IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2015 0742

FINDING INTO DEATH WITH INQUEST

Form 37 Rule 60(1)
Section 67 of the Coroners Act 2008

Deceased:	**IAN JOHN GILBERT**
Delivered on:	14 June 2018
Delivered at:	Coroners Court of Victoria, 65 Kavanagh Street, Southbank
Hearing date:	15 November 2017 and 6 February 2018
Findings of:	Coroner Rosemary Carlin
Police Coronial Support Unit:	Leading Senior Constable Ross Treverton
Representation	Mr S Cash for Dr Lim Mr C Madder for Ms Barca Mr R Ajzensztat for the family of the deceased

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HER HONOUR:

INTRODUCTION

1. This case raises important issues about the relationship between prescribing doctor and dispensing pharmacist.

2. In January 2015, Ian John Gilbert was 77 years old, independent and living alone in Croydon. He had four daughters and one step-daughter and was close to his ex-wife. He was described as *'a remarkable man with a heart of gold'* who was cherished by family and friends.

3. On 29 January 2015, during a routine visit to a general practitioner (**GP**), Mr Gilbert was prescribed methotrexate to treat a flare-up of psoriasis, an uncomfortable but non-life-threatening skin condition. He was given no blood tests and it was prescribed as a daily dose.

4. Methotrexate is a potent chemotherapy drug sometimes used to treat severe recalcitrant psoriasis by way of a single weekly dose. Mr Gilbert had taken it once before, in about 2006, when it was prescribed by a dermatologist. Treatment of psoriasis with methotrexate should never be initiated by a GP and should never occur without first conducting blood tests to determine its safety.

5. The dispensing pharmacist immediately recognised that the daily dose prescribed by the GP was potentially dangerous and called him to convey her extreme concern. The GP assured her that he had checked the dose and it was correct. Though she was not at all reassured, the pharmacist felt obliged to dispense the medication in accordance with the prescription and did so.

6. Over the next few days, Mr Gilbert's health deteriorated as he began to experience serious symptoms of methotrexate toxicity. He was admitted to hospital on 4 February 2015 and died on 13 February 2015.

7. Mr Gilbert did suffer from a range of serious medical conditions, but his death from complications of methotrexate toxicity was needless and entirely preventable. If appropriate tests had been conducted by his GP they would have shown that his pre-existing medical conditions contraindicated the use of methotrexate at all, let alone at the dose prescribed.

8. I held an inquest to examine the circumstances surrounding the prescribing and dispensing of methotrexate to Mr Gilbert and whether those circumstances revealed any opportunities to prevent deaths from occurring in similar circumstances in the future. Of particular interest was whether pharmacists needed to be empowered in their dealings with medical practitioners, and if so, how to facilitate it.

CORONIAL INVESTIGATION

General purpose of a coronial investigation

9. Mr Gilbert's death was reported to the Coroners Court of Victoria on 13 February 2015. His death was unexpected and unnatural and, as such, clearly reportable under the *Coroners Act 2008* (Vic) (**the Act**).

10. Coroners independently investigate reportable deaths to find, if possible, identity, cause of death and, with some exceptions, surrounding circumstances.[1] Cause of death in this context is accepted to mean the medical cause or mechanism of death. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death.

11. 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 about any matter connected to the death under investigation.

12. When a coroner examines the circumstances in which a person died, this is not to lay blame or attribute legal or moral responsibility to any individual or institution. Rather, it is to determine causal factors, particularly any systemic failures, with a view to preventing, if possible, deaths from occurring in similar circumstances in the future. This prevention role assumes particular significance in this case because there is an inbuilt failsafe mechanism against unsafe prescribing by a doctor, namely the intervention of a pharmacist, but it failed. Further, the failure occurred, not because the error in prescribing was not detected (it was), but because the medication was dispensed despite the error.

13. Coroners do not determine guilt or negligence; these are the province of other jurisdictions. Indeed, the Act specifically prohibits coroners from making a finding or comment that a person has, or may have, committed an offence. A coroner should set out relevant facts, leaving others to draw their own conclusions from the facts.

14. Whilst it is sometimes necessary to examine whether particular conduct falls short of acceptable or normal standards, or was in breach of a recognised duty, this is only to ascertain whether it was a causal factor or a mere background circumstance. That is, an act or omission will not usually be regarded as contributing to death unless it involves a departure from reasonable standards of behaviour or a recognised duty. If that were not the case many perfectly innocuous

[1] Section 67 of the *Coroners Act 2008* (Vic) (**the Act**) requires a coroner investigating a reportable death to find, if possible: (a) the identity of the deceased; (b) the cause of death; and (c) the circumstances in which the death occurred unless an inquest was not held, the deceased was not in state care and there is no public interest in making findings as to circumstances.

preceding acts or omissions would be considered causative, even though, as a matter of common sense, in no way have they contributed to death.

15. When assessing the conduct of a professional person regard must be had to the prevailing standards of the particular profession or specialty. It is also important to allow for the effects of hindsight on the determination of whether a person acted appropriately.

16. The standard of proof applicable to findings in the coronial jurisdiction is the balance of probabilities with the *Briginshaw* qualification.[2] A finding that a person has caused or contributed to death should only be made after taking into account the possible damaging effect of such a finding upon the character and reputation of that person and only if the evidence provides a comfortable level of satisfaction as to the finding.

17. The *Briginshaw* qualification is of particular significance in this case as the professional conduct of a medical practitioner and a pharmacist is under scrutiny. Given the serious consequences for health professionals of an adverse finding or comment by a coroner, such comment or finding should not be made without clear and cogent evidence.[3]

History of this investigation

18. Mr Gilbert's daughters, Amanda and Kristy Gilbert, first raised concerns in relation to the prescription of methotrexate to their father in an email to the Court on 16 February 2015. During the course of my investigation I received a number of emails from Amanda and Kristy outlining their concerns with the prescribing of methotrexate and their father's subsequent hospital care.

19. I obtained relevant medical records for Mr Gilbert and received a coronial brief compiled by Detective Senior Constable Daniel Sullivan (the Coroner's Investigator). The brief comprised statements and correspondence from witnesses, including Kristy, police, treating medical practitioners and the dispensing pharmacist.

20. I reviewed Mr Gilbert's hospital care with the assistance of independent medical professionals from the Coroners Prevention Unit,[4] to whom I am grateful. I determined that the care by

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[2] *Briginshaw v Briginshaw* (1938) 60 CLR 336, especially 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...'.*

[3] *Anderson v Blashki* [1993] 2 VR 89 at 95 and *Secretary to the Department of Health and Community Services v Gurvich* [1995] 2 VR 69 at 74.

[4] The Coroners Prevention Unit is a specialist unit within the Coroners Court staffed by researchers and independent medical professionals, including emergency medicine physicians, with the function of assisting coroners in their investigative and prevention roles.

Eastern Health was reasonable and required no further investigation. On 30 June 2017, I held a mention hearing to discuss my preliminary views and the future course of my investigation. As a result of this hearing I decided to hold an inquest, which proceeded on 15 November 2017 and 6 February 2018.

21. At various stages during my investigation interested parties filed expert reports and submissions. Final submissions, after the inquest, were filed on 5 and 9 March 2018.

Focus of the coronial investigation and inquest

22. There were no issues in relation to Mr Gilbert's identity, the date and place of his death, nor the medical cause of his death. As usual, the primary focus of the coronial investigation and inquest into Mr Gilbert's death was the circumstances in which he died, specifically the factors that led to the inappropriate prescribing and dispensing of methotrexate and any prevention opportunities arising.

23. At inquest evidence was given by the following witnesses:

    (a) Kristy Gilbert;

    (b) Dr Stephen Lim, the GP who prescribed the methotrexate;

    (c) Ms Jennifer Barca, the pharmacist who dispensed it;

    (d) Ms Pamela Mathers, expert community pharmacist commissioned by Ms Barca;

    (e) Dr John Stanton, expert GP commissioned by Dr Lim; and

    (f) Dr Peter Hay, expert GP commissioned by the family.

24. Dr Lim and Ms Barca both gave evidence willingly when afforded the protection of a certificate under section 57 of the Act.[5]

Sources of evidence

25. This finding is based on the totality of the material gathered during my investigation into Mr Gilbert's death. This includes the Coronial Brief (version 5), the oral evidence of all witnesses who testified at inquest, any documents tendered at inquest, the final submissions of Counsel. It is unnecessary to summarise everything. It will remain on the Court file[6] and I will refer only to so much as is relevant or necessary for narrative clarity.

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[5] Under Section 57 of the Act evidence covered by a certificate and any information obtained directly or indirectly as a consequence of that evidence cannot be used against the witness in any proceeding except in respect of the falsity of the evidence.

[6] From the commencement of the *Coroners Act 2008* (the Act), that is 1 November 2009, access to documents held by the Coroners Court of Victoria is governed by section 115 of the Act.

METHOTREXATE AS A TREATMENT FOR PSORIASIS

Published resources

26. Information for consumers of methotrexate is available online, or at pharmacies, in the form of Consumer Medicine Information (**CMI**) leaflets. A number of other resources and pharmaceutical prescribing reference guides are available online, including manufacturer Product Information (**PI**) which is available on the Therapeutic Goods Administration (**TGA**) website and elsewhere, Monthly Index of Medical Specialties (**MIMS**), and Therapeutic Guidelines.[7] MIMS and the Therapeutic Guidelines require a subscription (commonly held by GP practices) but CMIs and the Product Information on the TGA website are accessible for free. GPs also frequently have access to the online and hardcopy subscription service, the Australian Medicines Handbook.

Consumer Medicine Information

27. The CMI published by the manufacturer of Methoblastin tablets, Pfizer Australia Pty Ltd (**Pfizer**), describes methotrexate as a chemotherapy medicine used to treat severe psoriasis and severe rheumatoid arthritis and some types of cancers. It explains that it works by blocking an enzyme needed by cells to live, thereby inhibiting the growth of some cells that are growing rapidly in psoriasis and cancer. It is also an immunosuppressant leading to less pain, swelling and joint damage in arthritis.

28. The CMI contains many warnings about the drug, including contraindications and potential side effects. It lists a number of situations in which the medicine should not be taken, with *'severe kidney problems'* at the top of the list. Under the heading *'Important Dosage Instructions'* it warns *'[o]verdoses of methotrexate may cause serious illness or death'* and then states that for rheumatoid arthritis and psoriasis the tablets should be taken *'ONCE A WEEK on the same day each week'*.[8]

29. A very similar CMI is published by Hospira Australia Pty Ltd (**Hospira**), the manufacturer of a different brand of methotrexate tablets, DBL methotrexate.

Monthly Index of Medical Specialties

30. The very first sentence of the MIMS Full Prescribing Information contains a warning, which is repeated elsewhere in the document:

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[7] The versions of the reference guides available in January 2015 are either still current, or the same in relevant respects to current versions.

[8] The 2018 revised version of that CMI contains an additional warning at the beginning of the document that the usual dose is once weekly and that overdoses may cause serious illness or death.

Methotrexate must only be used by physicians experienced in antimetabolite chemotherapy, or in the case of nononcological conditions, by a specialist physician [my emphasis].

31. The document continues:

Patients should be fully informed of the risk of fatal or severe toxic reactions involved with the administration of methotrexate and should be under constant supervision of the physician. Deaths have been reported with the use of methotrexate. In the treatment of psoriasis and rheumatoid arthritis, methotrexate should be restricted to severe, recalcitrant, disabling disease which is not adequately responsive to other forms of therapy and only when the diagnosis has been established, by biopsy and/or after consultation.

32. Under ***Contraindications***, severe renal impairment was the first listed condition. The reason is later explained as follows:

As methotrexate is excreted primarily by the kidney, its use in the presence of impaired renal function may lead to drug accumulation with resultant toxicity or even additional renal damage. The renal status of the patient should be determined prior to and during methotrexate therapy.

33. Under the heading ***Use in elderly***, is the caution:

Due to diminished hepatic and renal functions as well as decreased folate states in elderly patients, relatively low doses should be considered and these patients should be closely monitored.

34. Under the heading ***Psoriasis chemotherapy***, the need to assess renal and liver function and blood elements by examination and laboratory testing before beginning methotrexate, periodically during treatment and before re-instituting therapy after a rest period, is emphasised. A single test dose of 5 to 10 mg *'parenterally'*[9] one week prior to initiation of therapy to test for any idiosyncratic reaction is recommended. The document then states that there are three commonly used general types of dosage schedules: weekly single dose (not to exceed 50mg), divided dose over three (or four) days (not to exceed 30mg per week), and finally, daily oral with a rest period. Recommended doses for a 70 kilogram adult are then set out for each of the three schedules. Most relevantly is stated:

(3) Daily dose schedule: 2.5 mg orally daily for five days followed by a rest period of at least 2 days. Daily dosage should not exceed 6.25mg.

[9] By injection.

Product Information

35. The PIs published by Pfizer and Hospira are available on the TGA website and elsewhere online. The Hospira PI is identical to the MIMs Prescribing Information. Pfizer's PI is not identical, but is very similar, including the information about there being three commonly used dosage schedules for psoriasis.

Australian Medicines Handbook

36. The Australian Medicines Handbook 2013 contains similar warnings about the need for caution if there is renal impairment. In relation to dose, it states *'They should be taken once a week on the same day each week; they must not be taken every day.'*

Therapeutic Guidelines

37. Similarly the entry in the Therapeutic Guidelines specifies that methotrexate should be taken on a particular day, once weekly. It notes that lower doses may be required for the elderly or people with impaired kidney function and that therapy should be initiated only by, or in conjunction with an expert.

Specialist medical practice

38. During my investigation I received opinions from two specialist medical practitioners in relation to methotrexate, namely Dr Adriene Lee, the dermatologist who had previously prescribed methotrexate to Mr Gilbert, and a clinical toxicologist and emergency medicine physician, Associate Professor Naren Gunja.[10] Notwithstanding that MIMS and the supplier PIs indicated there were three common types of dosing schedules for treatment of psoriasis, Dr Lee and Dr Gunja confirmed that methotrexate should be taken once a week, not daily, as indicated in all the other resources. Dr Lee also confirmed that standard practice before prescribing methotrexate involves organising baseline blood tests.

39. Associate Professor Gunja explained that *'daily dosing of low dose methotrexate (eg 5mg daily) has higher likelihood of toxicity, than a weekly larger dose (eg 20mg weekly)'*. He said *'[m]ethotrexate should never be prescribed daily ... daily methotrexate is not recommended in healthy young individuals, let alone the elderly, frail or those with renal impairment'*. Further, he said methotrexate should not be prescribed at all to patients with moderate to severe renal impairment (eg eGFR less than 45).

[10] Expert report dated 21 December 2017 commissioned by Ms Barca.

BACKGROUND

40. In July 2014 Mr Gilbert was admitted to Maroondah Hospital for what his daughters thought to be a chest infection.[11] A letter from a general physician at Eastern Health explained the reality of Mr Gilbert's health situation thus:

> *Mr Ian Gilbert was recently admitted to hospital with an exacerbation of his COPD,[12] some mild cardiac failure and renal failure ... The ultrasound of his kidneys did show that he has two smallish kidneys with marked cortical thinning which really isn't likely to improve dramatically and I noticed that his eGFR is still about 11 which were (sic) about the same as it was previously ... it looks as if he is more or less in a chronic condition in that regard.... He is due to see you in about a week's time and if you could just keep regular checks of his renal function and see which way that is going. ... His Potassium level, his renal function, his blood pressure and antihypertensives and his diuretics are all going to need to be gradually adjusted. I think it is best if he keeps seeing one Practitioner who gets to know him reasonably well and to make those adjustments and take regular tests.*

41. This letter was marked as *typed* on 21 August 2014 and sent to Dr Taine, GP, at the Croydon Family Practice Clinic (**CFPC**) (formerly called the Croydon Health Clinic). Mr Gilbert had attended CFPC for many years and seen a number of different GPs, including Dr Lim, who he first saw in 2002.

42. Despite the letter referring to Mr Gilbert returning to see Dr Taine at CFPC *'in about a week'*, in fact he did not. CFPC's records show that Mr Gilbert's last visit to CFPC was on 19 August 2014, that is, before the date of that letter.

43. Rather than return to CFPC, it appears that Mr Gilbert decided to change clinics after his hospital stay, as in September 2014, he attended the Croydon Medical Clinic (**CMC**) for the first time. Coincidentally, Dr Lim, who had left CFPC when it was sold in July 2014, had commenced practicing at CMC in the same month.

CIRCUMSTANCES OF DEATH

The prescribing

44. On Thursday 29 January 2015, Mr Gilbert had his first appointment with Dr Lim at CMC. He liked Dr Lim and was comfortable with him. As was their habit, Mr Gilbert's daughters, Kristy and Amanda, accompanied their father to this appointment as they liked to support him and keep abreast of his health issues.

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[11] T 11.22.

[12] Chronic obstructive pulmonary disease, also known as chronic obstructive airways disease, COAD.

45. Dr Lim had last seen Mr Gilbert on 17 April 2014 at CFPC. He noted from CMC's records that Mr Gilbert had attended CMC twice, on 22 and 26 September 2014. On both occasions he complained of anxiety and was seeking repeat prescriptions, which accorded with Dr Lim's recollection of treating him. Dr Lim did not have access to CFPC's records and specifically, was unaware of the letter of 21 August 2014 – the notes of the 26 September consultation referring only to a recent hospital admission *'for pneumonia'*.

46. Dr Lim obtained Mr Gilbert's written authorisation to obtain his CFPC records and in the meantime asked to be reminded of his history. Amanda told Dr Lim of her father's COPD, previous abdominal aortic aneurysm repair (in about 2008) and previous broken femur. Kristy was certain that they also told Dr Lim their father *'had some prior kidney damage'*,[13] whereas Dr Lim claimed in his statement that he believed Mr Gilbert's renal function was not impaired.[14] In evidence, Dr Lim conceded the possibility that the daughters may have mentioned kidney damage, but if they did, *'it didn't register'*.[15]

47. Dr Lim checked Mr Gilbert's blood pressure (105/56)[16] and prescribed his usual medications (for COAD, high blood pressure and high cholesterol and frusemide, a diuretic).[17]

48. Towards the end of the consultation, Mr Gilbert mentioned that he was suffering a flare-up of his psoriasis, particularly his upper back and legs. On examination, Dr Lim noted *'an obvious scaly rash'*.[18] Mr Gilbert told Dr Lim that about five years ago he had been prescribed methotrexate by Dermatologist Dr Adriene Lee, which he had taken with good effect, but all the other treatments he had tried, such as UV light therapy and creams, were of little benefit.[19]

49. In his statement, Dr Lim claimed that he had *'tried to convince'* a resistant Mr Gilbert to see a dermatologist and that Mr Gilbert was *'most insistent'* that he prescribe methotrexate. In evidence he quickly resiled from those claims, saying only that he told Mr Gilbert that *'such a situation is best handled by a dermatologist'*,[20] but he did not tell him, nor indeed try to

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[13] T 11.29 and 24.12.
[14] Dr Lim submitted an undated letter to the Coroner's Investigator, which was received by him on 19 October 2015. Although it was a letter, not a sworn statement, it was included in the coronial brief and for convenience I shall refer to it as his statement.
[15] T 78.23 and T 95.18.
[16] Kristy thought her father's blood pressure was normal, but as explained later Dr Stanton considered it worryingly low.
[17] In evidence Dr Lim could not recall exactly why Mr Gilbert was taking frusemide. He agreed that kidney function naturally declines as a person ages, but attributed his fluid retention to *'a natural development in life among the elderly'*, rather than anything more sinister. He believed that Mr Gilbert did not have cardiac failure, another cause for fluid retention, but Dr Voselis' letter revealed that he was in fact, in mild cardiac failure.
[18] Dr Lim's statement. Dr Lim claimed to have examined both areas, but Kristy claimed he only looked at the ankle.
[19] Mr Gilbert was in fact prescribed methotrexate in about 2006 as he saw Dr Lee between April 2006 and November 2007. Although Kristy claimed that Dr Lim was told this, I accept Dr Lim's evidence on this point as it is supported by his contemporaneous notes, allowing for an obvious typographical error.
[20] T 77.18.

persuade him, that he should see one. Further, he said that Mr Gilbert, who was *'a very gentle person ... was not insistent ... but... displayed a very very keen ... desire ... to be relieved'*.[21]

50. Dr Lim had previously prescribed methotrexate to other patients, but only when it had been initiated by a specialist. He knew that it was indicated only for severe and recalcitrant psoriasis. As he was unaware of the appropriate dosage, he consulted MIMS online. He knew of the existence of other guidelines, such as the Australian Medicines Handbook, but only consulted MIMS as it was the easiest one to access. He estimated, accurately, that Mr Gilbert weighed about 70 kg and interpreted the entry under *Psoriasis Chemotherapy* ([34] above) to mean that it was acceptable to choose a dose anywhere between 2.5 to 6.25mg a day, especially as the total weekly dose would then be less than 50mg. He chose 5mg a day because the medication came in 2.5mg tablets, so it was easy. He then provided Mr Gilbert with a prescription for *'METHOTREXATE TABLETS 2.5mg (METHOBLASTIN) Qty 30. Take TWO tablets daily'* with five repeats. He told him to take the methotrexate for five days in conjunction with Folic acid tablets, which he also prescribed, and to return for review in one week.

51. Dr Lim explained in evidence that he had not intended to provide 30 methotrexate tablets, nor five repeats, but being new to CMC and unfamiliar with computerised prescription systems, he had failed to override the default settings. He also explained that he had failed to read the parts of MIMS that said that methotrexate for psoriasis should only be prescribed by a specialist, saying he *'only had a quick glance because it's so thick'*.[22]

52. Dr Lim performed no blood tests prior to prescribing the methotrexate even though he knew it was usual to do so (and may have glanced at that entry in MIMS) because, *'I did not believe Mr Gilbert's renal function was impaired and I was aware the drug had been prescribed in the last 5 years by the dermatologist, Dr Adrian (sic) Lee. In these circumstances I decided to prescribe the medication and then to check his renal function when he returned a week later'*.[23] For the same reason, he did not inform Mr Gilbert of any side effects.

53. Dr Lim's contemporaneous notes of the consultation were very brief, consisting of a recording of his blood pressure, a note: *'flre [sic] up of Psoriasis affecting the upper back and legs very distressing'* and then a list of prescriptions printed. Next to the methotrexate prescription he also noted *'(had it for close to a month 54 [sic] years ago under Dr A Lee when he had a flare up) check up in 1 week'*.

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[21] T 78.9.
[22] T 100.23.
[23] His statement.

The dispensing

54. After seeing Dr Lim, Mr Gilbert and his daughters drove to their usual pharmacy, Chemmart Pharmacy at Arndale Shopping Centre. Jennifer Barca, the pharmacist and sole proprietor of the business, had known the Gilbert family for at least 12 years. She knew Mr Gilbert took medication to control his COPD and blood pressure, but knew nothing about his renal function.

55. Mr Gilbert waited in the car whilst Amanda and Kristy went inside with his prescriptions. A dispensing technician made up the prescriptions and gave them to Ms Barca to authorise. Ms Barca immediately recognised that the daily dosing appeared to be wrong. She told Kristy and Amanda that methotrexate was usually taken once a week, not daily and asked them to wait while she called Dr Lim to clarify.

56. Ms Barca also knew Dr Lim, having spoken to him a number of times about other prescriptions. She described him as quietly spoken, as indeed, did Kristy and Amanda. On this occasion she told him that methotrexate was usually taken weekly and conveyed her *'extreme concern'*[24] with the daily dose, describing it as possibly lethal. To her surprise, Dr Lim confirmed his prescription, saying that he had checked it on MIMS. She described him as *'firm'*, *'confident and 'resolute'*.[25]

57. In evidence Dr Lim agreed that this conversation would have taken place within about an hour of his consultation. He also agreed that it was quite unusual for a pharmacist to question the prescribed dose. It is surprising therefore, that in his statement Dr Lim claimed to have no specific recollection of the conversation with Ms Barca. Nevertheless, in evidence he agreed that Ms Barca had expressed *'extreme concern'*[26] about the dose, although he believed that if she had said it could be lethal (which he did not recall) he would have changed the dose. He said:

I regard it, that point in time, as something she wanted to clarify ... She is concerned, but she wanted to be sure ... that I knew what I was doing ... That is how I looked upon that conversation. ...

I had checked the dose already and ... was quite sure I was on the right track ... [and] that's what the guideline say.[27]

58. Dr Lim said that he double checked MIMS after speaking to Ms Barca and remained satisfied. He did not look anywhere else, nor speak to anyone else.

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[24] Statement dated 3 June 2015.
[25] Statement dated 3 June 2015 and T 16.16.
[26] T 80.28.
[27] T 90.

59. Ms Barca was not reassured by speaking to Dr Lim. She was so concerned for Mr Gilbert's safety she even changed the instructions on the medication label, before thinking better of it and changing it back. She gave the methotrexate to the daughters (at some stage they were also given a CMI brochure) and told them to make sure Mr Gilbert attended the review appointment with Dr Lim the following week. She explained, '*I tried to let them know how concerned I was without sort of um sacrificing their – their relationship with their doctor and um – yeah I just said to them "I wouldn't be taking that dosage"*'.[28] Kristy knew Ms Barca was concerned, but did not recall her expressing it quite that way.

60. In evidence Ms Barca claimed that she also told the daughters that the prescribed dose could be lethal, however I find this unlikely. It is not in her police statement, would not be preserving of the doctor-patient relationship and I accept Kristy's evidence that she would never have allowed her father to take the methotrexate if it had been said.

61. It is much more likely, indeed I accept, that Ms Barca told Dr Lim the dose could be lethal. That claim was in her statement, she was not similarly constrained in her approach to Dr Lim and she maintained her position when challenged, explaining *'I think that's why I was so surprised that he didn't [stop it], yeah, because I said it in as strong as possible terms'*.[29]

62. Ms Barca knew she had the option of not dispensing the medication, but for some reason she was not prepared to do it. She explained that she believed the doctor-patient relationship was stronger than the relationship between pharmacist and patient. She also believed there was a power imbalance between doctor and pharmacist, but agreed that she was an experienced pharmacist dealing with a GP who was quietly spoken and polite. Whilst there were some *'interesting doctor characters out there ... [who] just don't like to be told at all'*,[30] Dr Lim, she said, was not one of them. When asked specifically why she dispensed the methotrexate, she replied, *'it's a good question. I don't know. I mean – I don't know. Yeah, I really don't know'*.[31]

63. After the daughters left the pharmacy, Ms Barca completed a Clinical Intervention form, on the pharmacy computer to record her interaction with Dr Lim for future reference. Although she had spoken to prescribing doctors on many occasions, this was the first time she had encountered a situation where she believed the dose could be fatal and where her concerns were ignored.

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[28] T 129. 17 and also her statement dated 3 June 2015.
[29] T 132.21.
[30] T 141.11.
[31] T 142.19.

Mr Gilbert's decline

64. Over the next few days Mr Gilbert began to experience severe rashes, ulcers, blisters, pallor and temperature fluctuation. As these were some of the serious side effects listed on the CMI brochure, Kristy called the number on the brochure for the Poisons Information Centre. She was told to monitor Mr Gilbert, and contact a doctor if the side effects got worse. The next night Kristy called the Poisons Information Centre again. This time the operator seemed more concerned and advised her to call an ambulance or see the doctor the next day. In the morning Kristy called Dr Lim who agreed to a home visit as her father was too unwell to go out.

65. Dr Lim arrived at Mr Gilbert's house at 6.00pm on Wednesday 4 February 2015. Kristy showed him the side effects listed on the CMI brochure. She confirmed that Mr Gilbert had taken methotrexate before, but pointed out it was about eight years ago. Dr Lim determined that Mr Gilbert should go to hospital and hand wrote a referral to accompany him in the ambulance.[32]

66. Mr Gilbert arrived at Maroondah Hospital Emergency Department at 7.16pm complaining of lethargy, diarrhea, and a sore throat. His vital signs were normal but blood samples showed marked abnormalities, including marked deterioration of renal function, acidosis, anaemia, and low white cell count. He was treated and transferred to Box Hill Hospital the next day, as he required haemodialysis for his kidney failure.

67. At Box Hill Hospital Mr Gilbert was assessed by the renal team. Tests were ordered to determine a possible source of sepsis, his kidneys were imaged and there was strict observation of fluid balance. The Poisons Unit was consulted, and advised administration of folinic acid to counteract presumed methotrexate toxicity. Over the next few days Mr Gilbert received haemodialysis and was reviewed at least daily by the renal unit. He was also reviewed by the neurology team due to tremors, and the dermatology unit due to worsening rash, considered to be methotrexate-induced erosive plaques.

68. On 9 February 2015, Mr Gilbert developed confusion and two days later, shortness of breath necessitating MET[33] calls. A CT scan of the chest was performed, which showed no pulmonary embolus but did show some non-specific nodularity in the right lower lobe and a small pleural effusion. Further tests were performed to look for a source of infection and Mr Gilbert was

[32] That referral letter listed *'kidney dysfunction'* amongst Mr Gilbert's past history, however I regard that as a neutral fact on the issue of whether Dr Lim was told of the kidney problems on 29 January 2015, as there is little doubt he was told on 4 February 2015.
[33] Medical Emergency Team.

commenced on additional antibiotics. His increased work of breathing was believed to be a compensatory response to his underlying metabolic acidosis, not due to his lung disease.

69. On 12 February 2015, Mr Gilbert developed a distended abdomen, possibly due to bowel obstruction. A nasogastric tube was inserted and a CT[34] scan of his abdomen and pelvis was ordered. Early the next morning a further MET call was made, as Mr Gilbert had become unresponsive with low blood pressure. He had significant abdominal distension with guarding, likely due to an acute abdomen. Resuscitation was attempted with fluids and metaraminol to increase his blood pressure, but there was no improvement.

70. Discussions took place between the Intensive Care Unit, renal and surgical teams, and a decision was made to palliate Mr Gilbert as his poor condition meant that he was unlikely to survive surgery or even a CT scan. Mr Gilbert was declared deceased at 4.00am on 13 February 2015.

MR GILBERT'S CAUSE OF DEATH

Post mortem examination

71. On 17 February 2015, Forensic Pathologist Dr Heinrich Bouwer conducted an autopsy on the body of Mr Gilbert at the Victorian Institute of Forensic Medicine (VIFM). The autopsy revealed significant natural disease affecting multiple systems. There was marked scarring of the kidneys which were small and atrophic. The left renal artery ostium was completely occluded by atheroma and there was marked stenosis of the right renal artery ostium. There was a renal cell carcinoma in the right kidney, cardiac enlargement, triple vessel coronary artery atherosclerosis and pulmonary emphysema. There was also caseous calcification of the mitral valve annulus.

72. Dr Bouwer noted that Mr Gilbert was diagnosed with methotrexate toxicity in life. To his knowledge, ante mortem methotrexate levels were not performed, however he observed:

    (a) there was evidence of myelosuppression (low haemoglobin and white cell count) with subsequent sepsis, and worsening kidney failure (markedly elevated creatinine and urea);

    (b) post mortem microbiology blood cultures grew coagulative negative *Staphylococcus* species which was of clinical significance and was the likely organism responsible for Mr Gilbert's sepsis. There was also evidence of invasive fungal bronchitis. A C-reactive protein (marker of infection and inflammation) was markedly elevated at 125.8mg/L (reference range <5.0); and

[34] CT stands for computed tomography, a diagnostic tool.

(c) post mortem biochemistry showed marked renal impairment.

73. Dr Bouwer commented that potentially life-threatening hepatotoxicity, pulmonary damage and myelosuppression are sometimes seen with the use of methotrexate as either high or low dose therapy, while nephrotoxicity is a manifestation of high dose therapy that occurs rarely, if ever, with low dose methotrexate therapy.

74. After reviewing all the evidence, including medical records from Box Hill Hospital and CMC and post mortem microbiological samples, he formulated the cause of death as:

1(a) Complications of methotrexate toxicity in a man with chronic renal impairment, chronic obstructive pulmonary disease, cardiomegaly and ischaemic heart disease.

75. No issue was taken with Dr Bouwer's formulation of the cause of death and I accept it.

EXPERT COMMENTARY ON DR LIM'S TREATMENT

Concessions

76. At the end of his evidence Dr Lim agreed that he had prescribed the incorrect dose of methotrexate and that he should have ordered blood tests before prescribing it at all. He explained that whilst he knew methotrexate was dangerous he had underestimated the extent of its toxicity.

Dr Stanton

77. Dr Stanton described it as *'uncommon'* for a GP to initiate methotrexate treatment.[35] He accepted that daily dosing was inappropriate, but believed it was reasonable for Dr Lim to rely on the dose information in MIMS, as MIMS was the most common therapeutic guideline used by doctors. Dr Stanton had only ever provided repeat prescriptions for single weekly doses of methotrexate and characterised the prescribing information in MIMS in referring to three dosing schedules, as *'inconsistent'*, *'confusing'* and, in his experience, *'not accurate'*.[36] Although he did not know how Dr Lim arrived at the actual dose he prescribed, Dr Stanton considered it fell within the MIMS daily dosing schedule.

78. Whilst Dr Stanton made some valid points and agreed that Dr Lim should have undertaken base line blood tests, my overall impression was that he was endeavouring to excuse Dr Lim. He gave evidence that he did not believe Dr Lim was *'required to actually read the full MIMS prescribing information'*[37] (which was voluminous), but acknowledged that the direction that

[35] Report dated 5 February 2017.
[36] Report dated 5 February 2017 and T 188.19.
[37] T 187.20ff.

'methotrexate must only be used by ... by a specialist physician' occurs in the very first sentence. He suggested that perhaps Dr Lim had only referenced the abbreviated version of MIMS, which does not have the initial boxed warning, but conceded that even then competent professional practice would have required him to note the potential adverse reactions, contraindications and precautions set out in that document.[38]

79. Dr Stanton considered that Dr Lim was entitled to rely on the fact that Mr Gilbert had previously taken methotrexate without any problems. Further, having made a general enquiry about his health, he believed Dr Lim was not obliged to specifically ask whether Mr Gilbert had renal impairment, as the general enquiry should have elicited that information.

80. When asked about the telephone call from Ms Barca, Dr Stanton said:

In my personal experience if I am prescribing something that I'm unfamiliar with and the pharmacist telephones me and queries the dose, I'd ask them what their recommendation is and provided that recommendation was also within the guidelines I would most likely follow the pharmacist's advice.[39]

81. That evidence notwithstanding, he went on to say that he considered Dr Lim's response to be reasonable.

Dr Hay

82. Dr Hay was very critical of Dr Lim, who he described as clearly out of his depth and not accepting of that fact even when advised of it (by Ms Barca). He said GPs should never initiate systemic (second line) treatments for psoriasis, rather they should refer patients potentially warranting such treatment to a dermatologist. He believed that it was unreasonable for Dr Lim to have prescribed methotrexate at all, let alone without first undertaking the necessary preliminary tests. He noted that Mr Gilbert was at significantly heightened risk of renal impairment because of his age, history of smoking and known co-morbidities, as well as the fact he was taking frusemide and coversyl, which may themselves impair renal function.

83. Unlike Dr Stanton, Dr Hay thought the fact that Mr Gilbert had previously taken methotrexate should have been of little comfort to Dr Lim. Similarly, the fact Dr Lim had previously treated Mr Gilbert did not excuse him from performing a thorough examination. He explained: *'a year*

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[38] Dr Lim had previously identified the MIMS Full Prescribing Information as *looking like* the document he accessed. T 101.
[39] T 195.1.

in the life of a 77 year old man is quite different to a year in the life of a 25 year old man',[40] meaning that at that age a lot can happen in one year, let alone five years or more.

84. In Dr Hay's opinion, Mr Gilbert's known co-morbidities meant a doctor *'need[s] to be very careful about initiating any particular therapy that has some significant risk attached to it'.*[41] He remarked that Mr Gilbert's blood pressure, which was low, should also have been a concern.

85. Dr Hay dismissed Dr Lim's explanation that he intended to perform blood tests when Mr Gilbert returned, as illogical. If any results were abnormal, it would not then be known whether it was because of the methotrexate or some other cause, hence the need for baseline tests.

86. Dr Hay found it completely unacceptable that Dr Lim did not read MIMS, more thoroughly, explaining that for an unfamiliar drug, especially one known to be toxic, he always referred to the boxed warning at the beginning and also looked for any other applicable sections, such as treatment in the elderly. He said it would not have been acceptable only to look at the abbreviated version.

87. In relation to Ms Barca's telephone call Dr Hay said this:

[T]hat's a very significant phone call. It's showing significant concern. To dismiss it out of hand without doing anything further is arrogant at best and stupid at worst. I just can't believe that you would not as an intelligent person question your own decision making because ultimately, as I say, we all make mistakes. ... good pharmacists are there to help me and help the patient ... it should be a partnership.

PHARMACISTS' DISPENSING OBLIGATIONS

88. Pharmacists have professional responsibilities in relation to the dispensing of medications. These obligations are enshrined in legislation and are also set out in various publications available on the internet and otherwise.[42]

89. The fundamental obligation of a pharmacist is to take reasonable steps to ensure that the dispensing of a medicine in accordance with a prescription is consistent with the safety of the patient.[43] The pharmacist is required to exercise an independent judgment about the safety of the medicine and to contact the prescriber in case of doubt.[44]

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[40] T 227.6.
[41] T 226.28.
[42] See, for example the *Pharmacy Regulation Act 2010* and the websites of the Department of Health and Human Services website, the Pharmacy Board of Australia and the Pharmaceutical Society of Australia.
[43] Section 32 of the *Pharmacy Regulation Act 2010.*
[44] Pharmacy Board of Australia's *'Guidelines for Dispensing Medicines'.* See also the Pharmaceutical Society of Australia's . *Standard and guidelines for pharmacists performing clinical interventions.*

90. The version of the Pharmacy Board of Australia's *Guidelines for Dispensing of Medicines* applicable in January 2015, provided no specific assistance to pharmacists as to how to resolve any potential conflict with the prescriber as to the safety of a medicine. However, the current version makes it clear that the ultimate decision rests with the pharmacist. It states:

If the prescriber cannot be contacted, or if on consultation with the prescriber there is a difference in opinion regarding the safety of the prescription, professional judgement must be exercised by the pharmacist in deciding appropriate action to take.

At all times the dispensing of a prescription or any other action taken by the pharmacist must be consistent with the safety of the patient. If the pharmacist decides not to dispense the prescribed medicine, the patient must be informed about the reasons for the decision and the alternative options available to the patient regarding their medication needs.

91. Although primarily aimed at drugs of dependence and prescription shopping, two publications on the Department of Health and Human Services (**DHHS**) website, *Intervening to ensure Safe Appropriate and Lawful Supply* and *Interventions by Pharmacists* also emphasise that the pharmacist must apply his or her own judgment about the safety of prescribed medication. The former publication states *'[t]he knowledge and experience of a pharmacist might be the only barrier to undesirable outcomes'.*[45] Similarly, the Pharmaceutical Society of Australia's publication, *Standard and guidelines for pharmacists performing clinical interventions* states *'Pharmacists have a fundamental role in and responsibility for optimising health outcomes and minimising medication misadventure'.*[46]

Expert opinion

92. In her expert report, community pharmacist, Pamela Mathers said that refusal to supply *'is the absolute last resort, as it often does not resolve the issue, as it only transfers it to another pharmacy or causes harm to the pharmacist/doctor relationship and/or the pharmacist/patient relationship'*. She opined that given Ms Barca's well founded concerns, she must *'have had to be influenced by something compelling to satisfy herself to dispense the medicine'.*[47]

93. When it was pointed out to Ms Mathers in Court that in fact Ms Barca's concerns were not allayed by speaking to Dr Lim, she said *'I don't truly accept that because having those ... concerns and ringing the doctor, he must have said something ...'*. Then followed this exchange:

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[45] Version dated April 2014.
[46] March 2011
[47] Dated 29 October 2017.

Q: Aren't you essentially saying that you believe she must have been reassured in some way because you cannot envisage her dispensing that medication unless she was reassured? Isn't that what you're really saying? - A: I think that's fair comment, yes, yes. Yeah.[48]

94. Given the actual, not her presumed, situation, Ms Mathers then suggested that the way Ms Barca should have dealt with the situation was to ask Kristy and Amanda to leave the prescription with her so she could do some more research. Armed with that greater knowledge, Ms Barca could then have re-approached the doctor and been more forceful in her dealings with him.

DISCUSSION AND CONCLUSIONS

95. As previously explained, my examination of the circumstances leading to Mr Gilbert taking a fatal course of methotrexate was not for the purpose of finding fault, but rather to identify cause, albeit the distinction can sometimes seem artificial. It is hoped that the investigation of cause may reveal whether any systemic failures contributed to Mr Gilbert's death, therefore giving rise to opportunities for prevention in the future.

96. It is also important to reiterate that the conduct of professionals should be assessed against the reasonably expected behaviour of a person with the same expertise confronted with the same scenario, without the benefit of hindsight and with due regard to the principles of *Briginshaw*. Acknowledging those parameters, the evidence in this case not only permits an adverse finding against Dr Lim and Ms Barca, it compels it.

97. Mr Gilbert died because a dangerous drug was inappropriately prescribed and then dispensed. The fact the drug was intended to treat a non-life threatening skin condition makes his death all the more tragic and the decisions to prescribe and dispense all the more inexplicable.

Dr Lim

98. At the end of his evidence Dr Lim explained that he was now a lot more cautious and would no longer step outside the limit of his experience. He expressed his deep sorrow and sympathy for Mr Gilbert's family and explained how over the years he and the Gilberts had established a friendship and rapport. He said, *'I've always endeavoured to be as helpful as I can to them. When other doctors have turned them down for any reasons ... letters or anything at all, they knew they could come to me ...'*

99. Doctors are not machines devoid of emotion. It is only natural that they may like certain patients and develop affection for them. There is nothing wrong with that as long as it does not cloud their professional or ethical judgement. It is not the role of a doctor to be a patient's

[48] T 161. The transcript is inaccurate.

friend, or ally, or to be helpful when good medical practice dictates otherwise. I have no doubt that Dr Lim was seeking to appease Mr Gilbert's suffering by prescribing methotrexate, but in his eagerness to please he completely failed in his duty of care to Mr Gilbert as a patient. As Dr Hay said, any therapy has to be based simply on the best interest of the patient, not the patient's desires.[49]

100. Methotrexate is undoubtedly a dangerous drug. That much I am sure Dr Lim knew. He should not have prescribed it without ensuring that it was safe and appropriate for him to do so. To reach that level of satisfaction Dr Lim should have done more than simply have recourse to the dosage information in MIMS. At the very least he should have studied MIMS in more detail. As an experienced medical practitioner he should have appreciated that the most important information for him to read was the very beginning of the MIMS extract which contains the warnings. If he had read that and nothing else, he would have realised that as a GP, he should not be prescribing methotrexate at all.

101. Dr Lim's error in prescribing methotrexate was compounded by his failure to order baseline blood tests. It is likely that the results of such blood tests would have contraindicated the prescribing of methotrexate at all.[50] Again, anything more than a cursory read of MIMS would alert a doctor to the importance of this precautionary measure prior to prescribing such a dangerous drug. Dr Lim's reason for not doing so, was not, however, that he was unaware of the need for those tests, but rather that he did not believe Mr Gilbert's renal function was impaired *and* that Mr Gilbert had taken methotrexate about five years ago without any problems. His explanation does not withstand scrutiny.

102. True it is that there is no evidence that Dr Lim knew anything about Mr Gilbert's impaired kidney function prior to the consultation on 29 January 2015. True also, that the evidence that he was told about it during that consultation is not all one way (notwithstanding Dr Lim's concession that he might have been).[51] However, even if nothing was said about Mr Gilbert's kidneys in that consultation, it would not justify a belief that his kidneys were not impaired. It would not justify making no specific enquiry and it would not justify not ordering baseline blood tests. Dr Lim knew that kidney function declines with age. He should have known that

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[49] T 225.9.

[50] Associate Professor Gunja's opinion was that methotrexate was contraindicated in a person with an eGFR less than 45. Mr Gilbert's was 11 according to the physician's letter of 21 August 2014.

[51] The fact Kristy and Amanda did not appreciate the extent or significance of their father's kidney problems makes it more likely that it may not have featured in their thoughts. For example, at the first appointment with CMC in September 2014, Amanda completed a document which listed Mr Gilbert's history as COAD, hypertension, aortic aneurysm and psoriasis, but did not mention kidney problems. Further, Dr Lim gave evidence that he knew enough about methotrexate at that time, that if he had been told it would have caused him alarm.

loss of kidney function may be asymptomatic, meaning that a patient may be unaware of it.[52] He should have known that frusemide and coversyl may affect kidney function, and he should have known that there is a much greater potential for health to decline in a person of Mr Gilbert's age than a younger person, let alone a person with his co-morbidities and his history of smoking.

103. It was also completely unreasonable for Dr Lim to rely on the fact that Mr Gilbert, a 77-year-old man, said that he was prescribed methotrexate five years ago with no ill effect, to satisfy himself that it was safe to prescribe it in that consultation. The fact Mr Gilbert actually took methotrexate eight or nine years ago, not five, is further demonstration of the folly of relying on that information.

104. Counsel for Dr Lim submitted that his client was misled by MIMS. I accept that Dr Lim relied upon the information in MIMS about the existence of three dosing schedules and chose a dose which appeared to be in conformity with the third schedule. I also accept that the MIMS guidelines (and the Product Information for that matter) are confusing in this respect and appear to be out of kilter with medical practice and other prescribing reference guides. The fact remains however, that Dr Lim should not have prescribed methotrexate at all and he certainly should not have prescribed it without first performing blood tests.

105. Dr Lim's response to the telephone call from Ms Barca is lamentable. Even on his own version of the call, Ms Barca made it clear to him she was extremely concerned about the dose. If nothing else that call should have made him read MIMS more carefully, or have regard to other resources, or consult with colleagues. Doing any of those things should have revealed to him the danger of proceeding. Instead, he confirmed the dose. Simply double checking the information he had already read was a wholly inadequate response. As Dr Hay said, a doctor who ignores such a call does so at his or her peril. Unfortunately, as this case reveals, it is also at the peril of the patient.

Ms Barca

106. I have sympathy for Ms Barca who clearly felt conflicted. However, in reality her choice was clear. Since she was not satisfied that the prescribed dose of methotrexate was safe, she should not have dispensed it.

107. Counsel for Ms Barca submitted, that psoriasis can be serious and disabling and the need for efficacious treatment, such as methotrexate, should not be underplayed. I accept this, but as a

[52] Dr Stanton agreed that renal impairment, even significant renal impairment, could be asymptomatic.

refusal to dispense would have carried absolutely no risk to Mr Gilbert's health (unlike the decision to dispense), the right choice should have been even more obvious.

108. Ms Mathers suggested that the decision to refuse supply often does not resolve the issue, but transfers it to another pharmacy. Following on from this, Counsel for Ms Barca submitted that I could not be satisfied that if Ms Barca had refused to dispense, Mr Gilbert would not have obtained the medicine from another pharmacy.

109. I find it unlikely that the Gilberts would have taken the prescription elsewhere if Ms Barca had refused to dispense it and told them why. In any case my role is not to speculate, but to evaluate actual conduct. What may have happened if Ms Barca had refused to dispense does not detract from her obligation to not do so. The fact that someone else may not do the right thing, is no excuse for not doing the right thing oneself and, to Ms Barca's credit, she did not suggest that this was so.

FINDINGS

110. Having investigated the death of Ian Gilbert and having held an Inquest in relation to his death on 15 November 2017 and 6 February 2018 at Melbourne, I make the following findings, pursuant to section 67(1) of the Act:

(a) that the identity of the deceased was Ian John Gilbert, born 8 December 1937;

(b) that Mr Gilbert died on 13 February 2015 at Box Hill, Victoria, from complications of methotrexate toxicity in a man with chronic renal impairment, chronic obstructive pulmonary disease, cardiomegaly and ischaemic heart disease; and

(c) in the circumstances set out above.

COMMENTS and RECOMMENDATIONS

Pursuant to section 67(3) and 72(2) of the *Coroners Act 2008*, I make the following comments and recommendations connected with the death:

1. Mr Gilbert's death was, as I have said, entirely preventable. His premature death was a tragedy for his family who clearly loved him dearly. I also have no doubt that his death was devastating for Dr Lim and Ms Barca, professionally and personally, notwithstanding their role in it. Their distress and regret was obvious throughout the inquest.

2. During the inquest I invited witnesses and parties to consider how similar deaths might be prevented in the future. I am grateful for their assistance and the assistance offered by the Coroners Prevention Unit in this regard. I am satisfied that there are a number of possible prevention opportunities, some quite specific to the facts of this case and some of wider import.

Nothing will bring Mr Gilbert back, but the thought that some good may come out of his death may give small comfort to his family.

Preventing inappropriate prescribing

3. The first and most obvious area to address in reducing the risk of methotrexate-related harm is the process by which methotrexate is prescribed. Dr Hay suggested one way to effectively prevent GPs from inappropriately initiating methotrexate therapy would be to designate methotrexate as an authority required medication. Ms Barca supported this proposal through her Counsel. If methotrexate were an authority required medication, a doctor (not just a GP) proposing to prescribe methotrexate would need to obtain approval in advance from the Commonwealth Department of Human Services. Whilst the process would not prohibit a GP from prescribing methotrexate, Dr Hay believed it would be a major disincentive because of their time pressures.

4. The designation of methotrexate as an authority required medication does appear to have benefits. It would certainly promote reflection about the risks of the drug and prevent ad hoc and spontaneous prescribing, as occurred in this case. However, the utility and ramifications of such a proposal obviously need proper consideration. For example, there are different types of authority required medications – some require only that the prescriber enter a four-digit code and the prescribing decision is not scrutinised, whereas others require a telephone discussion or even written application. Further, I do not know whether making methotrexate an authority required medication would impact negatively on its use in cancer chemotherapy, or its use by dermatologists or other specialists. The Commonwealth Department of Human Services has the responsibility for designating medications to be authority required medications, and additionally has the broad expertise necessary to weigh the potential benefits and risks of making such a designation with respect to methotrexate. Therefore, I make the following recommendation.

> **Recommendation 1.** That the Commonwealth Department of Human Services consider whether methotrexate should be designated an authority required medication, to reduce the risk of harm and death resulting from inappropriate prescribing.

5. The second area to address is the inconsistency and ambiguity in methotrexate prescribing advice. In prescribing a daily dose of methotrexate Dr Lim had recourse to MIMS which stated, *'there are three commonly used general types of dosage schedules'* for methotrexate in the treatment of psoriasis, one of which is daily dosing with rest period. This advice is reflected in the Product Information for methotrexate produced by manufacturers Pfizer and Hospira, but

is inconsistent with other prescribing reference material and, according to the expert evidence in this case, inconsistent with medical practice.

6. The advice as to there being three commonly used dosage schedules, including a daily dose with rest period is still current in MIMS and the Product Information of Pfizer and Hospira. Further, that Product Information is readily available on the TGA website. Therefore, I make the following recommendations.

> **Recommendation 2.** That MIMS Australia, Pfizer Australia Pty Ltd, and Hospira Australia Pty Ltd review their methotrexate prescribing advice for treatment of psoriasis, to ensure the advice reflects current clinical practice and evidence and is framed in such a way as to clearly mitigate the risk of inappropriate daily dosing as occurred in the death of Ian Gilbert.
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> **Recommendation 3.** That the Commonwealth Department of Health ensure that any Product Information for methotrexate made available by the Therapeutic Goods Authority, reflects current clinical practice and evidence and is framed in such a way as to clearly mitigate the risk of inappropriate daily dosing for treatment of psoriasis as occurred in the death of Ian Gilbert.

7. It is also vitally important that other potential sources of information on methotrexate prescribing for treatment of psoriasis carry consistent messages. In the course of my investigation, I became aware of an article on the treatment of psoriasis on the Royal Australian College of General Practitioners (**RACGP**) website with the potential to mislead GPs into thinking that it is within their purview to initiate methotrexate therapy. The article, which was written by a dermatologist, states: *'One systemic treatment available to the GP is methotrexate. This is given weekly but requires monitoring of full blood count, renal and liver function'*[53] [my underlining]. In my view, material available on the RACGP website should contain a clear directive to GPs that they should never initiate methotrexate therapy and should only ever provide repeat prescriptions in controlled situations. Dr Lim did not have recourse to the RACGP website and it was not implicated in his prescribing decision. I therefore make no specific recommendation to the RACGP, but I do invite it to review the information it makes available to its members on methotrexate and psoriasis in light of my observation about this article, and more generally, the issues revealed by this case.

[53] Reprinted from Australian Family Physician, Vol 40, No 7 July 2011.

Preventing inappropriate dispensing

8. I turn now to the question of how to prevent inappropriate dispensing. This is a matter that has wider import than the drug methotrexate.

9. Pharmacists are independent health care professionals with a duty to ensure the medication they dispense is safe and appropriate. In this sense, pharmacists bear a responsibility for patient safety just as other health care professionals do. Clearly, pharmacists are not responsible for inappropriate prescribing by doctors. However, they perform a vital failsafe role in preventing inappropriately prescribed medication from reaching patients. As stated on the DHHS website, *'[t]he knowledge and experience of a pharmacist might be the only barrier to undesirable outcomes'*.[54] Since Ms Barca recognised the prescription error and was aware that she could refuse to dispense, the question is why she didn't. This was a question even she found difficult to answer.

10. Doctors and pharmacists should trust and respect each other, whilst retaining their independence. In dismissing her concerns, it appears that Dr Lim did not afford Ms Barca the respect she deserved. In dispensing the methotrexate despite her concerns, it appears that Ms Barca afforded Dr Lim too much respect, or at least lost sight of her role as an independent safeguard against inappropriate prescribing.[55]

11. Similarly, whilst pharmacists should respect the doctor-patient relationship, they should not underestimate their own importance in the delivery of health care. Regard for the doctor-patient relationship should not prevail against their own duty to prevent *'medication misadventure'*.[56]

12. From the outset of my investigation I was interested in how pharmacists in the position of Ms Barca could be empowered to observe their professional and ethical responsibilities. Although their responsibilities are clear, this case illustrates the practical difficulty that may be encountered in compliance. Ms Barca was a pharmacist with 35 years' experience and Dr Lim was not an overbearing personality, yet Ms Barca still felt obliged to follow his directions.

13. Community pharmacists, like Ms Barca, are often sole practitioners. They lack the collegiate support enjoyed by hospital pharmacists and may be professionally isolated. They may be young and inexperienced. The evidence in this case revealed that although there are ad hoc

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[54] DHHS publication: *Intervening to ensure Safe Appropriate and Lawful supply.*
[55] At T 141.27, Ms Barca agreed she deferred to Dr Lim.
[56] Pharmaceutical Society of Australia's publication *Standard and guidelines for pharmacists performing clinical interventions.*

methods for seeking advice, there is no central body for community pharmacists to consult when faced with difficult decisions arising in the course of their day.[57]

14. Counsel for Ms Barca submitted that the Pharmacy Board of Australia's *Guidelines for Dispensing of Medicines* (**the Guidelines**) should be more prescriptive as to how a pharmacist should deal with the sort of difference of opinion that arose in this case. He said the Guidelines should provide illustrations of how to manage such situations and provide telephone numbers for advice. Whilst, I am satisfied that the fundamental obligation of pharmacists not to dispense medicine unless they are satisfied it is safe and appropriate to do so, is clear, I agree that more assistance could be provided to community pharmacists to enable them to discharge this obligation in difficult situations.

15. In my view the single most effective measure would be a professional advice service. Such a service could, for example, be staffed by senior pharmacists who volunteer to receive calls on a rotational basis. I would not envisage that the service would be overrun, although if it were, it would simply prove the need for it. Importantly, advice from such a service would reassure and embolden community pharmacists in situations of conflict.

16. The concern that a pharmacist's refusal to dispense may simply create a problem for another pharmacist, should also be addressed in the amended Guidelines. It is an interesting question (and one that was not the subject of evidence or submissions), as to whether a pharmacist presented with a prescription he or she considers unsafe is obliged to return it to the patient. In any case, if the pharmacist does return it, I see nothing preventing the pharmacist from noting on the prescription that he or she has refused to dispense it and why.

17. Unlike hospital pharmacists, community pharmacists may have only limited information about a patient's medical conditions at their disposal. At one point in her evidence Ms Barca indicated her belief that knowledge of Mr Gilbert's impaired kidney function (which she did not have) would have provided her with the fortification she needed to refuse to dispense the medication. Again the Guidelines could deal with this issue. Whilst a customer may not tell them, there is nothing to stop a pharmacist from asking about a customer's health, especially the existence of contraindicated conditions.

18. The Pharmaceutical Society of Australia advocates documentation by pharmacists of the type of clinical intervention that occurred in this case.[58] However, a question I canvassed during the

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[57] This is to be contrasted with, for example, Victorian barristers who are able to call a representative from the Victorian Bar's Ethics Committee, to discuss and receive advice on ethical dilemmas.

[58] Pharmaceutical Society of Australia, *Standard and guidelines for pharmacists performing clinical interventions,* March 2011.

inquest was what happened to the Clinical Intervention form completed by Ms Barca after her interaction with Dr Lim. Where did it go? What did it achieve? The short answer is it went nowhere and achieved nothing, other than being a contemporaneous record and an aide memoire to Ms Barca.

19. Coroners are frequently confronted with a lack of adequate note taking by health care professionals and I would never seek to dissuade anyone from making contemporaneous notes, especially detailed notes. That said, to simply file away a document such as a Clinical Intervention form for later use in the event of disaster, misses the potential opportunity to avert disaster in the first place. For example, in this case Ms Barca could have arranged for immediate delivery of the Clinical Intervention Form to Dr Lim and/or given a copy to Kristy and Amanda. Faced with a document outlining Ms Barca's concerns, it is possible Dr Lim may have sought to recall his prescription, and/or that Mr Gilbert's daughters may have sought alternative advice. In my view, guidance to pharmacists should cover not just the creation of such a form, but how to use it for maximum preventative effect.

20. The Pharmacy Board of Australia and the Pharmaceutical Society of Australia are best placed to determine precisely how to support pharmacists and implement prevention strategies in this challenging area. Further education and amending the Guidelines to provide illustrations and advice as outlined above, are obvious possibilities, as is the establishment of an advice service (with the number stated in the Guidelines). However, I am sure the Board and Society will have further ideas. I therefore make the following recommendations.

> **Recommendation 4.** That the Pharmacy Board of Australia and the Pharmaceutical Society of Australia consult with each other and any other professional body they deem relevant, as to what, if any, further guidance and support should be provided to pharmacists to enable and empower them to discharge their duty of care to patients in situations where they have a concern as to the safety and appropriateness of prescribed medication.
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> **Recommendation 5.** That the Pharmaceutical Society of Australia review its *Standard and guidelines for pharmacists performing clinical interventions* and consider the circumstances in which a pharmacist might be encouraged to provide a copy of a Clinical Intervention Form to the patient and/or prescriber and/or another person.

Provision of information to patients

21. Finally, I turn to the last area of possible prevention opportunity and that is the issue of the communication of important health information to patients. In a recent finding I discussed the

desirability of medical test results being distributed to patients as well as doctors, if for no other reason than to provide an additional safeguard against significant results going unnoticed.[59] The circumstances of this case gives rise to similar considerations. As outlined above the physician's letter of 21 August 2014 outlining important health information about Mr Gilbert was sent to Mr Gilbert's then GP, but not to Mr Gilbert. Mr Gilbert then changed GPs without ever seeing the original GP again, nor ever receiving a copy of that letter. Dr Lim was completely unaware of that letter, nor the significant information contained therein.

22. It is also clear that Kristy and Amanda had only a limited understanding of the extent and seriousness of their father's kidney damage. According to Kristy, in about 2008 they learned that their father had sustained some '*temporary damage*'[60] to his kidneys associated with his aortic aneurysm repair. The next time it came to the fore was in about August 2014 in a consultation with the author of the letter who told them *'that his kidneys were um not the best'*.[61] She explained *'but we were not aware of the actual state ah or severity of the ... kidney disease at that point'*.[62] Later she said his kidney problems were only *'vaguely mentioned'* during that consultation.[63]

23. I make absolutely no criticism of the physician. He was not a witness in the inquest and apart from the above, there is no evidence before me as to what he actually said in his August consultation. It is also completely normal practice for such letters to be sent only to GPs not to patients. The point is, however, that patients commonly do not take in what they are told in consultations. In Australia, unlike some other countries, patients are also free to change GPs and commonly do. If Mr Gilbert had been sent that letter it is reasonable to suppose that his daughters would then have appreciated the extent of his problems. It is also reasonable to suppose his daughters would have taken the letter to his new GP practice and that Dr Lim would have seen it. Faced with such a letter, the likelihood that Dr Lim would have prescribed methotrexate must be considerably reduced. With this in mind I again urge the medical profession, in particular specialist physicians, to send important medical information about patients directly to the patients themselves as well as their GPs. In cases where there has already been a consultation with the physician the argument, previously advanced, that there needs to be an interpretive filter in the form of a doctor, does not exist.

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[59] Finding into death with inquest of Mettaloka Halwala, COR 2015 5857, at [125] to [127].
[60] T 11.14 and T 23.31.
[61] T 11.20.
[62] T 11.25.
[63] T 51.30.

Other matters

24. Kristy Gilbert and Counsel for Ms Barca suggested some other practical measures to reduce the risk of methotrexate toxicity, such as altering the appearance of methotrexate tablets or bottles or limiting the number of tablets in a bottle. I have not canvassed these suggestions in this finding, not because I am of the view they lack merit, but because I am satisfied they do not arise strictly from the circumstances of Mr Gilbert's death.

Distribution list

25. A particularly admirable characteristic of health practitioners is their continuing eagerness not only to learn from issues arising in the practice of medicine, but also to refine this practice so as to improve patient safety and wellbeing. To this end, I include the RACGP, the Royal Australian College of Physicians, the Pharmaceutical Board and the Pharmaceutical Society of Australia in the distribution list, so that, apart from my comments and recommendations above, the lessons to be learned from Ian Gilbert's death can be disseminated to doctors and pharmacists in whatever way is deemed most appropriate and effective. If Ian Gilbert's death were to give doctors and pharmacists cause to reflect on how they relate to each other, this would, in my view, be a positive prevention outcome in and of itself.

26. I also distribute the finding to the Australian Health Practitioner Regulation Agency for information and so that it may take whatever action it sees fit in light of the facts revealed by this case.

I convey my sincerest sympathy to Mr Gilbert's family and friends.

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

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

Amanda Gilbert
Kristy Gilbert
Detective Senior Constable Daniel Sullivan, Coroner's Investigator
Dr Stephen Lim
Jennifer Barca
Dr John Stanton
Dr Peter Hay
Ms Pamela Mathers
Yvette Kozielski, Eastern Health
Royal Australian College of General Practitioners

Royal Australian College of Physicians

Commonwealth Department of Health Services

Therapeutic Goods Authority

Pharmacy Board of Australia

Pharmaceutical Society of Australia

Monthly Index of Medical Specialties Australia

Pfizer Australia Pty Ltd

Hospira Australia Pty Ltd

Australian Health Practitioner Regulation Agency

Victorian Department of Health and Human Services, Safer Care Victoria

Pharmaceutical Defence Limited

Signature:

ROSEMARY CARLIN
CORONER
Date: 14 June 2018.