

IN THE CORONERS COURT OF VICTORIA AT MELBOURNE COR 2017 002579

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2) Section 67 of the Coroners Act 2008

| Findings of: | Coroner Simon McGregor |
|-----------------|--|
| Deceased: | Jessica Higgins |
| Date of birth: | 15 July 1983 |
| Date of death: | 4 June 2017 |
| Cause of death: | 1(a) Hypoxic ischaemic encephalopathy complicating mixed drug toxicity |
| Place of death: | Austin Hospital, 147 Studley Road, Heidelberg, Victoria, 3084 |
| Keywords: | Ketamine, ketamine infusion, opioid, oxycodone, Victorian Rehabilitation Centre, methadone, Faculty of Pain Medicine, MATOD, Medication Assisted Treatment of Opioid Dependence, naloxone, Safescript, Royal Australian College of General Practitioners, RACGP |

INTRODUCTION

- 1. Jessica Higgins was a 33-year-old woman who lived in Watsonia with her mother, Margaret Phillips, at the time of her death.
- Ms Higgins suffered chronic pain and had a long history of treatment with opioids. In May 2017 she underwent an inpatient admission for a ketamine infusion with the aim of reducing her opioid use. She was discharged on 23 May.
- On 26 May Ms Phillips found Ms Higgins unresponsive on a couch in their home. Ms Higgins was resuscitated and taken to hospital, but she did not recover. She was declared deceased on 4 June 2017.
- 4. After reviewing the available evidence, I determined that an inquest into Ms Higgin's death was not required and, on 16 April 2020, I handed down findings into this matter. On 2 October 2020 however, Ms Higgins' treating practitioner, Dr David Bolzonello, applied to set aside the finding and re-open the coronial investigation which I granted on 28 October 2020.
- 5. This finding is the result of the original and re-opened coronial investigation.

THE CORONIAL INVESTIGATION

- 6. Ms Higgins' death was reported to the Coroner. It appeared to be unexpected, unnatural, or to have resulted, directly or indirectly, from an accident or injury and so fell within the definition of a reportable death in the *Coroners Act 2008* (**'the Act'**).
- 7. The role of a coroner is to independently investigate reportable deaths to establish, if possible, identity, medical cause of death and surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. The purpose of a coronial investigation is to establish the facts, not to cast blame or determine criminal or civil liability.
- 8. Under the Act, coroners also have the important functions of helping to prevent deaths and promoting public health and safety and the administration of justice through the making of comments or recommendations in appropriate cases about any matter connected to the death under investigation.

- 9. The coronial investigation in this case was undertaken on behalf of the coroner by a member of Victoria Police who was appointed as the Coroner's Investigator, Senior Constable Romualdo Pelle, who prepared a coronial brief of evidence in this matter. The brief includes statements from witnesses, including family, the forensic pathologist who examined Ms Higgins and treating clinicians. I have also had access to medical records and additional information from several of Ms Higgins' treating practitioners.
- 10. Whilst I have reviewed all the material, I will only refer to that which is directly relevant to my findings or necessary for narrative clarity. I have based this finding on the evidence contained in the coronial brief. In the coronial jurisdiction facts must be established on the balance of probabilities.¹
- 11. In considering the issues associated with this finding, I have been mindful of Ms Higgins' basic human rights to dignity and wellbeing, as espoused in the *Charter of Human Rights and Responsibilities Act 2006*, in particular sections 8, 9 and 10.

BACKGROUND

- 12. Beginning in 2006, Ms Higgins was employed as a supervisor for a bus service for disabled children. Over the following years she had a series of workplace issues resulting in chronic back pain. These impacted her ability to work, and she last worked in December 2012.²
- 13. From around 2007, Ms Higgins' primary medical practitioner for her chronic pain management was Dr David Bolzonello of the Alphington Sports Medicine Clinic.³ She initially saw him from a period of care from July 2007 to March 2008 and returned in March 2010 after a recurrence of lower back pain.⁴
- 14. When Dr Bolzonello was unavailable, Ms Higgins also saw Dr Anthony Sellars, a General Practitioner at the Mount Street Medical Centre. Dr Sellars had discussed Ms Higgins' case with Dr Bolzonello and was aware of her complex situation and the difficulties that arose in finding a lasting solution to treat her pain.⁵

¹ This is subject to the principles enunciated in *Briginshaw v Briginshaw* (1938) 60 CLR 336. The effect of this and similar authorities is that coroners should not make adverse findings against, or comments about, individuals unless the evidence provides a comfortable level of satisfaction as to those matters taking into account the consequences of such findings or comments.

² Statement of Margaret Phillips dated 18 August 2017, Coronial Brief; Statement of Dr Clayton Thomas dated 20 August 2017, Coronial Brief.

³ Statement of Dr Anthony Sellars dated 23 May 2019, Coronial Brief.

⁴ Statement of Dr David Bolzonello dated 26 September 2017, Coronial Brief.

⁵ Statement of Dr Anthony Sellars dated 23 May 2019, Coronial Brief.

- 15. At this time Ms Higgins had been prescribed the opioid pain reliever oxycodone (under the trade name Oxynorm) and the benzodiazepine diazepam (under the trade name Valium). She informed Dr Bolzonello that previous trials of pregabalin (under the trade name Lyrica) and amitriptyline (under the trade name Endep) had not been successful.⁶
- 16. Dr Bolzonello involved several specialists in Ms Higgins' care. These included spinal surgeon Mr Michael Johnson and pain specialist Dr Clayton Thomas. After obtaining several opinions, Ms Higgins underwent a L5/S1 spinal fusion in November 2013 performed by Mr Johnson.⁷
- 17. According to Dr Bolzonello:

Ms Higgins' postoperative course was stormy with multiple attendances to Epworth Hospital ED [Emergency Department]. She had repeat scanning all reassuring and was discharged each time on increased doses of Oxycontin [oxycodone]. Following time to settle, I would reduce the dose over time.⁸

18. Other surgical options were attempted as well as a ketamine infusion to attempt reduction of centrally mediated pain and to also attempt opioid reduction. Dr Bolzonello states that throughout 2015 and 2016 a goal of treatment was to reduce her general medication and to reduce her use of opioids.⁹

Pain management leading up to May 2017

- In 2016 Ms Higgins began to have recurring falls. These would result in ED attendances after which her opioid doses would be increased.¹⁰
- 20. On 10 February 2017 Ms Higgins was admitted to the Victorian Rehabilitation Centre under the care of Dr Thomas for pain management to prevent further falls. The attendance was arranged by Dr Peter Courtney, a pain specialist who performs specialised pain interventions including neuromodulation.¹¹

⁶ Statement of Dr David Bolzonello dated 26 September 2017, Coronial Brief.

⁷ Statement of Dr David Bolzonello dated 26 September 2017, Coronial Brief.

⁸ Statement of Dr David Bolzonello dated 26 September 2017, Coronial Brief.

⁹ Statement of Dr David Bolzonello dated 26 September 2017, Coronial Brief.

¹⁰ Statement of Dr David Bolzonello dated 26 September 2017, Coronial Brief.

¹¹ Statement of Dr Clayton Thomas dated 20 August 2017, Coronial Brief.

- 21. This admission lasted until 18 February. During this time, her medication included 40mg twice daily of a controlled-release formulation of oxycodone (under the trade name Oxycontin) along with between 40mg to 60mg per day of immediate-release oxycodone.¹²
- 22. On discharge, her medications included 40mg twice daily of controlled-release oxycodone and a maximum of 30mg daily of immediate-release oxycodone. She was also prescribed 215mg twice-daily of pregabalin (under the trade name Lyrica), a maximum of six tablets daily of 665mg controlled-release paracetamol and three-daily 2mg tablets of diazepam (under the trade name Valium).¹³
- 23. Between February and May 2017 Ms Higgins received prescriptions of oxycodone from both Dr Bolzonello and Dr Sellars. Dr Bolzonello held a permit from the Department of Health and Human Services¹⁴ to prescribe the Schedule 8 medication oxycodone to a maximum daily dose of 80mg. Dr Sellars did not hold a permit.¹⁵
- 24. The exact dosage of oxycodone prescribed by the two practitioners over this time is unclear from medical records. However, at times it exceeded 80mg per day.¹⁶
- 25. Dr Sellars notes that at around this time Ms Higgins presented several times requesting repeat prescriptions for various reasons, including nausea which caused her to vomit her medications, car break-ins resulting in medications being stolen and leaving medications in Phillip Island and Bright.¹⁷
- 26. During this time, Ms Higgins had a trial of spinal cord stimulation supervised by Dr Courtney. She reported significant improvement in pain and function but was uncertain about implanting a permanent device.¹⁸

¹² Statement of Dr Clayton Thomas dated 20 August 2017, Coronial Brief.

¹³ Medication Profile dated 17 February 2017, Victorian Rehabilitation Centre Medical Records.

¹⁴ Now the Department of Health.

¹⁵ Statement of Dr David Bolzonello dated 19 July 2019, Coronial Brief; Statement of Dr Anthony Sellars dated 23 May 2019, Coronial Brief.

¹⁶ Statement of Dr David Bolzonello dated 19 July 2019, Coronial Brief; Statement of Dr Anthony Sellars dated 23 May 2019, Coronial Brief.

¹⁷ Statement of Dr Anthony Sellars dated 23 May 2019, Coronial Brief.

¹⁸ Statement of Dr David Bolzonello dated 26 September 2017, Coronial Brief.

27. According to Dr Bolzonello, prior to consideration of implantation of a permanent spinal cord stimulator, Ms Higgins agreed to pursue opioid reduction. He adds that

Ms Higgins was aware through my education to her and her own reading that the medication itself could be the cause of her severe pain, i.e. opioid hypersensitivity syndrome.¹⁹

28. In a letter dated 2 May 2017, Dr Thomas stated that

I would like to deal with her medication under a ketamine infusion for a duration of seven days ... in order to get her off the OxyContin and rotate her onto [methadone] tablets. She was not able to tolerate Norspan [a buprenorphine transdermal patch]. She will need to be on some form of opioid replacement. The [methadone] would be reasonable pending her ability to tolerate it, side effects, etc.²⁰

29. The ketamine infusion had two purposes. First, ketamine acts as pain relief. Secondly, ketamine assists with the process of withdrawing from opiates. In Ms Higgins' case, Dr Thomas states that

[t]he aim of the ketamine infusion was not likely to lead to an improvement of pain but allowed us to wean her off her high-dose opioid analgesics.²¹

Ketamine infusion and opioid rotation

- 30. Ms Higgins was admitted to the Victorian Rehabilitation Centre (**VRC**) on 16 May 2017, and she began an infusion of ketamine at 4mg/hour. This was to increase over seven days to a maximum dose of 32mg/hour.²²
- 31. To commence the opioid rotation, Ms Higgins' oxycodone medication was converted to 'morphine equivalents': her total of 140mg daily oxycodone became 210mg morphine.²³

¹⁹ Statement of Dr David Bolzonello dated 26 September 2017, Coronial Brief.

²⁰ Letter from Dr Clayton Thomas to Allianz Australia dated 2 May 2017, Victorian Rehabilitation Centre Medical Records.

²¹ Unsigned statement of Dr Clayton Thomas typed 30 April 2019, Coronial Brief.

²² Infusion Orders dated 16 May 2017, Victorian Rehabilitation Centre Medical Records.

²³ Unsigned statement of Dr Clayton Thomas typed 30 April 2019, Coronial Brief.

32. Dr Thomas describes the second phase of the transition as follows:

The rotation from 210mg Morphine to [methadone] is not straight forward. A general rule guiding the rotation is a one to five ratio. She would therefore expect to be on 40 mg per day [methadone]. She was started on 5 mg twice per day on 17th [May] 2017.²⁴

- 33. Medical records confirm that Ms Higgins received 5mg methadone twice daily, at 8.00am and 8.00pm, on every day from 17 May to 22 May. Beginning on 20 May, her records note that she was prescribed a maximum of two 5mg doses of '*prn*' (as needed) methadone daily. She took one 5mg dose on 20 May, two on 21 May and two on 22 May.²⁵
- 34. On 22 May, a plan was made to increase her maximum of '*prn*' methadone to three 5mg doses per day. Despite this plan being documented at that time, nursing notes reflect her requesting diazepam and methadone for her pain at around 9.15pm on 22 May but it was not provided.²⁶
- Her ketamine infusion was ceased at 12.00am on 23 May. She requested doses of methadone and diazepam, which were provided.²⁷
- 36. She was provided her 8.00am regular dose of 5mg methadone that day. She did not receive any more doses of methadone before her discharge from the VRC at 1.10pm.²⁸
- 37. At the time of her discharge, Ms Higgins was prescribed several medications, mostly for pain relief. Some of these were the same as she had been taking on her admission: 215mg twice-daily of pregabalin and a maximum of six tablets daily of 665mg controlled-release paracetamol. Instead of taking 2mg diazepam three times daily, she was prescribed 5mg tablets of diazepam to be taken a maximum of three times a day, as required.²⁹
- 38. She was no longer prescribed any oxycodone. Her opioid pain relief was now in the form of methadone. Her prescription was for 10mg tablets of methadone with the following instructions as documented in her medication profile on discharge:

²⁴ Unsigned statement of Dr Clayton Thomas typed 30 April 2019, Coronial Brief.

²⁵ Medication Chart, Victorian Rehabilitation Centre Medical Records.

²⁶ Progress Notes dated 22 May 2017, Victorian Rehabilitation Centre Medical Records.

²⁷ Progress Note dated 23 May 2017, Victorian Rehabilitation Centre Medical Records; Medication Chart, Victorian Rehabilitation Centre Medical Records.

²⁸ Progress Note dated 23 May 2017, Victorian Rehabilitation Centre Medical Records; Medication Chart, Victorian Rehabilitation Centre Medical Records.

²⁹ Medication Profile dated 23 May 2017, Victorian Rehabilitation Centre Medical Records

Take HALF a tablet TWICE a day, in addition take HALF a tablet every SIX hours when required[.] Maximum of 3 tablets in 24 hours.³⁰

These instructions were printed on the box of 20 methadone tablets she was given at discharge.³¹

- 39. Dr Thomas has stated that the 'every SIX hours' portion of these instructions was 'incorrectly written by the pharmacy', and that a proper description of her dose on discharge was 'a regular dose of 5 mg twice per day and allowed up to 5 mg three times per day in addition'.³²
- 40. When Ms Higgins was receiving her medications at discharge, she requested that she be given them when her family were not present, as she stated her family became anxious when they saw how many medications she was prescribed. Staff complied with this request.³³
- 41. There is no documentation of any emergency post-discharge plan being made for Ms Higgins if the prescribed methadone did not manage her pain.
- 42. A Nursing Discharge Summary was sent to Dr Sellars as Ms Higgins' nominated General Practitioner. It noted '*Nil significant improvement in pain*'.³⁴

Opioid medication post-discharge

- 43. After Ms Higgins returned home from her admission, her mother noticed that her medications made her '*drowsy and disoriented*', that she slurred her speech and that she would often fall asleep at various times including whilst sitting at the dinner table.³⁵
- 44. Ms Phillips was concerned at the level of drugs Ms Higgins was taking. In particular, she had the impression that Ms Higgins was made so drowsy by her medication that she was not fully aware of when she had taken her pills and how many pills she was taking.³⁶

³⁰ Medication Profile dated 23 May 2017, Victorian Rehabilitation Centre Medical Records

³¹ Photograph, Coronial Brief.

³² Statement of Dr Clayton Thomas dated 9 July 2019, Coronial Brief.

³³ Progress note dated 23 May 2017, Victorian Rehabilitation Centre Medical Records.

³⁴ Nursing Discharge Summary dated 23 May 2017, Victorian Rehabilitation Centre Medical Records.

³⁵ Statement of Margaret Phillips dated 18 August 2017, Coronial Brief.

³⁶ Statement of Margaret Phillips dated 18 August 2017, Coronial Brief.

- 45. Ms Higgins saw Dr Bolzonello at the Alphington Sports Medicine Clinic on 25 May. He noted that her current prescription was '*[Methadone] 5mg BD [twice per day] Allowed to take extra 5mg up to 15/day (25mg total)*'. He did not make any note relating to drowsiness but did include the comment '*Feels better than before*'. He also noted that she was taking '*[Diazepam] 5mg tds [three times daily] prn [as needed]*'.³⁷
- 46. Dr Bolzonello recorded that Ms Higgins was seeing Dr Thomas the next Tuesday (30 May) and that she had sufficient tablets of methadone to last until that time.³⁸
- 47. Ms Higgins called Dr Thomas at 1.55pm on 26 May. He did not make a note of the phone call at the time, but later recalled the conversation as follows:

[•][W]e had a discussion about Ms Higgins' pain and the side effects from the medication, as well as the reasonableness of bumping up the medication. She felt that pain was still intrusive and in discussion we together elected to increase the dose of her methadone.³⁹

48. Ms Higgins then called Dr Bolzonello. Dr Bolzonello did not make a note of this phone call at the time, but he made a retrospective note on 29 May. In that note, he described the call as follows:

Called me Friday for script as had called Clayton Thomas to say pain wasn't in control. She advised me Clayton had suggested a whole tab (10mg) instead of half. I confirmed this with [him] by text message. Script was written Friday for [methadone] 10mg tds [three times daily].⁴⁰

- 49. At 2.56pm on 26 May, Dr Bolzonello sent a text message to Dr Thomas reading 'Just confirming you have advised Jessica to increase [methadone] from 5 mg to 10 mg [tds (three times daily)]'.⁴¹ At 2.58pm Dr Thomas responded 'Correct' and at 6.05pm Dr Bolzonello replied 'Tx'.⁴²
- 50. On that day, Ms Higgins attended Watsonia Pharmacy and was dispensed one box of 20 tablets of 10mg methadone from Dr Bolzonello's script, with the instructions '*Take ONE tablet THREE times a day*'. The script had no repeats.⁴³

³⁷ Progress note dated 25 May 2017, Alphington Sports Medicine Clinic Medical Records.

³⁸ Progress note dated 25 May 2017, Alphington Sports Medicine Clinic Medical Records.

³⁹ Statement of Dr Clayton Thomas dated 9 July 2019, Coronial Brief.

⁴⁰ Progress note dated 29 May 2017, Alphington Sports Medicine Clinic Medical Records.

⁴¹ The initial text concluded with '10 mg Todd' and was followed by a text reading 'Tds'. I interpret 'Todd' as being an unintended autocorrection for 'tds' which Dr Bolzonello amended with his following text.

⁴² Screenshot attached to statement of Dr Clayton Thomas dated 9 July 2019, Coronial Brief.

⁴³ Statement of Margaret Phillips dated 18 August 2017, Coronial Brief.

CIRCUMSTANCES IN WHICH THE DEATH OCCURRED

- On 26 May 2017, Ms Phillips went to bed at around 1.00am, at which time Ms Higgins was sleeping on a couch.⁴⁴
- 52. After Ms Phillips woke up the next morning, 27 May 2017, she noticed that Ms Higgins was still on the couch and that her lips were unusually blue. She called for her children to help and contacted emergency services at 10.26am, who told her to begin CPR. Ms Phillips and her daughter performed CPR until emergency services arrived.⁴⁵
- 53. Ambulance and MFB paramedics took over CPR. Paramedics continued CPR until 10.54am, at which time Ms Higgins' heart resumed circulating blood spontaneously.⁴⁶ Ms Higgins' blood pressure was supported via adrenaline infusion, she was placed on a ventilator, and then transported to Austin Hospital by ambulance.⁴⁷

Austin Hospital

- 54. Ms Higgins arrived at the Austin Hospital Emergency Department at 12.04pm. She was stabilised and transferred to the Intensive Care Unit (ICU) with a provisional diagnosis of opioid-related respiratory depression resulting in cardiac arrest.⁴⁸
- 55. Over the following days, repeated clinical examinations suggested that she had suffered a severe hypoxic brain injury. A magnetic resonance imaging scan on 31 May and an electroencephalogram on 1 June confirmed this. On 2 June, Ms Higgins was reviewed by ICU, Clinical Toxicology and Neurology services who all agreed that she had sustained a devastating hypoxic brain injury.⁴⁹
- 56. After discussion with Ms Higgins' family about Ms Higgins' prospects for recovery, the decision was made to withdraw active life-support measures.⁵⁰
- 57. Ms Higgins was declared deceased at 2.13pm on 4 June 2017.⁵¹

⁴⁴ Statement of Margaret Phillips dated 18 August 2017, Coronial Brief.

⁴⁵ Statement of Margaret Phillips dated 18 August 2017, Coronial Brief.

⁴⁶ Statement of Benjamin Reardon dated 8 September 2017, Coronial Brief.

⁴⁷ Statement of Benjamin Reardon dated 8 September 2017, Coronial Brief.

⁴⁸ Statement of Dr Shaun Greene dated 3 October 2017, Coronial Brief.

⁴⁹ Statement of Dr Shaun Greene dated 3 October 2017, Coronial Brief.

⁵⁰ Statement of Dr Shaun Greene dated 3 October 2017, Coronial Brief.

⁵¹ Statement of Dr Shaun Greene dated 3 October 2017, Coronial Brief.

IDENTITY OF THE DECEASED

58. On 2 June 2017, after the decision had been made to withdraw active life-support, Ms Higgins' sister Virginia Maher completed a statement confirming her identity. Identity is not in dispute and requires no further investigation.

MEDICAL CAUSE OF DEATH

- 59. On 7 June 2017, Dr Matthew Lynch, a Forensic Pathologist practising at the Victorian Institute of Forensic Medicine, conducted an autopsy upon Ms Higgins' body and reviewed a post-mortem computed tomography (**CT**) scan, a medical deposition, and the Police Report of Death for the Coroner.
- 60. Dr Lynch noted evidence of widespread hypoxic brain injury. He also found evidence of bronchopneumonia, which likely followed respiratory depression, and focal acute pyelonephritis.
- 61. Dr Lynch provided a written report, dated 18 July 2017, in which he formulated the cause of death as 'I(a) *Hypoxic ischaemic encephalopathy complicating mixed drug toxicity*'.
- 62. I accept Dr Lynch's opinion as to cause of death.
- 63. As Ms Higgins died sometime after the overdose which led to her death, toxicological analysis of post-mortem samples would not give useful information as to what substances she had consumed prior to her death, and there were no ante mortem samples sufficiently close to the time of her overdose to be useful.
- 64. Nonetheless, considering the circumstances of her death I am comfortable in concluding that she had taken only her prescribed medications prior to her death. Considering Ms Phillips' concerns that Ms Higgins may have been so affected by her prescribed levels of medication that she was not aware of how much she was taking, I accept the possibility that she may have consumed more than the prescribed quantity.

Intent

65. There is no evidence that Ms Higgins had any intentions of self-harm at this time. There is also no evidence that she was using any illicit drugs or any drugs which had not been prescribed to her.

66. On the basis of the evidence available to me, I find that Ms Higgins died as the unintended consequence of the consumption of her prescribed medications.

THE RE-OPENED CORONIAL INVESTIGATION

The previous investigation and finding

- 67. On 16 April 2020, I finalised my investigation into Ms Higgin's death and made the following findings:
 - a) The identity of the deceased was Jessica Higgins, born 15 July 1983;
 - b) The death occurred on 4 June 2017 at Austin Hospital, 145 Studley Road, Heidelberg, Victoria, from hypoxic ischaemic encephalopathy complicating mixed drug toxicity; and
 - c) The death occurred in the circumstances described above.
- 68. Prior to the reopening of the investigation into Ms Higgins' death, I made several adverse findings regarding the conduct of Dr Bolzonello and Dr Thomas in their treatment of Ms Higgins, specifically regarding the appropriateness of the communications between themselves and Ms Higgins, and the appropriateness of increasing her methadone dose via a telehealth appointment on 26 May 2017.
- 69. Further to these adverse findings, I directed that the Australian Health Practitioner Regulation Agency (AHPRA) be notified of the deficiencies in care provided by Dr Bolzonello and Dr Thomas, pursuant to section 144(1) of the *Health Practitioner Regulation National Law*. These notifications were appropriately investigated by AHPRA who determined that no further action was required.
- 70. Finally, pursuant to section 72(2) of the Act, I recommended that the Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists include in their forthcoming guidelines on ketamine infusion specific guidance on post-discharge planning that addresses how to communicate clinical decision-making surrounding changes in dosage of opioid medication and what information will be required before making any such changes
- 71. These findings were provided to the Interested Parties.

Application to set aside the findings dated 16 April 2020

- 72. On 2 October 2020, the Court received a *Form 43 Application to Set Aside Finding* from Dr Bolzonello, pursuant to section 77 of the Act.
- 73. In his application, Dr Bolzonello submitted that those paragraphs contained within of the original finding dated 16 April 2020 that were adverse in nature to him should be set aside based on a lack of procedural fairness and new evidence by way of the expert report submitted on behalf of Dr Bolzonello by Dr Seamus Dalton, a Consultant Physician in Rehabilitation Medicine, dated 27 August 2020.
- 74. Whilst an individual retains the right to apply for a judicial review of a Coroner's decision under section 87 of the Act, the Act further stipulates that this must be made to the Trial Division of the Supreme Court. Therefore, it is not necessary for me to resolve Dr Bolzonello's submissions regarding procedural fairness during the original investigation.
- 75. Under section 77 of the Act, however:

(1) A person may apply to the Coroners Court for an order that some or all of the findings of a coroner after an investigation (whether or not an inquest has been held) should be set aside.

To grant an application under this section, the court must be '(2)...satisfied that there are new facts and circumstances that make it appropriate to do so'.

76. Upon receipt of Dr Bolzonello's application, I considered Dr Dalton's report in light of the existing evidence and determined that it did, in fact, constitute 'new facts and circumstances' within the meaning of section 77(2), and that it was appropriate to grant Dr Bolzonello's application to set aside those findings so impugned and reopen the investigation.

The scope of the re-opened investigation

77. After considering all the material obtained during the initial coronial investigation in the context of the submissions made by Dr Bolzonello on 2 October 2020, including the expert report submitted by Dr Bolzonello's legal representatives from Dr Dalton, I determined that it was necessary for the Court to obtain further information.

- 78. The Court engaged the services of Dr Matthew Frei, Addiction Medicine Specialist, who reviewed Dr Dalton's submissions and provided an expert report in response dated 31 May 2022. This was provided to the Interested Parties and submissions in response to Dr Frei's report were received from Dr Bolzonello, Dr Dalton, and Dr Thomas.
- 79. Dr Dalton and Dr Frei's reports directly addressed the care that Ms Higgins received from Dr Bolzonello and Dr Thomas immediately prior to her death which was material to the adverse findings I originally handed down. I will therefore confine my findings to the issues raised and replies submitted within these reports. I have also had regard to the responses submitted by Dr Bolzonello and Dr Thomas in response to these reports.
- 80. The following review of Ms Higgins care contains my initial undisputed findings into Ms Higgins' death, as well as updated findings based upon the evidence provided by Dr Frei, as well as the responses from Dr Bolzonello and Dr Thomas.

REVIEW OF MS HIGGIN'S CARE

- 81. During my investigation, I noted the possibility that Ms Higgins' death was directly caused by her prescribed doses of medications. Another possibility put forward by Ms Phillips was that Ms Higgins took more than her prescribed doses due to confusion caused by the medications taken at the prescribed doses.
- 82. Although I could not find that either scenario is more likely than the other, I was satisfied that Ms Higgins' death was caused directly or indirectly by the prescription of medications, in particular methadone, in circumstances where her methadone dose had been increased on the day before her fatal overdose and she had been provided with a script for 20 tablets of 10mg of methadone.
- 83. Due to these concerns, I requested that case investigators from the Coroners Prevention Unit (CPU)⁵² review the evidence relating to Ms Higgins' death and provide advice on the course of my investigation. The CPU advised me that it would be prudent to obtain an expert opinion in this area and, in consideration of this advice, I directed that an expert report be obtained from Dr Frei which was provided to the Interested Parties for their review and response.

⁵² The Coroners Prevention Unit (CPU) was established in 2008 to strengthen the prevention role of the coroner. The unit assists the Coroner with research in matters related to public health and safety and in relation to the formulation of prevention recommendations. The CPU also reviews medical care and treatment in cases referred by the coroner. The CPU is comprised of health professionals with training in a range of areas including medicine, nursing, public health and mental health.

84. The responses I received from Dr Bolzonello and Dr Thomas in response to both my initial questions and Dr Frei's subsequent expert opinion were thorough and considered. Whilst I did not accept every point they have raised with respect to my concerns, I acknowledged that they acted in good faith and with the intention of ensuring that they provide the best possible care to other patients in the future.

Ketamine infusion for opioid rotation

- 85. The nursing discharge summary for Ms Higgins' inpatient admission from 16 May to 23 May reports '*Nil significant improvement in pain*'.⁵³
- 86. Dr Thomas was asked to comment on whether this should have raised concerns about Ms Higgins' opioid rotation. He first noted that his interpretation of her records was that her pain scores were slightly better over the course of her stay, but he agreed that one could also reasonably draw the conclusion that pain had not improved.
- 87. Despite this, he noted that the ketamine infusion had a dual purpose of pain reduction and for benefit in the withdrawal process for oxycodone. He submitted that the ketamine infusion *'certainly had allowed us to wean her off her high-dose opioid medications'* and so achieved that purpose.
- 88. I accept Dr Thomas' submission, and I accept that Ms Higgins' limited pain reduction during her ketamine infusion was not a cause for concern regarding the possibility of later overdose.⁵⁴

Post-discharge planning

- 89. The Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists has published a 'Proposal for practice guideline' on '*Low dose ketamine infusion in the management of chronic non-cancer pain*'.⁵⁵
- 90. The principles to guide the administration of ketamine infusions identified in this document include '*Clear pathway for follow-up*' and '*Clear line(s) of communication with patients*' primary health practitioner(s)'. The outlined proposal for best practice includes '*Emergency after-discharge plan, especially for recrudescence of "pain*'''.

⁵³ Nursing Discharge Summary dated 23 May 2017, Victorian Rehabilitation Centre Medical Records.

⁵⁴ I note that Dr Thomas is an experienced practitioner in this field. He advises that he 'admits up to six patients per week for ketamine infusion opioid wean and rotation' and is a Fellow of the Faculty of Pain Medicine: see unsigned statement of Dr Clayton Thomas typed 30 April 2019, Coronial Brief.

⁵⁵ Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists '*Proposal for practice guideline: Low dose ketamine infusion in the management of chronic non-cancer pain*' (2016).

- 91. There is no evidence of such an emergency post-discharge plan existing for Ms Higgins after she left the Victorian Rehabilitation Centre on 23 May, beyond Ms Higgins being invited to contact Dr Thomas if needed. Both Dr Bolzonello and Dr Thomas were invited to respond to my concerns that no such plan existed, and neither presented any evidence to the contrary.
- 92. As it occurred, Dr Thomas and Dr Bolzonello responded to Ms Higgins' request to treat her returning pain by way of two separate telephone conversations with Ms Higgins and an ambiguous text-message exchange. This process left crucial information as to Ms Higgins' presentation unknown. I consider that if a structure for information sharing and communication had been laid out on 23 May, it would have reasonably involved in-person review before any significant increase in dosage was prescribed. This is speculative, however, and the details to be included in such a plan would need to be subject to clinical judgment.
- 93. It is difficult to compare the actions of Ms Higgins' treating practitioners on her discharge to accepted professional standards, as standard practice for ketamine infusions appears to be varied. The proposal for guideline discussed above notes that '*There is substantial clinical variation in the use of ketamine infusions for chronic non-cancer pain*' and that '*There is a paucity of quality evidence concerning the use of ketamine infusions in patients with chronic non-cancer pain*'.
- 94. To prevent deaths such as Ms Higgins' from occurring in the future, it would be appropriate for the Faculty of Pain Medicine to consider what can be learned from Ms Higgins' death in their ongoing work of developing standards and best practices for ketamine infusion. A clear lesson to be taken from these tragic events is the importance of planning for the post-discharge period in vulnerable patients, with a focus on the structured sharing of information.

Consideration of escalated risk

- 95. There is evidence that rotation to methadone from another opioid is particularly risky where there has been a recent escalation in opioid consumption.⁵⁶
- 96. Dr Thomas was asked to comment on whether this particular risk had been considered in determining whether Ms Higgins should be rotated from oxycodone to methadone at that time.

⁵⁶ Zimmermann et al, "Rotation to Methadone after Opioid Dose Escalation" (2005) 19(2) *Journal of Pain & Palliative Care Pharmacotherapy* 25.

- 97. In his response, Dr Thomas went into greater detail about his decision-making process. He acknowledged throughout that Ms Higgins was a high-risk individual considering the quantities of opiate medication she was taking.
- 98. He also drew attention to her 'trajectory' of increasing oxycodone uses before her opioid rotation and the role this played in his decision to rotate her to methadone use.
- 99. From Dr Thomas' response, I am satisfied that he was fully aware of Ms Higgins' heightened vulnerability and risks following rotation under ketamine infusion. I am satisfied that his decision to perform the rotation at that time was sound and well-informed.
- 100. That consciousness of heightened risk, however, should have made Dr Thomas more careful with Ms Higgins' care post-discharge, including the consideration of alternative therapies and concurrent medications which will be discussed in the following sections.

Availability of alternative therapies

- 101. In consideration of Ms Higgins' increased risk, Dr Frei drew attention to several alternative therapies that may have been considered by Dr Thomas. This included the use of Medication Assisted Treatment of Opioid Dependence (**MATOD**), which Dr Frei noted is a "closely monitored structured program that use liquid methadone, usually provided daily at an authorised dosing site, and consumed while being observed by a clinician or pharmacist".⁵⁷
- 102. Dr Frei also opined that buprenorphine (which includes the brand name Suboxone) would have been a viable alternative therapy for Ms Higgins, noting that it has a "flattened dose effect curve, meaning high doses are not associated with increased respiratory depression and collapse as with full agonists" and that "Buprenorphine is far less likely to be found to contribute to multidrug toxicity related death compared to methadone".⁵⁸
- 103. In his reply submissions, Dr Thomas conceded that Ms Higgins would have been eligible for MATOD or buprenorphine but noted that one key criterion is aberrant usage and contended that he was not aware of Ms Higgins' history of aberrant usage prior to her death. Dr Thomas also notes that SafeScript, a current method of tracking prescriptions and aberrant usage, was not present at the time of Ms Higgins' care and was introduced in 2019.⁵⁹

⁵⁷ Statement of Dr Matthew Frei dated 31 May 2022.

⁵⁸ Statement of Dr Matthew Frei dated 31 May 2022.

⁵⁹ Statement of Dr Clayton Thomas dated 5 August 2022.

- 104. Dr Thomas also submitted that high-dose buprenorphine was not commonly used for patients suffering severe pain in 2017, and that prescribing processes were more complicated.⁶⁰ Dr Bolzonello agreed with this submission.⁶¹
- 105. Having reviewed the relevant submissions, it is reasonable to conclude that, whilst buprenorphine may have been a viable alternative to methadone for Ms Higgins, it was not available at the time of her death.
- 106. Furthermore, I note that whilst Dr Frei currently draws attention to the positives of a structured and closely observed methadone program for those recovering from addiction to opioids (MATOD), I note that MATOD is traditionally utilised as a replacement therapy, not a treatment strategy, and would not have been a viable option in Ms Higgins' case, given her frequent and fluctuating pain levels.

Change in dosage on 26 May 2017

- 107. In Dr Bolzonello's clinical note he made on 25 May 2017, he recorded Ms Higgins' prescription as '[methadone] 5mg BD [twice daily] Allowed to take extra 5mg up to 15/day (25mg total)'. This was also Dr Thomas' understanding of Ms Higgins' methadone prescription on her discharge from the Victorian Rehabilitation Centre.
- 108. If Ms Higgins contacted Dr Thomas and Dr Bolzonello on 26 May about her current dosage being insufficient, it is reasonable to assume that she was taking the maximum quantity of her as-needed doses, and so taking 25mg methadone per day.
- 109. On 26 May, Dr Bolzonello wrote a new script for 10mg methadone to be taken three times daily, with no specified allowance for as-needed doses. If this replaces the entirety of her previous prescription, including both regular and as-needed doses, then her regular dose would be 30mg methadone per day.
- 110. This appears to have been Dr Bolzonello's understanding of the change being made to Ms Higgins' methadone dose on 26 May 2017. Dr Thomas also states that this was his understanding, although he considers Ms Higgins' previous dose to have been a likely 20mg per day rather than a presumed 25mg per day.

⁶⁰ Statement of Dr Clayton Thomas dated 5 August 2022.

⁶¹ Statement of Dr Matthew Frei dated 31 May 2022.

- 111. Dr Bolzonello has submitted that this rate of change in dosage, from 25mg daily to 30mg daily, was within accepted guidelines. I accept this submission as a general statement, although I requested Dr Frei address this in his report to the court in light of Ms Higgins' particular circumstances.
- 112. In his report, Dr Frei opined that "*opioid dependence is characterised by loss of control and because methadone has some very specific and very significant risks*" and that methadone is known to accumulate as serum levels reach stable state. Dr Frei also opined that methadone doses should not be increased more frequently than every three days and that practitioners need to take particular care during the first week by "going slow, starting slow" to avoid cardiorespiratory compromise.⁶²
- 113. Dr Bolzonello recalled that, on 25 May 2017, Ms Higgins appeared "*clear eyed, lucid, and not drowsy*", and that, during his phone call with her on 26 May, she was "*alert and able to clearly and rationally articulate her discussion with Dr Thomas*".⁶³ Dr Thomas submitted that he was not aware of her history of aberrant medication usage and that, if she had reported any symptoms of sedation, he would not have prescribed further increases.⁶⁴
- 114. Given Ms Higgins' demonstrated tolerance to opioids, Dr Frei agreed that her dosing regimen was acceptable and that her increased dose of 30mg daily was "*within the range of starting doses in a tolerant patient*".⁶⁵ Therefore, in the absence of alternative therapies or symptoms of sedation, I find that Dr Thomas' and Dr Bolzonello's methadone treatment regimen was reasonable and appropriate.

Risks of methadone therapy

115. Whether Ms Higgins' increased dose was appropriate or not, I note that Dr Frei references the *"significant risk"* presented by the combination of drugs Ms Higgins was prescribed at the time (methadone, pregabalin, and diazepam). He also noted that Ms Higgins presented several *"yellow flags"* in her presentation.

⁶² Statement of Dr Matthew Frei dated 31 May 2022.

⁶³ Submissions of F M Ellis, Counsel for Dr Bolzonello dated 5 August 2022.

⁶⁴ Statement of Dr Clayton Thomas dated 5 August 2022.

⁶⁵ Statement of Dr Matthew Frei dated 31 May 2022.

- 116. Dr Frei further opined that it was "*difficult to dismiss the contribution of these three drugs together in causing respiratory depression*" and concluded that the combination of agents could not be excluded as potential contributor to her cardiac arrest.⁶⁶ I note that Dr Thomas agreed with this submission.⁶⁷
- 117. Dr Dalton, Dr Bolzonello, and Dr Thomas submitted that, if Ms Higgins had been taking the drugs as they were prescribed, then the risk of an overdose would have been "*extremely small*" however, noting that the risk of sedation and cardiorespiratory compromise was "*significantly mitigated*" due to Ms Higgins' prolonged use and tolerance.⁶⁸ Dr Thomas submitted that the evidence linking pregabalin to overdoses did not exist in 2017.⁶⁹
- 118. I do not accept this submission, noting that, whilst Ms Higgins' risk of overdose may have indeed been "*extremely small*", given her history of aberrant drug usage, the risk of adverse outcomes from the combination of drugs she was prescribed should have prompted greater care from her practitioners, whether she was "tolerant" or not. Furthermore, whilst Dr Bolzonello submitted that Ms Higgins was clear about her medication, I note the contrary statement from Ms Phillips that Ms Higgins "*seemed unclear about her medication*".⁷⁰
- 119. I note that Dr Thomas submitted that he was unaware of her history of aberrant usage⁷¹ which in turn gives rise to the question as to whether he *should* have been aware, however, I further note that the issue of practitioners being unaware of aberrant usage of medications by their patients is a well-recognised issue in the community, and appropriate steps have already been taken to address this issue, such as the introduction of SafeScript. Therefore, it is not necessary for me to further investigate this issue here.

Take home naloxone

120. In his report, Dr Frei noted the value of take-home naloxone in patients on high-dose opioid therapy. Dr Frei also noted that although Dr Thomas previously opined that take home naloxone would not have been of value in a patient in Ms Higgins' particular circumstances, it may have been of some benefit in her situation regardless.⁷²

⁶⁶ Statement of Dr Matthew Frei dated 31 May 2022.

⁶⁷ Statement of Dr Clayton Thomas dated 5 August 2022.

⁶⁸ Statement of Dr Seamus Dalton dated 29 July 2022; submissions of F M Ellis, Counsel for Dr Bolzonello dated 5 August 2022; statement of Dr Clayton Thomas dated 5 August 2022.

⁶⁹ Statement of Dr Clayton Thomas dated 5 August 2022.

⁷⁰ Statement of Dr Matthew Frei dated 31 May 2022.

⁷¹ Statement of Dr Clayton Thomas dated 5 August 2022.

⁷² Statement of Dr Matthew Frei dated 31 May 2022.

- 121. In his response to Dr Frei's report, Dr Thomas submitted that take-home naloxone was not widely used at the time of Ms Higgins' death, that she was living alone, and that she had explicitly instructed him not to discuss her condition with her mother, all of which presented significant challenges to the proper use of naloxone in the home environment.⁷³
- 122. Whether she would have used it or not, take-home naloxone could have been considered by Ms Higgins' practitioners. The value of this therapy has been demonstrated several times and has been validated through the implementation of the Department of Justice and Community Safety's (**DJCS**) 'Naloxone on Release' pilot program, which is designed to train prisoners to prevent, recognise, and respond to opioid overdoses through training and the provision of take-home naloxone kits upon release. I have previously made recommendations pertaining to this program which were accepted and supported by the DJCS and Department of Health.⁷⁴
- 123. Dr Bolzonello submitted to the court cannot be satisfied that Ms Higgins' death may have been preventable had take-home naloxone been available.⁷⁵ Given the court's responsibility not to make adverse findings or comments against individuals in their professional capacity, or against institutions, with the benefit of hindsight, I accept that submission, especially given Ms Higgins' documented reluctance to discuss her condition with her mother.

Lack of in-person review

- 124. As discussed above, in his response to my concerns Dr Thomas characterised the change in Ms Higgins' methadone dosage as moving from 'a likely dose of 20mg to 30mg per day'.⁷⁶
- 125. Dr Thomas stated that:

Although increasing Ms Higgins' methadone dosage from approximately 20mg to 30mg is not a large increase, on reflection I accept that it would have been wise to review Ms Higgins in person prior to advising her GP of the dose increase. If there was any evidence of sedation, then I would not have increased the dose. Given that she had seen Dr Bolzonello the day before on 25 May 2017, I accepted that this was not the case.⁷⁷

126. As discussed above, I accept that Dr Bolzonello considered the change in Ms Higgins' dosage to be from 25mg per day to 30mg per day.

⁷³ Statement of Dr Clayton Thomas dated 5 August 2022.

⁷⁴ COR 2019/4949; COR 2020/3629.

⁷⁵ Submissions of F M Ellis, Counsel for Dr Bolzonello dated 5 August 2022.

⁷⁶ Statement of Dr Clayton Thomas dated 9 July 2019, Coronial Brief.

⁷⁷ Statement of Dr Clayton Thomas dated 9 July 2019, Coronial Brief.

- 127. Whilst Dr Frei's report reassured me that the decision to increase Ms Higgins' methadone does to 30mg daily was reasonable and appropriate given her demonstrated tolerance to opioids, the subject of the findings so impugned in Dr Bolzonello's application to set aside the original findings into Ms Higgins' death focused on her physician's failure to keep accurate and comprehensive notes of their decision to increase her dose, as well as their failure to provide an in-person review on the day of her death.
- 128. Therefore, I specifically requested that Dr Frei review the decision of Dr Bolzonello to increase Ms Higgins' dose via a telehealth appointment rather than an in-person review and provide an opinion on the reasonableness of this decision.
- 129. Dr Frei noted that Ms Higgins had been reviewed by Dr Bolzonello on 25 May 2017 during which time she did not present with any adverse symptoms, including signs of sedation. Therefore, Dr Frei opined that the decision to increase Ms Higgins' dose the following day via a phone consultation was not unreasonable, especially given Dr Bolzonello's familiarity with Ms Higgins.⁷⁸
- 130. Dr Bolzonello and Dr Thomas have accepted, in a qualified form, that their decision to increase Ms Higgins' prescription without reviewing her in person was suboptimal. Dr Thomas' description of his decision-making has been quoted above, and Dr Bolzonello stated:

Whilst I accept that it would have been ideal to review Ms Higgins in person on 26 May 2017, in circumstances where I had reviewed her the day prior and noted no concerns with regards to her medication, where I did not consider there to be any risk in increasing Ms Higgins' maximum daily dose of methadone by 5mg and where she was to be reviewed by Dr Thomas on 30 May 2017, I was comfortable with providing her with the prescription.⁷⁹

131. I accept this submission and shall not maintain my earlier adverse comments, given Dr Frei's reassurance that Dr Bolzonello and Dr Thomas' practice was appropriate given the surrounding circumstances.

⁷⁸ Statement of Dr Matthew Frei dated 31 May 2022.

⁷⁹ Statement of Dr David Bolzonello dated 19 July 2019, Coronial Brief.

Communication surrounding change in dosage on 26 May 2017

- 132. The interpretation of Ms Higgins' changing dose set out above does not sit easily with Dr Bolzonello's text message to Dr Thomas discussing changing Ms Higgins' prescription from '5 mg to 10 mg [tds]'.
- 133. The change referred could be interpreted as replacing only the regular 5mg twice-daily portion of her previous dosage with 10mg three-times-daily, or as replacing only the 5mg three-timesdaily portion of her previous dosage which was being taken as needed with 10mg three-timesdaily. Either interpretation would represent a significant increase in her dosage of methadone.
- 134. Whilst I accept that the increase in Ms Higgins' dose was appropriate in light of the evidence of Dr Frei, I note the possibility that, based on the potentially ambiguous instructions Ms Higgins was provided on the day of her death, there was a real risk of her to become confused and taking higher dose of methadone than was intended to be prescribed.
- 135. Unfortunately, the fact of the lack of documentation of Dr Bolzonello's and Dr Thomas' discussions with Ms Higgins makes it impossible to conclusively determine what she was actually told about her new prescribed dosage.
- 136. I specifically requested that Dr Frei review the communications between Ms Higgins' and her physicians so as to provide advice on whether this contributed to Ms Higgins' subsequent death, and whether their documentation was consistent with accepted practices.
- 137. Dr Frei concluded that Dr Bolzonello's failure to document his communications with Dr Thomas and Ms Higgins did <u>not</u> contribute to her death, but opined that it is good practice to document "*relevant negatives*".⁸⁰ Dr Frei noted that there were some inconsistencies in Dr Bolzonello's reports when compared with his notes and opined that his failure to record all exchanges between himself, Ms Higgins, and Dr Thomas fell below the acceptable standard.⁸¹
- 138. In response, Dr Bolzonello submitted that the "*usual practice is to document positive findings*" and that Dr Frei's opinion "*contains elements of retrospectivity and hindsight*", contrary to standards expected of me under the Act. I do note that Dr Bolzonello accepted his failure to document the text message and interaction with Ms Higgins in his notes but submitted that this had "*no material consequence*" in her death.⁸²

⁸⁰ Statement of Dr Matthew Frei dated 31 May 2022.

⁸¹ Statement of Dr Matthew Frei dated 31 May 2022.

⁸² Submissions of F M Ellis, Counsel for Dr Bolzonello dated 5 August 2022.

- 139. Dr Bolzonello also submitted that there was no evidence that Ms Higgins misunderstood her medication regimen. He also noted that he has improved his record keeping practices and now incorporates SafeScript in his practice.
- 140. Dr Thomas conceded that his documentation was below standard but noted Dr Frei's position that this did not cause Ms Higgins' death. In his statement dated 9 July 2019, Dr Thomas accepted that his text messages should have been included in Ms Higgins' medical records. Dr Thomas also stated that he now takes extra precautions to make file notes and has completed further education in this area.
- 141. Whilst Dr Bolzonello's submissions are at odds with the recollection of Ms Higgins' mother regarding whether Ms Higgins was clear about her medication, I am prepared to accept Dr Frei's opinion that his communications with her did not contribute to her death. I further note that both doctors have acknowledged their failure to document all exchanges between providers and Ms Higgins and state that they have improved their practices.
- 142. I do not, however, accept Dr Bolzonello's submission that the "*usual practice is to document positive findings*". The practice of documenting pertinent negatives is well established within the medical community and provides a more comprehensive patient assessment than simply recording positives. I am fortified in this view by the expert opinion of Dr Frei noted above.
- 143. However, given that this matter has already been referred to the Australian Health Practitioner Regulation Agency which appropriately investigated the issue and determined that no further action would be taken, it is not necessary for me to make any further findings on this issue.

Schedule 8 Prescribing

- 144. One issue which became clear in my review of Ms Higgins' clinical course leading up to her admission for a ketamine infusion was that Dr Bolzonello and Dr Sellars were prescribing oxycodone outside the bounds of Dr Bolzonello's permit to prescribe oxycodone at a maximum of 80mg per day.
- 145. Dr Bolzonello had acknowledged that he provided prescriptions to Ms Higgins that exceeded the daily maximum dose provided by that permit. Dr Sellars states that he was acting under the assumption that he was able to prescribe drugs of addiction in the absence of Dr Bolzonello pursuant to Dr Bolzonello's permit, but he now understands that this is incorrect as he did not work at the same practice.

- 146. Both Dr Bolzonello and Dr Sellars have given evidence that they have undertaken further education as to the current legislation and regulations regarding prescription of Schedule 8 substances. Dr Bolzonello in particular advises that he now uses the SafeScript system as part of his standard practice.
- 147. The quantities prescribed were not, in themselves, irresponsible. Dr Bolzonello and Dr Sellars were clearly making efforts to control Ms Higgins' oxycodone use, and all practitioners involved were aware of the heightened risk Ms Higgins' trajectory of opioid use posed.
- 148. Although Dr Bolzonello's and Dr Sellars' practices with respect to permits may have been flawed, I do not find that they contributed to Ms Higgins' death. I am satisfied by the efforts they have made to reflect on and improve their practices.

Quality of clinical notes

- 149. A consistent frustration throughout my investigation into Ms Higgins' death was the quality of clinical notes. In particular, Dr Bolzonello's notes were often lacking in detail and sometimes made retrospectively. A particularly glaring issue is that the text message conversation between Dr Bolzonello and Dr Thomas on 26 May 2017 was not recorded in either of their medical records.
- 150. Both Dr Bolzonello and Dr Thomas have acknowledged issues with their practices with regard to documentation. Both have also provided evidence that they have undertaken further education and amended their practices to improve in the future. I am satisfied that they have addressed this issue through appropriate remedial actions.
- 151. Dr Bolzonello was informed of my concern that he might not have been able to confidently determine Ms Higgins' treatment course relying on notes with a low level of detail. He responded as follows:

Ms Higgins had been my patient since 2007 and was a patient with whose treatment course and progress I was well familiar. I frequently reviewed Ms Higgins and further, she was one of only two patients for whom I held a Schedule 8 permit at the time. As noted above, I accept that my progress notes may not have always adhered to the relevant criteria, but I do not consider that this impacted the treatment I provided to Ms Higgins following her discharge from the VRC.⁸³

⁸³ Statement of Dr David Bolzonello dated 19 July 2019, Coronial Brief.

152. I accept Dr Bolzonello's submission, and I do not find that the quality of his notes negatively impacted Ms Higgins' care.

COMMENTS PURSUANT TO SECTION 67(3) OF THE ACT

- 153. Ms Higgins' clinical course was complex, and her physicians were clearly committed to her care. They had great knowledge and experience and, until the tragic events following her discharge on 23 May 2017, appear to have provided a high standard of treatment.
- 154. Weaning sufferers of pain away from opioid medications is notoriously difficult, and Ms Higgins' practitioners' attempts were no doubt hindered by the reported increases in her dosage when she attended Emergency Departments.
- 155. Whilst I originally found that there was a "clearly identifiable flaw in clinical decision making" regarding the increase in Ms Higgins' dose on 26 May 2017 from an effective 25mg daily to 30mg daily, in light of Dr Frei's report and the subsequent submissions from Dr Bolzonello and Dr Thomas, I shall no longer record such a comment.
- 156. The issue with this case then, was not one of the exercise clinical judgment, but of communication. Dr Thomas states at one point '*[i]f she was reporting excessive sedation or other side effects there is no way I would have recommended to increase her methadone*'.⁸⁴
- 157. Whilst in the absence of good notes, it remains possible that Ms Higgins was suffering from the effects of sedation at the time that her dose was increased based on the testimony of Ms Phillips, I prepared to accept that neither Dr Thomas or Dr Bolzonello were aware of this at the time, and that Ms Higgins presented as her normal alert self during her in-person review on 25 May 2017.
- 158. Furthermore, after having carefully considered the practices of Dr Bolzonello and Dr Thomas with the assistance of Dr Frei's opinion, I am reassured that the decision to provide a telehealth consultation rather than an in-person appointment when increasing Ms Higgins' dose on 26 May 2017 was appropriate, given that this was only occurred because she had been appropriately reviewed in person by Dr Bolzonello the day before.

⁸⁴ Statement of Dr Clayton Thomas dated 9 July 2019, Coronial Brief.

Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists

- 159. Ms Higgins' death highlights the potential dangers of poor communication for patients in the vulnerable period post-discharge from a ketamine infusion for opioid rotation. To prevent such opportunities from being missed in the future, further guidelines and standards should be developed for treating patients in this situation.
- 160. The Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists has published a 'Proposal for practice guideline' on 'Low dose ketamine infusion in the management of chronic non-cancer pain'.⁸⁵ This followed a recommendation from Coroner Audrey Jamieson in her finding into the death of Margaret McCall.⁸⁶
- 161. This proposal has not yet been finalised into an endorsed guideline. Juliette Whittington, the Acting General Manager of the Faculty of Pain Medicine, has advised that 'a document development group has been reviewing the current clinical evidence to expand the document and make it a professional document for our faculty fellows'.⁸⁷
- 162. I commend the work of the Faculty of Pain Medicine in this area, and I anticipate the completion of this document.
- 163. The circumstances of Ms Higgins' death demonstrate crucial lessons which should be considered by the Faculty of Pain Medicine (FPM) in finalising this document. Ms Higgins' tragic outcome shows the importance of specific plans being made to communicate clinical decision-making and to decide what information is required before making decisions such as increasing dosage of opioid medications.
- 164. In my original finding into this matter, I made the following recommendation -

That the Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists include in their forthcoming guidelines on ketamine infusion specific guidance on post-discharge planning that addresses how to communicate clinical decision-making surrounding changes in dosage of opioid medication and what information will be required before making any such changes.

⁸⁵ Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists '*Proposal for practice guideline: Low dose ketamine infusion in the management of chronic non-cancer pain*' (2016).

⁸⁶ This finding is available on the Coroners Court of Victoria website with the Case ID COR 2012 4064.

⁸⁷ Email from Juliette Whittington to the Court dated 20 March 2020.

- 165. Since the publication of the original finding, the FPM provided a response to the court in which it advised that it would be producing a broader Position Statement on the use of ketamine in the treatment of patients with chronic non-cancer pain, noting that this approach would provide a detailed articulation of the ethical issues and evidence base involved in this issue.
- 166. Having reviewed the FPM's response, I am satisfied that they have appropriately engaged with my recommendation in their approach.

FINDINGS AND CONCLUSION

- 167. The standard of proof for coronial findings of fact is the civil standard of proof on the balance of probabilities, with the *Briginshaw* gloss or explications.⁸⁸ Adverse findings or comments against individuals in their professional capacity, or against institutions, are not to be made with the benefit of hindsight but only on the basis of what was known or should reasonably have been known or done at the time, and only where the evidence supports a finding that they departed materially from the standards of their profession and, in so doing, caused or contributed to the death under investigation.
- 168. Having investigated the death, without holding an inquest, I make the following findings pursuant to section 67(1) of the Coroners Act 2008:
 - (a) The identity of the deceased was Jessica Higgins, born 15 July 1983;
 - (b) The death occurred on 4 June 2017 at Austin Hospital, 145 Studley Road, Heidelberg, Victoria, from hypoxic ischaemic encephalopathy complicating mixed drug toxicity; and
 - (c) The death occurred in the circumstances described above.

⁸⁸ Briginshaw v Briginshaw (1938) 60 CLR 336 at 362-363: 'The seriousness of an allegation made, the inherent unlikelihood of an occurrence of a given description, or the gravity of the consequences flowing from a particular finding, are considerations which must affect the answer to the question whether the issues had 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...'.

RECOMMENDATIONS

- 169. Whilst I accept the submissions of Dr Thomas as to the specific unavailability of buprenorphine at the time of Ms Higgins' death, it is vital that practitioners, especially those specialising in chronic pain management, remain conscious of this alternative therapy in appropriate settings.
- 170. I therefore make the following recommendation (1):

I recommend that the Royal Australian College of General Practitioners and the Faculty of Pain Medicine reiterate to their members the importance of considering buprenorphine in chronic pain management in appropriate cases.

- 171. Furthermore, it is important that practitioners remain conscious of the need to consider the risks associated with concurrent medication prescribing in vulnerable patients, and that frequent reviews are undertaken in a face-to-face setting, to assess patients for signs of sedation or other adverse symptoms.
- 172. I therefore make the following recommendation (2):

I recommend that the Royal Australian College of General Practitioners and the Faculty of Pain Medicine reiterate the risks associated with patients who are prescribed multiple and concurrent medications with sedative properties, and that frequent reviews of patients ought be undertaken in a face-to-face setting to assess for adverse signs and symptoms.

- 173. Finally, as noted above, Ms Higgins' death prevents an opportunity to revisit the importance of ensuring that all interactions between providers and their patients are comprehensively documented in the patient's medical records, and that clear communication, including written records, is conducted in patients with multiple treating providers.
- 174. Furthermore, providers should always confirm, in writing, clear instructions for patients regarding their medication usage and doses to avoid any ambiguity or possible adverse outcomes.

175. I therefore make the following recommendation (3):

I recommend that the Royal Australian College of General Practitioners and the Faculty of Pain Medicine reiterate to their members the importance of practitioners ensuring that all interactions with their patients, especially those with multiple providers, are documented in clear, written form in the patient's medical record, and that all patients are instructed in clear, written terms regarding their medication usage and doses to avoid potential adverse outcomes.

I express my sincere condolences to Ms Higgins' family for their loss. I also wish to acknowledge the added distress that the prolonged coronial process no doubt caused them.

Pursuant to section 73(1A) of the Act, I order that this finding be published on the Coroners Court of Victoria website in accordance with the rules.

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

- (d) Ms Margaret Phillips, senior next of kin;
- (e) Dr David Bolzonello, care of Ms Cindy Tucker, Kennedys Law;
- (f) Dr Clayton Thomas, care of Ms Madhavi Ligam, Avant Law;
- (g) Dr Anthony Sellars;
- (h) Mrs Pauline Chapman, Austin Health;
- (i) Mrs Linda Shelley, the Victorian Rehabilitation Centre;
- (j) WorkSafe Victoria, care of Mr Steve Jacobs, Wisewould Mahony;
- (k) Mrs Janet Tucci, Adviceline Injury Lawyers;
- (l) Australian Health Practitioner Regulation Agency;
- (m) Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists; and
- (n) Senior Constable Romualdo Pelle, Coroner's Investigator.

Signature:



CORONER SIMON McGREGOR

CORONER

Date: 26 August 2022

NOTE: Under section 83 of the *Coroners Act 2008* ('the Act'), a person with sufficient interest in an investigation may appeal to the Trial Division of the Supreme Court against the findings of a coroner in respect of a death after an investigation. An appeal must be made within 6 months after the day on which the determination is made, unless the Supreme Court grants leave to appeal out of time under section 86 of the Act.