STATE
CORONER
VICTORIA

Case No: 3431/99

RECORD OF INVESTIGATION INTO DEATH

I, JACINTA MARY HEFFEY, Coroner, having investigated the death of DEBRA JOY SMEETON with Inquest held at the Coronial Services Centre, Southbank on the 29th and 30th August, 2002 FIND THAT the identity of the deceased was DEBRA JOY SMEETON and that death occurred on the 12th November, 1999 at 9 Billson Street, Beechworth from dothiepin toxicity in a setting of post-natal depression in the following circumstances:

1. The deceased gave birth to a daughter, Erin, on the 14th October, 1999 at the Wangaratta Private Hospital. She had been delivered of one previous child, a son, on the 11th April, 1996. She was aged 34 years and was happily married to James Smeeton. The couple lived at Beechworth.

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

03/09/99	Mrs Smeeton consults Dr. Ian Douglas, Psychiatrist
24/9/99	Deceased reviewed by Dr Douglas. He prescribes as a prophylactic against post-natal depression Dothiepin 25mg to be taken at night increasing from the 30/9/00 by increments of 25mg every second night until total nightly dose is 150mg.

14/10/99	Baby Erin born. Dosage of Dothiepin increased to 175mg on the 15th October and to 250mg on 18th October.
23/10/99	Deceased discharged home with baby on 250mg Dothiepin nocte with a prescription provided by Dr. Douglas.
4/11/99	Husband contacts Dr Douglas for urgent review. Dr Douglas increases Dothiepin dose to 275mg.
5/11/99	Further review by Dr Douglas.
10/11/99	Husband contacts Dr Douglas and home visit occurs. Dothiepin increased to 300mg nocte.
12/11/99	When he awakes, husband finds Mrs Smeeton deceased in bed.

3. A post-mortem examination was conducted. Toxicological analysis revealed fatal levels of the anti-depressant drug, dothiepin. Dothiepin toxicity was determined to be the cause of death.

4. The deceased had suffered severe post-natal depression following the birth of her son in 1996. Five weeks after his birth she was admitted to the Wangaratta Private Hospital with low mood, anxiety, feeling that she could not cope, sleep and concentration difficulties. She secreted a steak knife under her mattress and admitted to a plan to kill herself. She was admitted to the High Dependency Unit at the Melbourne Clinic where, after she initially failed to respond to Dothiepin, she underwent four courses of electro-convulsive therapy. She and the baby were subsequently transferred to Mother and Baby Unit at the Clinic. Altogether she was in hospital for about six weeks. She was discharged home to Beechworth on the 22nd June and was reviewed by Dr Ian Douglas on the 25th June. He continued to review her and to adjust the medication until she was stable after which she remained on a maintenance dose of 225 mg nocte until June 1997 after which it was phased out over three weeks.

   In a letter written by Dr Douglas in March 1997 to Dr Pearce, Obstetrician, he provided this history and went on:

   > *"Diagnostically she had a post-natal depression of psychotic type and of severe degree, with a high suicide risk."*

5. From all accounts, the deceased was very concerned about developing post-natal depression with her second pregnancy. It was for this reason that she sought a consultation with Dr Douglas when she had about six weeks to go to the projected birth date. The court heard that between the two pregnancies she had become a volunteer with PANDA (Post and Ante-Natal Depression Association) and had spoken at meetings about her experience with post-natal depression. As mentioned above, Dr Douglas started her on the anti-depressant Dothiepin. He told the court that he had sought advice from Associate Professor Ann Buist at Banksia House Mother and Baby unit, regarding medication as he was considering Lithium in view of a family history of Bi-polar disorder. Dr Buist, he said, advised him that on balance lithium "would not need to be used as this point and that prothiaden was a reasonable choice given the previous response".

From a reading of the hospital records, it would appear that Mrs Smeeton did not display symptoms of post-natal depression prior to her discharge from hospital.

6. Mr James Smeeton in his first statement in the Coronial Brief said:

> *"After returning home with the baby Debbie appeared to be in great spirits for approximately five days after which she started to display signs of depression. Over the next few days she started to complain about being tired and that she wasn't a good mother. These changes in her outlook would fluctuate from appearing to be completely normal to slightly depressed several times throughout the day. Finally on or about the 7th or 8th day...?she appeared to be quite unwell...?".*

He telephoned Dr Douglas who saw her that evening in his rooms. This was on the 4th November. Dr Douglas diagnosed the recurrence of post-natal depression of moderate severity. Based on the earlier telephone call from Mr Smeeton and prior to seeing Mrs Smeeton, Dr Douglas had telephoned the Melbourne Clinic to see if there was a bed available. After he saw Mrs Smeeton that evening, he decided not to admit but to wait and to review her the next day, after seeing how she responded to an increase in the medication. In his statement he noted that the Smeetons "expressed the desire not to go to hospital if possible...?". Mr Smeeton said that the possibility of the Melbourne Clinic was raised however Dr Douglas considered that he would wait to see how she responded to an increase in the medication.

7. On the 5th November, Dr Douglas reviewed Mrs Smeeton and she reported feeling improved. He telephoned over the succeeding days and the report was of fluctuating mood with some good periods. No suicidal ideas were reported. Hospitalization was not considered necessary. However, Dr Douglas kept that option open and only cancelled the bed on the 8th November.

Mr Smeeton described his wife's demeanour over the next few days as being very tired, wanting to lie down and little interest in the baby or Hamish, her son. After attending a local mothers "playgroup" on the 10th November he said that she returned "quite down" and "scared". She was apparently very distressed that she had succumbed to post-natal depression again. She also complained of a "racing heart".

Mr Smeeton telephoned Dr Douglas who came out to the house. In evidence, Dr Douglas said that Mrs Smeeton displayed little spontaneous input but did speak. He considered that she was similar to the way she had been on the 4th November.

Dr Douglas took her pulse and told the court that" it was consistent with someone on prothiaden". He considered her concern that she felt that her heart was going to jump out of her body was due to anxiety. He noted:

> *"Diagnosis: depression, moderate severity, nil psychotic features. Does not appear suicidal. He chose to increase the medication to 300 mg nocte."*

8. In July, 2002 a Statement was taken from Lynda Gray, a close friend of Debra. She recounted a telephone call from the deceased on the evening of the 7th November. Ms Gray described Debra as talking "very, very slowly". She was tearful, saying " it's got me again" and that she was scared. She also said that she was hearing voices, that she was sitting in the

lounge-room and could not move until after lunch. When Ms Gray offered to drive to Beechworth from Melbourne to see her she replied that her mother had just gone home and "Jim just wanted them to be a real family...?and that it (a visit from me) would put stress on them...". Following this phone call, Ms Gray called Mrs Amsden, Debra's mother, and told her about her concerns.

Mrs Amsden made a statement in which she confirmed this and said that she telephoned Dr Douglas' rooms on the 8th November and, as he was not there, left a message to call her back. This did not occur.

9. Dr Douglas was asked about this and it would appear that it was the first time he had learned of the deceased having heard voices. According to his notes, she had denied any delusional thoughts on the 10th November. He has noted in his records "nil psychotic features". In evidence he said that had he known of this he would have given consideration to a hospital admission at that time.

10. On the 11th November, Debra and her husband and children went for a walk around the lake. He described her as seeming "fairly well although not 100 %". She was tired on their return. That evening she watched TV with her husband and then retired early to bed whilst he waited up to complete the last feed with the baby. When he awoke the next morning he found her dead beside him. No suicide note was located.

A post-mortem examination was conducted and toxicological analysis revealed the presence of dothiepin in leg blood at a concentration of 2.9 mg/L. Analysis of the stomach contents revealed about 5 grams 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 8x75 mg tablets. Of the large amount apparently ingested it may only have required four extra 75 mg tablets (on top of the prescribed amount) to achieve this.

11. ***Issues raised by this death***

The major issues raised by this death and which were examined at inquest were largely to do with the medical management of the deceased by her treating psychiatrist, Dr Ian Douglas.

These were:

- **The appropriateness of the medication, including the type of medication, the dosage rate and the prescription regime.**

- **The attention to the risks associated with the medication, including information to carers as to the associated risks.**

- **Providing information to carers in relation to indicators of deterioration in mental health and related confidentiality issues.**

- **Whether at any time, Mrs Smeeton should have been hospitalized.**

I have discussed these under the general headings of Medication issues and Safety Management issues.

12. Medication issues

A discussion of Prothiaden

The terms prothiaden and dothiepin (the generic title) 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 who may 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 significant 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]

In his submission on behalf of Dr Douglas, David Martin of Counsel stated that:

> *"Clearly a relatively small number of 75 mg tablets, if taken one at a time, would be sufficient to cause death. In this instance, Mrs Smeeton, tragically and unfortunately, was determined to take her own life, and the fact that she had access to one or more repeats of her prescribed medication was immaterial and irrelevant to her ability to ingest a fatal dose?..."*

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*

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

50%. Therefore, any increase in prescribing the more toxic TCAs will lead to an increase in suicide rates from overdose of these drugs?..."[2]

Applying this, it would appear that if it is true that Mrs Smeeton was determined to take her own life, the access by her to the specific antidepressant medication cannot be said to be irrelevant or immaterial. Further, 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 Dr Douglas is not now regarded in the psychiatry profession as the first line drug of choice for the treatment of depression. 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.

Mrs Smeeton had taken Prothiaden during the acute phase of her previous episode of post-natal depression and had been on a maintenance dose for the next 12 or so months. Initially it had had little discernible effect, hence the need for electro-convulsive therapy. However, following her discharge from hospital, she continued to take it and further improvement was noted.

Dr Douglas told the court that he was aware of the overdose risks associated with Prothiaden at the time. However, he started Mrs Smeeton on Prothiaden as it had worked in the past and he told the court that at that time and it was believed to be safe during pregnancy and breast-feeding. He believed that it was less clear in 1999 as to whether this was the case with SSRIs.

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 only work for 70% of patients, it was reasonable to use a drug that was known to work on a particular patient.[3] Further, she said that it was clear that Mrs Smeeton had responded well to prothiaden on the last occasion. At that time the risk of relapse would have been high given that she had received only 4 treatments of ECT which is not a high number and this had not occurred.[4]

Taking these factors into consideration, I consider that this choice of medication was reasonable in the circumstances.

Dosage Rate and method of prescribing

The table in paragraph 2 above sets out the dosage rates of Dothiepin as prescribed by Dr Douglas. It can be seen that the dosage increased in response to the clinical deterioration on

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[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.

[3] See Transcript Page 133.

[4] See Transcript Page 135.

the 4th and 10th November.

Dothiepin is available from pharmacies in packets of 30 tablets in strengths of 75 mg or in capsules of 25 mg in packets of 50 capsules. Two repeats only are allowed. However an Authority can be sought under the Pharmaceutical Benefits Scheme for a larger quantity and Dr Douglas did this on the 22nd October, the day before Mrs Smeeton was discharged from hospital. He provided an "Authority Prescription" for 90 x 75 mg tablets to be taken 3 tablets at night. Five repeats were authorized.

In the hospital records, Dr Douglas notes on the 22nd October that Mrs Smeeton is "*for discharge tomorrow on dothiepin 250 mg oral nocte (script in front of this file)?...".*

A subsequent nursing note on the 23rd October confirms the discharge and notes "*script etc given to Debbie?...".*

The wisdom of prescribing such a large quantity of a drug which was potentially fatal in overdose was a matter that occupied some time during the inquest.

However, it would appear, as stated above, that only a small quantity of the drug would be lethal.

In all, Mrs Smeeton had three prescriptions filled after she was discharged from hospital. These were all dispensed at Kelly's Pharmacy at Beechworth by pharmacist Janice Orr. These were as follows:

25-10-99	Dothiepin 75 mg 90 TAKE THREE TABLETS AT NIGHT.
09-11-99	Dothiepin 25 mg 50 TAKE TWO CAPSULES AT NIGHT.
10-11-99	Dothiepin 75 mg 90 TAKE THREE TABLETS AT NIGHT.

The dispensing of the 75 mg tablets on the 10th November was 16 days after the previous dispensing on that original prescription. The original prescription provided for five repeats.

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 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 Douglas 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.

(Ms Orr, erroneously, it would seem, believed that the 20 day rule applied. However, she brought herself under another exception according to which the 20 day rule may be overridden if the pharmacist is advised that it is urgently needed for treatment or if a

previous supply had been destroyed, lost or stolen.)

It was submitted by Counsel acting on behalf of Mr Smeeton that this scenario creates an anomaly in that "it defeats one apparent purpose of the Schedule and would mean that a patient could stockpile large amounts of a very dangerous drug".

According to the report compiled by Stephen Marty, the Registrar of the Pharmacy Board of Victoria, the Authority Prescription is issued for a greater quantity on the basis that it will still amount to a month's supply, as will the repeats. The rationale behind it is to reduce the financial burden associated with medical consultations and more frequent dispensing.

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 Douglas appreciated that his 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.

13. Safety Management issues

The "safety plan" in relation to Mrs Smeeton

This was the second focus of the investigation into this death.

It involves a detailed examination of the management of the deceased by her treating psychiatrist Dr Douglas and his dealings with her husband who was her primary carer, having taken a month off work to care for her and the two children.

I draw no inference from the fact that the term "safety plan" was not used in discussions with Mr or Mrs Smeeton. It appears in Dr Douglas' clinical notes but not in the hospital notes. I was invited to deduce from this, along with the absence of any reference to "a safety plan" in his notes during his previous dealings with Mrs Smeeton, together with the uniformity in the appearance of his notes, that Dr Douglas fabricated them for the purpose of the inquest. Although not specifically put to him as an allegation, I consider that it is clear from the cross-examination of him that this was the intended imputation.

The term "safety plan" is a term which, according to Dr Douglas, is used by CAT teams. It is not a term he uses in discussion with patients. The apparent uniformity in his notes alone does not permit of the inference that these were fabricated and I make no finding in this

regard. Although he placed Mrs Smeeton on a comparable dose of prothiaden following her discharge from hospital in 1996, I am satisfied that her symptoms at that time were on the improve. A reading of the Melbourne Clinic notes at the time of her discharge are clear evidence of this. I do not consider that the absence of any advice to Mr and Mrs Smeeton about a safety plan in 1996 nor the absence of any reference to such in his notes at the time is sufficient to cast doubt on his credit in relation to his evidence in relation to her post-discharge course in 1999.

The communication of the "safety plan"

The competing evidence

Dr Douglas reviewed Mrs Smeeton in the presence of her husband on four occasions.

The first occasion was on the day prior to her discharge from hospital. Whilst their recollections differed I consider that the likely course of events is largely as deposed to by Dr Douglas. In the course of the conversation, Dr Douglas mentioned that her husband should be in charge of the medication. In fact, Mr Smeeton told the court that he did subsequently assume this role and at page 15 of the Transcript he said that he did so "as suggested by Dr Douglas". He said that he did this, not because he was informed of any inherent risk associated with that drug, but because he was told by Dr Douglas that all drugs can make you ill if too many are taken.

Dr Douglas gave evidence that he mentioned "very briefly and with many other matters being discussed" that if the depression returned, other measures, such as dealing with "dangerous objects" and always having someone with her, should also be considered.

Mr Smeeton did not recall this but, as he himself indicated, Dr Douglas seems not to have devoted a lot of time to it in the context of other matters discussed.

At this time, there was no real indication that the post-natal depression was returning and the plan was that Dr Douglas was going to keep in touch by telephone in any event. I do not think much turns on this discussion or the differing recollections in relation thereto.

The second face to face contact was on the 4th November after Mr Smeeton telephoned Dr Douglas with his concerns and his wife was reviewed at the hospital. Mr Smeeton told the court that on this occasion, Dr Douglas mentioned "hiding knives", that someone should be constantly with her and that he should manage the medication. He said that this was said in an "off-hand manner with a smile". He did not accord it much significance in the circumstances. He did, however, hide the kitchen knife block taking it to the laundry.

The next day, Dr Douglas again reviewed the deceased and she reported feeling improved. This was confirmed by Mr Smeeton.

The fourth review was at the house on the 10th November, when, again, Mr Smeeton telephoned Dr Douglas with his concerns. Both witnesses said that the deceased said very little on this occasion. The two men had a private discussion outside the house as Dr Douglas was leaving. According to his notes, Dr Douglas again noted " re-iterated safety

plan". He had previously made the same or similar notation for each of the last two consultations. Mr Smeeton denied that this occurred.

After Mrs Smeeton's death, Dr Douglas called on Mr Smeeton on the 12th November to convey his condolences. On that occasion, Mr Smeeton said to Dr Douglas that he felt guilty because he had not done what had been suggested to him in terms of concealing the medication. It was also put to him that he made the same comment to the police chaplain who also visited that day. Mr Smeeton agreed that he did say this.

I am inclined to accept Dr Douglas' account as to the number of times he mentioned the features of the safety plan. There was, however, only one occasion when this was mentioned to Mr Smeeton in the absence of his wife. Also, I have concerns about the manner in which the lethality of the drug was explained.

Dr Douglas told the court that it was his style not to stress the lethality of a drug in the presence of his patient, or, it would seem even to the carer. *"The carer, the husband or whoever may come out with that information inadvertently...?.so I have discussions in a much more general sense?...I specifically in this situation did not wish to say to Mrs Smeeton or Mr Smeeton, look this is this medication, it is highly toxic and this is the lethal dose. It was something I certainly did not want to say?..."*[5]

The adequacy of the Safety Plan and it implementation

In his statement, Mr Smeeton said that after the consultation on the 4th November, he "temporarily removed the medication from the bathroom but Debbie became upset and (said) I didn't trust her and I subsequently returned them to her control...?"

I think it is most unfortunate that this was not conveyed to Dr Douglas on the 10th November. It is a very poignant example of the difficulties Mr Smeeton was experiencing. He had a very sick wife who was behaving in such an uncharacteristic fashion, the care of a toddler and a baby to manage. I have no doubt that he did "want them to be a family" as Mrs Smeeton conveyed to her friend Lynda Gray. His wife's moods would fluctuate, with her seeming normal at times. This must have made the whole notion of exercising sole autonomy over her medication very difficult to manage. It should be remembered in this context that his wife had been solely responsible for her own medication for a considerable time on the previous occasion.

I am satisfied that he had no real appreciation of the lethality of the drug. This was a direct result of the failure of Dr Douglas to inform him in detail, in line with his espoused practice as set out above.

Whilst I understand the reasoning behind Dr Douglas' practice, I consider that it is more important to stress to the carer the true risks associated with the drug including its lethality and if there is a concern that this may somehow reach the ears of the patient then this is a risk worth taking. This latter risk may be reduced if the carer is warned about it at the same time. Had Mr Smeeton been aware of these facts, he may have resisted his inclination to humour his wife when she complained about his taking control over her medication. Also had he been aware, he may have confided to Dr Douglas in their private conversation on the

[5] See Transcript Page 62 Lines 19-27.

10th November about the difficulties he was experiencing about the medication and sought his advice.

I am aware also of the issues of confidentiality when dealing with a patient and that this may operate to discourage a doctor from discussing a patient with another person, even a family member.

Dr Douglas told the court:

> *"I avoid trying to speak separately from patients. I always prefer to have both parties there*."[6]

This case differs from the usual situation in which a psychiatrist is treating a person with depression in that the patient herself had, with the full knowledge of her husband, proactively sought assistance prior to the birth precisely to limit the chance of her developing a depressive illness. It was clear that she had significant insight into not only the illness but the impact it might have on her family. This was sufficient authority to speak separately to the husband. If there had been any doubt about this it should have been specifically raised before she became ill.

Once the recurrence of the illness was diagnosed on the 4th November, I consider that it became very much a "whole of family " issue. Mr Smeeton was, as I have said, confronted with a very difficult situation. It required understanding and patience, whilst dealing with the demands of a young family, often with little assistance from his wife due to her illness. His indication to her that he "wanted them to be a family" is not surprising but does demonstrate a desire to act as if there were no problem and, perhaps also, a degree of frustration. From all accounts Mrs Smeeton was, when well, a very well balanced person and a devoted mother. The changes he was observing in her, particularly when she was at times apparently "normal", were understandably very difficult to deal with.

In my view, a husband in Mr Smeeton's position really needs a great deal of support by way of advice and should be encouraged to confide his difficulties to the treating doctor.

Dr Douglas was, as I have said, unaware that the deceased was "hearing voices". He had asked her at each consultation whether she had any thoughts of self harm and if she was experiencing any psychotic features. On each of these occasions her husband was present.

Dr Douglas told the court that he had a good rapport with Mrs Smeeton, that she has always been open with him as evidenced by her confession to him during the 1997 illness of keeping a knife under the mattress. This confidence had, however, been in the absence of her husband. In the context of person who is, as part of her illness, experiencing feelings of low self-worth and a burden to others, who feels that her husband just wants to get back to normal life, it is perhaps not surprising that the deceased did not admit to psychotic features or thoughts of self-harm when asked in the presence of her husband.

Dr Douglas conceded that, in retrospect, it may have been a good idea to speak privately to his patient. He also said that *"acknowledging there was some possibility...?of her having a sophisticated knowledge of the post-natal depression...?she may have been either*

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[6] See Transcript Page 52 Lines 26-29.

minimizing or concealing the symptoms?...".[7]

Mr Smeeton told the court that some time after his wife recovered from her earlier illness in 1997 she told him of how she had "covered up" her feelings on occasions. He gave an example of how she told him that on one occasion when they left the hospital to go for a walk that she had spent much of the time trying to think of a way of running away.

Whilst it can be understood that nobody wanted to anticipate her becoming ill again, it would have been useful to analyse all these matters in preparation for any future illness so that all had a clear understanding of what may be expected. There was a useful precedent in this case. Mrs Smeeton was willing to talk about it when well. Indeed she had given public speeches about it. The lessons learnt from the earlier episode could have been very valuable in the strategic planning and management of a future episode.

In summary, the safety plan, whilst a reasonable one, was not in my view sufficiently impressed upon Mr Smeeton in that the lethality of the drug was not stressed and hence the need to be extra vigilant in its administration. The practice of always seeing Mrs Smeeton in the presence of her husband was unwise, given that any couple in that situation were likely to be undergoing considerable stress in their relationship as a result of the fluctuations in mood being exhibited by Mrs Smeeton and these, together with her feelings of inadequacy, might inhibit the patient from fully disclosing her true situation in the presence of her husband.

Should Debra Smeeton have been hospitalized?

The final matter for determination is that which was raised by the deceased's mother in her submission to the inquest at the conclusion of evidence.

The relevant time for this to have occurred was at the time of the consultation on the 10th November. Prior to that time and on the previous consultation on the 4th and 5th November in my view it was reasonable to assess how the deceased responded to the increase in medication.

However, on the 10th November, Dr Douglas observed that Mrs Smeeton had deteriorated to a similar state to that seen on the 4th November. It will be recalled that prior to seeing Mrs Smeeton on the 4th and as a result of the phone call from her husband, Dr Douglas had enquired about the availability of a bed at the Melbourne Clinic. It was ultimately decided to trial the increase in medication over the next 24 hours and, as it turned out, this did result in an improvement. Nevertheless he kept the bed option open for four days.

On the 10th November, the medication was increased, this time to 300 mg but no arrangement was made to review the patient the next day as had previously occurred. Of course, Dr Douglas was available by telephone, however it would seem that the picture is one of deterioration with increasing doses of medication to achieve an earlier effect. In my view it was not appropriate to rely on Mr Smeeton to assess how she responded to the increase in medication over the next few days.

[7] See Transcript Page 99 Lines 11-15.

Furthermore, on the 10th November, Mrs Smeeton was complaining of a rapid heart rate which was causing her anxiety. Given the knowledge that Dr Douglas had in terms of the cardiac complications that can arise with tricyclic medication, it is surprising that he did not record this complaint in his notes of that consultation. Nor did he make a note of the pulse rate. He told the court that he did take it and it was within a range of 60 and 100. He said that if it had been outside this range he would have arranged a hospital based assessment. Nevertheless he increased the medication dose, with no arrangement for early review.

The question of the increased pulse rate was mentioned in Professor Dennerstein's report. She commented:

> *"?...I presume that had Dr Douglas thought this (the report of a fast heart rate during that day) was due to the dothiepin, he would not have increased medication and would have hospitalized her if an increase was needed in order to rule out cardiovascular side-effect*s *by ecg and monitoring*..?."

In evidence, Professor Dennerstein was told of Dr Douglas' evidence that he had taken the pulse and it was within normal range to which she commented:

> *"Well, that was reasonable (ie the decision to take no further action) on his part, but given the symptom and the known cardio-toxicity of Prothiaden and that she was on quite a high dose then it would also have been reasonable for him to have ordered tests and I still don't quite understand why he increased it further, given the history that day?...".*[8]

In evidence Dr Douglas told the court that he considered the complaint of rapid heart rate was in response to the medication, but also due to anxiety.

I am aware that Dr Douglas had not been informed about the hearing of voices. In evidence he said that had he known he would have reviewed the whole matter with a view to hospitalization.

However it would seem that there was a sufficient basis for hospitalization on the 10th November without this knowledge. He elected to treat the condition which he considered to be the same as on the 4th November with an increase in medication notwithstanding the appearance of cardiac signs in response to it. He considered that she was the same as she had been on the 4th November and yet on that occasion he had kept open a bed at the Melbourne Clinic until the 8th November and arranged to review her himself the following day.

Dr Douglas told the court that he did give consideration to hospitalization and that Mr Smeeton had raised it. However he took the view that "she was still at that point moderately rather than severely psychotically depressed?...".[9]

I am aware of the perils of assessing a professional person's conduct and judgment with the benefit of hindsight. However, in my view, and for the reasons given, there was a strong

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[8] See Transcript Page 176 Lines 4-9.

[9] See Transcript Page 90.

objective basis for recommending hospitalization on the 10th November. At the very least, Mrs Smeeton should have been reviewed by Dr Douglas on the 11th November.

COMMENTS AND RECOMMENDATIONS

Some general comments

Quoting from an article by Dr Ann Buist [10]---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, 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 Yvonne Carrigg. 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 Debra Smeeton.

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

[10] Modern Medicine of Australia March 1995 edition.

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 (say 50 mg) 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. [11]

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 administer 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*

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[11] See Transcript Page 162-3

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".

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 the control of medication. *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*?...".)[12]

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*."

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[12] Case 287/2000.

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 in the community 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:

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