IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2013 4523

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)

Section 67 of the Coroners Act 2008 (Vic)

I, JOHN OLLE, Coroner having investigated the death of NOELA MCGOWAN
without holding an inquest:
find that the identity of the deceased was NOELA MCGOWAN
born on 20 August 1947
and the death occurred on 7 October 2013
at The Austin Hospital, 145 Studley Road, Heidelberg VIC 3084

from:

1(a) COMPLICATIONS FOLLOWING PARACETEMOL OVERDOSE

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

1. Noela McGowan was born on 20 August 1947 and was 66 years old at the time of her death. She was the recipient of a pension and resided at Hoppers Crossing with her partner Leon Boysen, with whom she maintained a close and loving relationship. She is survived by her partner and children.

2. A coronial brief was provided by Victoria Police to this Court, comprising statements obtained from family, witnesses, treating clinicians and investigating officers. I have drawn on all of this material as to the factual matters in this finding.

BACKGROUND AND CIRCUMSTANCES

3. Ms McGowan had a documented medical history of anxiety, insomnia, depression, panic disorder, chronic pain, hyperlipidaemia, chronic kidney disease, hypothyroidism, gastro-oesophageal reflux disease, elevated cholesterol, a sore throat and productive cough (August 2013) and pharyngitis (1 October 2013). She was prescribed temazepam, thyroxine sodium, tramadol hydrochloride, valium, crestor, maxolon and nexium EC. At no stage was she

prescribed or advised to take paracetamol.[1] Ms McGowan also had a history of suicidal ideation[2] and suicidal attempts, and had been admitted as a psychiatric inpatient in 1990 and 1993.[3]

4. At approximately 7.40am on 5 October 2013 Mr Boysen left for work and kissed Ms McGowan goodbye. Everything appeared to be normal, except that Ms McGowan was sick with a sore throat and flu/virus, which was getting worse. At approximately 4.15pm Mr Boysen returned home and located Ms McGowan lying on her back in bed, with her feet on the floor. She was breathing but not responding and her eyes were open but were not moving. Mr Boysen contacted emergency services and placed Ms McGowan in the recovery position while waiting for an ambulance.[4] A MICA ambulance arrived at 4.27pm. Ms McGowan was unconscious, breathing, had a weak pulse, mottled cold skin and a dry yellow mucous type substance around her mouth. Her body was jerking and posturing (arching her neck/back) while on the bed. She had very low blood pressure, a very low temperature and a very low blood sugar level. Oxygen was administered, an intravenous canula was inserted and intravenous fluids and glucose were administered to raise Ms McGowan's blood pressure. She was also wrapped 'cocoon style' in thermal blankets in attempt to raise her body temperature. At 4.48pm Ms McGowan was transported to Western Health, Footscray.[5]

5. Upon arrival at Western Health Ms McGowan's Glasgow Coma Scale was 8, indicating a severe neurological injury. Her peripheries were cool and pale, her breaths were spontaneous and she was hypotensive. Investigations revealed the presence of severe lactic acidosis with a serum lactate of 19, an arterial pH of 6.85, and a serum HCO^3 of 5. Liver function tests revealed an ALT of 1966 and clotting tests revealed an INR of 7.5. The clinical impression was that Ms McGowan had a severe Mersyndol overdose with associated liver impairment, coagulopathy, acute kidney injury and hypotension. Ms McGowan was intubated and her treatment plan included a fresh frozen plasma infusion to assist with the coagulopathy, N-acetycysteine infusion and the insertion of a central line and inotropic support for the

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[1] Statement of Dr Leonard Breger, dated 5 December 2013, Coronial brief, 13; Statement of Dr Manjit Dhaliwal, dated 5 December 2013, Coronial brief, 16.

[2] Statement of Dr Manjit Dhaliwal, dated 5 December 2013, Coronial brief, 16.

[3] Statement of Leon Boysen, dated 16 March 2014, Coronial brief, 1.

[4] Ibid 3.

[5] Statement of Lavinia Cannon, MICA paramedic, dated 20 April 2014.

hypotension. At 10.30pm Ms McGowan was transferred to the Austin Hospital Intensive Care Unit for specialist treatment.[6]

6. Upon arrival at the Austin Hospital Ms McGowan was commenced on therapies in accordance with the Austin Hospital fulminant liver failure protocol, including noradrenaline, vasopressin and hydrocortisone for shock state, N-Acetyle cysteine for paracetamol overdose, hypertonic saline to reduce cerebral oedema, and high volume continuous veno-venous haemofiltration for control of electrolytes, acute renal failure and to remove toxic by-products not removed in patients suffering fulminant liver failure. Intraveous dextrose was given to prevent hypoglycaemia and broad spectrum antibiotics were administered to treat sepsis. Ms McGowan had a high cardiac output, in keeping with liver failure. At approximately midday on 6 October 2013 Ms McGowan developed marked cardiovascular instability and difficulty with ventilation which prompted the need for bronchoscopy and further cardiac assessment. Investigations suggested the presence of cardiac depression and a cardiac stimulant was commenced with initial improvement. Despite intensive and full supportive therapy, Ms McGowan continued to deteriorate. Ms McGowan was deemed to be not appropriate for liver transplantation, as she was too unwell for anaesthesia and due to concurrent social exclusion criteria. Ongoing critical care support was assessed as futile and, after discussion with Ms McGowan's family, life sustaining therapies were withdrawn and Ms McGowan passed away on 7 October 2013.[7]

7. While providing treatment to Ms McGowan on 5 October 2013, MICA paramedics observed a large number of empty prescription medication packets both next to her bed and in the en-suite. The medication included Mersyndol x 100, Stemetil, Maxolon and Valium.[8] On the same day Mr Boysen also observed two empty Mersydnol packets in the ensuite bin and half a packet in her drawer.[9]

8. Ms McGowan's sister Rhonda Magnussen stated that during the Christmas or Moomba prior to passing away, Ms McGowan informed that she was going to take an overdose, had enough of life and wanted to be with members of her family who had passed away.[10]

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[6] Statement of Dr Om Naidu, Registrar, Western Health, dated 23 January 2014, Coronial brief, 19-20.

[7] Statement of A/Prof Daryl Jones, Austin Health, dated 24 February 2014, Coronial brief, 21-3.

[8] Statement of Lavinia Cannon, above n 5.

[9] Statement of Leon Boysen, above n 3, 4.

[10] Statement of Rhonda Magnussen, dated 27 March 2014, Coronial brief, 8.

POST MORTEM INSPECTION AND REPORT

9. A post mortem inspection and report was undertaken by Dr Sarah Parsons, Forensic Pathologist at the Victorian Institute of Forensic Medicine. Dr Parsons reported that following external examination and review of the Form 83, medical deposition and post mortem CT scan the cause of death is complications following paracetamol overdose.

10. Ante-mortem blood specimens were unavailable for toxicological testing. Post-mortem toxicological analysis of blood detected drugs consistent with therapeutic administration within a hospital setting.

FURTHER INVESTIGATION

Ms McGowan's history of over-the-counter ('OTC') codeine combination analgesics dependence; in particular, Mersyndol

11. The coronial brief contains evidence indicating that Ms McGowan developed a dependence on Mersyndol. It is more likely than not that Ms McGowan may have developed a dependence on codeine, which was contained within the Mersyndol.

12. Codeine is a highly addictive pharmaceutical opioid, and regular users can quickly develop dependence and addiction to OTC codeine combinations. Recently published Australian research suggests there has been a significant increase over time in problematic use of OTC codeine products. The authors concluded:

> While much attention has been paid to stronger opioids such as oxycodone and fentanyl [...] the rate of treatment episodes for codeine dependence suggests attention should be paid to this 'weaker' opioid.[11]

13. Mr Boysen stated that Ms McGowan became 'quite dependant' on Mersyndol for two years, due to taking it for lower back pain and migraines. Although he thought she had reduced her consumption of them in August 2013, when cleaning her room after she passed away he found four full packets of Mersyndol hidden away. He also acknowledged that she would use them to

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[11] Nielsen S, et al, "Changes in non-opioid substitution treatment episodes for pharmaceutical opioids and heroin from 2002 to 2011", *Drug and Alcohol Dependence*, vol 149, April 2015, p.213.

'help her sleep or relax'.[12] Ms McGowan's son Graeme stated that Ms McGowan started taking Mersyndol approximately 8 years prior to her death to 'sleep and calm' her, that there was a period when she would go through a packet every one or two days, that she would ask his partners to 'buy a couple of packets for her' and that he was informed by his aunty that in the weeks prior to passing away, Ms McGowan had access to approximately 15 packets of Mersyndol.[13] Mrs Magnussen further reported that approximately every two weeks her sister would attend a chemist in Hoppers Crossing and buy two packets of Mersyndol, and would sometimes then catch a taxi to another chemist in Werribee to buy more Mersyndol.[14]

14. Although Ms McGowan died of complications following *paracetamol* overdose, it is more likely than not that the paracetamol toxicity originated from her consumption of Mersyndol. Consequently, at my request, the Coroners Prevention Unit[15] reviewed this matter and investigated access to over-the-counter codeine combination analgesics. I have used this information to assist my finding.

Mersyndol

15. 'Mersyndol' is the brand name for two different codeine combination analgesics manufactured by Sanofi-Aventis and sold in tablet form. Mersyndol DayStrength contains a combination of 9.6mg codeine phosphate and 500mg paracetamol per tablet. Mersyndol Forte contains a combination of 30mg codeine phosphate, 450mg paracetamol and 5mg doxylamine per tablet. The evidence contained within the coronial brief (statements of witnesses that Ms McGowan purchased Mersyndol over the counter, and the records from Hogans Corner Pharmacy which suggests the Mersyndol was dispensed without a script) strongly suggests that Ms McGowan was purchasing over the counter 'Mersyndol DayStrength', as opposed to 'Mersyndol Forte'.

16. Mersyndol DayStrength is a Schedule 3 poison under the Poisons Standard. A Schedule 3 poison is defined as:

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[12] Statement of Leon Boysen, above n 3, 2-3.

[13] Statement of Graeme McGowan, dated 17 March 2014, Coronial brief, 10-11.

[14] Statement of Rhonda Magnussen, above n 10, 6.

[15] A specialist service for coroners created to strengthen their prevention role and provide them with expert assistance. Hereafter referred to as 'CPU'. The role of the CPU is to assist coroners investigating deaths, particularly deaths which occur in a healthcare setting. The CPU is staffed by healthcare professionals, including practising physicians and nurses, who are independent of the health professionals and institutions under consideration. The CPU professionals draw on their medical, nursing and research experience to evaluate the clinical management and care provided in particular cases by reviewing the brief of evidence, medical records, the autopsy report and any particular concerns which have been raised.

Pharmacist Only Medicine – Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.

17. As no prescription is required, Mersyndol DayStrength is described as being an over-the-counter (OTC) codeine combination drug. Mersyndol DayStrength is not listed on the Pharmaceutical Benefits Scheme (PBS), which is why it did not appear in Ms McGowan's Pharmaceutical Benefits Scheme Patient Summary, which was provided to the Court.

18. Ms McGowan held an account with Hogans Corner Pharmacy, Hoppers Crossing. Consequently, her Mersyndol purchases were recorded and reveal that between 1 June 2013 and 30 September 2013 Ms McGowan was dispensed a total of 760 tablets of Mersyndol from Hogans Corner Pharmacy. It is unknown how much Mersyndol Ms McGowan additionally obtained through direct purchase from Hogans Corner Pharmacy, which may not have been recorded on her account. It is also unknown how many other pharmacies she attended to obtain Mersydnol, and how much Mersyndol was purchased for her by other people during this period. As Mersyndol is an OTC drug, there are unlikely to be dispensing records from any pharmacy for most of these dispensing events.

What has been done to-date in relation to access to OTC codeine combination drugs

19. There have been a number of recent steps taken to address misuse of OTC codeine combination drugs:

20. The Pharmacy Board of Australia has developed a set of guidelines on supplying Schedule 3 medicines in pharmacy:

> The particular statutory obligations on the supply of Schedule 3 medicines must be observed. The pharmacist must be satisfied that there is a therapeutic need. This means more than agreeing to supply the medicine on request, or merely asking patients if they have used the medicine previously and know how to use it.
>
> Only one package is to be supplied at a time unless there are exceptional circumstances, documentation of which ideally should be kept. The sale of multiple packs of Schedule 2 or Schedule 3 medicines (other than in exceptional circumstances) and failure to comply with local jurisdiction

regulations applying to Schedule 2 and Schedule 3 medicines and these guidelines may be considered as unprofessional conduct.[16]

21. The Pharmaceutical Society of Australia ('PSA') has produced and published a guidance document for the provision of Combination Analgesics Containing Codeine. In 2015 the PSA added a new cautionary advisory label (No.24) for pharmacists to use when supplying OTC analgesics to advise consumers for potential for addiction with continuous use, together with a consumer information leaflet explaining the risks of these products. The PSA also have a guidance document titled 'Guidance for the provision of combination analgesics including codeine', and has developed education and training resources that explicitly address how to raise and discuss issues of addiction and harm minimisation with patients.[17]

22. The Pharmacy Guild of Australia ('PGA'), in partnership with other stakeholders, developed a warning label for OTC codeine products which states 'For 3 days only – Can cause addiction' which have been widely distributed and are being used by community pharmacies.[18] Further, some individual pharmacies are noted to have policies of recording sale of OTC codeine products, although this is not linked across all pharmacies so does not allow a pharmacist to know when a customer has attended another pharmacy for the same type of drugs.

Real-time monitoring of dispensing of OTC codeine products

23. There is currently no legal requirement for pharmacists to record the supply of OTC sales of codeine products. Although some individual pharmacies have chosen to implement recording of such supply to customers, the record is only helpful in checking whether a customer has previously purchased OTC codeine products at that pharmacy, which does not address the issue of 'pharmacy shopping', which appears to have occurred in this case.

24. The PGA believes that there needs to be a real-time monitoring solution, which involves the patient consenting to the recording of information about the supply of codeine products onto a central database that can be accessed by all pharmacies Australia-wide.[19] The PSA also supports real-time prescription monitoring and has called for the Electronic Recording and

[16] Statement of Allan Crosthwaite, dated 28 April 2015, The Pharmacy Guild of Australia.

[17] Statement of Bill Suen, dated 30 April 2015, Pharmaceutical Society of Australia.

[18] Statement of Allan Crosthwaite, above n 16.

[19] Ibid.

Reporting of Controlled Drugs initiative to be expanded to include all drugs of dependence, including OTC analgesics.[20]

Rescheduling of OTC codeine products

25. The Royal Australasian College of Physicians ('RACP') notes that codeine is not permitted to be dispensed OTC in most of Europe and the United States, and notes that "legislation may go some way to reduce" OTC codeine harms in Australia.[21] The PGA does not support rescheduling of OTC codeine products as this would reduce access to those with a genuine therapeutic need, while increasing the burden on the health system (e.g people needing to go to the doctor for a script for a combination preparation they used to be able to buy over the counter). The PGA submitted that real-time monitoring would be a "more sophisticated tool" for combating misuse and associated harms.[22] This issue is currently being considered by the Therapeutic Goods Administration.

Consumer education

26. The PGA advocates the need for a consumer education campaign designed to inform the public about the risks associated with misuse of OTC codeine products.[23] The PSA agrees that public education, particularly about the harmful effects of prolonged use/misuse of paracetamol and ibuprofen, is extremely important and proposes putting further 'very clear' mandatory warning labels on OTC codeine combinations regarding the risks of ibuprofen and paracetamol taken at high doses or for long periods.[24]

27. Professor Colin Chapman, Community Pharmacist, Immediate Past-Dean at Monash University Faculty of Pharmacy and Pharmaceutical Sciences and Member of the PSA, also supports enhanced direct/explicit warning labels about the toxicities associated with excessive doses of paracetamol, and provides an excellent overview of how this could be achieved. He recommended that the Australian Pharmaceutical Formulary be amended to include a new 'Caution and Advisory Label' (CALs) warning about excessive doses of paracetamol, and

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[20] Statement of Bill Suen, above n 17.

[21] Statement of Dr Matthew Frei, dated 30 April 2015, The Royal Australasian College of Physicians.

[22] Statement of Allan Crosthwaite, above n 16.

[23] Ibid.

[24] Statement of Bill Suen, above n 17.

suggested that it can be used whenever paracetamol/codeine combination products are supplied or dispensed.[25]

COMMENTS

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

Real-time monitoring in relation to dispensing of OTC codeine products

28. Evidence contained within the coronial brief indicates that Ms McGowan had developed a dependence on OTC Mersyndol, a codeine combination analgesic. Ms McGowan also appeared to also be 'pharmacy shopping'; attending a pharmacy at Hoppers Crossing to purchase Mersyndol and then sometimes catching a taxi to a pharmacy in Werribee to purchase more Mersyndol. Mandatory reporting of sales of codeine products would enable detection of pharmacy shopping. Pharmacists could prevent over-supply of OTC codeine products to customers and also direct customers to appropriate clinicians to address their codeine dependence. I support real-time monitoring of dispensing of OTC codeine products. However, I cannot make a comment as to what monitoring solution would be most appropriate in this circumstance, and welcome consideration of this aspect of real-time monitoring in relation to dispensing of OTC codeine products.

RECOMMENDATIONS

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

29. With the aim of minimising risk and preventing like deaths, I recommend that a new 'cautionary and advisory' label be included in the Australian Pharmaceutical Formulary, warning about the toxicities associated with excessive doses of paracetamol, and I recommend that the CAL be used whenever paracetamol/codeine combination products are supplied or dispensed.[26]

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[25] Statement of Prof Colin Chapman, dated 5 May 2015.

[26] Statement of Prof Colin Chapman, dated 5 May 2015.

FINDING

30. I am satisfied, having considered all of the evidence before me, that no further investigation is required. I am satisfied that there is no evidence to suggest the involvement of any other person in this death.

31. The evidence satisfies me that the medical management and care provided by Ambulance Victoria, Western Health and The Austin Hospital was reasonable and appropriate in the circumstances, having regard to the complexities involved.

32. I find that Noela McGowan died on 7 October 2013 and that the cause of her death is complications following paracetamol overdose. While it is possible that Ms McGowan consumed the drugs with the intention of taking her own life, I am not able to make any finding as to intent based on the evidence available, and find that it is more likely than not that the death was accidental.

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

The family of Noela McGowan;
The Pharmaceutical Society of Australia;
The Royal Australasian College of Physicians;
The Pharmacy Guild of Australia;
Investigating Member, Victoria Police; and
Interested parties.

Signature:

JOHN OLLE
CORONER
10 August 2015