Advice from the RANZCP is cited.

The madman of our nightmares is not a schizophrenic but an akathisiac

All over the world, clinicians are reviewing all their suicidal patients and finding among them chronic akathisia subjects behaving like borderlines,their lives a living hell, battling a death wish, violent, suicidal, toxic and psychotic, with homicidal impulses, ego-alien outbursts of violence, unable to articulate internal agitation, her condition attenuated, but never fully relieved, by co prescribed sedatives or worse, self - administering alcohol or whatever else is available.

The greatest satisfaction I have had in my 38 years as a psychiatrist has come from success in giving lives back to those who have suffered from this totally debilitating and unrecognised iatrogenic disorder for up to eight years

If the FDA figures are right, and some of these are akathisia cases,

the relative risk of using atypicals and SSRIs together has to be so high as to be off the graph.

Some doctors are not aware that hallucinations are a common side effect of SSRIs, and they introduce an atypical.

This spells AKATHISIA, sooner rather than later.

•Much literature was published in the1970s and 1980s on suicide and homicide associated with akathisia,

induced by traditional neuroleptics,

75 suicides in one paper,
6 homicides in another.

Many papers by Theordore van Putten, Jerome Schulte, M. Katherine Shear cited in Mad in America Robert Whittaker Perseus Publishing 2002. Medline Search, akathisia suicide violence

This is about risk management.

If they are making suicide attempts on SSRIs the prescriber has increased the RR of that behaviour statistically by 2.2 minimum to 10 or more.
If they are taking both, the risk is immeasurably higher. They interact and both groups are neurotoxic.

Withdrawal can be tricky and that's when we lose them, if we are not alert and the patient is not warned

If the patient is not hospitalised for obsessive and sudden urges. Looking for hooks to hang from, electric sockets to electrocute themselves, windows to jump from.
If relatives are not warned.

Patients will tell only if you explain why you need to know.
I have had up to 18 akathisia patients on a 21 bed ward in a fortnight in August and they all needed to be there. We lost the 19th one I and should not have done.

Zyprexa was a blockbuster and one of the ten most prescribed drugs in Australia in 2002. This means that it is being given, off label' to people who do not suffer from schizophrenia.

The Melbourne Age reported on a Victorian psychiatric unit that suffered 13 suicides in 13 months, in 2002-3. (Anonymous: (2004, March 17). Critical condition The Age. Melbourne.

Suicide risk is more than 1 in 500.

I in 500
too rare for clinicians to see as being abnormal.
They need advice from suicide epidemiologists and statisticians.
Like the Jicks.

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
.

Litigation arising out of these hazards against health departments and doctors could produce another medical indemnity crisis.

The problem can be diverted to the source, the PhaRMAs, which collectively have deceived the Commonwealth, taxpayers, patients and prescribers

Not only the companies, but their Chief Executives and Boards, should be held responsible for ensuring the reliability of prescribing information and be held liable for the consequences of having provided prescribers and patients with information which is false or misleading, misrepresented or intentionally withheld.

In 1974, Ivan Illich popularised a term,

iatrogenesis, for the 'new' epidemic of doctor-made disease

it is
clinical, when sickness is caused by medical care;

social, when health policies reinforce ill health;
and
structural when the medical profession undermines the confidence of people in their own ability to recover

Illich I. Limits to Medicine: The Expropriation of Health. London: Penguin Books, 1975.

The World Health Organization,bearing information that psychiatric services increase suicide rates in developing countries, has been trying to tell the west for decades that problems occur when people take psychotropic drugs for too long or come off these drugs suddenly and not gradually.

They do not prevent relapse.
Rather they increase relapses.

Suppl. 20 (1992) cited in Mad in America Robert Whittaker Perseus Publishing 2002

In his critique of Illich, Vicente Navarro wrote

that the responsibility for iatrogenesis did not lie with the medical profession

but with the powerful corporate classes which decide what and how health care is delivered.

The corporate classes control governments, insurers and PhaRMAceutical companies who, in turn, profoundly influence the behaviour of trusting doctors.

Navarro's somewhat unpopular views of medical practice have been amply demonstrated in the history of big PhaRMA.

Vicente Navarro: the Industrialization of Fetishism,: a Critique of Illich.in Medicine under Capitalism.

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 CONFERNENCE, 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 PhaRMAs 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 **R**elative **R**isk, **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 l**egally** 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, 803-777-6870, www.suicide expert.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.l. 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

Prozac v all TCAs	**RR =**	**6.6**
Prozac v Tofranil	**RR =**	**1.9**
Prozac v Amitriptyline	**RR =**	**4.0**
Prozac v Prothiaden	**RR =**	**2.1**
Prozac v Lofepramine	**RR =**	**4.04**

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 Jacks 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.*

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

Total excluding Fluoxetine 132 Suicides per 195,931 Patients

Fluoxetine 67 Suicides per 100,000 Patients

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 <u>≤</u> **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 **30**/100,000#
Sweden **0**/100,000
Antedating SSRIs Simon, von Korff
30/100,000

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.

Drug	No. Patients	No. Suicides	Suicides/ 100,000 Patients
Fluoxetine	12692	31	244 (C.I. 168 Š340)
Sertraline	12734	22	173 (C.I. 110 Š255)
Seroxat/Paxil	13741	37	269 (C.I. 192 Š365)
Fluvoxamine	10983	20	183 (C.I. 114 Š274)
Total SSRIs	**50150**	**110**	**219/100,000**
Mirtazapine	13,554	13	96 (C.I. 53-158)

Source: ANTIDEPRESSANTS AND SUICIDE BRIEFING PAPER 2004, JUNE 20TH 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 =	**219**/100,000.
Prozac	**244**/100,000
Aropax	**269**/100,000
Luvox	**183**/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 7th 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 2nd 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

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

Investigational Drug	Patient No	Suicide No	Suicide Attempt No	Suicides & Attempts as a % of Patient No
Sertraline	2,053	2	7	0.44%
Active comparator	595	0	1	0.17%
Placebo	786	0	2	0.25%
Placebo Washout		0	3	
Paroxetine	2,963	5	40	1.52%
Active comparator	1151	3	12	1.30%
Placebo	554	0	3	0.54%
Placebo Washout		2	2	
Nefazodone	3,496	9	12	0.60%
Active comparator	958	0	6	0.63%
Placebo	875	0	1	0.11%
Mirtazapine	2,425	8	29	1.53%
Active comparator	977	2	5	0.72%
Placebo	494	0	3	0.61%
Bupropion	1,942	3	----	
Placebo	370	0	----	
Citalopram	4,168	8	91	2.38%
Placebo	691	1	10	1.59%
Fluoxetine	1,427	1	12	0.91%
Placebo	370	0	0	0.00%
Placebo Washout		1	0	
Venlafaxine	3082	7	36	1.40%
Placebo	739	1	2	0.41%
All New Drugs	21,556	43	232	1.28%
All SSRIs	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.

- **I 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)

AKATHISIA, VIOLENT CRIME AND PRODUCT LIABILITY.

Forensic implications:

Civil

and

Criminal.

Suicides and homicides and Product Liability, and how to avoid trouble.

Yolande Lucire
PhD, MB BS DPM FRANZCP

Forensic Psychiatrist.

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

Completed Suicide is the measurable tip of an iceberg of disturbing side effects:

akathisia, agitation, mania, psychosis, deliberate self harm, suicide, violence and HOMICIDE

they occur mostly on

starting, stopping, changing dose up or down and irregular dosing.

Or if co-prescribed medication is added or removed.

Withdrawal can start four weeks after stopping the drug, and can go on for three months or more.

Homicide by the mentally disordered (criminologists jargon) is rising in NSW.

The number of homicides pleading mental health has rocketed from about 6 a year to 36.

The Sentinel Events Committee chaired by the Hon. Professor Emeritus Peter Baume AO,

charted the rising mental health suicide numbers since 1993.

Dr Bill Barclay AM looked at 9 Homicides by patients

under Mental Health Care

The report is called Tracking Tragedy

Much literature was published in the1970s and 1980s on suicide and homicide associated with akathisia,

induced by traditional neuroleptics,

75 suicides in one paper,
6 homicides in another.

In a 1985 paper, Schulte linked akathisia with psychotic acts of murder and suicide.

He wrote, "The following five case histories of 23-52 yr old males are reported to bring attention to the potential for severe violence, as a result of akathisia, following such administration of a neuroleptic (major tranquilliser) for

acute psychiatric symptoms.

Many papers by Theordore van Putten, Jerome Schulte, M. Katherine Shear cited in Mad in America Robert Whittaker Perseus Publishing 2002. Medline Search, akathisia suicide violence

•A series of homicide judgements under a variety of different jurisdictions and conditions have highlighted the link between antidepressant, and in particular SSRI use and violence.

•The first of these cases in 1994 followed Joseph Wesbecker's shooting dead 8 people and injuring 12 others before killing himself at his place of work, a printing press in Louisville Kentucky.

"

•Wesbecker had been taking fluoxetine (Prozac) for 4 weeks. The case put a number of pharmaceutical company documents about drug-induced activation into the public domain.

•The evidence for the existence of a problem, however, in principle applies to other SSRI agents also.

•If the scientific case is persuasive, the legal principles that apply to such cases will need to be mapped.

•From David Healy unpublished

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

Many hundreds of of suits over suicides and homicides have been settled by PhaRMAs

and over 100 homicides
have been defended as caused by SSRIs, and many survivers and relatives of the dead have been compensated.

Not committed by psychotic persons,

but by patients treated for

anxiety, eating disorders,OCD and menstrual problems

and overwhelmingly, by children.

Since 1994, SSRI-induced akathisia that has been recognised in the Diagnostic and Statistical Manual (DSM IV TR), where it is coded as a movement disorder, but it fits equally well into drug induced psychotic states or with organic brain syndromes.

A useful concept is "the “akathisia- prone patient” as one who is likely to develop akathisia on tricyclics, lithium, SSRIs, Zyprexa, Risperdal, Solian and Seroquel as well as a variety of other medications.

Akathisia accompanies the taking of the medication but it can also occur if the drug is stopped suddenly rather than slowly.Withdrawal Akathisia is congruent with supersensitivity psychosis, about which there is a substantial literature.

It is rare to see a person who has been on these medicines for some time who is not also taking co-prescribed tranquillisers of one kind or another

The akathisiac is agitated restless and almost manic at times.

Obsessive suicidal and violent and homicidal ideation is experienced as ego alien, “not me, I do not want to die or kill, I cannot understand these impulses and drives.

Improbable people commit homicide. Improbable people obsessively create homicide lists

Multiple homicide is common and violent.

Suicide following homicide is very common

If you ask, they will tell you, even in jails. They have been thinking of suicide and homicide for ages, in two of my cases, for 8 years

Breggin defined a *stimulant continuum* beginning with lesser degrees of insomnia, nervousness, anxiety, hyperactivity and irritability,

which progresses toward more severe agitation, restlessness, aggression and varying degrees of mania.

Mania or manic-like symptoms include disinhibition, grandiosity; sleep disturbances and out-of-control aggressive behaviour.

They cycle into depression and suicidality.

They can produce a combined state of *stimulation and depression,* an *agitated depression,* with a high risk of suicide and violence.

Ann Blake Tracy, Ph.D., author of Prozac: Panacea or Pandora?,

She has been studying the violent, dark side of SSRI drugs for ten years.

She has researched 32 murder/suicides that involved women and their children.

By interviewing their families and studying autopsy reports, news accounts and medical histories, she has determined that in 24 of these 32 cases, the women were taking Prozac or another SSRI.

Robert Whittaker wrote about

"the madman of our nightmares"

who was not a schizophrenic but an akathisiac,

having just taken, or taken himself off, prescribed medication.

Akathisia suicide and depressive suicide are as different as chalk and cheese.

Akathisia homicide is also different from any other, and can and should be differentiated.

It attracts an absolute defence of involuntary intoxication leading to dissociation and non-insane automatism.

Whittaker Robert: Mad In America. Perseus Publishing.2002.

Professor Perminder Sachdev has proposed a classification of one of these, **akathisia.**

Other than in rare neurological disorders or in the aftermath of epidemics of encephalitis lethargica, akathisia is drug induced akathisia, (DIA) and always iatrogenic.

Acute akathisia (AA)may emerge after only two or three doses of an SSRI.

It is called tardive akathisia(TA) when it develops late in treatment.

Chronic akathisia (CA)

Withdrawal akathisia (WA)is clinically identical and may develop up to three months after stopping the medication.

It may be associated with a manic shift as well as rebound depression.

It does not get better unless akathisia inducing medications are ceased, and even then, it might take time to recede.

Sachdev, P: Akathisia and Restless Legs. Cambridge University Press 1996

Who is at risk for akathisia?

Some people (6-20% of some populations) cannot deal with SSRIs at all and react catastrophically to only one or two doses.

Many medicines are metabolised by the P450 cytochrome system, 1000 enzymes, and are determined by 50 different genes.

Not every person has all the genes and all the enzymes.

Genetics of the metabolism, of transporter and neuro-receptor systems, may hold the answer to the mystery of why different people respond differently to the same substances.

Akathisia is both idiosyncratic and dose related.

Children are 6 times as vulnerable as adults. Immaturity of cytochromes systems

Enzymes that metabolise medicines can be carefully "induced" by slowly increasing doses, but they are inhibited by cannabis and some medicines.

One can predict that a problem will occur with combined use, but not whether if it will be suicide, violence, sedation or psychosis.

If too much is given, or is given too quickly, a “traffic jam” occurs, and an oversupply of psychoactive metabolites recirculates and acts, unpredictably, on brain receptors.

Tanaka E, and Hisawa S: (1999). Clinically significant pharmacokinetic drug interactions with psychoactive drugs: antidepressants and antipsychotics and the cytochrome P450 system. Journal of Clinical Pharmacy & Therapeutics, 24(1), 7-16.

Other vulnerability factors are smoking cannabis use, speed psychosis, liver problems alcohol use and brain damage or injury or developmental delay.

If they had a bad reaction before to a drug requiring P450.

If two medicines need P450, do not use them together. MIMS says Caution. Warn and get permission.

Embarrassed, and guilt ridden, they do not confess their homicidal impulses.

Eliciting them needs careful questioning.

These experiences can go on for hours or years, or can be acted on very quickly, in a matter of minutes.

•Schulte reported five case of akathisia homicide in 1985..

•17th February 2005. Below are some of the 100 cases of homicides and attempted homicides that have occurred on SSRIs.

Some were suicides/attempted suicides, some homicides, many multiple and violent homicides, followed by suicide or sucide attempt.

The pharmaceutical industry has settled, often out of court then those cases are not available as gag orders are usually a part of the terms of the settlement.

•Christopher Bernaiche, 26, (Prozac) of South Rockwood in 2002. Two days after Prozac dosage doubled, fired wildly around killing 2 men, and wounded 3 others after pool game argument. (Defense pleaded mentally ill and Prozac induced rage, jury verdict 1st degree murder. Judge has recently ordered a retrial as prosecution withheld info sent to them relating to evidence linking Prozac and violence. Retrial Pending)

Young man in Amarillo, TX (Prozac, Ritalin and another antidepressant) burned down a church and pastor's home. Sergi Babarin (Luvox withdrawal) The Salt Lake Family History Library shooting leaving three dead. Dr. Debra Green (Prozac) Kansas City, MO, set her home on fire, killing her children.

•Eric Harris aged 17 (Zoloft then Luvox) and Dylan Klebold aged 18 in Colombine school shooting in Littleton, Colorado, killed 12 students and 1 teacher, and injured 23 others, before killing themselves.

•David John Hawkins aged 76, Australia (Zoloft) strangled his much loved wife with no warning. (Judge found: "I am satisfied that but for the Zoloft he had taken, he would not have strangled his wife").

Christopher Pittman, aged 12, (Paxil then Zoloft). Known amongst family as 'pop-pops shadow', he had always been very close to his grandfather. Shortly after being prescribed Zoloft he shot both his grandparents dead and burned the house down. Imprisoned, he waited 3 years for trial, and was then tried as an adult - a practice acceptable in the USA. (Defense pleaded involuntary intoxication. Preparing for the expected homicidality-zoloft link, Pfizer lawyers involved themselves early into the case with prosecution. Jury opted for murder verdict)

•Another boy in Pocatello, ID (Zoloft) had a stand off at the school.

•Jarred Viktor aged 15 (Paxil), after five days on Paxil he stabbed his grandmother 61 times.

•Chris Shanahan aged 15 (Paxil) in Rigby, ID who out of the blue killed a woman.

•Christopher Vasquez (Zoloft) killed Michael McMorrow in Central Park

Boy in Pocatello, ID (Zoloft) in 1998 who in seizure activity from Zoloft had a stand off at the school.

Chris Shanahan aged 15 (Paxil) in Rigby, ID who out of the blue killed a woman.

Mrs. Phil Hartman (Zoloft, but also taking Cocaine) , killed her husband and then herself. (Wrongful death court case was filed but settled by the Zoloft manufacturer).

•Marilyn Lemak (Zoloft) of Naperville, IL killed her three children.

•Larry Gene Ashbrook (Prozac) killed seven people and himself in church in Fort Worth Texas.

Kristine Marie Cushing, age 39 (Prozac) shot and killed her two children, then shot herself in failed suicide attempt.

Christina Fetters aged 14 (Prozac) in Iowa who killed her favourite aunt.

.

Williams Evans (Zoloft) shot one co-worker at the Ohio Bureau of Employment Services before shooting himself in Columbus, OH.

Kenneth Seguin (Prozac) drugged his two children, cut their wrists and dumped their bodies in a nearby pond before driving home and killing his wife with an axe while she slept.

David Rothman (Prozac) killed two co-workers and himself at the Dept. of Agriculture in Inglewood,CA.

Luke Woodham aged 16 (Prozac)

Anu Singh, well described in Helen Garner's book, Joe Cinque's Consolation, Prozac homicide by a diagnosed borderline.

•Cory Baadesgaard (Paxil then 300 mgs Effexor) in Matawa, WA school shooting. This was not long after being taken off Paxil cold turkey and changed over to Effexor.

•Young man in Amarillo, TX (Prozac, Ritalin and another antidepressant) burned down a church and pastor's home.

•Sergi Babarin (Luvox withdrawal) The Salt Lake Family History Library shooting leaving three dead. Dr. Debra Green (Prozac) Kansas City, MO, set her home on fire, killing her children.

•Daryl Dempsay, 35, (Zoloft) stabbed his wife and two children at their home in Burlington, Kan., then shot and killed himself. Mark Barton, Atlanta day trader, (Prozac) killed his family and others in a shooting spree before taking his own life

•Gloria B. (Prozac) in Pleasant Grove, UT killed her 17 year old son with a sledge hammer while he slept before she attempted suicide by drinking drain cleaner.

•Larry Butzz, (Prozac) a superintendent of schools in Ames, IA shot his wife, son and daughter before shooting himself.

•Michael McDermott (Prozac) - Software tester who walked into work and shot seven co-workers.

•Joseph T Wesbecker, Kentucky (Prozac) went into work with an AK-47 and a couple of pistols, killed 7 co-workers injured 12.

•Gail Ann Ransom. (Prozac) Became increasingly violent after beginning Prozac treatment culminating in the strangulation of her mother.

•Jason Hoffman (Effexor and Celexa) - school shooting in El Cajon, California

•Victor Brancaccio (Zoloft) aged 16, Florida, Learning disability. 2 months into Zoloft & with increasing hostility and anger, killed a woman who said something which upset him while he was taking a walk to try to calm down. (Judge refused to instruct the jury re involuntarily intoxication, Victor was convicted of 1st degree murder, life sentence)

•Jeff Franklin (Prozac and Ritalin), Huntsville, AL, killed his parents as they came home from work using a sledge hammer, hatchet, butcher knife and mechanic's file, then attacked his younger brothers and sister

•Neal Furrow, (Prozac) in LA Jewish school shooting reported to have been court-ordered to be on Prozac along with several other medications.

•Andrea Yates (Remeron-Effexor) of Houston, TX, drowned her five children in the bathtub. The drugs had been prescribed at one and a half times the maximum dose.

•Elderly man (Paxil) in Dallas, TX strangled his wife before shooting himself twice in the chest.

•Lynwood Drake III, (Prozac and Valium) of California, shot and killed six people before shooting himself.

•Larry Ashbrook (Prozac) killed seven people and himself in a Forth Worth, Texas, church. Hank Adams: (Prozac) Former San Diego Deputy Sheriff shot his wife and himself to death in front of his seventeen-year-old daughter

•Reginald Payne (Prozac) UK teacher aged 63, eleven days into Prozac suffocated his wife and then committed suicide by jumping off a cliff.

•Duncan Murchison, (Prozac) threatened to murder his girlfriend while on a rampage

Larramie Huntzinger (Zoloft) ran his car into three young girls killing two in Salt Lake City, UT.

•Mary Hinkelman (Prozac), a nurse in Baroda, MI shot her two small daughters and her sister before shooting herself.

•Lisa Fox (Prozac) shot her small son and her dog before shooting herself in Brighton, MI.

•Debi Louselle (Zoloft) shot her daughter and then herself in Salt Lake City, UT.

•Andrew Myers, 28 (Zoloft) Within two weeks of starting on Zoloft he hit a long-time friend in the head with a spiked, pronged brass knuckle-type weapon known as a "ninja key ring" during an argument. Attempted murder charges. (Acquitted - Zoloft induced).

•Leslie Demeniuk, Florida, (Zoloft then Paxil) killed her four-year-old twin sons in 2001. (Trial is on hold while prosecutors appeal a judge’s ruling that two defense experts could testify that Demeniuk was “involuntarily intoxicated” and “psychotic” as a result of taking Zoloft and then Paxil.).

•Donald Schell, (Paxil). 48 hours after starting Paxil, he killed his wife, daughter, granddaughter and himself. (Jury found Paxil at cause and ordered GlaxoSmithKline to pay $6.4 million to surviving family members.).

•Merrilee Bentley Australia, (Paxil then Effexor) attempted murder (with suicide) of her young daughters. (Judge ruled that Effexor had "gravely impaired" Merrilee Bentley's capacity for rational thought and action. He imposed a two-year suspended jail sentence and told her she was free to go home.)

•Elizabeth Bush aged 13 (Paxil) was responsible for a school shooting in Pennsylvania.

•Nick Mansies (Paxil) who was convicted of killing a little boy selling cookies door to door. Sue Gray, Orange County, CA (Paxil) who co-workers described as a very caring nurse, killed several elderly people. Officer Stephen Christian (Prozac) who ran into a police substation shooting at fellow officers and was killed;

•Williams Evans (Zoloft) shot one co-worker at the Ohio Bureau of Employment Services before shooting himself in Columbus, OH.

•Christina Fetters aged 14 (Prozac) in Iowa who killed her favourite aunt.

•Anyone wanting the full list can email me at lucire@ozemail.com.au.

•In the pipeline are Zypban and Zyprexa homicides and suicides. Any drug that produces akathiis acan cause homicide.

•Many are followed by medical negligence cases, and these are often successful.

•They can be diverted onto the PhaRMA if it can be demonstrated (and it can now) that they PhaRMA knew and did not warn.

SCHOOL SHOOTERS: PRESCRIBED MEDICATIONS INVOLVED.

•Here are the last major school shooters and the link under each name is a reputable news source that connects them all with SSRI's (selective serotonin reuptake inhibitors) like Prozac, Ritalin, Zoloft, Luvox, Paxil, and others:

•1) May 20 1999: T.J. Solomon, a 15-year-old wounds six at Heritage High School in Conyers, Ga.. http://add.about.com/health/add/library/weekly/aa052599.htm CNN Reports That T.J. Solomon was on Ritalin.

•2) April 16 1999: Shawn Cooper, a 15-year-old sophomore wounds one at Notus Junior-Senior High School in Notus, Idaho. http://www.boiseweekly.com/archive/v7i42/cope/cope_col.html Reports that Cooper was abused and medicated.

•3) April 20 1999: Eric Harris and Dylan Klebold kill thirteen and wound twenty three at Columbine High School. http://www.washingtonpost.com/wp-srv/national/daily/april99/antisocial04299.htm Eric Harris, The apparent leader of the attack had been on Zoloft andLuvox.

•4) May 21, 1998: Kip Kinkel, a 15-year-old kills four and wounds twenty three at Thurston High School in Springfield, Ore.. http://www.drugawareness.org/washtimes.html Kinkle Had been taking Prozac.

•5) March 24, 1998: Mitchell Johnson, 13, and Andrew Golden, 11, opened fire on their classmates and killed five and wounded eleven at Westside Middle School in Jonesboro, Ark.. Arkansas Online http://www.ardemgaz.com/prev/jonesboro/brygolden24.html Andrew Golden's Medical Records released to Courts but not open to the public From Jon Rappaport of the Truthseeker foundation: http://www.nfgcc.org/schoolviolence.htm A Doctor from Georgetown University commented on Network television that one of the boys had previously been treated for violent behavior. (Treated with what?)

•Little Timmy. 10 year old (Prozac) in southern Florida.

•7) Ben Garris, a 16-year-old in Baltimore who stabbed his counsellor to death. http://www.ariannaonline.com/columns/files/070998.html

•8) Kristina Fetters, a 14-year-old from Des Moines, Iowa, who stabbed her favorite great aunt in a rage that landed her a life sentence. http://www.ariannaonline.com/columns/files/070998.html

•9) Pfizer, The Manufacturer of Zoloft is being sued by a Kansas family for the Suicide of their 14 year old son on Zoloft. http://www.ariannaonline.com/columns/files/061099.html

•10) The estate of Brynn Hartman, Wife of the Saturday Night Live Comedian, Phil Hartman, is also suing Pfizer, since Mrs. Hartman had been on Zoloft when she killed her husband and herself! http://www.ariannaonline.com/columns/files/061099.html

Psychiatric Drug Facts

Peter R. Breggin, M.D.

Paxil Withdrawal Suit Resolved

- A California lawsuit against Glaxo SmithKline (GSK) charged the drug company with failing to warn the public about the dangers of Paxil withdrawal. Glaxo SmithKline (GSK), the manufacturer of the antidepressant Paxil, resolved the suit in January 2002. The results of the resolution, including any settlement by defendant Glaxo SmithKline, were not announced. The outcome was described as a resolution rather than a settlement.
- Psychiatrist Peter Breggin, M.D. was the plaintiff's medical expert and worked closely with the attorneys in formulating the suit..

•True. Pfizer's Zoloft Litigation Manual (an exhibit at 12 year old Christopher Pittman's murder trial)

•"INTRODUCTION

•A. Purpose

•This manual is prepared in anticipation of litigation to assist Pfizer's lawyers, and lawyers in prosecutors' offices with common interests, in responding to a civil claim or criminal defense in which someone alleges that his wrongful, violent conduct should be excused because,when he committed the violent act, he was taking the antidepressant medicine that is marketed under the brand name Zoloft (generic name: sertraline or sertraline HCI).

This manual describes how Zoloft works, its indications (that is, when it should be prescribed), andits side effects, and offers guidance on how attorneys can rebut scientifically unsubstantiated claims that Zoloft can induce violent behavior.

The manual also describes the themes that Pfizer's lawyers or similarly-situated attorneys are likely to encounter and how those themes can be rebutted.

•The manual is not intended to provide a complete scientific understanding of depression and its treatment, nor does it seek to explain all of the scientific underpinnings of antidepressant therapy.

•Therefore, it is important for attorneys to consult with an expert knowledgeable about those matters (generally, a psychiatrist or pharmacologist) who can further assist in rebutting allegations the defendant makes regarding Zoloft.

Reputable physicians are in the best position to inform the jury of accepted scientific principles that rebut allegations that Zoloft caused or contributed to violent behavior.

HUNDREDS of THESE

- **ELI LILLY AND COMPANY,**
- an Indiana Corporation,
- Defendant.
- Case No. 95-00185ACK
- **INDEPENDENT ACTION TO SET ASIDE JUDGMENT FOR FRAUD ON**
- **THE COURT**
- JUDGE: Hon. Alan C. Kay
- Pursuant to Rule 60(b), Federal Rules of Civil Procedure, Plaintiffs Susan K. Forsyth, individually and as Personal Representative of the Estates of June M. Forsyth and William D. Forsyth, and William D. Forsyth, Jr. bring this independent action to set aside the April 7, 1999, Judgment in favor of Eli Lilly and Company and against Plaintiffs in the case entitled Susan K. Forsyth, individually and as Personal Representative of the Estates of June
- M. Forsyth and William D. Forsyth, and William D. Forsyth, Jr. v. Eli Lilly and Company,. The basis of this independent action is that the Judgment was obtained by a fraud on the Court

The good news is that these cases against doctors can now be defended as the responsibility to warn of catastrophic side effects lies with the PhaRMAs.

They have this information and had tried to hide it. New York's Attorney General, Eliot Spitzer, conducted successful litigation against GlaxoSmithKline for non-disclosure of risk,. specifically in the case of Aropax. It has obtained an undertaking by PhaRMAs to place details of clinical trials, even those previously undisclosed, on the internet. These postings on the FDA website have forensic utility to show the extent to which the advertising differs from what was found in clinical trials presented for licensing purposes.

http://www.fda.gov/cder/approval/index.ht

Expert evidence is available to show how what doctors were told differs from what PhaRMAs know.

It is suggested that because akathisia is primarily an internal sensation, clinicians must be certain to question patients before ruling out its presence.

Patient histories should be taken prior to the use of neuroleptic agents in emergency rooms in order to elicit a potential for violence.

Professor Sachdev suggests how such problems might be avoided: by informed and ethical practice. I submit that his protocol would be an appropriate standard of care for the HCCC to endorse. I quote:

Ethical and legal issues

Because Drug Induced Akathisia (DIA) is an iatrogenic disorder which leads to serious distress, may compromise the psychiatric status of the patient, may lead to impulsive actions (aggression or self harm) and may become chronic and resistant to treatment, it is of much ethical concern and may lead to litigation. The most common allegations against psychiatrists, in reference to medication side-effects, pertain to two areas: negligence and informed consent (Lawson, 1989).

A negligence or 'tort' action is successful if the plaintiff can establish by a preponderance of evidence (i.e., more convincingly than the contrary can be established by the defendant) that the psychiatrist violated his or her duty to care for the patient (by an act of omission or commission), leading to physical or emotional injury to the patient. In the case of akathisia, an appropriate standard of care will involve:

•(i) performing a detailed assessment of the patient to establish the diagnosis that indicates treatment with a neuroleptic or other akathisia-inducing medication;

•(ii) considering suitable alternatives to the prescription of such medication;

•(iii) prescribing the drug in the appropriate dosage, and for the proper duration, as is generally considered by the majority of the profession; (

•(iv) recognizing the side-effect early, alerting the patient to it and taking the appropriate measures, which include reviewing the offending medication and monitoring and treating the akathisia when indicated

(v) recognizing the risk of Tardive Akathisia (TA) and Withdrawal Akathisia (WA), and using generally recommended practices for long-term treatment, while being cognizant of the attendant risks;

(vi) consulting with psychiatrist colleagues and, if necessary, experts in the field, in case of doubt.

This protocol is only courteous common sense in prescribing any medication or treatment as every treatment has an attendant risk.

This shares responsibility and decision making empowering the patient who has a right to decide what treatment she wants, and what risks she will take for what benefits.

Concern over suicide rate of mental health patients. 31/01/2005. ABC News Online
http://www.abc.net.au/cgi-bin/common/printfriendly.pl?http://www.abc.net.au/news/newsitems/200501/s1292466.htm

ANTIDEPRESSANTS & SUICIDE: RISK-BENEFIT CONUNDRUMS David Healy MD ..
www.healyprozac.com/GhostlyData/JPCNDHealy.pdf

Defining Genetic Influences on Pharmacologic Responses
http://medicine.iupui.edu/flockhart/

Healthy Skepticism: Countering misleading drug promotion
http://www.healthyskepticism.org/

Welcome to DrugDigest: DrugDigest is a noncommercial, evidence-based, consumer health and drug information site dedicated to empowering consumers to make informed choices about drugs and treatment options
http://www.drugdigest.org

International Journal of Risk & Safety in Medicine 16 (2003/2004) 31–49 31
IOS Press
Suicidality, violence and mania caused by selective serotonin reuptake inhibitors (SSRIs): A review and analysis Peter R. Breggin

www.breggin.com/31-49.pdf

http://www.sntp.net/prozac/breggin_prozac_1.htm

Dr. Ann Blake Tracy, International Coalition for Drug Awareness – Ann Blake Tracey author of Prozac: Panacea or Pandora?.
http://www.disinfo.com

http://www.postgradmed.com/issues/2003/08_03/ditto.htm

http://www.biopsychiatry.com/

U.S. Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH
http://www.healyprozac.com

About AHRP

Mission Statement

The Alliance for Human Research Protection (AHRP) is a national network of lay people and professionals dedicated to advancing responsible and ethical medical research practices, to ensure that the human rights, dignity and welfare of human subjects are protected, and to minimize the risks associated with such endeavors.
http://www.ahrp.org

Social Audit
This website began as an investigation of problems with antidepressant drugs – not only their adverse effects on many users, but also what the problem signalled about the conduct of the competent authorities, and the adequacy of their institutions and process. As the problem unfolded, notably between 1997 and 2003, it revealed a glimpse of pharmageddon - a world of sickness created and sustained by exploitation of the fear of disease, indifference to real health needs, dependence on authority, and misplaced trust in the triumph of drug benefits over harm. These are the main themes in *Medicines out of Control?*

http://www.socialaudit.org.uk

http://www.socialaudit.org.uk/6040000.htm#New

United States Food and Drug Administration.

http://www.fda.gov/cder/drug/default.htm#Clinical%20Trials

FDA Public Health Advisory

March 22, 2004

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

http://www.fda.gov/cder/drug/antidepressants/AntidepressanstPHA.htm

FDA Talk Paper
T03-70
October 27, 2003

http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01283.html

FDA Issues Public Health Advisory Entitled: Reports Of Suicidality in Pediatric Patients Being Treated with Antidepressant Medications for Major Depressive Disorder (MDD)

http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01256.html

FDA Talk Paper FDA Issues Public Health Advisory Entitled: Reports Of Suicidality in Pediatric Patients Being Treated with Antidepressant Medications for Major Depressive Disorder (MDD) October 27, 2003
Media Inquiries: 301-827-6242
Use of SSRI antidepressants in children and adolescents - updated 15 October 2004

Adverse Drug Reactions Advisory Committee
(Replaces statement of 17 June 2004)

http://www.tga.gov.au/adr/adrac_ssri.htm

Meta-Analysis: Efficacy & Safety of Antidepressants for Children - Brit Medical Journal Sat, 10 Apr 2004

http://www.ahrp.org/infomail/04/04/10.php

RANZCP "News" release **News release**

For immediate release 22 April 2005.

SSRI guide released by Australia"s leading medical colleges

A guide has been released by three of Australias leading medical colleges on the use of Selective Serotonin Reuptake Inhibitors (SSRIs) to treat children and **adolescents** with depression.

In a joint statement released in Melbourne today, the Royal Australian and New Zealand College of Psychiatrists, the Royal Australasian College of Physicians and the Royal Australian College of General Practitioners said the document would serve as a clinical guide for general practitioners and other prescribers.

The three colleges were asked by the Federal Governmentís Adverse Drug Reactions Advisory Committee (ADRAC) to produce the guide.

The chair of **RANZCP** Committee for Psychotropic Drugs and other Physical Treatments, Dr Bill Lyndon, said the three colleges were responding to questions

being raised about the possible relationship between **antidepressants** and suicidal thinking and suicidal behaviour.

This news release was no news at all but was an ackowledgement of the FDA advisory which had first been posted in the united states on October 27th , 2003, 18 months earlier..

August 2004

National Prescribing Service News 35
• Prescribing pointers: Starting, stopping and changing antidepressants
• Talking points—improving treatment compliance
• The role of psychological and behavioural therapy
• What's what
• References
• Case study for GPs (PDF)
• Case study for pharmacists (PDF)

http://www.nps.org.au/site.php?content=/html/news.php&news=/resources/NPS_News/news35

Eli Lilly and Company Clinical Trial Registry
This site contains information about clinical trials sponsored by Eli Lilly and Company. This information is not intended to replace the advice of a health care professional. Only a physician can determine if a specific medicine is the correct treatment for a particular patient. If you have questions regarding any information contained in this site, please consult a physician.
http://www.lillytrials.com

THE **LILLY SUICIDES**

The story behind the claims that SSRIs such as Prozac and Zoloft can create aggression and suicidal tendencies as side-effects.

www.namiscc.org/News/2002/Fall/TheLillySuicides.htm - 49k

Prior research reports, using data compiled by the World Health Organization found that that some infants among those who suffered withdrawal symptoms after birth, had convulsions. See:
http://www.ahrp.org/infomail/05/02/05.php

Another study, presented at a large international gathering of physicians--Digestive Disease Week 2005 (DDW), reviewed the records of hospital inpatients admitted with acute GI bleeding between June and December 2003. The authors found that "the use of a common type of antidepressant may increase gastrointestinal (GI) bleeding." The Northwestern physicians who conducted the study noted that bleeding from SSRIs is similar to that caused by the use of non-steroidal anti-inflammatory drugs

(NSAIDs, known as pain relievers).

They emphasized the danger of prescribing multiple drugs: "This is a potent example of the need for doctors to be particularly conscientious about potential side effects when prescribing multiple medications for their patients."
However, in psychiatry, indiscriminate prescribing of drug cocktails (polypharmacy) is the current norm and practice. Psychiatrists' practices fail to consider the horrific consequences borne by their patients--Psychiatry's first loyalty appears to be to their industry supporters--Current prescription algorithms in psychiatry--which we call Psychiatry for Dummies--were formulated to increase profits for drug manufacturers. See, the documented case of horrors experienced by a victim of polypharmacy Aliah Gleason, a 13 year old school child.

Medicating Aliah, in Mother Jones.
http://www.motherjones.com/news/feature/2005/05/medicating_aliah.html

WELCOME TO THE
SSRI INFORMATION BOARD

http://www.network54.com/Forum/182310

RANZCP clinical practice guidelines, an embarrassment to evidence based practitioners.

http://www.ranzcp.org/members/publications/cpg.asp

HC 42-I
[Incorporating HC 1030-i-iii]
Published on 5 April 2005
by authority of the House of Commons
London: The Stationery Office Limited
House of Commons Health Committee
The Influence of the Pharmaceutical Industry
Fourth Report of Session 2004–05
Volume I
Report, together with formal minutes
Ordered by The House of Commons
to be printed 22 March 2005
£15.50
www.publications.parliament.uk/ pa/cm200405/cmselect/cmhealth/42/42.pdf

NSW Mental Health Sentinel Events Review Committee
Tracking Tragedy
A systemic look at suicides and homicides amongst mental health inpatients

First Report of the Committee December 2003

www.health.nsw.gov.au/policy/ cmh/publications/track**tragedy**2.pdf

BMJ 2003;327:288-289 (2 August), doi:10.1136/bmj.327.7409.288-c
Letter

Antidepressant prescribing and suicide Antidepressants do not reduce suicide rates

EDITOR—Hall et al show that the biggest increase in the use of antidepressants in 1990-2000 has been in the 15-44 age group.1 Simultaneously the rate of suicide for this age span has increased in Australia. For men aged 25-34 the use of antidepressants has increased more than six times during the period and the suicide rate has increased by almost 17%.

http://bmj.bmjjournals.com/cgi/content/full/327/7409/288-c

Khan et al found an excess of suicidal acts on **antidepressants**. compared to placebo, which has been replicated in two other analyses (10,11). **...**

www.healyprozac.com/GhostlyData/JPCNDHealy.pdf

Are **Antidepressants** as Ineffective as They Look?

Khan, A., & Brown, WA (1991) Who should receive **antidepressants**? Suggestions from

placebo treatment. Psychopharmacology Bulletin, 27, 271-274. **...**

www.journals.apa.org/prevention/ volume5/pre0050026c.html - 21k

This is article number 45. Total number of articles in current **...**

Hall et al do not show that **antidepressants** reduce the rate of suicide. **...**

Free Full Text] **Khan** A, **Khan** S, Kolts R, Brown WA. Suicide rates in clinical **...**

www.drugawareness.org/Archives/ 3rdQtr_2003/record0045.html - 11k

THE PROS AND CONS OF SSRI **ANTIDEPRESSANTS**

Of the newer **antidepressants**, venlafaxine may be slightly more effective. **...**

Khan A, **Khan** S, Kolts R, Brown WA. Suicide rates in clinical trials of SSRIs, **...**

www.behindthemedicalheadlines.com/ articles/anti_depressants.shtml - 20k - Cached - Similar pages

Study Reveals startling numbers of suicides on new SSRI **...**

Study Reveals startling numbers of suicides on new SSRI **antidepressants ...**

A recent study conducted by Arif **Khan**, medical director of the Northwest **...**

www.healingsearch.com/_ReportPages/ study_reveals_startling_numbers_.htm - 14k - Cached - Similar pages

Antidepressant-Placebo Debate

Khan, A., Leventhal, RM, **Khan**, S., & Brown, WA (2002). Severity of depression and response to **antidepressants** and placebo: An analysis of the Food and Drug **...**

www.srmhp.org/0201/media-watch.html - 23k -

disinformation | **antidepressants** and antipsychotics increase **...**

antidepressants and antipsychotics increase suicide risk by up to 68 times **...** Dr. Arif **Khan** presented his research at a recent meeting sponsored by the **...**

www.disinfo.com/archive/pages/article/id2675/pg1/ - 32k –

Journal of Clinical Psychopharmacology - Fulltext: Volume 21(2 **...**Because "established" **antidepressants** often (about half the time) do not **...** Brown WA, **Khan** A. Which depressed patients should receive **antidepressants**? **...**

www.psychopharmacology.com/pt/re/jclnpsychopharm/ fulltext.00004714-200104000-00001.htm -

Journal of Clinical Psychopharmacology - Fulltext: Volume 22(1 **...**

Severity of Depression and Response to **Antidepressants** and Placebo: An **...** Brown WA, **Khan** A. Which depressed patients should receive **antidepressants**? **...**

www.psychopharmacology.com/pt/re/jclnpsychopharm/ fulltext.00004714-200202000-00007.htm -

[More results from www.psychopharmacology.com]

PROTECT YOUR CHILDREN NOW:

http://www.antidepressantsfacts.com/index.html

MEDICAL REPORTS: DANGEROUS NEUROLOGICAL SIDE-EFFECTS OF PROZAC (Sarafem, fluoxetine)

***** Prozac (fluoxetine)-induced Mental-state, Perceptual and Emotional Changes *****

***** Prozac-induced Akathisia & Mania can lead to aggressive and/or homicidal behaviours *****

SUICIDE RATES HAVE DOUBLED FOR CHILDREN OF 5-14 YEARS OLD OVER THE PAST 20 YEARS!

Antidepressant & Children-suicide link: Last year 15 million prescriptions written for children & teens

***** 5-14 year old: Doubling of Suicide rates over past 20 Years - Research by J.W. Prescott, Ph.D. *****

FORGET THE ANTIDEPRESSANT SUICIDE ISSUE

Look at the Physical Side-Effects of Antidepressants Reported by Medical Physicians

***** Severe Body & Brain Damaging Side-Effects of Antidepressants *****

Protect Your Children Against Bush's (July 2004) Forced U.S. "Mental Health Screening" and Psychiatric Drugging Program for ALL Americans

***** The Federal PPRA Act of 1998** ***

A bitter pill: Merrilee Bentley believes antidepressants drove her to try to kill her two children. Now, a senior judge has supported her claim.

A Bitter Pill

by Richard Guilliatt, *Sydney Morning Herald* Originally published: June 19, 2004

They were lauded as the miracle drugs: a new generation of antidepressants that promised to make us "better than well". But for Merrilee Bentley they did the opposite: her spiral into darkness ended when she tried to kill herself and her two children.

http://www.astrocyte-design.com/bitter-pill.html

Overview of problems in Australia.

www.lucire.com.au

CURRICULUM VITAE

Dr Yolande Lucire

PhD MBBS DPM FRANZCP

FORENSIC & MEDICO-LEGAL PSYCHIATRY

Website www.lucire.com.au

Most papers are available in full on the website.

Qualifications

1996	PhD UNSW in Arts and Social Sciences
1970	Member then Fellow, Royal Australian & New Zealand College of Psychiatry
l967	Diploma of Psychological Medicine, London,
l964	MB BS University of Sydney

Work:

1972	-Private practice, originally child nd family, then general, forensic and medico-legal psychiatry in Sydney
2001	Conjoint Senior Lecturer, Psychiatry, Rural Medical School.
1997-2005	Consultant Psychiatrist, Nolan House, Albury,
1994/5	Consultant Forensic Psychiatrist, London, Devonshire Place
	Locum Consultant Psychiatrist East Ham Memorial Hospital
	Fellow. Wellcome Institute for the History of Medicine.
1983 -1995	Senior Forensic Psychiatrist, Consultant to Department of Corrective Services NSW, and Long Bay Prison Hospital.
l972 - l980	Consultant (VMO) South Sydney Hospital, (including Rehabilitation) Psychiatrist, Rozelle Hospital, Sydney
1972-	to present Consultant Psychiatrist in private practice, Sydney
1967-1972	General Practice
l968 - 1970	Senior Registrar in Child Psychiatry, Royal Alexandria Hospital for Children
1967	Registrar, Sutton & Belmont Hospital, Surrey, UK.
1965	SRMO, Netherne Hospital, Surrey, UK.
l964.	RMO, Prince Henry Hospital,

Book

Constructing RSI; Belief and Desire UNSW Press 2003.

Refereed publications

1 Factors Affecting Conception in Women Seeking Termination of Pregnancy. Medical Journal of Australia l975 (pages 824-27).

2. **Neurosis in the Workplace.** l986 Medical Journal of Australia 145: 323-7. This paper has been given many citations both in medical and in social science journals.
3. **PhD Ideology and Aetiology: RSI: an epidemic of craft palsy**
4. **Medea - Anatomy of a Multicide.** Journal of the Australian Academy of Forensic Sciences. December 1993.
5. **Social Iatrogenesis of Epidemic Neurosis. (RSI)** Journal of Community Health Studies XX (2) 1988.
6. **The Bearing of Daubert on Sexual Abuse Allegations.** Journal of the Australian Academy of Forensic Sciences. vol 32 no. 245-59

7 **The Medical Evidence in the First 50 Administrative Appeals Tribunal Decisions.** Legal Service Bulletin, Dec. l982. (Australian) Analysis of the difficulties of evaluation of Invalid Pension applicants.

8 **I Fear the Greeks.** Legal Service Bulletin, Feb. l981. A medico-political expose of Social Security Conspiracy (prepared originally for a conference of psychiatry and law but deemed sub-judice at the time). Submission to the Minister and Commission of Inquiry into Social Security Prosecutions.

Conferences, submissions other publications

9 **The Adversary System or a Better Way?** Read at the RANZCP Conference l983. Prepared as a submission on the Invalid Pension problem for Senator Grimes in l982.

10 **When Emotions get Converted.** On the genesis of RSI as Conversion Disorder Safety Australia, Feb. l986. Read at Medical Mythology conference, Nov. l985.

11 **Institutionalised & Rewarded Neurosis: RSI, the Australian Disease.** Australian Institute of Management Journal, Apr. l986.

12 **Differential Diagnosis of Conversion.** Read at RANZCP Annual Conference, May l986.

13 **Resistance to paradigm shift, The Injury Theory versus the Psycho social Model of Causation in Epidemic RSI**. Read at RANZCP Annual Conference, May l986. Analysis of sources of resistance to the psycho social model.

14 **The Use of Proforma for Disability Evaluation.** Unpublished but widely read. Presented RANZCP conference, Hobart, May l985.

15 **The First Forensic Interview, "RSI" - the Use of a Pre-Printed Proforma.** Presented November l985 and available in video from the Institute of Psychiatry, Rozelle Hospital. Also available in print.

16 **Square Pegs in Round Holes: A Comparison of Medical & Legal Concepts of "Causation" in Epidemic Neurosis, using the epidemic of RSI** Proceedings of Conference of the Medico-legal Society of Victoria. Kotakinabalu 1986.

17 **Workers' Compensation: A New Approach** Submission to writers of white paper on workers' compensation in NSW (l986). (Unpublished).

18 **Theory and Philosophy of Assessment: An analysis of the sources of variance in expert opinion evidence**. Forensic Psychiatry Bulletin l986.

19 **RSI, an Epidemic of Craft Palsy.** A chapter commissioned by Dr. (now professor) Professor Ivor Jones, then Snr. lecturer in Psychiatry, Melbourne University, for text book, "Essentials of Australian Forensic Psychiatry", l986. (This book was never published)

20 **Analysis of the Function of the Expert, in "The Expert Witness Self- Examined"** in book, The Expert Medical Witness, Federation Press l989.

21 **The Role of the Psychiatric Assessor in Personal Injury Claims.** Presented at RANZCP Forensic Psychiatry Conference Leura, November 1990.

22 **Repetitive Strain Injury - An Epidemic of Craft Palsy.** Proceedings of the Medico-Legal Society of NSW. Vol. 8, pages 134-146.

23 **Chronic Fatigue Syndrome: What is a disease?** Debate with the Prince of Wales Hospital, Presented in November 1990 at the Institute of Psychiatry in NSW for Continuing Medical Education.

24 **The NSW Mental Health Review Tribunal** , first seven years of operations. Presented RANZCP Forensic Section Conference Nov 15-20, 1991.

25 **Life events and getting sick with "RSI".** Presented RANZCP Forensic Section Conference Nov 15-20, 1991.

26 **The Narcissist in the Culture of Compensation.** Presented 1992 RANZCP Conference Brisbane.

27 **The five colour theorem: A model to elucidate the components of illness, disease and morbidity.** Presented at Philosophy and Psychiatry conference 1996.

28 **Can a Linear Medical Model Identify Causation of Illness?** In preparation

29 **How to do a Sex Abuse Evaluation.** RANZCP Conference Forensic Section, June 2000, Port Douglas

30 **The Politicization of Medicine and the Medicalization of Industrial Relations.** Presented at Garran and Baxter conference on Psychological Injury, To be published In Journal of the Australian Academy of Forensic Sciences.

32 **Critique of the Medical Practice Act 1992.** Presented at the Plenary Session of the Australian Academy of Forensic Sciences September 11, 2001.

33 **Comparison Codes Medical Practice Act and Common Law.** Whither 200 years of due process?

34 **Comparative Analysis of Paradigmatic Assumptions of the True Believers and The Sceptics contributing to Moral Panic about Child Sexual Abuse.**

35 **Health Status and Predicament in Claimants for RSI 1986-1992.** RANZCP Forensic Section Conference, 2001

36 **The Social Construction of the War Neuroses: Are We Being Served?** Commissioned for 11th Brigade Senior Medical Officers Conference, 14 July, 2001 Townsville Presented again RANZCP Forensic Section Conference, 2001

37 **Politicising Medicine and Medicalizing Industrial Relations** (repeated) RANZCP Forensic Section Conference, 2001

38 **Towards and taxonomy of confabulation** RANZCP conference Brisbane June 2001.

39. **Submission to Proceedings Before Standing Committee On Law And Justice . Inquiry Into Child Sexual Assault matters** . At Sydney on Friday 10 May 2002

40 **Confabulation: Forensic Issues.** ANZAPPL Conference July 2002. Darwin

41 **.Submission to Review of the law of Negligence:**

http://www.google.com.au/search?q=cache:fLSVEzzxGHQJ:www.pc.gov.au/inquiry/workerscomp/subs/sub102.rtf+negligence+Lucire&hl=en&start=4&ie=UTF-8

42: **SSRIs: Forensic Issues. Risk benefit analysis and potential for litigation In Australia**. Duty to warn?. (PowerPoint) Presented at RANZCP Forensic Section Conference October 2003 Geelong

43 **The use of textual analysis in differentiating true from fabricated sex abuse allegations,(**PowerPoint) Presented at RANZCP Forensic Section Conference October 2003 Geelong

44 **SSRIs: Do they cause suicide? The Science: Daubert Admissible evidence. Australian** Academy of Forensic Sciences, May 19, 2004. In Press. Also Interantional conference of medical law, Sydney

45. **SSRIs and their effects on Mental Health Presentations: A plausible Hypothesis.** ,(PowerPoint) Presented at RANZCP Forensic Section Conference October 2004, Fremantle.

46 **New Drugs New Problems PowerPoint, presented Section of Forensic psychiatry, April 9 2005.**

47 New Drugs New Problems Medico-political expose of the suicide crisis in Mental Health, Australian Journal of Forensic Sciences.

48 **The Ethics of the Solitary Empiricist: how PhaRMAs changed common human unh0phhines into a deficit disease.** Blackheath Philosophy Forum May 9 2005.

Do Second Generation Antidepressants Cause Suicide? A Daubert Hearing. Health, Australian Journal of Forensic Sciences. May 19. 2004.

49 **Effects of Second Generation Antidepressants and Antipsychotics on Mental Health Services in Australia**. Royal Australian and New Zealand College of Psychiatrists 40th Conference, Convention Centre, Sydney 22 to 27 May. 2005.

50 **Akathisia and Crime: Product Liability issues**. Royal Australian and New Zealand College of Psychiatrists 40th conference, Convention Centre, Sydney 22 to 27 May. 2005.

Associations:

Convener NSW Section of Forensic Psychiatry1988-1993.

Committee member Australian New Zealand Association of Psychology, Psychiatry and the Law, NSW Branch. 2001-

Convener Forensic Section RANZCP 1989-1994

Council member, Australian Academy of Forensic Sciences, 2001-

Fellow of the RANZCP, Member Forensic Section