IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2012 0380

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)
Section 67 of the ***Coroners Act 2008***

I, IAIN TRELOAR WEST, Deputy State Coroner having investigated the death of Dane Alexander HORTLE

without holding an inquest:

find that the identity of the deceased was Dane Alexander HORTLE

born on 14 August 2009

and the death occurred on 30 January 2012

at The Royal Children's Hospital, 50 Flemington Road Parkville, 3052 Victoria

from:

1 (a) TRAMADOL TOXICITY IN THE SETTING OF ADENOTONSILLECTOMY IN A CHILD WITH PIERRE ROBIN SEQUENCE

Pursuant to section 67(1) of the **Coroners Act 2008**, I make findings with respect to **the following circumstances**:

1. Dane Hortle was a 2-year-old boy who was the son of Mr Mark Hortle and Ms Aderyn Free.
2. Dane's medical history included a cleft palate, Pierre Robin Sequence, tied tongue and a mild obstructive sleep apnoea. On 4 April 2011, he underwent surgery to repair his cleft palate, release his tongue tie and have grommets inserted. Medical records show the administration of pain relief medication including Tramadol by nursing staff on 4 and 5 April 2011. There were no complications as a result of his surgery, although it was noted by his parents upon discharge that his breathing subsequently became more laboured. It was considered that Dane may have suffered from swelling from the surgery and after some time, his breathing returned to what it was before the surgery.
3. During a follow up visit to the Monash Medical Centre on 23 September 2011, Dane was diagnosed with '*severe obstructive sleep apnoea with marked deterioration from previous study December 2010 after clef palate repair.*' He was referred to Respiratory Physician Dr Jo Harrison and during subsequent consultations, surgeries such as tonsillectomy, partial adenoidectomy and jaw distraction were discussed. Ultimately the decision was made to proceed with a tonsillectomy and partial adenoidectomy.
4. On 24 January 2012 at 7am, Dane was admitted to the Royal Children's Hospital (RCH) where Dr Eric Levi performed the procedure under close supervision of Dr Caroline Ryan (Ear Nose and Throat Surgeon). Medication records show the administration of pain relief

medication including Tramadol by nursing staff on 24 January 2012 at 1.15pm and 7.45pm. There were no complications with the surgery and Dane was kept overnight for observation. At 2am on 25 January 2012, Dane exhibited evidence of oxygen desaturation where his levels dropped to 79%. However, this self-resolved within 30 seconds. His last dose of medication was paracetamol at 3am.

5. On 25 January 2012 at 8.30am, Dane was discharged from the RCH. Dr Levi provided Dane's parents with a prescription for 25mg of Tramadol and 180mg of Paracetamol. Tramadol comes in various formulations including oral drops, capsules, tablets and parenteral preparations. Ms Free asked Dr Levi what Tramadol was and he stated that it was '*slightly stronger than Panadol*' and that it was to be given alternative to Panadol to keep up a constant level of pain relief. Dr Levi indicated that he does not believe that he gave Dane's parents information regarding the method of administering the Tramadol or possible side effects, expecting the Pharmacist to provide that information.

6. Ms Free attended the Wood Pharmacy at the ground floor of the RCH which is an independently owned retail pharmacy. The Hospital pharmacy which is also located within the RCH is subject to the Hospital's procedures and directions and is only able to fill prescriptions for patients of the Hospital. Ms Free was provided with Tramal Oral Drops by the pharmacist and was informed of the dosage required (100mg/mL, 10 drops four times a day) and Paracetamol (3.75mg four times a day). The family commenced their journey home to Wodonga at about midday. Prior to leaving, Dane was administered Paracetamol by Ms Free as prescribed. At about 2.30pm, Ms Free provided Dane with his first dose of Tramal. She utilized the built in dropper to measure 10 drops into the cap of the bottle and gave it to her son to drink.

7. The family arrived in Wodonga between 4-4.30pm and Dane appeared to be happy, riding his bike outside for a short period of time. At 5.30pm, he was administered Paracetamol as prescribed. He ate a small amount of dinner and was drinking water and juice. At about 9pm, he was administered his second and final dose of Tramal by Mr Hortle. He also used the built in dropper to administer 10 drops and Dane fell asleep shortly after taking the medication.

8. On 26 January 2012 at 6.45am, Ms Free checked on Dane and noted that his breathing sounded congested and he had brown mucus coming from his nose and mouth. She contacted the RCH and attempted to wake her son, but he was unresponsive.

9. At 6.58am, paramedics arrived and found Dane to be cyanosed around the lips. He also had a slow respiratory rate, pinpoint pupils and was deemed unconscious with a Glasgow Coma Score of 3. He was conveyed to the Albury Base Hospital where he was identified to be suffering multi organ failure, cardiac failure, probable seizures, severe lactic acidosis, severe hypoglycaemia, renal impairment and coagulopathy. He was subsequently resuscitated and intubated.

10. At 3.40pm, Dane was transferred by Air Ambulance to the RCH Intensive Care Unit arriving at 4.22pm. A CT head scan showed diffuse cerebral oedema, multiple areas of hypodensity, developing hydrocephalus and tonsillar herniation of likely hypoxic ischaemic origin. MRI brain scan confirmed the severity of the brain injury. Neuroprotective measures were undertaken and he remained stable for the first 24 hours. A repeat MRI brain on 28 January 2012 showed progressive decompression of the brainstem from the cerebellum. Dane was taken to theatre for a posterior fossa decompression with muscle flap. The scan confirmed the severity also of the supratentorial lesions.

11. A further MRI brain scan on 30 January 2012 clearly showed brainstem compression and diffuse lesions of the cerebellum and supratentorial white and grey matter and basal ganglia. Blood tests, metabolic screens and viral studies and CSF analysis never showed sign of infection. The scans were reviewed by the neurologist Dr Freeman who confirmed hypoxic ischaemic origin of the lesions identified and predicted a very poor neurological outcome. On the basis of this and the high risk of sudden cardiac arrest secondary to tonsillar herniation, both parents decided to withdraw active treatment. Dane was declared deceased on 30 January 2012. The treating physician at the RCH thought the possible cause of death was airway obstruction leading to prolonged hypoxic injury. They also considered Tramadol induced seizure and aspiration as a cause of respiratory depression although felt this was unlikely since two previous doses had been received without side effects.

Forensic Pathology Results:

12. Forensic Pathologist Dr Yeliena Baber from the Victorian Institute of Forensic Medicine performed an autopsy on Dane and provided a written report of her findings. Post mortem examination revealed a slightly dysmorphic male child with no obvious micrognathia. There was evidence of recent medical intervention as described in the clinical history. Internal examination reveals an anatomically normal larynx with two small areas of ulceration immediately below the vocal cords consistent with intubation. There was no evidence of oedema, infection or haemorrhage. There was no evidence of micrognathia. Histology showed mild chronic sialadenitis within the submandibular gland. Some chronic inflammation was seen in the larynx, however none to a degree that would be considered significant. Features were seen within the heart consistent with the ante mortem use of inotrope, and there was ischaemic hepatitis within the liver.

13. Neuropathology showed extensive watershed infarction and extensive patchy white matter infarction with neuronal ischaemic injury throughout both hippocampi. Dr Padma Pao, Consultant Radiologist at the RCH reviewed the ante mortem CT and MRI scans with a view to nasopharyngeal airway measurements. On the MRI of 26 January 2012, there was narrowing of the nasopharyngeal airway at the level of the adenoids to approximately 2.3 mm in calibre. Reviewing a publication (*Upper Airway Measurements During Inspiration and Expiration in Infants, Paediatrics vol. 84, no. 1 July 1989*) upper airway measurements of infants at six weeks of age had a posterior airway space of 10.5 mm i.e. almost adult size. However, adenotonsillectomy procedures are performed frequently on children of varying ages (and adults), and these postoperative features of airway narrowing will be present in all cases without subsequent demise of the patient.

Scope of the Investigation of the Death:

14. The Court received correspondence from Dane's family, and solicitors acting on their behalf, raising multiple questions to which they are seeking answers. Whilst I understand their need for answers, I have limited my investigation to identifying and recording the essential facts sufficient to enable the findings required by s.67(1) of the *Coroners Act 2008*.

Expert Opinions:

15. Toxicology showed therapeutic levels of morphine, midazolam and bupivacaine. Tramadol in ante mortem blood was found at a concentration of 1.4mg/L and in post-mortem blood at 0.1mg/L. Dr Baber subsequently requested an expert opinion from Dr. Dimitri Gerostamoulos, Chief Toxicologist at VIFM regarding these levels. Dr Gerostamoulos noted that the recommended dose of Tramadol oral drops in children between the ages of 2 and 12 years is '*1-2 mg/kg, 3 or 4 times daily. Dane was 12.8kg and therefore according to recommended doses should receive 12.8 – 25.6 mg x 3 -4 times per day. This is equivalent to*

50 – 100 mg assuming administration 4 times daily. The amount administered to him was 100mg daily. The concentration of tramadol detected in the ante mortem specimen is elevated and consistent with excessive administration and has the potential to produce toxicity. The blood concentration of 1.4 mg/L in the ante mortem specimen does not seem consistent with either the recommended dose or the amount instructed to be given to Dane... The laboratory has examined a sample bottle of Tramal drops to correlate the amount of drug dispensed as per instructions. The amount of tramadol dispensed after 20 drops is equivalent to 50mg. This is equivalent to 0.5mL of Tramal drops which is stated by the manufacturer.'

16. He summarized that '*a higher dose of Tramadol or multiple doses of Tramadol had been given. The recommended dose of oral drops of tramadol of 50-100 mg/day would not result in concentrations of 1.4 mg/L. Even the dose as instructed by the referring physician/clinician of 100mg would not result in the determined concentration of 1.4mg/L of Tramadol in blood unless this child was genetically unable to metabolise tramadol or had liver/kidney dysfunction.*' No evidence of renal dysfunction was identified and microbiology showed no significant pathogens.

17. In Dr Baber's opinion, Dane's death was due to extensive cerebral infarction as a result of respiratory depression due to tramadol toxicity. This is in the setting of adenotonsillectomy in a child with Pierre Robin sequence. There is no doubt that the ante mortem Tramadol levels were excessive. According to Dr Gerostamoulos, convulsions are reported in adult patients receiving Tramadol at recommended dose levels; larger doses of Tramadol can lead to respiratory depression. It is not possible to determine to what extent the craniofacial anomalies and postoperative swelling may have contributed to the hypoxic event on the night of 25 January 2012 which then lead to the clinical course described above.

18. A further expert opinion was obtained from Clinical Pharmacologist at the Austin Hospital, Dr Chris O'Callaghan. His findings were that;

    a. In healthy children, the half-life of Tramadol has been recorded as 3-4 hours but it is slightly longer in young adults.

    b. A substantial concentration of Tramadol was found in Dane's blood about 21 hours after the last known ingestion. This suggests that his ability to remove Tramadol was impaired. Tramadol is removed by both the kidneys and liver. At the time of the Dane's admission to the Albury Hospital, he was displaying signs of renal and liver dysfunction that had almost certainly been present for some hours. Thus, delayed drug removal may have contributed to the elevated Tramadol concentration.

    c. If it is assumed that Dane's ability to clear Tramadol was normal until the night of 25 January, only about 1/3 of the first dose of Tramadol would have been in his body at the time of the second dose.

    d. An elevated Tramadol concentration would be expected to inhibit respiration which may cause hypoxia (low oxygen levels in blood). Thus it could be that Dane's cerebral damage was caused by respiratory sedation secondary to an excessive dose of Tramadol. The likelihood of this scenario is increased by his known history of respiratory problems, so even if the dose was not massive, Dane would have been more at risk than other children.

    e. Tramadol can also cause seizures. Dane's blood test at Albury Hospital revealed elevation of the plasma creating kinase which is an enzyme derived from muscle and which is often elevated after strenuous muscle activity e.g.: a seizure. It is

conceivable that Tramadol caused a seizure which caused inadequate ventilation which resulted in brain damage.

f. Dane's death was most likely caused by an excessive dose of Tramadol that caused a seizure, respiratory depression or both and this led to irreversible and severe brain damage.

g. The characteristics of Tramal Oral Drops are '*consistent with the overdose being accidental*' and it is specifically designed for use in adult patients. The documentation for its use recommends doses that are specific to adults and potentially toxic to children.

19. Dr O'Callaghan queried whether Tramal Oral Drops should continue to be used in Victorian health care settings and advised the Court to seek further input on this matter. As a result, the Coroners Court obtained further statements from;

    a. Dr Michael Fraser (Chair, Child and Young Person's Health Network)

    b. Professor Edward Shipton (Dean, Faculty of Pain Medicine)

    c. Dr Noel Cranswick (Clinical Pharmacologist, Royal Children's Hospital)

    d. Dr Jane Leong (Vice President bioCSL)

20. The statements received suggested that none of the formulations of Tramal, including Oral Drops are approved by the Therapeutic Goods Administration for use in children less than 12 years of age in Australia. The use of Tramal Oral Drops in children under the age of 12 years of age is off license.

21. Professor Shipton also made it clear that for children under 12 years of age, the risk increased as the child's age decreased due to the smaller and smaller volumes required. The risks increased further depending on medical co-morbidities such as craniofacial abnormalities, obstructive sleep apnoea or potential bleeding, some conditions which Dane suffered from. Further, measuring a dose accurately would be difficult '*when administering to a small child who may be distressed, crying and/or struggling due to recent surgery. It would be easy to overdose due to high concentration of solution.*' The Faculty does not believe there is a situation where Tramal Oral Drops are the best clinical option for children under 12 years of age for acute pain.

22. Dr Cranswick's opinion makes it clear that Tramal Oral Drops are not as safe as other preparations of Tramadol '*due to the significant risk of mis-dosing and given their concentration, the risk of significant overdose*. Further, '*Tramadol Oral Drops should never be used in children for any indication because of the safety risks*' and '*Tramadol Oral Drops should not be used as a clinical option in treating paediatric patients.*' BioCSL, the distributors of Tramal in Australia also do not endorse or recommend the use of Tramal Oral Drops in children under 12 years of age.

23. Professor Shipton, Dr O'Callaghan and Dr Cranswick conclude that the removal of Tramal Oral Drops from the Australian Register of Therapeutic Medicine would be an improvement in safety for children and would have minimal clinical implications in **paediatric** medicine. However, Professor Shipton noted that removal could disadvantage a significant number of adult patients with severe pain.

Submissions from the RCH:

24. On 4 September 2015, the RCH provided submissions indicating the following;

a. That Dane was not prescribed Tramal Oral Drops by Dr Levi upon discharge. He was not prescribed either a particular brand (Tramal) or a particular formulation (oral drops). The prescription was for the drug Tramadol 25mg, four times a day as required.

b. All drugs for use in the Hospital have to be approved by the Drug Usage Committee. The Committee did not approve using Tramadol in oral drop form for use in the Hospital (including the Hospital's pharmacy). The Hospital used and continues to use other forms of tramadol for patients and the Hospital's practice before and after Dane's death was to administer tramadol 50mg capsules.

c. The fact that a drug is 'off license' does not mean it is not safe for paediatric use. It is standard clinical practice to prescribe 'off license' medications in a paediatric setting...It is the Hospital's view that without the use of 'off licence' medications, children would be significantly under treated.

d. Dr Levi's usual practice in relation to what he would advise parents on discharge is that parents should be careful about the amount of pain relief they give and they should not exceed the daily doses of the drugs. There is no basis on which the Coroner can be actually satisfied on the *Briginshaw*[1] standard that Dr Levi failed to impress upon Dane's mother the need to comply with the maximum daily dose of Tramadol, and to be careful when giving him pain medication. Dr Levi did not need to go on and explain the possible complications if the prescribed dose was exceeded- the critical information was to be careful and not exceed the prescribed dose.

Changes to RCH Procedures and Systems since Dane's death:

25. The RCH has made a number of 'significant system improvements in relation to the information given to patients at discharge as well as changes in post-operative care.' Since Dane's death, a new information sheet for parents in relation to tonsillectomy and adenoidectomy discharge care was developed. The information sheet is now given to all patients upon discharge.

    a. The information sheet includes suggestions about checking on the child at least twice per night for bleeding or difficulty breathing and also recommends that a parent sleep in the same room as the child if they are under four years of age.

    b. Parents whose children had been discharged with Tramadol prescriptions are also now provided with the Hospital's Tramadol information sheet whilst they are still on the ward, prior to discharge. The information sheet contains clear instructions in relation to how to take Tramadol as well as providing a warning in relation to the oral formulation which states

        i. '*A liquid product of oral drops is also available. The liquid drops are very strong and designed and licensed for use by adults only. The RCH does not stock and does not recommend the use of oral drops because of the risk of overdose in small children.*'

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[1] *Briginshaw v Briginshaw* (1938) 60 CLR 336 at pages 362-363 '...reasonable satisfaction is not a state of mind that is attained or established independently of the nature and consequences of the fact or facts to be proved. The seriousness of an allegation made, the inherent unlikelihood of an occurrence of a given description, or the gravity of the consequences flowing from the particular finding are considerations which must effect the answer to the question whether the issue has been proved to the reasonable satisfaction of the Tribunal. In such matters "reasonable satisfaction" should not be produced by inexact proofs, indefinite testimony or indirect inferences..."

c. Parents of children who have been discharged with a Tramadol prescription are also encouraged to have their prescriptions filled at the Hospital pharmacy, rather than a community pharmacy as Tramadol drops are not available.

d. The Hospital also developed an internal protocol for post-operative management of patients undergoing tonsillectomy and adenoidectomy. This identifies that certain groups of children including those with severe OSA on oximetry *may* need to say in hospital for more than one night. The protocol indicates the criteria for a child to stay a second night are;

   i. Three or more clusters of desaturation under 80

   ii. One large, severe desaturation-either prolonged or into the 70s and;

   iii. If significantly worse than the pre-operative test.

e. The Hospital submits that Dane would have not met the 2015 criteria to stay on additional night because he only had one, or possibly two, minor desaturations that self-resolved within 30 seconds and because his oximetry results following surgery had improved.

f. A standardised analgesic ladder was developed which moved Tramadol from a second line analgesic to a third line analgesic for tonsillectomy and adenoidectomy.

g. Tramadol oral drops have never been part of Hospital medication formulary. The Hospital has updated its Pharmacopoeia (the Hospital's internal dosing reference) to clearly recommend capsules as the preferred formulation and a statement that the RCH does not recommend the use of concentrated drops because of its significant risk of overdose in small children.

h. The Hospital endorses the view of Dr Noel Cranswick that if Tramadol oral drops were removed from the Australian Register of Therapeutic Goods, it would be an improvement in safety for children.

i. Dane was not prescribed Tramal Oral Drops but rather Tramadol which is a standard analgesic provided to children following tonsillectomy and adenoidectomy.

j. The Hospital submits that just because they prescribed Tramadol which Dane took, is insufficient to justify causation in this case. The prescription would only be causal if there was some departure from the standard of reasonable care in so prescribing-no expert opines that the prescription of Tramadol was inappropriate.

k. The Hospital submits that there is simply no causal connection between Dane's discharge from the Hospital and his death or that any conduct of the Hospital during Dane's admission was an '*essential link*' in the chain of causation of his death.

Submissions from Wisewould Mahony:

26. On 19 October 2015, Wisewould Mahony, the solicitors for the Hortle family provided submissions indicating the following; For determining causation for death 'it is sufficient if a person's act or omissions are *a* cause of the relevant event.'[2] It follows that there can be a finding that there was more than one cause of Dane's death, with no need to characterise or seek to identify whether a cause is essential or primary.

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[2] *Keown v Khan* (1999) 1 VR 69 at 16

a. In considering the conduct of the Hospital, the proper inquiry is whether there was an aspect of the Hospital's conduct which was wrongful, in the sense that there was a departure from the standard of care required from the Hospital and its staff to Dane, and if so, whether the wrongful conduct was an element in the set of actual conditions that were sufficient to cause Dane's death.[3] The wrongful acts or omissions in this case were part of the set of conditions that led to Dane being dispensed with Tramal Oral Drops and suffering an accidental overdose.

b. They disagree that there is no basis on which the Coroner can be satisfied on the *Briginshaw* standard that Dr Levi failed to impress upon Ms Free the need to comply with the maximum daily dose of Tramadol and to be careful when giving pain medication. Dr Levi's claimed 'usual practice' is contrary to the evidence of Ms Free about what he told her on Dane's discharge. Notably, Ms Free did not say that Dr Levi impressed on her the need to comply with the maximum daily dose of tramadol or to be careful when providing the pain medication.

c. Further, that Dr Levi failed to warn Ms Free about the side effects of Tramadol as well as the possible toxicity if the prescribed dose was exceeded which was contrary to the standard expected of a medical practitioner. According to *Roger v Whitaker*[4] the doctor has a duty to '*warn a patient of material risk inherent in the proposed treatment; a risk is material if in the circumstances of the particular case, a reasonable person in the patient's position if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient if warned of the risk, would be likely to attach significance to it.*' Ms Free or a person in her position would have viewed these matters as significant, first to whether or not tramadol was the appropriate medication and secondly, to make sure that steps were taken to avoid the inherent risk in tramadol in drop form by obtaining it in another form or obtaining another medication and it would have affected how the medication was given.

d. Where there has been a failure to warn, causation does not require direct evidence from Ms Free or Mr Hortle about what they would have done if appropriately warned.

e. Dr Levi should have specified for the Tramadol to not be in oral form given what he already knew of Dane's particular medical conditions and due to the fact that the Hospital and its staff knew that Tramadol in oral drops could lead to accidental overdose in children which is why they did not use it in that form.

f. In the circumstances where there is no basis for finding that either of Dane's parents deliberately or intentionally administered him an excessive dose of tramadol, it is submitted that it would be open to find that Dane died from an accidental overdose of tramadol where that risk is an inherent characteristic of Tramal Oral Drops especially when administered to a small child.

g. They disagree that Dane would have not met the criteria to stay an extra night with regards to the Hospital's new protocols for post-operative management of patients. This is due to the fact that;

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[3] *March v E & M Stramere Pty Ltd* (1991) 171 CLR 506 at 509

[4] (1992) CLR 479 at 16

i. The protocols require continuous monitoring with an oximeter overnight but Dane was not monitored continuously, only until about 4.30am.

ii. Dane had a desaturation that was 79-which was in the 70s as required by the Hospital's criteria. The fact that it was not prolonged and self-resolved does not prevent the criteria for a further night having been met. It is unknown how many events of desaturation had been in place given his lack of continuous monitoring.

Dr Levi's Tramadol Prescription:

27. I accept the submission made on behalf of the Hospital that Dr Levi did not prescribe Dane Tramal Oral Drops upon his discharge, nor a particular formulation of the medication. I further accept that Tramadol in oral drop form was not approved for use in the Hospital.

28. It is clear from Dr Levi's statement that he was aware Tramadol could be dispensed in a number of ways, including oral drops.

29. His stated belief is that he would not have given Dane's parents specific information regarding the method of administration, as such information was dependent on the form in which the Tramadol was dispensed. Accordingly, he must have been aware of the possibility that it would be dispensed in oral drop form.

30. Dr Levi would have or should have been aware that oral drops were not approved for use in his hospital.

31. As the prescribing doctor he should have known of the potential for accidental overdose in administering oral drops.

32. Dr Levi knew or should have known Dane had a history of respiratory problems and that this would put him at greater risk of respiratory depression from accidental overdose.

33. I am satisfied that when Dr Levi prescribed Tramadol for Dane, he should have made it clear that it be dispensed in tablet or capsule form. Dr Levi's failure to do so was outside the parameters of reasonable health care practice.

34. I am further satisfied, however, that Dr Levi's omission falls into the category of being a background circumstance and was not causative of Dane's death.

COMMENTS:

Pursuant to section 67(3) of the *Coroners Act 2008*, I make the following comments connected with the death:

a) Tramal (tramadol hydrochloride) Oral Drops, along with other Tramal formulations, are not approved by the Therapeutic Goods Administration for use in children under 12 years of age.

b) As can be observed, a number of experts believe the removal of Tramadol Oral Drops from the Australian Register of Therapeutic Goods would be an improvement in safety for children as they could not be inadvertently dispensed for use in this age group, or overdosed. This view is endorsed by the RCH.

c) Nevertheless, removal from the Register could disadvantage a significant number of adult patients and children over 12 years of age in management of acute and chronic pain in circumstances where they are unable to swallow tablets or capsules.

RECOMMENDATIONS

Pursuant to section 72(2) of the *Coroners Act 2008*, I make the following recommendations connected with the death:

a) The Therapeutic Goods Administration investigate the clinical need for Tramal Oral Drops in adults and paediatric patients above 12 years of age in order to determine whether it is appropriate to remove this medication from the Australian Register of Therapeutic Goods.

b) Doctors prescribing Tramadol medication to their patients upon discharge from RCH, advise family that it be dispensed at the hospital pharmacy, rather than a community pharmacy.

I direct that a copy of this finding be provided to the following:

Mr Mark Hortle & Ms Aderyn Free

Mr John McGirr, Wisewould Mahony Lawyers

Ms Angela Woodward, Lander & Rogers

Professor Jeremy Oats, Chair CCOPMM

Dr Michael Fasher, Royal Australian College of General Practitioners

Professor Edward Shipton, Australian & New Zealand College of Anaesthetists

Associate Professor Noel Cranswick, The Royal Children's Hospital Melbourne

Ms Tammy O'Connor, The Royal Children's Hospital Melbourne

Dr Emma McGrath, The Royal Children's Hospital Melbourne

Ms Jane Leong, bioCSL Limited

Therapeutic Goods Administration, info@tga.gov.au

Signature:

IAIN WEST
DEPUTY STATE CORONER
Date: **10 December 2015**