IN THE CORONERS COURT

OF VICTORIA

AT MELBOURNE

Court Reference: COR 2013 5866

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)

*Section 67 of the **Coroners Act 2008***

I, AUDREY JAMIESON, Coroner having investigated the death of RONAK SATYAJIT WARTY

without holding an inquest:

find that the identity of the deceased was RONAK SATYAJIT WARTY

born 9 January 2003

and the death occurred on 20 December 2013

at Monash Medical Centre, Clayton

from:

1 (a) COMPLICATIONS OF ANAPHYLAXIS

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

1. Ronak Warty was 10 years old at the time of his death. He lived in Burwood East with his parents and older brother, and was an active soccer player. Ronak's medical history included probable asthma, anaphylaxis with a known allergy to nuts and dairy products, and vitamin D deficiency. He had an anaphylaxis action plan, which included the use of an EpiPen® adrenaline autoinjector.
2. At approximately 6.00pm on 13 December 2013, Ronak and his family ate dinner at home, purchased from a restaurant. At about 8.45pm, Ronak drank 'Green Time Natural Coconut

Drink', and subsequently experienced shortness of breath and vomiting. Zyrtec®[1] and a few puffs of a salbutamol[2] inhaler were administered, but Ronak refused the use of an EpiPen®; he was averse to needles. Emergency services were called at approximately 9.20pm, and when a Mobile Intensive Care Ambulance (MICA) paramedic arrived at 9.28pm, Ronak was conscious, alert and oriented, with a Glascow Coma Scale[3] score of 15/15. Ronak's skin showed flushing of the face, with slight swelling, and he described a slight feeling of a swollen tongue and airway, but that this was not severe. Ronak's skin was sweaty, but there was no obvious urticaria. His speech was in short words and phrases, and he appeared nauseated. A back up ambulance with two extra paramedics arrived at 9.31pm, and Ronak was administered with adrenaline via intramuscular injection at 9.33pm.

3. Ronak was subsequently transferred by road ambulance to the Monash Medical Centre, Clayton Emergency Department (ED). In the ambulance, Ronak became very agitated and experienced increasing respiratory difficulties; he was given intramuscular and intravenous adrenaline.

4. Ronak presented to the ED at 9.48pm, semiconscious with ineffective laboured respirations, requiring bag and mask support. Ronak was transported to the paediatric resuscitation cubicle and treated by a team of medical and nursing staff, and his oxygenation improved within the first five minutes of ventilation. At 10.10pm however, Ronak became more difficult to ventilate, possibly due to severe bronchospasm. At 10.20pm, Ronak became bradycardic and suffered cardiac arrest. He was intubated and following 41 minutes of resuscitation, involving continuous cardiopulmonary resuscitation (CPR) and multiple rounds of intravenous adrenaline, spontaneous circulation and output returned at 11.01pm.

5. Ronak was re-intubated, as a leak had occurred around the tube. A chest x-ray showed hyperexpanded lung fields, and he was given steroids and antibiotics. Medications including ketamine and hydrocortisone were administered, and he was transferred to the Intensive Care Unit (ICU).

6. In the ICU, Ronak was kept cooled, sedated and stabilised on adrenaline infusion. On 15 December 2013, Ronak was warmed and sedation ceased, but his pupils remained fixed and

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[1] Zyrtec® (cetirizine) is an antihistamine that reduces the effects of natural chemical histamine in the body. It is used to treat cold and allergy symptoms.

[2] Salbutamol, also known as albuterol and marketed as Ventolin among other names, is a medication that opens up the medium and large airways in the lungs.

[3] The Glascow Coma Scale is a quick, practical standardised system for assessing the degree of conscious impairment in the critically ill and for predicting the duration and ultimate outcome of coma, primarily in patients with head injuries. The scale is now measured out of 15, with 15/15 being the best possible score.

dilated. At 1.34pm on 16 December 2013, a nuclear medicine brain scan confirmed that Ronak had no Central Nervous System flow or activity. At 1.20pm on 20 December 2013, therapy was withdrawn and Ronak's life support ceased.

INVESTIGATIONS

Forensic pathology investigation

7. Dr Noel Woodford, Forensic Pathologist at the Victorian Institute of Forensic Medicine, performed a full post mortem examination on the body of Ronak, reviewed a post mortem computed tomography (CT) scan, e-medical deposition and clinical notes from Monash Medical Centre and referred to the Victoria Police Report of Death, Form 83.

8. Dr Woodford reported that he discussed Ronak's death with Chemical Pathologist Dr James Doery on 29 April 2014. Dr Doery informed Dr Woodford that initial pathology testing had shown non-reactivity to coconut, but very high reactivity to milk (RAST). Skin prick testing while Ronak was in the ICU had shown 7mm wheals to histamine and the coconut drink. There was non-reactivity to other components of the meal thought to have been ingested by Ronak on the evening of 13 December 2013. Dr Doery had suggested that the timeframe of the events strongly implicated the coconut drink as the cause of Ronak's clinical deterioration.

9. At autopsy, Dr Woodford observed congested lungs with mucoid sputum within bronchi; chronic asthmatic changes in lungs with patchy bronchopneumonia; swollen markedly softened brain with brainstem haemorrhages and global hypoxic-ischaemic cerebral injury; and congested viscera. Dr Woodford opined that his findings were consistent with the history of cardiorespiratory arrest leading to catastrophic global brain injury, which was the ultimate cause of death.

10. Toxicological analysis of ante-mortem plasma sampled in hospital on 13 December 2013 at 10.00pm, did not identify any common drugs or poisons. Analysis of plasma sampled in hospital on 14 December 2013 at 1.00am, showed a tryptase level of 22.6 µg/L.[4] Dr Woodford reported that tryptase testing[5] is a marker of anaphylaxis, and while the level was only mildly

[4] The normal clinical range is <12.0.

[5] Increased levels of tryptase can normally be detected up to 3 to 6 hours after the anaphylactic reaction. Levels return to normal within 12 to 14 hours after release.

elevated, it was nevertheless consistent with anaphylaxis. Testing of post mortem serum for coconut-specific IgE was negative.[6]

11. Dr Woodford ascribed the cause of Ronak's death to complications of anaphylaxis.[7]

Police investigation

12. The circumstances of Ronak's death have been the subject of investigation by Victorian Police on my behalf.

13. Police obtained statements from Ronak's father Satyajit Warty, MICA paramedic Bernard Rieniets, Monash Medical Centre Clayton staff: Emergency Physician Simon Craig, Head of General Paediatrics Catherine McAdam, and General Physician and Allergy / Immunology Consultant Sara Barnes, and General Practitioner Srilal Kariyawasam.

14. In the course of their investigation, police identified that Ronak had been diagnosed with anaphylaxis at the age of eight months old. Mr Warty reported that his son was allergic to dairy products and nuts, but had outgrown his allergy to eggs.

15. Ronak's family closely monitored the food he ate. Mr Warty reported that the family were very careful when they bought food, to make sure it contained none of the items Ronak was allergic to. Mr Warty stated that he attended school camps so that he could monitor the food Ronak ate; he took home cooked food for Ronak to the camps.

16. Dr Kariyawasam stated that Ronak, his parents and his brother understood the seriousness of his condition very well, and took all possible precautions to avoid him coming into contact with dairy, lactose, nuts and eggs. Dr Kariyawasam said that an anaphylaxis action plan was in place and that Ronak's parents were familiar with the plan. Ronak had last been prescribed an EpiPen®, 300mcg / 0.3mL on 29 November 2012.

17. Paramedic Rieniets reported that when he arrived at the Wartys' address, it was clear that Ronak was extremely unwell. Paramedic Rieniets related that Ronak's parents had stated they initially did not believe his condition severe enough to administer the EpiPen®. Electronic records from

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[6] The antigen specific IgE to coconut was shown at a level of 0.14 kUA/L. The normal clinical range is <0.35. The coconut score was reported as 0.

[7] Dr Woodford reported that anaphylaxis is a severe acute allergic reaction which may be associated with acute broncho-constriction (apparent as wheeziness and shortness of breath due to restricted airflow) and low blood pressure (shock). Chronic asthma is commonly seen in people with an allergic tendency and in some cases of anaphylaxis the major manifestation is an acute exacerbation of asthma leading to respiratory and cardiac arrest. Hypoxic-ischaemic injury of the brain, as in this case, is the result of reduced brain perfusion (blood flow) following the cardiorespiratory arrest.

Ambulance Victoria suggest that Ronak was frightened of needles and had resisted the administration of the EpiPen® when he first started exhibiting signs of an anaphylactic reaction. In his statement, Paramedic Rieniets noted that Ronak was needle phobic, and that he had needed the assistance of Mr Warty and another paramedic to hold him so as to administer adrenaline, as despite being very unwell, he was still very resistive of the needle. Between 9.34pm and 9.46pm, as Ronak's respiratory condition deteriorated, there were three separate notations by ambulance paramedics of his distress and resistance in response to the use of a needle.

18. Dr McAdam reported that Ronak's death had been the subject of a case review at Monash Medical Centre, to consider whether any care management issues could identified. Staff did not identify any deficiencies in Ronak's care. Dr McAdam stated that allergy testing conducted at the hospital detected that despite a history of anaphylaxis to dairy and nuts, Ronak's RAST IgE levels indicated a significant allergy to dairy, but not to nuts or coconut.

19. Dr McAdam opined that the predisposing factors to Ronak having such a severe reaction included unrecognised, chronic and persistent asthma. While Ronak had been prescribed a salbutamol inhaler, Dr McAdam noted that Mr Warty denied a diagnosis of asthma. In addition, she noted that the delay in administration of the EpiPen® may have contributed to Ronak's subsequent poor response. Dr McAdam added that Ronak had been outdoors prior to his illness, on a windy, warm summer's day, which may have caused him to be sensitised by pollens. His subsequent reaction may have been more severe as a result.

20. In an undated report provided to the Court, prepared after speaking with Ronak's father on 17 December 2013, Chemical Pathologist Dr James Doery reported that Ronak had over many years consumed the same meals, from the same restaurant, that he had eaten on the night of 13 December 2013. However, Ronak had never previously consumed the Green Time brand of coconut drink. Dr Doery opined that the time sequence on 13 December 2013, strongly implicated the involvement of the coconut drink in Ronak's anaphylactic reaction.

21. Dr Barnes said that results from Ronak's RAST testing reported on 16 December 2013, indicated that Ronak was most likely allergic to milk, to which he had very high reactivity. Dr Barnes subsequently undertook the skin prick allergy testing on the morning of 19 December 2013. The results indicated a positive reaction to the 'Green Time Natural Coconut Drink', with a 7x5mm wheal. Dr Barnes stated that as a consequence of both the RAST and skin prick

testing, it was determined that Ronak was sensitised to cow's milk and also to the 'Green Time Natural Coconut Drink'.

22. Mr Warty stated that he had bought the can of 'Green Time Natural Coconut Drink' from Hong Market in Burwood One Shopping Centre. Before Ronak drank the beverage on 13 December 2013, Mr Warty checked the ingredients on the can's label and was satisfied that the drink did not contain any allergens. Mr Warty said that Ronak also checked the can to make sure.

23. Mr Warty reported that following Ronak's death, the 'Green Time Natural Coconut Drink' was discovered to contain milk and was recalled from the market. Mr Warty stated that this action came about because he notified Anaphylaxis Australia, who requested that Food Safety Victoria conduct tests on the product. The tests confirmed that the drink contained dairy products that were not displayed on the label.

Subsequent action taken in relation to the 'Green Time Natural Coconut Drink'

24. A report of analysis by Microbiology Analyst Glenda Scott, dated 5 June 2014, detected beta-lactoglobulin and milk (Casein) protein residue in the Green Time Natural Coconut Drink.

25. The Australian Competition and Consumer Commission's (ACCC) website, 'Product Safety Recalls Australia',[8] lists 'Narkena Pty Ltd – Green Time Natural Coconut Drink – 510ml' as a drink that was recalled on 24 January 2014. Specific product information[9] included that the defect was 'the presence of an undeclared allergen (milk)', and the hazards were that 'any consumers who have a milk allergy or intolerance may have a reaction if the product is consumed.' The website also noted that the product had been 'available for sale at Asian grocery stores and small independent supermarkets in NSW, QLD, SA, ACT and VIC'.

26. Food Standards Australia New Zealand (FSANZ) is an independent statutory agency established by the *Food Standards Australia New Zealand Act 1991* (Cth), and is part of the Australian Government's health portfolio.[10] The FSANZ website publishes recalls for products that have reached consumers, and 'Green Time Natural Coconut Drink' is listed on the site.[11] A search of the word 'coconut' on this website, indicates that at least 22 beverages involving 'coconut' were

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[8] See: https://www.recalls.gov.au/content/index.phtml/itemId/952828, accessed 10 May 2016.

[9] See: https://www.recalls.gov.au/content/index.phtml/itemId/1055524, accessed 10 May 2016.

[10] See: http://www.foodstandards.gov.au/about/Pages/default.aspx, accessed 10 May 2016.

[11] See: http://www.foodstandards.gov.au/industry/foodrecalls/recalls/Pages/Green-Time-Natural-Coconut-Drink.aspx, accessed 10 May 2016.

recalled across Australia since October 2010 after being found to contain an undeclared milk allergen.

Letter of concern from Mr Satyajit Warty dated 26 November 2014

27. The Court received a letter of concern from Mr Warty dated 26 November 2014. Inter alia, Mr Warty noted:

> *'Ronak died due to anaphylaxis caused by an incorrect labelled and titled product. As you are aware, the can stated 'Natural Coconut Drink' and the ingredients were completely misdeclared. In effect, my son was killed by a corporate entity by not declaring the product correctly.'*

28. In addition, Mr Warty expressed concerns as to other products on the market that may be mislabelled, and the risks to other people. He also expressed concerns as to the amount of time taken for the 'Green Time Natural Coconut Drink' to be recalled following Ronak's death. Mr Warty queried the management of Ronak's condition by ambulance paramedics, and emphasised the importance of training parents and families of children with anaphylaxis.

29. The Court was informed on 5 January 2015 that Mr Warty had passed away in December 2014.

Statement from Mrs Kalpana Warty dated 4 April 2016

30. The Court received a statement made by Mrs Warty dated 4 April 2016. Mrs Warty stated that Ronak was breastfed for his first 12-18 months. When he was fed the milk supplement product, S26, at around three months of age, he had vomited. The family had been advised by doctors not to persist. At approximately seven months of age, following the ingestion of egg pasta, Ronak was diagnosed with allergies to nut, dairy and egg products.

31. Mrs Warty stated that when Ronak was diagnosed with allergies, the family were given an explanation of the importance of understanding and monitoring allergic reactions. The family were provided with an EpiPen® and instructed on its use. The family travelled with the EpiPen® on aircraft and were alert to warning signs including breathlessness, redness, hives and vomiting. The family had an anaphylaxis plan, and provided the plan, EpiPen®, zyrtec and subutamol inhaler to the school nurse when Ronak began school. Mrs Warty confirmed that great care and diligence was taken to supply appropriate foods for Ronak to eat outside the home. Mrs Warty reported that she had spent a lot of time volunteering at Ronak's school to ensure that he was as safe as possible. She had been present during an incident when Ronak had unexpectedly been exposed to an allergen at the school, and an EpiPen® had been administered

immediately. He made a quick and good recovery on this occasion. Mrs Warty said that Ronak was a cautious boy and had a very good understanding of the risks he faced and the action he needed to take to protect himself from allergens.

32. Mrs Warty noted that during Ronak's anaphylactic reaction on 13 December 2013, she had interpreted Ronak's vomiting to be a response to a rich soup he had eaten, as he was not displaying other usual signs of anaphylaxis. She said they had no indication to use the EpiPen® up until the time the MICA ambulance arrived at their home. She added that while waiting for the ambulance, they had commenced to work through the anaphylaxis plan.

Statement from Dr Ian Humphrey dated 23 December 2014

33. The Court received a statement from Consultant Paediatrician and Allergist Dr Ian Humphrey dated 23 December 2014. Dr Humphrey reported that he saw Ronak on several occasions between 2003 and 2006. At a review on 3 April 2006, Ronak was advised to continue avoiding cow's milk proteins, egg and nuts. Dr Humphrey provided a copy of his letter to General Practitioner Dr Kariyawasam dated 3 April 2006. In this letter, Dr Humphrey reported test results 100% predictive of allergy to cow's milk and egg. Dr Humphrey also provided a letter dated 14 September 2006, which was provided to Ronak's family to explain his allergies and carrying of an EpiPen® as they travelled overseas, and detailed an allergic reaction action plan.

Further statement from Dr Srilal Kariyawasam dated 12 September 2014

34. The Court received a further statement from General Practitioner Dr Srilal Kariyawasam dated 12 September 2014. Dr Kariyawasam stated that Ronak had been referred to Allergy Specialist Dr Collin Little in April 2006 and January 2008, and Allergist Dr Ian Humphries in June 2012.[12] Dr Kariyawasam reported that both of Ronak's parents were thorough with his anaphylaxis action plan and the importance of him avoiding dairy and nuts. Dr Kariyawasam provided copies of Ronak's anaphylaxis action plans, which noted confirmed allergens as nuts, dairy products and milk, and advised the usage of EpiPen® at a dose of 300mcg/0.3ml.

35. In a letter sent to Dr Kariyawasam on 4 February 2008, Dr Little reported that as of 4 February 2008, Ronak was strongly allergic to egg white and somewhat allergic to cow's milk. Dr Little advised that these allergens must strictly be avoided in Ronak's diet until reassessment with skin tests in a couple of years' time.

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[12] I note that this evidence is inconsistent with evidence provided by Dr Humphries, which suggested that he last saw Ronak in 2006. I remain unclear on the reason for this discrepancy.

Allergy & Anaphylaxis Australia Correspondence

36. The Court received correspondence from Maria Said, President of Allergy & Anaphylaxis Australia, dated 12 February 2014. Ms Said suggested that Ronak's death 'brings many issues on food labelling, imported foods, and appropriate immediate investigation considering public safety, to the forefront'.

37. Ms Said reported that following discussions with Ronak's father, she received a confidential food recall notice on 24 January 2014, stating that the 'Green Time Natural Coconut Drink' was being recalled, because it contained undeclared milk. Ms Said expressed concern that the incorrectly labelled product was in the market place for more than a month following Ronak's death, which had been suspected to have been triggered by the drink.

38. *Inter alia*, Ms Said encouraged targeting allergen awareness and regulatory requirements training at food importers, small retailers and specialty outlets; training in the requirements of mandatory reporting obligations to the ACCC in the event of death or serious injury caused by a food product; authorities to conduct regular surveys for compliance with allergen labelling requirements; increased surveillance on allergen labelling by the Imported Food Inspection Program; better access to allergy specialist care via formal allergy clinics; and mandatory reporting of anaphylactic reactions requiring adrenaline.

New South Wales Criminal Proceedings

39. The NSW Food Authority charged Narkena Pty Ltd, the food importing and wholesale business that had imported the 'Green Time Natural Coconut Drink', with six offences under the *Food Act 2003* (NSW).[13]

40. On 15 September 2015, at the Downing Centre Local Court, Narkena Pty Ltd entered pleas of guilty to three charges under the *Food Act 2003* (NSW).[14]

41. The sentencing judgment was delivered by Magistrate Atkinson on 18 November 2015. Her Honour referenced the parties' agreement as to facts and noted that the Victorian Department of Health[15] had purchased two cans of 'Green Time Natural Coconut Drink'; one produced in May

[13] A suppression order was made by Local Court Deputy Chief Magistrate Mottley at the Sydney Downing Centre on 18 August 2015, in relation to the name of the deceased child.

[14] Two of the charges related to s 18(3) and one charge related to s 21(3). The remaining three charges were withdrawn.

[15] The Department of Health is now known as the Department of Health and Human Services.

2013 and the other in June 2013. The analysis of the samples had detected casein protein, which is found in mammalian milk, making up to 80% of the protein in cow's milk.

42. Her Honour noted the objects of the *Food Act 2003* (NSW) included ensuring food for sale is both safe and suitable for human consumption, and to prevent misleading conduct in connection with the sale of food. Her Honour emphasised that people rely on food being properly labelled.

43. Her Honour held that 'it was apparent from the evidence given during sentencing that the company did not apparently appreciate the significance of differences in food standards between Taiwan and Australia and the importance of ensuring that the drink complied with Australian food standards. It relied on information that was being provided by the manufacturer... instead of making its own enquiries and even when the label changed on the product.' Her Honour further noted that 'until recently there has apparently been no independent testing of the contents of food that has been imported...' In the judgment, Her Honour did not accept that Narkena Pty Ltd had shown no remorse, but did say that it had been limited.

44. Her Honour convicted Narkena Pty Ltd in relation to each of the three offences, and applied a total of $18,000 in fines. Narkena Pty Ltd was also ordered to pay the NSW Food Authority costs in a sum of $24,000.

Mention Hearing on 12 May 2016

45. A Mention Hearing was held on 12 May 2016, in order to progress my investigation, and enable parties to raise any further matters that might warrant the holding of an Inquest, or alternatively an in-chambers Finding. Deborah Foy of Counsel appeared at the Mention Hearing on behalf of Mrs Warty,[16] while Andrew Imrie of Counsel appeared on behalf of Allergy & Anaphylaxis Australia.[17]

46. At the Mention Hearing, Ms Foy withdrew the Form 26 Application for Inquest, dated 13 February 2014 which had been submitted by Mr Barrie Woollacott on behalf of the Warty family. I noted that given the criminal prosecution, I was concerned about the requirements under the *Coroners Act 2008* to avoid duplication of processes. I considered that the mislabelling of the 'Green Time Natural Coconut Drink' was the key issue, and that this had been addressed in the criminal proceedings, and did not necessitate an Inquest for me to finalise my investigation.

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[16] Mr Barrie Woollacott, solicitor at Slater & Gordon, instructed Ms Foy.

[17] Ms Claire Gomo, solicitor at Clayton Utz, instructed Mr Imrie. Allergy & Anaphylaxis Australia were not formally an interested party, but were given leave to appear at the Mention Hearing.

47. Ms Foy submitted that Mr Warty had been concerned about the length of time it took for the recall to occur, and that the family might be assisted by some analysis of why the recall was not undertaken sooner. Mr Imrie submitted that Allergy & Anaphylaxis Australia had two main concerns: the mislabelled product being on the shelves containing a milk product, and the one month delay in the recall following Ronak's death.

48. Following the submissions at the Mention Hearing, I determined to seek further information which would address why it took over a month after Ronak's death to recall the 'Green Time Natural Coconut Drink'.

FURTHER INFORMATION FOLLOWING THE MENTION HEARING

Statement provided by the Victorian Department of Health and Human Services

49. By email dated 27 May 2016, the Court received a statement from Carmel Flynn, Director of Health Protection at the Department of Health and Human Services' (DHHS) Regulation, Health Protection and Emergency Management division.

50. Ms Flynn noted that the DHHS receives thousands of complaints every year pertaining to a wide variety of different food safety issues, each of which may present a different public health risk; the higher the risk to public health, the swifter the departmental response. Ms Flynn said that as food allergens pose a very high risk to allergic members of the community, the DHHS responds to complaints about them as a matter of urgency.

<u>The usual process following a complaint about a food allergen to the Food Safety Unit</u>

51. Ms Flynn stated that the process when the DHHS' Food Safety Unit receives a complaint about a food allergen generally includes:[18]

    - The Food Safety Unit receives a complaint[19] alleging an allergic response after the consumption of a packaged food.
    - The Food Safety Unit seeks to obtain as much information as possible from the complainant/caller/writer to:
        - Establish the veracity of the complaint;

[18] Ms Flynn noted that there are different labelling requirements for the declaration of the presence of food allergens in food, depending on whether the food sold is packaged or not. For the purpose of responding to my request for information, the usual process for responding to a complaint alleging an allergic response after the consumption of a packaged food was described.

[19] Typically complaints are received via email to the Food Safety inbox at foodsafety@dhhs.vic.gov.au or via telephone call to the Food Safety Hotline at 1300-364-352.

- Ascertain whether the product had allergen of labelling or not; and
- Clearly identify the product to enable it to be purchased and submitted for urgent allergen analytical analysis.

- Obtain the product from the marketplace and deliver it to the government laboratory, the National Measurement Institute in Port Melbourne, for urgent allergen analysis.
- If the results of the analysis return a negative result for any/all food allergens, the complainant is advised and no further action is taken.
- If the results of analysis return a positive result for an undeclared allergen, it is highly likely that a food recall will be the required next step. The level of the allergen is relevant, but generally speaking, if the analytical result is positive, a food recall will likely be required.
- Depending on the geographical location of the manufacturer / importer of the product, the relevant state or territory food regulator liaises with the relevant food business to guide them through the recall process. This involves putting them in urgent contact with FSANZ, who has a statutory role in coordinating food recalls in Australia. Where a food allergy incident occurred in Victoria, but the food is imported by a food company located in another state, the Food Safety Unit refers the matter to the other state with all relevant information and evidence to allow for the necessary follow-up action.
- The home jurisdiction liaises with FSANZ and the food business, to ensure that the recall is conducted accurately and swiftly.
- The food recall is released by FSANZ and actioned by food regulators in accordance with the FSANZ Government Food Recall protocol.

Timeline of events involving the Food Safety Unit after Ronak's death

52. Ms Flynn provided the Court with a timeline of events involving DHHS' Food Safety Unit following Ronak's death. In particular, the timeline noted that the Food Safety Unit was advised by Ms Said on 10 January 2014 that Ronak had died after consuming a tinned coconut milk drink and having an anaphylactic reaction. In response, and on 10 January 2014, the Food Safety Unit requested product details from Ms Said to assess the label and arrange for nut and dairy analysis. On 16 January 2014, Ms Said provided the product details relating to 'Green Time Natural Coconut Drink'. That day, the Food Safety Unit visited randomly selected Asian food retailers and purchased two different batches of the product for nut and dairy analysis. On

the morning of 17 January 2014, the Food Safety Unit delivered the products to the National Measurement Institute and arranged for urgent analysis. On 23 January 2014, the certificates of analysis were received from the laboratory showing that both products contained dairy milk. That day, the Food Safety Unit referred the results of analysis to the NSW Food Authority, as they were the relevant food regulator for the importer of the product. On 24 January 2014, the importer instigated a food recall of the product, overseen by the NSW Food Authority.

53. Ms Flynn emphasised that the Food Safety Unit was not made aware of the details of the product to enable analysis until 16 January 2014, upon which action was instigated as a matter of urgency.

Reporting requirements

54. Ms Flynn added that there are no requirements for members of the public to report cases of food allergen-related reactions to food regulators or food companies. However, the Australian Competition and Consumer Commission (ACCC) does require mandatory reporting from food businesses, regarding the death, serious injury or illness of a person to the ACCC *'that they become aware of and that someone believes was caused by the use of a consumer good and they supply those goods or provide a related service for those goods.'*[20] The DHHS had no information to indicate that Ronak's death was reported to Narkena Pty Ltd, thus it was believed no mandatory report was submitted.

55. In addition, Ms Flynn advised that there are no current requirements for hospitals or members of the medical community to report cases of food allergen-related reactions, anaphylaxis and/or death to food regulators. There is a hospital reporting system in Victoria called the Victorian Admitted Episodes Dataset (VAED), which provides a dataset of the causes, effects and nature of illness and is used to support research and funding. However, the VAED is not 'real-time' as hospitals report it quarterly, and it does not provide a level of detail on the cause of an anaphylactic reaction to allow food regulators to undertake a food allergen investigation.

56. Ms Flynn opined that the question of whether medical staff should be responsible for alerting authorities about foods which are suspected to be problematic raises a number of complex policy and regulatory issues. Allergic responses are numerous, and mostly do not pertain to food. Further, in order for a food regulator to instigate a food recall conversation with a food

[20] http://www.productsafety.gov.au/content/index.phtml/itemId/982086

company, a sealed sample is typically required to be analysed rather than an open product from the patient's home, which may have been accidentally cross-contaminated.

57. Ms Flynn stated that appropriate action in response to such reports from medical staff would only be able to be taken by food regulators for products suspected of breaching food labelling law. This means that medical staff would need to know the following information for meaningful reports to be submitted to food regulators:

    - Food legislation as it pertains to food allergens. Ideally, food regulators would require reports which pertain to packaged food, which has been sold (rather than provided at a private function), where no allergens are declared on the label.
    - Clearly identifiable details of the product to allow for product identification and analysis – including batch number, product name, photos of the label where possible.
    - Food allergy history of the patient to enable food regulators to know what allergen to test for.
    - The contact details of the patient or parents of the patient to allow for follow-up and the obtaining of statements where required.

<u>Areas of planned and potential improvement identified</u>

58. Ms Flynn stated that with the intention of trying to provide educative information, build relationships and encourage reporting of food allergen-related incidents, the Food Safety Unit is in the process of developing the following pieces of work:

    - A simple fact sheet advising the person or the parent that if they have presented to the hospital due to an allergic reaction to a packaged food to contact the Department's Food Safety Unit to ensure that any food recalls are undertaken as required. This public fact sheet could be distributed to all general practitioners and hospitals, with an educative cover letter to the medical staff.
    - Establishing a working group comprising, but not limited to, representatives of the medical and hospital community, the Victorian Coroners' Court and associated offices, including the Victoria Police Coronial Support Unit, to develop an ongoing collaborative, working relationship to ensure appropriate information sharing.

59. Ms Flynn advised that the DHHS' Food Safety Unit has also identified three key areas where improvements could be made with respect to encouraging the reporting to food regulators of

food allergen-related incidents. The improvements focused on the provision of educative information to, and relationship-building between the DHHS and the following persons:

- Members of the public presenting to the medical community due to an adverse reaction to a food – specifically people with allergies to food allergens and parents of children with allergies to food allergens;
- The medical community (incorporating general practitioners, emergency rooms and hospitals); and
- The Victorian Coroners' Court and associated offices, including the Victoria Police Coronial Support Unit.

National food standards

60. Ms Flynn added that intergovernmental food regulation arrangements are in place to ensure consistent food standards across Australia and New Zealand. These arrangements are underpinned by the *Food Regulation Agreement 2002*, an intergovernmental agreement between the Commonwealth, States and Territories, and the *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Food Treaty). Ms Flynn added that food standards are developed by the Commonwealth statutory authority, FSANZ.

Statement provided by Food Standards Australia and New Zealand

61. By email dated 17 May 2016, Owen Walsh, General Counsel at FSANZ provided a statement signed by Amanda Hill, Manager of FSANZ's Food Safety and Response Section.

62. Ms Hill stated that one of FSANZ's functions is responsibility for coordinating recall action, at the request of the Australian states and territories. In practice, this means that when FSANZ is notified of a food recall, it liaises with the food business and the relevant state or territory government to gather and collate the necessary information. This information is then disseminated by FSANZ to state and territory governments, other government bodies and the food industry. The relevant state or territory food enforcement agency has jurisdiction for the location of the recalling business' head office, and becomes the home jurisdiction for the recall, ensuring the business meets all of its responsibilities when recalling food.

63. Ms Hill provided a timeline relating to the action taken by FSANZ following Ronak's death. In particular, the timeline specified that FSANZ was notified at 2.30pm on 23 January 2014 by the NSW Food Authority, to expect a recall to be phoned through by Narkena Pty Ltd that

afternoon. At approximately 5.00pm, Narkena Pty Ltd phoned FSANZ to initiate a recall of the 'Green Time Natural Coconut Drink'. On the morning of 24 January 2014, FSANZ received all final information relating to the recall from Narkena Pty Ltd, assisted the business to finalise a press advertisement for the recall, and issued the recall at 10.52am.

COMMENTS

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

1. It is alarming that mislabelled food stuffs are being imported, thus misleading the public about the contents of these products. This is particularly concerning given that Victoria has an ever increasingly high rate of people, particularly children, with food allergies. I recently completed an investigation into the death of Jack Irvine,[21] a 15 year old boy who died in 2012 following an anaphylactic reaction to an unlabelled cookie containing nuts to which he was allergic. The fathers of both Jack and Ronak each contemporaneously turned their minds to the issue of whether the implicated foodstuff contained allergens. In Ronak's case, where the 'Green Time Natural Coconut Drink' was packaged, Mr Warty's inspection of the product was not supported by the labelling, and has thus not prevented consumption. As the rate of food allergies amongst children increases, so does the potential for further deaths in circumstances where food labelling standards are not observed.

2. Children with food allergies and anaphylaxis are dependent on their parents and others to provide them with food free of the potentially fatal allergen. Ronak's death highlights that despite the diligence of his parents in the purchasing and providing of food to Ronak, they had been misled to the highest degree. There was no ability for Mr Warty to discern about whether there was any risk to Ronak, because the product failed to make any mention that it indeed contained the fatal allergen, dairy.

3. Where the community is so dependent upon food labelling, it is crucial that strict standards are upheld for all packaged products that reach shop shelves, and particularly including those that are imported from overseas. From the outcome of the criminal proceedings, it is evident that Narkena Pty Ltd did not exercise the level of rigour for content labelling standards required in Australia for imported food stuffs.

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[21] COR 2012 4117

4. I am also concerned that had it not been for Mr Warty's engagement with Allergy & Anaphylaxis Australia, and Ms Said's subsequent report to the Victorian DHHS, the 'Green Time Natural Coconut Drink' may still have been on the shelves and criminal proceedings may not have been conducted against Narkena Pty Ltd. The responses of both the DHHS and FSANZ appear to have been timely and appropriate in the circumstances. Indeed, the delay appears to have occurred between the date of Ronak's initial reaction on 13 December 2013, and Ms Said's provision of product details to the DHHS on 16 January 2014. This is by no means a criticism of Ms Said. Rather, despite the RAST and skin prick testing conducted in the days following Ronak's reaction, it appears that medical professionals at Monash Medical Centre have not chosen to report the product to the DHHS. Delays in recalling mislabelled products appear to arise out of the lack of mandated reporting, and thus the efficiency, effectiveness and existence of the recall becomes dependent on people such as Mr Warty and Ms Said to report the mislabelled product.

5. The evidence suggests that a more responsive and regulated reporting framework is required, to ensure that offending, mislabelled packaged food products are not permitted to remain on shelves undetected. In the interim, I welcome the DHHS' development of a fact sheet to advise a person or parent if they have presented to hospital following an allergic reaction to packaged food to contact the Food Safety Unit to ensure appropriate recalls are undertaken. I also welcome its distribution to all general practitioners and hospitals, with an educative cover letter for medical staff.

6. I am alarmed that the circumstances surrounding Ronak's death could have happened, however I acknowledge that the legislative framework in place has been effective in a reactionary sense, in that the 'Green Time Natural Coconut Drink' was recalled, prosecution occurred and penalties were imposed.

RECOMMENDATIONS

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

1. There is an increasing prevalence of people in Australia, particularly children, who suffer from allergies and anaphylaxis.[22] In particular, hospital admission rates for food-related anaphylaxis

[22] Liew WK, Williamson E, Tang MLK. Anaphylaxis fatalities and admissions in Australia. Journal of Allergy and Clinical Immunology 2009; 123: 434-42.

have increased in all age groups since 2004-2005.[23] With the aim of protecting and promoting health in children with allergies and anaphylaxis, and monitoring, reporting and responding to circumstances that give rise to severe reactions in a timely and effective manner, **I recommend** that the Secretary of the Victorian Department of Health and Human Services, Ms Kym Peake, investigate, consult widely and formulate a program for mandatory reporting for children who present at hospitals and emergency departments with anaphylaxis.

2. AND with the aim of more agilely and reliably responding to incidents triggering severe allergic or anaphylactic reactions, **I further recommend** that the Secretary of the Victorian Department of Health and Human Services, Ms Kym Peake, incorporate into the process of formulating the mandatory reporting program, interrogation of the sources of anaphylaxis, whereby if, as in Ronak's case, it becomes apparent that a contributing factor involves a packaged foodstuff, or labelling of a packaged foodstuff, the report can be directly referred to the Department's Food Safety Unit.

3. With the aim of increasing awareness of the need to report mislabelled packaged food products, **I recommend** that the Secretary of the Victorian Department of Health and Human Services, Ms Kym Peak, encourages the Food Safety Unit to action the identified ways to improve reporting to food regulators of food allergen-related incidents, and take steps to provide educative information to, and relationship-building with, members of the public presenting to the medical community due to an allergic reaction to a food, and their parents; and the medical community (incorporating general practitioners, emergency rooms and hospitals).

4. With a view to protecting and supporting children with food allergies and anaphylaxis, and responding to a significant public health issue, **I recommend** that the Victorian Minister for Health, The Hon. Jill Hennessy MP supports the formulation of a mandatory reporting scheme by the Department of Health and Human Services, regarding children with anaphylaxis presenting to hospitals and emergency departments, by proposing appropriate legislation for this framework.

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[23] Mullins RJ, Dear KB, Tang ML. Time trends in Australian hospital anaphylaxis admissions in 1998-1999Journal of Allergy and Clinical Immunology 2015; 136(2): 367-75. This finding was made on a background that studies from the United Kingdom, the United States, and Australia have reported increased childhood food allergy and anaphylaxis prevalence in the 15 years after 1990.

FINDINGS

On the evidence available to me, I find that Ronak, who was highly allergic to dairy milk, died after ingesting 'Green Time Natural Coconut Drink', a product that had been imported from Taiwan and mislabelled, so as to not declare that it contained dairy.

I further find that Ronak's parents were careful to ensure that he was not exposed to allergens, and that Ronak's father checked the ingredients listed on the product's label prior to its consumption by Ronak. I find that it would have been ideal if Ronak's Epipen® had been administered as soon as he began to display symptoms including vomiting, but in the circumstances I am unable to determine whether earlier administration would have prevented Ronak's untimely death.

I have not identified any issues in relation to the management of Ronak by Ambulance Victoria or Monash Medical Centre, and I find that their attendance and subsequent care was reasonable and appropriate in the circumstances.

I accept and adopt the medical cause of death as ascribed by Dr Noel Woodford, and find that Ronak Satyajit Warty died tragically from complications of anaphylaxis.

Pursuant to section 73(1A) of the *Coroners Act 2008,* I order that this Finding be published on the internet.

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

Mrs Kalpana Satyajit Warty

Mr Barrie Woollacott, Slater and Gordon Lawyers, on behalf of the Warty family

Ms Maria Said, Allergy & Anaphylaxis Australia

Ms Claire Wesson, Clayton Utz, on behalf of Ms Maria Said

Mr Peter Phan, Phan Lawyers, on behalf of Narkena Pty Ltd

The Victorian Minister for Health, The Hon. Jill Hennessy MP

Ms Katherine Lorenz, Chief Legal Officer, Monash Health

Professor Jeremy Oats, Consultative Council on Obstetric and Paediatric Mortality and Morbidity

Ms Tamar Heath, Murdoch Children's Research Institute

Ms Kym Peake, Secretary of the Victorian Department of Health and Human Services

Ms Fiona Jones, Manager Regulation & Incident Management, Food Safety Unit, Department of Health and Human Services

Mr Owen Walsh, General Counsel, Food Standards Australia New Zealand

Senior Constable Sam Yakopo

Signature:

AUDREY JAMIESON
CORONER

Date: **3 June 2016**