CORONERS COURT
OF NEW SOUTH WALES

Inquest:	Inquest into the death of Linus Fred PHILLIPS
Hearing Dates:	18, 19, 20 and 21 February 2020; 14 October 2021
Date of Findings:	9 August 2024
Place of Findings:	Coroners Court of New South Wales at Lidcombe
Findings of:	Magistrate Joan Baptie, Deputy State Coroner
Catchwords:	CORONIAL LAW – cause and manner of death – cardiac arrhythmia – Torsades de Pointes – medical prescription of methadone (Physeptone tablets) – appropriateness of dosage, induction rate and medical supervision of methadone prescription – application to Pharmaceutical Services Unit ("PSU")/ Pharmaceutical Regulatory Unit ("PRU") for authority to prescribe methadone; responsibilities, objectives, functions and policies of the PSU/PRU – referral pursuant to *Health Practitioner Regulation National Law* (NSW)
File Number:	2014/00315189
Representation:	Counsel Assisting the Coroner: Ms L Whalan SC, instructed by Mr P Armstrong and Ms C Healey-Nash of the Crown Solicitor's Office Dr Michael Huber: Dr P Dwyer SC, instructed by Mr R Lei of Avant Dr William Huang: Ms K Burke, instructed by Ms M Nicolle of Meridian Lawyers NSW Ministry of Health: Mr B Bradley, instructed by Ms F Menniti of McCabes Lawyers
Findings:	**Identity:** The person who died was Linus Fred Phillips. **Date of death:** Mr Phillips died on 24 October 2014.

Place of death:
Mr Phillips died at 97/6 Stanley Street, Darlinghurst.

Cause of death:
Mr Phillips died as a result of cardiac arrhythmia, probably Torsades de Pointes, due to the combined effects of coronary artery atherosclerotic disease, sleep apnoea, methadone and other drugs which had a QT prolonging effect.

Manner of death:
The medical prescription of Physeptone tablets which were lawfully prescribed to him, but in dosages which were too large, the induction rate too rapid and inadequate medical supervision.

Recommendations:

To the NSW Ministry of Health

1. In respect of the Pharmaceutical Regulatory Unit and the Medical Committee, it is appropriate that the requirements for applications for authority to prescribe Physeptone be examined, particularly with regard to the threshold of 400mg as the oral morphine equivalent daily dose ('oMEDD') to be reached before an application is escalated. Additionally, consideration should be given to examining the appropriate information that should be sought from the prescriber about the patient's level of tolerance for Physeptone when applying for authority to prescribe.

2. The NSW Ministry of Health consider what steps should be taken to educate doctors about the existence and the role of the Pharmaceutical Regulatory Unit, with respect to applying for an authority to prescribe and supply drugs of addiction where required under the *Poisons and Therapeutic Goods Act 1966*.

Referrals:

1. Pursuant to s. 151A (2) of the *Health Practitioner Regulation National Law* (NSW) a copy of the transcript of the evidence from the Inquest is to be sent to the Health Care Complaints Commission and the Medical Council of NSW along with a request that the management of Mr Linus Phillips by Dr William Huang in October 2014 be examined.

2. Pursuant to s. 151A (2) of the *Health Practitioners Regulation National Law* (NSW) a copy of the transcript of the evidence from the Inquest is to be sent to the Health Care Complaints Commission and the Medical Council of NSW

along with a request that the management of Mr Linus Phillips by Dr Michael Huber in October 2014 be examined.

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Introduction

1 This inquest concerns the death of Mr Linus Fred Phillips. Mr Phillips was known to his family and friends as 'Buddy'. He has been described variously as intelligent, charming, very sensitive and a highly motivated man, dedicated to the responsible management of his pain and to improving his levels of functioning.

2 Mr Phillips was born on 11 January 1949 in Los Angeles, California. He died at his home in Darlinghurst, NSW on 24 October 2014 at the age of 65 years.

3 In the weeks prior to his death, Mr Phillips had been prescribed Methadone in the form of Physeptone tablets for pain management.

4 The identity, date and place of Mr Phillips' death are not in dispute. This inquest has focused on the manner and cause of his death and any contributing circumstances.

5 Mr Phillips' sister, Ms Ffiona Phillips, expressed her family's sorrow and sense of loss in her evidence before the Court. In her family statement to the Court, Ms Phillips described her brother as being "very altruistic and very spiritual" and that "he's missed by all of us, and I think about him a lot."

6 I acknowledge Mr Phillips' family's profound loss and continuing heartbreak and would like to express my sincere condolences and respect for their loss. I would also like to acknowledge and thank Ms Phillips for her contribution and participation in this inquest. I hope that Mr Phillips' memory has been honoured by the careful examination of his medical treatment during this inquest and the lessons that have been learned from the circumstances of his tragic passing.

The role of the coroner and the scope of the inquest

7 A coroner is required to investigate all reportable deaths and to make findings as to the person's identity; as well as when, where and how they died. A coroner is also required to identify the manner and cause of the person's death. In addition, a coroner may make recommendations that the coroner considers to be necessary or desirable, which may improve public health and safety.

8 During these proceedings, evidence was received in the form of statements and other documentation, which was tendered in court and admitted into evidence.

9 In addition, evidence was received from Mr Phillips' treating General Practitioner ("GP"), Dr Miodrag (Michael) Huber; as well as his treating specialist in addiction medicine, Dr William Wei Yi Huang, who were practicing from the same medical practice, Darlinghurst Medical Centre ("DMC"). Both

Dr Huber and Dr Huang prescribed a number of pharmaceuticals to Mr Phillips, including Physeptone.

10 Expert evidence was received in the form of a number of reports; as well as jointly from three experts by way of an evidentiary conclave. Two further experts gave evidence separately. In addition, two witnesses gave evidence in relation to their professional responsibilities at the Pharmaceutical Services Unit ("PSU")/ Pharmaceutical Regulatory Unit ("PRU") of the NSW Ministry of Health ("the Ministry"). The police officer in charge of the coronial investigation, Sergeant Evan Facey, also gave evidence in these proceedings.

11 All the material placed before the Court has been thoroughly reviewed and considered. I did not have the benefit of hearing from each of the witnesses and have relied on the transcript of proceedings. The witnesses gave their evidence before the State Coroner who subsequently recused herself.

12 I have been greatly assisted by the written submissions prepared by Senior Counsel Assisting the Coroner, Ms Lesley Whalan SC, and the other legal representatives. I have embraced their descriptions at times in these findings.

13 During these proceedings, significant issues and concerns arose as to the adequacy of the medical management and treatment of Mr Phillips after he had been prescribed Physeptone and its contribution to the manner of his death.

Mr Phillips' life

14 Mr Phillips was born in California and grew up and went to school in New Mexico. He had a passion for the high-altitude desert and the mountainous terrain of the New Mexico region.

15 As a teenager and as a young adult, Mr Phillips was an outstanding athlete. He successfully engaged in competitive sporting activities, including long distance running, tennis and basketball. He sustained a number of injuries during his sporting endeavours which began to manifest after he stopped competing, particularly involving injuries to his shoulder, back and knees.

16 Mr Phillips married when he was 27 years old and has one son. He was subsequently divorced. Mr Phillips was a qualified electrician from 1980 until 2007.

17 In 2007, Mr Phillips had to stop working due to significant knee pain. He underwent bilateral knee surgery in the United States of America ("USA") which left him with considerable residual pain. He was prescribed opiates to assist with his pain management.

18 In 2008, he came to Australia to provide full time care for his elderly mother and was granted Australian citizenship in 2009. Whilst in Australia, he continued to seek ongoing treatment and advice for his orthopaedic issues, particularly relating to his right knee.

The list of issues considered during the inquest

19 These proceedings focused on the medical treatment Mr Phillips received from September 2013 until 24 October 2014. In particular, the focus was on an eleven (11) day period during which Mr Phillips was first prescribed Physeptone and commenced ingesting the medication on 13 October 2014 until his death on 24 October 2014.

20 Prior to the commencement of the hearing, the following List of Issues was prepared and circulated to the parties with sufficient interest in these proceedings:

1. The cause of death, including the contribution, if any, of prescribed medication, including methadone (Physeptone).

2. The manner of death, including:

   a. The appropriateness of the type, dosage and frequency of medication prescribed by Dr Huber or Dr Huang between 10 October 2014 and 24 October 2014;

   b. The appropriateness of the prescription of Physeptone in a patient with the medical background, comorbidities and circumstances of Mr Phillips;

   c. The appropriateness of the coincident prescription of Physeptone and other drugs prescribed (including Stilnox, Ciprofloxacin and Domperidone) in a patient with the medical background, comorbidities and circumstances of Mr Phillips;

   d. Whether investigations were required and had been sufficiently undertaken in connection with commencing treatment with Physeptone, including ECG examination, blood tests, renal function and liver function;

   e. Whether Dr Huber and Dr Huang had adequate knowledge of the drugs prescribed, including the risks of potential interactions and side effects;

   f. The joint management of Mr Phillips' condition (for which Physeptone was prescribed) by Dr Huber and Dr Huang with respect to:

      i. Their respective roles, obligations and responsibilities in monitoring and managing Mr Phillips; and whether those were properly fulfilled given Mr Phillips' medical background, comorbidities and circumstances;

      ii. The adequacy of the communication between Dr Huber and Dr Huang in monitoring and managing Mr Phillips.

21 After the first four days of hearing, two further issues were addressed, which concerned the PSU's grant of authority to Dr Huang to prescribe Physeptone to Mr Phillips. Those further issues were:

g. The NSW Department of Health, PSU's consideration and determination of Dr Huang's application ("the Application") dated 13 October 2014 for authority to prescribe Physeptone and Endone to Mr Phillips and whether the authorisation given to Dr Huang on 16 October 2014 to prescribe Physeptone was at that time consistent with the responsibilities, objectives, functions and policies of the PSU.

h. How the PRU (formerly the PSU) would currently process and determine the Application (that is, if made as at October 2021) in accordance with the current responsibilities, objectives, functions of the PRU and the policies and guidelines that complement the applicable legislation, being the *Poisons and Therapeutic Goods Act 1966*.

Factual background

Complex medical history prior to Mr Phillips' first consultation with Dr Huber on 11 September 2013

22 Mr Phillips had a complex medical history which included:

i) Chronic knee pain. He had had a right total knee replacement for his right knee osteoarthritic pain.
ii) He was likely to have pes anserinus syndrome which causes pain from muscular origin.
iii) He was an opioid dependent patient with a high risk relating to prescription opioids, which meant he had an increased risk of unsanctioned opioid abuse and opioid-seeking behaviour.
iv) Renal stones and prostate issues.
v) Sleep apnoea.

23 Mr Phillips was referred to the medical practice, DMC, by Dr John Rooney, orthopaedic specialist. At that time, Mr Phillips was under the specialist management of Dr Rooney for advice and treatment of his right knee.

24 Mr Phillips was scheduled to undergo a right revision of his total knee replacement on 10 October 2013.

25 To better understand Mr Phillips' complex medical, therapeutic and medication needs during 2013-2014, an appraisal of his treatment notes, referrals and prescriptions have been reproduced in an abridged form.

Consultations with Dr Huber from 11 September 2013

26 Dr Huber recorded that Mr Phillips was already prescribed the following medications in his consultation notes dated 11 September 2013:

a. Zolpidem 0.5mg (sedative to assist sleeping);
b. Finasteride 5mg mane (for prostate);
c. Terazosin 2mg (for hypertension);
d. Trazodone 50mg (for depression);
e. Omeprazole 20mg mane (gastroesophageal symptoms);
f. Simvastatin 40mg mane (for high cholesterol);
g. Mobic 15mg mane (non-steroidal anti-inflammatory drug);
h. Fluoxetine 40mg mane (SSRI anti-depressant); and
i. Hydrocodone 10mg 4 hourly maximum 8 in 7 days (opioid for pain). Hydrocodone is also known as Vicodin.

27 During the first consultation on 11 September 2013, Dr Huber prescribed Prozac 20mg, however, his clinical notes did not record a diagnosis of depression or symptoms consistent with such a diagnosis.

28 Dr Huber also requested pathology testing, including liver function tests, urea, electrolyte creatinine, uric acid, calcium, blood sugar levels – fluoride, pH, lipids, vitamin D and magnesium. The results of the pathology testing were reported on 16 September 2013.

29 Mr Phillips consulted with Dr Huber again on 20 September 2013. The pathology results were discussed; as well as Mr Phillips' family medical history which was significant for carcinoma of the colon and type II diabetes mellitus. A referral letter was provided to Mr Phillips for a gastroscopy procedure to be performed by Dr Robert Feller. A glucose – oral tolerance test was ordered and the results reported to Dr Huber on 24 September 2013.

30 On 1 October 2013, Mr Phillips consulted with Dr Huber. The glucose tolerance tests indicated an insulin resistance. Mr Phillips was prescribed Diabex XR 500mg.

31 On 10 October 2013, Mr Phillips underwent a surgical revision of his right total knee replacement, performed by Dr Rooney at St Vincent's Private Hospital. On 15 October 2013, Mr Phillips was admitted to St Luke's Hospital for rehabilitation. The St Luke's Medication Profile indicated that Mr Phillips was prescribed oxycodone tablets 20mg sustained release 3 x per day, oxycodone tablets 5mg sustained release 3 x per day, and meloxicam tablets 15mg 1 x per day for pain relief. Mr Phillips was instructed to gradually reduce the oxycodone tablets and to aim to reduce the meloxicam, anti-inflammatory medication.

32 On 31 October 2013, Mr Phillips consulted with Dr Huber for the third time. Dr Huber noted the recent surgery on his right knee; as well as the previous total knee replacement in 2007. He also recorded details of the narcotic analgesia that Mr Phillips was currently prescribed by Dr Rooney as:

"has been on oxycontin 25mg tds/also was on endone 15mg tds – b/c has run out of endone has been taking hydrocodone [has them from USA].
R knee pain is controlled with current medications"

33 During this consultation, Dr Huber recorded Mr Phillips' past history of prostate issues, renal stones and the necessity for a renal ultrasound. Dr Huber also noted, for the first time, Mr Phillips' history of sleep apnoea.

34 Dr Huber also referred Mr Phillips to Dr Huang, who practiced as a specialist in addiction medicine. Dr Huang is a registered medical practitioner and Fellow of the Australasian Chapter of Addiction Medicine ("FAChAM"). Dr Huang practiced at the same medical centre as Dr Huber, DMC.

Consultations with Dr Huber and Dr Huang from 31 October 2013

35 Dr Huber's referral letter to Dr Huang suggested that the reason for the referral was for drug dependency and Mr Phillips' desire to cease narcotic medication, rather than for specialist pain management. Dr Huber noted that:

"He presents with long standing narcotics – prescribed dependence that he wants to get off – he has been on them for 6 yrs."

36 Dr Huber inserted extracts from his clinical notes relating to the three consultations. These extracts disclosed the history of recent knee surgery and the associated pain, however, did not provide a detailed medical or surgical history.

37 Dr Huang consulted with Mr Phillips on the same day as the referral. Dr Huang's clinical notes recorded:

"104 plus 2717
8 Vicodin daily 6 years in USA
Now post revision right total knee replacement 10/10 2013 John Rooney. On 75mg daily Oxycontin 60mg daily Endoe (sic)
Contact NSW PSU Targin or Methadone conversion"

38 Dr Huang wrote to Dr Huber:

"Thanks for referring Linus who took 6-8 Vicodins equivalent to 160mg oral morphine daily. Now post revision right knee surgery on 10th of October 20143 (sic) on Oxycodone 135mg daily po. Has opiate induced constipation. Has run out of Oxycontin. I prescribed him Targin 40/20 tds and reduced his endone. As you state he is very pleasant and motivated.
I have written to NSW Health PSU as to whether they will approve this program or discuss a methadone conversion with me.

Thanks for this much appreciated referral."

39 An undated letter prepared by Dr Huang to the Duty Pharmacist at the PSU (consistent with his clinical notes from 31 October 2013) noted:

"He states the operation has improved his pain issues, but he needs to do physiotherapy and hydrotherapy for a few more weeks. He is

then keen to taper his narcotics. I propose to do this initially by using Targin and reducing the Endone. He has severe opiate induced constipation. I have opened him to the idea of methadone conversion as I am familiar with prescribing and tapering this drug.
I request PSU to discuss the case with me. I have attached his operative notes."

40 On 31 October 2013, Dr Huang also completed a Mental Health Assessment for Mr Phillips. The GP Mental Health Plan attached to the Assessment indicated that Dr Huang identified the diagnosis as prolonged administration of opiate for non-cancer pain. The plan stated:

"Goal: Slow detoxification
Action/Tasks: Work with addiction physician regarding opiate tapering comply with medications."

41 Dr Huang and Dr Huber jointly managed Mr Phillips' treatment from 1 November 2013 until 12 March 2014.

42 The PSU granted the authority sought by Dr Huang on 1 November 2013. The Confirmation of Issue of Authority dated 1 November 2013 was valid until 1 October 2014 and authorised:

"(1) Oxycodone 40mg/Naloxone 20mg
(2) Oxycodone 20mg/Naloxone 10mg
(3) Oxycodone HCL 5mg tablets"

(Targin is the trade name for Oxycodone/Naloxone. Endone is the trade name for Oxycodone HCL [Hydrochloride].)

The following conditions were placed on the Authority:

"The amount prescribed shall not exceed
(1) Three (3) tablets daily
(2) Up to one (1) tablet daily
(3) Up to fifteen (15)mg daily"

43 On 6 November 2013, Mr Phillips consulted Dr Huang. Mr Phillips reported that his leg was feeling much better after the surgery performed by Dr Rooney. He confirmed that he was doing weights and cycling. He was also attending Over-eaters Anonymous ("OA") and Alcoholics Anonymous ("AA").

44 Mr Phillips was ingesting Targin 40mg/20mg oxycodone 15mg daily. He confirmed with Dr Huang that he was attending one pharmacy only and Dr Huang noted that there was no evidence that he had consulted with any other medical practitioners during that period.

45 Dr Huang and Mr Phillips also discussed a reduction in his narcotic analgesia usage. Mr Phillips was accepting of a reduction as long as he could have the maximum PSU quantity of 20 per week. Dr Huang noted that Mr Phillips was "willing to trial a 40mg drop in Targin collection." Mr Phillips was to collect 14 Targin and 20 Endone tablets for the week.

46 On 13 November 2013, Mr Phillips consulted with Dr Huang. He was experiencing pain during his physical therapy sessions and when walking long distances. Dr Huang recorded that Mr Phillips was "motivated to take a 20mg drop in Targin this week." The clinical notes recorded that Mr Phillips remained on antidepressants and "sleep medication", although the prescribed medication was not specified in the notes.

47 On 20 November 2013, Mr Phillips again consulted with Dr Huang. He was undertaking physiotherapy twice weekly and had joined the local swimming pool. He was attending OA, AA and Narcotics Anonymous ("NA") and had participated in a sleep apnoea study. Mr Phillips had a 'reduction diary' and it was noted "seeks a further reduction".

48 On 27 November 2013, Mr Phillips attended on Dr Huang. He confirmed that he had joined a gym as recommended by his physiotherapist at St Luke's Hospital and "presents to me a drop to 55mg daily po." It is assumed that this notation refers to the prescribed Targin. The sleep apnoea study indicated that Mr Phillips' condition was severe and recommended that he use a CPAP machine. On the same day, Mr Phillips also saw Dr Huber, who recorded and noted the diagnosis of severe obstructive sleep apnoea.

49 On 4 December 2013, Mr Phillips consulted with Dr Huang who noted that he was making substantial progress with his opioid weaning. Dr Huang recorded in his notes:

> "Maintaining his reduction regime see scan now toward 25-35mg daily of Oxycodone. Less than half of when he started treatment (sic). Maintaining his regular physiotherapy visits twice a week. Confident in physio. Hard physio yesterday moving today was hard. Advised to return to his mediations (sic).
> Gait show steady improvement.
> Endone increase aloowable (sic) according to PSU authroity (sic) increased short acting justified on basis of active reconditioning program."

50 On 12 December 2013, Mr Phillips consulted Dr Huang who noted that Mr Phillips was experiencing pain in the medial aspect of his right knee and was advised that it would be satisfactory to administer 35mg of oxycodone daily whilst doing his aggressive physical program.

51 Mr Phillips also consulted with Dr Huber on 12 December 2013. Dr Huber noted Mr Phillips' right knee pain and also that he was suffering from a sinus condition which may require surgery. Dr Huber prescribed 14 Stilnox tablets 10mg. This was the first reference in the clinical notes to the prescription of Stilnox.

52 On 20 December 2013, Mr Phillips saw Dr Huber. Mr Phillips was recorded as being "stressed and anxious". He was recorded as indicating that he was not sure if the Prozac that he had been prescribed, being an antidepressant, was providing much benefit. Dr Huber's notes do not record any discussion in relation to narcotic analgesia or pain management.

53 On 8 January 2014, Mr Phillips saw Dr Huang. Mr Phillips' attendance and progress was noted and the following was recorded:

> "Doesn't require a script for Targin this week. Explained probably good to make the physical reconditioning gains on opiate therapy. Physical reconditioning would most likely lead to the lowest requirement for opiates in the long term.
> Progress since starting was 135mg daily Oxycodone. Now plateau 35mg daily Oxycodone. Next drop 25mg daily Oxycodone.
> Staying with Authority guideline of 20 Endone tablets weekly. Zero Targin. For the next few weeks and review. Followed by slow weekly reduction of the endone supply which expires of Authority in October. Max total daily oxycodone Targin is 25mg daily po. Expressed motivation determined to keep going down on oxycode (sic) load. Advised 'tortoise can beat the hare' in opiate weaning.
> This week Endone twenty 5mg tablets prescribe nil Targin.
> Change to half hour appointments."

54 On 9 January 2014, Mr Phillips saw Dr Huber for constipation.

55 On 15 January 2014, Mr Phillips consulted with Dr Huang. It was noted that his daily dose of oxycodone was 25mg and that he was continuing with his intense physiotherapy regime. Dr Huang noted that the plan was to reduce Mr Phillips' daily prescription of oxycodone to 20mg the following week. Dr Huang prescribed 20 Endone tablets for that week.

56 On 22 January 2014, Mr Phillips saw Dr Huang and it was noted that Mr Phillips had reduced his oxycodone intake to 20mg daily. They discussed the plan to reduce his intake again the following week to 10mg daily.

57 Mr Phillips consulted with Dr Huber on 24 January 2014. Mr Phillips advised that he was presently on a daily dosage of Endone 10mg. Mr Phillips had completed a sleep study with a CPAP machine at St Luke's Hospital. Dr Huber noted that Mr Phillips remained depressed and considered a referral to a psychologist.

58 Mr Phillips consulted with Dr Huang on 29 January 2014 and confirmed that he had maintained his daily dose of oxycodone 10mg. Dr Huang noted that Dr Rooney had advised a daily dose of 5mg of Endone and Mr Phillips was advised accordingly.

59 On 5 February 2014, Mr Phillips consulted with Dr Huang. He confirmed that he was still taking 5mg of Endone daily and attending the gym and physiotherapy. Dr Huang noted that Mr Phillips' mood was flat and that he was experiencing right shoulder scar pain, and ordered an ultrasound and an x-ray. In effect, Dr Huang had assumed the role of Mr Phillips' GP, rather than his pain management specialist.

60 On 12 February 2014, Mr Phillips again consulted with Dr Huang. Dr Huang recorded:

> "Today was his first day abstinent. Having attacks of renal colic. Advised most people consider acceptable to use Endone if has renal colic." The notation is unclear whether this indicated that Mr Phillips had ceased one or both of the prescribed opiates. It was further noted that Mr Phillips was taking Prozac 60mg daily which he was to reduce over the following three weeks, although could return to the original dose if agitation or anxiety occurred.

61 Mr Phillips consulted Dr Huber on 13 February 2014 in relation to his recent history of renal colic; as well as discomfort in the penis and suprapubic area. The CT and ultrasound results were available and noted.

62 On 14 February 2014, Mr Phillips consulted with Dr Huber. The CT revealed a renal pelvis stone and a stone in the ureter. Dr Huber and Dr Huang discussed these results and Dr Huang indicated that he was happy for Mr Phillips to have opioids to assist in managing that pain.

63 On 15 February 2014, Mr Phillips consulted with Dr Huber and confirmed that he had consulted with Dr Yuen, Urologist. It was noted that Mr Phillips was taking 10mg of Endone and 15mg of Oxycontin. Dr Huber also commenced Mr Phillips on Targin 10mg three times daily.

64 On 26 February 2014, Mr Phillips consulted Dr Huang and Dr Huber separately. Dr Huang recorded "stones lasered" and "max oxycodone 45mg (Targin Endone) reduced drug frees day two." Dr Huang also reduced Mr Phillips' daily dose of Prozac to 40mg.

65 Dr Huber's consultation notes also refer to Mr Phillips having the renal stone shattered on 20 February 2014 and experiencing post operative pain. He also noted that Mr Phillips had been leasing a CPAP machine since 22 February 2014 and was attending the gym. Dr Huber noted that it was too early to determine if the CPAP machine was assisting and that Mr Phillips still needed Stilnox to assist with sleep.

66 Mr Phillips consulted with Dr Huber and Dr Huang separately on 5 March 2014. Dr Huber noted "epigastric recurrence" and the results of gastroscopy biopsies. He also noted a "sliding hiatus hernia."

67 Dr Huang noted that Mr Phillips was experiencing minimal knee pain but was having either renal or abdominal pain. Dr Huang provided a referral to Dr Sethi, gastroenterologist.

68 On 12 March 2014, Mr Phillips saw Dr Huang. Dr Huang's notes indicated, "Taking 30mg daily total oxycodone second daily for abdominal pain." Dr Huang indicated that he intended to review Mr Phillips' opiates the following week, however, he did not see Mr Phillips again until 9 October 2014.

69 Between 12 March 2014 and 9 October 2014, Mr Phillips consulted Dr Huber on twelve occasions. His medical complaints included significant constipation,

right leg pain, right thigh pain, significant depression and moderate anxiety, dizziness and nausea.

70 Records from the Darlinghurst Chemist suggest that Mr Phillips had no narcotic analgesia dispensed between 29 January 2014 and 15 September 2014. Dr Huber's notes indicated that he prescribed 28 tablets of Targin 40mg/20mg bd on 13 August 2014, 26 August 2014 and 16 September 2014. On 16 September 2014, Dr Huber noted the diagnosis of sleep apnoea and provided a prescription for Stilnox.

Joint Management by Dr Huber and Dr Huang resumes in October 2014

71 Mr Phillips consulted with Dr Huang on 9 October 2014, albeit without a new referral from Dr Huber. It is unclear why Mr Phillips returned to consult with Dr Huang at that time. Dr Huang's notes indicate that Mr Phillips was experiencing symptoms including anxiety, depression, chronic pain, past addictions and left testicular pain. He was not on a neuropathic pain agent and Dr Huang prescribed him Lyrica 75mg. His MRI results were discussed; as well as the likelihood that he may require back surgery according to the MRI findings.

72 On 10 October 2014, Mr Phillips saw Dr Huber. The treatment notes confirmed that the back surgery had been scheduled for 27 October 2014. Dr Huber noted that Mr Phillips "has been in a lot of back pain" and was "taking endone/targin", however, he did not record the relevant dosage.

73 Mr Phillips also consulted with Dr Huang on 10 October 2014. Dr Huang increased the prescription dosage of Lyrica to 150mg daily. Dr Huang noted:

> "Back pain Endone and Targin from Dr Huber. Asked whether opio[i]ds work in any way at all for his pain. Bearability. Waking becoming a problem. Focus in opio[i]ds pre and post operation. Vicodin weaker than Endone now. Four endone by 1730 today in 8 hours. No effect from Targin. May need opiate rotation from Targin. **Discussed opiate rotation using an authority such as physeptone**, may be hard to get him off, or durogesic, risks sleep apnoea. Titration should be careful. Trialled with Lyrica" (emphasis added).

Dr Huang's notes continued:

> "Operation is sch[e]duled on 27th of October not a long way away. Discussed he needs some carers respite from his mother which contributes to his depression. Discussed his pain. High risk o[f] opio[i]ds and didn't get sleep apnoea machine. Discussed with Dr Huber just Lyrica. Discussed opio[i]ds with duty pharmacist at PSU on Monday, willing to consider physeptone tablets. Naturally I am familiar with methadone even though it is a complex drug. I will apply for a physeptone authority now. Discussed can't safely prescribe opio[i]ds until he has a sleep apnoea mask. Until he gets a mask incomplete use of opioids is justified with his co-morbidity. Asked to bring in a CPAP mask before any significant opio[i]d dose escalations. Advised effective CPAP would make him feel much

better. Trialled mask this year during his kidney stones. He is aware he has to show us a mask to get opio[i]ds. Targin 20/10 bd po".

74 On 11 October 2014, Mr Phillips saw Dr Huber and the notes recorded that Mr Phillips was feeling better about the impending surgery. The clinical notes did not reflect any reporting of pain. The notes reflected a conversation about the importance of CPAP treatment.

75 On 13 October 2014, Mr Phillips consulted with Dr Huang and produced a CPAP mask. The notes recorded:

> "Presents to me with Resmed CPAP mask, new PSU authority is required. The patient does not want Targin. 'Doesn't work' Physeptone methadone is the most effective agent in neuropathic pain. Claims Lyrica did not work. Called St Vincent's Pain Clinic no awner (sic).
> Valdoxan samples working well and may require weaning from pristiq if he prefers it. Less procrastination less irritability
> Worst area of pain is down left leg, likely reflecting spinal stenosis. Area[] o[f] lateral right leg paraest[h]esia. Gait markedly impaired.
> **PSU application, Physeptone**, can't cope on oxycodone" (emphasis added).

76 On 13 October 2014, Dr Huang also completed the Application for Authority to Prescribe a Drug of Addiction. The application sought to prescribe physeptone 10mg slow induction from 20mg daily to a maximum dose of 50mg and, in addition, Endone three times a day per oral for breakthrough pain. Dr Huang confirmed in the application that he was happy if the Endone requested was declined. The dosage and frequency of the Physeptone was 10-25mg bd (twice per day) po (per oral) collection 2nd, 3rd daily pharmacy at DMC and for Endone 5mg, three times a day po collection 2nd, 3rd daily.

77 Records obtained from the Darlinghurst Chemist confirm that Physeptone tablets 10mg were dispensed on 13 October 2014, with instructions to take one tablet, twice a day on 14 October 2014, two in the morning and one at night on 15 October 2014 and then to collect four daily from the pharmacy.

78 On 14 October 2014, Mr Phillips consulted with Dr Huber. Dr Huber recorded that Mr Phillips:

> "has felt a bit 'unfocused' this am – bumping into things/couldn't focus [on] what people were saying – that was before he took physeptone this am [didn't have any last night] – after he took physeptone 10mg this am – felt better – more focused and in less pain.
> planned dosage – 10mg bd on 14/10/14, than (sic) 20mg mane and 10mg nocte on 15/10/14, than (sic) 20mg bd."

Dr Huber also issued a repeat script for 25 tablets of 10mg Motilium despite Mr Phillips indicating that he had not been taking the Motilium previously prescribed.

79 On 15 October 2014, Mr Phillips again consulted with Dr Huber. Mr Phillips did not report the adverse symptoms he had experienced the previous day. Dr Huber contacted the pharmacist and requested that Mr Phillips receive his Physeptone medication for 16 October and 17 October 2014, so that he could administer the dosages first thing in the morning when his pain was worse.

80 On 16 October 2014, Dr Huang noted that the Physeptone authority had not been processed by the PSU. Dr Huang contacted the duty pharmacist at the PSU and later that day the PSU issued a 'Confirmation of Issue of Authority' authorising the prescription of 10mg of Physeptone tablets to Mr Phillips with a dosage of up to 50mg daily. The authority was valid from 16 October 2014 until 1 December 2014.

81 Mr Phillips saw Dr Huang on 17 October 2014 for the last time. Dr Huang recorded the following:

> "Physeptone helpful more effective pain release. Last dosed 20mg at 6am Had endoscopy today. Feels more nergetic (sic) on it. Advised PSU authority is 50mg daily 3rd daily collect every 3 days. Denies any seedation(sic) claims he is more lucid. Claims he is using CPAP machine and this stand alone is making him feel better. Also finding Valdoxan very helpful with sleep at night. Bowels are con[s]tipated uses movicol, advised liley (sic) to need movicol.
> US report explained nil significant.
> Pupils 2mm. Left hip left thigh pain. Right knee Gait completely dysfunctional. Mood better than last review physeptone now 20mg mane 10mg midi 20mg nocte po Repeat fo[r] Cipro? To settle orchitis Short script needs review."

82 Mr Phillips last saw Dr Huber on 21 October 2014. Dr Huber noted:

> "was 'completely gone' on 50mg/7 physeptone – lasted 2 days/bumping into furniture/incoherent – would fall asleep mid sentence/sleeping most of the time – was ok on 20mg bd – yesterday took physeptone 20mg mane 'and that was it' – still feel a bit 'hung over today'.
> suggest to reduce to 10mg bd and assess the pain control – than (sic) increase by 10mg/7 depending on response – pt [patient] told needs to accept some degree of pain but can reduce it in severity with tabs"

Dr Huber also prescribed Stilnox tablets 10mg ½ nocte.

83 The dispensing history from the Darlinghurst Chemist recorded that on 21 October 2014 a further prescription for 20 Physeptone tablets 10mg was filled with the direction that two tablets should be taken in the morning, one tablet at midday and two tablets at night. That prescription related to 50mg per day with Mr Phillips collecting 15 tablets every third day.

Events on 24 October 2014

84 On 24 October 2014, Ms Ffiona Phillips arrived home at around 7:20pm. At 10:00pm, Mr Phillips' mother went to check on him and heard him push out a

gush of air. She attempted to shake him awake, however he was unresponsive. Mrs Phillips called to her daughter who entered the bedroom and noted that Mr Phillips was lying face down on the bed. He was fully clothed and still wearing his shoes. Ms Phillips commenced CPR for approximately 15 minutes and then contacted triple zero for an ambulance. The paramedics attended at the home, however, Mr Phillips could not be revived.

85 Police also attended the home. Senior Constable (as he then was) Facey located a backpack owned by Mr Phillips and located a number of medications inside the bag. They were (corrected as follows):

a) Micardis Plus (Telmisartan/HCL – 80mg/12.5mg) – Dr Huber – 9/10/14
b) Metformin Hydrochloride 500mg (25/120 tabs) – Dr Huber – 9/9/14
c) Sozol (Pantoprazole 40mg) (18/40 tabs) – Dr Huang – 13/10/14
d) Ciprol 500 (ciprofloxacin 500mg) (12/14 tabs) – Dr Huang – 23/10/14
e) Motilium (Domperidone 10mg) (27/100 tabs) – 23/10/14
f) Lyrica (Pregabalin 150mg) (unopened/56 tabs) – Dr Huang – 10/10/14
g) Physeptone (Methadone 10mg) (12/20 tabs) – Dr Huang – 13/10/14
h) Valdoxan (Agomelatine 25mg) (1/7 tabs) – Dr Huber – 13/10/14
i) Terazosin 2mg – Dr Alex Berdy (USA) – 17/9/14
j) Finasteride 5mg – Dr Alex Berdy (USA) – 7/8/14
k) Stildem (Zolpidem tartrate 10mg) (23/28 tabs) – Dr Huber – 21/10/14
l) Avamys nasal spray
m) Vitamin E Dietary supplement
n) Stay awake – caffeine
o) Vitamin B12 Dietary supplement
p) Dulera – inhaler

86 Dr Huang was informed of Mr Phillips' death and recorded the following notes on 27 October 2014:

> "Contacted
> PSU number was Authourity (sic) 50mg 315353-12 2014, 16th of October, No more than three days supply as interim. checked with Darlibnhurst (sic) pharmacy supply limits of the authroity (sic) were not broken. He did not present sedated, but in pain. Last dispensed on 21st of October 2014 by Medical Centre pharmacy. Was seen well on 23rd of October unsedated in pain and did not collect. I am concerned that sedation and dose reduction and the supply of stilnox were not discussed with me even though I was off on 21st of October.
> Body found by sister and mother, sister answered phone.
> Called MIPS my insurer in view of sleep apnoea, morbid obesity death certificate not inappropriate. Methadone discussed with insurer supply controls were not broken. Strong history of opiate tolerance with initial oxycontin 25mg tds and Endone 15mg tds at presentation to me for previous authority. Equiv[alent] 180mg of morphine, ceiling dose of authority was 50mg equivalent to 150mg of morphine. Events discussed with regular GP Dr Huber on the phone today."

87 On 31 October 2014, Dr Huang recorded the following clinical note:

> "Called by Kings Cross Police, patient underwent Autopsy, toxicology to follow. Informed by police sister who is a vetrinary (sic) nurse blames the methadone. I have contacted my insurer MIPS Dr Daly and asked Primary Health care to send the file notes to MIPS. I have expressed my concern to the pharmacy that supply occurred when the patient was sedated as documented by Dr Huber but he maintains he had contacted me on the 21st and prescribed Stilnox despite documenting the patient was sedated. I maintain I did not receive an appropriate call from Dr Huber about the sedation and would not have added a CNS depressant during methadone induction. Especially the presence of methadone induction."

88 On 27 October 2014, Dr Huang prepared a Medical Certificate of Cause of Death, recording the cause of Mr Phillips' death as:

a) Acute Myocardial Infarction – less than one day;
b) Obstructive sleep apnoea – 10 years; and
c) Morbid Obesity – 15 years.

He also recorded "hypercholesterolemia – 15 years" as "Other significant conditions".

89 Dr Isabel Brouwer conducted an autopsy on 28 October 2014. Dr Brouwer subsequently prepared a post-mortem report dated 14 January 2015, where she identified the cause of death as "a fatal cardiac arrhythmia due to the combined effects of coronary artery atherosclerotic disease, sleep apnoea and Methadone. Obesity and type II diabetes mellitus should be considered as significant contributing factors."

90 Dr Brouwer reviewed the toxicological analysis, noting the presence of Methadone measured in the preserved blood specimen at a level of 0.33mg/L. Dr Brouwer noted, "Methadone concentrations in fatalities have been reported to range from 0.4-1.8mg/L."

91 Later in her report, Dr Brouwer commented that:

> "The deceased was diagnosed with sleep apnoea. People suffering from obstructive sleep apnoea are at higher risk of dying from heart related problems than the general population. Sleep apnoea is a condition that causes sufferers to stop breathing for numerous brief periods during sleep. This causes oxygen levels in the body to drop and carbon dioxide levels to climb, straining the heart. Methadone is known for its respiratory depression effect and one would think that it would not be the drug of choice for pain relief in a patient known with sleep apnoea.
>
> It is not clear from the limited provided history why Methadone was the drug of choice for pain relief."

92 In addition, the toxicological analysis "also quantified the oral anti-diabetic drug, Metformin, and the angiotensin II receptor antagonist, Telmisartan, used for the treatment of cardiovascular diseases".

93 Screening tests indicated the presence of desvenlafaxine (Pristiq). The toxicology report noted that no methods were available in the laboratory for the quantitation of this medication. Similarly, the toxicology reported noted that no methods were available in the laboratory for the analysis of ciprofloxacin, pantoprazole, domperidone, pregabalin, agomelatine, terazosin, hydrochlorothiazide, mometasone, formoterol and fluticasone.

Evidence of Dr Huber and Dr Huang

Dr Huber's evidence in statement form

94 Dr Huber provided four statements relating to the investigation into Mr Phillips' death. The four statements were dated 13 May 2016, 20 June 2016, 12 February 2019 and 24 January 2020.

95 Dr Huber's first statement set out Mr Phillips' presenting conditions. Additionally, Dr Huber stated that he "spoke often to Dr Huang about Mr Phillips' medical conditions". He stated that in October 2014, he was "keen to reduce the dosage of Physeptone" and indicated that he discussed this reduction with Dr Huang, however, did not provide details of these discussions, nor the date(s) on which they occurred.

96 Dr Huber's second statement referred to the autopsy report prepared by Dr Brouwer and the report prepared for this inquest by Dr Tim Ho, Consultant Anaesthetist and Pain Management Specialist. Dr Huber confirmed his understanding that Stilnox can increase the risk of respiratory depression and, if combined with other drugs, can worsen respiratory depression.

97 In addition, Dr Huber stated that he first prescribed Stilnox to Mr Phillips on 21 October 2014. This assertion appeared to be at odds with the Darlinghurst Chemist printout dating from 1 January 2014, which indicated that Mr Phillips received Stilnox prescribed by Dr Huber and dispensed on 11 February 2014, 5 March 2014, 9 May 2014, 31 July 2014, 13 August 2014, 26 August 2014, 6 September 2014, 16 September 2014 and 9 October 2014.

98 In relation to the prescriptions dated 13 October 2014 and the subsequent prescription of Stilnox on 21 October 2014, Dr Huber explained that these were to help Mr Phillips sleep and that Mr Phillips used this prescription conservatively from the time it was first prescribed on 12 December 2013 until 21 October 2014. Furthermore, Mr Phillips had sleep apnoea and opioid abuse and Dr Huber was concerned that "we" needed to give him as much support as possible. Dr Huber stated that Dr Huang introduced Mr Phillips to Physeptone on 15 October 2014 and the adverse reaction on 21 October 2014 appeared to relate to the increased dose of Physeptone to 50mg.

99 Dr Huber confirmed in his third statement that he was not aware of the QT prolongation effect of methadone at the time he was managing Mr Phillips in 2014. This comment was in response to the opinion expressed by the expert Dr Hester Wilson in her report dated 26 April 2018 and tendered in these proceedings. Dr Huber further stated that even if he had been aware, he would have been reassured by two ECGs performed on 9 and 10 October 2013, and

a further ECG undertaken during the sleep study on 13 November 2013, showing normal QTc intervals.

100 Dr Huber indicated that he did not discuss any aspect of Mr Phillips' management regarding physeptone with Dr Huang and "left methadone management totally in his [Dr Huang's] hands". Dr Huber stated that he "did not have much experience with it [methadone]". Dr Huber confirmed that the advice that he gave Mr Phillips about dosages on 21 October 2014 was "based on his response to previous methadone dosages, before 50mg level was reached."

101 Additionally, Dr Huber stated that he had "very limited experience" of motilium (domperidone) and was guided by the advice from Mr Phillips' gastroenterologist. Dr Huber confirmed that he was not aware of motilium's interactions with other drugs prescribed to Mr Phillips in October 2014.

102 Dr Huber stated that he was "not aware of any breakdown in communication between myself and Dr Huang". Dr Huber's statement indicated that he had spoken with Dr Huang after Mr Phillips' consultation on 21 October 2014, when Mr Phillips had referred to "bumping into things". Dr Huber affirmed that, "I recall Dr Huang agreed with the treatment plan."

103 In relation to their joint management of Mr Phillips, Dr Huber stated that he would discuss any management issues with Dr Huang in the area behind the front desk of the medical practice. He would familiarise himself with Dr Huang's treatment notes and they would discuss patients on an "as needed basis".

104 In his fourth statement, Dr Huber clarified his assertion that the conversation with Dr Huang about Mr Phillips' presentation on 21 October 2014 took place in person and not by telephone. Dr Huber acknowledged that he should have contacted Dr Huang on 21 October 2014 and that the details of their conversation should have been recorded in Mr Phillips' medical record.

<u>Oral evidence given by Dr Huber at the inquest</u>

105 Dr Huber confirmed the details he had provided and contained in his CV. He obtained his medical degree in 1976 and commenced practice as a GP in 1987. He was not a fellow of the Royal Australian College of General Practitioners.

106 Dr Huber ceased practising medicine in December 2014.

107 Dr Huber confirmed that when he referred Mr Phillips to Dr Huang it was on the basis that Dr Huber and Dr Huang would jointly manage Mr Phillips' medical needs. Dr Huber confirmed the following in relation to that joint management arrangement:

- both doctors could access clinical notes relating to Mr Phillips in a shared computer system;
- communication with Dr Huang was always on an informal basis rather than by way of a formal meeting;
- there were no case conferences; and

- they would usually discuss patients, including Mr Phillips, in an area behind the front desk at the DMC.

108 Dr Huber stated that he was aware of Mr Phillips' severe sleep apnoea on 27 November 2013. He could not recall if he had discussed this diagnosis with Dr Huang although he was aware that Dr Huang was prescribing Targin and Endone for the purpose of tapering Mr Phillips' narcotic dependency at that time.

109 Dr Huber confirmed that, at the next consultation he had with Mr Phillips on 12 December 2013, Mr Phillips was keeping a diary of his opioid use. He was also aware that Mr Phillips was regularly attending physiotherapy and support meetings. By the end of 2013, Dr Huber was of the view that Mr Phillips was making positive progress with his opioid weaning under Dr Huang's management and was continuing with physiotherapy and group support.

110 On 13 February 2014, Mr Phillips had developed acute renal colic. Dr Huber confirmed that this was known to be a very painful condition. Dr Huber confirmed that he would have spoken with Dr Huang about Mr Phillips being prescribed opioids to cope with the pain on 14 February 2014. Mr Phillips was subsequently prescribed Targin for pain relief.

111 At the consultation on 26 February 2014, Dr Huber was able to confirm that Mr Phillips had obtained a CPAP machine and that he still required Stilnox to assist him to sleep.

112 Dr Huber next consulted with Mr Phillips on 5 March 2014. He confirmed that Mr Phillips was experiencing epigastric pain associated with his hiatus hernia. Dr Huber confirmed that the opioids Mr Phillips was receiving were appropriate given his significant pain caused by a number of physical complaints.

113 Dr Huber confirmed that part of his role in the joint management of Mr Phillips with Dr Huang was to remind Mr Phillips to regularly consult with Dr Huang. Dr Huber was of the view that Mr Phillips was always keen to consult Dr Huang and did not require reminding. On 12 March 2014, Dr Huang had entered a notation in the clinical notes stating, "Review ag[a]in opiate with me next week." Dr Huber could not recall if he had reminded Mr Phillips to consult with Dr Huang when he saw him on 14 March 2014 and did not record any notes to that effect.

114 Dr Huber stated that the next consultation he had with Mr Phillips occurred on 9 May 2014. He indicated that he would have made a note if there had been any other consultations in the interim.

115 Dr Huber confirmed that he recorded in his notes that Mr Phillips had been off pain medication for over seven to ten days, although he did not specify details of the medication. He also confirmed that he did not know whether Mr Phillips was still seeing Dr Huang during this period and admitted that even if he (Dr Huber) had spoken with Dr Huang at this time, he would not have recorded that conversation in his treatment notes.

116 Dr Huber agreed that he had seen Mr Phillips on 13 May 2014. At this time, Mr Phillips was experiencing difficulty walking and weight bearing. Dr Huber again did not recall if he had discussed his case with Dr Huang. He conceded that he had "no idea" what Mr Phillips' pain medication or dependency status was as at 13 May 2014.

117 Dr Huber indicated that by 26 June 2014, Mr Phillips was presenting as an even more complex patient in the sense that "he was getting more problems". Despite his presentation, Dr Huber did not enquire whether Mr Phillips was ingesting any pain medication. Dr Huber was aware, after receiving a letter from Dr Rooney, that Mr Phillips had again sourced Vicodin from the USA. Dr Huber conceded that he did not ask Mr Phillips about his use of Vicodin as he was distracted by all the other issues Mr Phillips had presented with at that consultation.

118 Dr Huber confirmed that he had received correspondence from Dr Rooney dated 30 June 2014, which Dr Huber discussed with Mr Phillips during his consultation on 15 July 2014. Dr Rooney was of the opinion that the origin of Mr Phillips' current pain was muscular in nature. Dr Huber was of the view that Mr Phillips had been overdoing his exercise regime and suggested to him that he should ease the intensity of his program. In addition, Dr Huber confirmed that he provided Mr Phillips with a prescription for Stilnox during a consultation on 31 July 2014 as Mr Phillips had been on that medication for "several years" and was taking it for his sleeping problems.

119 Dr Huber confirmed that Mr Phillips' pain presentation on 13 August 2014 was different. He noted that Mr Phillips had a pronounced limp and the pain was going into his knee, and he was clearly depressed. Mr Phillips indicated that he felt that he was sleeping too much, which Dr Huber perceived was related to his depression. Dr Huber again made no enquiry with Mr Phillips as to his current prescribed medications. Despite this, Dr Huber prescribed Targin 80mg a day, to be taken 40mg twice per day. He prescribed a 28 day course, however, the DMC records indicate that Dr Huber prescribed another course of Targin on 26 August 2014.

120 Dr Huber was asked whether he had considered referring Mr Phillips to Dr Huang on 13 August 2014. He responded, "I don't know that I ever thought that he wasn't under him. I obviously was aware that he wasn't seeing him, but I don't recall specifically telling him that, telling the patient specifically to go and see him. I can't remember when he next saw Dr Huang after that." Dr Huber confirmed that he would have wanted Mr Phillips to continue to consult with Dr Huang, even though he could not recall telling him that specifically. He also stated that if he had asked Mr Phillips to confirm his current medications, he would have recorded them in his notes. As no such notation appears in his treatment notes, it can be reasonably inferred that Dr Huber did not ask Mr Phillips to confirm his current medications on this occasion.

121 During the consultations on 2 September 2014 and 9 September 2014, Dr Huber confirmed that Mr Phillips was experiencing significant pain. On 9 September 2014, he agreed that Mr Phillips told him that he was taking morphine he had sourced from the USA. Dr Huber confirmed that he did not

ask Mr Phillips how much he was taking, the frequency nor the type of morphine he was ingesting.

122 On 16 September 2014, Dr Huber confirmed that Mr Phillips' pain had worsened. Dr Huber noted that Mr Phillips was scheduled to see Dr Parkinson, neurosurgeon, on 25 September 2014. Dr Huber also confirmed that Mr Phillips had indicated that he was falling asleep all the time. Mr Phillips stated that he had not accessed a CPAP machine and Dr Huber was of the view that the appropriate diagnosis was sleep apnoea and advised Mr Phillips not to drive a motor vehicle until he had arranged a CPAP machine.

123 Dr Huber saw Mr Phillips on 10 October 2014. Dr Huber confirmed that he did not refer Mr Phillips to Dr Huang on 9 October 2014 nor on 10 October 2014. The records confirm that Mr Phillips attended on Dr Huang on 9 October 2014 after an extended absence. Dr Huber arranged for Mr Phillips to see a gastroenterologist on 10 October 2014 and to have a testicular ultrasound on 15 October 2014.

124 On 10 October 2014, Dr Huber also prescribed Ciproxin (also known as Ciprofloxacin). Dr Huber confirmed that he was not aware at that time of the QTC prolongation effect of that drug.

125 On 11 October 2014, Dr Huber prescribed Motilium to Mr Phillips on the advice he received from Dr Tattersall, gastroenterologist. Again, Dr Huber did not appreciate that Motilium could lead to QT prolongation. Dr Huber stated that he had prescribed the drug simply on the basis of the recommendation from Dr Tattersall and because he perceived that Mr Phillips was so incapacitated by oesophageal dysmotility.

126 At the same consultation on 11 October 2014, Dr Huber noted that Mr Phillips was feeling less depressed on the higher dose of Pristiq and that his back pain was a little better. Dr Huber stated that it was extremely likely that he had discussed Dr Huang's recommendation of "just Lyrica" with Dr Huang but had no independent recollection. Dr Huber was of the view that the Lyrica would have assisted with the back pain and shooting pain that Mr Phillips was experiencing.

127 Dr Huber saw Mr Phillips on 14 October 2014. Mr Phillips confirmed that he had purchased a CPAP machine from Sydney Sleep Centre.

128 Dr Huber indicated that Dr Huang had stated that he was going to apply for an authority from the PSU to dispense Physeptone for Mr Phillips. According to Dr Huber, Dr Huang did not discuss the dosage of Physeptone with him. Dr Huber maintained that he became aware of the dosage during the consultation with Mr Phillips on 14 October 2014. Dr Huber noted that during the same consultation, Mr Phillips had stated that he was a bit unfocused in the morning, bumping into things and could not focus on what people were saying before he took the Physeptone that morning.

129 Also on 14 October 2014, Dr Huber noted that Mr Phillips had not been taking his prescribed dosage of motilium. Dr Huber stated the following in regards to Dr Tattersall's advice surrounding the prescription of motilium:

- Motilium was not a drug that he (Dr Huber) was familiar with, and he would not routinely prescribe motilium.
- Dr Huber regarded the advice from Dr Tattersall to be strong advice for "a very, very significant problem" relating to Mr Phillips' dysmotility, which involved a choking potential.
- Dr Huber said he "would have been rather blindly guided by the advice from the specialist".
- Dr Huber did not tell Dr Tattersall that Mr Phillips was taking prescribed methadone in the form of Physeptone.
- Dr Huber conceded that it was his role to advise Dr Tattersall that Mr Phillips was on methadone and did not know why he did not do that.

130 Dr Huber made the following concessions relating to methadone:

- He did not have much experience with methadone and was not aware whether it was long or short acting, or whether it was an accumulating drug.
- He agreed that he was aware that it could lead to respiratory depression as an opioid pain relief.
- He did concede that Mr Phillips was in a high risk category on methadone given his diagnosis of sleep apnoea, however considered that that risk was somewhat mitigated after Mr Phillips gained access to a CPAP machine. Indeed, Dr Huber indicated that he believed that the CPAP machine would afford Mr Phillips adequate protection, however had since learnt that it is not sufficient.

131 Dr Huber maintained that he did not consider that he was responsible for the monitoring of Mr Phillips on Physeptone and that someone more experienced, like Dr Huang, was dealing with that aspect of his management. Dr Huber stated that he recorded the planned dosage on 14 October 2014 "just to record it so I've got some idea what, what's happening."

132 In his evidence, Dr Huber maintained that he had nothing to do with Mr Phillips' Physeptone management at all. This would appear to be at odds with the evidence that Dr Huber contacted the pharmacist on 15 October 2014, to ask the pharmacist to give Mr Phillips his Physeptone dose for 16 and 17 October 2014 that day, being 15 October 2014. Dr Huber's reasoning for this intervention was to ensure that Mr Phillips had his prescribed pain relief when he attended for his gastroscopy on 16 October 2014. Dr Huber confirmed that he was aware that the PSU could also specify a collection regime and that he did not enquire whether the collection regime he was directing was authorised. Dr Huber stated that he was not aware that Dr Huang had specified the collection regime on Mr Phillips' Physeptone script.

133 Dr Huber maintained that he did not consider whether he should have spoken with Dr Huang about the collection regime he was directing. Dr Huber conceded in his evidence that he should have done this first. Dr Huber agreed that it was inconsistent to say that he had left the management of the

Physeptone to Dr Huang on the one hand, but conversely to have then made arrangements for the collection of the Physeptone by Mr Phillips.

134 Dr Huber agreed that he saw Mr Phillips for the last time on 21 October 2014. Mr Phillips told him on this occasion that he "was 'completely gone' on 50mg/7 of physeptone -lasted 2 days". Dr Huber stated that he had sought clarification from Mr Phillips to confirm that Mr Phillips was indicating that he had taken 50mg on 17 October 2014 and was then "completely gone" for two days, rather than having taken 50mg the first day and then another 50mg the following day. Mr Phillips confirmed that he had only taken one 50mg dose on 17 October 2014.

135 Dr Huber indicated in his evidence that he believed that this note was clear enough to him, however accepted that, with a drug such as methadone, it was important that the note was sufficiently clear for others to understand. He accepted that it would have been clearer if he had recorded the dates of the dosage that Mr Phillips had taken2q each day, rather than his recording method. He conceded that he had recorded the note in the less acceptable fashion even though he regarded Mr Phillips' description as being "the side effect of methadone."

136 At the same consultation, Dr Huber confirmed that he had prescribed Mr Phillips Stilnox at a 10mg dose, being half a tablet at night. At the time, he believed that it was safe to prescribe this dose. He conceded in his evidence that he should not have prescribed Stilnox in that setting and that it was unsafe to have done so.

137 Dr Huber described two conversations he said he had with Dr Huang relating to Mr Phillips' presentation on 21 October 2014. Dr Huber contended that the first conversation occurred after he asked the receptionist at the practice when Dr Huang was next expected to attend the practice. He stated that he was told Dr Huang was expected on Thursday or Friday of that week. Dr Huber maintained that he told Dr Huang that Mr Phillips had reported that he was bumping into furniture. Dr Huber stated that he did not recall Dr Huang saying anything to him about this development. Dr Huber contended that he told Dr Huang that Mr Phillips was confused and that he had reduced Mr Phillips' dose of Physeptone in response to his presentation. Dr Huber stated that he told Dr Huang that he had informed Mr Phillips that he would have to accept some degree of pain given that he was due to have back surgery on 27 October 2014.

138 The second conversation, according to Dr Huber, occurred after both doctors had learnt of Mr Phillips' death. According to Dr Huber, Dr Huang told him that Mr Phillips had passed away and that his sister was upset when she spoke with Dr Huang. Dr Huber maintained in his evidence that he then said to Dr Huang, "[R]emember I said to you last week and said how he was bumping into things and so on?" Dr Huber stated that again Dr Huang did not respond "other than what he wrote in the notes that ... I spoke to him on the phone, which I didn't." Dr Huber asserted that he spoke with Dr Huang in person. Dr Huang had a different recollection of this exchange.

139 Dr Huber did not recall receiving a telephone call from the Darlinghurst Chemist on 23 October 2014 in relation to his prescription of Stilnox to Mr Phillips. Dr Huber stated that Dr Huang had never alerted him to not prescribing Stilnox to Mr Phillips after he had commenced on Physeptone.

140 Dr Huber confirmed that he did not consider Physeptone was "the main cause of (Mr Phillips') passing". As such, he did not disagree with the contents of Dr Huang's Death Certificate (Medical Certificate Cause of Death).

Dr Huang's evidence in statement form

141 Dr Huang provided a detailed statement in these proceedings dated 11 October 2019. In his statement he referred to his clinical notes and other documentation relating to his management of Mr Phillips from October 2013 until October 2014. In his statement he also referred to his rationale for his decision-making in relation to his treatment of Mr Phillips.

142 In his statement, Dr Huang also made a number of admissions about errors that he had made in relation to his management of Mr Phillips whilst prescribing Physeptone.

143 Dr Huang made the following concessions:

- The doses of Physeptone that he had prescribed to Mr Phillips were too high in all of the circumstances.
- The induction or dose acceleration was too high, or too rapid.
- The supervision of Mr Phillips at the time of his Physeptone induction was inadequate.
- There was inadequate communication between himself as the pain specialist, the GP, being Dr Huber, and the pharmacist, given Mr Phillips' complex presentation.
- He should have done more to ensure that Dr Huber and the pharmacy were aware of the need to consult with him directly if there were any signs of over-sedation or if any additional medications were proposed to be prescribed once Mr Phillips had commenced on Physeptone.

144 Dr Huang indicated that he had previously managed another patient successfully for the management of severe pain by prescribing methadone tablets. He accepted that his past success with other patients had made him complacent in relation to managing Mr Phillips on Physeptone.

145 Dr Huang stated that he had recommended Physeptone to Mr Phillips as he wanted to avoid the stigma associated with liquid methadone, particularly for a person attending NA.

146 As such, Dr Huang made an application to NSW Health PSU, to obtain the authority to prescribe Physeptone tablets to Mr Phillips.

147 In relation to that application, Dr Huang believed that he was subjecting his prescribing and treatment plan to an external review by a specialist pharmaceutical body, being the PSU. This issue was explored at some length during the inquest.

148 Dr Huang accepted that, in relation to Mr Phillips, he was not prescribing in accordance with the NSW Health Opioid Treatment Program ("OTP") by prescribing outside the recognised guidelines. In addition, he accepted the expert evidence of Professor John Saunders relating to the guidelines that existed at that time.

149 Dr Huang stated that he was not aware that Dr Huber had been prescribing Stilnox until after Mr Phillips' death. He agreed that he should have been aware of the history of Stilnox prescribing to Mr Phillips; both from the DCM records, as well as the Mental Health Assessment form dated 9 October 2014.

150 Dr Huang accepted that in such a complex case, an ECG investigation was warranted, although he noted that it was not his practice in 2014 to order an ECG prior to commencement on methadone. Further, he noted that during his training in addiction medicine, other addiction specialists supervising him had not routinely required an ECG when prescribing methadone.

151 Dr Huang accepted that other medications can adversely interact with methadone. He conceded that the combined effect of Domperidone (motilium) and methadone can increase the QT interval in a patient's heart. Dr Huang appeared less clear about the combined effect of Ciprofloxacin with Methadone and whether prescribing both to Mr Phillips was either appropriate or an error. He did concede that Ciprofloxacin would reduce the rate of the patient's methadone metabolism or clearance rate.

Oral evidence given by Dr Huang at the inquest

152 Dr Huang confirmed that he graduated from the University of Sydney in 1988 with a Bachelor of Medicine and Surgery. In 1991, he graduated with a Master of Medicine from the University of Sydney. He obtained his PhD in 1998 from the University of Sydney. In 1999, he was granted a Fellowship of the Australian College of Rural and Remote Medicine. In 2012, he obtained his Fellowship of the Australasian Chapter of Addiction Medicine, Royal Australasian College of Physicians. He commenced addiction medicine specialist training in January 2008. He worked briefly as a GP in 2006.

153 Dr Huang commenced working part-time as a GP at the DMC in 2009. Darlinghurst Chemist was located in the same building as the DMC.

154 In 2013 and 2014, Dr Huang was continuously managing about 30 patients on the NSW Health OTP.

155 Dr Huang confirmed that no case conferences were held at DMC during that time. He conceded that in respect of a drug such as methadone, the addiction specialist should be the coordinator of the case conference.

156 Dr Huang believed that the pharmacy would have access to a document called the Methadone NSW "Methadone Induction Checklist" and that an experienced pharmacist would implement the known protocols. He agreed that his prescribing history was "very much an injecting heroin prison type of

population" and that methadone induction in a holistic patient was different from his usual population.

157 Dr Huang conceded that he should have managed Mr Phillips' induction in a much more careful manner. For example, he agreed that he should have held a very firm case conference with the pharmacist and with Dr Huber and he ought to have set boundaries so that no decisions regarding methadone (Physeptone) were to be made by anyone except by him. He agreed that he had made an assumption that the pharmacy would have followed the Methadone Induction Checklist protocol, but did not make that enquiry with the pharmacy.

158 Dr Huang confirmed that Mr Phillips was the only patient of his that was being prescribed Physeptone rather than the more commonly prescribed liquid methadone. He further confirmed that Mr Phillips was the only patient that he was jointly managing with Dr Huber at that time and believed Mr Phillips was the only patient that he had ever managed on opioids jointly with Dr Huber.

159 Dr Huang indicated that his intention in prescribing methadone to Mr Phillips was to palliate him until his upcoming surgery with Dr Parkinson in late October 2014. Dr Huang was of the view that liquid methadone may not have been appropriate in Mr Phillips' circumstances, and that Mr Phillips may have refused liquid methadone.

160 Dr Huang had considered a longer trial of the prescription drug Lyrica for pain management. Due to the degree of compression on Mr Phillips' spinal disc, Dr Huang was concerned whether Lyrica would have been effective pain management as he was firmly of the view that methadone was the most effective agent for neuropathic pain. Dr Huang conceded that he experienced some difficulty in assessing Mr Phillips' compliance with Lyrica and was therefore unaware that Mr Phillips did not take the 150mg dose of Lyrica prescribed to him on 10 October 2014, stating "I didn't know what he was doing with it". As such, he did not ascertain whether Mr Phillips was dosing with Lyrica prior to commencing him on Physeptone.

161 During this interim period, Dr Huang wrote to the Pain Clinic at St Vincent's Hospital. He followed up with a number of telephone calls, leaving messages with the Pain Clinic. He received a response on 6 November 2014.

162 Dr Huang confirmed that he issued a prescription for Physeptone prior to receiving a written authority from the PSU and directed Mr Phillips to commence his first dose on 14 October 2014. Dr Huang accepted in his evidence that he should have waited for that authorisation.

163 Dr Huang confirmed that the only time that he saw Mr Phillips during this induction period was on 17 October 2014. He agreed that this was a significant shortfall.

164 In addition, he conceded that it would have been more appropriate to have started Mr Phillips on a dose of 20mg of Physeptone and increased the dosage to 25mg or 30mg by 27 October 2014 for his scheduled surgery.

165 Dr Huang was adamant that he did not speak with Dr Huber about Mr Phillips' presentation on 21 October 2014. Dr Huang's account appears to be supported by contemporaneous notes, whereas Dr Huber did not record any contemporaneous notes. The conflict between the two doctors on this issue cannot be resolved to an appropriate standard of satisfaction. A finding on this issue is not necessary given the concessions each doctor has made.

166 Shortly after Mr Phillips' death, Dr Huang left the DMC practice, breaking his employment contract. It would appear that this was directly related to his misgivings surrounding his role in the treatment of Mr Phillips. At the time of giving evidence, Dr Huang was employed as an addiction medicine physician at Canberra Hospital's alcohol and drug service.

Expert Evidence

167 The following experts assisted the Court by providing written expert reports:

- Professor John Saunders, Consultant Physician in Internal Medicine and Addiction Medicine, prepared a report dated 16 March 2018;
- Dr Richard Hallinan, Specialist in Addiction Medicine, prepared a report dated 17 December 2019;
- Dr Hester Wilson, Specialist in Addiction Medicine and GP, prepared a report dated 26 April 2018;
- Professor Ian Whyte, Consultant Clinical Toxicologist and Pharmacologist, prepared a report dated 30 March 2018;
- Dr Tim Ho, Pain Specialist and Rehabilitation Specialist, prepared a report dated 17 August 2015.

168 Each of the above experts also gave oral evidence in these proceedings.

169 Professor Saunders, Dr Hallinan and Dr Wilson participated in a conclave giving their evidence concurrently.

170 Professor Whyte and Dr Ho gave evidence independently of the other experts.

Issue 1: Cause of death

171 As noted above, Dr Isabel Brouwer, forensic pathologist, was of the opinion that the cause of Mr Phillips' death was "cardiac arrhythmia" due to the "combined effects of coronary artery atherosclerotic disease, sleep apnoea and methadone."

172 In his statement, Professor Saunders was of the view that the "terminal event was a cardiac arrhythmia to which (he) would be prone because of his coronary artery disease, sleep apnoea and methadone". In his evidence, Professor Saunders noted the combined pathologies of coronary artery disease, obstructive sleep apnoea and methadone as probably precipitating a fatal arrhythmia. Professor Saunders opined that methadone (Physeptone) was a significant and substantial contributing factor.

173 Professor Saunders was of the view that there are considerable risks involved in combining opioids (Physeptone) and central nervous system depressants, such as zolpidem (Stilnox) and benzodiazepines.

174 Dr Wilson deferred to the opinion of Dr Brouwer, forensic pathologist.

175 Professor Whyte, Consultant Clinical Toxicologist and Pharmacologist, was of the opinion that Mr Phillips' cause of death was due to cardiac arrhythmia. He opined that that cardiac arrhythmia was a specific type of abnormal heart rhythm known as Torsades de Pointes, which is associated with QT prolongation. Professor Whyte noted that Mr Phillips had been prescribed a number of medications that are known causes of QT prolongation including: Ciprofloxacin, Domperidone (Motilium), and Methadone (Physeptone). At the time of his death, Mr Phillips was taking each of those medications with the exception of Domperidone (Motilium).

176 Professor Whyte referred to the toxicology examination relating to Mr Phillips' post-mortem and noted that the drug detected in that examination with the greatest evidence of QT prolongation and the development of Torsades de Pointes was methadone.

177 Professor Whyte's specific expertise in this area is significant. At the time of the inquest, he was the Director of the Department of Clinical Toxicology and Pharmacology at the Calvary Mater Hospital, NSW. He also trained as a GP and during his clinical practice as a toxicologist had "looked after over 30,000 patients with drug overdose – and many of them took drugs which produced QT prolongation."

178 Professor Whyte stated that he adhered to his opinion outlined in his report "overall" and noted that the "[r]eview of the effects of multiple medications affecting the QT interval, all with a risk of TdP [Torsades de Pointes], and the additional risk imposed by the known metabolic drug interactions between these agents makes it more likely than not that drug-induced QT prolongation and torsades de pointes with subsequent sudden cardiac death was the direct cause of Mr Phillips' death."

179 In his oral evidence, Professor Whyte confirmed that when writing his written report for these proceedings he had assumed that Mr Phillips was also ingesting Domperidone (Motilium) immediately prior to his death, and that Domperidone was a drug known for QT prolongation which can produce Torsades de Pointes. Professor Whyte provided the following qualification to his earlier report stating:

> "the information I had when I wrote that report was that he was on domperidone which is a known potent QT prolonging drug which can produce Torsade[s]. He was on methadone which is a known potent QT prolonging drug that can produce Torsade[s] and he was also on ciprofloxacin which is a known drug for producing QT prolongation and occasionally producing Torsade[s] but not as potent as the other two, and ciprofloxacin also interferes with the metabolism of domperidone.

From the forensic pathology report on the drugs that were subsequently looked for, on the most recent report domperidone wasn't found although ciprofloxacin and methadone were which means that he was on one drug with known QT prolongation and production of Torsade[s] ... A second drug with lesser efficacy, if you'd like to call it that, in producing the long QT and Torsade[s] but wasn't on the domperidone so the most likely cause of any QT prolongation and Torsade[s] that may have happened and I believe did would have been the methadone with an additional effect from the ciprofloxacin but not nearly as great an effect as you would have expected with domperidone there as well."

180 Professor Whyte provided the following description of the clinical and pharmacological features involved in Mr Phillips' death. He stated:

"I've looked after over 30,000 patients with drug overdose – and many of them took drugs which produced QT prolongation. In those cases we put them in the intensive care unit. We put them on continuous monitoring and we watch them until the QT goes back to normal so we actually see what happens when they get Torsade[s], if they do and we need to know that because we obviously need to treat it and we know, we have worked out and confirmed what the literature says about the precipitating events, and it is an extra beat that fires off at exactly the wrong time for the patient or the right time for the arrhythmia and the typical picture is exactly that which occurred during the death of Mr Phillips.

My understanding is that he was feeling very sedated and tired and went to bed around 3 o'clock in the afternoon and he had sudden death about seven hours later. We – I understand that he didn't have his CPAP mask on at the time of death and therefore he's gone to bed, in a man who is known to have severe obstructive sleep apnoea who desaturates regularly during the night. Each time he desaturates he's going to make his heart short of oxygen. From the autopsy we know that his coronary arteries were certainly not normal – they weren't occluded to indicate that he had a heart attack but they were clearly not normal – so the blood supply to his heart is potentially compromised which makes the lower oxygen that he is breathing in less effective in the heart and in that situation where your heart gets ischaemic you fire off more and more and more ectopic beats.

If an ectopic beat fires off and it doesn't hit any T wave in that vulnerable period nothing happens – well you get the ectopic but then everything settles down – but the longer you go firing off more and more, and it gets even worse when you go into rapid eye movement sleep because all of your muscles relax so your upper airway relaxes so your obstructive sleep apnoea gets worse, and you've also got reduction in your rate and depth of breathing caused by the central sleep apnoea effect of methadone, then – and the QT prolonging effect is making your vulnerable part of your T wave longer seems what, what happens is that you go along doing perfectly okay until eventually just one of those multiple ectopics that

are now firing off because of all of the things that are going on hits a T wave at the wrong time, you flick into Torsade[s] and if you are one of the unlucky ones you'll go into ventricular fibrillation and die.

If you're – if you're a lucky person rather than an unlucky then you'll come back out of it and you may do that several times over the period but he may well have had several episodes of Torsades and only the final one was the one that didn't revert – we don't know but that context particularly in someone who may well have had some abnormality of one or more of his channels, who was also on a diuretic which can change your magnesium, your potassium and your calcium levels, who had ischaemic heart disease, who had obstructive sleep apnoea and was getting hypoxic, all of these things make him a much more potentially risky candidate for giving any drug that prolongs QT, let alone two."

181 Professor Whyte explained why he was of the opinion that methadone (Physeptone) was the probable cause of death as compared with being a possible factor, noting the complex mix of features.

182 Professor Whyte gave the following evidence:

"Professor Olaf Drummer published a series of deaths during induction of methadone therapy in Victoria and showed that as induction therapy became a bit more aggressive there was a higher incidence of sudden death and that sudden death typically occurred within the first two weeks. In fact, a whole – a full quarter of the deaths occurred in the first two weeks and they were sudden cardiac deaths, i.e., arrhythmic deaths, so it's a typical picture when you start methadone and you die early that it's an arrhythmic death and that the methadone is the cause."

183 Whilst giving evidence, Professor Whyte was asked to assume that Mr Phillips had ingested methadone at the rate of 20mg on 14 October, 30mg on 15 October, 40mg on 16 October, 50mg on 17 October, nil on 18 October, nil on 19 October, 20mg on 20 October, Dr Huber directed 20mg on 21 October (10mg twice per day) although it is unclear if Mr Phillips ingested those amounts that day, and unknown amounts on 22, 23 and 24 October 2014. Professor Whyte commented that:

"One of the things about methadone that makes it very tricky to use in this way is that in young, fit, healthy people with normal livers their concentration of methadone will fall from its peak after a dose to half that concentration in about 24 hours or so. As people age, even if they have no active organ injuries or organ illnesses or any other co-existing illnesses their half life goes out to 36 hours and sometimes up to 54 hours. If you look at something around the one and a half day mark or 36 hours that means that if you start someone on a constant dose of methadone and give it to them every day it will take around seven days before the full effect of that methadone has reached a steady state concentration at which it will stay if you continue that dose, so it's not something you can give and then the next day, having given an increased dose, determine what the effect

of the first dose really was, which is why the recommendations are to start someone on a dose, keep them on that dose for two or three days so you can see what's happening and then increase the dose if they're in redouble, not do it every day.
The problem with doing it every day is that after four days he's on 50 milligrams a day it's going to take another week or so before the full effect of that 50 milligrams is evident. Now, if he had none the next day and the day after – which given the symptoms he presented with on 50 milligrams a day would be a very appropriate thing to do – then you will decrease the eventual concentration he will reach but you won't change the time it will take to get there if you put him back on methadone. All you've done is you've – you've got a 48 hour gap where he hasn't had any. He's still got methadone on board during that 48 hours. It's falling slowly and only reaches about half the concentration that it was when it was stopped by the end of that 48 hours, by 36 to 48 hours, then restarting at 20 means that he's not restarting from zero as he was at – right at the beginning. He's restarting at effectively already still on 20 to 25 so restarting at 20 is the same as if he had gone back to 40 because of the residual methadone still left over from 48 hours of not having it – the two days of not having it."

Professor Whyte agreed that it is both long-lasting and cumulative.

184 Dr Tim Ho, Pain Specialist and Rehabilitation Specialist, deferred to the expert opinion expressed by Professor Saunders and Professor Whyte, with respect to the cause of, and contributing factors in, Mr Phillips' death. In his earlier written report, Dr Ho had expressed his view of the role that Physeptone had played in terms of possibilities, rather than probabilities.

185 Dr Richard Hallinan is a specialist in addiction medicine. In his evidence, Dr Hallinan doubted Professor Whyte's opinion that methadone had most probably contributed to Mr Phillips' death in terms of a cardiac arrhythmia, due to QT prolongation and Torsades de Pointes. He noted that a diagnosis of cardiac arrhythmia is one of exclusion as it cannot be diagnosed during a post-mortem autopsy.

186 Dr Hallinan opined that there was no direct evidence which would confirm that Mr Phillips suffered a cardiac arrhythmia. Dr Hallinan noted that, in addition to his ingestion of methadone, Mr Phillips had a number of conditions which may have resulted in cardiopulmonary failure. The other conditions that Dr Hallinan noted included coronary artery atherosclerotic disease, sleep apnoea, and the ingestion of multiple medications, which in combination, may have contributed to his cause of death.

187 Dr Hallinan was of the opinion that Mr Phillips had risks of arrhythmia which related to ischaemic heart disease and sleep apnoea, not just his use of methadone.

Consideration of expert evidence on cause of death

188 On the available evidence there was a broad consensus amongst the experts as to the cause of Mr Phillips' death, with one dissenting opinion outlined above. The Court has come to the conclusion, on the balance of probabilities, that Mr Phillips died as a result of a cardiac arrhythmia, being Torsades de Pointes, due to the combined effects of coronary artery atherosclerotic disease, sleep apnoea, methadone and other drugs which had a QT prolonging effect.

Issue 2: Manner of death

189 As set out above, Issue 2 in this inquest was comprised of six sub-issues, namely:

a. The appropriateness of the type, dosage and frequency of medication prescribed by Dr Huber or Dr Huang between 10 October 2014 and 24 October 2014;

b. The appropriateness of the prescription of Physeptone in a patient with the medical background, comorbidities and circumstances of Mr Phillips;

c. The appropriateness of the coincident prescription of Physeptone and other drugs prescribed (including Stilnox, ciprofloxacin and Domperidone) in a patient with the medical background, comorbidities and the circumstances of Mr Phillips;

d. Whether investigations were required and had been sufficiently undertaken in connection with commencing treatment with Physeptone, including ECG examination, blood tests, renal function and liver function;

e. Whether Dr Huber and Dr Huang had adequate knowledge of the drugs prescribed, including the risks of potential interactions and side effects;

f. The joint management of Mr Phillips' condition (for which Physeptone was prescribed) by Dr Huber and Dr Huang with respect to:

    i. Their respective roles, obligations and responsibilities in monitoring and managing Mr Phillips; and whether those were properly fulfilled given Mr Phillips' medical background, comorbidities and circumstances;

    ii. The adequacy of the communication between Dr Huber and Dr Huang, in monitoring and managing Dr Phillips.

190 These issues, relating to the question of the manner of Mr Phillips's death, are clearly inter-related.

Issues 2(a), 2(b), 2(c) and 2(e)

a. The appropriateness of the type, dosage and frequency of medication prescribed by Dr Huber or Dr Huang between 10 October 2014 and 24 October 2014;

b. The appropriateness of the prescription of Physeptone in a patient with the medical background, comorbidities and circumstances of Mr Phillips;

c. *The appropriateness of the coincident prescription of Physeptone and other drugs prescribed (including Stilnox, ciprofloxacin and Domperidone) in a patient with the medical background, comorbidities and the circumstances of Mr Phillips;*
e. *Whether Dr Huber and Dr Huang had adequate knowledge of the drugs prescribed, including the risks of potential interactions and side effects.*

191 Dr Hester Wilson, Specialist in Addiction Medicine and GP, reported that Dr Huang's care and treatment of Mr Phillips during the period from late 2013 until early 2014 was appropriate during this time when he was being weaned off opiates. Dr Wilson was also of the view that Dr Huber's notes were adequate and that he had made appropriate referrals to specialists and directed relevant medical tests and investigations.

192 Dr Wilson was critical of Dr Huber when he was prescribing oxycodone during the period August to September 2014. Dr Wilson stated that it was "risky" due to the likelihood that Mr Phillips' tolerance levels may not have been sufficient for the dose being prescribed. Dr Wilson noted that "[s]tarting a daily dose of 120mg morphine equivalent is risky in the non-tolerant patient." It should be noted that Dr Huber's evidence amounted to that he was not aware of Mr Phillips' level of tolerance in that period and made no enquiry of him in that regard.

193 Dr Wilson also expressed concerns regarding Dr Huber's prescription of an 80mg dose of oxycodone in August 2014, as it was unclear if Mr Phillips had been using opioid medications in the months prior to this and specifically whether he had an opioid tolerance at this time.

194 Dr Wilson also noted her concern in relation to the administration of agomelatine together with ciprofloxacin by Dr Huang. Dr Wilson explained that the prescriptions are contraindicated as ciprofloxacin can inhibit the metabolism of agomelatine, leading to a significant increase in agomelatine. This can result in sedation, fatigue, agitation, dizziness and cyanosis. Professor Whyte did not identify this as having a causal or contributing role in Mr Phillips' death.

195 The experts then provided their opinions in relation to the appropriateness of the prescription of Physeptone to Mr Phillips in October 2014. In that context, Dr Huang's evidence was that he was sufficiently concerned about the appropriateness of prescribing Physeptone at this time that he contacted the Pain Clinic at St Vincent's Hospital seeking a review. The evidence suggests that Dr Huang did not receive any communication in response from the Pain Clinic until after Mr Phillips' death. In addition, Dr Huang also contacted the PSU for an authority to prescribe Physeptone and Endone. His evidence was that he sought the assistance of the PSU. Dr Huang, however, issued a script to Mr Phillips prior to receiving approval from the PSU.

196 Dr Hallinan and Dr Wilson both expressed a view that it was not inappropriate to prescribe Physeptone to Mr Phillips and that a starting dose of 20mg was reasonable.

197 Dr Hallinan was of the view that Mr Phillips did not necessarily need to be placed on the OTP, which would involve the prescribing of methadone syrup rather than Physeptone tablets. Professor Saunders expressed an opposing view, indicating that he was of the opinion that Mr Phillips should have been placed on the OTP and should have received methadone syrup rather than the Physeptone tablets.

198 Dr Hallinan also expressed the view that there was no particular benefit to prescribing Physeptone for neuropathic pain, although Physeptone could provide other benefits for pain management.

199 Dr Ho expressed a view in his report that choosing to prescribe Physeptone in a high-risk patient with severe sleep apnoea, diabetes and also prescribed Stilnox was inappropriate.

200 Dr Hallinan, Dr Wilson and Professor Saunders all agreed that given the complexities of Mr Phillips' case, that it would be difficult to safely manage his use of Physeptone as an outpatient. Professor Saunders expressed the view that Mr Phillips should have been admitted as an inpatient as the "only viable option." Dr Hallinan agreed that managing Mr Phillips' use of Physeptone as an outpatient would be "difficult to achieve" and that "there would have been a lot of bases to cover". Dr Wilson agreed with Dr Hallinan's opinion.

201 Dr Ho expressed the opinion that:

> "With Physeptone induction, in pain medicine field, we usually, we start at 20 milligrams but we do not increase at daily rate, so in pain medicine we increase by 5 to 10 milligram every week. In addiction medicine – I also do work in addiction medicine as well – in addiction medicine we increase by 5 milligrams every three days, and especially in this high-risk patient appropriate monitoring is needed. The reason that the slow increment is required in the guideline for opiate treatment program is there is because there has been deaths related to even low dose methadone..."

202 Professor Whyte commented on the requirement that the prescriber of medication must be familiar with the content of the product information, including contraindications, prior to prescribing them to a patient. Dr Hallinan and Dr Wilson also expressed a similar view.

203 Professor Whyte noted that Mr Phillips already had a high-risk baseline. He noted that Mr Phillips was already prescribed domperidone and expressed the decision to also prescribe ciprofloxacin as questionable, at best. Furthermore, Professor Whyte stated that the decision to prescribe methadone in a high-risk patient on domperidone was highly questionable, particularly when he presented with conditions such as sleep apnoea and concomitant sedative drug therapy.

204 Professor Whyte expressed a similar view to that of Dr Ho, that even if methadone was to be administered, a lower starting dose and a more gradual increase in dose would be mandatory.

Issue 2(d)

d. Whether investigations were required and had been sufficiently undertaken in connection with commencing treatment with Physeptone, including ECG examination, blood tests, renal function and liver function tests.

205 In evidence, Dr Huang conceded that ECG monitoring should have been conducted with Mr Phillips before he was commenced on methadone.

206 Dr Ho, Dr Wilson and Professor Saunders were critical of Dr Huang's decision not to order ECG testing prior to commencing Mr Phillips on Physeptone. Dr Wilson commented that this was particularly the case where the patient was currently prescribed Ciprofloxacin and Domperidone, which are known to cause QT elongation in some patients.

207 Dr Hallinan expressed the view that ECG testing should have been considered at this time.

208 Dr Ho expressed the view that Mr Phillips should have been sent for renal function testing prior to commencing Physeptone. The other experts were not critical that no renal testing was undertaken. None of the experts were critical of Dr Huang that liver function testing was not ordered.

209 Dr Huber conceded in evidence that when he prescribed Motilium on 11 October 2014, he was not aware that it could lead to QT prolongation. Further, he conceded that he was unaware of the interaction between Motilium and Physeptone with respect to the QT prolongation.

210 In relation to the above, Dr Wilson stated that it was the responsibility of GPs "to be aware of the issues around the medicines we do prescribe." Dr Wilson agreed that would be true of motilium and methadone, and indeed, "[i]t would [be true] for any drug."

211 Dr Wilson was also asked about her view of Dr Huber's role and responsibilities where another specialist is involved in providing joint care. Dr Wilson responded that "if a specialist is managing another medication you don't have experience of, then you don't feel you need to understand that medication", however "you need to take responsibility for the medicines that you prescribe ... because of the risk, the potential risk, of not doing that."

212 Dr Huber made concessions in his evidence that he didn't know much about methadone in October 2014; in particular, he did not know that it was an accumulating drug, as well as a long-acting drug.

213 Dr Wilson was critical of Dr Huber's actions in giving Mr Phillips advice about Physeptone dosages and for contacting the Darlinghurst chemist to alter the collection regime on 15 October 2014. Dr Wilson commented:

> "the medication was being managed by another doctor, a medication that Dr Huber didn't know ... it would have been better for him to leave it to ... Dr Huang – get in contact with Dr Huang ... and seek advice. You know, the reality for us in general practice is if you don't

> have experience with managing methadone ... you may not realise the importance of supervised dosing or ... staged supply in that program. Many GPs are not aware of ... those provisions. However, what Dr Huber is saying is that 'I left it in the other doctor's hands' but then got involved in that, without advice, without support."

Dr Wilson confirmed her opinion that Dr Huber's involvement was not acceptable practice.

214 Dr Wilson was asked to comment on Dr Huber's consultation with Mr Phillips on 21 October 2014, in light of Dr Huber's admission during evidence that he should not have prescribed Stilnox. Dr Wilson confirmed that providing such a prescription was not acceptable practice "given the history, no." Furthermore, Dr Wilson confirmed that it was her opinion that Dr Huber prescribing Physeptone, during that consultation when Mr Phillips presented as being "'completely gone', incoherent, sedated", was "very much a concern" and that the "[a]cceptable and advisable practice would ... have been for Dr Huber to contact that doctor."

215 Professor Saunders was asked to comment on whether it was acceptable practice for Dr Huang to prescribe ciprofloxacin to Mr Phillips on 17 October 2014, and noted that, "Ciprofloxacin does not prolong the QTc interval". However, he noted that:

> "The major issue of ciprofloxacin is its effect on the metabolism of methadone. Methadone is metabolised by a cytochrome P450 component called CYP3A4 which is inhibited by ciprofloxacin and so there is the potential for the methadone – the metabolism methadone to be inhibited leading to an accumulation of methadone and increasing plasma levels. It is what we call a pharmacokinetic interaction. Now, I did not consider ciprofloxacin to be of primary importance given the fact that the post-mortem levels of methadone in Mr Phillips were within the normal range. So I didn't see evidence of significant inhibition of methadone metabolism by ciprofloxacin."

216 The medical experts were asked to provide their opinion in relation to Dr Huang's decision to prescribe Lyrica to Mr Phillips on 9 and 10 October 2014.

217 The evidence confirmed that Dr Huang had prescribed Lyrica 75mg to Mr Phillips on 9 October 2013 and the following day increased the prescribed dose to 150mg. It would appear that Mr Phillips had not taken the 150mg dose as the packet was located by Senior Constable Facey unopened when he searched Mr Phillips' home after he was found deceased. The evidence confirmed that Dr Huang did not enquire whether Mr Phillips had taken the 150mg of Lyrica or not. Dr Huang conceded that he could have placed Mr Phillips on a longer trial of Lyrica, however, Dr Huang had doubted the effectiveness of the drug on the basis of the degree of compression of Mr Phillips' spinal disc. On 13 October 2014, Dr Huang commenced prescribing Physeptone to Mr Phillips.

218 Professor Saunders, Dr Hallinan and Dr Wilson were all critical of Dr Huang's failure to establish whether Mr Phillips had taken the 150mg dose of Lyrica or not, before declaring that the Lyrica trial had failed and then prescribing Physeptone. Professor Saunders stated that, in his view, Lyrica was "less good for pain emanating from Mr Phillips' condition" but he "certainly should have inquired about whether the patient had taken the Lyrica" and certainly should have done so prior to commencing him on a course of Physeptone.

219 Dr Hallinan did not believe, in Mr Phillips' case, that Lyrica would produce a positive response. He was critical of Dr Huang's failure to make the enquiry with Mr Phillips and stated that "he made an error in not getting to the bottom of treatment adherence – and that is obviously critical to medicine to... make sure ... your patients are taking the medicines." Dr Wilson agreed.

220 Dr Huang regarded Physeptone as the most effective agent for neuropathic pain and recorded his view in his clinical notes. None of the experts agreed with Dr Huang's assertion. Dr Ho stated that he would not have regarded Physeptone as even a third-line treatment for neuropathic pain and Dr Wilson referred to literature which cited Physeptone as a fourth-line treatment for neuropathic pain.

Issue 2(f)

f. The joint management of Mr Phillips' condition (for which Physeptone was prescribed) by Dr Huber and Dr Huang with respect to:

i. Their respective roles, obligations and responsibilities in monitoring and managing Mr Phillips; and whether those were properly fulfilled given Mr Phillips' medical background, comorbidities and circumstances; and

ii. The adequacy of the communication between Dr Huber and Dr Huang, in monitoring and managing Mr Phillips.

221 It is clear from the evidence that the roles of Dr Huang and Dr Huber began to overlap well before October 2014. Dr Huang was practicing as an addiction specialist and Dr Huber was practicing as a GP at the same medical centre. Their roles, however, appeared to blur with Dr Huang conducting mental health assessments and prescribing antidepressants and antibiotics, and Dr Huber providing advice with regards to the dosages of Physeptone and the dispensing regime for that pharmaceutical. At other times, there appeared to be a lack of co-ordination and collaboration between the two doctors.

222 While Dr Hallinan and Professor Saunders were critical of their management, Dr Wilson summed it up as follows:

> "really, it's about ... how they worked collaboratively. There weren't clear roles and responsibilities for this complex patient. ... there needed to actually be clear collaboration around what their roles and responsibilities were. So I think for me, pragmatically, that's one of the issues that actually affected the quality of care for this patient."

Evidence relating to the Pharmaceutical Services Unit/Pharmaceutical Regulatory Unit

Issue 2(g)

g. The Pharmaceutical Services Unit's consideration and determination of Dr Huang's application ('the Application') dated 13 October 2014 for authority to prescribe Physeptone and Endone to Mr Phillips and whether the authorisation given to Dr Huang on 16 October 2014 to prescribe Physeptone was at that time consistent with the responsibilities, objectives, functions and policies of the Pharmaceutical Services Unit.

223 Physeptone cannot be prescribed to a patient in NSW unless "a proper authority" to prescribe is issued in accordance with the *Poisons and Therapeutic Goods Act 1966* (NSW) ("the *P&TG Act*"). Physeptone is a type B drug of addiction pursuant to Regulation 123 of *the Poisons and Therapeutic Goods Regulation 2008* (NSW).

224 At the time of Mr Phillips' treatment, and pursuant to section 28A(1) of the *P&TG Act*,

> "The Secretary may, on the recommendation of the Medical Committee, approve a medical practitioner as a prescriber of drugs of addiction."

Dr Huang appears to have previously received that approval.

225 At the time of Mr Phillips' treatment, section 29 of the *P&TG Act*, stated:

(1) An application for the authority of the Secretary referred to in section 28 is to be in a form approved by the Secretary.

(2) Any such application may be referred by the Secretary to the Medical Committee.

(3) The Secretary may give an authority for the medical practitioner or nurse practitioner by whom any such application is made to prescribe for or supply to the person to whom the application relates any drug of addiction specified in that authority for the purpose of the treatment of that person.

(4) Where the Secretary refers an application to the Medical Committee, the Secretary shall take into consideration any report of that Committee relating to that application made before the authority is granted.

226 Dr Huang could not prescribe Physeptone to Mr Phillips without an authority. He applied for an authority on 13 October 2014, using a form prescribed by the Secretary. An authority to prescribe Physeptone was issued to Dr Huang on 16 October 2014 with conditions pursuant to section 29(3) of the *P&TG Act*.

227 The relevant daily doses of Physeptone prescribed by Dr Huang were:

- 14 October 2014 20mg
- 15 October 2014 30mg
- 16 October 2014 40mg
- 17 October 2014 50mg

In the following days, it is less clear what doses were ingested, however, it would appear that they did not exceed 50mg per day.

228 In his statement dated 11 October 2019, Dr Huang conceded that the doses of Physeptone prescribed to Mr Phillips were too large and the induction regime too rapid. In addition, he also conceded that his supervision of the induction was deficient. The experts unanimously agreed with those concessions.

229 In light of Dr Huang's concessions and the expert opinions provided during the inquest, further information was sought from the PSU relating to the procedures and oversight of the process for the authorisation of the prescription of Physeptone to Mr Phillips in October 2014.

230 Further material was produced by the PSU/PRU in response to a subpoena and tendered in these proceedings. In addition, formal responses were received from Mr Aleksandar Gavrilovic, Principal Pharmaceutical Officer ("PPO") and Manager of the Monitoring and Compliance team within the PRU, Legal and Regulatory Services Branch at NSW Health dated 19 February 2020, 18 March 2020, 8 October 2020 and 13 October 2021. A statement from Ms Joanne Zeilinga, the officer who signed and issued the authority to prescribe Physeptone to Mr Phillips on 16 October 2014, was also provided and tendered in these proceedings.

Ms Zeilinga's Evidence

231 Dr Huang's application for an authority to prescribe Physeptone to Mr Phillips was processed and granted by Ms Zeilinga in October 2014. At that time, Ms Zeilinga was a Senior Pharmaceutical Officer ("SPO") at the PSU. She held the formal qualifications in Pharmacy and was a Registered Pharmacist with the Australian Health Practitioner and Regulatory Agency ("AHPRA"). She had been a SPO at the PSU since January 2013.

232 Ms Zeilinga confirmed that a key task she performed was to "review applications for drugs of addiction and the issuance of authorities to prescribe drugs of addition in response to those applications, in accordance with legislation." Additionally, Ms Zeilinga performed "other tasks such as fielding phone calls from healthcare professionals regarding the requirements of the legislation".

233 Ms Zeilinga had no independent recollection of her involvement in Dr Huang's application made in October 2014. Additionally, Ms Zeilinga had no recollection of the conversation with Dr Huang on 16 October 2014. Ms Zeilinga noted that if a practitioner telephoned her to check on the status of an application or to discuss the conditions of the authority, her usual practice was to record the conversation on the associated worksheet. Ms Zeilinga confirmed that she had not recorded any conversation with Dr Huang on the worksheet, however, conceded that it was possible that Dr Huang had contacted the PSU as he described. Ms Zeilinga also noted that calls from practitioners are managed by Pharmaceutical Support Officers and calls are only referred to a SPO if required.

234 Dr Huang had made contemporaneous notes of his conversation with the PSU on 16 October 2014, which was consistent with his assertion that he had contacted the authority as he had not received notification of his application registered with the PSU on 13 October 2014.

235 Ms Zeilinga confirmed that the authority was granted as an interim authority valid until 1 December 2014. The authority permitted Dr Huang to prescribe Physeptone (likely from 16 October 2014), with the condition that the prescribed dose was limited to 50mg daily. Other conditions were that "no additional medication [was] to be prescribed" and "that there is no evidence of any unauthorised drug of addiction being prescribed by other practitioners or of illegal drug use".

236 Ms Zeilinga confirmed that there were no "red flags" apparent in the 2014 application received from Dr Huang. She stated that she would have reviewed the previous application to prescribe opioids submitted by Dr Huang on 31 October 2013.

237 Ms Zeilinga was aware that Mr Phillips was 65 years of age, however, she had not specifically considered his age during her assessment of the 2014 application as he was not particularly old at 65 years of age.

238 Ms Zeilinga reviewed the medical reports annexed to the 2014 application and was satisfied that Mr Phillips' diagnosis primarily related to pain management rather than addiction management. Ms Zeilinga confirmed that it was not important from a regulatory point of view what type of pain was present, rather that it was the identification of "pain is ... sufficient for us to consider it", that is, granting the authority to prescribe.

239 Ms Zeilinga had concluded that the objective of the 2014 application was similar to the October 2013 plan, that being to wean Mr Phillips away from opioid dependency, by prescribing Physeptone and both treating his pain and weaning him from his dependency at the same time.

240 Ms Zeilinga was of the view that Mr Phillips was to receive frequent reviews from Dr Huang, rather than the dispensing pharmacist. A patient receiving methadone on the OTP would receive their dose daily in a syrup form and would be observed at the time of dosing by the pharmacist. However, Ms Zeilinga confirmed that it was not her practice to make further enquiries with the applicant doctor to determine how frequently the prescribing doctor would review their patient if that patient was not on the OTP.

241 Ms Zeilinga stated that her role was regulatory, rather than clinical. Ms Zeilinga indicated that the clinical decision-making and management relating to the authorised drug the subject of the application, was solely the domain of the applicant doctor.

242 In that regard, Ms Zeilinga was asked why it was then necessary for the applicant doctor to provide additional medical reports. Ms Zeilinga indicated:

> "So, in this case, the medical reports would've – didn't indicate any diversion or aberrance viewed, so generally when you've received

medical reports, there would be some more indication of the more information in there that might indicate that, so things such as patient escalated or patient has come back early for their prescription, and that sort of – so those sort of clues or indicators that might be a problem."

She continued, stating, "The other thing is that where there's ... additional medical reports, it's just I guess supports that the pain indication that the patient was – had legitimate pain problem and not – and not purely an addiction one."

243 Ms Zeilinga agreed that the provision of medical reports by the applicant doctor provided information as to whether the prescriber was an isolated prescriber or part of a coordinated care team. She confirmed that the fact that Dr Huang was a specialist physician in addiction medicine and not a GP was a relevant factor in granting the authority to prescribe. Ms Zeilinga agreed that she would expect that an "addiction medicine physician would understand the ideal induction, supervision and management from a clinical point of view in relation to the drug Physeptone."

244 Ms Zeilinga confirmed that there is no requirement for the applicant doctor to provide a list of other medications which are being prescribed at that time. Ms Zeilinga confirmed that when an applicant doctor provided a list of medications currently prescribed to the applicant, such information would not alter the PSU's processing and determination of the application, even if the list of medications included medications which were contraindicated or required extreme caution in their administration. Ms Zeilinga stated:

> "It wasn't part of the process to – to do that, so because very – you wouldn't often get a list of medicines that get – that come with an application, however, if there was a medicine that was also scheduled, so another drug of addiction, for example, that you notice on that list, that – that would pique interest of like, if there was, you know, another – basically another drug that required an authority, you would follow that up."

245 Ms Zeilinga confirmed that as a SPO she was aware of the types of matters which were required to be referred to the PPO. The types of matters included those cases that involved a drug dependent person who had complex comorbidities and who was the subject of an application to the PSU. Ms Zeilinga stated that:

> "I think my interpretation was, as I mentioned before, the complexity of the comorbidities often were around the behaviours around the use of the medicine. So rather than any complex clinical comorbidities, we were, you know, that wasn't something which we were asked to focus on. And we had to try to refrain from that because we're not – we're not acting as clinicians in our role. So it was more understanding the comorbidities with a – with a backdrop of the potential, without indicators of aberrant behaviours. ... I didn't see them as two separate elements that were not connected."

246 Specifically relating to Dr Huang's application on behalf of Mr Phillips, she stated that:

> "I see comorbidity as a comorbid condition of, say, addiction with a – with a presentation of pain as well. So in this particular situation, there is a comorbidity but without any of the risk of diversion. ...I read that as where there are concerns to do with diversion, use of illicit drugs, aberrant behaviours, together with any conflict comorbidities."

247 Ms Zeilinga agreed that conditions such as hypertension, sleep apnoea and diabetes were comorbidities, however stated that, "I was thinking of the pain comorbidity with the addiction comorbidity. So less about the other chronic pain – the other chronic conditions that he may have been managed for."

248 Ms Zeilinga confirmed that there would be regular team meetings involving the SPOs and the PPO, where a range of topics could be raised and discussed. Ms Zeilinga also stated that she would inform the PPO if she received an application relating to a complex patient or if the opioid morphine equivalent daily dose ("oMEDD") was very high. The PPO would then give consideration as to whether the application should be referred to the Medical Committee. Ms Zeilinga confirmed that she did not have the authority to directly refer any matter to the Medical Committee.

249 Section 30(4) of the *P&TG Act* states:

> "The Medical Committee shall consider every application referred to it under section 28A or 29(2) and shall, as soon as practicable after the application is referred to it, furnish to the Secretary a report in writing containing a recommendation whether or not an approval or authority of the kind applied for should be given and whether, if given, it should be unconditional or subject to specified conditions."

250 Ms Zeilinga also understood that, in 2014, the Medical Committee would review applications with a very high oMEDD, that is, an oMEDD greater than 500mg. She confirmed that this oMEDD limit had been reduced to 400mg, but was unsure of when this change occurred.

251 Ms Zeilinga noted that Dr Huang had been issued with an authority for Mr Phillips in 2013, for "quite a high dose of opioids", however, she had no information as to Mr Phillips' opioid tolerance in 2014, except that the application had been lodged by the same prescriber, who she presumed would have knowledge regarding Mr Phillips' current (2014) tolerance.

252 Dr Huang's 2014 application stated that he was proposing to prescribe 10–25mg twice daily. Ms Zeilinga indicated that "when we issue an authority, we issue it for the – for the total amount for the day. We don't sort of issue it based on the specific dose and frequency".

253 Ms Zeilinga conceded that she was aware in 2014 of the difficulties associated with measuring the oMEDD, which was "due to the complex pharmacokinetic nature of the medicine and the very individual effect it has on the person, that it's difficult to draw an oral morphine equivalent daily dose and that it varies.

But a factor of five is considered a conservative. And also, I guess this is all supported by, you know, that we have an oMEDD calculator that we use from the Faculty of Pain Medicine..."

254 Ms Zeilinga stated that she was unaware of any scientific basis for applying a factor of five to obtain the oMEDD, however, that was the process used at the time at the PSU.

255 Ms Zeilinga confirmed that the standard application form used by Dr Huang did not ask the practitioner to identify the oMEDD, and that the oMEDD was calculated by the SPO at the PSU.

256 Ms Zeilinga agreed that the person in the best position to assess the oMEDD is the treating doctor or specialist. She confirmed that the officers at the PSU could only use guidelines, whereas she assumed that the addiction specialist "based on their knowledge of, especially from an addiction medicine specialist with, I presume, a good amount of training in this area would – would be best placed to determine that, more directly for the patient."

257 Ms Zeilinga confirmed that based on Dr Huang's proposal to prescribe 10-25mg daily, a factor of five was applied as described above, resulting in an oMEDD of 250mg daily for Mr Phillips.

Issue 2(h)

h. How the Pharmaceutical Regulatory Unit (formerly the Pharmaceutical Service Unit) would currently process and determine the Application (that is, if made as at October 2021) in accordance with the current responsibilities, objectives, functions of the PRU and the policies and guidelines that complement the applicable legislation, being the Poisons and Therapeutic Goods Act 1966.

Mr Gavrilovic's Evidence

258 Mr Aleksandar Gavrilovic was a PPO at the PRU at the time he gave evidence in these proceedings on 14 October 2021, although he was on secondment to the Real-time Prescription Monitoring Project. He was not employed at the PSU in October 2014, although he had been employed at the PSU from 2008 until 2010.

259 As a PPO, Mr Gavrilovic would attend Medical Committee meetings regularly, at the request of the Medical Committee, however, was not an active participant during the meetings.

260 In his letter dated 18 March 2020 (Exhibit 8), Mr Gavrilovic stated that:

> "The aim of the authority system is to provide a means of control over the prescribing of drugs of addiction, according to the principle that one practitioner is responsible for the prescribing of such drugs to a particular patient. Records of authorities issued by PRU can be used to inform a further applicant that their authority cannot be approved if another prescriber currently holds such authority."

261 In his statement dated 8 October 2020, Mr Gavrilovic indicated that the statutory function of the PRU pursuant to the *P&TG Act* is to regulate and preserve the integrity of the legitimate supply chain of scheduled substances, including medicines that are drugs of addiction. He further stated:

> "the PRU performs a regulatory function in the prescribing of opioid medications. The regulatory function of the PRU is to protect public health and safety by regulating and preserving the integrity of the legitimate supply chain of scheduled substances, including medicines that are drugs of addiction. The purpose of the PRU in assessing an application is to consider whether the application is made by a clinician operating within the lawful practice of their profession, or who it explicitly authorises to undertake regulated activities, and by providing for authentication of the identity of the authorised person. The legislative aim is to reduce patient's doctor-shopping for drugs of addiction for non-therapeutic purposes.
>
> The PRU performs its regulatory purpose to reduce risks and harms to the public by reducing the diversion of substances liable to abuse, misuse and trafficking such as medicines that are drugs of addiction, to the illicit supply chain. It is concerned with supply for intentional diversion by authorised persons, and by reducing opportunity for demand for misuse or diversion of these substances. To this end, the PRU is concerned with ensuring a dosage is within a reasonable threshold and the mode of delivery for that medicine (for example, an injectable) is suitable.
>
> Apart for this regulatory function, the purpose of the PRU is not to interfere with the clinical decision-making of a specialist medical practitioner."

262 During his evidence in these proceedings, Mr Gavrilovic confirmed on a number of occasions, that the role of the PRU/PSU was purely regulatory and refuted suggestions that the PSU and the Medical Committee entered the area of clinical management in a manner which was inconsistent with being purely regulatory or serving the statutory purpose by maintaining the integrity of the supply chain of restricted drugs to minimise the risk of diversion and abuse.

263 Mr Gavrilovic confirmed that in addition to the Unit changing its name from the PSU to the PRU, there were four other areas of change to the Unit's operations since October 2014. The four areas are:

- Conditions 1311 and 1312;
- Changes to the application form to prescribe drugs of addiction;
- A referral to the Medical Committee is now made if the oMEDD is calculated at 400mg rather than 500mg daily; and
- Practitioners are referred to the Australian and New Zealand College of Pain Medicine ("ANZCA") website to assist in the calculation of the oMEDD for an application.

264 Mr Gavrilovic confirmed that Conditions 1311 and 1312 are similar in nature and are now inserted into every authority granted to prescribe a drug of addiction and to advise that a PRU decision is not an endorsement or support

for treatment involving drugs of addiction which are the subject of a practitioner's application. He stated that the condition is there "to make it clear to practitioners who receive any authority from the ministry that this is not an endorsement of their therapy, that it's not ... an evaluation of their clinical management of the patient. It's just fulfilling a regulatory role." He also confirmed that it "has been talked about over many years ... but yes I think it's fair to say that Clause 1311 is probably attributable to this unfortunate circumstance where it could be misunderstood what the PRU's role is, and not directly related to Mr Phillips."

265 Mr Gavrilovic confirmed that the current application form now seeks "different and additional" information from the Form 1 application prepared by Dr Huang on behalf of Mr Phillips, dated 13 October 2014.

266 The current application form superseded earlier forms from April 2019 and is currently identified and referred to as PN04/19. The current Form PN04/19 reflects the other two changes, namely the reduced rate of 400mg oMEDD that the oMEDD is calculated at before an application is referred to the Medical Committee and the requirement that an applicant practitioner is directed to the ANZCA website "to calculate the oMEDD".

267 Section C of Form PN04/19 refers to the "Drug authorisation details" and indicates to the practitioner applicant:

> *oral Morphine Equivalent Daily Dose (oMEDD) is the opioid dosage as compared to oral morphine.*
> *Opioid prescribing recommendations in general practice (published by ACI Pain Management Network) are as follows:*
> - *<40mg daily oMEDD for non-cancer pain for a maximum 90 days*
> - *<300mg daily oMEDD for cancer pain*
>
> *For opioid doses >100mg daily oMEDD, a specialist review is recommended.*
> *To calculate the oMEDD go to*
> *http://fpm.anzca.edu.au/documents/opioid_dose_equivalence or*
> *http://www.opioidcolculator.com.au/*
> *More information about the role of opioids in chronic non-cancer pain and further resources go to*
> *http://www.oci.health.nsw.gov.au/chronic-pain*
> *Note: For non-opioid drugs, 'Total oMEDD' details are to be left blank."*

268 Section F of Form PN04/19 references "Pain Management details". Question 9 asks, "Are you applying to prescribe a total oMEDD >400mg? If the answer is "N", the practitioner applicant is to "Go to Q12". If the answer is "Y", the practitioner applicant is then asked at Question 10, "What analgesic medications is the patient currently taking (including opioids and non-opioids)?" Question 11 states, "What other medications have been trialled?"

269 Mr Gavrilovic confirmed that the inclusion of Questions 10 and 11, "related to the fact that if the oMEDD is over 400, the matter will be referred to the medical committee, and the medical committee has asked that this information be

provided to them in their consideration of the application." Mr Gavrilovic also confirmed that if Dr Huang had assessed that Mr Phillips' equivalent daily dose was 500mg, he would have been required to list analgesic medication currently being taken, being both opioids and non-opioids.

270 Question 12 is the next mandatory question on Form PN04/19. It states, "What other non-pharmacological pain relief treatments have been trialled?" Mr Gavrilovic was asked why the regulator would have an interest in knowing what non-pharmacological pain relief treatments had been trialled. Mr Gavrilov stated that, "From a regulator's point of view, I – I don't think they have an interest." He continued by stating that he believed that "it's a prompt to the applicant to consider if they have, in fact, tried non-pharmacological intervention."

271 Mr Gavrilovic was asked how such a question was reflective of the regulatory role of the PRU and he responded, "Well, I don't think that it interferes with a regulatory role. As I said, it's – there are other aspects of that document that also refer to non-regulatory behaviour by a practitioner. I don't think that's inconsistent with the ministry's overarching intention to contribute to quality use of medicine."

272 Mr Gavrilovic then stated that "the intent of this question and the questions preceding it are things that do come up in discussions at the medical committee on a regular basis, and I'm not sure that I can answer it any differently." It should be noted that Question 12 is a mandatory question, whether or not the application is to be referred to the Medical Committee.

273 Mr Gavrilovic stated that "The scope of the medical committee isn't defined in the legislation" when asked why Question 12 would "be of interest to the medical committee if its role is confined to preventing or reducing the risk of supply of addictive drugs." He confirmed that, "It does not specify that they must limit themselves to only regulatory matters. In fact, their scope is left reasonably wide."

274 Mr Gavrilovic agreed that the Medical Committee doesn't confine itself to matters of regulation of drugs of addiction. He was asked to provide examples of where the Medical Committee was not confined and he stated "a clear example of, if you like, trying to give instruction to the prescriber about how to potentially avoid an escalating dose of opioids."

275 The following exchange occurred:

"Q. That's a clinical management issue, you'd agree?

A. I'd agree that it's not strictly regulatory."

Q. What's your reluctance to embrace it as a clinical management matter?

A. Well, because – because they – they also recognise that it – it's not possible to offer clinical management of a patient that they're not actually treating themselves. The best that they can ever do is to provide advice and guidance about that patient's management, which the doctor can choose to follow

or not, but it's – it – it would be inappropriate for somebody to remotely try and manage a patient's clinical treatment."

276 Given that Dr Huang believed that the PSU had some sort of clinical approval or oversight role, Mr Gavrilovic was asked about the document titled "*Medical Committee – August 2013, Criteria and requirements for issuance of authorities for Chronic non-cancer pain*" ("*Medical Committee – August 2013* document"). The document's stated purpose is, "To provide clarity and transparency for medical practitioners on the process of authorisation to prescribe opioids for chronic pain conditions when required by Section 28 of the P&TG Act".

277 Mr Gavrilovic indicated that he was not aware that this document was previously distributed to medical practitioners.

278 The following exchanges appear in the transcript:

"Q. This particular document does not tell medical practitioners that the PRU does not have a role in endorsing clinical or patient management decisions, does it?

A. From my recollection of reading the document, no, I don't think it does.

...

Q. You said you weren't aware of this document going to medical practitioners, even though it's (sic) stated purpose is to provide medical practitioners with clarity and transparency, are there other documents currently available to medical practitioners that you know are distributed to them, which explain the role of the PRU?

A. There are a number of documents that are available from our website, we – we no longer – we no longer send documents out, we just refer them to the links on the website, and there are certainly documents that explain the legal requirements for an authority, and makes it clear that that is administered by PRU. There are also guidelines for practitioners about their management of drugs of addiction and – and other medicines, which are also generated by PRU and make it clear that PRU is responsible for the whole of the supply chain, if you like, and not just restricted to schedule A drug, and there are also I think links to some reference documents."

279 Mr Gavrilovic also noted that there were still medical practitioners who did not know that the PRU existed, nor that there is a requirement for a medical practitioner to apply for an authority to prescribe drugs of addiction. He estimated that the PRU would send out about 80 to 90 letters per year to medical practitioners who they believed had issued prescriptions without the appropriate authority.

280 The "*Medical Committee – August 2013*" document referred to "co-morbidities", as did the Standard Operating Procedures current as at October 2014, which also referred to "contra-indications". Mr Gavrilovic indicated that the reference to "complex co-morbidities" in the *"Medical Committee – August 2013*"

document was qualified by the use of the term "aberrant behaviour" and as such, only applied where a patient was at high risk due to that type of behaviour. He confirmed that the use of the term comorbidities in the PRU context did not refer to comorbidities in the medical or clinical sense, and the use of the word for two different and distinct purposes was "unfortunate that that term could be interpreted to be something else, but it's really – really trying to look at it from the point of view of the things that are relevant to a regulator". Similarly, the use of "contra-indications" was not being used to reflect an understanding that a medication had the potential for an adverse interaction with the drug for which an authority is being sought and that the only meaning that applied was in a regulatory sense.

281 The "*Medical Committee – August 2013*" document was dealing with applications for 500mg or more of oMEDD in 2013 and stated "please advise PSU on which formula/conversion table to be used for calculations." Neither the earlier form applicable to Dr Huang's application, nor the current form, require that information on the face of the application.

282 Mr Gavrilovic agreed that the reason the current form does not offer a conversion factor is because his "understanding of the pharmacokinetics is that it can be variable from individual to individual, and therefore there is no accepted standard way of estimating the oMEDD from the dose of methadone". Mr Gavrilovic indicated that the PRU takes a conservative approach by adopting a conversion factor of five, noting that it "is not necessarily a precise conversion for – applicable to every patient, but it is a way for staff within PRU to – to manage that aspect of – of deciding whether they need to refer or not."

283 Indeed, the ANZCA website, referenced in the current PRU application form to assist a practitioner to calculate the oMEDD, does not include Physeptone as "Methadone [and other drugs stated] are not included in this table due to their complex and variable pharmacokinetics."

284 Mr Gavrilovic noted that "medical practitioners will tend at that point to write, 'Cannot – cannot convert this to oMEDD because the entry doesn't appear in the ANZCA table'. So sometimes practitioners are a bit confused about what to do at this point and may even leave it blank, but that would be a potential trigger for contacting the prescriber to make them aware of how we are calculating the oMEDD."

285 Mr Gavrilovic indicated that a patient's degree of tolerance for opioid medications was a relevant factor for the prescribing doctor to consider when calculating the oMEDD for Physeptone. Mr Gavrilovic was asked whether it was also a question for the regulator to consider when calculating the appropriate rate. Mr Gavrilovic responded, "It's difficult to always relate tolerance, because that's such a variable concept for a patient as well, so yes, we want, if you like, a – a – an easy, arithmetic way of establishing an oMEDD for our purposes, which in this case would be to either refer to a medical committee or not, but the fact that a patient may be on a high dose isn't always equivalent to understanding just how much tolerance they have for a particular drug, and it's never quite as straightforward as just measuring the oMEDD."

Despite that, he accepted that this is the very basis on which an application is referred to the Medical Committee.

286 Mr Gavrilovic indicated that "experts in the field", including from the Royal College of GPs, pain specialists and psychiatrists, had suggested that the conversion factor of five was conservative and that a conversion factor of three was adequate. He agreed that a factor of three had the capacity to underestimate what the oMEDD might be and why the PRU continued to adopt the more conservative factor of five.

287 Mr Gavrilovic stated that the "number of applications that we receive for methadone is quite low, the majority of the drugs that are being applied for, there is an easy and accurate oMEDD value that can be referred to in the guide, and therefore, there's not a question of doubt, there's no question about whether it's appropriate to refer or not".

288 In the context of Mr Phillips' death, together with the fact that methadone is not included in the ANZCA conversion table because of its complex and variable pharmacokinetics and the small number of applications, the question remains why the legislation and departmental policy has not been reviewed to ensure the safety of the patient and the integrity of the regulatory body.

289 In addition, Mr Gavrilovic confirmed that the Medical Committee continues to meet at least six times per year, and more often to address any backlog.

Considerations

Professional Referral of Dr Huang and Dr Huber

290 Senior Counsel Assisting, Ms Whalan SC, submitted that both Dr Huang and Dr Huber should be referred to the Executive Officer of the Health Care Complaints Commission and/or the Medical Council of NSW, as well as to the Executive Officer of the Health Protection Service ACT in relation to Dr Huang, pursuant to section 151A of the *Health Practitioner Regulation National Law* (NSW) ("the *National Law*").

291 Sections 151A(2) and (3) state:

> (2) If a coroner has reasonable grounds to believe the evidence given or to be given in proceedings conducted or to be conducted before the coroner may indicate a complaint could be made about a person who is or was registered in a health profession, the coroner may give a transcript of that evidence to the Executive Officer of the Council for the health profession.
> (3) If a notice or a transcript of evidence is given to the Executive Officer under this section –
> (a) a complaint is taken to have been made to a Council about the person to whom the notice or transcript relates; and
> (b) the Executive Officer must give written notice of the notice or transcript of evidence to the National Board for the health profession in which the person is or was registered.

292 Section 151A of the *National Law* does not define or provide any guidance as to what may constitute "reasonable grounds". Section 3A states that:

> (1) The main guiding principle of the national registration and accreditation scheme is that the protection of the health and safety of the public must be the paramount consideration.

293 Section 3B states that:

> In the exercise of functions under a NSW provision, the protection of the health and safety of the public must be the paramount consideration.

294 Section 151A of the *National Law* provides a mechanism where evidence received during coronial proceedings may serve to ground a complaint to the Medical Council. The section does not provide any basis for how such a complaint is to be assessed, investigated or considered, nor what action may be taken.

295 Senior Counsel Assisting noted the provisions of section 151A(2) of the *National Law* and submitted that the "language of the section plainly imposes a low threshold". In other words, section 151A(2) does not impose a requirement that the evidence in these proceedings has established a complaint, but rather that the section may be enlivened if the coroner has reasonable grounds to believe that the evidence may indicate that a complaint could be made.

296 Clearly, section 151A(2) is not mandatory. It permits a coroner the discretion as to whether a complaint should be made by providing the transcript of the proceedings to the Medical Council of New South Wales.

297 Section 144 of the *National Law* provides a number of grounds for a complaint about a registered health practitioner, as follows:

a) A complaint the practitioner has, either in this jurisdiction or elsewhere, been convicted of or made the subject of a criminal finding for an offence.
b) A complaint the practitioner has been guilty of unsatisfactory professional conduct or professional misconduct.
c) A complaint the practitioner is not competent to practise the practitioner's profession.
d) A complaint the practitioner has an impairment.
e) A complaint the practitioner is otherwise not a suitable person to hold registration in the practitioner's profession.

298 Section 139B of the *National Law* provides an extensive definition of the types of conduct which may be categorised as unsatisfactory professional conduct. The most pertinent consideration in relation to these proceedings would appear to be section 139B(1)(a), which reads as follows:

> 139B (1) ***Unsatisfactory professional conduct*** of a registered health practitioner includes each of the following—
>
> (a) Conduct that demonstrates the knowledge, skill or judgment possessed, or care exercised, by the practitioner in the practice of the practitioner's profession is significantly below the standard

reasonably expected of a practitioner of an equivalent level of training or experience. ... (emphasis in original)

299 In the abovementioned construction of the provisions of the *National Law*, it would appear that if there were reasonable grounds to believe that the evidence given during this inquest may indicate a complaint could be made, a transcript of that evidence may be provided to the Medical Council.

Submissions on behalf of Dr Huang

300 Dr Huang's legal representative, Ms Kim Burke of counsel, made the following written submissions:

"Reasonable grounds do not exist to make the referral as:

(i) The evidence does not disclose that Dr Huang was a rogue on his own frolic, rather he was a concerned practitioner attempting to palliate Mr Phillips' chronic pain on an interim measure, to help get him to his surgery date;

(ii) The lapse of time since Dr Huang provided treatment and management of Mr Phillips was 8 years ago, and almost immediately after finding about Mr Phillips' death, he altered his practice in late 2014, and changed the circumstances in which he did practice by early 2015;

(iii) He gave voluntary, appropriate and willing evidence as to his errors as to his treatment and management of Mr Phillips;

(iv) His level of insight was apparent both in his written statement and in oral evidence.

A referral at such a late stage after the death of Mr Phillips and the changes he has made to his practice would not fulfil the objective and guiding principles of the National Law."

301 Ms Burke submitted that the appropriate test for referral relies on an assessment of the "reasonable grounds" that "the evidence given ... or to be given ... may indicate a complaint could be made", rather than an assertion of "unacceptable conduct" by Dr Huang.

302 Ms Burke submitted that "reasonable grounds" include considering Dr Huang's evidence, in the context of the treatment and management he provided to Mr Phillips at the relevant time, including:

(i) the complexities of Mr Phillips' case;

(ii) Dr Huang's goal in prescribing Physeptone for chronic pain was for palliation to get Mr Phillips to his planned surgery;

(iii) Dr Huang's prior experience as an addiction specialist in reinducing other patients with riskier profiles, using the same pharmacy;

(iv) Prescription of Physeptone is a tablet form of methadone and is used in general practice for people with pain; it has benefits for chronic pain relief;

(v) Dr Huang's attempt (which included both correspondence and telephone calls to the clinic), to have Mr Phillips reviewed by a pain specialist and difficulties associated with achieving that referral;

(vi) Dr Huang's understanding at the time he submitted the authority application to the PRU, was that he was submitting a treatment plan for review, he understood the PRU provided oversight;
(vii) Dr Huang's level of understanding regarding the PRU was based on his "habit as a solo practitioner to resort to my peers who are often extremely busy so quite often – to check what I was up to, I would resort to the PSU";
(viii) Ms Zeilinga's evidence that she reviewed medical reports to ascertain that the diagnosis was a pain condition not an addiction condition. She did not identify any red flags;
(ix) Document entitled, "*Medical Committee – August 2013, Criteria and* requirements *for issuance of authorities for chronic non-cancer pain*";
(x) Standard Operating Procedures applicable in October 2014, "where there are any concerns due to contra-indications, co-morbidities or high doses, the case should be referred to the PPO for review and advice";
(xi) Mr Gavrilovic's evidence that the Medical Committee did not confine itself to matters of regulation of drugs of addiction.

303 Ms Burke further contended that "'Reasonable grounds' also includes taking into account the length of time that has elapsed since Mr Phillips' death; and considering the steps put in place by Dr Huang, so soon after Mr Phillips' death, to alter his practice and the manner in which he treats and manages patients."

304 In addition, on 19 April 2024, Dr Huang's legal representatives made a further written submission confirming that Dr Huang had moved from the ACT to NSW and was currently practicing as an addiction medicine specialist in the public system in NSW. It was also submitted that the professional referral of Dr Huang "so late after the management and prescribing in issue (almost 10 years), and so long after the completion of evidence and submissions, is not and would not be demonstrative of procedural fairness".

305 Ms Burke also submitted that her client was not placed on notice prior to the commencement of the inquest that there was a possibility that a copy of the transcript of his evidence could be the subject of a referral pursuant to section 151A(2) of the *National Law*. In that regard, it was submitted that he had been denied procedural fairness.

306 I turn then to deal with Ms Burke's submissions that her client would be denied procedural fairness if he was referred to the Medical Council, specifically regarding the lapse of time and the lack of notice prior to the commencement of these proceedings that he was at risk of being referred to the Medical Council.

307 In relation to the first issue, being the lapse of time and the self-imposed changes to the nature of his practice, it would appear that these issues fall within the ambit of subjective factors, most properly required to be determined after a referral to the Medical Council.

308 In relation to the second issue, it is noted that Dr Huang received legal advice from an early stage and was represented during these proceedings. It is clear that the State Coroner hearing the inquest, determined that pursuant to section 57 of the *Coroners Act 2009*, Dr Huang had a "sufficient interest in the subject-matter of the proceedings, to appear in person in the proceedings or to be represented by an Australian legal practitioner." In addition, it should be noted that the expert opinions provided in formal reports prior to the commencement of proceedings clearly indicated the likelihood that Dr Huang would be criticised professionally. It is not unusual, in those circumstances, that Dr Huang may be considered for referral to the Medical Council.

309 I am not of the view that either issue raised on behalf of Dr Huang amounts to a denial of procedural fairness.

310 I did not have the opportunity to assess Dr Huang whilst he gave his evidence before the Court on 19 February 2020. Senior Counsel Assisting noted that "[t]here can be no doubt about the compassion with which each doctor approached Mr Phillips as a patient, nor any doubt that each doctor wanted to help Mr Phillips manage his significant pain and other physical and other psychological challenges."

311 It is accepted that Dr Huang made various concessions, both in his statements admitted into evidence in these proceedings; as well as in his oral evidence.

312 There does not appear to be any dissent from the assertion that Dr Huang made appropriate concessions relating to his treatment and conduct. It is conceded by Ms Burke that his "prescription dose of Physeptone was too high, the rate of its induction was too fast and there was, a lack of review and supervision during induction." Additionally, there were clearly significant shortcomings in terms of the joint management and collaborative oversight of Mr Phillips in October 2014 by both Dr Huang and Dr Huber.

313 The matters raised by Ms Burke in relation to the "reasonable grounds" for a referral can be broadly categorised as subjective matters. Their relevance does not relate to the commencement phase provided by section 151A, but rather to considerations which the Medical Council or the Health Care Complaints Commission ("HCCC") may have pursuant to section 145B.

314 Section 145B of the *National Law* identifies the various courses of action available to the Council upon receipt of a complaint, including:

a) make any inquiries about the complaint the Council thinks appropriate;
b) refer the complaint to the HCCC for investigation;
c) refer the complaint to a Professional Standards Committee or the Civil and Administrative Tribunal;
d) direct a health practitioner to attend counselling; and
e) determine that no further action should be taken in respect of the complaint.

315 In Dr Huang's case there has been a significant lapse of time since Mr Phillips' death, together with Dr Huang's written and oral concessions of his shortcomings and his voluntary relinquishing of his GP's registration in 2016.

316 It is not for this jurisdiction to consider the appropriateness of any possible civil penalty which may be imposed if a medical practitioner was referred pursuant to the legislation, however, it is noted that, if there has been no further professional transgression in circumstances where there has been such a significant elapse of time, the imperative for professional condemnation and correction may be lessened.

317 Taking into consideration the circumstances relating to Dr Huang's professional involvement in Mr Phillips' care and treatment, I intend to refer his conduct to the HCCC and the Medical Council of NSW, pursuant to section 151A of the *National Law*.

Submissions on behalf of Dr Huber

318 On behalf of Dr Huber, it was submitted that "the requisite evidentiary foundation and standard of proof is not met for a number of serious findings ... urged against Dr Huber."

319 Firstly, it was contended that it was Dr Huang's responsibility to implement a joint case management plan and ensure that Dr Huber was informed of their joint treatment of this complex case. It was submitted that Dr Wilson's evidence supported the contention that Dr Huber's involvement should not be the subject of criticism, as Dr Wilson stated, "It would be unusual for GPs who don't have experience with methadone to know about its side effects." Dr Wilson, however, did also note that, "it is our responsibility as prescribers to be aware of the issues around the medicines we do prescribe. And so if there is – if you know that a patient on a medicine, you're thinking of prescribing another one and you don't have expertise or great understanding, then you do need to check whether it is – whether there are interactions before you prescribe."

320 Contrary to the submission, the evidence, particularly that provided by Dr Wilson, suggests that Dr Huber also had an implicit responsibility to access information which would assist in determining if any medicine should be prescribed by a GP.

321 Secondly, it was submitted that when the "emergency response" presented itself after Mr Phillips complained that he was "completely gone", Dr Huber provided Mr Phillips with advice on dosage and contacting the pharmacy to alter the collection regime. It is again accepted that Dr Huang had a primary role in the administration of the Physeptone, however, it is clear that Dr Huber was criticised for his involvement by Dr Wilson when she stated:

> "The medication was being managed by another doctor, a medication that Dr Huber did not know ... it would have been better for him to leave it to Dr Huang – get in contact with Dr Huang ... and seek advice. [T]he reality for us in general practice is if you don't have experience with managing methadone ... you may not realise the importance of supervised dosing or ... staged supply in that program. ... Many GPs are not aware of ... those provisions".

That criticism appears justified in these circumstances.

322 Thirdly, it was submitted that Dr Huber prescribed Motilium on the advice of Dr Tattersall, a gastroenterologist. In his evidence, Dr Huber conceded that he was unaware at the time that this drug could cause or lead to QT prolongation. He admitted that he similarly did not know the possibility that the drug Ciproxin (Ciprofloxacin) could also have the same effect in relation to the QT prolongation. He similarly conceded that he should not have prescribed Stilnox to Mr Phillips on 21 October 2014. He indicated that he was aware that Stilnox could increase the risk of respiratory depression. He was also aware that Mr Phillips was at risk on methadone by reason of his severe sleep apnoea, however, was reassured when Mr Phillips presented with a CPAP mask.

323 It is accepted that Dr Huber's care and treatment of Mr Phillips prior to the introduction of Physeptone was generally appropriate. On Dr Huber's behalf, and "in light of the expert evidence and the concessions made by both Dr Huber and Dr Huang during the hearing", it was accepted that "the overall management of Mr Phillips was poorly coordinated, with neither being fully aware of the possible side effects and interactions of the medications they were prescribing him".

324 Again, the Court is significantly concerned by Dr Huber's conduct, care and treatment of Mr Phillips in October 2014. Dr Huber seeks to excuse his shortcomings and failures by sheeting many of the medical decision-making and management responsibilities onto Dr Huang.

325 It is noted that Dr Huber has not been registered as a GP for a number of years. It is further noted the number of years that have elapsed since Dr Huber's inappropriate management of Mr Phillips in 2014. These are subjective matters which no doubt will be considered by his professional regulatory body.

326 I intend to refer Dr Huber's conduct to the HCCC and the Medical Council of NSW pursuant to section 151A of the *National Law*.

The Pharmaceutical Services Unit/Pharmaceutical Regulatory Unit

Submissions on behalf of the Ministry of Health

327 In response to Senior Counsel Assisting's assertion that the doses of Physeptone prescribed by Dr Huang to Mr Phillips were "too large, the induction regime too rapid and the supervision deficient" the Ministry contended that:

> "the dosage rate, induction regime and supervision requirements are all clinical matters outside the purview of Senior Pharmaceutical Officers within the Pharmaceutical Regulatory Unit. Unlike treating physicians, it is not the role of a regulatory pharmacist to make clinical decisions about patient management (leaving aside the limits of their statutory function, as a matter of practice it is observed those officers do not have access to the patient for the purpose of clinical review, do not have access to all relevant clinical records and history and are not medical officers charged with clinical responsibility for the patient)."

328 The Ministry noted Dr Huang's understanding of the function of the PSU in 2014, however submitted that the decision to prescribe Physeptone to Mr Phillips in 2014 and the reasonableness of that decision were matters for peer medical review and was "a clinical matter which ought to be within the knowledge of prescribing medical officers".

329 The Ministry noted that the Physeptone was being prescribed for pain relief by a physician specialising in pain management and as such, was not a "red flag" from a regulatory point of view.

330 The Ministry submitted that:

> "To avoid any possible inference that regulatory authority may equate to clinical endorsement, the Ministry observes that from September 2017, every authority issued is endorsed with a condition which expressly states that the granting of such authority 'is not an indication that the treatment is clinically appropriate or necessary', 'is not an endorsement or support of this treatment by the Ministry of Health' and/or 'is not an endorsement or support of this treatment by the Ministry of Health'."

331 The Ministry maintained that the "issuance of the authority to prescribe Physeptone in 2014 was in accordance with its responsibilities, objectives, functions and policies and that such authority would be issued today, subject to a condition emphasising that the authority itself was not an endorsement of treatment by the prescribing practitioner".

332 The Ministry contended that Senior Counsel Assisting's "one paragraph analysis is perfunctory and could inadvertently be read to conflate the power delegated to a Senior Pharmaceutical Officer in the Pharmaceutical Services Unit with the functions of the Medical Committee. The Ministry makes clear that the Pharmaceutical Regulatory Unit is not and its officers are not a source of clinical review of treatment decisions made by specialist or other medical officers." Indeed, the Ministry stated that, "The clinical decision to prescribe drugs of addiction to a particular patient is matter (sic) for the professional judgment of the authorised clinician. If there is a clinical concern arising from the fact that a drug of addiction was prescribed to a particular patient, this is a matter for the relevant health professional council to review."

333 The Ministry noted that Senior Counsel Assisting explored the areas of the use of the terms complex comorbidities, tolerance to opioids and the calculation of the oMEDD, however maintained that none of these would have resulted in Dr Huang's application being referred to the Medical Committee.

334 The Ministry submitted that "care should be taken to avoid conflating the delegated regulatory power of a Senior Pharmaceutical Officer with the statutory function of the Medical Committee to provide advice to the Secretary." In that regard, the Ministry noted that the "Medical Committee is not part of the Pharmaceutical Regulatory Unit and it does not approve or decline applications".

335 In that regard, and taking into account section 30(4) of the *P&TG Act*, the Ministry submitted that:

> "the role of the Medical Committee is to consider any application referred to it and prepare a report containing a recommendation as to whether approval should be given and any conditions that ought attach to such approval. Once that report is to hand, pursuant to section 29(4) of the [*P&TG Act*], the officers within the Pharmaceutical Regulatory Unit are obliged to take any recommendation made by the Medical Committee into account in their subsequent exercise of delegated power to approve (or otherwise) such an application."

336 The Ministry submitted that the revised application for authority to prescribe refers to information that the "Medical Committee is likely to require" before

> "providing advice to the Secretary (or her delegate) on that novel application. It is efficient that this information be provided with the initial application. However, that doesn't elevate the delegated regulatory power of a Senior Pharmaceutical Officer to one of a clinical review as mooted by Senior Counsel Assisting."

337 In relation to the situation where a number of practitioners annually are not aware that the PRU exists at all or that there was a requirement to apply for an authority to prescribe certain drugs, the Ministry submitted that the number is about 90 practitioners per year and that it is not a "'far reaching problem' or involving a 'significant number of practitioners', though acknowledges that the extent of the issue is difficult to estimate".

338 In addition, the Ministry stated that if Dr Huang's 2014 application was received today, it would have been granted with the addition of Condition 1311. It is noted that the current oMEDD is 400mg, which would still be in excess of Dr Huang's prescription of 50mg per day, that is an oMEDD of 250mg.

Determination

Issue 1: The Cause of Mr Phillips' Death

339 There does not appear to be any dispute between the parties that the cause of Mr Phillips' death was cardiac arrhythmia triggered by the combined effects of coronary artery atherosclerotic disease, sleep apnoea and methadone.

340 The legal representatives for Dr Huber submitted that the Court could not be satisfied to the *Briginshaw* standard, that the type of arrhythmia involved was probably Pointes de Torsades, as identified by Professor Whyte in his written and oral evidence. The basis for the submission was that a Pointes de Torsades arrhythmia cannot be detected post-mortem. It is noted, however, that no cardiac arrhythmia is capable of being detected post-mortem. It is noted that all the experts agreed that the probable cause was an arrhythmia, with the exception of Dr Hallinan.

341 Given that stated level of satisfaction presented by all but one of the experts, the Court can have a reasonable satisfaction with respect to the involvement of

a cardiac arrhythmia. It is further noted that at the time Professor Whyte gave his oral evidence, he was the Director of the Department of Clinical Toxicology and Pharmacology at the Calvary Mater Hospital, NSW and had a significant level of clinical practice as described in his evidence. His expertise in that regard was not challenged, although his conclusion relating to the presence of a cardiac arrhythmia and the type of arrhythmia was disputed by Dr Hallinan.

Issues 2(a)–(f): The Manner of Mr Phillips' Death

342 Mr Phillips experienced a lengthy history of physical pain resulting from multiple sporting injuries and associated medical surgeries. These left Mr Phillips with persistent and ongoing pain, which had been treated with opiate medication for a number of years.

343 Mr Phillips was engaged with his medical treatment and was motivated to wean himself off opiate medications and to remain pain free.

344 Mr Phillips was a co-operative patient. Both Dr Huber and Dr Huang expressed their admiration for his efforts.

345 Dr Huber and Dr Huang had provided appropriate and adequate care and treatment to Mr Phillips up until October 2014, when Mr Phillips was commenced on the oral prescription, Physeptone.

346 Mr Phillips should have been an admitted as an inpatient to manage his significant comorbidities when he was commenced on Physeptone in October 2014.

347 Dr Huber submitted that he conducted adequate investigations and made appropriate referrals in respect of the joint management of Mr Phillips during the October 2014 period.

348 There are three areas where Dr Huber's management of Mr Phillips was significantly lacking during that period. The three areas relate to when Dr Huber prescribed Physeptone on 21 October 2014, without consulting with Dr Huang; his involvement in altering the collection regime on 15 October 2014 and his prescription of Domperidone and Stilnox.

349 Dr Huang accepted that "the prescription dose of Physeptone was too high, the rate of its induction was too fast and there was, a lack of review and supervision during induction."

350 In addition, there appears to have been no supervision of Mr Phillips by Dr Huang after he was commenced on Physeptone.

Issues 2(g) and (h): The Pharmaceutical Services Unit /Pharmaceutical Regulatory Unit

351 In October 2014, Dr Huang received the PSU's authority to prescribe a prescription of Physeptone to Mr Phillips where the daily dose was too high

and the induction to the medication was too rapid and where Dr Huang stated that he expected to receive guidance from the PSU.

352 Dr Huang's assertion during his evidence that he perceived that the PSU had some type of clinical approval or oversight role, led to a review of the role of the PSU at the time of the authorisation to prescribe in October 2014, as well as the current role of the PRU, in these proceedings.

353 As discussed above, the Ministry drew attention to/referred to the regulatory function of the PRU/PSU as being to "protect the integrity of the supply chain of drugs of addiction and to minimise the risk of diversion and abuse." In that regard, the Ministry submitted that the "responsibilities, objectives, functions" of a SPO, referred to in Issue 2(g), "must be derived from the words of the instrument that gives power to that officer to perform that specific regulatory function". It is accepted that this is an appropriate interpretation of the statutory purpose of Part 4, Division 2 of the *P&TG Act*. The evidence that was adduced in these proceedings, however, was capable of suggesting that the activity of the PSU and the Medical Committee may not have always had a strict regulatory purpose.

354 In relation to Dr Huang's assertion referred to at [349] above, it is noted that in September 2017, Condition 1311 was inserted into every authority granted, to advise medical practitioners that a PRU decision is not an endorsement or support for the proposed clinical treatment of a patient. It would seem that there is an available inference that there was some concern or possibility that practitioners may have perceived, albeit incorrectly, that the PRU was providing some type of oversight of clinical decisions.

355 It is accepted that the role of the Medical Committee is to consider an application referred to it and to furnish a report containing a recommendation as to whether approval should be given and any conditions that ought to attach to such an approval. It is not the role of the Medical Committee to approve or decline any applications for an authority to prescribe drugs of addiction.

356 In 2013, the "*Medical Committee – August 2013*" document stated that its purpose was "To provide clarity and transparency for medical practitioners on the process of authorisation to prescribe opioids for chronic pain conditions when required by Section 28 of the P&TG Act." This stated purpose, when considered in conjunction with the evidence of Mr Gavrilovic that 80 to 90 practitioners per annum were believed to have issued prescriptions without the appropriate authority (see at [279] above), reflects that there was a need to provide clarity and transparency on the issuance of authorities. However, the document did not comment on the role of PSU officers and that their role is regulatory only, nor did it inform practitioners that the issuing of an authority is not an endorsement of treatment.

357 It is noted that pursuant to section 30AA(2) of the *P&TG Act*, the Medical Committee is empowered to obtain medical information in respect of an approval or authority referred to it by the Secretary and one where the review of the approval or authority is with respect to a possible contravention of the *P&TG Act*.

358 The current application form does not seek to obtain this information from the bodies referred to in section 30AA(2) of the *P&TG Act*, but rather from the doctor applicant at the initial stage of applying for an authority to prescribe. The current form appears to seek further information or medical reports for the purpose of referring this information to the Medical Committee, prior to a referral being made to the Medical Committee. Mr Gavrilovic outlined, in his evidence, that the Medical Committee asked for this information to be provided to them in their consideration of a referral. As such, it may be perceived that the manner in which the information is being sought is not in keeping with the statutory function and purpose of the Medical Committee pursuant to the legislation. The Ministry submitted that, "It is efficient that this information be provided with the initial application". Whilst it is accepted that this may be "efficient" for both the PRU and the Medical Committee to have this information provided by the applicant doctor, it is not an exercise of its regulatory function pursuant to the relevant legislation.

359 In addition, it would appear that question 12 on the current form, being a "prompt" about clinical matters, is not strictly exercising a regulatory function with respect to the integrity of the supply chain of restricted drugs to minimise the risk of diversion and abuse.

360 It is concerning that despite the number of years since Mr Phillips' death, there still appear to be a number of practitioners who are unaware of the existence of the PSU and Medical Committee; as well as the need to apply for an authorisation to prescribe drugs of addiction.

The need for recommendations

361 Section 82 of the *Coroners Act 2009* (NSW), permits a Coroner to make recommendations which are necessary or desirable in relation to the death of a person the subject of an inquest.

362 Senior Counsel Assisting has suggested that the Court consider making two recommendations directed to the Ministry arising from the evidence.

First proposed recommendation

363 Senior Counsel Assisting's first proposed recommendation is that:

a. In respect of the PRU and the Medical Committee, it is appropriate that the requirements for applications for authority to prescribe Physeptone be examined, particularly with regard to the threshold of 400mg as the oMEDD to be reached before an application is escalated. Additionally, examine the appropriate information that should be sought from the prescriber about the patient's level of tolerance for Physeptone when applying for authority to prescribe.

364 The Ministry submitted that it does not support this recommendation. The Ministry contended that experts have been consulted on the most appropriate conversion factor and that those experts have indicated that a conversion factor of three, rather than the current factor of five, is scientifically acceptable. The Ministry highlighted that "applications for Schedule 8 opioids at doses

lower than 400mg oMEDD (including Physeptone) are presently referred to the Medical Council where it is found that the application varies from therapeutic standards." The Ministry did not seek to provide its view in relation to the second part of the recommendation, relating to seeking appropriate information indicating the patient's level of tolerance when applying for an authority to prescribe.

365 It is noted that the recommendation is confined to Physeptone, due to its complex and variable pharmacokinetic nature. It was noted by Senior Counsel Assisting that, "The recommendation proposed is not to consider a reduction in the parameters for escalation or referral to some value less than 400mg ..., nor that it be reviewed ... only that the PRU's criterion for escalation and referral in relation to Physeptone be examined."

366 In determining whether it is appropriate to make the recommendation as proposed by Ms Whalan SC and opposed by the Ministry, the following relevant evidentiary matters have been taken into consideration. Those matters include:

- There is no standard guideline for the calculation for oMEDD conversion for Physeptone.
- Methadone has a complex and variable pharmacokinetic nature.
- The ANZCA website, which stipulates that "Methadone [and other drugs stated] are not included in this table due to their complex and variable pharmacokinetics" (see at [283] above).
- Ms Zelingia's evidence that she was aware in 2014 of the difficulties associated with measuring the oMEDD, which was "due to the complex pharmacokinetic nature of the medicine and the very individual effect it has on the person" (see at [253] above).
- Dr Gavrilovic's evidence that "experts in the field" were consulted by the Ministry on the conversion ratio (see at [286] above).
- Dr Ho's reference, in his report, to guidelines suggesting a conversion ratio of 5:1 to 8:1 for Physeptone (Tab 26, p. 4).
- Dr Hallinan's statement, in his report, that: "the calculation of (any opioid conversion) methadone dose based on opioid equivalence is inherently flawed, and for this reason methadone is seldom included in such conversion tables" (Tab 29A, p. 7).

367 Considering the abovementioned relevant evidentiary matters, I have determined that the proposed recommendation is both necessary and desirable to ensure the protection of the health and safety of the public.

Second proposed recommendation

368 The second recommendation proposed by Senior Counsel Assisting is:

b. The Ministry consider what steps should be taken to educate doctors about the existence and the role of the PRU and the Medical Committee, with respect to granting authorities to doctors to prescribe S8 drugs including Physeptone.

369 It was submitted on behalf of the Ministry that this recommendation was unnecessary. The Ministry advised that there are "three major projects ... now

being advanced in relation to authorisation of controlled drugs in NSW." The three projects are "a new legislative regime to replace the existing [*P&TG Act*]", a "project to develop an enhanced Authority Management System, which will provide for online processing of authorisations", and "SafeScript NSW" which will provide for real-time prescription monitoring in NSW.

370 The Ministry submitted that "there is limited value in rolling out an education programme before these programmes are completed (and indeed, it may cause confusion to medical practitioners to deliver an education programme on the current legislation when such legislation is intended to be repealed in the near future)."

371 On 29 January 2024, I instructed those assisting me to write to the Ministry requesting further information on the following matters:

a. the status of the first project outlined in the submissions of the Ministry, the proposed legislative reform to replace the existing *P&TG Act*; and
b. whether the PSU maintains the view submitted that there is limited value in rolling out an education programme ahead of the identified projects and whether any further steps have been taken since the Ministry's submissions to educate doctors (collectively, not individually) about the existence of the PSU and the Medical Committee with respect to granting authorities to doctors to prescribe drugs of addiction including Physeptone.

372 In response, the Ministry provided a letter dated 16 February 2024 from Monique Reyes, Principal Project Office for the Review of the Poisons and Therapeutic Goods Act and Regulation of the (PSU) (formerly the PRU) of the Ministry.

373 In relation to the first request, Ms Reyes advised that the *Medicines, Poisons and Therapeutic Goods Act 2022* ("*MPTGA*") was passed by Parliament in November 2022, to commence on proclamation. An exposure draft of the *Medicines, Poisons and Therapeutic Goods Regulation 2023* ("*MPTGR*") was published for consultation from September to December 2023. Ms Reyes stated that it is anticipated that the *MPTGA* and the *MPTGR* will commence in 2025, subject to approvals.

374 In relation to the second request, Ms Reyes stated that it is "not within the remit of PSU to provide educational programmes for the professions, and specifically not education on clinical practice matters". Nevertheless, Ms Reyes noted that the introduction of education and training accompanied the introduction of SafeScript NSW, and that a further program will also be conducted as part of the project to implement new functions in SafeScript NSW. While the main focus of this program will be to education prescribers about how to use the tool, the program will also enhance general awareness of the PSU and the need to apply for authority to prescribe and supply drugs of addiction where required under the *P&TG Act*

375 Ms Reyes also stated that "[t]here are continuing educational initiatives on regulatory compliance planned to be undertaken with the continuing rollout of SafeScript NSW as well as the implementation of the new *MPTGA* and *MPTGR*", including the recent recruitment of two Communications and

Awareness officers by the PRU. Part of the work being undertaken by those officers is focused on ensuring that "effective communication strategies are deployed ahead of the *MPTGA* and *MPTGR*".

376 Further, as had been previously submitted by the Ministry, Ms Reyes concluded:

> "Respectfully, it would not promote public health and safety by diverting those efforts to design, devise and roll out education strategies for an old legislative scheme. Indeed, that may well serve to confuse the intended audience and undermine efforts to effectively promote communication of the new regime."

377 It is noted that no legislative change has been proclaimed to date, some 2.5 years after this inquest was conducted and the proposed legislative change is not anticipated to be proclaimed until 2025.

378 It is accepted that the proposed legislation, referred to as the *MPTGA,* will provide a distinctly different framework to the current Act. Ms Reyes stated that the proposed recommendation "would not promote public health and safety by diverting those efforts to design, devise and roll out education strategies for an old legislative scheme."

379 Ms Reyes also noted that "While the main focus of this program will be to educate prescribers about how to use the tool, the program will also enhance general awareness of the PSU and the need to apply for authority to prescribe and supply drugs of addiction where required under the P&TG Act." It would appear from this statement that there is an ongoing need and an imperative to provide education about the need to apply for an authority to prescribe and supply drugs of addiction where required under the *P&TG Act.*

380 Further, medical practitioners are more than competent to receive educational direction on a number of matters relating to their legislative obligations.

381 The relevant evidentiary matters which have been highlighted in this inquest suggests that a recommendation is both necessary and desirable to ensure the protection of the health and safety of the public.

382 The second recommendation is:

b. The Ministry consider what steps should be taken to educate doctors about the existence and the role of the PRU with respect to applying for an authority to prescribe and supply drugs of addiction where required under the *P&TG Act.*

Concluding remarks

383 Mr Philips was hopeful that his forthcoming surgery would improve his mobility and reduce his chronic pain. In that regard, he was also prepared to undertake a course of Physeptone to assist with his pain prior to surgery, as well as assist in his attempts to wean himself off opioids. He attended as directed and co-operated at every stage with medical referrals and treatment.

384 Unfortunately, Mr Phillips should not have been prescribed Physeptone without being admitted as an inpatient to monitor his tolerance and his comorbidities.

385 I would like to record my gratitude to Senior Counsel Assisting, Ms Lesley Whalan SC, and her instructing solicitors, Mr Paul Armstrong and Ms Caitlin Healey-Nash, for their assistance with this complex case.

386 I would like to acknowledge and thank the Officer in Charge, Sergeant Evan Facey, for his investigation of this case.

387 Finally, I would like to again record my most sincere condolences to Mr Phillips' family, particularly his sister, Ms Phillips.

Findings

388 The findings I make pursuant to section 81(1) of the *Coroners Act 2009* (NSW) are:

Identity
The person who died was Linus Fred Phillips

Date of Death
Mr Phillips died on 24 October 2014

Place of Death
Mr Phillips died at 97/6 Stanley Street, Darlinghurst

Cause of Death
Mr Phillips died as a result of cardiac arrhythmia, probably Torsades de Pointes, due to the combined effects of coronary artery atherosclerotic disease, sleep apnoea, methadone and other drugs which had a QT prolonging effect.

Manner of Death
The medical prescription of Physeptone tablets which were lawfully prescribed to him, but in dosages which were too large, the induction rate too rapid and inadequate medical supervision.

Recommendations

To the NSW Ministry of Health

1. In respect of the Pharmaceutical Regulatory Unit and the Medical Committee, it is appropriate that the requirements for applications for authority to prescribe Physeptone be examined, particularly with regard to the threshold of 400mg as the oral morphine equivalent daily dose ('oMEDD') to be reached before an application is escalated. Additionally, consideration should be given to

examining the appropriate information that should be sought from the prescriber about the patient's level of tolerance for Physeptone when applying for authority to prescribe.

2. The NSW Ministry of Health consider what steps should be taken to educate doctors about the existence and the role of the Pharmaceutical Regulatory Unit, with respect to applying for an authority to prescribe and supply drugs of addiction where required under the *Poisons and Therapeutic Goods Act 1966*.

Referrals

1. Pursuant to s. 151A(2) of the *Health Practitioner Regulation National Law* (NSW) a copy of the transcript of the evidence from the Inquest is to be sent to the Health Care Complaints Commission and the Medical Council of NSW along with a request that the management of Mr Linus Phillips by Dr William Huang in October 2014 be examined.

2. Pursuant to s. 151A(2) of the *Health Practitioner Regulation National Law* (NSW) a copy of the transcript of the evidence from the Inquest is to be sent to the Health Care Complaints Commission and the Medical Council of NSW along with a request that the management of Mr Linus Phillips by Dr Michael Huber in October 2014 be examined.

389 I close this inquest.

Magistrate Joan Baptie
Deputy State Coroner

9 August 2024