IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

COR 2020 004482

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)

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

Findings of:	Coroner Simon McGregor
Deceased:	Sotirios Temopoulos
Date of birth:	17 December 1943
Date of death:	16 August 2020
Cause of death:	1(a) Chest sepsis in a man with ischaemic heart disease
Place of death:	Eastern Health, Wantirna Hospital, 251 Mountain Highway, Wantirna, Victoria, 3152
Keywords:	Box Hill Hospital, Quality Pharmacy, medication error, Webster pack, bronchopneumonia, COVID-19, Fred Dispense software.

INTRODUCTION

1. On 16 August 2020, Sotirios Temopoulos was 76 years old when he died at Box Hill Hospital (**BHH**) following an admission on 27 July 2020 with sepsis, pneumonia, and acute-on-chronic renal disease. At the time of his death, Sotirios lived at 3 Eley Road, Blackburn South, with his wife, Ekaterini.

2. Sotirios was born in Florina, Greece, and moved to Australia with Ekaterini in 1963. The couple bought a home in Hawthorn before eventually moving to Blackburn South where they remained until his death. Sotirios worked as a labourer before retiring in his early 50s.[1]

3. Sotirios' medical history included multiple myeloma with a myelomataus lesion in his cervical spine for which he had surgery in 2013, however he continued to suffer ongoing neuropathic pain and was prescribed a fentanyl patch and pregabalin.[2]

4. Sotirios was also diagnosed with a deep vein thrombosis, pulmonary embolism, meningitis, a stroke, liver steatosis, depression, pre-diabetes, metabolic syndrome, chronic renal impairment, and hypercholesteraemia.[3]

5. At the time of his death, Sotirios was prescribed colecalciferol, coloxyl with senna, oxycodone, escitalopram, atorvastatin, pantoprazole, aspirin, vaciclovir, lenalidomide, and Targin (oxycodone/naloxone).[4] Sotirios' and Ekaterini's medications were delivered by their local pharmacy, Quality Pharmacy, on a weekly basis in separate Webster packs.[5]

THE CORONIAL INVESTIGATION

6. Sotirios' death was reported to the Coroner as it fell within the definition of a reportable death in the *Coroners Act 2008* (the Act). Reportable deaths include deaths that are unexpected, unnatural or violent or result from accident or injury.

7. The role of a coroner is to independently investigate reportable deaths to establish, if possible, identity, medical cause of death, and surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. The

[1] Coronial brief, statement of Jim Temopoulos dated 22 September 2020, pages 23-25.
[2] Coronial brief, statement of Dr Shirley Tang dated 10 October 2020, page 44.
[3] Coronial brief, statement of Dr Shirley Tang dated 10 October 2020, pages 44-45.
[4] Coronial brief, statement of Dr Shirley Tang dated 10 October 2020, pages 44-45.
[5] Coronial brief, statement of Ekaterini Temopoulos dated 10 September 2020, page 36.

purpose of a coronial investigation is to establish the facts, not to cast blame or determine criminal or civil liability.

8. Under the Act, coroners also have the important functions of helping to prevent deaths and promoting public health and safety and the administration of justice through the making of comments or recommendations in appropriate cases about any matter connected to the death under investigation.

9. Victoria Police assigned an officer to be the Coroner's Investigator for the investigation of Sotirios's death. The Coroner's Investigator conducted inquiries on my behalf, including taking statements from witnesses – such as family, the forensic pathologist, treating clinicians and investigating officers – and submitted a coronial brief of evidence.

10. This finding draws on the totality of the coronial investigation into the death of Sotirios Temopoulos including evidence contained in the coronial brief. Whilst I have reviewed all the material, I will only refer to that which is directly relevant to my findings or necessary for narrative clarity. In the coronial jurisdiction, facts must be established on the balance of probabilities.[6]

11. In considering the issues associated with this finding, I have been mindful of Sotirios' basic human rights to dignity and wellbeing, as espoused in the *Charter of Human Rights and Responsibilities Act 2006*, in particular sections 8, 9 and 10.

MATTERS IN RELATION TO WHICH A FINDING MUST, IF POSSIBLE, BE MADE

Circumstances in which the death occurred

First presentation to Box Hill Hospital Emergency Department

12. In 2020, Sotirios was commenced on lenalidomide, a chemotherapy medication, for his multiple myeloma which he would have infused at BHH once a month. On 20 July 2020, Sotirios was unable to attend his oncology appointment at BHH due to increasing back pain and kidney pain following a fall from his bed one week prior.[7]

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

[7] Coronial brief, statement of Jim Temopoulos dated 22 September 2020, pages 26-27; statement of Dr Eugene Teh dated 21 September 2020, page 78.

13. After liaising with Sotirios' haematologist, his son, Jim Temopoulos, took Sotirios to the BHH emergency department (**ED**) where he was diagnosed with a new compression fracture of his lumbar spine, as well as old compression lumbar fractures. These were treated conservatively over following four days.[8]

14. On 24 July 2020, Sotirios was discharged. Jim attended BHH but was not allowed to attend the ward due to the ongoing COVID-19 restrictions. Jim stated that he was informed that Sotirios' medications were going to be sent to his local pharmacy, Quality Pharmacy.[9]

15. Shalini Ratnayake, pharmacist at BHH, stated that she received the discharge prescriptions for Sotirios which she reconciled against his 'Best Possible Medication History' which had been completed by the ED pharmacist on his arrival to BHH. Following a review of Sotirios' medications (which included any changes to regular medications that had occurred during his hospital admission), it was identified that no medications would need to be supplied by the BHH pharmacy.[10]

16. Shalini stated that she then contacted Ekaterini and explained that there were no changes to Sotirios' Webster pack medications other than his Targin being changed from once daily to twice daily. Shalini also stated that she confirmed these instructions by requesting that Ekaterini repeat back to her the instructions. Given the minimal changes to Sotirios' medication regimen, it was decided that a medication list was not required.[11]

17. I note that Ekaterini stated that the BHH pharmacy called and informed her that Quality Pharmacy would deliver Sotirios' medications to their house but did not explain what the medication was, what it was for, or how many medications would be delivered.[12]

<u>Delivery of medications</u>

18. At approximately 11.00am, Eric Lau, Aged Care pharmacist at Quality Pharmacy, stated that Ekaterini called Quality Pharmacy with a query about her own medication. She rang again a few hours later and was placed on hold however it appears she ended the call before her query could be answered by the staff at Quality Pharmacy.[13]

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[8] Coronial brief, statement of Jim Temopoulos dated 22 September 2020, pages 26-27; statement of Dr Eugene Teh dated 21 September 2020, page 78.
[9] Coronial brief, statement of Jim Temopoulos dated 22 September 2020, pages 28-29.
[10] Coronial brief, statement of Shalini Ratnayake dated 29 September 2020, page 50.
[11] Coronial brief, statement of Shalini Ratnayake dated 29 September 2020, page 50.
[12] Coronial brief, statement of Ekaterini Temopoulos dated 10 November 2020, page 36.
[13] Coronial brief, statement of Hen (Eric) Lau dated 19 August 2020, pages 56-57.

19. Eric stated that he rang Ekaterini back that afternoon and spoke to her about her prescription which was to be faxed to the pharmacy by her general practitioner (**GP**). After being advised that Quality Pharmacy had not received the prescription yet, Ekaterini agreed to follow up with her GP.[14]

20. At approximately 5.00pm, Ekaterini received a delivery of three medications in a paper bag to her residence, however she stated that she did not recognise the medications and did not believe that they had been prescribed to Sotirios in the past.[15] She later spoke to Jim who confirmed the instructions he had been given at BHH for administering Sotirios' medications with her. Ekaterini then gave Sotirios his evening dose.[16]

Second presentation to BHH ED

21. On 25 July 2020, Jim checked in with Ekaterini who told her son that Sotirios was complaining of nausea and pain. She was concerned about his condition and wanted to call an ambulance, however Sotirios refused.[17] That evening, she gave Sotirios his evening medications, including the three new medications that had been delivered the previous day.[18]

22. On 27 July 2020, Sotirios and Jim attended a telehealth consult with his GP, Dr Shirley Tang. Jim explained to Dr Tang that Sotirios was in pain and had decreased oral intake. Dr Tang stated that she attributed these symptoms to his recent discharge and recovery and increased his Targin dose before scheduling a follow up appointment in four days' time.[19]

23. Late that evening, when Sotirios' condition did not improve, Jim contacted 000. Ambulance Victoria paramedics attended the address at 10.44pm and found Sotirios to have shortness of breath with low oxygen saturations and abdominal discomfort. Jim also explained that Sotirios had decreased urine output, nil bowel motions since his discharge, and had been vomiting. As Sotirios was being loaded into the ambulance, the paramedics discovered that the additional medications that had been delivered were prescribed in someone else's name.[20] [21]

[14] Coronial brief, statement of Hen (Eric) Lau dated 19 August 2020, pages 56-57.
[15] These medications were later confirmed to be valsartan, simvastatin, and lorazepam.
[16] Coronial brief, statement of Ekaterini Temopoulos dated 10 November 2020, page 37.
[17] Coronial brief, statement of Jim Temopoulos dated 22 September 2020, pages 29-30.
[18] Coronial brief, statement of Ekaterini Temopoulos dated 10 November 2020, page 37.
[19] Coronial brief, statement of Dr Shirley Tang dated 10 October 2020, pages 45-46.
[20] Coronial brief, statement of Tamara Kovess dated 3 September 2020, page 72.
[21] The medications were in the name of Pauline Spinosa-Cattela.

24. On arrival at the BHH ED, Sotirios was diagnosed with pneumonia, hypovolaemia, an acute-on-chronic renal injury, and delirium. He was admitted to the ICU where a consensus was reached with his family that Sotirios was not for invasive procedures such as intubation and cardiopulmonary resuscitation. He was commenced on inotropic support and renal replacement therapy however he was later diagnosed with a type II myocardial infarction which was treated with anticoagulant therapy.[22]

25. On 1 August 2020, Sotirios' condition stabilised, and he was moved to the general medical ward for ongoing management, however he had persistent delirium and impaired functional recovery due to his delirium and decreased oral intake despite multi-modal therapy, and, according to clinicians at BHH, his condition "followed a predictable course of clinical deterioration towards the end-of-life phase…against the backdrop of pre-existing comorbidities".[23]

26. On 12 August 2020, a decision was made in consultation with Sotirios' family to transfer him to palliative care. On 14 August 2020, Sotirios was transferred to the Palliative Care Unit at Wantirna Health.[24]

27. On 16 August 2020 at 7.20am, Sotorios passed away.[25]

Identity of the deceased

28. On 16 August 2020, Sotirios Temopoulos, born 17 December 1943, was visually identified by his son, Jim Temopoulos.

29. Identity is not in dispute and requires no further investigation.

Medical cause of death

30. Forensic Pathologist Dr Heinrich Bouwer from the Victorian Institute of Forensic Medicine (**VIFM**) conducted an autopsy on 19 August 2020 and provided a written report of his findings dated 6 April 2021.

[22] Coronial brief, statement of Dr Eugene Teh dated 21 September 2020, page 79.
[23] Coronial brief, statement of Dr Eugene Teh dated 21 September 2020, page 80.
[24] Coronial brief, statement of Jim Temopoulos dated 22 September 2020, page 33.
[25] Dr Amelia McLean, Wantirna Health Medical E-Deposition dated 16 August 2020, page 2.

31. The post-mortem examination revealed bilateral acute bronchopneumonia secondary to aspiration, subacute myocardial infarction in the mid left ventricular and septal walls, mild to moderate coronary artery atherosclerosis, marked nephron and diabetic glomerulosclerosis (Kimmelsteil-Wilson's disease), a patent foramen ovale, marked benign prostatic hyperplasia, trabeculated bladder, cholelithiasis, and bilateral healed rib fractures.

32. Toxicological analysis of post-mortem samples identified the presence of valsartan, citalopram, and metoclopramide.[26] The testing regime did not include analysis for simvastatin; however, this was unlikely to have caused any significant side effects.

33. Post-mortem biochemistry confirmed marked renal impairment and dehydration with elevated creatinine and urea levels. Glucose was not elevated. The inflammatory marker C-reactive protein and procalcitonin were elevated, in keeping with chest sepsis.

34. Dr Bouwer noted that the autopsy confirmed bilateral bronchial pneumonia with evidence of aspiration of stomach contents. There was a subacute myocardial infarct involving the anterior and posterior wall of the ventricle and septum, likely secondary to sustained hypotension in the setting of medication error and underlying sepsis.

35. Dr Bouwer provided an opinion that the medical cause of death was from 1 (a) chest sepsis in a man with ischaemic heart disease. Dr Bouwer opined that the death was from natural causes.

36. I accept Dr Bouwer's opinion.

CPU REVIEW

37. To assist with my investigation into Sotirios' death, I requested that the Coroners Prevention Unit (**CPU**) [27] review the circumstances surrounding Sotirios' passing, as well as the care he received.

[26] Some of these drugs are likely to have been administered during Sotirios' medical treatment at BHH.

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

38. The CPU considered evidence including evidence contained within the coronial brief, Sotiros' patient health summary from Blackburn South Medical Centre, a statement from Charles Khallouf, found and Chief Executive Office of Quality Pharmacy Group, and a statement from the Pharmaceutical Society of Australia (**PSA**).

Contributing factors

39. The CPU identified the following eight distinct possible contributing factors to Sotirios' death.

Medication changes

40. As noted above, the only prescribed changes to Sotirios' medications related to the frequency of his Targin dose. No new or additional medications were prescribed by BHH or his GP following his first presentation to BHH ED.

Discharge from BHH and discharge medications

41. The CPU noted that, when Jim arrived at BHH to collect his father, he was informed the medications were going to be dispensed by the hospital pharmacy. When Sotirios was transferred from the ward to reception for collection, he was transferred by a staff member and without any medication. When Jim enquired about the medication, a nurse attended and informed him the medication was to be sent ("faxed") to Quality Pharmacy.

Communication between BHH and Ekaterini

42. As noted above, Shalini Ratnayake contacted Ekaterini and communicated that Sotirios' Webster pack had not been changed, however the frequency of his Targin dose had been. The Targin was not in the Webster pack but in its original container. Ms Ratnayake stated that the information provided to Ekaterini using the "teach back method"[28], and an agreement was reached that due to the minimal change, a medication list wasn't required.

Communication between BHH and Quality Pharmacy

43. Ms Ratnayake did not recall communicating with Quality Pharmacy, however the managing pharmacist, Dr. Tam Vuong, stated that the BHH pharmacy contacted Quality Pharmacy and informed them that there were no changes to Sotirios' medications.

[28] Ekaterini was asked by Shalini to repeat back to her the instructions that she had provided to confirm that she understood.

Dispensing of medications

44. Quality Pharmacy's usual practice was for a technician to collect the medication and label it with the patient's label which included the name of the medication, the dosage, the patient's name, and medication instructions. The label also contains the initials of the dispensing technician and the pharmacist.

Labelling of medication bags

45. The CPU noted the possibility that, when Ekaterini called Quality Pharmacy on 24 July 2020, pharmacist Eric Lau may have searched her details on the pharmacy computer to allow him to call her back, inadvertently resulting in an address label being printed. It is likely that this label was affixed to a delivery bag and delivered to the Temopoulos' address by mistake.

The effects of the COVID-19 pandemic.

46. The CPU noted the statement from Mr Lau in which he stated that Quality Pharmacy has an "Aged Care Room" which looks after the "nursing home supplies", including sorting and dispensing Webster packs. These are stored within baskets allocated to each nursing home.

47. The CPU further noted that, on 24 July 2020, there were 39 baskets in the Aged Care Room however, due to the ongoing COVID-19 density requirements, staffing had been split into two separate shifts limited to approximately five people – half of the normal staffing levels present during pre-COVID operating hours.

<u>Statement response from Charles Khallouf, Founder and CEO of Quality Pharmacy Group</u>

48. In his statement to the court, Mr Khallouf detailed the Fred Dispense Software used by Quality Pharmacy. Mr Khallouf stated that, whilst the dispensing software does allow for multiple users on separate screens to view the same patient profile at the same time, only one user will be able to use the dispense function, with the other users being limited to a "viewing position" only. Mr Khallouf further clarified that since July 2020, there have bene software updates that prompt users to provide their initials to record terminal users.

49. Mr Khallouf stated that Quality Pharmacy's internal investigation had been unable to determine the circumstances in which the address label for Sotirios had been printed but clarified that there was no indication that the dispensing process itself had not been followed. He noted that the error appeared to have been caused by the incorrect delivery address label being affixed to the delivery bag.

50. When questioned as to whether there was a final check between the dispensed medication and the delivery bag label, Mr Khallouf stated that it was standard practice for the individual preparing the medication for delivery to check the labels to ensure that the correct medication had been placed in the bag, however this was not considered to be a separate final check.

51. Mr Khallouf stated that:

> The usual process was that after each private delivery medications were dispensed and labelled and checked by a pharmacist they would be immediately packaged and labelled for delivery. Accordingly, we did not consider that there was a significant risk of placing an address label for one patient on the package for another patient.

52. Mr Khallouf affirmed that, following the internal investigation in the wake of Sotirios' death, Quality Pharmacy explicitly requires that medication labels are checked against those affixed to the bag itself, in addition to previous checks, with signed confirmation required before packages are sealed and stored for delivery.

Summary

53. The CPU identified that, at the time of Sotirios' discharge, there appeared to have been several discussions regarding the faxing of medication requirements to Quality Pharmacy, however, given that there was only a slight change to his pre-existing Targin medication, no faxing was required. Following Ms Ratnayake's discussion with Ekaterini on the phone, it was believed by BHH that an understanding had been reached, however.

54. Due to the ongoing COVID-19 restrictions, Sotirios' family were not allowed on the ward therefore communication with the Temopoulos family was predominantly via telephone which may have contributed to the miscommunication surrounding the "fax".

55. As noted above, it is likely that when Ekaterini telephoned Quality Pharmacy on 24 July 2020, the Temopoulos' details appeared on the computer system. At an unknown time, an address label with Sotirios' address was printed and incorrectly affixed to a medication bag however, despite an intensive investigation, it has not been established how this occurred.

FINDINGS AND CONCLUSION

56. The standard of proof for coronial findings of fact is the civil standard of proof on the balance of probabilities, with the *Briginshaw* gloss or explications.[29] Adverse findings or comments against individuals in their professional capacity, or against institutions, are not to be made with the benefit of hindsight but only on the basis of what was known or should reasonably have been known or done at the time, and only where the evidence supports a finding that they departed materially from the standards of their profession and, in so doing, caused or contributed to the death under investigation.

57. Whilst my investigation in the circumstances surrounding Sotirios' tragic death has been unable to demonstrate exactly how the address label was incorrectly affixed to another person's medication bag, I note that Quality Pharmacy's internal review has taken appropriate remedial actions in the wake of this incident, including adding a separate and final check of medications to be delivered, which includes a pharmacist to check and sign a record confirming that the correct medications have been placed in the correct bag.

58. Pursuant to section 67(1) of the *Coroners Act 2008* I make the following findings:

    a) the identity of the deceased was Sotirios Temopoulos, born 17 December 1943;

    b) the death occurred on 16 August 2020 at Eastern Health, Wantirna Hospital, 251 Mountain Highway, Wantirna, Victoria, 3152, from *chest sepsis in a man with ischaemic heart disease*; and

    c) the death occurred in the circumstances described above.

[29] *Briginshaw v Briginshaw* (1938) 60 CLR 336 at 362-363: 'The seriousness of an allegation made, the inherent unlikelihood of an occurrence of a given description, or the gravity of the consequences flowing from a particular finding, are considerations which must affect the answer to the question whether the issues had been proved to the reasonable satisfaction of the tribunal. In such matters "reasonable satisfaction" should not be produced by inexact proofs, indefinite testimony, or indirect inferences…'.

RECOMMENDATIONS

59. Medication errors continue to be a common and significant issue in the health community, with discrepancies especially prevalent on admission and discharge. The World Health Organisation articulated the need to improve communication specifically during points of transition, noting that communication styles, distracting environments, and a lack of standardisation contribute to 80 per cent of medical errors resulting from transitional miscommunication.

60. In 2019, the PSA produced a report titled "Medicine Safety: Take Care"[30] which highlighted that medication-related problems account for up to 250,000 hospital admissions annually, with an additional 400,000 presentations to emergency departments likely due to medication-related issues. Furthermore, over 90 per cent of patients have at least one medication-related problem post-discharge from hospital.

61. The PSA has previously campaigned for the introduction of a national incident and near miss reporting mechanism for medication errors and other clinical incidents across the health system. This was a key recommendation to government from a consensus report of key health stakeholders who held a medicine safety forum in December 2019.

62. In support of this proposal, and in furtherance of my prevention role pursuant to section 72(2) of the Act, I make the following recommendation:

    I recommend that the Federal Health Minister conducts a feasibility study for the introduction of a national incident and near miss reporting mechanism for medication errors.

I convey my sincere condolences to Sotirios's family for their loss.

[30] Available at https://www.psa.org.au/wp-content/uploads/2019/01/PSA-Medicine-Safety-Report.pdf

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

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

Ekaterini Temopoulos, Senior Next of Kin

Safer Care Victoria

Yvette Kozielski, Eastern Health

Charles Khallouf, Quality Pharmacy

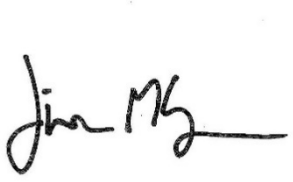
Pharmaceutical Society of Australia

Dr Shirley Tang, care of Rebecca Kovacs, Avant Law

The Honourable Mark Butler, Minister for Health and Aged Care

Detective Senior Constable Joanne Poynoton, Victoria Police, Coroner's Investigator

Signature:



CORONER SIMON McGREGOR

CORONER

Date: 3 November 2022

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