IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2013 002123

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)
Section 67 of the ***Coroners Act 2008***

I, ROSEMARY CARLIN, Coroner having investigated the death of KELLY ELIZABETH HALL without holding an inquest:
find that the identity of the deceased was KELLY ELIZABETH HALL
born on 10 January 1970
and the death occurred on 16 May 2013
at residential premises, St Albans, Victoria

from:

1(a) MIXED DRUG TOXICITY INCLUDING METHADONE

Pursuant to section 67(1) of the *Coroners Act 2008* there is a public interest to be served in making findings with respect to the following circumstances:

1. Kelly Elizabeth Hall was born on 10 January 1970. She was 43 years old when she died of combined drug toxicity in May 2013. Ms Hall lived with her father, John Hall, in St Albans, Victoria. She is survived by her family.

2. Victoria Police compiled a brief for the Coroner which included statements from John Hall, letters from Ms Hall's treating general practitioners, Dr Elizabeth Leder and Dr Craig Smith and statements from investigating police officers. During my investigation I obtained additional material as follows: reports from a forensic pathologist, a toxicologist and Medicare; medical and pharmacy records; a supplementary letter from Dr Leder and a

supplementary letter from Dr Smith[1]. I also received advice from the Coroners Prevention Unit (**CPU**) as to Ms Hall's clinical management and the coordination of care between her general practitioners.

MEDICAL AND PRESCRIBING HISTORY

3. Ms Hall's medical history included heroin and benzodiazepine addiction and alcohol abuse. She also suffered hepatitis C, morbid obesity, chronic back pain and sciatica, anxiety and depression. She is reported to have been diagnosed with borderline personality disorder by a psychiatrist at North Western Mental Health in 2007.

4. Ms Hall regularly consulted with two general practitioners, Dr Leder at Barkly Street Medical Centre in St Kilda and Dr Smith at St Mary's Medical Centre in St Albans. Dr Leder was her main general practitioner. She first attended Barkly Street Medical Centre in 1994 and began seeing Dr Smith in 2007. Dr Leder and Dr Smith both prescribed medication to Ms Hall and although they became aware of each other, they did not formally coordinate their care of Ms Hall.

5. In 1995 Dr Leder obtained a permit from Drugs and Poisons Regulation (**DPR**) at the then Department of Human Services (now Department of Health and Human Services (**DHHS**)) to prescribe methadone to Ms Hall as opioid replacement therapy. She said Ms Hall participated in a methadone program from 1995-1997 but then 'developed another heroin habit'. In January 2000 she re-commenced methadone and this continued until her death. As well as methadone Dr Leder prescribed anti-depressants and benzodiazepines to Ms Hall.

6. In 2007 Ms Hall began seeing Dr Smith and he treated her for a range of conditions including lumbar disc prolapse, anxiety and depression. He prescribed amitriptyline (brand name Endep) for depression and pregabalin (brand name Lyrica) to manage her pain.

7. According to Dr Leder, Ms Hall's mental and physical health declined after her mother became ill in about 2010. She described Ms Hall as not coping with family stressors, drinking heavily at times, using heroin and 'buying' prescription medication.

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1 In this Finding words within quotation marks are direct quotations from the statements or letters of the individuals concerned and shall not be the subject of further citation.

8. From June 2010, Dr Leder prescribed Ms Hall five takeaway doses of methadone per week. She divided these doses so that Ms Hall could only access two doses on the first occasion and three doses on the second occasion.

9. According to Dr Leder, Ms Hall mentioned that she was also seeing Dr Smith during consultations in September and October 2011. Dr Leder requested that Ms Hall bring in Dr Smith's contact details as she intended to add his name to her *Team Care Arrangement* and forward a copy to him, however 'unfortunately this did not occur'. Dr Leder said Ms Hall told her Dr Smith was prescribing Lyrica for her back pain. Dr Leder stated 'I did not inform Dr Smith of what drugs I was prescribing as I was not in contact with Dr Smith'.

10. According to Dr Smith, he first became aware Ms Hall was also seeing Dr Leder on 23 February 2012. Dr Smith said he spoke to Dr Leder around February or March 2012 and explained he was treating Ms Hall. He said they discussed what drugs Dr Leder was prescribing and her DPR permit. Despite that, Dr Smith said he was unaware that Dr Leder was prescribing methadone and believed her permit was to prescribe opioids for analgesia. He reported that he was unaware that Ms Hall had a longstanding benzodiazepine dependence, nevertheless he stopped prescribing benzodiazepines to Ms Hall after 23 February 2012. He also said he checked the *Doctor Shoppers Hotline* and confirmed Ms Hall was not listed as doctor shopping.

11. On 19 March 2013 Ms Hall attended Dr Leder and obtained her 'usual prescriptions'. She informed Dr Leder she was consulting Dr Smith, who was closer to her home, for her 'other medical concerns'. Dr Leder prescribed methadone syrup (45mg daily); diazepam (25mg daily), oxazepam (30-60mg nightly as needed) and zopiclone (7.5mg nightly as needed) all for anxiety and insomnia; duloxetine (120mg daily) for depression; and a paracetamol-codeine combination medication (500mg paracetamol and 30mg codeine per tablet, daily dose not specified) for back pain. The methadone was dispensed at twice-weekly pharmacy attendances, and included five takeaway doses dispensed for unsupervised consumption per week. The diazepam was dispensed with the methadone, in quantities consistent with the amount required to last until the next pharmacy attendance.

12. On 2 April 2013 Ms Hall attended Dr Smith. He noted she had a dental infection which required antibiotics. He prescribed amitriptyline (50mg nightly) for depression and anxiety,

paracetamol and codeine as analgesia, zopiclone (15mg nightly) for insomnia and pregabalin (450mg daily) for her disc prolapse.

13. Ms Hall had the prescriptions she obtained from Dr Leder and Dr Smith dispensed in the weeks leading up to her death. All of Dr Leder's prescriptions were dispensed by the one pharmacy, Nam Anh Pharmacy. Dr Smith's prescriptions were dispensed by two different pharmacies, Thao Nguyen Pharmacy and TA LY & TV LY Pharmacy.

CIRCUMSTANCES OF DEATH

14. At around 7 p.m. on 16 May 2013, Ms Hall's father noticed the pet cat trying to get into his daughter's bedroom. The last time he had seen his daughter was about 3.a.m. when she was going to bed after falling asleep in front of the television. Mr Hall opened the door and saw his daughter hunched over on the floor. She was unresponsive and he telephoned emergency services.

15. Paramedics arrived shortly after, but found that Ms Hall was already deceased.

16. Police also attended the scene. They located a number of empty prescription medication packets and related items on the bedroom floor, in a plastic rubbish bag and on Ms Hall's bed. Of relevance there were two empty methadone bottles with expiry dates 16 and 17 May 2013, a prescription to Ms Hall from Dr Smith for pregabalin, drug paraphernalia, a zip lock bag containing remnants of white powder, empty blister packs of diazepam, pregabalin, paracetamol and duloxetine, and partially full blister packs and/or boxes of diazepam, pregabalin, duloxetine and amitriptyline.

FORENSIC MEDICAL EXAMINATION

17. Dr Yeliena Baber, Forensic Pathologist at the Victorian Institute of Forensic Medicine conducted an autopsy on Ms Hall on 21 May 2013 and reviewed the results of toxicological testing of blood specimens taken from Ms Hall.

18. Toxicological analysis detected **methadone** (0.4mg/L) and its metabolite EDDP (0.05mg/L), **amitriptyline** (0.6mg/L) and its metabolite nortriptyline (0.4mg/L), **pregabalin** (15mg/L),

duloxetine (0.37mg/L), **diazepam** (0.5mg/L) and its metabolite nordiazepam (0.8mg/L) and **paracetamol** (21mg/L).

19. Interpretation of post mortem toxicology is difficult because many drugs are subject to post mortem changes and there may be considerable overlap between therapeutic and toxic levels. Some of the drugs in Ms Hall's system appeared elevated, however there is no clear evidence that Ms Hall had consumed any of the drugs in excess of the levels prescribed to her.

20. Kerry Crump, Senior Toxicologist at VIFM reported that the combination of drugs in Ms Hall's system could result in toxic or fatal outcomes. She noted that a number of the drugs are central nervous system (**CNS**) depressants (such as the benzodiazepines) and interact with each other to produce more profound CNS and respiratory depression and sedation. In particular, pregabalin interacts with opioid analgesics and other CNS depressants and methadone has an additive CNS depressive effect when used concurrently with alcohol and other CNS depressants. Further, the toxic effects of amitriptyline may be enhanced by other drugs[2].

21. Dr Baber's autopsy did not identify any natural disease to a degree that may have caused or contributed to death. Histology revealed mild chronic ischaemic changes within the heart and features in the liver suggestive of viral hepatitis. Dr Baber found that the combination of drugs detected in Ms Hall's blood was likely to have been fatal. She determined her cause of death to be mixed drug toxicity including methadone. I accept that opinion.

SOURCE OF THE FATAL COMBINATION OF DRUGS

22. Ms Hall died from a combination of methadone, amitriptyline, pregabalin, duloxetine, diazepam and paracetamol.

23. The evidence indicates the prescription only drugs were prescribed by Dr Leder (methadone, duloxetine, diazepam) and Dr Smith (amitriptyline, pregabalin). The paracetamol could have come from panadeine forte prescriptions from Dr Leder and/or Dr Smith and/or over the counter Panadol.

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2 Methadone is known to interact with amitriptyline to produce cardiac effects and duloxetine is known to interact with amitriptyline to produce serotonin syndrome.

ISSUES IDENTIFIED

Coordination of care

24. Ms Hall died from a combination of pharmaceutical drugs prescribed by two different medical practitioners who were aware of each other but did not coordinate their care. The importance of medical practitioners knowing what drugs their patients are taking and in what amounts, has been often repeated in this Court. This case is yet another illustration of the fact that combinations of prescription drugs, even if taken at therapeutic levels, can have serious, even fatal effects.

25. Better knowledge sharing and coordination of care between Dr Leder and Dr Smith would have provided each practitioner with a more complete clinical picture to inform his or her treatment of Ms Hall and may have led to a modification of prescribing given the known interactions of the drugs each was prescribing.

26. Dr Leder stated 'I had requested that Kelly Hall keep me informed about any other drugs she may be prescribed by other doctors. She complied with my request and would tell me about other treatments and medication she was receiving elsewhere'. Despite stating this, when asked what drugs Dr Smith was prescribing, Dr Leder only reported knowing about pregabalin.[3]

27. General practitioners should entertain a degree of suspicion about what their drug dependent patients tell them as to their drug use. Apparently trustworthy patients may be unreliable, forgetful or dishonest. General practitioners would be wise not to rely on such patients to report medications prescribed to them by other medical practitioners. Where possible they should seek independent verification by contacting the other treating practitioners.

Take away methadone

28. Dr Leder had been prescribing Ms Hall five takeaway methadone doses per week since June 2010 despite knowing of her drug dependence and alcohol use.

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3 Dr Leder was asked this in correspondence from the Court.

29. DPR is responsible for guidance and regulation around the delivery of opioid replacement therapy in Victoria. Its key policy for this purpose is the *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, which was first published in 2006 when the DPR was part of the Department of Human Services. The DPR, under the auspices of the Department of Health, published a revised Policy for Maintenance Pharmacotherapy for Opioid Dependence in January 2013.

30. Both the 2006 and 2013 versions of the policy provide strong guidance as to when patients should be given access to takeaway methadone dosing. This guidance is necessary because takeaway methadone dosing creates a range of opportunities for harmful use and misuse that do not exist in supervised dosing (where the methadone is consumed in front of a pharmacist at a pharmacy). The risks include:

- hoarding and consumption outside the recommended dosing schedule;
- unsafe consumption, for example by injecting rather than drinking the methadone or taking it in combination with alcohol or other CNS depressants;
- diversion (sharing methadone or selling to other people); and
- third parties gaining access to methadone.

31. The documented contraindications to takeaway methadone dosing include harmful alcohol use, regular heroin use and dependent benzodiazepine use[4], all of which Dr Leder noted in the months leading up to Kelly Hall's death.

32. Dr Leder said she consulted the DPR policy. She acknowledged that under the policy, Kelly Hall's 'self-reported lack of stability demanded a high level of supervised methadone dosing', and that her takeaway dose prescribing was 'outside these guidelines'. She knew Ms Hall was impulsive, sometimes abused alcohol and heroin, was benzodiazepine dependent and sometimes bought other prescription drugs, however she was also grossly obese with limited mobility and no car and access to the nearest pharmacy was difficult. She believed Ms Hall would be 'safer if she remained on pharmacotherapy and connected to medical supervision and support'. Dr Leder made the decision to continue with takeaway methadone treatment as she was 'reassured' by the facts that Ms Hall's dose was relatively low at 45mg daily, her pharmacist had no concerns, there was never an issue with lost or stolen doses, Ms Hall was

4 See pages 25 and 26 of the *Policy for Maintenance Pharmacotherapy for Opioid Dependence* 2013 version.

truthful and regular in her appointments and never presented to her or the pharmacist as drug or alcohol affected.

33. Ms Hall's use of other drugs in combination with her methadone placed her at greater risk of a fatal overdose. I acknowledge the difficulties involved in making these decisions, however I am not persuaded departure from DPR guidelines was justified in Ms Hall's case. That Ms Hall could not be trusted with takeaway methadone is illustrated by the fact attending police found two empty bottles of methadone at her home dated 16 and 17 May 2013, indicating she either consumed her 17 May bottle before the due date or otherwise disposed of the contents.

Long-term diazepam prescribing

34. Dr Leder had been prescribing diazepam and oxazepam to Ms Hall since at least 2010. The dosages had remained constant throughout. Medicare and Nam Anh Pharmacy records indicate that at least since 2011 the diazepam was prescribed privately meaning that it was not covered by the pharmaceutical benefit scheme and not recorded by Medicare.

35. Dr Leder noted on Ms Hall's diazepam prescriptions that it was to be dispensed daily. The arrangement with Nam Anh Pharmacy was that it was to be dispensed with Ms Hall's methadone and on the same takeaway regime.

36. Benzodiazepines such as diazepam and oxazepam are commonly prescribed to treat a range of conditions including insomnia and anxiety disorders. However, they are highly addictive and patients with a history of drug dependence are particularly susceptible to becoming addicted to them. For this reason published guidelines only support long term prescribing in exceptional circumstances.

37. In the two letters she provided for the coronial investigation Dr Leder indicated she was prescribing diazepam to Ms Hall to treat her anxiety and insomnia. By contrast, Dr Leder's undated *GP Management Plan* recorded that Ms Hall was 'Stable on 25mg Valium daily' for her 'Benzodiazepine Addiction'. This plan contained a notation 'consider gradual weaning of dose'.

38. In 2015 The Royal Australian College of General Practitioners published guidelines on its website as to prescribing benzodiazepines: *Prescribing drugs of dependence in general practice, Part B – Benzodiazepines.* The DHHS website also has *Therapeutic Guidelines* as to the prescribing of benzodiazepines and other drugs. Both guidelines make it clear that long term therapeutic use of benzodiazepines is rarely justified. Further, both guidelines advocate treatment of benzodiazepine dependence by gradual reduction of the dose over time with the goal of complete cessation, rather than any form of maintenance therapy, such as suggested by Dr Leder's *GP Management Plan.*

39. Dr Leder stated she tried several strategies to reduce Ms Hall's benzodiazepine consumption and 'had proposed weaning regimes'. She said she counselled Ms Hall regarding her diazepam use, however she 'seemed to go from one stressful situation to another and felt she could not cope with a benzodiazepine reduction while stressed'. She also said she referred Ms Hall to other clinicians to assist with the plan to reduce her benzodiazepine consumption.

40. No doubt Dr Leder faced a difficult situation in treating Ms Hall, however this is the case with most, if not all, drug dependent patients. Optimal care required a more diligent approach to reducing and then eliminating Ms Hall's benzodiazepine usage, particularly given Ms Hall was a long term user of other drugs and was on opioid replacement therapy.

Contacting the DPR

41. Section 33 of the *Drugs Poisons and Controlled Substances Act 1981 (Vic)* requires a medical practitioner to notify DPR if he or she has reason to believe a patient is drug-dependent and the patient requests or is supplied a drug of dependence. Drugs of dependence, listed in Schedule 11 to the Act, include all benzodiazepines.

42. Aside from any legal obligation, it is best practice for medical practitioners to contact DPR about drug dependent patients because of the information they can glean. DPR staff are empowered to inform medical practitioners about previous notifications received and other practitioners' stated intent to supply drugs, or not, to the patient, as well as the following information:

- Whether any other medical practitioner holds a permit to treat a patient with Schedule 8 poisons, including patients receiving methadone or buprenorphine to treat opioid dependence
- Aliases that have reportedly been used by drug seeking patients
- Whether reports of forged or fraudulent prescriptions, or of obtaining drugs of dependence by false representation, have been received in relation to the patient.

43. The more information a medical practitioner has about a complex drug dependent patient the greater the scope for identifying potential interventions, or at the very least of preventing harm by unwittingly prescribing drugs which may interact with other drugs or permit excess consumption.

44. Dr Leder did not inform the DPR that she was prescribing benzodiazepines to Ms Hall. She explained that she did not believe she needed to do so given that she held a permit to prescribe methadone to Ms Hall. She was 'under the impression one notification was sufficient' because over the years DPR had notified her 'of any benzodiazepine notifications it had received from other prescribers for patients for whom I held a pharmacotherapy permit'. Dr Leder indicated that after enquiring with DPR as to her obligations in future she would make a separate notification to DPR when prescribing benzodiazepines to a drug dependent patient.

45. Dr Smith stated he called the 'Doctor Shoppers hotline' to confirm Ms Hall was not on it. However, the 'Doctor Shoppers hotline' is only one - and an imperfect - avenue to find out about potential drug seeking patients.[5] Information should also be sought from DPR as a matter of course. Additionally I note that Kelly Hall would not be accurately described as a doctor or prescription shopper; she informed Dr Smith and Dr Leder about one another, and as already noted they failed to coordinate their prescribing to her.

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5 The Prescription Shopping Information Service (PSIS) is run by the Commonwealth Department of Human Services. A doctor who has concern that a patient is accessing medications in excess of therapeutic need can register with the PSIS and then call a hotline number to find out whether the patient has met the Prescription Shopping Program criteria. The criteria are that within a three-month period the patient has been supplied (a) pharmaceutical benefits from six or more different prescribers, or (b) 25 or more target pharmaceutical benefits, or (c) 50 or more pharmaceutical benefits. If the patient meets the criteria, the doctor is alerted and can find out further information about the medications supplied to the patient and how many prescribers were involved.

While the PSIS can be a useful resource when a person is obtaining large quantities of medications on the PBS from several doctors, it would have been of no use for understanding the drugs dispensed to Kelly Hall, who was attending only two doctors and was being dispensed at least dizepam on private scripts outside the PBS system.

FINDINGS

46. Kelly Hall died on 16 May 2013 after consuming a combination of pharmaceutical drugs prescribed to her by two different general practitioners, Dr Leder and Dr Smith.

47. Kelly Hall was at risk of a pharmaceutical overdose given her history of drug use and drug dependence.

48. A number of the drugs taken by Ms Hall were capable of interacting to produce more pronounced central nervous system effects and/or toxic effects. Drugs prescribed by Dr Leder and Dr Smith were capable of interacting in this way.

49. The combination of drugs taken by Kelly Hall was fatal and she died from mixed drug toxicity.

50. Dr Leder and Dr Smith knew about each other but did not co-ordinate their care of Ms Hall. In particular, they did not ascertain precisely what the other was prescribing.

51. There is no evidence to indicate that Kelly Hall intended to end her life and I find that her death was accidental.

COMMENTS

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

1. Apart from establishing the cause and circumstances of reportable deaths, coroners have another fundamental role and that is to identify ways of preventing similar deaths in the future.

2. Pharmaceutical drug overdoses tend to enliven this prevention role. I note that the CPU recently compiled and analysed its updated data on Victorian drug overdose deaths for the period 2009-2015. A copy of the CPU's Data Summary, dated 16 March 2016, is annexed to my colleague Coroner Jamieson's recent finding into the death of Frank Frood (COR 2012 004080). The highlights of the analysis include:

- Between 2009 and 2015 there was an average of 376 overdose deaths per year in Victoria. The annual frequency of Victorian overdose deaths declined between 2009 (379 deaths) and 2010 (342 deaths), however every year since then it increased, reaching 420 deaths in 2015.
- Most deaths each year (70% on average) were the result of combined drug toxicity rather than a single drug. Further, pharmaceutical drugs consistently contributed to approximately 80% of overdose deaths each year. By contrast illegal drugs contributed to around 40% of overdose deaths each year between 2009 and 2014 (52% in 2015); and alcohol consistently contributed to just under 25% of all overdoses across the period.
- Among pharmaceutical drugs, benzodiazepines were the most frequent contributing drug group to Victorian overdose deaths – and the benzodiazepine diazepam was the most frequent individual contributing drug. Year on year, between 2009 and 2015, the annual frequency of overdose deaths in which benzodiazepines played a contributory role increased steadily. Opioid analgesics were the next most frequent contributors, followed by antidepressants and antipsychotics.

3. The CPU Data Summary shows that the dominant role of pharmaceutical drugs in Victorian overdose deaths has not diminished despite increasing awareness of the dangers of pharmaceutical drugs and recent safety-focused initiatives such as improved prescribing guidelines, drug rescheduling and reformulation of some drugs into (purportedly) safer preparations.

4. In the context of the Data Summary, it is clear that the death of Ms Hall was typical of the overdose deaths Victoria's coroners investigate. In saying this I do not in any way intend to diminish the significance of the death for Ms Hall's family and loved ones. Rather, I am highlighting the urgency of addressing the pharmaceutical drug related issues that underpinned Ms Hall's death, and which underpin so many other deaths of Victorians each year.

Royal Australian College of General Practitioners (RACGP) guidelines

5. Ms Hall fatally overdosed on a combination of drugs prescribed by two different medical practitioners who knew about each other but did not co-ordinate their care. The RACGP standards and guidelines for coordination of care in general practice and prescribing drugs of

dependence emphasise coordination between clinicians at a single clinic and between general practitioners and other health providers, including specialists, but not between general practitioners at different clinics. Guidelines for coordination of care between general practitioners at different clinics would appear a natural and warranted extension of the existing guidelines, particularly in the absence of a system for real-time prescription monitoring.

Real Time Prescription Monitoring (**RTPM**)

6. Whilst communication between doctors was an issue in Ms Hall's death, it was facilitated by a broader systemic issue, being the lack of a real time prescription monitoring (**RTPM**) system for drugs dispensed in Victoria.

7. If RTPM had existed Dr Leder and Dr Smith would have been aware of what the other was prescribing without the need to make contact. Further, the three different pharmacies dispensing the drugs prescribed by Dr Leder and Dr Smith in the weeks before Ms Hall's death would have been aware of all drugs prescribed to her. It is possible this greater knowledge would have led to a modification of prescribing by the doctors or an intervention by a pharmacist, thereby preventing Ms Hall's death.

8. There is an ongoing urgent need for Victoria to implement a RTPM system to achieve reductions in pharmaceutical drug related harms and deaths. An RTPM system will, for the first time, enable prescribers and dispensers to find out what drugs a presenting patient has been dispensed in what quantities, when and by whom. This will have enormous benefits in assisting clinicians to make informed prescribing and dispensing decisions, and to coordinate the care they provide to patients.

9. In addition, an RTPM system will enable a range of other prevention-focused interventions: for example identifying doctors whose prescribing practices might be clinically suboptimal so they can be provided targeted education; identifying prescription shoppers; and providing automated warnings to prescribers and dispensers regarding potential issues with drug interactions and drug quantities.

10. For over 15 years Victorian coroners have been calling for the implementation of an RTPM system in Victoria. Victorian coroners have directed recommendations in at least 10 findings

to the DHHS (and its predecessor the Department of Health) regarding the urgent need for an RTPM system since the *Coroners Act 2008* was enacted.

11. In a 23 September 2015 response to Coroner Olle's recommendations in the death of James Dougan (20104459), Victorian Department of Health and Human Services Acting Secretary Kym Peake indicated that an RTPM Project Taskforce had been established and that the Government had committed $300,000 to evaluate and plan for the implementation of a RTPM system. He stated:

> *This implementation planning work will ensure that Victoria implements this important and potentially lifesaving system in the most effective way.*

12. Coroners Court of Victoria representatives were invited to participate in a November 2015 stakeholder consultation as part of this RTPM implementation planning process.

13. In February 2016 the Victorian Department of Health and Human Services published a Communique providing an update of the RTPM Taskforce's progress, which indicated, inter alia, that:

> *All Health Ministers have agreed to work together towards the timely implementation of real-time prescription monitoring across all States and Territories.*
>
> *The outcomes of the Victorian planning projects are currently being considered by the Victorian Government and the department will continue to provide updates and engage with all key stakeholder groups as implementation progresses.*

14. Whilst appearing to herald further progress, this February 2016 Communique is cause for concern, in so far as it suggests that the Victorian RTPM implementation is dependent upon national implementation of the RTPM project, known as the Electronic Recording and Reporting of Controlled Drugs (ERRCD) initiative.

15. My colleagues Coroner Olle and Coroner Jamieson have previously raised doubts about the wisdom of Victoria linking its RTPM implementation efforts to any national initiatives given the potential for delay[6].

16. I acknowledge the complexities of implementing a RTPM system and that there appears to have been progress, however Victorians continue to die from fatal overdoses involving pharmaceutical drugs. If Victoria links its RTPM efforts with nationally coordinated initiatives I too am concerned that there could be ongoing significant delays with the consequence that prescription deaths will continue unabated.

Rescheduling of benzodiazepines

17. As already noted, the CPU overdose deaths data shows that benzodiazepines were the most frequent contributing drug group in Victorian overdose deaths for 2009-2015 and every year the frequency increased. Clinically suboptimal prescribing of benzodiazepines – including prescribing higher than recommended doses, prescribing for longer than recommended periods, prescribing to drug dependent patients, prescribing multiple benzodiazepines in combination, and prescribing without checking whether other doctors are also prescribing the same drugs – is a recurring theme in coroners' investigations into Victorian overdose deaths. There is clearly an urgent need to re-visit the question of benzodiazepine rescheduling, which in my view has still not been satisfactorily resolved.

18. By way of background, in Australia most poisons (including medicines) are classified by the Therapeutic Goods Administration (**TGA**) into one or more Schedules according to the Poisons Standard (which comprises in chief the Standard for the Uniform Scheduling of Medicines and Poisons, or **SUSMP**). The level of Schedule determines the level of control over the availability of that poison. As explained in the 2011 iteration of the SUSMP:

> *Poisons are not scheduled on the basis of a universal scale of toxicity. Although toxicity is one of the factors considered, and is itself a complex of factors, the decision to include a substance in a particular Schedule also takes into account many other criteria such as the purpose of use, potential for abuse, safety in use and the need for the substance. This*

6 Finding into death without inquest of James Pirotta (20095181) delivered on 15 February 2012 and Finding into death without inquest of Kirk Ardern (20122254) delivered on 7 April 2014.

Standard now lists poisons in nine Schedules according to the degree of control recommended to be exercised over their availability to the public. Poisons for therapeutic use (medicines) are mostly included in Schedules 2, 3, 4 and 8 with progression through these schedules signifying increasingly restrictive regulatory controls.[7]

19. Schedule 4 poisons are:

Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.

20. Schedule 8 poisons are:

Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

21. In 2012 most of the benzodiazepines prescribed in Australia (with the exception of flunitrazepam) were listed in Schedule 4 of the SUSMP. However, given that they are highly addictive drugs, are frequently abused and misused, and are involved in more Victorian overdose deaths than any other drug type, there has been a persistent concern that as a group benzodiazepines would be more appropriately listed in Schedule 8. Acting on this concern, on 18 May 2012 Coroner Jamieson recommended in her Finding into the death of David Trengrove that:

To reduce the harms and death associated with benzodiazepine use in Victoria, within 12 months the Therapeutic Goods Administration of the Australian Government Department of Health and Ageing should move all benzodiazepines into Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons.

22. In its initial response dated 6 November 2012, the TGA rejected this recommendation for a number of reasons including the cost of tighter regulation to both the government and the

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7 Australian Government Department of Health and Ageing, Poisons Standard 2011, 2 August 2011.

pharmaceutical industry, and the lack of evidence that rescheduling would have saved David Trengrove's life. However, on 29 November 2012 the TGA announced an invitation for public comment regarding a proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8 of the SUSMP and confirmed in correspondence with the Court, that Coroner Jamieson's recommendation was being treated as an application for rescheduling.

23. On 23 May 2013, a delegate of the Secretary to the Department of Health and Ageing published the interim decision and reasons for decision regarding the proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard). The decision was that among the Schedule 4 benzodiazepines, only alprazolam[8] should be rescheduled to Schedule 8. The reasons for the interim decision comprised the following:

a) Alprazolam has increased morbidity and mortality in overdose with possible increased toxicity. It does not appear to have any additional therapeutic benefits compared with any other substance in the class.
b) There has also been a rapid increase in use of Alprazolam compared with other benzodiazepines and evidence of widespread misuse.
c) Concerns of possible increased toxicity.
d) Concern that current pack size is inappropriate for indications.
e) There is evidence of abuse of the substance and misuse with opioids.
f) Listing in Schedule 8 of Alprazolam does not restrict its short-term use for the approved indication.

24. Coroner Jamieson responded to this decision, indicating that while the decision to reschedule alprazolam was welcomed, all other benzodiazepines should also be moved to Schedule 8 because benzodiazepines generally (not just alprazolam in particular) are targeted for misuse and diversion; dependence and fatal overdose and misuse in combination with opioids likewise occurs across all benzodiazepines; and the qualitatively similar pharmacological effects of all benzodiazepines mean that any initiative to limit access to one benzodiazepine will most likely shift harms to other benzodiazepines rather than reducing overall harms.

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8 Alprazolam is available under brand names such as Xanax, Kalma, Alprax, Ralozam amongst others.

25. On 28 June 2013 the TGA published its final decision that only alprazolam would be rescheduled to Schedule 8 and the scheduling of all other benzodiazepines would remain the same[9]. Coroner Jamieson, in a subsequent finding into another death from combined drug toxicity including heroin, methadone and multiple benzodiazepines, repeated her concerns that rescheduling alprazolam in isolation would simply shift harms to other benzodiazepines and recommended that all other benzodiazepines be rescheduled to Schedule 8 because they present the same risks as alprazolam.[10]

26. The TGA did not respond to this recommendation.

27. I am aware there is an argument that rescheduling simply promotes a black market for drugs. With this in mind, I requested the CPU to investigate what preliminary evidence we have regarding the effect of the alprazolam rescheduling on Victorian overdose deaths. The CPU advice is Attachment A to this finding. It indicates that following the rescheduling of alprazolam in February 2014 there was a marked decrease in the annual frequency of overdose deaths where alprazolam played a contributory role. However, there was no accompanying overall decrease in the frequency of overdose deaths in which benzodiazepines contributed. Further, the decline in alprazolam contribution to deaths was accompanied by a rise in the contribution of diazepam and clonazepam thus demonstrating how the rescheduling of only one benzodiazepine merely shifts the harm to other benzodiazepines.

28. This preliminary data illustrates the efficacy of rescheduling problem drugs and reinforces the need for all benzodiazepines to be rescheduled to Schedule 8.

Other matters

29. I distribute this Finding to the Australian Health Practitioner Regulation Authority for information and to take whatever action it deems appropriate in relation to the issues identified in this Finding.

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9 Therapeutic Goods Administration, "Reasons for scheduling delegates' final decisions, June 2013", <http://www.tga.gov.au/industry/scheduling-decisions-1306-final.htm>, 28 June 2013, accessed 2 July 2013. A decision was also made to amend the SUSMP to include a new entry in Appendix D, paragraph 5 for benzodiazepine derivatives with the consequence that possession of benzodiazepines without authority (that is pursuant to a valid prescription) is now illegal.

10 Finding into death without inquest of Kirk Ardern (20122254) delivered on 7 April 2014.

RECOMMENDATIONS

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

1. I recommend that the Victorian Department of Health and Human Services take the national lead in immediately implementing a Real Time Prescription Monitoring system in Victoria to tackle the ever-increasing toll of pharmaceutical drug related deaths in the state.

2. In light of the evidence that the rescheduling of alprazolam has not reduced benzodiazepine contribution to overdose deaths in Victoria I recommend that within 12 months the Therapeutic Goods Administration move all benzodiazepines into Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons.

3. I recommend the Royal Australian College of General Practitioners (RACGP) consider revision of their standards and guidelines to provide best practice guidance on coordination of care in general practice between general practitioners at different clinics.

Pursuant to section 73(1A) 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:

The family of Ms Kelly Hall;
Australian Health Practitioner Regulation Agency;
Royal Australian College of General Practitioners;
Victorian Department of Health and Human Services;
Commonwealth Department of Health;
Therapeutic Goods Administration;
Dr Elizabeth Leder;
Dr Craig Smith;
Investigating Member, Victoria Police; and
Interested Parties.

Signature:

ROSEMARY CARLIN
CORONER
Date: 22 April 2016

Annexure A

Coroners Prevention Unit Advice on the effect of alprazolam rescheduling

Coroners Prevention Unit Advice

Date: 8 April 2016

Re: Impact of alprazolam rescheduling on benzodiazepine involvement in Victorian overdose deaths

Background

In February 2014, alprazolam was rescheduled by the Therapeutic Goods Administration (TGA) into schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

Impact of rescheduling on Victorian overdose deaths

Drawing data from the Coroners Court of Victoria's overdose deaths register, Table 1 shows the annual frequency of Victorian overdose deaths 2009-2015 by major contributing drug groups. Please note when interpreting the Table 1 data that most Victorian overdose deaths each year involve multiple contributing drugs, which is why drug group frequencies do not sum to total overdose deaths each year.

There was no reduction in the frequency of overdose deaths generally, or overdose deaths involving benzodiazepines specifically, following the February 2014 rescheduling of alprazolam.

Table 1: Most frequent contributing drug groups to overdose deaths, Victoria 2009-2015

Drug groups	2009	2010	2011	2012	2013	2014	2015
Total overdose deaths	**379**	**342**	**362**	**367**	**380**	**387**	**420**
Benzodiazepines	160	169	180	199	212	215	220
Opioid analgesics	177	145	183	212	192	186	183
Illegal drugs	147	149	153	133	166	164	217
Antidepressants	122	106	101	142	134	144	151
Alcohol	94	85	88	80	94	94	97
Antipsychotics	63	64	65	78	75	81	82
Non-benzo anxiolytics	35	28	33	38	56	48	56
Non-opioid analgesics	26	25	30	52	41	49	43
Anticonvulsants	18	14	13	10	37	45	44

Table 2 shows the annual frequency of Victorian overdose deaths involving the major contributing benzodiazepines. (Again, multiple benzodiazepines can contribute in a single death, which is why the individual benzodiazepine frequencies do not sum to the annual totals). The table indicates:

The annual frequency of overdose deaths involving alprazolam declined markedly in 2014 and 2015 compared to previous years.

The annual frequency of overdose deaths involving diazepam continued to climb, as did the annual frequency of deaths involving clonazepam.

Table 2: Most frequent contributing individual benzodiazepines in overdose deaths, Victoria 2009-2015

Year	2009	2010	2011	2012	2013	2014	2015
Total overdose deaths involving benzodiazepines	**160**	**169**	**180**	**199**	**212**	**215**	**220**
Diazepam	104	109	124	133	164	169	176
Alprazolam	62	56	43	57	45	28	21
Temazepam	28	22	48	35	22	20	25

Oxazepam	18	19	44	41	17	19	28
Nitrazepam	17	16	11	24	26	13	17
Clonazepam	7	9	14	18	19	25	31

These tables tend to support the conclusion that the rescheduling of alprazolam did not reduce overall fatal benzodiazepine harms in Victoria, but rather resulted in fatal harms shifting to other benzodiazepines.

▪ Drug Utilisation Sub-Committee (DUSC) report

On 1 October 2015, the DUSC within the Pharmaceutical Benefits Advisory Committee (PBAC), published an Outcome Statement reporting on their review of the utilisation of certain medicines.

The DUSC commented on the effect that rescheduling has had on the utilisation of alprazolam for panic disorder:

> The DUSC considered that rescheduling has helped to curb use of alprazolam and that this is evident in both the PBS and non-PBS prescription market. The PBS use of alprazolam declined by about one third immediately after rescheduling from schedule 4 to schedule 8 on 1 February 2014 and has continued to decline since. The DUSC noted this decline was unique to alprazolam and not observed in other benzodiazepines.
>
> Around the time of the rescheduling, approximately double the number of patients switched from alprazolam to diazepam or oxazepam compared to usual levels. The DUSC considered a shift to be expected, but noted there may not be a decline in overall use of benzodiazepines unless further steps are taken to reduce and cease benzodiazepine use. The DUSC was also concerned that there could be a shift to other potentially inappropriate medicines such as antipsychotics.

The DUSC comments regarding the switch from alprazolam to other benzodiazepines are supported by the Victorian overdose deaths data.

▪ Further historical note

The Victorian overdose deaths data is also consistent with earlier research from the Australian Primary Health Care Research Institute and the Australian National University, which examined benzodiazepine dispensing in Australia over a 20-year period.[11] The research, published in 2013, showed that when examining individual benzodiazepines the rate of dispensing could change quite markedly over time, but the overall quantity of benzodiazepines dispenses did not substantially change during the period. They noted that:

> The long-term overview of benzodiazepines reveals that as the use of one formulation has decreased, another has taken its place. Declining use of flunitrazepam appears to have led to increased use of alprazolam. If alprazolam use declines as a result of action against that specific product, it seems likely that clonazepam or another agent will take its place which may not have lower toxicity [...] This suggests that to reduce use and abuse, regulatory action should apply across the whole class, and comprehensive changes in prescribing are required and should include public and prescriber education and live monitoring of prescribing and/or dispensing.

The authors predicted that the rate of benzodiazepine dispensing was unlikely to change, following increased regulation of an individual drug within the class.

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[11] M. Islam, K. Conigrave, C. Day, Y. Nguyen & P. Haber (2013) Twenty-year trends in benzodiazepine dispensing in the Australian population, *Internal Medicine Journal.*