CORONERS ACT, 2003

SOUTH  *AUSTRALIA*

FINDING OF INQUEST

An Inquest taken on behalf of our Sovereign Lady the Queen at Whyalla and Adelaide in the State of South Australia, on the 27th, 28th, 29th and 31st days of March 2006, the 4th day of April 2006, the 23rd and 24th days of May 2006 and the 16th day of June 2006, by the Coroner's Court of the said State, constituted of Mark Frederick Johns, State Coroner, into the death of Ian Myles Smith.

The said Court finds that Ian Myles Smith aged 2 years, late of 208 Cartledge Avenue, Whyalla died at the Whyalla Hospital and Health Services Inc., Wood Terrace, Whyalla, South Australia on the 7th day of June 2000 as a result of morphine toxicity. The said Court finds that the circumstances of his death were as follows:

1. Introduction

1.1. Ian Myles Smith, more commonly known as Myles, died at the Whyalla Hospital on Wednesday, 7 June 2000. He was two years and two months old at the time.

1.2. Myles was the son of Jillian Allbrite and Allan Smith. He had two sisters, Davina and Kylie. On Monday, 5 June 2000, Myles and his sisters were at Cartledge Avenue, Whyalla with their mother Jillian. Their father, Mr Smith, had some of his medications in the house at Cartledge Avenue. According to accounts subsequently provided to staff at Accident and Emergency at Whyalla Hospital by Ms Allbrite and Mr Smith, the children gained access to Mr Smith's medication including Kapanol, a slow release morphine preparation, Panadeine Forte, and Epilim, a medication for the treatment of epilepsy.

1.3. An autopsy was performed by Dr John Gilbert of the Forensic Science Centre on 8 June 2000. Dr Gilbert noted that there was no anatomic cause for death found at

autopsy but that a very high, and potentially lethal level of morphine was identified in the blood. 3.9 milligrams of morphine were identified in the stomach contents, and morphine and codeine were identified in the urine. Dr Gilbert expressed the opinion that death was clearly due to morphine toxicity.

1.4. At around 3:15 pm on 5 June 2000 Myles Smith, together with his sisters, was admitted to the Whyalla Hospital. He remained at the hospital until his death.

1.5. The main questions for consideration in this Inquest have been the treatment received by Myles Smith at the Whyalla Hospital, the circumstances surrounding his ingestion of the drugs, and finally the pharmacokinetic behaviour of the drugs in Myles body leading up to his death.

2. Circumstances surrounding ingestion of drugs

2.1. Jillian Allbrite

Jillian Allbrite gave evidence at the Inquest. She said that she was the mother of Myles and that Allan Smith was his father. They had two other children, Davina who was three at the time of Myles' death, and Kylie was eleven months. By June 2000 Jillian and Allan were not living together. Jillian lived with Davina and Kylie at her house at Cartledge Avenue and Allan lived at his house with Myles. The couple would occasionally stay together under one roof. But generally, Jillian was responsible for the care of Davina and Kylie and Allan for the care of Myles. Sometimes all three children would be in the care of Jillian.

2.2. Jillian stated that on the day in question Allan had not stayed the previous night but had brought Myles to Jillian's house so that he would be free to do his housework. Jillian stated that Allan had not brought any bags of clothing for Myles as would be the case if he were to be staying. She did not know that Allan had brought his medication with him. She stated that Allan stayed for approximately half an hour.

2.3. Some time after Allan left, she stated that the children were resting. She took the opportunity to take some peelings to the compost heap and then went to the toilet. As she was finishing in the toilet, Davina came to her and said that Myles had dad's tablets. She went and saw Myles with an empty blister strip in his hand. She took it and told Myles and Davina to go and sit on an nearby couch. She found Kylie with

some medication also which she took from her. She then put all of the medications she could find in a plastic bag and rang the ambulance.

2.4. Jillian Allbrite was aware that Allan was taking morphine and Panadeine Forte for his back pain and Epilim and another medication for epilepsy. She stated that he would "carry the lot" in a plastic bag with him. She was concerned about that practice and had told him on a number of occasions not to leave the plastic bag of medication around where the children could get it. She stated that he would leave it in full view of everybody – sometimes on the floor, sometimes on the dining table and sometimes on his chair in the lounge. She stated that she would often pick it up and place it on top of the wardrobe in her room so the children could not get to it. She raised this with Allan but it did not do any good.

2.5. She gave evidence that ultimately Allan took her and the children to the hospital and they arrived at about 2:55 pm. She said that she stayed with the children at all times while at the hospital and that she did not have any morphine or Kapanol with her, although she did have some Epilim with her which she took for bipolar disorder.

2.6. Jillian Allbrite stated that the next morning she thought that Myles sounded chesty and she raised this with Dr Connolly. Dr Connolly said that Myles would be kept in overnight but that the girls could go home. When Allan came to take Jillian and the girls home, Jillian took the girls outside the ward while Allan stayed with Myles to calm him down because he was upset at being left behind. She stated that Allan stayed with Myles for approximately five minutes and then came out and they left the hospital with the girls.

2.7. Ms Allbrite gave evidence that she never gave medication to Myles in an effort to calm him down. She gave evidence about a fire at a previous house in around August 1999. It was at that point that the arrangement was made that Allan would look after Myles and she would look after Davina and Kylie because she found it difficult to cope with three children and with moving house.

2.8. She gave evidence that after Myles died, while she was at the hospital, social workers from Families and Communities came to the hospital and took Davina and Kylie. The girls were then placed into foster care and there is a long-term order the effect of which is to remove the girls from her custody and guardianship.

2.9. Ms Allbrite gave evidence that she has never given and never gave Myles Kapanol. She said that she had never given any of the children medication to settle their behaviour. She stated that she did not give Myles any Kapanol or morphine after he was admitted to the hospital. She stated that she did not see anybody else do that either.

2.10. Allan Smith

Mr Smith gave evidence at the Inquest. He stated that he is 59 years old and lives at Hodgson Street, Whyalla. As at June 2000 he said that Myles had been living with him for six months. At that time Allan was not working but was on a disability pension. Since Myles' death he has suffered a partial stroke and has been very ill since then. His concentration was affected by the stroke and this was noticeable as he gave his evidence. He described the medication that he was on, including Kapanol, Panadeine Forte and Epilim. He stated that it was his practice when he was staying at Cartledge Avenue to put his medication in the boot of his car and lock it there. When he was at his own home he would put the medication up high so that Myles could not get to it.

2.11. On 5 June 2000 he said that he had stayed at Cartledge Avenue overnight. It will be recalled that Jillian Allbrite stated to the contrary. I am unable to decide which version of events to accept. However, the fact that Allan's medication was clearly inside the house at Cartledge Avenue suggests that he probably stayed the previous night contrary to Jillian Allbrite's recollection of events. In the end, nothing turns on this.

2.12. Allan stated that he asked Jillian to keep Myles so that he could do some work at home. He said that he placed his medication in the middle of the bed (Jillian's bed) underneath the eiderdown so that no one could see it. He said he thought this would be alright. He said, contrary to the evidence of Jillian, that he told Jillian where the medication was. I am unable to determine whether Allan in fact told Jillian that he had left the medication in the house. Each has a different version of events – the fact of the matter is that the medication was, according to Allan, left on the bed underneath the eiderdown. Jillian does not dispute this, although she said that she had looked at the bed and had not seen the medication. It is possible that she did not see it because Allan had placed it under the eiderdown.

2.13. The next time he saw Jillian was at approximately 2:30 pm when she informed him that the children had probably ingested some of his medication. He gave an account of having gone back to Jillian's house to try and ascertain how much Kapanol might have been missing but that he could not do so with any precision. There was some confusion in his evidence as to whether he returned to Cartledge Avenue once or twice that afternoon to search for the remaining drugs. At this distance from the event, and having regard to his medical condition, it is not surprising that Allan is confused about precisely what happened that afternoon. In any event, nothing turns on this.

2.14. Allan gave evidence that he returned to his home on the afternoon of 5 June and returned to the hospital the following day to pick up Jillian and the girls. He acknowledged that he stayed behind to calm Myles down and remained for a couple of minutes.

2.15. Allan stated that he never gave Myles any medication to calm him down, not even Panadol. He said that he had never had cause to give Myles any medication.

2.16. Allan stated that Jillian was in the habit of dosing the children with Panadol so that they would sleep and she could have time to herself. He stated that she would do this ten or twelve times a week.

2.17. Allan Smith stated that he did not give Myles any Kapanol. He mentioned that he had left a yellow "dolphin" torch covered up with the medication underneath the eiderdown. He said that he had had to hide it to stop Myles from turning it on all of the time and wasting the batteries.

2.18. Allan Smith denied the allegation of Jillian Allbrite that he used to leave his tablets lying around in places where the children could have gained access to them. He denied that Jillian had ever commented on his leaving tablets around. He stated that he believed that the children could not get to the medicine which he had left on the bed as they could not climb onto the bed. However, he acknowledged that the children could still pull the quilt off the bed. It was put to him that it was risky to leave the medication on the bed but he denied this on the basis that he had told Jillian that it was in the bedroom and that she did not let the children into the bedroom. He acknowledged that the bed was probably not a good place to hide the medicine.

3. Effect of evidence of Allan and Jillian

3.1. In the result, neither Allan nor Jillian admitted to giving Myles or any of the other children Kapanol deliberately at any time. Specifically, neither of them admitted to doing so on 5 June 2000 or any subsequent time up until Myles' death.

4. Treatment at Whyalla Hospital

4.1. A number of the nursing staff responsible for the treatment of Myles gave evidence at the Inquest about the care that Myles received while in hospital.

4.2. Nurse Teresa Quinn

Nurse Teresa Quinn was a registered nurse working on the afternoon shift at Accident and Emergency at Whyalla Hospital on 5 June 2000. She gave evidence that at about 3:15 pm on that date Ms Allbrite (who was then known as Mrs Smith) presented at the hospital with her three children.

4.3. Nurse Quinn made the following entry in the hospital notes, which were admitted and marked as Exhibit C14:

> 'possible ingestion Kapanol 20mg x 7
> Panadeine Forte 1 or 2
> Epilim 500mg ? amount probably none or very few (as per dad).
> Medications belong to father.
> Mum found children x 3 with medications at 1400.
> Dad states he is certain as to amount of medications (Kapanol and Panadeine Forte) missing.
> Poisons information contacted. Advise observations and admission and assessment by M/O.
> 1520 per phone Dr Connolly.
> Will review later. Observe.'

4.4. Nurse Quinn took observations of Myles Smith and the other children. The observations for all three were normal. She contacted the Poisons Information Centre to seek advice. The Poisons Information Centre asked for confirmation of the time of ingestion which Nurse Quinn confirmed as being at around 2:00 pm. The centre requested that she physically check the mouths of the children to see if there was evidence of medication. This she did, without seeing any evidence of medication. The Poisons Information Centre advised that the children should be seen by a doctor and admitted overnight.

4.5. Nurse Quinn then contacted Dr Connolly and he advised her to observe the children and said that he would see them later.

4.6. Nurse Quinn said that at about 6:55 pm that evening Dr Connolly attended at the hospital, assessed the children and requested that they be admitted overnight for observations. Nurse Quinn stated that Myles and the other children showed no signs of drug ingestion during their period in Accident and Emergency; that dinner was ordered for them; that Myles ate most of his dinner; that during the period in Accident and Emergency four sets of observations on the children were conducted which were all normal.

4.7. Nurse Melanie McAtee

Nurse Melanie McAtee was a registered nurse working in the Paediatrics Ward of the Whyalla Hospital on 5 June 2000. She was on duty on the evening of that day.

4.8. She was contacted prior to the admission of the Smith children to the Paediatrics Ward by Nurse Quinn who informed her of the possibility that the three children had ingested seven Kapanol and one or two Panadeine Forte capsules. She conducted interviews and assessments of all three children with Mrs Smith. She noted that Myles' vital signs and oxygen saturations were satisfactory and that his pupils were equal and reacting. These observations were made at 7:45 pm on the evening of 5 June.

4.9. Nurse McAtee stated that she made further observations of Myles every half hour. She noted that at 8:15 pm Myles breathing was 20-24 respirations per minute and his oxygen saturations were 98 percent. At 8:45 pm his breathing was 24 respirations per minute and his oxygen saturations were 98 percent. At 8:00 pm Myles had a half piece of toast and some milk and as asleep when Nurse McAtee finished her shift at 10:45 pm. She conducted a handover of the three children with Nurse Ferdinands who was on duty for the night shift.

4.10. Nurse McAtee explained that the children were placed in a bay which contained four beds. She stated that Myles looked tired and appeared to be more tired than the other two children. She stated that Mrs Smith was feeding the baby (Kylie) by breast. She stated that she performed half hourly observations because of the possibility of morphine toxicity and said "I wanted to be a bit over cautious".

4.11. I found Nurse McAtee to be a good witness who gave her evidence in a straightforward and helpful manner. Nurse McAtee made further half hourly observations, the last of which was made at 2230. She stated that she was not worried about the observation results obtained from Myles (nor for that matter any of the other children) because each of the results revealed a stable condition.

4.12. Nurse Quirk

Nurse Quirk also gave evidence at the Inquest. She stated that on 5 June 2000 she was on the afternoon shift and assisted Nurse McAtee on the Paediatrics Ward. Nurse Quirk is an enrolled nurse and assisted Nurse McAtee in making some of the observations referred to above. She relieved Nurse McAtee while the latter had a meal break. She did not observe anything untoward in relation to Myles or the other children.

4.13. Nurse Ferdinands

The next witness was Nurse Ferdinands, a registered nurse within the Paediatrics Ward at the Whyalla Hospital who was, on 5 June 2000, working on the night shift commencing at 10:30 pm.

4.14. Nurse Ferdinands stated that Nurse McAtee handed over to her and in doing so told her that the three Smith children had been brought to Accident and Emergency after a possible ingestion of Kapanol and Panadeine Forte and Epilim. She was told that they had not been given a gastric lavage and that the Poisons Information Centre had been contacted and that the plan was to observe the children overnight.

4.15. Nurse Ferdinands was an excellent witness. She gave her evidence in an open and frank manner and it is clear that she performed her duties conscientiously and diligently. She made her first observation of Myles at 11:15 pm and noted that he was asleep with respirations of 18 breaths per minute, which was normal.

4.16. She gave a statement which was admitted as Exhibit C18 in these proceedings in which she said that early in her shift, she took the initiative of making a computer search for information regarding Kapanol overdose. She printed the results of her search and noted that there is a specific antidote against the respiratory depression which results from opioid overdose, namely naloxone. It became apparent during the course of the Inquest that naloxone is also known by the name Narcan. Nurse Ferdinands obtained the rate per kilogram at which Narcan should be administered,

and then made calculations based upon the weights of the three Smith children as shown in their admission notes, of the appropriate dose rates for each child. She wrote those dose rates against the names of each child on the printout. The printout appears in the hospital notes, Exhibit C14.

4.17. Nurse Ferdinands then took the further precaution of going to another part of the hospital to obtain the Narcan in case it was needed. She brought the Narcan back to the Paediatrics Ward so that it would be available at short notice. She determined from the computer printout already referred to a timeframe for when the effects of the ingestion of Kapanol would be at their highest. From the printout she determined that the maximum effects would have occurred at 12 hours after ingestion and she confirmed with Mrs Smith that the time of ingestion (if it occurred) would have been around 2:00 pm on 5 June. With that information she calculated that the maximum effect would occur at around 2:00 am on 6 June, during her shift.

4.18. She made further observations of Myles at 12 midnight and noted that he was asleep and breathing normally. At 1:00 am she checked his pulse and was able to hear noises in his chest. She checked his oxygen saturations and found them to be 96 percent. She then woke him and checked his pupils which were constricted and corresponded with size 2 on the neurological chart but were reactive to light. She noted the pupil constriction to be one of the side effects of either Kapanol or Panadeine Forte. She checked the other two children at the same time and noted that they showed no signs of respiratory distress. She was concerned that Myles' pupils were constricted notwithstanding the darkness of the room. At 1:20 am, according to a note made by Nurse Ferdinands in Exhibit C14, she contacted Dr Connolly and discussed the situation with him. The note shows that he ordered Narcan to be given if required, but for the time being to continue observations.

4.19. When Nurse Ferdinands heard about Myles' death on 7 June 2000, she made a note of her recollection of the night shift of 5/6 June 2000. In that note she refers to the discussion with Dr Connolly and in particular notes a discussion with him about the weights and dosages for Narcan in the event that it was required. In that note, which was admitted and marked C18a, Nurse Ferdinands states that the pulse oximeter was used to monitor Myles' oxygen saturations continuously for the rest of the night. The hospital notes of observations made by her record that at 0300 Myles' oxygen saturations were down to 84 percent with a respiration rate of 14 breaths per minute.

However, in her personal note, Exhibit C18a, she notes that on administering oxygen via a Hudsons mask the saturation returned to 99 percent within seconds. At 0500 the hospital notes (Exhibit C14) record a drop to 88 percent of oxygen saturations, once again returning to 99 percent rapidly on the application of oxygen via the Hudsons mask. At 0600 the hospital notes show a further observation of oxygen saturations at 88 percent, once again returning to 99 percent on oxygen. In her personal notes (Exhibit C18a) Nurse Ferdinands records that she would enter the room and assess him each time the oximeter alarmed which would occur if the oxygen saturations fell below 90 percent or if the probe fell off his finger (which she has recorded as having happened often).

4.20. Nurse Ferdinands notes that at 0300 Myles sat up and smelt some toast which Nurse Ferdinands was having and asked to have some, which he did, together with a drink.

4.21. In her personal notes (Exhibit C18a), Nurse Ferdinands records a summary of the conversations that she had with Jillian Smith. She notes that Jillian asked her to check whether the Department of Families and Communities had been notified of this hospital admission. She stated that she had "only just got them off her back" (referring to the Department of Families and Communities). The note records that Jillian stated that the incident was "fathers fault – told him time and again not to leave his tablets around, also has left his tobacco around before, Myles has actually rolled his own".

4.22. Nurse Ferdinands stated that at no time was Myles comatose or unable to be awakened. He would stir when she made her observations and at no time did she think the situation had progressed to the stage where Narcan was needed. She also spoke with another nurse during her shift who thought that her treatment was appropriate. She noted that there were occasions during her shift when Myles had episodes of inspiratory stridor some of which resolved themselves without intervention on her part but others of which resolved when she physically moved him up the bed. At the completion of her shift she did a handover to Nurse Kelly who came on early on the morning of 6 June.

4.23. Nurse Ferdinands was diligent and attentive in her duties. She is to be commended.

4.24. Nurse Kelly

Nurse Kelly assumed primary responsibility for the care of Myles and the other children at approximately 0700 on 6 June 2000. Nurse Kelly gave evidence at the Inquest. She also gave a statement to Detective Senior Constable Foweraker which was admitted and marked Exhibit C19. She stated that she is a registered nurse and works at the Whyalla Hospital in the Paediatrics Ward. She stated that Nurse Ferdinands gave her a handover at the commencement of her shift. She was advised of the possible ingestion of Kapanol, Panadeine Forte and Epilim by the Smith children and was advised that Myles' respiration had dropped to 14 breaths per minute along with oxygen saturations dropping. She was advised that Nurse Ferdinands had applied oxygen from approximately 2:00 am onwards and was aware of Myles' noisy breathing. Nurse Kelly stated that Nurse Ferdinands had informed her of the direction by Dr Connolly to administer Narcan if the need arose but was aware of the fact that Myles was responding well to oxygen. She carried out observations at 8:00 am on 6 June and noted that Myles' respirations were 24 breaths per minute but his saturations were low at 89 percent. Accordingly she applied oxygen and his saturations immediately rose to 99 percent. She observed Myles having breakfast.

4.25. Nurse Kelly stated in Exhibit C19 that Dr Connolly attended at the ward between 8:30 and 9:00 am and examined the children. She stated that Dr Connolly was going to discharge all three children but that she pointed out to him that Myles had been breathing noisily overnight and that Dr Connolly then decided to keep Myles in "because he was of the opinion that Myles had a chest infection or asthma". She said that Dr Connolly instructed that Myles be commenced on Amoxil due to his chest infection. It should be noted that Dr Connolly, when he gave evidence, gave a different version of this exchange. For reasons which will appear later I prefer the evidence of Dr Connolly.

4.26. Nurse Kelly stated that after breakfast Myles was quite active but that at 9:15 am he became tired and slept for approximately half an hour. She stated that she went to morning tea at about 11:00 am and when she returned Kylie and Davina had been discharged. She stated that just after 12:00 pm Myles fell asleep again and at that time his observations were 20 breaths per minute with oxygen saturation at 98 percent. After lunch she did a handover to Nurse Barrett and for the remainder of her

shift she was nursing a six week old baby. She recalled that Myles woke up at about 3:15 pm and was watching television. She went off duty at 3:20 pm that date.

4.27. Nurse Kelly gave evidence that she was the only nurse on the ward during the morning looking after the paediatric patients. She stated that as far as she was concerned Myles was remaining in hospital for a breathing problem and not an overdose. As far as morphine toxicity was concerned it was her view that he was out of the toxicity danger zone.

4.28. It will be recalled that Nurse Ferdinands had been conducting very regular observations during her shift, the last observations being recorded at 0600. These observations were half hourly to hourly. Upon the commencement of Nurse Kelly's shift, observations moved from being done half hourly to being done much less frequently. Indeed, a neurological chart had been maintained for Myles from the time he entered hospital in the Accident and Emergency Department, through the period of his care under Nurses Quinn, McAtee and Ferdinands in the Paediatrics Ward until 0600. That chart ceased at the end of Nurse Ferdinands' shift. Only two entries are recorded on the graphics chart by Nurse Kelly, one at 0800 and another at 1200, both of which have been referred to above. The progress notes contain only a brief report from Nurse Kelly which appears to have been written at 1200. It is misleading in that it refers to oxygen saturation results for 0800 even though it was written at 1200.

4.29. Nurse Kelly was asked to explain why she decided to cease frequent neurological observations. She was unable to provide any satisfactory explanation. To the extent that she claimed to have been of the opinion that the purpose of Myles' hospitalisation had changed from a precautionary stay with frequent observations to guard against the possibility of drug ingestion to a stay for a possible chest infection, I do not accept this explanation. Nurse Kelly took it upon herself to cease frequent observations as soon as her shift started; but Dr Connolly did not attend to review Myles and the other children for some two hours after the commencement of Nurse Kelly's shift. It will be remembered that Myles in particular, had suffered distinct signs of morphine toxicity during Nurse Ferdinands' shift, and that Nurse Ferdinands had been quite concerned for him. Indeed Nurse Kelly's first observations at 0800 recorded unacceptably low oxygen saturations for Myles at 89 percent.

4.30. In the witness box, Nurse Kelly displayed an unhelpful attitude and was inclined to be argumentative.

4.31. Nurse Holsman

Nurse Holsman gave evidence at the Inquest and provided a statement to Detective Senior Constable Foweraker which was tendered and admitted as Exhibit C20. She stated that she was on the early shift on the morning of 6 June 2000, and during that shift Nurse Kelly requested that she check on Myles Smith. He was asleep and Nurse Holsman roused him and noted that his oxygen saturations were low and gave oxygen to which he responded.

4.32. Nurse Barrett

Nurse Barrett gave evidence at the Inquest. She also gave a statement to Detective Senior Constable Foweraker which was admitted and marked as Exhibit C21. She stated that she commenced work on the afternoon shift in the Paediatrics Ward at 2:15 pm on 6 June 2000 and received a handover from Nurse Kelly in relation to the patients in the ward that afternoon, including Myles Smith. She was told by Nurse Kelly that the Smith children "had supposedly taken some Kapanol but the two girls had been discharged by Dr Connolly but Myles was kept in because of a possible chest infection" (Exhibit C21).

4.33. She said that she had been told that the supposed ingestion of drugs had taken place the previous afternoon approximately 24 hours before her shift started. She was told that Myles remained on for a chest infection. She stated that she was really busy. She stated that she was carrying an irritable baby around for most of the shift. She made only one entry in the progress notes in Exhibit C14 at 2150 hours. The note is not particularly helpful. There is only one other observation recorded by Nurse Barrett at the time of 1900 hours at which she records temperature, pulse and respiration rates but not oxygen saturation. She stated that she was required to care for five children on the ward that afternoon. The shift started with four children and there was an admission shortly after she started.

4.34. She acknowledged that she did not do any other physical observations of Myles after 1900 hours. She stated that he was asleep on the ward when she started her shift but that he awoke at around 3:30 pm and was awake until 6:30 pm. She stated:

> 'As far as I was concerned I was looking after a child with a possible chest infection and not an overdose because it was so long after he was supposed to have taken the medication.'
> (Exhibit C21, p3)

4.35. She stated in evidence that Myles was extremely naughty during the period that he was awake in the afternoon of 6 June. She stated that he was hitting another child in the room and was extremely active; that she tried to do observations of him but he would not let her and ran away; she thought he was quite well; "I just have some recollection with having a fight with him to give it (Amoxil) to him"; he was fighting with another child over toys and pulling a girls hair (T195). In short, she stated that she was happy with his condition and that he looked like a perfectly normal child.

4.36. Nurse Bentley

The next witness was Nurse Bentley. She also made a statement to Detective Senior Constable Foweraker which was admitted as Exhibit C22. She was a registered nurse in the employment of Whyalla Hospital and on 6 June 2000 was called in to duty as the second registered nurse for the Intensive Care Unit. The ICU had been moved to a bay adjacent to the Paediatric Ward because of painting work that was being carried out in ICU Department.

4.37. She stated that at about 6:30 pm she heard some crying coming from the Paediatric Ward and went in to check what was going on as Nurse Barrett was busy at the desk. She went into the ward and noticed that Myles Smith had been involved in a fight with another child and that Myles was holding a toy and standing in the room. She noted that Myles had puffy eyes and looked tired and she asked Nurse Barrett why Myles was in hospital. Nurse Barrett told her that Myles had a chest infection but that he had originally been admitted for possible ingestion of drugs the previous afternoon. She asked what sort of drugs and was told Kapanol, Panadeine Forte and Epilim.

4.38. Nurse Bentley gave evidence that she said to Myles words to the effect "If you're tired, sweetheart, you can sleep here" (T220); she then turned back to Nurse Barrett and when she looked at Myles again he had gone to bed. She commented that his motor skills to get into the bed, his obedience at the suggestion that he go to bed, were evidence of a cognitive function not consistent with narcotic effect. She also noted that Myles had four wet nappies that day according to the notes, which is indicative of a well hydrated child. Her experience of heavily sedated people is that they tend to be

dehydrated. This is another reason that she did not regard Myles as being affected by narcotics.

4.39. She also stated that at 9:00 pm she had settled a colicky baby and returned the baby to the ward. At that time she saw that Myles was asleep in bed although wriggling around under the covers of his bed. She waited for him to settle which he did and then she left.

4.40. Nurse Hurst

The next witness was Nurse Hurst who was an enrolled nurse working at Whyalla Hospital. She was on night shift on 6 June 2000 starting at 10:30 pm on the Paediatrics Ward. She normally worked on the surgical ward but had been called in from holidays to assist. She stated that when she arrived at around 10:30 pm she walked past the Paediatrics Ward and could hear a child breathing noisily and went in and had a look at him. The child was Myles. She went to the desk and asked Nurse Barrett who preceded her on the afternoon shift what was wrong with Myles. Nurse Barrett explained that he and his sisters had been admitted for queried ingestion of Panadeine Forte and Kapanol, the sisters had been released but Dr Connolly wished Myles to stay in hospital because of his breathing, he had been drowsy and breathing noisily all shift, but his observations had been stable and fine and he had just been drowsy throughout the day.

4.41. Nurse Hurst received a further handover from Nurse Barrett who then left. She then went and checked the patient's charts and after doing so prepared a bottle for another patient. She then went back in and checked all of the children and noticed that Myles was huddled down at the foot of his bed. She straightened him up and put him back up towards the top of the bed and he stirred a little, opened his eyes, looked towards the light and then closed his eyes and promptly went off to sleep again.

4.42. She stated in her evidence that even for a chesty child his breathing sounded somewhat unnatural. She stated that she was relieved that he stirred when she straightened him up before she went off to feed a baby called Lily. She was feeding Lily for about 45 minutes after which she returned to the Paediatrics Ward to find Myles on all fours with the bedclothes down below his nappy. As she reached down to pull the bedclothes up she could not hear his raspy breathing any longer so she placed her hands on his ribs to see if she could feel him breathing and could not. She

then turned him over and put her head down to listen for a heartbeat and could not hear anything. She then ran out to the nursing station and told another nurse what was happening. That nurse asked another nurse to ring 80 (the emergency number) and get the emergency trolley. She stated that another nurse started mouth to mouth and while that was happening she grabbed an oxygen tube, took the face mask off and while mouth to mouth was continuing the tube was inserted. She began chest compressions, ECG dots were put on Myles and he was connected to the monitor. IV access was then gained and resuscitation measures were taken. Myles was intubated, and CPR continued but Myles remained asystole and unresponsive and was ultimately certified as having died.

4.43. Nurse Hurst was clearly very much affected by Myles' death. One can readily sympathise with her position bearing in mind that she had only been on duty for approximately an hour and a half when she found him unresponsive. It is notable that she had also checked on him only 45 minutes before and that he had stirred and opened his eyes.

4.44. Dr Connolly

The next witness to give evidence was Dr Connolly. Dr Connolly said that he became a general practitioner after having qualified in the United Kingdom. He practised as a general practitioner for 3 years in the United Kingdom between 1984 and 1987. He has been a GP in Whyalla since 1988. He is on the Privileging Board for the Far North and is Chair of the Eyre Division of General Practice. He has been doing obstetrics for 18 years and has used Narcan on newborn children affected by the narcotics administered to their mother for pain relief during childbirth.

4.45. He stated that Mr Smith and Ms Allbrite are still his patients.

4.46. Dr Connelly confirmed that Nurse Quinn had contacted him on the afternoon of 5 June 2000 at approximately 3:20 pm. She told him that three children whom she named had been admitted following the possible ingestion of the medications Kapanol, Panadeine Forte and Epilim. She told him that the time of possible ingestion was between 1:30 and 2:00 pm. He was told that the amount possibly ingested was up to seven Kapanol, although possibly only four. Nurse Quinn informed him that she had contacted the Poisons Information Centre. He gave evidence that he then said to Nurse Quinn words to the effect, "shall we give Ipecac?"

– a drug which he had used in the past to produce vomiting in persons who had possibly ingested poisons. Nurse Quinn responded that the Poisons Information Centre did not suggest Ipecac but rather that the children be admitted for observation.

4.47. Dr Connolly gave evidence that he then asked Nurse Quinn whether she wished him to come up to the hospital. Nurse Quinn responded by saying that she was able to deal with the situation for the time being. Dr Connolly asked that neurological observations be carried out half hourly to hourly. He said that he could come up to the hospital at short notice. At the time of the call he was consulting in his surgery but stated that he would come up to the hospital if there was any change.

4.48. Dr Connolly gave evidence of attending the hospital at approximately 6:00 pm. He stated that the children were in a side room with Mrs Smith at Accident and Emergency. He examined the children's heart, lungs and neurological systems and noted that the children were all very active and running around. He noted no abnormalities. He then went to casualty to examine some other patients and came back to admit the children to the Paediatric Ward.

4.49. He also gave evidence that he saw the children later that evening while attending to another sick paediatric patient who required the insertion of an IV cannula at approximately 8:00 pm. He noted that Myles and Davina were watching television at that time and seemed to be well.

4.50. He gave evidence that at around 1:00 am on Tuesday morning (but acknowledging that it could have been as late as 1:20 am) he was awakened by a telephone call from the hospital. It was Nurse Ferdinands who reported that she was concerned because although his observations were stable, Myles pupillary size had gone from 5 to 2 on the neurological chart in a darkened room. Dr Connolly regarded this as a strong sign of morphine ingestion. He then had a discussion with Nurse Ferdinands in which he asked her to check the weights of the children and together they worked out the appropriate dose of Narcan to be given to each of them. Nurse Ferdinands confirmed that she was happy for matters to be left at that. Dr Connolly said that he offered to go to the hospital and place an IV cannula in Myles for easy access in the event that it was necessary to administer Narcan but Nurse Ferdinands said there was no need and that she would call him if necessary. Dr Connolly pointed out to her that it was also possible to administer Narcan by an injection into the buttocks. Dr Connolly did not

remember any reference by Nurse Ferdinands to Myles having difficulty breathing. His understanding was that Nurse Ferdinands was very happy with the instructions which he gave to her and would come back to him if required.

4.51. Dr Connolly next saw the children at 9:00 am that morning. He said that he examined them. Davina and Myles were sitting inside the ward eating Rice Bubbles at a table and chair by the window. Mrs Smith and the baby Kylie were also in the ward. Dr Connolly went to Myles to check the pupillary size. Nurse Kelly followed him in. He shone his torch in both Davina and Myles' eyes and noted the pupillary size to be between 2 and 3 and reactive to light, but that the conditions were very bright and sunny. Dr Connolly then left Myles not having noticed any problem with his breathing or chest.

4.52. At that point Mrs Smith said that she thought Myles might have asthma. Dr Connolly then thought perhaps Myles might be a little bit congested but only to a small extent. Mrs Smith noted that Mr Smith smoked at home to which Dr Connolly responded appropriately. He then went to the desk and started to read Myles' notes for the night. Nurse Kelly said that Myles had been chesty overnight. On reading the notes and noting the observations that had been made since 1:00 am when the telephone call was made to him, he said to Nurse Kelly that all of the children should be kept in. However, Nurse Kelly said there was a problem with that proposal because ICU had been moved into the paediatric area. By way of a compromise Dr Connolly suggested that the girls could go at around lunchtime, being some 24 hours after the suspected ingestion, but that Myles was to stay in. Nurse Kelly asked what should be done if the parents wanted to take Myles home and Dr Connolly said that the staff could call him at 6:00 pm that night and let him know if the family wanted to take Myles home at which point Dr Connolly would be likely to agree provided that Myles was stable. Matters were left at that for the time being, with Dr Connolly making an entry in the progress notes as follows:

> "Better today but chesty. Dad smokes. Keep in today.'

4.53. Dr Connolly stated that he did not record the pupillary reaction taken from Myles at 9:00 am. He did notice that the neurological chart for Myles had ceased to be recorded at 6:00 am. He stated that his own clinical impression of Myles was that he was stable and active on the ward with no sign of impaired neurological function.

Therefore if he had been asked, he would have agreed to the discontinuance of neurological observations.

4.54. In cross examination it was put to Dr Connolly that a person reading the note in the progress notes for 6 June would not realise that he had kept Myles in for morphine ingestion. It was put to Dr Connolly that he was no longer concerned about the morphine ingestion. Dr Connolly disputed this and stated that he would not have admitted the child to hospital "with that chest". However, Dr Connolly acknowledged that in the notes for Davina Smith he made a reference to Ian being kept in with "some bronchitis only". Dr Connolly stated that he expected the morphine to have been out of Myles' system. My impression of his evidence was that he was motivated to keep Myles in because of the chest infection, but would not have done so if it were not for the background of the drug ingestion.

4.55. Counsel for the hospital put to Dr Connolly Nurse Kelly's version of their conversation in relation to the possible discharge of the children. Dr Connolly did not agree with the proposition that the only reason he kept Myles in was because of Nurse Kelly's suggestion to that effect.

4.56. Dr Connolly gave evidence that he prescribed Amoxil for a possible chest infection and that Amoxil would have no effect on Myles' conscious state. Dr Connolly was asked if he had given Nurse Ferdinands instructions about what circumstances Narcan would be appropriate. He stated that if Myles' saturations or pulse rate dropped or if he became semi-comatose that Narcan would be appropriate, that he conveyed this to Nurse Ferdinands and that he had great respect for Nurse Ferdinands capabilities.

4.57. It was also put to Dr Connolly that one of the reasons for keeping Myles in hospital was a "social reason" related to Myles' father having had problems with his motor vehicle. Dr Connolly denied this and stated that he had no knowledge of Mr Smith's problems with his vehicle. He stated that Myles was the only child that had showed any sign of morphine ingestion and he thought it necessary to keep him in for further observations with the secondary reason being the possible chest infection.

4.58. Dr Connolly gave evidence that the administration of Narcan in the absence of morphine toxicity would not have been harmful, but that "kids don't like needles". He thought that as to morphine ingestion, by 9:00 am on 6 June that Myles would be moving into the recovery phase. He stated that he did not order blood or urine tests

because the Poisons Information Centre had not recommended such tests and in any event the results would not have come back until the next day, which would have been outside the critical period.

5. Kapanol – its pharmacology

5.1. Professor Geoffrey Gourlay

Professor Gourlay provided reports for the Court which were admitted as Exhibits C25 and C25a. He also gave evidence. He is Chief Medical Scientist in the Pain Management Unit at Flinders Medical Centre and Associate Professor in the Department of Anaesthesia and Pain Management at Flinders University. He has a distinguished and extensive association with a number of international organizations concerned with pain management. Since 1980, he has worked full-time in the pain management area in an interdisciplinary setting involving scientists and clinicians. He has daily interaction with clinicians using drugs to optimise pain management and extensive experience with morphine. He was involved in the development of Kapanol by the South Australian company Fauldings.

5.2. Professor Gourlay described the composition of Kapanol capsules. He stated that it is a pellet formulation encased in a capsule. All the capsules are identical. The pellets contained within the capsule are quite small with a diameter of between one and two millimetres. Each pellet has an inert core and a solution of morphine is sprayed on the core and allowed to dry. A further coat is sprayed over the top of the pellet once the morphine has dried. That coat is designed in a way that allows a controlled release of the morphine. It has what Professor Gourlay described as a "pH dependent release profile". The effect of this is that the rate of dissolution in the acidic environment of the stomach is relatively low. However, when the pellet passes through the pylorus into the duodenum, the pH changes from an acidic environment to a neutral environment. When that happens, the morphine is released at a rate which is two and a half times greater on average than the rate of release within the stomach (T296-297).

5.3. Professor Gourlay said that although morphine can be released in the stomach, the stomach does not absorb the morphine. The absorption all occurs within the duodenum.

5.4. Professor Gourlay expressed the opinion that the blister packs within which the Kapanol capsules are marketed are such that a child would be unlikely to be able to remove the capsules unassisted. However, while there is no doubting Professor Gourlay's scientific expertise, he has no particular expertise in relation to the capacity of children to manipulate blister packs. His evidence stands in stark contrast with that of Dr Connelly who considered that a blister pack such as that used for Kapanol would be readily opened by a two year old. On this point I prefer the evidence of Dr Connelly. I deal with this issue further when discussing Exhibit C30 (paragraph 9).

5.5. Professor Gourlay also gave evidence (T303) that children would be unlikely to wish to swallow Kapanol capsules or the pellet contained within them. His hypothesis was that there was no "reward" in the sense that the outer coating of the capsule itself is tasteless. The pellets themselves are tasteless, but if masticated, would be bitter in taste. For this reason Professor Gourlay thought it unlikely that a child would consume more than one Kapanol capsule. However, he acknowledged that he has no particular expertise in relation to children's behaviour. While Professor Gourlay's logic is attractive, I do not believe that it affords an adequate basis to conclude that Myles could not have ingested the Kapanol capsules voluntarily. Professor Gourlay suggested it was more likely to be palatable if combined with yoghurt or ice-cream or jam. However, as noted, there is no evidence to support the conclusion that Myles ingested the Kapanol capsules other than voluntarily.

5.6. Professor Gourlay said (T306) that although there is not much evidence about the rate of metabolism of morphine in young children, the common wisdom in the academic community at present is that, by the age of one month, children essentially have the same capacity to metabolise morphine as adults. He provided an article from the Journal of Paediatrics in support of this contention which was admitted as Exhibit C25c.

5.7. At T311-312 Professor Gourlay described his expectation of the behaviour of the after effects of morphine or Kapanol ingestion. Assuming that there had been an ingestion at around 2:00 or 2:30 pm on 5 June, he stated that "there's going to come a time when the peak level comes". After that, the morphine effect is going to fall. He stated that as it falls the symptoms of high morphine concentrations will dissipate. The pupils will get bigger, the oxygen saturations will improve, and the level of

sedation will abate so that the child will become more active. He concluded that the peak levels of an ingestion at approximately 2:30 pm on 5 June would have occurred at some time prior to 8:00 am on 6 June at the latest.

5.8. He explained that morphine concentrations in urine are not a reliable indicator of rate of metabolism for reasons which it is not necessary to explore here.

5.9. At T322, Professor Gourlay stated his explanation for Myles' death from morphine toxicity in the early hours of 7 June 2000: "to me he must have been given a second dose somehow".

5.10. The effect of Professor Gourlay's evidence is that once the morphine concentrations in Myles' system started to abate as they appeared to do from approximately 8:00 am on 6 June, with levels of energetic activity that morning, and for a considerable period that afternoon, the effects of the ingestion on 5 June must have been at an end by, at the latest, 2:00 pm on 6 June 2000. Yet the evidence shows that Myles died approximately thirty-five hours after the supposed time of ingestion. Professor Gourlay could offer no explanation for this other than the speculative hypothesis of a second dose of morphine.

6. The pharmacobezoar hypothesis

6.1. Professor Gourlay was questioned about the possibility that a pharmacobezoar would explain the circumstances of Myles' death. At T327 he explained that a pharmacobezoar is a concretion or a solid mass or aggregation of multiple doses that have been given. He said that when a tablet is taken it is designed to disintegrate. Pharmacobezoar can occur where multiple doses are taken (usually as an overdose). The multiple tablets can come together in the stomach and form a large mass or concretion. This is usually seen at autopsy because it is of significant size. The effect of the pharmacobezoar is to give rise to a delayed toxicity creating an unexpected situation which often takes clinicians by surprise.

6.2. However, Professor Gourlay thought that the formation of a pharmacobezoar was unlikely (T329) because Kapanol is a pelletised capsule and not a tablet. He considered that because of the granular nature of Kapanol, the formation of a pharmacobezoar was "highly unlikely".

6.3. At T339 Professor Gourlay described the impact of naloxone or Narcan, the morphine antagonist. He stated that Narcan has a dramatic and immediate effect in that it displaces morphine from the receptors in the brain and spinal cord. However, it is short acting, and so if there is a continuing absorption of morphine there is a need for supplemental doses of Narcan. On the basis of this proposition, Professor Gourlay stated that the administration of Narcan in the early hours of morning of 6 June would not have prevented a second peak occurring on the night of 7 June.

6.4. At T347-348 Professor Gourlay said that the fact that Myles showed significant morphine effect in the early hours of the morning of 6 June is a contra-indication of the subsequent formation of a pharmacobezoar from the initial ingestion, because it is unlikely that significant releases of morphine into his system would have occurred at an earlier stage if a pharmacobezoar were being aggregated, because the impact of such an aggregation is to "lock away" the morphine until some subsequent time. At T350 Professor Gourlay re-emphasised his view that the hard coating of Kapanol pellets is such that the possibility of pharmacobezoar with such pellets is exceedingly low. Later on that page he described the likelihood as "highly unlikely".

7. Dr Matthew Ryan

7.1. Dr Ryan gave evidence at the Inquest. He is a Fellow of the Australian College for Emergency Medicine. He was requested to provide a report in relation to the death of Myles Smith and his report was dated 25 May 2005. It was admitted in evidence as Exhibit C26.

7.2. At T378 Dr Ryan stated that in his opinion the expected peak concentration for an overdose of slow release morphine, while not known for sure in children, would be expected to be anywhere from about three hours to twelve hours post ingestion.

7.3. I note that in general Dr Ryan's evidence was generally supportive of Professor Gourlay's evidence and opinion.

7.4. At T384 Dr Ryan stated that he agreed with the decision not to administer Narcan at 1:00 am on the morning of 6 June because according to the notes Myles' conscious state was then normal. In expressing this opinion he stated that he placed a considerable weight on the description of the nursing staff that at 1:00 am Myles was "sleeping but easily rousable". The staff member who made that note was Nurse

Ferdinands, who I have found to be an excellent witness. I think Dr Ryan is well justified in placing weight on her account of Myles' condition at that time.

7.5. In his report (Exhibit C26), Dr Ryan comments that 2150 on 6 June was an opportunity for intervention. He stated that that was the first time that he could see in the notes that it was documented that Myles had both a depressed conscious state and breathing difficulties. At T395 however, he stated that at 2150 by his calculations approximately thirty-two hours had passed since Myles was supposed to have taken the morphine. He stated "It is not unreasonable to say that the people looking after this child may have thought that the danger period for the morphine was well and truly passed at 32 hours." He repeats that remark at T398.

7.6. At T401, Dr Ryan was asked to comment on Professor Gourlay's hypothesis that a second dose was administered. He responded that the "best information available" suggests that peak level would normally be expected between three and twelve hours post ingestion and "I can't exclude the possibility of a second dose".

7.7. At T404 in cross examination, it was put to Dr Ryan that the note at 2150 hours on 6 June may have been a summary of the entire shift and this would account for the apparent incongruity between the references to Myles being very sleepy but also "eating and drinking well". At T407 Dr Ryan stated that he interpreted the nursing note for 2150 "awake for only a short time" to be a reference to a brief period of wakefulness at the time of the 2150 assessment, as opposed to meaning "awake for a short time during the entirety of the shift". If the note meant that he had been awake for only a short time during the entirety of the shift, that would place a different complexion on the interpretation of the nursing note of 2150 and cause Dr Ryan to accept the possibility that at 2150 Myles may not have had a lowered conscious state. I note that when a person is asleep one cannot assess their conscious state. It is necessary to rouse them and then formally assess their conscious state. Dr Ryan agreed that in his report, he had assumed that a proper assessment of Myles' conscious state had been carried out at 2150.

7.8. At T418 Dr Ryan stated that in his report (Exhibit C26) he had assumed that 2150 was a time when Myles had low oxygen saturations and a depressed conscious state. However, he stated that he accepted the possibility that 2150 only referred to the time

at which the note was made and that the reference to a lowered conscious state may have referred to any time during the nurse's shift and not necessarily 2150.

7.9. In the end there was no means of resolving precisely what was meant by the nursing note at 2150. At T419 Dr Ryan reflects this when he says "The difficulty I suppose is there is no clear description of the child's conscious state." In essence the lack of detailed notes recording a Glasgow coma score regularly during 6 June 2000 make it extremely difficult to form an assessment of Myles' conscious state during that day. However, what is notable is that he was certainly extremely active between 3:00 pm and 6:20 pm, to the extent that he was playing quite roughly with other children, having disputes with other children about toys, and resisting the administration of his Amoxil medication by Nurse Barrett in a quite a vigorous way. During those times, it is clear that his conscious state was certainly not lowered.

7.10. There is certainly a dilemma in this case which is well summarised by Dr Ryan at T416:

> 'I was very surprised at the sequence of events where early in the morning of the 6th there were some clinical findings which could have been interpreted as morphine toxicity. If we separate the fact that he had a normal conscious state it is then surprising that there is periods over the day, long periods over the day with normal consciousness and then he goes on to die that next night. That is surprising to me and it doesn't fit with what I understand of the pharmacokinetics of Kapanol.'

7.11. I took Dr Ryan to defer to the opinion of Professor Gourlay in discounting the possibility of the formation of a pharmacobezoar as an explanation for why morphine toxicity caused Myles' death some thirty-five hours after the supposed time of ingestion (see generally T410).

8. Summary

8.1. In summary it can be seen that there are unusual features to this case. The common wisdom of the experts was that the peak period for morphine toxicity after a Kapanol overdose should have been in the region of three to twelve hours post ingestion. The only explanations for Myles having died from morphine toxicity thirty-five hours post the supposed ingestion are:

1. The behaviour of Kapanol in Myles Smith did not conform to the expected pharmacokinetic behaviour of Kapanol. In other words, that the common wisdom, based as it is on incomplete studies of very young children, is wrong.

2. That, contrary to the opinion of Professor Gourlay, a pharmacobezoar was responsible for a delay in the release of morphine into Myles' system, and that this is the explanation for his death from morphine toxicity so long after the suspected ingestion. Against this must be weighed the fact that there were signs of morphine toxicity in Myles to quite a significant extent in the early hours of the morning of 6 June, and these signs are not consistent with the formation of a large pharmacobezoar in his body at that time which would have tended to reduce the availability of morphine for absorption by reason of its aggregation into the pharmacobezoar.

3. That a person or persons unknown administered a second dose or doses of morphine to Myles at some time between 2:30 pm on 5 June and his death in the early hours of the morning of 7 June 2000. Clearly there is no evidence to safely conclude that there was a second dose and the possibility of a second dose can be nothing more than speculation.

8.2. The state of the evidence is such that I am unable to explain how Myles Smith came to have a level of morphine in his system sufficient to cause his death in the early hours of the morning of 7 June 2000. For the reasons expressed by Professor Gourlay I think it unlikely that a pharmacobezoar was responsible. Certainly no evidence of a pharmacobezoar was noted at autopsy and typically in cases where a pharmacobezoar has formed, it is noted at that stage. In the circumstances, I can only conclude that the medical profession should be warned that Myles Smith's was an apparent case of morphine toxicity appearing some thirty-five hours after the suspected time of ingestion of an overdose of Kapanol, and that the approach acceptable in adults of assuming that the danger period has passed within twelve hours or so is not a safe assumption in the case of very young children. However, I make no criticism of Dr Connolly or any of the staff of the Whyalla Hospital in relying on the assumption in this case. The information was based on that provided by the Poisons Information Centre and apparently conformed with the best available scientific knowledge. For these reasons, I do not consider that the care of Myles by the hospital or Dr Connolly was in any way to be criticised. It would have been preferable had the notes been

expressed with greater clarity so that the course of Myles' condition could have been more readily ascertained. Beyond that, I make no comment.

9. The packaging of Kapanol and similar dangerous drugs

9.1. A letter dated 10 April 2006 was received by Counsel Assisting me in this matter. It was sent by Dr Ronald Somers, the Unit Head, Injury Surveillance and Control, Acting Director, Epidemiology Branch with the Department of Health.

9.2. Dr Somers is a member of a specialist sub-committee on child resistant packaging convened in 2005 by the Therapeutic Goods Committee of the Therapeutic Goods Administration of Australia. According to Dr Somers there is currently no performance standard for child resistance covering the blister pack packaging commonly used for pharmaceuticals in Australia. On the other hand other countries have standards that require child panel testing of blister packaging intended for use with medications considered hazardous. Dr Somers provides evidence that two year old Australia children can access medications contained in blister packaging. With respect to Professor Gourlay whose views on this subject differed, I can readily accept the evidence contained in Dr Somers' letter that two year old children could access medications in blister packaging quite readily. Dr Somers' letter makes reference to a letter by Elizabeth Hender and Corrine Balit published in the Medical Journal of Australia in 2005 entitled "Which medicines do young children access from blister packs". The letter states:

> 'Our study shows that blister or strip packs currently in use did not prevent children accessing drugs. This finding calls into question whether blister or strip packaging that has not been child tested presents an adequate safety barrier.'

9.3. The children involved in that study were between the ages of one and three years, with twenty four cases of children between the ages of one and two years of age accessing medication directly from blister packs, and ninety five case of children between the ages of two and three years accessing medication directly from blister packs.

9.4. The letter from Dr Somers and the attached letter to the Editor of the Medical Journal of Australia (together forming Exhibit C30) are attached to these findings.

10. The involvement of the Department for Families and Communities with the children of Jillian Allbrite

10.1. Material available to the Court showed that there has been an extensive involvement of the Department for Families and Communities and its predecessor agencies with the children of Jillian Allbrite and Allan Smith. By letter dated 5 April 2006 to the Crown Solicitor, Counsel Assisting me in this matter advised that:

> 'The Coroner formally invites the Department for Family and Community Services to make a written submission as to the Department's approach to the issues arising out of the Smith family and the considerations affecting whether intervention could have occurred prior to Myles' death. The Coroner may be making reference to this in his findings.'

10.2. No such submission was received. Of course, this invitation did not preclude the making of any oral submissions that the Department might have instructed the Crown Solicitor to make. Had an application been received for leave to appear for that purpose, leave would have been granted. Instead, correspondence was received stating that the Department did not have enough time to respond, that in any event the "principle of sub judice" meant that it was "inappropriate to seek to make submissions at this time". The "principle" of sub judice thus invoked related to proceedings which are apparently on foot in the Children's Court. I do not accept that there is any relevant principle of "sub judice" which prevents a litigant in the Children's Court from attending the Coroner's Court to assist that Court when it is appropriate and necessary to do so. Matters of confidentiality can be addressed as and when they arise by appropriate orders if necessary. The sub judice convention is one which governs debate in the Houses of Parliament in relation to matters which are before a Court. I have not previously heard of it being invoked to preclude discussion of material in a Court simply because the same material is in some way relevant to the subject matter of proceedings in another Court. In my view this objection to assisting the Coroner's Court was misconceived.

10.3. Finally, it was said that a particular officer of the Department for Families and Communities was unable through illness to provide necessary instructions. In answer to this I can only say that one would have hoped that the Department's capacity to make submissions in relation to the matters foreshadowed in the letter from Counsel Assisting to the Crown Solicitor would not have been hindered by the unavailability of one officer.

10.4. In my opinion, the role of the Department for Families and Communities is one which requires investigation in this case. Accordingly, I have decided, pursuant to section

52S(3)(e) of the Children's Protection Act, 1993, to refer the death of Ian Myles Smith to the Child Death and Serious Injury Review Committee established under that Act. I indicate that the transcript and exhibits in these proceedings will be made available to the Committee to assist it in its review.

11. Recommendations

Pursuant to section 25(2) of the Coroners Act 2003 I recommend:

1. That the Minister for Health give consideration to the contents of Exhibit C30 with a view to considering the introduction of appropriate standards in South Australia for the child-proofing of blister packaging for hazardous pharmaceuticals.

2. That the Child Death and Serious Injury Review Committee carry out a review, pursuant to section 52S(3)(e) of the Children's Protection Act, 1993, into the death of Ian Myles Smith.

Key Words: *Access by children to dangerous medication; Blister packaging; Children - leave unattended, Family & Community Services - Dept of; Kapanol; Morphine (Morphine Toxicity); Slow Release Opiates;*

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

Seal the 16th day of June, 2006.

State Coroner

Government of South Australia

Department of Health

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10 April, 2006

Ms Sophie Downey
Counsel Assisting
State Coroner's Office
302 King William St
Adelaide

Dear Ms Downey,

Re Ian Myles Smith

Thank you for the opportunity to comment on the child resistance of blister packaging for medications sold in Australia.

The range of therapeutic products that require child resistant packaging, *and the standards that should apply to that packaging,* are currently under government review. This work is being done to support the implementation of a single, bi-national regulatory body, the Australia New Zealand Therapeutic Products Authority, that will ultimately replace both the **Therapeutic Goods Administration (TGA)** in Australia, and **Medsafe** in New Zealand.

I am a member of the specialist Subcommittee on Child Resistant Packaging that was convened in 2005 by the Therapeutic Goods Committee of the TGA to consider amongst other Terms of Reference:

> *"Issues related to the child-resistant packaging of therapeutic products that are of concern to injury prevention agencies and health departments, including the performance of blister packaging as a child resistant barrier"*

Documents relating to the proposed requirements for child-resistant packaging under the Australia New Zealand Therapeutic Products Authority were released on 4th April 2006 for stakeholder consultation (http://www.anztpa.org/consult/crp.htm).

An extract from Page 3 of the draft Managing Director's Order contained on that website indicates that serious doubt exists about the assumed inherent child resistance of blister packaging:

> *"At this time, requirements for non-reclosable child-resistant packages such as blister or foil strips do not involve performance testing, but instead are based on specified materials of construction.* ***While this form of packaging has been regarded to date as inherently child-resistant, and there is historical evidence that this is so, there is also mounting evidence that the robustness and effectiveness of blister or foil strip packaging as a child barrier needs to be increased in order to further reduce instances of accidental childhood poisoning"*** *(emphasis added).*

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In spite of this consensus view, there is no proposal under the new scheme to require that standard blister packaging be replaced by more robust blister styles, even for the most toxic medications.

There is currently no performance standard for child resistance covering the blister packaging commonly used for pharmaceuticals in Australia.

At the present time, there is a major disparity between the packaging requirements that apply to reclosable packaging (ie bottles with caps) and those that apply to non-reclosable packaging (blisters or strips), for medications that are considered sufficiently hazardous to warrant special protective measures. A specific performance standard applies to bottles, but there is no such standard for blisters.

Under the current Therapeutic Goods Order No 65 (TGO-65), *Child Resistant Packaging for Therapeutic Goods*, only reclosable containers have to be tested with panels of children to show that they meet the requirements of (among other things) Australian Standard AS 1928-2001 *Child Resistant Packages*.

Other countries have standards that require child-panel testing of blister packaging intended for use with medications considered hazardous.

Countries including the USA, UK, Germany and Canada have standards that require child testing of blister packaging intended for use with medications deemed sufficiently hazardous to require child-resistant measures. In the USA such standards have been in place since the early 1970's. Canada has had a relevant standard since 2000.

The UK's **Medicines Control Agency** implemented last year requirements similar to those in North America, following the death in Year 2000 of a three-year-old child who extracted 44 iron tablets from blister packaging.

Relevant Research Evidence

Research undertaken by Burford Research Consultants in the UK in 1995, and the US Consumer Product Safety Commission (CPSC) in 1998, provided evidence that conventional blister packaging is not sufficiently child resistant. In the former study, 40 children aged 42-51 months were given 15 placebo tablets in a blister package. The test results from two five-minute test periods showed:

- 17 (42.5%) of the children accessed all fifteen tablets in the first five minutes, prior to demonstration; and
- 36 (90%) of the children accessed all fifteen tablets during ten minutes of testing, subsequent to demonstration.

The latter study by the CPSC involved children aged 42-51 months being given unlimited numbers of conventional blister packages. The test results from two 5-minute test periods showed:

- The average number of conventional blisters opened was 23 (range 0-85); and

- The average time to open the first blister was 169 seconds.

My Unit's own research involving Australian children confirms the overseas finding that conventional blister packaging is not inherently child resistant. In 2003 and 2004 an independent test agency which does the majority of the Australian certification for child-resistant packaging was selected to test three blister packages containing placebos. Two of these blister packages were typical of blister packaging used in Australia, and the third was a more robust blister package that had been shown in overseas studies to exhibit superior child-resistant properties.

As Australian Standard 1928-2001 does not require child testing for blister packaging, the testing was conducted using British Standard BS 8404:2001 *Packaging-Child resistant packaging-Requirements and testing procedures for non-reclosable packages for pharmaceutical products*. The requirements of this standard specify that the packaging fails if the child removes more than eight units from the package within a ten-minute session (made up of two five-minute test sessions and a demonstration opening if the child fails to open any blisters during the first five minutes).

In our tests, each child was given one blister card of ten placebos. The first conventional blister package failed the test requirements of BS 8404:2001. Nine of the ten children tested were able to remove all ten placebos in the first five minutes. The time taken to get the first placebo out ranged from one second to two hundred and eighty-five seconds. The average number of placebos the children were able to remove in the first five minutes was nine.

While the children were able to see the placebos through the clear plastic blisters on the first blister card, the second conventional pack tested was opaque with perforations between the blister pockets (not dissimilar to Kapanol, the product involved with Ian Myles Smith). The second pack also failed the requirements of BS 84904:2001. Of the ten children tested, seven were able to remove more than eight placebos within ten minutes. The time taken to remove the first placebo ranged from 20 to 320 seconds (average 122 seconds). The average number of placebos the children were able to remove in the first five minutes was about six.

The low level of child resistance that this study found for the conventional blister packaging tested is similar to overseas research findings. Note that the third package tested (incorporating a secondary layer applied directly to the foil of a conventional blister pack) met the child test requirements of BS 8404:2001. The number of placebos removed in ten minutes ranged from zero to eight. The time taken to remove the first placebo ranged from 87 to 593 seconds (average 346 seconds). Nearly half of the children did not remove even one placebo from the pack during ten minutes of testing. None of the children were able to remove more than two placebos in the first five minutes. This finding illustrates the important difference between the concepts of child resistance and child proofness. Even robust packaging is not child proof, but it can be markedly more child resistant than standard packaging.

Age of children used to test child resistance of packaging.

The peak age at which children are at risk of poisoning by pharmaceuticals is 2-3 years. The age of children specified for testing in the US, German, UK and British

Standards however is *above* this age (ie 3.50–4.25 years). The use of slightly older children is justified on the grounds that:

- Older children are easier to work with;
- Older children are likely to be more capable than younger children, ie the packaging is challenged with children most likely to have the dexterity to succeed; and
- Ethical considerations are better managed. A child's participation in such a trial has an unintended "teaching" effect that may increase the likelihood of the child accessing medicine in a subsequent real life setting. There would be serious ethical issues in testing younger children who are already at their peak statistical risk of poisoning.

Evidence that two-year-old Australian children can access medications in blister packaging.

Data on the type of packaging (reclosable versus non-reclosable) associated with accidental medication exposures in children are not routinely collected by Australian Poisons Information Centres. Information on the particular medication, or how the child accessed it, is likewise not available from other routine sources (e.g. ABS deaths data, hospital-separations data).

The attached letter, "Which medicines do young children access from blister packs", by Elizabeth Hender and Corrine Balit, was published in the *Medical Journal of Australia* in 2005. I believe that it reports the only study where data were collected on the means by which children accessed medicines. The aim of the study was to determine which medicines children younger than five years accessed directly from strip or blister packaging. Callers phoning the NSW Poisons Information Centre were questioned about the circumstances of the poisoning incident. Hender and Balit reported that over a nine-week period in 2003 there were 186 exposures where "the caller said the medicine was normally in a blister or strip pack, and the child obtained it directly from the pack". Their letter states:

> "Our study shows that blister or strip packs currently in use did not prevent children accessing drugs. This finding calls into question whether blister or strip packaging that has not been child tested presents an adequate safety barrier."

That study reported the collated results of children less than five years of age.

Given the age of Ian Myles Smith, contact was made with one of the authors, Corrine Balit, to request information about how many two year olds were in this total. Her email reply dated 5th April 2006 advised:

> "For the study data that were presented in the *MJA* regarding blister packs there were 24 cases between the ages of 1 and 2 years of age who accessed medication directly from the blister pack. There were 95 cases of children between the age of 2 and 3 years of age that accessed medication directly from the blister pack."

Use of blister packaging for pharmaceuticals required to be in child-resistant packaging.

Specific data on the proportion of pharmaceuticals in blister packaging is not available, however we have estimated that approximately 80%of the pharmaceuticals that require child resistant packaging in Australia are packaged in blisters. This estimate is based on a review of the type of packaging used for 720 products listed in the relevant government circular (TGO-65).

There are advantages in using blister packaging for pharmaceuticals, compared with use of reclosable packaging, in relation to:

- Enhanced protection of the product over a long shelf-life;
- Tamper- evidence;
- Enhanced patient adherence with dosage regimens: patients can more easily tell if they have taken or missed a dose; and
- Convenient storage and portability.

As a result of these advantages, the proportion of drugs packaged in blisters is likely to be maintained or increased.

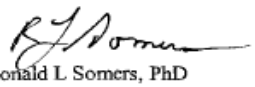
Conclusion

Australia has a poor tradition in pharmaceutical packaging. The most toxic medications, even those where a single tablet would be lethal to a child, can be sold in the same style of blister pack as non-hazardous preparations.

This is allowed even though these blister packs are now known, from overseas and Australian research, to be easily opened by young children.

Overseas, specific nominated drugs can only be sold in blister packs with proven child-resistant properties, but in Australia no proof of blister-pack safety is required. No tests are conducted to evaluate the child-resistance of the packaging—blister packs are simply assumed to be child resistant, in the face of excellent evidence to the contrary.

Evidence from recently reported poisoning cases suggests that some two-year-old children can readily access medication from a standard blister pack.



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Letters

Which medicines do young children access from blister packs?

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TO THE EDITOR: Although there are few deaths due to poisoning in Australian children, from 1993 to 1997 there was an average of more than 2500 admissions to hospital per year for assessment of poisoning with medicines in children younger than 5 years.[1]

Child-resistant packaging has been effective in preventing accidental poisoning with prescription medicines and aspirin in young children in the United States.[2,3] In the US, both reclosable and non-reclosable (blister or strip) packaging used for pharmaceuticals required to be in child-resistant packaging is tested to confirm its effectiveness in preventing access by children.[4] In Australia, only reclosable packaging is required to be child-tested. Blister or strip packaging, which has not usually been child-tested, is accepted as an alternative to child-resistant reclosable packaging.[5]

We conducted a study at the New South Wales Poisons Information Centre (NSWPIC) over 9 weeks from 18 July to 17 September 2003. Our aims were to ascertain which medicines children younger than 5 years access directly from blister or strip packaging, and whether assessment at a hospital was recommended. The study was approved by the Ethics Committee of the Children's Hospital, Westmead.

Callers ringing about a suspected accidental ingestion of a solid dose medicine in a child younger than 5 years were asked whether the child accessed the medicine directly from a blister or strip pack. There were 318 accidental exposures to solid dose medicines in these children during the study period. In 186 exposures (58%), the caller said the medicine was normally in a blister or strip pack and the child obtained it directly from the pack.

A wide range of medicines (40 different drugs or drug groups) were associated with the exposures; the most common were oral contraceptives (49 exposures) and paracetamol (27 exposures). Some of the exposures involved medicines that can cause severe toxicity when children ingest a small number of dose units, such as clonidine, olanzapine, narcotic analgesics, and tricyclic antidepressants.

In 36 exposures where the child obtained the medicine directly from the pack, the caller was advised to take the child to hospital (Box). Many of the medicines associated with these exposures (eg, paracetamol, preparations containing narcotic analgesics, antidepressants, antihistamines, iron and clonidine) are required to be in child-resistant packaging.[5]

Our study shows that blister or strip packs currently in use did not prevent children accessing drugs. This finding calls into question whether blister or strip packaging that has not been child-tested presents an adequate safety barrier.

No outcomes of drug ingestion are known in this study, which is a limitation. However, assessment of these children in hospital represents a financial burden to the health care system regardless of the outcome. Further studies would be required to quantify the harm associated with exposures to medications packaged in blister or strip packaging in young children and to assess the effectiveness of such packaging in the prevention of poisoning.

Drugs accessed from blister or strip packs where child required referral to hospital

Drug or drug group	Number of exposures
Paracetamol	8
Paracetamol/narcotic combination analgesics	3
Selective serotonin re-uptake inhibitors	3
Antidepressant: other/unknown	2
Antiemetics	2
Antihistamines	2
Cough/cold preparations, no paracetamol	2
Iron	2
Other (eg, clonidine, olanzapine)	12
Total	**36**

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