CORONERS ACT, 2003

SOUTH *AUSTRALIA*

FINDING OF INQUEST

An Inquest taken on behalf of our Sovereign Lady the Queen at Adelaide in the State of South Australia, on the 19th, 20th, 21st and 22nd days of February 2013 and the 8th day of March 2013, by the Coroner's Court of the said State, constituted of Anthony Ernest Schapel, Deputy State Coroner, into the death of Cynthia Joy Pauley.

The said Court finds that Cynthia Joy Pauley aged 72 years, late of 10 Rosslyn Avenue, Manningham, South Australia died at the Ashford Hospital, Anzac Highway, Ashford, South Australia on the 20th day of September 2010 as a result of intrathecal toxicity of bupivacaine and morphine. The said Court finds that the circumstances of her death were as follows:

1. Introduction and cause of death

1.1. Cynthia Joy Pauley died at the Ashford Hospital (the Ashford) on 20 September 2010. She was 72 years old.

1.2. Mrs Pauley had been an inpatient at the Ashford since 1 September 2010 on which day she had been transferred from the Blackwood Hospital.

1.3. In 2002 Mrs Pauley had been diagnosed with parotid acinic carcinoma (cancer of the salivary gland) that had required a parotidectomy. In 2010 it was discovered that Mrs Pauley's cancer had returned and had spread to her lung and brain. As well, there were localised tumours in her temple. These latter tumours were excised and Mrs Pauley also underwent a course of chemotherapy. The disease would metastasise into other parts of her body including the cranial cavity, the right lung, the right pleural cavity, the liver, other organs and her skeleton. In August 2010 Mrs Pauley experienced a fall from which she suffered a pelvic fracture, believed to have been

contributed to by metastatic cancer to that part of her skeleton. The fracture resulted in uncontrolled pain that ultimately required her transfer to the Ashford on 1 September 2010 where she would remain until her eventual death.

1.4. During Mrs Pauley's admission within the Ashford she was subjected to a number of differing pain management regimes, all of which involved the administration of analgesic medication via varying modalities of delivery.

1.5. I will deal with the circumstances surrounding Mrs Pauley's death on 20 September 2010, but it is pertinent here firstly to refer to the results of Mrs Pauley's post-mortem examination.

1.6. Mrs Pauley's death was reported to the State Coroner in the belief that Mrs Pauley's analgesic medication, at that time being delivered by way of a spinal line, may have played some part in her death. A post-mortem examination of Mrs Pauley was carried out by Dr John Gilbert who is a forensic pathologist at Forensic Science South Australia (FSSA). Dr Gilbert compiled two post-mortem reports, dated respectively 21 February 2011[1] and 1 August 2011[2], the latter of which was compiled and supplied following an independent clinical overview of the circumstances of Mrs Pauley's death as provided by Dr Penny Briscoe, the Head of the Pain Management Unit of the Royal Adelaide Hospital (RAH)[3].

1.7. In Dr Gilbert's first post-mortem report he noted the existence of metastatic cancer in the various parts of Mrs Pauley's body to which I have already referred. However, notwithstanding the widespread nature of her disease, Dr Gilbert could find no clear anatomical cause for Mrs Pauley's death. That is not to say that Mrs Pauley had not been extremely ill prior to her death; nor does it mean that Mrs Pauley would not ultimately have died from her metastatic disease sooner rather than later. What Dr Gilbert's report signified was that there was no evidence of a pathological process that explained the deceased's acute deterioration and death on 20 September 2010. What is clear though is that on the day of her death Mrs Pauley had been administered with a bolus dose of analgesia by way of an intrathecal catheter. The analgesia had consisted of a mixture of significant dosages of morphine, which is an opioid analgesic, and bupivacaine an analgesic drug also commonly used in spinal

[1] Exhibit C6
[2] Exhibit C6a
[3] Dr Briscoe's report and annexures are Exhibits C12a, C12b and C12c

anaesthesia. It is now common ground, and I so find, that the quantities of both morphine and bupivacaine were, if not in and of themselves excessive, certainly excessive in combination having regard to their method of administration. Both morphine and bupivacaine at significant levels were detected in Mrs Pauley's cerebrospinal fluid (CSF) after her death. Mrs Pauley's blood also contained therapeutic concentrations of other analgesic medications including hydromorphone, morphine, fentanyl, amitriptyline and naloxone. Hydromorphone, fentanyl and amitriptyline had been administered during the days prior to her death by means other than a spinal line. Naloxone had been administered following Mrs Pauley's collapse on 20 September 2010 in order to counteract the effects of the large intrathecal dose of morphine that had been administered together with bupivacaine.

1.8. Dr Gilbert gave evidence during the course of this Inquest. He explained that at the time of the preparation of his first report the significance of the concentrations of morphine and bupivacaine within the deceased's CSF was a matter that was not fully understood. In this report Dr Gilbert cited the cause of Mrs Pauley's death as 'mixed drug toxicity (fentanyl, hydromorphone and amitriptyline with intrathecal morphine and bupivacaine) complicating palliative treatment of disseminated acinic cell carcinoma of parotid gland'[4]. In this initial report Dr Gilbert stated as follows:

> 'Death appears to have resulted from adverse effects of intrathecal morphine and bupivacaine administration and these effects may also have been contributed to by the other opioid drugs being administered at the time (fentanyl and hydromorphone). Co-administration of amitriptyline with opioid drugs enhances their analgesic and CNS depressant effects and is therefore included in the cause of death.' [5]

The fact that no anatomical cause of death could be found with respect to Mrs Pauley was naturally suggestive of a strong connection between the medication that Mrs Pauley had received and her death.

1.9. In his first report Dr Gilbert added a rider that an overview of the matter by a pain management clinician with expertise in intrathecal drug administration would be appropriate. This recommendation gave rise to the clinical overview and report that was provided by Dr Briscoe to whom I have already referred. Dr Gilbert then provided his addendum report.

[4] Exhibit C6, page 1
[5] Exhibit C6, page 2

1.10. Dr Gilbert's brief addendum report states as follows:

> 'An opinion regarding the clinical management in this case was sought by the Coroner from Dr Penny Briscoe, Head, Pain Management Unit, Royal Adelaide Hospital. I have had an opportunity to read Dr Briscoe's report and it is clear that the death resulted from intrathecal bolus administration of inappropriately large doses of bupivacaine and morphine. The doses used and the bolus mode of administration were more appropriate for epidural administration. The error appears to have arisen due to a failure to appreciate that the catheter used, which had been placed by an external consultant, was intrathecal rather than epidural.
>
> In light of Dr Briscoe's opinion, which is well supported by the medical records, I wish to amend the cause of death as follows:
>
> **CAUSE OF DEATH**:
> Intrathecal toxicity of bupivacaine and morphine.' [6]

1.11. During the course of this Inquest, the precision of Dr Gilbert's revised cause of death was questioned. In particular, it was suggested by some entities represented in the Inquest that the reference to the toxicity of the two analgesic medications was something of an overstatement of their effect. However, for reasons that will appear below I have accepted Dr Gilbert's revised description of the cause of death. I find the cause of Mrs Pauley's death to have been intrathecal toxicity of bupivacaine and morphine.

2. Issues at Inquest

2.1. In this Inquest I examined a number of issues that called for evaluation, including the circumstances in which Mrs Pauley came to be administered with excessive doses of analgesic medication, the contribution of that medication to the cause of Mrs Pauley's death, the adequacy of monitoring following the administration of that medication and the adequacy of measures that were undertaken in an endeavour to resuscitate Mrs Pauley following her collapse.

2.2. The Inquest did not examine broader questions concerning the general management of Mrs Pauley's disease and in particular whether the treatment of her disease and attempts to aid in her rehabilitation were sufficiently aggressive. This was a matter that was beyond the scope of the Inquest. Nor was the Court in anyway tasked to examine the general appropriateness and adequacy of Mrs Pauley's pain management save and except for the examination into the circumstances in which she was

[6] Exhibit C6a

administered an excessive bolus dosage of analgesic medication on the day of her death. Nevertheless, consideration of Mrs Pauley's recent history of pain management was necessary as it provided a background to the events of the day of her death.

3. The state of Mrs Pauley's illness as at the day of her death

3.1. Dr Brian Stein was Mrs Pauley's oncologist. Dr Stein is a Fellow of the Royal Australian College of Physicians. He is a full-time medical oncologist specialist in private practice at the Adelaide Cancer Centre. A significant proportion of Dr Stein's professional responsibilities are conducted at the Ashford. Dr Stein provided a statement to the investigating police[7]. As well, he gave oral evidence at the Inquest.

3.2. Dr Stein first met Mrs Pauley in January 2010 just after her major surgery that had involved resection of the cancer of the temporal bone which had invaded into the dura. She also had metastatic disease elsewhere at that time. In his statement Dr Stein makes it plain that Mrs Pauley was incurable. The aim of her therapy was essentially palliative, but with active therapy of the malignancy in the first instance. Within a month it was evident that Mrs Pauley had increased pain and a scan showed that she had a significant worsening of her cancer in the lung and pleura. Although several months of chemotherapy had resulted in a temporary stabilisation of her cancer, by July of 2010 it was evident that Mrs Pauley's disease had worsened both systemically and within the temporal region. There was some further consideration given to recommencing chemotherapy but the progress of her disease and complications would overtake such considerations.

3.3. In August 2010 Mrs Pauley had a fall. Significant bony metastatic disease caused pathological fractures of the pelvis. For this, Mrs Pauley underwent some radiotherapy. Mrs Pauley was initially admitted to the Blackwood Hospital and in due course was admitted to the Ashford for pain management. Dr Stein explains in his statement that Mrs Pauley spent the remainder of her time in and out of hospital because of the fractures and the pain associated with them, which was her major symptomatic issue. In terms of her overall disease she was deteriorating with evidence of progression. By September 2010 Dr Stein's impression was that not only did Mrs Pauley have an incurable illness, but that she would die from it in the near future.

[7] Exhibit C7c

3.4. According to Dr Stein, Mrs Pauley's final admission at Ashford was associated with severe pain from her pelvic fractures and metastatic disease. Dr Stein speaks of a family meeting on 16 September 2010 which clarified the aim of treatment. At that meeting Mrs Pauley's family had enquired whether Mrs Pauley's illness was terminal to which Dr Stein had indicated that it was. He also indicated that she would certainly not get better in the long term and that it was very unlikely in the short term. There was further consideration given to rehabilitation but in the event this seemed an unlikely proposition. Mrs Pauley herself stated that she thought she needed a hospice. Dr Stein explains in his statement that at that time, which was 4 days prior to her death, Mrs Pauley was a woman who was dying and was in a great deal of pain. These considerations would influence decisions about her management.

3.5. As Dr Stein explains, pain remained a substantive issue with Mrs Pauley and was influenced and triggered by her posture. If she endeavoured to move, she experienced very severe pain. It was this pain on movement that led to the institution of spinal analgesia.

3.6. In his statement Dr Stein indicated that although it was difficult to be precise about Mrs Pauley's prognosis, he estimated that as of 20 September 2010 Mrs Pauley 'was in the last days of her life'[8].

3.7. Dr Stein's oral evidence was consistent with the contents of his witness statement except that he expressed Mrs Pauley's life expectancy in weeks and months rather than days. Dr Stein gave further detailed evidence as to the usual course of Mrs Pauley's disease. He explained that parotid carcinoma, or cancer of the salivary gland, might involve a good long term prognosis, and it is apparent that had Mrs Pauley remained disease free for a number of years. However, a small proportion of patients will develop metastatic disease. Those patients have a poor prognosis, are incurable and their average survival is of the order of 4 to 8 months. Dr Stein explained that Mrs Pauley's metastatic progression was aggressive and so in her case the course of morbidity was relatively short. However, Dr Stein clarified his statement regarding possible further chemotherapy. He explained that on the face of it Mrs Pauley was not fit enough to undergo further chemotherapy because much of her incapacity seemed to stem from pain. However, consideration was given to whether a better pain management regimen would be able to improve her level of

[8] Exhibit C7c, page 7

function such that they might be able to offer her further chemotherapy. At the time of her final admission to Ashford, Dr Stein explained that Mrs Pauley's functional state was not good enough to allow administration of chemotherapy without grave and substantive risk of life threatening side effects. He suggested that if the 'basic markers' are not met, chemotherapy almost always proposes more damage than benefit and it is only in exceptional circumstances that chemotherapy would be proposed[9]. Dr Stein also explained that none of her disease was amenable to surgical treatment[10].

3.8. In his oral evidence Dr Stein elaborated upon Mrs Pauley's condition as at 16 September 2010, the day of the family meeting. Dr Stein suggested that at that point Mrs Pauley was entering the terminal phase of the terminal illness. There was discussion between Mrs Pauley and her family about a plan. Mrs Pauley herself indicated that she thought she needed a hospice. There was discussion about exploring the option of Mrs Pauley going to the Modbury Hospice, either with the possibility of using that as a stepping stone to home or with a view to remain there for the duration of what remained of her life. Dr Stein at that point thought that this duration might be a matter of weeks. By 16 September 2010 Dr Stein believed that the situation regarding Mrs Pauley had crystallized and that by then there was no expectation of '*any significant and dramatic turnarounds*'[11]. At that point there was nothing to suggest that chemotherapy was a realistic proposition. He believed that in reality, progression of the disease had entered '*the end game of the treatment*'[12]. Successive scans showed steady growth, and further deterioration was inevitably going to occur. Dr Stein's account of this meeting is largely supported by a note made in Mrs Pauley's Ashford progress notes.

3.9. On 17 September 2010 Dr Stein made a further note to the effect that Mrs Pauley's maximum life expectancy would be approximately 2 months. In his oral evidence Dr Stein stated that it was possible that Mrs Pauley had only a matter of days[13].

3.10. Dr Stein next saw Mrs Pauley on 20 September 2010. In the intervening period since 17 September 2010, Mrs Pauley had been seen by Dr Cheong, another medical oncologist and professional colleague of Dr Stein.

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[9] Transcript, page 46
[10] Transcript, page 48
[11] Transcript, page 63
[12] Transcript, page 63
[13] Transcript, page 101

3.11. Finally, Dr Stein referred to the fact that by 20 September 2010 pain was a constant part of Mrs Pauley's life and had been so for several weeks. Simple things like getting up and going to the toilet were painful because '*she was literally walking on broken bones*'[14]. In addition she had thoracic pain from her chest disease.

3.12. Dr Cheong, who had seen Mrs Pauley over the weekend of 18 and 19 September 2010, provided a statement to police[15]. Dr Cheong had first seen Mrs Pauley on 2 September 2010 in her capacity as Dr Stein's locum cover. Dr Cheong's impression was that Mrs Pauley had much incident pain involving difficulty standing and sitting due to the fractures in her pelvis. She was too unwell to consider having further chemotherapy. The type of pain that Dr Cheong had identified in the first instance was still evident when she again saw Mrs Pauley on the weekend of 18 and 19 September. Pain management was then still an issue and consideration was given to a different analgesic regime. Dr Cheong's impression was that Mrs Pauley's family were struggling with the concept that she was dying and in a terminal state. Dr Cheong's own view as to whether any further treatment might forestall Mrs Pauley's death was that it was 'certainly unlikely given the nature of her illness and her functional status'[16]. Dr Cheong's view of Mrs Pauley's prognosis is set out in the following extract from her statement:

> 'It is difficult to estimate a person's prognosis, but given Mrs Pauley's poor physical status demonstrated in that she really needed assistance with most things. She had a large burden of disease. She was unlikely to ever be fit enough to consider more chemotherapy; of which there is limited data in terms of how much benefit she would have gotten from additional chemotherapy. I believe given she had progressive disease and poor functional status that I think we were looking at short weeks to short months at most, with significant ongoing deterioration in function and symptoms.' [17]

3.13. Professor Ian Maddocks was Mrs Pauley's palliative care physician. Professor Maddocks is a Doctor of Medicine and a Fellow of the Royal Australasian College of Physicians. He is a palliative medicine physician. He was Professor of Palliative Care for several years at Flinders Medical Centre (FMC). He has been working as a consultant palliative care physician since that time at the Ashford. Professor Maddocks provided a statement to the investigating police[18] and he also gave oral evidence. Professor Maddocks explained in his evidence that as a palliative care

[14] Transcript, page 93
[15] Exhibit C11
[16] Exhibit C11a, page 4
[17] Exhibit C11a, page 6
[18] Exhibit C10c

physician he is asked to see people for whom it is usually clear that no further medical treatment will provide therapeutic benefit and who are approaching death in the foreseeable future. The main object of palliative care is to make the life that is remaining to a person as comfortable and as good as possible. The care that he provides addresses the full range of symptoms, not just pain but other physical symptoms including nausea and distress. Professor Maddocks is a consultant physician working mainly with the oncologists who refer patients to him.

3.14. It is evident from the Mrs Pauley's clinical notes from the Blackwood Hospital that Professor Maddocks had also seen Mrs Pauley at that hospital. An entry made by Professor Maddocks on 26 August 2010 notes:

> 'In the event of sudden deterioration no resuscitation to be attempted.' [19]

Professor Maddocks gave oral evidence at the Inquest. Unfortunately, this entry was not the subject of any questioning on that occasion. However, following his evidence, Professor Maddocks provided an affidavit in which he acknowledges that he made the entry, but states that he has no independent recollection of the circumstances surrounding the making of the above clinical entry[20]. However, Professor Maddocks surmised that only Mrs Pauley had been consulted about this decision. Professor Maddocks does not recall whether he spoke to Dr Stein about this entry. The entry, relating as it does to the way things stood a month before Mrs Pauley's death, is of uncertain significance in the light of the events with this Inquest is concerned except that it lends some support to the contention that it is unlikely that at any material time Mrs Pauley harboured unrealistic expectations in respect of a recovery. Certainly by 26 August 2010, when one examines Dr Stein's evidence, it was clear that Mrs Pauley was suffering from an illness that would ultimately cause her inevitable death. In any event, it has not been necessary of the Court to have regard to this entry in reaching its conclusions about the events of 20 September.

3.15. It was Dr Stein who had referred Mrs Pauley to Professor Maddocks in the first instance. Professor Maddocks was aware that Mrs Pauley was ultimately transferred to the Ashford with severe cancer that was regarded as terminal at that point in time. At that time Professor Maddocks was of the view that Mrs Pauley's pain was poorly controlled. Professor Maddocks was naturally aware that Mrs Pauley had carcinoma

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[19] Exhibit C15
[20] Exhibit C10d

of the parotid with widespread metastases in various places such as the lungs and bones. He was also aware that she had pathological bony fracture cracks which were causing her much pain. It was that pain, and predominantly pain in the pelvis, that constituted the principal focus of Professor Maddocks' care. As to his view of Mrs Pauley's prognosis, Professor Maddocks stated in his oral evidence as follows:

> 'I think that prognosis is always difficult to know, but in conversations on the unit, conversations between me and Dr Stein - I think we were agreed that Mrs Pauley's life was quite limited and that it was probably only a matter of weeks that she had ahead for her because the disease had progressed. There was no prospect of further treatment and she was needing to receive quite significant doses of pain killer to remain comfortable. All that tends to make you feel that there is not a long time left for her.' [21]

Professor Maddocks added that he could not envisage Mrs Pauley ever being able to move without pain. He suggested that she was, in a sense, fated to have pain with movement and for that reason any prospect of rehabilitation was unrealistic. In addition, rehabilitation takes several weeks. He added that if the physician's view of a patient is that there is only a short period of time left for them, the patient will probably be better off not putting themselves through rehabilitation but instead accepting that death is imminent and for them to face it as quietly and comfortably as they can[22]. Professor Maddocks agreed that the same sentiment applied to the broader question of treatment generally and to other decisions that the physician might make having regard to whether or not treatment would be effective[23].

3.16. Finally, Professor Maddocks told the Court that several people including Dr Stein and himself had endeavoured to raise with Mrs Pauley's family, and with her husband in particular, Mrs Pauley's poor prognosis and the likelihood that there was going to be no improvement[24].

4. <u>Mrs Pauley's pain management at Ashford</u>

4.1. Mrs Pauley's pain management had been difficult to effect due to the fractures within her pelvis. Although she was comfortable at rest, she had significant incident pain whenever she mobilised. On admission to Ashford she was managed with a combination of analgesic medications that included a subcutaneous infusion of hydromorphone and midazolam with amitriptyline at night.

[21] Transcript, page 263
[22] Transcript, page 266
[23] Transcript, page 266
[24] Transcript, page 270

4.2. Mrs Pauley was confused and disoriented in hospital and so consideration was given for the insertion of a spinal catheter in an endeavour to improve her pain management and hopefully to reduce the amount of opiate medication that she was requiring.

4.3. On 4 September 2010 Professor Maddocks arranged for a spinal catheter to be inserted at FMC on 6 September 2010. Mrs Pauley was transferred to FMC on 6 September 2010 where Dr Dilip Kapur inserted an intrathecal line that was connected to a portal on her lower chest wall.

4.4. I pause here to mention that there is a significant difference between an intrathecal line and an epidural line, both of which are spinal methods of analgesic delivery. Although the evidence suggested that the word ‘epidural’ was frequently used to describe generically a spinal line, be it epidural or intrathecal, there is an important distinction insofar as the intrathecal catheter is inserted directly into the CSF surrounding the spine. On the other hand, an epidural catheter is inserted into the epidural space. The major significance in the distinction is that significantly less analgesic medication is required when an intrathecal line is utilised. The medication may be delivered by way of an infusion that might take place over several hours or by way of bolus which is a much faster method of delivery, although it was evident that views might well differ as to whether bolus administration of analgesia by way of an intrathecal line is appropriate.

4.5. Mrs Pauley was returned to the Ashford on the day of the intrathecal line insertion, although the portal was not needled until 8 September 2010. The delay is explained by a perceived need for the portal incision to sufficiently recover.

4.6. There was a great deal of evidence available in this Inquest to demonstrate that the fact that Mrs Pauley’s line was an intrathecal line was well understood, or should have been well understood, by all concerned with her pain management at Ashford, including the nursing staff. The fact that it was an intrathecal line was well documented in the clinical record and in correspondence.

4.7. The spinal infusion was commenced on 8 September 2010. The infusion included bupivacaine that was commenced at a rate of 3mls per 24 hours. The dosage was increased over the next 3 days to 10mls per 24 hours. In the event, Mrs Pauley complained of right leg weakness and was seen to be dragging her foot. As a result, the infusion was reduced to 5mls per 24 hours.

4.8. The question of Mrs Pauley's possible rehabilitation was still a live one as of 15 June 2010. However, the rehabilitation centre that had been identified would not accept a patient with a spinal line insitu. For reasons that cannot be fully understood, but which are said to have some connection with the fact that the rehabilitation centre would not accept Mrs Pauley with an insitu spinal line, Mrs Pauley's intrathecal infusion was ceased on 15 September 2010. Nevertheless the portal remained in place, thus enabling future spinal administration to be effected if necessary.

4.9. Following and including 15 September 2010 Mrs Pauley was provided with pain management that, as before, consisted of other forms of analgesia including hydromorphone and amitriptyline.

4.10. Professor Maddocks reviewed Mrs Pauley on the morning of 20 September 2010. Professor Maddocks formed the view that in order for Mrs Pauley to be able to mobilise without undue discomfort, it was in Mrs Pauley's best interests for her spinal analgesic medication to be reinstituted. That morning Professor Maddocks made the following entry in the patient's progress notes:

> 'Maddock (sic)
> Conversation (with notes) re epidural/intrathecal. It is not clear that has helped but try BD injection prior to movement into the portal to further explore. Is intrathecal – must watch sterile technique.' [25]

4.11. It will be seen from this entry that Professor Maddocks clearly had within his mind at the time of making the entry that Mrs Pauley's modality of spinal analgesia was intrathecal. That he understood this is established by the fact that he appropriately referred to the need for greater care in terms of sterile technique with insertion of the needle.

4.12. However, when Professor Maddocks later that morning came to write out the order for the spinal analgesia, he ordered a bolus dose of 5mg of morphine and 3ml of bupivacaine, twice daily and the order clearly refers in Professor Maddocks' handwriting to 'epidural portal'. It is clear that a bolus dose of such medication was inappropriate and excessive if administered by way of an intrathecal portal.

4.13. Professor Maddocks who gave evidence in the Inquest has at all times since these events candidly accepted that the error was his. I should point out that the error is not

[25] Exhibit C4, page 72

due to any lack of knowledge or expertise on Professor Maddocks' part. There is no suggestion for example that such dosages would have been inappropriate in the setting of epidural administration even by way of bolus. It was simply, and tragically, a case of Professor Maddocks, at the crucial moment, not realising that Mrs Pauley had an intrathecal line in place.

4.14. The bolus dosage was administered by Ashford nursing staff at approximately 10:10am. It took approximately 10 minutes to deliver. The nurse in question was Registered Nurse Jadwiga Maliniak. Nurse Maliniak gave oral evidence in the Inquest. In the course of her evidence Nurse Maliniak made it plain that she was personally aware that Mrs Pauley had in place an intrathecal catheter as opposed to an epidural catheter. However, I was satisfied having regard to what might reasonably be expected as far as nursing knowledge and expertise is concerned, that Nurse Maliniak should not be criticised for not having questioned the dosages or modality of administration as ordered by Professor Maddocks. It is possible that nursing staff in a dedicated pain management unit such as those that exist at the FMC or the RAH, might have picked up on the error, but I was by no means certain that Nurse Maliniak in her clinical setting would necessarily have possessed sufficient expertise to have done so.

4.15. It was pointed out during the course of the evidence, particularly by Dr Briscoe, that a intrathecal bolus dose of bupivacaine 0.5% 3mls was that which might be appropriate in order to effect local anaesthesia in some surgical procedures, for example to repair a fractured neck of femur. However, in such a surgical setting, support of the patient's vital functions such as blood pressure, which due to the effects of the analgesia can significantly fall, are carefully monitored and maintained by way of professional anaesthetic expertise. In this particular case, however, no such monitoring and support was provided as there was no surgical setting in existence, and so the combination of circumstances consisting as they did of the delivery of a anaesthetic quantity of bupivacaine in particular, its rate of administration by way of intrathecal line and a failure to monitor was all in error. Again, I do not criticise nursing staff for a failure to monitor as it was not a setting that in their belief required the level of scrutiny that would have been appropriate in a surgical environment.

4.16. In any event Mrs Pauley was checked by nursing staff at 10:45am at which point Mrs Pauley was found to be unresponsive.

5. Mrs Pauley's collapse and the contribution of excessive analgesic medication to the cause of death

5.1. It is necessary first to reflect upon Mrs Pauley's reaction following the administration of the bolus dose of medication. At the time of administration, Mrs Pauley had been seated in a chair next to her bed. She was waiting for her husband. She was fully responsive at that time[26]. The administration of the medication took approximately 10 minutes and Nurse Maliniak asserted in her evidence that she remained in the room until approximately 10:30am. As alluded to earlier, at 10:45am Mrs Pauley was found to be unresponsive. She exhibited slow, shallow breathing. A medical emergency was called at that time. The medical emergency team (MET) arrived on the ward. At 10:50am, her systolic blood pressure was found to have descended to 56. Naloxone, which Dr Stein believes he ordered per phone, was intravenously administered to Mrs Pauley with a view to counteracting the effects of morphine specifically. It was believed that the naloxone was given with good effect. By 10:55am her blood pressure had risen from 56 systolic to 128 systolic. According to Nurse Maliniak Mrs Pauley had also now become responsive.

5.2. Mrs Pauley was returned to her bed and, according to Nurse Maliniak, Mrs Pauley was able to ambulate the very short distance from chair to bed. According to the MET record, the MET team left the room at about 11:10am. Nurse Maliniak remained in the room. Mrs Pauley was at this point very distressed but appeared to improve. I did not understand there to be any further vital sign parameters taken in the ensuing minutes except that Mrs Pauley's oxygen saturation was observed to remain at 100%, although this is a somewhat unreliable measuring stick as she was receiving 12 litres of oxygen via a mask. In any event at 11:30am Mrs Pauley's condition worsened and she again became unresponsive. Her oxygen saturation descended to 89% on 12 litres of oxygen and her blood pressure once again descended to significantly hypotensive levels.

5.3. A second MET call was made and a naloxone infusion was established. Neither Dr Stein nor Professor Maddocks were present during these events as they were not at the Ashford. However, Dr Stein was consulted by telephone and Professor Maddocks would attend at the Ashford in the early afternoon when he ordered intravenous saline. Mrs Pauley never regained consciousness after her second collapse at

[26] Transcript, page 114

11:30am and by early afternoon she was clearly hypoxic and shut down. Professor Maddocks certified life extinct at 2:30pm. Mrs Pauley's family were present when she passed away. Of significance Professor Maddocks made the following entry in the progress notes:

> 'Clearly the intrathecal dose was excessive.' [27]

5.4. The events that almost immediately followed the administration of the medication in and of themselves are strongly suggestive of a connection between that administration and Mrs Pauley's collapse. In particular, her unresponsiveness and drop in blood pressure is consistent with the effects of medication such as this, and her rallying to the administration of naloxone suggests that at least morphine had been at work as far as Mrs Pauley's suddenly deteriorating presentation was concerned.

5.5. Furthermore, the fact that Dr Gilbert found no anatomical features to explain a sudden death notwithstanding Mrs Pauley's widely disseminated metastatic cancer is also strongly suggestive that the medication administered had a significant role to play in Mrs Pauley's collapse and demise.

5.6. In his final address to the Court Mr Homburg, counsel for Dr Stein, sought to separate the contribution of the medication to Mrs Pauley's initial collapse on the one hand, from its contribution to the cause of her death some 4 hours later on the other. To my mind this presents an unrealistic dichotomy that is unsupported by evidence. Firstly, there was no significant intervening event between Mrs Pauley's initial collapse and recovery and then her death. Secondly, it will be remembered that although there was that 4 hour hiatus, Mrs Pauley's second collapse occurred within only a matter of minutes after her initial resuscitation. Thirdly, from that point forward she remained utterly unresponsive and moribund. It would stretch one's credulity to conclude that Mrs Pauley's second collapse, period of unresponsiveness and eventual death was wholly unconnected with her first collapse or with the administration of medication that clearly had precipitated that first collapse.

5.7. Although Mr Harris QC for Professor Maddocks questioned the precision of Dr Gilbert's use of the word 'toxicity' in the recitation of the cause of death, I did not understand Mr Harris to share any view that the excessive dose of analgesic medication had not been intrinsically implicated in Mrs Pauley's ultimate death. Mr

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[27] Exhibit C4, page 73

Harris on behalf of Professor Maddocks accepted that the overdose of the medication was a contributing factor to Mrs Pauley's death. Mr Harris accepted that the consequences of the overdose set in train a sequence of events which ultimately led to Mrs Pauley's death. However, both Mr Homburg and Mr Harris submitted to the Court that to describe the cause of death in terms of the toxicity of the medications was an oversimplification having regard to the fact that Mrs Pauley was already very ill and had been medicated prior to the events in question with other analgesic medication. Mr Harris points to Mrs Pauley's underlying disease process as possibly having contributed to the adverse effects in terms of low blood pressure and respiratory depression. Mr Harris did not in any way, however, eschew the significant point that Mrs Pauley would not have died at that time but for the administration of the morphine and bupivacaine in those quantities and by that method of delivery. This to my mind is a concession well made. However, notwithstanding that acknowledgment, Mr Harris suggested that even though on a purely 'but for' basis there was an obvious contribution to Mrs Pauley's death by reason of the over dosage of medication, the cause of death should not be confined merely to a recitation of that fact alone. Mr Homburg supported that submission.

5.8. There was another issue raised that sought to bring into question the contribution of bupivacaine to Mrs Pauley's collapses and death. I will deal with this question presently, but it is worthy of note that Dr Gilbert who is the origin of the description of Mrs Pauley's cause of death, and whose evidence I accept, did not in any way seek to differentiate between the possible effects of the two medications. If Mr Harris' and Mr Homburg's objection to the use of the word 'toxicity' is properly understood, it is that there was nothing intrinsically fatally toxic about the dosage in the sense that it would inevitably have caused the demise of a person of sound wellbeing, whereas Mrs Pauley was a very ill woman. However, it seems to the Court that 'toxicity' is a concept that does not intrinsically imply a fatal result in all cases. What might be toxic in respect of one consumer of the substance or substances in question, may not be toxic, or as toxic, in another. The fact of the matter is that the combination of substances were toxic in Mrs Pauley's case and their toxicity led to her death. This is so regardless of whether or not the combination of substances would have had fatal consequences in another person and regardless of whether or not the effects of the combination of substances might have been reversed by more vigorous resuscitation.

5.9. The only material that might have contradicted the contention that the analgesic medication was the cause of Mrs Pauley's death was a rather vague and unconvincing surmise posited by Dr Kapur, and not put to Dr Gilbert, that Mrs Pauley may have experienced an acute natural event precipitated by her cancer. The purport of Dr Briscoe's evidence is that Mrs Pauley's collapse was the consequence of the excessive analgesic medication that she received on the morning of 20 September 2010. I prefer and accept that evidence. Dr Gilbert's evidence and opinion as to the cause of death was based upon that premise. I prefer and accept that evidence as well.

5.10. Finally on this point I should mention the possible effect of Section 17 of the Consent to Medical Treatment and Palliative Care Act 1995 (the Act). I will mention this provision in another context below, but it is worthy of note in the context under discussion here that in respect of the care of people who are dying, for the purposes of the law of the State section 17 governs what might be properly regarded as a cause of death where the administration of medical treatment for the relief of pain has made a contribution to the cause of death and might otherwise have been regarded as an intervening cause. Section 17(3) of the Act stipulates as follows:

> '(3) For the purposes of the law of the State-
>
> (a) the administration of medical treatment for the relief of pain or distress in accordance with subsection (1) does not constitute an intervening cause of death.'

5.11. I take this provision to mean that in the case of a person whose death is imminent, say, from cancer, and where treatment for the relief of pain has substantially contributed to or hastened the person's death, the cause of death is nevertheless to be regarded as cancer for the purposes of the law[28]. The basic premise of the operation of section 17(1) is a patient who is in the terminal phase of a terminal illness. A terminal illness is defined in the Act as an illness or condition that is likely to result in death. The terminal phase of a terminal illness is defined as the phase of the illness reached when there is no real prospect of recovery or remission of symptoms on either a permanent or temporary basis. I did not hear argument as to the necessary elements of what might constitute the terminal phase of a terminal illness. Nor did I hear any argument as to the applicability of these definitions to the facts of this case. However, section 17(3) in any case is only enlivened where, pursuant to section 17(1), the

[28] Whether or not the purposes of the law of the State include purposes other than those associated with the determination of criminal or civil liability is a matter which in the light of what follows does not need to be decided here

administration of medical treatment for the relief of pain in respect of a patient in the terminal phase of a terminal illness has been undertaken in good faith, without negligence and in accordance with proper professional standards of palliative care. For reasons that should be apparent from these findings so far, it would be difficult if not impossible to characterise Mrs Pauley's medical treatment for the relief of pain, as administered on the morning of 20 September 2010, as having conformed with treatment of the kind described in section 17(1). Accordingly, in my view section 17(3) of the Act would not apply. Thus even if Mrs Pauley's death from disseminated cancer was inevitable, there is in my view no legal restriction in assigning her cause of death as an event or circumstance that intervened as it did here.

5.12. For all of the above reasons I am satisfied that the description of Mrs Pauley's cause of death as provided by Dr Gilbert is accurate and appropriate.

5.13. That description of Mrs Pauley's cause of death is valid in my view regardless of the competing views as to the respective contributions of bupivacaine on the one hand and morphine on the other. I turn to that issue now. In some senses the issue is moot, but there is some relevance to the question as on one view of the matter Mrs Pauley may have survived the events of 20 September 2010 if greater resuscitative attention had been paid to the possible effects of bupivacaine as opposed to morphine.

5.14. Dr Dilip Kapur, to whom I have already referred, is a senior consultant in the Pain Management Unit at FMC. He was in fact Director of the Unit at the time of these events. Dr Kapur obtained his primary medical degree in the UK in 1985 and gained further specialist qualifications in 1990. He is a Fellow of the Australian and New Zealand College of Anaesthetists and a Fellow of the Faculty of Pain Medicine of that College. It will be remembered that Dr Kapur was the medical practitioner who inserted the intrathecal line and had initially prescribed the pain management regime for Mrs Pauley at the time of the insertion. However, he had no influence on the events surrounding Mrs Pauley's death.

5.15. Dr Kapur opined that the bupivacaine that had been administered to Mrs Pauley on 20 September 2010 was limited. He believed that if it had played a significant role in cause of death, the fatal effect of bupivacaine would have occurred much sooner. In addition in his view the opioid concentration in the post-mortem CSF, no doubt from the morphine, was unusually high. Although he prefaced his remarks by indicating

that it was possibly conjecture on his part, Dr Kapur offered that the most likely cause of Mrs Pauley's respiratory failure was the effect of the morphine[29]. Dr Kapur did say that the major physiological effects of bupivacaine include blockage of the autonomic nervous system which results in a falling blood pressure and quite often a falling heart rate. Dr Kapur acknowledged that, as had been pointed out by Dr Briscoe, bupivacaine is utilised in anaesthesia where any descent in blood pressure and heart rate is professionally supported whereas in this case no specific measures were taken to support blood pressure and heart rate. He therefore agreed that the circumstances surrounding the administration of Mrs Pauley's medication were different from what they would have been in a surgical setting. When asked as to what could happen when such bodily functions are not supported he said:

> 'Well, there is actually extensive literature on this and what will happen with unsupported and critical side effects from spinal anaesthesia it can progress to cardiac arrest.'[30]

5.16. Dr Briscoe pointed out that the magnitude of the dosage of bupivacaine given intrathecally by way of bolus is the dosage that it used for hip replacement surgery. She said that any anaesthetist administering such an anaesthetic medication would have an intravenous line in with a drip running and would be monitoring blood pressure, pulse rate, the patient's general condition and would be prepared to administer vasopressors in order to keep the blood pressure up if necessary. She said that the blood pressure can fall quite precipitously. Dr Briscoe suggested that the morphine would have contributed to Mrs Pauley's presentation, but it was difficult to know precisely what its contribution was. She expressed the opinion that the main issue with Mrs Pauley, particularly with her blood pressure going down to $^{56}/_{32}$ was a significant bupivacaine effect. In her view the improvement in responsiveness after the administration of naloxone could in part have been the product of the stimulation caused by the events that were taking place in respect of her resuscitation[31]. In short, Dr Briscoe was of the view that the effect of the bupivacaine within the bolus given at 10:10am was overwhelmingly the cause of Mrs Pauley's collapse[32].

5.17. One matter of particular relevance from Dr Briscoe's evidence is that in the first 30 to 40 minutes following the administration of the medication, and where the blood

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[29] Transcript, page 217
[30] Transcript, page 195
[31] Transcript, page 311
[32] Transcript, page 313

pressure was seen to descend to $^{56}/_{32}$, in an elderly person that could have been enough to cause other effects such as cardiac ischaemia and cerebral hypoxia and changes may have been difficult to detect. This raised a question as to whether or not hypoxic brain damage may have already been sustained as a result of low blood pressure. I add at this point that in her oral evidence Dr Briscoe said that she could not be certain whether or not Mrs Pauley would have recovered with full resuscitative measures[33]. In her initial report she expressed the view in respect of Mrs Pauley's cardiovascular/respiratory collapse that if Mrs Pauley 'had been resuscitated appropriately it was potentially a reversible event'. I return to this issue.

5.18. I have found it difficult to decide which of the evidence of Dr Kapur or Dr Briscoe should be preferred. Both were witnesses of similar expertise in almost identical fields of medicine. However, I did not understand Dr Kapur to be saying that in his view bupivacaine could be discounted as having played no role whatsoever. I am persuaded that there was a contribution to Mrs Pauley's collapse by virtue of the effects of bupivacaine.

6. Efforts at resuscitation following Mrs Pauley's collapses

6.1. I have already referred to the administration of naloxone as an antidote to the effects of morphine administration. It is worthy of note that naloxone counteracts the effects of morphine but does not reduce the amount of morphine that is active either within the bloodstream or CSF. Accordingly, there will come a point where the effect of naloxone as an antidote will cease.

6.2. Dr Briscoe gave evidence that apart from the administration of naloxone, other resuscitative strategies had been available in her opinion. In particular, in her view, the effects of bupivacaine had not been addressed. Dr Briscoe explained that bupivacaine administered in this fashion and in this quantity would be prone to give rise to significant physiological effects such as a maximum drop in blood pressure after approximately 20 minutes and a maximum drop in the heart rate after approximately 15 minutes[34]. These parameters in her view require careful monitoring and possibly supplemental oxygen. Dr Briscoe said that naloxone does not have any impact on the reversal of effects of bupivacaine. Dr Briscoe expressed the view that

[33] Transcript, page 312
[34] Transcript, page 308

the 5mg of morphine contributed to Mrs Pauley's presentation[35], but its precise role was difficult to identify. For Dr Briscoe the main issue, particularly with the dropping of blood pressure to $^{56}/_{32}$, was that this was a sign of significant bupivacaine effect. Dr Briscoe opined that Mrs Pauley's recovery in response to naloxone was consistent with a partial reversal of the opioid effect but also the stimulation surrounding the events concerned with her resuscitation. In order to counteract the effects of bupivacaine Dr Briscoe suggested that in addition to the administration of naloxone, which was designed to deal with the effects of morphine only, fluid should have been administered to Mrs Pauley and she should have been provided with oxygen. In addition she should have been provided with a vasopressor and with close monitoring. Dr Briscoe did not believe that transfer to intensive care would have been absolutely necessary, but that she needed resuscitation. This would not necessarily have meant intubation and ventilation. Dr Briscoe would have preferred that Mrs Pauley be transferred to a recovery area or a high dependency area.

6.3. The measures that Dr Briscoe referred to were not administered to Mrs Pauley except to the extent that at 1:30pm, and at a time when it would have had no effect, Professor Maddocks ordered normal saline intravenously.

6.4. The resuscitation that was provided to Mrs Pauley was provided by the Ashford MET. However, it is clear from Dr Stein's own evidence that he had some significant input into the decisions that were made about the nature of Mrs Pauley's resuscitation. Dr Stein told the Court that by 20 September 2010 the question of Mrs Pauley's resuscitation status had not been '*properly sorted out*' with her[36]. Dr Stein spoke about the dilemma in his mind as to what should take place when he was called on the phone after Mrs Pauley's first collapse. He believed that he had given the order for the administration of naloxone in the first instance. Dr Stein explained his thought processes regarding resuscitation as the events unfolded. Although Mrs Pauley had not specifically said that she did not want to be resuscitated, much of the conversation between them had indicated to him that she accepted that she was dying. His understanding of her wishes was that she would not want resuscitative modalities that involved intensive care[37]. Dr Stein explained the purpose of administering naloxone without conducting other resuscitative measures. He told the Court that the only

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[35] Transcript, page 310
[36] Transcript, page 67
[37] Transcript, page 67

aspect of Mrs Pauley's collapse that would be readily reversible would be the effects of the opiate morphine. He explained the difficulty with reversing opiate; the effect of opiate being that in a person who had been on opiates for a long time such as Mrs Pauley had been, and where a very large dose of naloxone is given, the risk is run that the person will be reduced into a state of acute opiate withdrawal, bringing all of their pain back to bear. Dr Stein did say that transfer to an Intensive Care Unit would have occurred to him at the time of these events, given that here was a patient who had collapsed and was in imminent danger. Dr Stein explained as follows:

> '… the calculus that one goes through in these circumstances is, how much can intensive care help, how much can intensive care of similar measures harm, and what has the patient indicated to you. As I have said before we didn't have a formal 'not for resuscitation' order, but from our conversations, I was confident that Mrs Pauley certainly did not want extreme measures. In terms of the damage that intensive care can do if you have somebody who is in the throes perhaps of dying; you might go from being in a comfortable room where you can be with friends and family, to a large open area. You have people; in her situation she would have had to have an arterial line, a central venous line, a bladder catheter and circulatory support, and quite possibly, ventilation. If she had actually had a formal cardiac arrest, CPR with the likelihood of broken bones, rattling around her fractures and exacerbating her pain - so there was certainly in my mind the significant question: did the patient want it.' [38]

Dr Stein went on to say that his feeling from conversations with Mrs Pauley was that she would not have wanted treatment of that kind.

6.5. Dr Stein explained that all of these thought processes and communications with staff at the point of Mrs Pauley's collapse had occurred while he was on the telephone. There was a further telephone conversation when she collapsed for the second time and the MET was recalled. Dr Stein explained that he had a discussion with the MET practitioner on the telephone. He was appraised by a MET doctor of Mrs Pauley's further deterioration. Dr Stein was asked to clarify what Mrs Pauley's resuscitation status was, what further measures should be taken and whether in the event of a cardio respiratory arrest she would need to be given CPR. What occurred to Dr Stein at this point was that there were a number of possibilities explaining Mrs Pauley's second collapse and that one was that the effect of the naloxone had ceased and a second possibility was that the bupivacaine was starting to have a general depressant affect.

[38] Transcript, page 69

He believed that if that was the case the only real solution was intensive support. In this regard Dr Stein explained as follows:

> '… the literature's actually fairly clear that patients who are in the kind of situation with cancer that she's in actually are unresuscitatable if they have a cardiopulmonary arrest, so I would have been very much saying, no, we should not give her cardiopulmonary resuscitation and as I've said before I thought that the likelihood of success versus the likelihood of harm and sort of bringing in what I understood her wishes to be would have mitigated against intensive care. If we were going to go for an intensive care option the logical time would have been on the first occasion.' [39]

He went on to say that he believed that it was reasonable to prescribe further naloxone in an endeavour to combat opioid overdose. Dr Stein believed that Mrs Pauley's capacity to cope with any other measures was limited. He said:

> 'I rather doubt that she would have survived the ordeal.' [40]

Dr Stein gave me to understand that any not for resuscitation orders were really instigated by him that morning. Dr Stein said that he would have regarded intensive care treatment at her stage of illness as a matter of prolonging death rather than promoting survival[41]. Dr Stein explained that he also naturally took into account the state of Mrs Pauley's cancer. In this respect he referred to the issue as to what type of existence Mrs Pauley would have been returned to in the event of successful resuscitation, having regard of course to her ongoing problems with pain[42]. He said:

> 'So it did weigh into my account the fact that she had a malignant disorder that was giving her significant symptoms, and providing substantial issues with her palliative care, and for which we really were not expecting a prolonged period of life. So that definitely did weigh in the balance.' [43]

6.6. I add that in his evidence Professor Maddocks agreed that as of 20th September following Mrs Pauley's collapse, a non resuscitation order would have been appropriate[44].

6.7. On behalf of Dr Stein, Mr Homburg of counsel argued that Dr Stein's position in relation to resuscitation could be encapsulated in the proposition that full resuscitation measures would have imposed a burden on Mrs Pauley that was not justified by her

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[39] Transcript, page 75
[40] Transcript, page 77
[41] Transcript, page 78
[42] Transcript, page 78
[43] Transcript, page 78
[44] Transcript, page 269

prognosis. While acknowledging an element of paternalism concerning that attitude, Mr Homburg submitted that Dr Stein's responsibility and obligation had been to make a decision which in his judgment would have been in Mrs Pauley's best interests having regard to prevailing medical standards and the wishes of the patient. Mr Homburg further argued that a doctor was not under any duty to either implement or continue treatment that in the doctor's view was either futile or not in the best interests of the patient. On the other hand, Mr Homburg also acknowledged the difficulty involved where the acute episode that gives rise to the need to consider resuscitation in the already moribund patient arises from medical error.

6.8. Mr Homburg did not refer me to the provisions of the Consent to Medical Treatment and Palliative Care Act 1995 to which I have referred in another context. Section 17(2) of that Act states as follows:

> '(2) A medical practitioner responsible for the treatment or care of a patient in the terminal phase of a terminal illness, or a person participating in the treatment or care of the patient under a medical practitioner's supervision, is, in the absence of an express direction by the patient or the patient's representative to the contrary, under no duty to use, or to continue to use, life sustaining measures in treating the patient if the effect of doing so would be merely to prolong life in a moribund state without any real prospect of recovery or in a persistent vegetative state.'

As seen earlier, the terminal phase of a terminal illness is defined as the phase of the illness reached when there is no real prospect of recovery or remission of symptoms on either a permanent or temporary basis'[45]. In his oral evidence Dr Stein obliquely referred to the concept of the terminal phase of a terminal illness and suggested that as things stood on 16 September 2010, the day of the family meeting, Mrs Pauley was 'entering' that phase of her illness. It is a matter of certainty that Mrs Pauley was experiencing a terminal illness. It is arguable that she was also in its terminal phase. Unfortunately, I did not hear argument as to whether or not Mrs Pauley had entered the terminal phase of her illness, or whether or not it could be argued that to have resuscitated Mrs Pauley would have been *merely* to have prolonged her life in a moribund state, but I understood the evidence to strongly suggest that as of the day of Mrs Pauley's death there was no real prospect of recovery or remission of symptoms either on a permanent or temporary basis. It is also worthwhile observing that Section 17(2) does not differentiate between a situation in which life sustaining measures are designed to reverse the effects of medical misadventure on the one hand or to

[45] Section 4 of the Consent to Medical Treatment and Palliative Care Act 1995

resuscitate a patient who has had an acute but naturally occurring life threatening event that might respond to resuscitation on the other. However, it is fair to say that it would be idle to suggest that this not is a highly relevant matter to be considered when any decision as to the nature of resuscitative measures comes to be made.

6.9. In the event, the Court does not need to make any comment on the decision not to provide Mrs Pauley with full resuscitative measures other than to make the following observations. Dr Stein expressed regret that in discussing the nature of Mrs Pauley's resuscitation on the telephone with the MET team doctor he did not establish what the attitude of Mrs Pauley's family was. He acknowledged that this was a matter that he should have canvassed. The Court agrees with this acknowledgement. Plainly in the circumstances, that included the fact that Mrs Pauley's collapse was as the result of misadventure, that there had been other available resuscitative means by which a reversal of Mrs Pauley's condition could at least potentially have been reversed and that Mrs Pauley's family could not have been expecting her demise that very day, there should have been some discussion with Mrs Pauley's family about the nature of the resuscitative measures that were available, those that would be implemented and those that would be withheld.

6.10. I understood the effect of Dr Briscoe's evidence to be that there was no certainty that full resuscitative measures would inevitably have reversed the effects of the excessive medication, even if bupivacaine had played a significant role in the collapse, or that Mrs Pauley's death would inevitably have been prevented. The Court is therefore unable to make any positive finding as to that issue.

7. <u>Recommendations</u>

7.1. Pursuant to Section 25(2) of the Coroners Act 2003 I am empowered to make recommendations that in the opinion of the Court might prevent, or reduce the likelihood of, a recurrence of an event similar to the event that was the subject of the Inquest.

7.2. There was considerable discussion during the Inquest concerning methods by which the medication error in this case could be prevented in the future. Much of this evidence concerned means by which the nature of the spinal line, be it epidural or intrathecal, could be identified with certainty. The difficulty in this case was that when the needle was removed from Mrs Pauley's portal on 15 September 2010 there

was no visible means by which the nature of her spinal line could be identified. This is because all that is seen from the outside is the portal beneath the skin. Thus the presence of labels on the line or needle is really beside the point. In any case there were multiple entries within Mrs Pauley's clinical record to indicate that the line in question was an intrathecal line. It was not a case of there being any misunderstanding about that fact. Nurse Maliniak was fully aware that Mrs Pauley's was an intrathecal line, as was Professor Maddocks who only that same morning had referred to that fact in Mrs Pauley's clinical record.

7.3. There was also some discussion during the course of the Inquest as to whether or not nursing staff should be in a position to question the appropriateness of spinal analgesic medication at the time of its administration. The difficulty in this case is that the nurse in question would have been required to be familiar with what constitutes an appropriate dose of both morphine and bupivacaine by way of intrathecal bolus administration. Mr Bonig who appeared as counsel for Nurse Maliniak and the Ashford urged the Court to be hesitant in making any recommendation regarding education of nursing staff in relation to the issue of appropriate dosage. Mr Bonig made the point that there is a need for care against implementing a regime where nursing staff are expected to second guess or query the orders of medical practitioners. That is not to say that where there is an obvious error nursing staff should not draw it to the attention of a person in authority. However, Mr Bonig argues that the responsibilities of nursing staff should not be elevated beyond what it should be. I agree with that submission and have nothing further to add.

7.4. The only other matter that requires consideration is the need for better monitoring following intrathecal bolus administration of analgesic medication. In this regard the Court recommends that the General Manager of the Ashford Hospital draw to the attention of all clinical staff the need to closely monitor the vital signs of a patient to whom such analgesia has been administered.

7.5. The issues in this Inquest raise a further important question that concerns the need for clarity in relation to not for resuscitation (NFR) orders and the appropriateness of resuscitation measures in general in respect of the dying. Since these events, as explained in the statement of Ms Sue Leimann[46], Operations Manager and Director of Nursing at the Ashford Hospital, measures have been implemented in order to clarify the position. The measures include improved and clearer documentation. The

[46] Exhibit C14

dilemma that Dr Stein described in his evidence as to whether or not full resuscitative measures would be implemented in Mrs Pauley's case may have been avoided if Mrs Pauley's resuscitation status had been frankly discussed and documented at a time prior to the day of her death. However, as was pointed out in the Inquest, significantly different considerations may apply where the collapse of a dying patient is not due to the acute effects of the disease but due to a medical misadventure. It seems to the Court that it would be unrealistic for hospitals and clinicians to have to raise with dying patient the possibility of such a rare and unlikely event.

7.6. In this case Dr Stein candidly acknowledged that it would have been better if there had been some consultation with Mrs Pauley's family about the extent of resuscitative measures to be applied in this case. Professor Maddocks in his supplementary affidavit points to the need for the patient's family members to be involved in discussions concerning resuscitation in the event of a sudden deterioration or collapse. Again, it would not seem appropriate for family members to be asked to signify an attitude in advance of a medical mishap occurring in respect of their dying family member.

7.7. After careful consideration the Court does not see the need to make any other recommendations in this case.

Key Words: Medication Error; Mixed Drug Toxicity; Pain Management

In witness whereof the said Coroner has hereunto set and subscribed his hand and

Seal the 8th day of March, 2013.

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Deputy State Coroner

Inquest Number 2/2013 (1454/2010)