STATE
CORONER
VICTORIA

Case No: 1106/00

RECORD OF INVESTIGATION INTO DEATH

I, JACINTA MARY HEFFEY, Coroner, having investigated the death of YVONNE CARRIGG with Inquest held at the Wangaratta Magistrates Court on the 22nd and the 23rd August 2002 and at the Coronial Services Centre, Southbank on the 30th August 2002 FIND THAT the identity of the deceased was YVONNE CARRIGG and that death occurred on the 13th April, 2000 in bushland beside the River Edi in Northern Victoria from dothiepin toxicity against a setting of post-natal depression in the following circumstances:

1. The deceased gave birth to a son, Alex, on the 24th January, 2000. She had had two daughters previously, the last having been born approximately eight years before. She was divorced from their father and at the time of her death was in a happy and stable de facto relationship with the father of her son, Steven Wosniak. The couple lived at Edi.

2. For ease of identification I have listed relevant dates as follows:

24/01/00	Baby Alex born.
29/01/00	Mother and baby discharged home.
02/02/00	Deceased admitted to Clinic at the Wangaratta Base Hospital for treatment of post-natal depression. Commenced on Prothiaden.

19/02/00	Discharged home on 150 mg Prothiaden. Haloperidol 1.5. (twice daily)
24/02/00	Seen by GP Dr. Faragher. Receives prescription for two months supply of Prothiaden 75 mg to be taken twice daily. HIC Authorisation obtained for quantity of 60 tablets. Five repeats.
01/03/00	Review by Dr. Faragher.
05/03/00	Re-admission to Kerford Clinic.
21/03/00	Transfer from Kerford Clinic to Mother and Baby unit at Banksia House, Austin Hospital.
07/04/00	Discharge home on Prothiaden 250 mg. Haloperidol 1.5 mg (once daily).
10/04/00	Telephone contact by Laura Parisotto Community Case Manager. Later that day deceased telephones Banksia House and complains of feeling anxious and not coping.
12/04/00	Home visit by Laura Parisotto. Appointment for follow up visit the next day and for visit by Maternal and Child Health Nurse. Review by Dr. Faragher. Further prescription for 30 Prothiaden 25 mg and advised to take the 75 mg tablets previously prescribed three times daily. Medication for new (25mg) prescription dispensed by Symons Amcal Pharmacy, Wangaratta and repeat filled for 60 x 75 mg tablets.
13/04/00	At 1 AM, Mr. Wosniak finds deceased missing. Located around 2.30 AM and dies soon afterwards.

3. The deceased's post-natal course following her first two pregnancies had been complicated by severe depression. In 1991, following the birth of her second child, this had resulted in an overdose post-discharge, re-admission to hospital in Wodonga and several courses of electro-convulsant therapy for puerperal psychosis. Her general practitioner in Wodonga had reviewed her early in her third pregnancy and had recommended starting on anti-depressant medication, Zoloft, ante-natally From correspondence on the file it would appear that initially she agreed to this course, however changed her mind "in view of its unknown effects on pregnancy".

4. On the morning of the 2nd February 2000, 9 days post-delivery, she had been found in the yard at home with a knife in her hand and, when asked about this episode later at the Kerford Clinic to which she was admitted later that day was "unable to explain what her thoughts were?...". She was noted to be anxious, with lowered mood and blunted affect. She was commenced on Prothiaden and Haloperidol and, according to psychiatrist Dr. Sue Carey, responded well to treatment. Her discharge medication on the 19th February was Prothiaden 75 mg mane and nocte and haloperidol 1.5 mg twice daily.

   No discharge summary was prepared. Dr. Carey told the court that this should have been done and she could not account for it not having been done.

   Follow-up post-discharge was to be performed by community psychiatric nurse Laura Parisotto. Dr. Carey told the court that it was left to Ms. Parisotto to negotiate with the patient to see if she would come back to see Dr. Carey or see her general practitioner, Dr. Faragher.

   In fact, there is no evidence that Ms. Parisotto saw the deceased at this time or at any time prior to her re-admission to the Kerford Clinic on the 5th March. She told the court that she saw Ms. Carrigg on only two occasions after the birth, on the 31st January and on the 12th April. She had telephone contact on the 10th April.

The lack of a discharge summary to assist the general practitioner and the absence of any follow-up in the community and consequential liaison with the general practitioner, meant that there was no effective discharge plan. There was no communication between Dr. Faragher and Dr. Carey during this time. Dr. Faragher told the court that she did not contact Dr. Carey as she felt confident that Yvonne Carrigg was able to tell her the truth about her medication regime.

Although ultimately these matters may not have had a bearing on the eventual outcome, they remain of concern and represent less than optimal management in my view.

5. On the 5th March, the deceased was re-admitted to the Kerford Clinic after she had woken early and left the house "planning to jump off a cliff". She was anxious and low in mood. According to the notes made on her admission there was no evidence of thought disorder. She made self-derogatory remarks about her ability as a mother, talked of suicidal thoughts and "felt everyone would be better off without her...". She complained of recent poor sleep and concentration. From the 7th March consideration was being given to transferring her to the mother and baby unit at Banksia House at the Heidelberg Austin Hospital. A bed became available and she was transferred there with baby Alex on the 21st March. At that time she was being prescribed Prothiadin 75 mg mane and 150 mg nocte and Haloperidol 1.5 mg twice daily.

6. Dr. Peter Bosonac, Senior Psychiatry Registrar at Banksia House provided a statement for the Coronial Brief. He charted Yvonne Carrigg's clinical progress through to her discharge. He noted improvement in her mood and attachment to her baby following an increase in Prothiaden dosage to 250 mg nocte. As her anxiety level reduced, the Haloperidol dose was reduced to 1.5 mg once daily.

A decision was made to discharge her home on the 7th April.

A detailed discharge plan was designed involving contact with Dr. Faragher and Case Manager Laura Parisotto and Child and Maternal Health Care. Family therapy was recommended to address some behavioral difficulties with one of her daughters and, at a meeting which the deceased and Mr. Wosniak attended with a clinical psychologist on the day of discharge, the 7th April, this recommendation was agreed to.

A reading of the entries in the notes for the last few days of her stay at Banksia House attest to a significant improvement in mood, sleep patterns and confidence in caring for her baby. Dr. Bosonac records that Ms. Carrigg was mildly anxious about going home but that she agreed to access the supports set in place as part of the discharge plan.

A detailed interim discharge summary was prepared and forwarded to Dr. Carey, Dr. Faragher and Ms. Parisotto.

The deceased was provided with seven days supply of the Prothiaden and the Haloperidol.

7. It does not appear that there was any discussion with Mr. Wosniak, and certainly there is no record of any in the patient's notes, as to the caution that needed to be exercised with respect to the medication. However, Mr. Wosniak told the court that he had observed how cautious the Kerford Clinic had been with respect to medication and that when Yvonne had been home after the first admission, between the 19th February and the 5th March, he had taken

responsibility for administering it to her, "hiding it in different spots". Her parents had come to help following her discharge from Banksia House. Mr. Wosniak would give them the medication the night before as he left early to go to work.

8. On the 12th April, after she had been seen by Dr. Faragher and received a new prescription, the deceased went with her parents to a pharmacy. In his statement her father commented: "We had no idea as to what had been prescribed...?". It would appear that no questions were asked of their daughter in this respect and nor did her parents take over the custody of the medication. The deceased had obtained two packets of 30x75 mg tablets and one packet of 30x25 mg tablets of Prothiaden. As recounted in the table in paragraph 2 above, Dr. Faragher told the deceased to increase the number of 75 mg tablets to be taken, notwithstanding that it differed from the number indicated in the original prescription and, therefore, in the further repeats.

9. As set out in the chronology above, Ms. Carrigg was seen by both Ms. Parisotto and Dr. Faragher on the 12th April, the day before her suicide. Dr. Faragher had last seen her on the 1st March, Ms. Parisotto on the 31st January. Dr. Faragher told the court that on the 12th April, she assessed that there was a slight deterioration which she put down to anxiety associated with her daughters returning home from an access visit with their father. She described her as having a flatter affect. Dr. Faragher telephoned Ms. Parisotto to make sure that she was going to visit her the next day. She herself planned to see her in a week's time.

Ms. Parisotto had visited the deceased that morning. There had been a lengthy gap since their last contact. There had been two hospital admissions in between. As a psychiatric nurse, I have no reason to doubt that Ms. Parisotto is qualified to assess acute or current suicidality. The problem both for her and Dr. Faragher was that of assessment of *any deterioration since the Banksia House discharge.* There was, inevitably a problem of continuity here.

It is true that Ms. Parisotto telephoned Ms. Carrigg on the 10th April to line up an appointment and in the course of the conversation questioned the deceased about her mood. However, the information provided to her that she was "feeling very relaxed and happy" is at odds with the telephone call made the same day to Banksia House in which she complained of not coping and being anxious. The time of the call from Ms. Parisotto was not recorded.

10. In the five days from discharge to review by Ms. Parisotto and Dr. Faragher, the only evidence available as to her state of mind was that provided by members of her family. There is, however, an entry in the Banksia House records which suggests that the Maternal and Child Health Care nurse at Wangaratta had had some contact with her on the 10th April The entry records a call from the nurse to Banksia House in which the caller "*voiced concerns re Yvonne's inability to cope at home. Mental state ↓. Queried if we would have her back in needed. Aware Case Manager and GP were involved in her follow-up".*

11. The statements provided by Mr. Wosniak and his sister Colette McNeill refer to a telephone call made by the deceased to Colette in which she asked if Colette would be prepared to resume full time care of the baby Alex. Ms. McNeill had previously cared for Alex when the deceased had been in the Kerford Clinic. Colette subsequently on that day phoned her brother to discuss this latest development. In her statement she said that the call from the deceased happened at about 1.30 PM on the 10th April. Mr. Wosniak's statement says that

this occurred on the 11th April.

Yvonne's father, John Seager, also made a statement about this period, during which he and Yvonne's mother were staying with the family to help especially as Mr. Wosniak was at work. Again, his dates do not tally with those of Mr. Wosniak or some of the other material. For example on the 10th April, he states that "the PND nurses called in". Ms. Parisotto gave evidence that she telephoned only on that day. However, it could be that he is referring to the Maternal and Child Health nurse calling that day. As I have said, there was a phone call to Banksia House from that nurse later that day. He has the deceased calling Banksia House on the 11th April, rather than the 10th.

It would appear that there were a number of underlying stressors on the deceased during this period. Her former husband had been disruptive, calling to change the access arrangements and to bring the girls home earlier than planned. From the statement of Colette McNeill, there was some tension between her mother and the deceased's father, John Seager.

These issues were not canvassed at any length at the inquest. It is not the purpose of this Finding to assign blame to any person. (The Submission on behalf of the family is misconceived in this respect in that it seeks a finding of contribution relying on Section 19 (1) (e) Coroners Act. This has been repealed). However it is important to include this material as part of the background. Dr. Faragher mentioned in evidence that when she reviewed the deceased on the 12th April, she was concerned about the girls coming home. This change in the arrangement may well have had a bearing on her mental state, increasing anxiety and concerns about her own confidence in managing her baby and her family. Inter-personal tensions may also have influenced her state of mind. According to Ms. McNeill, on the 12th April, Yvonne came to her house and in the course of the conversation about the tensions between the two families, started to cry and said "I'm too much trouble for everyone".

12. Family tensions are probably inevitable at a time when a family member, normally mentally well, starts to behave in ways and to express ideas of a kind not usually associated with them. I have no doubt that Yvonne's family and Mr. Wosniak's family provided as much support as they were able in the circumstances.

13. On the evening of the 12th April, Mr. Wosniak told the court that Ms. Carrigg "seemed happy" and they went to bed as normal. At 1 AM on the 13th April, Mr. Wosniak woke to the baby's crying. Ms. Carrigg was not in the bed beside him. After conducting a quick search of the house, he called the police and continued to search. Senior Constable Rick Thewlis arrived soon after and assisted in the search. Shortly after 2 30 AM, she was found still alive but unconscious. Efforts to resuscitate her were unsuccessful and she died before an ambulance could get there.

A post-mortem examination was conducted and toxicological analysis revealed the presence of Dothiepin in leg blood at a concentration of 6.0 mg/L. Analysis of the stomach contents revealed about 800 mg of the drug. The usual therapeutic blood concentration is about .5 mg/L. According to the toxicology report, fatalities have been associated with ingestion of 600 mg. This is the equivalent of 8 x 75 mg tablets.

14. The real issue that this tragic death raises (and that of Debra Smeeton (3431/1999 which was heard at the same time) is that of the appropriateness of the anti-depressant medication

Prothiaden prescribed in both cases, the dosages and dispensing arrangements and the lack of any effective "safety plan" to minimize the risk of overdose.

15. Medication issues

A discussion of Prothiaden

The terms prothiaden and dothiepin are used interchangeably throughout this finding.

I am grateful to Professor Lorraine Dennerstein, who provided a report to the inquest as an independent expert, for also providing a large number of articles on the issue of anti-depressant medication to treat post-natal depression and psychosis.

As stated, the deceased was prescribed the drug, Prothiaden (or Dothiepin). This, the court heard, belongs to a class of anti-depressants known as tricyclic anti-depressants (or TCAs). This is an older style drug which was commonly used and currently still used to treat major depressive illness. In evidence, it was contrasted with the newer agents, and in particular, the selective serotonin reuptake inhibitors (or SSRIs). The toxicity of TCAs is well described in the literature and studies have shown them to be highly cardio-toxic, even in moderate overdosage. Obviously this has implications when prescribed for a person recognized to be at risk of suicide.

SSRIs, on the other hand, have become the first-line agents for the treatment of depression because of their favourable side effect profile, ease of use and proven efficacy.

It would appear that there is no recognized difference in efficacy between the two types of drugs. The major difference is that SSRIs are safer *in overdose* than TCAs. One study provided by Professor Dennerstein reported that during the (then) ten years that SSRI antidepressants had been marketed there had been few fatal overdoses and moderate overdoses of up to 30 times the common daily dose produced only minor symptoms.[1]

An article published in Psychological Medicine, 2001 made the following observation:

> *"Deaths from antidepressant overdose account for a small proportion of overall suicides but a much higher proportion of suicides in those being prescribed an antidepressant. One estimate is that the proportion of suicides from antidepressant overdose among depressed patients prescribed an antidepressant may be as high as 50%. Therefore, any increase in prescribing the more toxic TCAs will lead to an increase in suicide rates from overdose of these drugs?..."*[2]

Professor Dennerstein told the court that women tend to use drugs to kill themselves as the preferred method of suicide.

In summary, therefore, the drug prescribed by the doctors in this case is not now regarded in the psychiatry profession as the first line drug of choice for the treatment of depression.

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[1] "SSRI Safety in Overdose" by Barbey and Roose J Clin Psychiatry 1998 page 42 -48

[2] "Deaths from antidepressants in England and Wales 1993-1997: Analysis of a new national database". Shal et al. Psychological Medicine 2001, 31, 1203-1210 at page 1209.

Whilst it may be as efficacious as SSRIs, it is known to be cardiotoxic in overdose. It follows that it should be prescribed with caution for the treatment of persons at high risk of suicide.

The choice of Prothiaden in this case

Dr. Sue Carey initiated the tricyclic medication when she directed that dothiepin be the first line drug to treat the deceased on the first admission to the Kerford Clinic. She based this decision, she told the court, on the fact that the deceased was breast-feeding at the time and SSRIs were not then established to be as safe, the severity of the depressive/psychotic state (in that she considered that tricyclics were more effective [3]), and because Yvonne had had a good response in 1991 to another tricyclic, Doxepin. At the same time, she was aware of the cardio-toxic dangers of Dothiepin, but not that it was any more toxic than other tricyclics.[4]

It was reasonable for Dr. Faragher to continue the same medication directed by a Consultant Psychiatrist.

Both Professor Dennerstein and Associate Professor Ann Buist agreed that it was reasonable to administer a drug that had worked in the past.

Professor Dennerstein told the court that 30% of patients do not respond to any anti-depressant. On the assumption that prothiaden may work for only 70% of patients, it was reasonable to use a drug of a class that was known to work on a particular patient in the past.

Based on these consideration, I consider that the choice of medication was reasonable in the circumstances.

Dosage rate and method of prescribing

Dr. Faragher was aware of the cardio-toxic effects in overdose, however she considered that an overdose was unlikely based on her assessment of the patient. For this reason, also, she considered it was a reasonable course to prescribe a greater quantity than allowed under the PBS and to seek an Authorisation to this effect. Dr. Carey told the court that she would not have done this, but would be "working closely with her case manager and family and an ongoing risk assessment regarding that person, which is our usual practice in the community...?".[5]

(I draw no conclusion from the fact that Ms. Carrigg was provided with only one week's supply from both the Kerford Clinic and Banksia House on discharge as this may have been related to financial issues rather than purely to safety issues.)

According to the Schedule of the Pharmaceutical Benefits Scheme, Dothiepin is a drug for which two repeats only are allowed. Pursuant to the Scheme, in this case, a repeat may not be dispensed on the same day or within the next 4 days, unless there has been a "Regulation 24 authorisation". This is to be contrasted with a drug for which the schedule allows 5 or

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[3] See Carrigg Transcript Page 57

[4] See Carrigg Transcript Pages 55-56

[5] See Carrigg Transcript Page 32.

more repeats, in which case there is a 20 day minimum wait for dispensing of a repeat. As stated, Dothiepin is not such a drug.

In this case, however, Dr. Faragher had obtained an "Authority Prescription" for 5 repeats. It was not *the schedule* that allowed 5 repeats. Therefore, the 20 day rule did not apply. The only rule that did apply was that there be a minimum of 4 days between repeats.

If this is the case, it would seem to pose an anomaly in which an Authority Prescription permitting more repeats than allowed under the Schedule, would enable more than a month's supply to be dispensed on several occasions within the space of a month.

Mr. Marty points out that the clinical prudence of the prescription dose and the assessment of any increased risk is the responsibility of the prescribing medical practitioner. It was not clear, however, that Dr. Faragher appreciated that her patient was in a position to obtain 90 x 75 mg tablets every five days until the repeats ran out.

In one sense this is academic in that it would appear that possibly only 4 extra tablets needed to be taken to induce cardiac problems. Nevertheless, as a matter of public health and policy it warranted scrutiny and I have made recommendations which appear at the conclusion of this Finding.

Safety Management Issues

There was no effective "safety plan" in existence at any time after the deceased became ill. Such as there was, was ad hoc and informal.

Mr. Wosniak was not advised as to the lethality of the drug by any professional. He told the court that he was careful to conceal it from his partner and assumed responsibility for administering it at night. He did this, not because he had been warned by anybody but because he had seen how careful with medication Kerford Clinic had been when Ms. Carrigg was under their care. After Yvonne's discharge from Banksia House, her parents came to help out and he went back to work. He told the court that he gave her parents the medication each night as he had to leave for work very early. He gave them no instructions. He said that he assumed they would know "because it gave messages on the boxes...". By this I assume he means the typed directions pasted on the box by the pharmacist.

The Court had been told that after receiving the detailed Discharge Summary from Banksia House, Dr. Faragher had noted the increase in the medication from the original prescription she had written and obtained authorization for. She verbally advised Ms. Carrigg to take extra tablets from that to make it up to the new maximum. I have gone into some detail about the risks associated with this in the Comments and Recommendation section of this Finding. Having said that, I acknowledge that Dr. Faragher was following a common practice. I mention it here as the comment by Mr. Wosniak is an example of the dependence on the written instructions by immediate members of the family who are unaware of the amended verbal directions given by the doctor.

I have already commented on the absence of any evidence that Ms. Parisotto reviewed the deceased following her first discharge from Kerford Clinic. Following discharge from Banksia House, it is clear that the staff there went to some trouble to ensure that every

person who needed to know the details of her current mental state and medication regime were informed and checked that there would be adequate follow up in the community.

The deceased was seen by Dr. Faragher some five days later and Dr. Faragher noted that she telephoned Ms. Parisotto after that to ensure follow-up. Ms. Parisotto has no note or recollection of the call. At no time did Dr. Faragher involve any other member of the family in the issue of medication. She told the court that this would "place the stress on families and on the relationship".[6] Further, she considered Yvonne to be sensible and honest and able to self-medicate.

Ms. Parisotto's evidence on this issue is quite vague. In evidence, she initially said that she had discussed a "safety plan" with the family on the 12th April after hearing family concerns about Yvonne taking off at speed in the car. The impression given was that this discussion was confined to the issue of removing from her access to the car keys. She told the court that she had no idea that the deceased on that day had access to so much medication and said that had she known she would have discussed it with Mr. Wosniak and the deceased's mother to ensure that they would look after the medication "if that was OK with Yvonne?...".[7]

Later in her evidence, however, she said that in her conversation with the deceased on the 12th April "she (Yvonne) denied any suicidal intent and that she was quite happy for her mother and Stephen to hold onto the medication for her, so that was quite-I felt satisfactory." She made no written entry of this conversation in her notes.

Neither Dr. Faragher nor Ms. Parisotto considered the deceased to be at any significant risk of suicide on the 12th April. It is difficult to evaluate this at this point. I am sure that they both had her interests at heart and would have acted appropriately had they assessed her in any other way. The subjectivity of these sorts of assessments, although based on expertise, makes them fallible. It is for this reason that a systemic approach to risk management is necessary. It is impossible to design a system that removes all possibility of suicide in a determined person. The aim should be, however, to travel as far down that path as practically possible. The deceased had a past history of overdose, she had been recurrently severely depressed with psychotic features since the birth of her son requiring hospitalization on two occasions, her situation fluctuated. In my view, inadequate safeguards were instituted to protect her from herself.

COMMENTS AND RECOMMENDATIONS

Some general comments

Quoting from an article by Dr. Ann Buist [8]---Post-natal depression affects about 14% of women. It may commence prior to the birth or within the first three months and lasts at least 3 weeks. The severity of the disorder may be masked and may fluctuate. The symptoms may include: lowered mood, labile mood, tearfulness, irritability, high levels of anxiety,

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[6] See Carrigg Transcript Page 120.

[7] See Carrigg Transcript Page 70 Lines 3-8.

[8] Modern Medicine of Australia March 1995 edition.

sleeping difficulties, lethargy and suicidal ideas.

If the woman develops post partum psychosis, this will almost always have its onset in the first month. These patients usually need management in an inpatient setting.

Amongst the risk factors for post-natal depression are past psychiatric history and family psychiatric history, particularly bipolar disorder.

I have researched the National Coronial Information Service data base for Victoria and have located three other deaths since July 2000 by overdose of dothiepin in women suffering from post-natal depression.

This inquest was conducted at the same time as the inquest into the death of Debra Smeeton. I have prepared a series of Comments and Recommendations to be attached to each Finding. Therefore not all of the following relate specifically to or arise from the death of Yvonne Carrigg.

I have divided the recommendations into those dealing with the **medication issues** and those dealing with **safety management issues**.

Medication issues

I was greatly assisted by suggestions from Mr. Stephen Marty Registrar of the Pharmacy Board of Victoria, Associate Professor Ann Buist and Professor Lorraine Dennerstein in this regard.

The recommendations may be incapable of implementation at the present time, however, it is hoped that they suggest appropriate measures for future consideration.

Education issues for medical practitioners

1. The court heard in the course of both inquests that increasingly general practitioners are treating patients with post-natal depression whereas in the past the treatment would have been provided by consultant psychiatrists. Dr. Buist said that at the Austin Hospital, virtually no tricyclics have been prescribed over the past year.

   As she pointed out in her report, education is critical for the purpose of information about the selection of anti-depressants for this condition. It is difficult for busy practitioners, particularly where they serve large populations such as in rural areas, to keep up to date with all the latest literature about drugs. As part of the National PND program of which she is the National Director, this nation-wide educational program for health professionals includes drug treatment and safety issues and they are encouraged consider tricyclics as a last resort because of the cardio-toxic effects in overdose.

   As Professor Dennerstein's second report makes clear, the Australian Pharmaceutical Index for twelve months to September 2000 suggests that SSRIs now have 51.45% of market share compared with Dothiepin 10.12% and this is an encouraging sign.

Nevertheless, medical practitioners should be alerted to the perils associated with overdose of this drug and encouraged to exercise particular caution in terms of the amount of repeats and the method of dispensing. It may be appropriate in a particular case to limit or ration the number of tablets to a few days supply at a time during the acute phase of the illness by arrangement with the patient's pharmacist.

Packaging of Dothiepin

2. Dothiepin as I indicated is available in 25 mg capsules (packets of 50) and 75 mg tablets. Professor Dennerstein pointed out that the higher dosage increases its adverse potential. Furthermore, it is dispensed in packets of 30. It is clear that it may require only a handful of the tablets to cause cardiac arrhythmia and sudden death.

   The number of tablets is based on a month's supply and is convenient for this reason. However, the risk of overdose would be reduced if packaging were available in lesser dosages or alternatively if 75 mg tablets were available in quantities of less than 30.

   Given the significant lethality of the drug and the population it is designed to serve, it would be helpful to provide such flexibility to prescribing doctors for use in the cases where the patient is at high risk of suicide.

Anomaly in Schedule to National Health (Pharmaceutical Benefits) Regulations

3. As was pointed out in the submission made by Mr. Counsel on behalf of Mr. Smeeton, the Schedule of Pharmaceutical Benefits provides for only two repeats of 75 mg Prothiaden. This has the effect that there is a dispensing gap of only five days in respect of repeats. Given the concerns as to the lethality of the drug, it would seem to be safer to place it in the schedule category which allows up to five repeats. This would satisfy the financial and convenience concerns of patients on a "maintenance dose" and also allow discretion to the prescribing practitioner who can still prescribe two repeats but be assured that no repeat may be dispensed within 20 days, therefore limiting the risk of stockpiling.

Discrepancy between written and verbal medication directions

4. It would seem that there is no embargo against a doctor giving oral instructions to patients which conflict with the instructions written on the prescription. This is more likely to happen in the circumstance where the doctor has decided to alter the medication regime and the patient is still being dispensed the medication based on repeats of the original prescription and with the same written instructions pasted on the packaging.

   That this can happen is rather surprising given the detailed specificity of the National Health (Pharmaceutical Benefits) Regulations in relation to prescriptions.

   This situation is complicated when there is a special authorization from the Health Insurance Commission which is what occurred in each of these cases. Dr. Dennerstein told the court that neither doctor could have written a new prescription if it was desired to increase the dosage without a fresh authority and if one had been sought it would not

have been granted as, according to the Commission records, it could be calculated there would still be tablets in existence or which could be dispensed. [9]

Another by-product of this practice is seen when consideration is given to the Pharmacy Board of Victoria Guidelines of 1999 at paragraph 438 where they require pharmacists to provide "full and extensive counselling" to (amongst others) psychiatric patients. The practice, apparently acceptable, of the doctor verbally altering the administration and dosage instructions might, in some cases, work to defeat the safety purpose of this guideline. The pharmacist in ignorance of any change may derive some comfort from the dosage instructions even though he or she may have some concerns as to the presentation of the patient. For the same reason, he or she may inadvertently fail to warn of symptoms that may occur at a higher dosage rate.

Of course, in many cases, the discrepancy between the written and actual administration directions may become apparent in the course of the counseling. But it is not difficult to imagine a case in which it does not.

A confused or severely depressed patient (or another person assisting them to obtain or dispense the medication and who is unaware of the change) may take or administer the drug at the original written dosage which, in turn, may lead to a clinical deterioration. As will be seen in the following recommendations regarding safety management, a *"whole of family approach"* is urged which involves often removing the responsibility of medication from the patient to another person. It is critical that this person or persons are aware of the true administration picture and are not able to be misled by the pharmacist's instructions pasted on the bottle or package.

I have listed just some of the risks attending this practice. I consider that a way should be found to match the "pasted written instructions" and the altered instructions as verbally directed by the doctor. I consider that there should be provision under the Regulations for an Authorized Prescription to be "replaced" with another Authorized Prescription to this end. The current situation results in the Health Insurance Commission's records reflecting a wrong picture which does not tally with the reality. I consider that medical practitioners should be urged to advise patients, *and/or their carer,* in situations where the medication is likely to be reviewed at a future consultation, to return with the remainder of the tablets and the repeat prescription. The writing on the label on the packet could then be amended. The repeat prescription could then, if necessary, be destroyed and replaced by a fresh prescription. Ideally a way should be found that produces the desired result without causing financial or other hardship for the patient.

I urge that each of the organizations and agencies to whom this Finding is forwarded give consideration to finding a suitable resolution to this problem.

Safety Management Issues

The hazards associated with the prescription of the drug could be minimized if the prescribing doctor adopted what I have called a "whole of family approach".

[9] See Transcript Page 162-3

Whilst I am aware of the need to build a confidential relationship with a patient, in both of these cases, the patient was aware *in advance* of the possibility of the development of the illness. Therefore a golden opportunity existed for strategic planning in advance in consultation with trusted family members and, if thought necessary, with the patient's permission, written and signed documentation to this effect. Whilst I am also aware that in a large number of cases, these "contracts" are subsequently not abided by, in some cases they are and at the very least it should provide a measure of protection for the doctor.

I have listed below a number of matters which I consider that these inquests have highlighted.

(a) Care should be taken to review the patient for part of each consultation in the absence of family members. This would enable a patient to be encouraged to divulge any symptoms that she is otherwise reluctant to tell her family. After all, a common feature of the illness is the feeling of being a burden to others. I believe it is critical that the patient has this outlet as part of her therapy and to enable future treatment planning. The treating doctor may undertake to keep the information to him or herself if this is considered necessary to maintain an open dialogue with the patient in the future.

(b) It is also important to review the patient for part of each consultation in the presence of at least one other family member. This will ensure that any change in medication is thoroughly canvassed with that person. The changes could be written down if necessary. The family member may be useful to validate an account given by the patient. The presence of the family member may re-assure the patient that she is supported at home by a person who is interested in being kept informed about her illness and that she is not alone in her efforts to combat it.

(c) The treating doctor should also, on a regular basis, speak privately with a family member particularly to discover if there are any aspects of the illness that have not been volunteered by the patient but which are within that person's knowledge but not mentioned in a joint consultation perhaps for fear of distressing the patient.

(d) The doctor should inform members of the family of the types of signs and symptoms that may indicate a deterioration. Particularly any indication of delusional thoughts or hallucinations should ring alarm bells and prompt an urgent call to the doctor. If this plan had been set up, a telephone message to call a family member would receive prompt attention.

(e) A "safety plan" should be set up in the event that the patient may develop symptoms of post-natal depression or after the symptoms have become apparent. Again, this should involve all members of the immediate family likely to be on hand during the first few weeks after the birth. Critical to the plan would be <u>the control of medication</u>. *Every person involved in the care of the patient should know what the plan is.*

(In one of the coronial cases I researched the following is extracted. It related to a woman who had been treated for recurrent post-natal depression for many years. Due to failure to respond to other medications, her doctor placed her on Dothiepin in the month prior to her death.

"He states although he was aware of the greater risk of toxicity, he still decided to take this course of treatment due to the failure of other medications to combat the depression. A system was put in place whereby the deceased would not have access to a large volume of medication at any time. The deceased's husband? was responsible for allocating medication to the deceased. He further stated that prescriptions would come in the mail and he would fill them at the chemist. On the day of her death the deceased was home with her mother (who) was unaware of the system that (the doctor) and (the deceased's husband) had put in place. The deceased has then collected the mail and has seen the prescription. She has then informed her mother that she needed more pills, so her mother took her to fill the prescription. The deceased has then ingested a large quantity of pills and consequently died in her bedroom?".[10]

Further, any items likely to be used to self-harm, (based on, for example, past history) should be removed from access. Car keys and knives are a good example.

Finally somebody should be with the deceased at all times.

It is very important that the treating doctor should encourage the carers in their role, invite them to tell of any difficulties that have been encountered in implementing the safety plan and re-assuring them and reinforcing the importance of their role.

Stephen Marty in his report commented:

"It has been my experience that patients and carers do not remember more than two or three points from consultations and sessions where advice is provided and that written communication reinforced by verbal advice is the preferred method."

He recommends that safety plans should be provided in writing. I adopt this recommendation.

(f) I consider that upon discharge from a psychiatric facility, a discharge summary should always be prepared and forwarded to all health professionals who may be involved in the future management of the patient.

An effort should be made to co-ordinate all those persons so that a clear plan is in place to follow-up the patient and provide support.

Ideally, such a patient should be reviewed by one of the on-going professionals very soon after discharge so that there is as much continuity of care as possible and also so that there is able to be established a "baseline measure" from which to plot further progress or deterioration.

I propose to forward a copy of this Finding, Comments and Recommendations to the following:

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[10] Case 287/2000.

The State Minister for Health;
The Minister for Community Services;
The Pharmacy Board of Victoria;
The Health Insurance Commission;
ADRAG;
The Royal Australian and New Zealand College of Psychiatrists;
The Royal Australian College of General Practitioners;
The Therapeutic Goods Administration (TGA); and
Australian Medical Association (AMA) Victoria.

JACINTA HEFFEY

CORONER