QUEENSLAND COURTS

CORONERS COURT OF QUEENSLAND

FINDINGS OF INQUEST

CITATION:	**Inquest into the death of William John HOUSE, Vanessa Joan WHITE, Jodie Anne SMITH; and Daniel Keith MILNE**
TITLE OF COURT:	Coroners Court
JURISDICTION:	Southport
FILE NO(s):	2012/3089, 2012/4575, 2012/2948, 2014/545
DELIVERED ON:	21 May 2018
DELIVERED AT:	Southport
HEARING DATE(s):	21 June 2017, 26 - 29 June 2017
FINDINGS OF:	James McDougall, Coroner
CATCHWORDS:	Coroners: inquest, prescription opioids, drugs of dependence, opioid overdose, oxycodone, fentanyl, Schedule 8 medications, controlled drugs, doctor shopping, prescribing practices, real-time prescription monitoring, electronic recording and reporting of controlled drugs.

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Introduction

1. A joint inquest into the deaths of Mr. William House, Ms. Jodie Anne Smith, Ms. Vanessa Joan White and Mr. Daniel Keith Milne was convened in order to consider the universal and widespread issues associated with the growing misuse of opioid prescription medication in Queensland, and more broadly, Australia. These tragic deaths were selected as a representative sample from a large number of other similar deaths as they are typical of the circumstances in which death often occurs as a consequence of prescription opioid abuse.

2. There have been more than 20 coronial inquests held in Australia that have considered deaths associated with prescription opioid abuse. Various recommendations have been made by Coroners as to measures which could be taken to effectively address and mitigate issues associated with regulatory shortfalls in the dispensing and monitoring of these drugs, inappropriate prescribing practices, doctor-shopping and the current lack of clinical education provided to medical professionals. Universally, Coroner's, with the support of a majority of Australia's peak medicine, pharmacy and consumer bodies, have called for the introduction of a real-time prescription monitoring system to enable the effective management of the prescribing and supply of drugs of dependence, including prescription opioids, and to significantly reduce the risk of ongoing future harm posed by the abuse of these medications. A similar sentiment has been expressed by the Queensland Health Ombudsman in his recent investigation report into the appropriateness and effectiveness of the current regulatory system for scheduled medicines as it applies to health sciences.

3. In this joint inquest, I have considered the broad issues associated with opioid medication misuse, as well as the sufficiency of the monitoring presently in place in relation to the prescribing and dispensing of Schedule 8 medication and the implementation of the Commonwealth Government's initiative, the Electronic Recording and Reporting of Controlled Drugs (ERRCD).

Issues for inquest

4. On the third of March 2017 and 5 May 2017, at pre-inquest hearings, the following issues were determined for consideration at inquest:

    (a) The findings required by s.45 (2) of the *Coroners Act 2003;* namely the identity of the deceased person, when, where and how they died and the cause of their death.

The prescribing of drugs of dependence by a number of different General Practitioners to each of the deceased, often at concurrent times.

(c) The provision of drugs of dependence by treating Hospitals to the deceased.

(b) The sufficiency of monitoring currently available in relation to the prescribing and dispensing of drugs of dependence in Queensland.

(c) The adequacy of current practices in relation to the sharing of information between Hospitals, General Practitioners and the agencies responsible for monitoring the prescribing of drugs of dependence medicine, in relation to the overall management of shared patients.

(d) What further actions could be undertaken to prevent doctor shopping and inappropriate prescribing of drugs of dependence in Queensland?

(e) What further actions could be undertaken to ensure that an integrated approach by all relevant participants is provided to patients, who are prescribed drugs of dependence?

An Overview of Schedule 8 Regulatory Framework in Queensland

5. Schedule 8 medicines are prescription-only medicines that have specific restrictions placed on their supply and use because of their dependence forming nature and high levels of misuse (*Poisons Standard).* Schedule 8 medicines, include a range of pharmaceutical drugs, most notably pharmaceutical opioids used for very strong pain relief, and some benzodiazepines. Current regulations for these controlled drugs are stipulated in separate State and Territory legislation.

6. The controlled drugs, which are the focus of this inquest are Oxycodone and Fentanyl. Oxycodone is an opiate analgesic used for the treatment of moderate to severe pain, which is more commonly available as an immediate release tablet, Endone or OxyNorm, or a slow/modified release tablet, OxyContin. Fentanyl is a powerful narcotic analgesic used for the treatment of moderate to strong pain. It can be administered by way of a lozenge, injection or, more commonly, a slow release patch directly adhered to the skin. Fentanyl patches, which are designed to manage chronic pain, are more prone to misuse, as the drug can be extracted and subsequently injected. It is impossible for the user to know of the concentration of the drug they are injecting, which can tragically lead to an almost immediate overdose.

7. The regulatory framework for monitoring the prescribing, dispensing and use of Schedule 8 medicines in Queensland is multifaceted. By way of summary, chief legislative responsibility, pursuant to the *Health Act 1937*, rests with Medicines Regulation and Quality (MRQ), previously known as the Drugs of Dependence Unit (DDU), which sits within the Chief Medical Officer and Healthcare Regulation Branch of the Queensland Department of Health. The *Health Act* grants investigative and other associated powers to the Department of Health Chief Executive and delegates to enforce subordinate legislation, such as the *Health (Drugs and Poisons) Regulation 1996* ('the Regulation'). This Regulation provides a wide range of controls over the manufacture, labelling, prescription, dispensing and supply of medications included in the *Poisons Standard,* so as to ensure the intentional or negligent misuse of such drugs is significantly reduced.

8. MRQ was formed following the Australian Royal Commission of Inquiry into Drugs in 1979, in response to a recommendation as to the need for a discrete monitoring unit.1The mission of MRQ is stated as follows:

> *To minimise the harms to the public from inappropriate controlled drugs use by providing a high quality effective monitoring, investigative, enquiry and research service within a dynamic, multi-disciplinary working environment.*

9. MRQ has regulatory responsibility for the following:

- State regulation in the treatment of persons with controlled drugs (Schedule 8), and some restricted drugs of dependency (Schedule 4 drugs).

- Data collection and analysis concerning the prevalence of the inappropriate and unlawful prescribing and use of Schedule 8 drugs and some Schedule 4 drugs.

- MRQ also administers and has a policy role in aspects of the Queensland Opioid Treatment Program (QOTP) that deals with opioid substitution therapies, such as methadone and buprenorphine, for treatment of drug dependent persons.

10. Medical practitioners are generally authorised to obtain, possess, prescribe, dispense and supply Schedule 8 medicines to the extent necessary to practice without obtaining any explicit approvals. The Regulations requires that approval be sought to treat drug dependent persons, notify the Department of Health of intended long-term treatment of persons with Schedule 8 medicines (i.e. for more than 8 weeks), and any further information as requested. In these circumstances, prescribers are required to complete a *Report to the Chief Executive*.

Applications for approval are managed by MRQ, pursuant to the Health (Drugs and Poisons) Regulation 1996.

11. Computerised monitoring was introduced in 1983 (MODDS) to assist in identifying '*inappropriate and unlawful prescribing and use of the major narcotics*.' On a monthly basis, electronic records of all Schedule 8 prescriptions dispensed at community pharmacies in Queensland are uploaded by dispensers and entered into the MODDS database by MRQ. It is therefore the repository of information about these medicines, as provided by medical practitioners, specialists, pharmacies, members of the public, police, ATODS and any other stakeholders/notifiers. Administration of Schedule 8 drugs by hospital services, however, are not captured. MODDS also includes information about a persons' admissions and discharges to the Queensland Opioid Treatment Program, records of approvals granted to doctors under the Regulation, and details of enquiries made about individual patients. On a monthly basis, electronic records of all Schedule 8 prescriptions dispensed at community pharmacies in Queensland are uploaded by dispensers and entered into the MODDS database by MRQ.

12. The MODDS database is the repository of information about these medicines, as provided by medical practitioners, specialists, pharmacies, members of the public, police, ATODS and any other stakeholders/notifiers. Administration of Schedule 8 drugs by hospital services, however, are not captured. MODDS also includes information about a persons' admissions and discharges to the Queensland Opioid Treatment Program (QOTP), records of approvals granted to doctors under the Regulation, and details of enquiries made about individual patients.

13. Access to the MODDS database is restricted to appropriately authorised and trained officers of MRQ and ADIS of the Metro North Hospital and Health Service. These officers are involved in the administration of the Regulation, and provide information to doctors about their legal obligations, as well as the Schedule 8 medicine prescription history of patients for the purpose of the 24/7 Telephone Enquiry Service.

14. MODDS ''*facilitates running customised, targeted surveillance alerts and reports',* as well as prescriber profiling, identifying 'soft touch' prescribers. It also allows for the profiling of patients to identify drug seeking behaviour. Regular reviews of the database by MRQ surveillance officers identify 'surveillance alerts', namely *Doctor shopping, Fentanyl surveillance, High dose identification,* and *Ex-program obtaining of Schedule 8 medicine scripts.*

15. As of 2012, MODDS also facilitated the provision of a 24/7 state-wide confidential telephone 'enquiry service' for medical practitioners and pharmacists. This service allowed medical practitioners to seek certain information, including:

- The controlled drug prescriptions an individual has obtained.
- Ascertain whether an individual is a former or current QOTP registrant.
- Ascertain whether a person is known to be drug dependent.
- Ascertain whether a person is obtaining controlled drug prescriptions from multiple doctors.
- Seek approval to treat a patient with a controlled or a restricted drug.
- Discuss patient management issues with a Clinical Advisor or the MRQ Medical Director.
- Report concerns about diversion of controlled drugs or QOTP medications.
- Report concerns about inappropriate prescribing by another doctor.

16. This service uses the Alcohol and Drug Information Service (ADIS) to triage all incoming calls during core business hours and intake of after-hour calls. ADIS has access to the MODDS database, in order to provide medical practitioners with non-medical/clinical information. Calls, which may require more complex advice, are returned by MRQ senior advisers the following working day. MRQ note that this enquiry service is *'one of the main prevention/education strategies used by MRQ in furthering its goal of minimising the harm resulting from the inappropriate use of controlled and restricted drugs of dependency'.*

17. In 2014 alone, MRQ responded to more than 20,000 calls on the telephone enquiry service, which is almost double that received since 2010. A majority of calls reportedly related to queries about a patient's schedule.

Doctor Shopping and Inappropriate Prescribing

18. MRQ monitoring can detect persons who obtain controlled drug prescriptions from multiple doctors, more commonly known as 'doctor-shopping'. MRQ state that, *'in most instances MRQ will correspond with all treating doctors and seek to have them liaise so that one doctor becomes the primary prescriber'.* Where a patient has a history of illicit or injecting drug use, the prescribers may be asked by MRQ to refer the patient to ATODS for assessment, and possible management on the QOTP.

19. Patterns of inappropriate prescribing practices, such as breaches of the Regulation, prescribing outside the terms of an approval or prescribing to a drug dependent person can also be monitored by MRQ. In certain cases, the inappropriate prescribing by a general practitioner can lead to the reporting of the matter to the Medical Board, and a possible cancellation (partial or full) of a doctor's authority to use controlled drugs.

20. The MRQ has prosecutorial powers pursuant to regulation. However, it seeks to modify behaviour by monitoring behaviour by advice and appropriate treatment. During the inquest, the MRQ Director, Mr. William Loveday confirmed that it was the practice of MRQ to initially correspond with general practitioners involved in a patient's care, if they suspected that the person was 'doctor-shopping'.

Growth in opioid prescribing

21. MRQ data confirms that there has been a pronounced growth in the number of Schedule 8 prescriptions provided by general practitioners. For example, in 2006, the monthly average was 62,850, whereas in 2012 it had increased substantially to 132,800, with the yearly amount rising from 754,200 to 1,593,344.22 Furthermore, since 2000 there has been an 846% increase in the base supply of oxycodone. Between 2006 and 2010 there has been a three-fold increase in fentanyl prescriptions. This is consistent with the increase globally, in particular in the United States of America.

Therapeutic Opioid Drug of Dependence Committee

22. The Therapeutic Opioid Drug of Dependence Committee (the Committee) was established in 1992 to assist the Department of Health in providing particular and general advice about complex matters in relation to the use of controlled drugs. The Committee is comprised of the Medical Adviser, Chief Medical Officer and Healthcare Regulation Branch, and may include at least one representative with pain management specialty experience, a representative from medical specialties, which includes RACP, RANZCP, RACGP or the College of Rural and Remote Medicine, other medical practitioners working in the addiction/dependence field, general practice or pain management, and a registered senior practicing Pharmacist. MRQ refers complex pain management cases to the Committee for their advice on the *'treatment and management of persons with controlled drugs'.* These recommendations are then relayed to treating general practitioners.

Opioid Guidelines – General Practitioners

23. The Royal Australian College of General Practitioners (RACGP) endorses the Royal Australian College of Physicians (RACP) Guidelines for the *Prescription Opioid Policy: Improving management of chronic non-malignant pain and prevention of problems associated with prescription and opioid use*. This policy recognises the increasing use of opioids to manage chronic non-malignant pain

in Australia and New Zealand, with concern raised as to the unsanctioned and mismanaged use of prescription opioid medications. Between 1990 and 2003 there had been a fourfold increase in the supply of oxycodone. A number of reasons were cited for this increase in opioid prescribing, including the growth in chronic pain and a greater willingness by general practitioners to prescribe opioids.

24. Accordingly, the guidelines were developed to review the prescription of opioids for chronic non-malignant pain in Australia and New Zealand, so as to improve the management of chronic pain with these medications, and address the associated issues, which were arising. A number of improvements to the prescribing and regulation of opiate medication were identified through this policy, including:

    - Further integration between primary care and specialist services, recognizing the crucial role general practitioners play in providing care to those with chronic pain.

    - The need for clinical guidelines for managing chronic non-malignant pain in patients with problem drug use and or aberrant drug behaviours.

25. Recently, RACGP have released their own guidelines in relation to the prescribing of controlled drugs.

26. These comprehensive guidelines were developed to ensure general practitioners are supported to appropriately prescribe drugs of addiction within the regulatory framework and to recognise and manage high risk situations appropriately. Relevantly, Part A of the guidelines states the following:

    - Patients should be appropriately evaluated to determine the complexity of services required.

    - A risk stratification model is provided to assist with the safe management of patients in a primary care setting, which may necessitate co-management with specialist support and should be referred on for management in a specialist setting.

    - Patients are categorised into three groups. Group III are patients, which require management by specialist services. These patients represent the most complex cases, and are either misusing prescription drugs or pose a significant risk to both themselves and to the practitioner. RACGP note that the failure, or inadequate transfer of care of these patients, poses a major risk to their safety, and commonly results in adverse outcomes for the patient. The clinical framework recommends that GP's insist on high

standard referral letters for clinical handover or shared care arrangements from secondary care before accepting the ongoing care of a patient.

- In cases of suspected or identified drug dependence, the guidelines note that inter-professional dialogue is imperative to effectively manage the complexities associated with these high-risk patients, who are being prescribed Schedule 8 medications.

- GP's are required to be accountable prescribers of drugs of dependence and must prescribe within legislative frameworks, professional standards and approved clinical guidelines. Good prescribing practices involve the careful and considered diagnosis, clear therapeutic goals, the use of non-drug therapies where suitable, prescribing appropriate types, formulations and amounts of medications, explaining the effects of medications and any risk of dependence, and implementing regular medication reviews.

27. Part C of the guidelines, which will relate to opioid prescribing, were due to be finalised in 2017, but were not available at the date of inquest.

Clinical Guidelines and Programs

28. Clinical Guidelines developed by Queensland Health in relation to the use of Opioids in Chronic Non-Malignant Pain state that:

> *While opioid therapy for chronic non-malignant pain may provide analgesic benefit for some patients, the evidence regarding improvement in function is limited. It is likely that only a minority of patients with chronic non-cancer pain will gain benefits from long term opioid medication, and the decision to prescribe opioids in these patients should only be made following these guidelines and may require consultation with a specialist (e.g. pain management clinic, alcohol and drug specialist, psychiatrist).*

29. The Guidelines stipulate that opioids should only be prescribed after a '*full assessment process, which includes: a pain diagnosis, mental health, alcohol and other drug dependency issues, a trial of non-opioid analgesia and non-drug treatments, and a corroborating history from other health professionals.*' Furthermore, a pain diagnosis should be made, as opioids are only useful in defined nociceptive (mechanical) or neuropathic pain. Only after this diagnosis has been made should a trial be initiated.

30. The Guidelines state that opioids should generally not be used to treat headaches (including migraines), and poorly defined general pain, such as fibromyalgia, chronic visceral pain or non-specific lower back pain. If opioids are thought to be appropriate, then a four to six week trial of oral long-acting opioid analgesics should be undertaken to determine their suitability. Only one medical practitioner should have responsibility for prescribing opioid medication. Patients should be encouraged to use a single pharmacist for dispensing.

31. If opioids are prescribed then it is vital that they are seen as only one part of the treatment (i.e. to provide analgesia to improve function) and that ongoing self-management and functional improvement is expected and desirable. Patients should also be subject to regular review of the pain diagnosis and comorbid conditions.

32. The Guidelines note that:

> *The goals of pain management are to increase the ability to function, to reduce pain and suffering and enhance quality of life while minimising the risk of adverse effects. To accomplish these goals, pain management most often required a broad array of interventions, only one of which is opioid prescription. In prescribing opioids the aim is to reduce pain without causing side effects this the patient is then able to achieve their desired outcomes on treatment. These outcomes may require a team approach and the services of clinical psychology, graded activity, and a practice nurse with the focus on patient self-management rather than multiple visits to health practitioners.*
>
> *Clinical decisions about the ongoing use of opioids require a careful assessment of all outcomes. Specific goals of opioid treatment will vary according to the patient's circumstances, however, these should be documented prior to an opioid trial. The goals of treatment may be as simple as 'being able to hang out the washing', or as significant as 'being able to return to work full-time'. It is important that any goals of treatment are realistic, achievable, and are regularly reviewed by the patient and GP.*

33. The maximum dosing threshold for selected opioids are as follows:

- Morphine (MS Contin) – 10-20 mg twice daily (120mg/day)
- Oxycodone (OxyContin) – 5 mg twice daily (80 mg/day)
- Fentanyl (Durogesic) – 12 mcg/hr (25 mcg/hr)

<u>The Queensland Opioid Treatment Program</u>

34. The QOTP Clinical Guidelines 2012 state that the aim of the program is to enable a '*significant reduction of the client's unsanctioned opioid use*' in order to reduce the risk of an overdose. Treatment is provided by public clinics and also private prescribers. The QOTP Guidelines recommend that the initial consultation should include a thorough history (medical, psychological, family, social, drug-related problems) and a general examination with an emphasis on organs that may have been damaged due to drug use. The examination should also include the presence of need-track marks, signs of drug intoxication or withdrawal, and a psychological/psychiatric examination.

35. The Guidelines recommend supervised dosing of buprenorphine/ naloxone combination in the first two months unless there is no facility available. The Guidelines note that it is common for drug-dependent clients to do well in treatment for a time, and then relapse to periods of drug use. Indicators of this relapse are listed to include, self-reporting, evidence of diversion, clinical evidence (such as intoxication), recent injection marks and deterioration in psychological, physical and social wellbeing. It is usual in these circumstances to stop take-away doses until the client/patient has stabilised for 12 weeks or more.

Commonwealth Prescription Shopping Program

36. The Commonwealth Prescription Shopping program (PSP) is a 24/7 telephone information service administered by the Department of Health Services on behalf of the Department of Health, which assists prescribers in making prescribing decisions by identifying patients who may be obtaining PBS subsidized medicines in excess of medical need.

37. The Program is administered at a national level in accordance with Regulation 20 of the *Human Services (Medicare) Regulations 1975.* Sub-regulation 20(9) states that a prescription shopper means a person who in any three month period has had supplied to them:

- Pharmaceutical benefits prescribed by 6 or more different prescribers; or
- A total of 25 or more target pharmaceutical benefits; or
- A total of 50 or more of pharmaceuticals benefits.

38. Sub-regulation 20(8) defines target pharmaceutical benefits, which includes a number of categories of the Anatomical Therapeutic Chemical classification system, such as N02 Analgesics.

39. Sub-regulation 20(5) provides for the disclosure of PBS information about whether a person is considered as a prescription shopper, a prescriber or an approved supplier.

40. The program is said to provide information and an Alert Service to prescribers to assist with their decisions. Prescribers accessing the service are required to be registered with the service and need to be verified prior to the disclosure of any patient information. Prescribers are provided with advice on whether a patient meets the program's criteria, and if so, a Patient Summary Report can be provided on request. This is generally done on the same. The Report lists the PBS items and the quantity supplied to the patient over the previous 3 months.

A request for the Report can also be made through the Department's Health Professional Online Service, which is then sent to a prescribers account almost immediately.

41. With respect to the Alert Service, PBS data is used to determine whether a patient meets the program's criteria. Analysis of this data is said to enable *'the Department to proactively contact prescribers to provide them with information about patients who may be obtaining PBS medicines beyond their medical need'.* Letters are also sent to patients notifying them if they have been identified under the PSP. In the 2004-2005 financial year, 4.934 calls were made to the service. In 2012-2013, this number had grown to 34,359 calls. In 2012-2013, there were 447,518 instances of patients found to have met the criteria for the PSP. Of these, 50% met the criteria for having been supplied prescribed medication by 6 or more practitioners. In 2012-2013, 1032 individual patients and their prescribers received 7941 letters issued by the Prescription Shopping Alert Service.

42. At present, there are no plans to change the services delivered under the program.

Summary of Circumstances

43. I now set out a summary of the circumstances of the deaths of William House, Jodie Anne Smith, Vanessa Joan White and Daniel Keith Milne.

William House

44. William House was 30 years old at the time of his death.

45. At 3:00 pm on 27 August 2012, House was discharged from the Gold Coast Hospital (GCH) into police custody in relation to outstanding criminal warrants. He was taken to the Southport Watch House. He appeared in the Magistrates Court at Southport on 28 August 2012, and was released from police custody on a bail undertaking at 1:12 PM.

46. At around 5:00 pm that day, Mr. House's sister, Ms. Vanessa Price attended his residence at 10/51-57 Meron Street, Southport having been unable to contact him via telephone from around midday. Upon arrival at Mr. House's residence, Ms. Price saw that his wheelchair was being used to prop open the front door. She entered the dwelling and saw him slumped over the low-lying television cabinet with his neck resting on the top of the television. He appeared to be breathing and his back was warm to touch.

47. Ms. Price proceeded to walk around the apartment to try and ascertain what had occurred before contacting a friend, Jan-Rene Horowitz, who attended the residence a short time later. Mr. Horowitz and Ms. Price proceeded to place Mr. House on his back on the lounge room floor, at which time his face turned blue. Mr. Horowitz called the Queensland Ambulance Service (QAS) and was provided with instructions on administering cardiopulmonary resuscitation (CPR). Unfortunately, despite further resuscitation attempts by QAS officers upon arrival, he was unable to be revived. Police were subsequently called to attend the residence.

48. Police found that there were no signs of forced entry nor any evidence of a struggle taking place. A search of the dwelling located a tax invoice from Pharmacy Essentials at Southport for the purchase of one box of Durogesic (Fentanyl) patches and OxyContin 80 mg tablets, which had been dispensed on 2:48 pm that day. Multiple medical prescriptions and medications, including Fentanyl and OxyContin were also found. Other medications located at the residence included Baclofen, Clonazepam, Clexane, Sandomigrin, Omeprazole, Epilim, Levetiracetam, Pariet and Tetrabenazine.

49. In addition, numerous syringes (in excess of 50) capped and uncapped were found at various places throughout the apartment. Droplets of blood were observed in the kitchen, lounge, hallway and bathroom areas of the house. A freshly blood stained tissue next to an uncapped syringe was also found on the kitchen bench top.

Post-mortem findings

50. On 29 August 2012, an external and full internal post-mortem examination was conducted by Pathologist, Dr Dianne Little. A number of toxicological tests were also carried out.

51. At autopsy, multiple old and recent track marks were observed on Mr. House's elbows and his upper left forearm. Granulomas containing birefringent and other foreign material were also found in the lungs, which were consistent with chronic intravenous drug use.

52. Toxicological analysis of samples taken at autopsy detected the presence of fentanyl, as well as its breakdown product norfentanyl. The fentanyl was present at a blood level of 16ug/kg, which is above the reported therapeutic range (1-11 ug/kg), and within the reported fatal range (3-28 ug/kg). The norfentanyl present was at a very low level suggesting there was little time for metabolism of the drug between the time of administration and the time of death.

53. Other drugs also detected were aminoclonazepam (the breakdown product of the anticonvulsant drug, Clonazepam), amitriptyline (antidepressant),

leveiracetam (anticonvulsant) and propofol, all at levels within the reported therapeutic ranges. Valproic acid (Epilim, an anticonvulsant drug) was also present at a level below the reported therapeutic range.

54. Dr Little noted that Mr. House had a history of epilepsy, as documented in the medical records, for which he was prescribed a number of anticonvulsants. Examination of his brain showed a small benign blood vessel tumour in the right parietal lobe, which may have also caused seizures.

55. In Dr Little's opinion, Mr. House's cause of death was as a result of acute fentanyl toxicity in a man with epilepsy. She notes that there was evidence found at autopsy of long-standing intravenous drug use. Given his documented history of epilepsy, she surmised that the high level of fentanyl ingested either directly caused Mr. House's death and/or interacted with his epilepsy to cause a fatal seizure.

Medical history

56. On 7 September 2007, Mr. House was involved in a motor vehicle accident, and sustained a fracture to his right ankle. He was admitted to the Gold Coast Hospital (GCH) as a result and made substantial complaint about excruciating pain in the ankle area. He was initially treated with OxyContin, Tramadol and morphine before an open reduction of the fracture was conducted. Upon discharge from hospital on 14 September 2007, Mr. House was provided with OxyContin 10 mg tablets, Panadeine Forte and Brufen.

57. On 19 September 2007, Mr. House first consulted with General Practitioner, Dr David Seton, at the Surfers Paradise Day and Night Medical Centre (SPD&NMC). On this occasion, he requested further pain management associated with his recent ankle surgery. Dr Seton prescribed him OxyContin 20 mg tablets, Endone 5 mg tablets and Keflex 500 mg capsules.

58. On 19 September 2007, Mr. House first consulted with General Practitioner, Dr David Seton, at the Surfers Paradise Day and Night Medical Centre (SPD&NMC). On this occasion, he requested further pain management associated with his recent ankle surgery. Dr Seton prescribed him OxyContin 20 mg tablets, Endone 5 mg tablets and Keflex 500 mg capsules.

59. On 19 November 2007, a letter by GCH Emergency Department (ED) Consultant, Dr David Spain addressed to Dr Seton outlined a presentation by Mr. House on 18 November 2007. He alleged that he had been assaulted, although the only evident injury was an abrasion on his right hand. Dr Spain noted in correspondence on the hospital file that:

He has had several attendances here recently and whilst an inpatient had behaviour that is likely suggestive of great potential for therapeutic dependence.

This has been discussed with him. He has been advised that we need to cease narcotic oral analgesia. He has been given prescription for paracetamol 100 tabs, tramal (50mg) 20 tabs and voltaren 50mg 50 tabs. I suggest he no longer requires any ongoing oral narcotic analgesia and this would be against his interest longer term.

He will be mobilised by physio due to his alleged ankle pain (note xrays show no new injury to this or left shoulder area).

60. Unfortunately, Dr Seton did not receive this correspondence. A copy of the letter was also not contained within the SPD&NMC records. At inquest, Dr Seton agreed that this information would have been important as it would have alerted him to potential drug seeking behaviour by Mr. House.

61. In November and December 2007, Mr. House regularly attended the SPD&NMC practice, predominantly consulting with Dr Seton. A majority of these appointments related to pain management and further scripts for various opiate pain relief medications.

62. In November and December 2007, Mr. House attended a number of orthopaedic GCH outpatient clinics for ongoing management of his alleged ankle pain.

63. On 18 December 2007, Mr. House presented to the GCH ED complaining of neck pain, headaches, rash, vomiting, as well as face and joint inflammation. He was admitted and various testing was undertaken, including an MRI of his right foot and ankle, as well as his brain.

64. On 8 January 2008, whilst still an inpatient at the GCH, Neurologist, Dr Simon Broadley requested that Mr. House be reviewed by Dr Anthony Espinet, an Anesthetist and Chronic Pain Specialist within the hospital. During this consultation, it was noted that Mr. House appeared to be visibly distressed by headache pain and was unable to be assessed. Accordingly, he was provided with Morphine, Fentanyl and Endone.

65. Dr Espinet was called to give evidence during the inquest. In relation to the functions of the Pain Clinic within the GCH as of 2008, he noted that this was a 'non-funded chronic pain service', which only operated for half a day a week. There was a two-year patient waiting list upon its commencement in 2007. He further noted that:

There was no funding for there to be any junior medical staff, inpatient beds, allocated time for inpatient reviews or ongoing management. There was also no secretarial support. I ran the clinic by myself. I did this in addition to my full-time

work load in anaesthetics. Because of the very limited resources, I was only able to see pain management inpatients at the request of the specialist caring for a patient. I would see these patients during my lunch break or out of hours at the end of the day. I could in effect only offer a brief, ad hoc and limited advisory service. It simply was not possible to be involved in any of the day to day management, or regular follow-up of the patients. I offered some general direction regarding pain management to the specialist who had requested the review.

66. Mr. House was one of the earliest chronic pain patients with whom Dr Espinet consulted. He noted that Mr. House was a complex patient to manage, as he had multiple medical and socials problems, which were constantly changing. He was also involved with a number of different medical experts, which meant that his management was not overseen by one particular specialist. Dr Espinet noted that he had not been made aware of Dr Spain's letter, dated 19 July 2007.

67. In relation to Mr. House's presentation on 8 January 2008, Dr Espinet stated that he had been an inpatient for some 21 days prior to his involvement, and a number of analgesic treatments had been trialled without success, including morphine, Panadeine and lignocaine infusion. His initial impression was that Mr. House had cervical facet joint pain, as well as supraorbital and occipital neuralgia and temporalis muscle pain. He had planned to do further examinations once the pain was more settled. Dr Espinet decided to prescribe him a single dose of morphine, Fentanyl patch (50 mcg/hr) and Endone (PRN), as he had been administered narcotic pain relief on a number of occasions previously whilst he was an inpatient. He recalls discussing his decision to commence Mr. House on a Fentanyl patch with Dr Broadley, who agreed that it was appropriate.

68. On 10 January 2008, Dr Espinet attended upon Mr. House once again. After conducting a complete physical and neurological examination, It was determined that he should continue to be provided with opiate pain relief medication with further testing to be conducted, including a lumbar epidural catheter to run infusion, MRI and X-Rays. Dr Espinet was of the view that Mr. House's pain problems were related to a persisting atlanto-occipital and atlanto-axial joint dysfunction, a persisting whip lash injury, S1 joint dysfunction and likely Complex Regional Pain Syndrome (CRPS) of the right foot.

69. In addition to other specialists, Mr. House was subsequently seen by Dr. Espinet on a number of occasions whilst he remained an inpatient at the GCH. Following various measures, including bilateral steroid injections, epidurals and regular pain relief medication, he was said to have gradually improved. He was reportedly able to mobilise without difficulty.

70. Dr Espinet noted that at no time was he invited to participate in a joint conference with Mr. House's treating neurologists or other doctors about his management or progress. Dr Espinet stated that he did not have the capacity or resources to lead

this, and Mr. House was admitted as a neurology patient, rather than under his care.

71. On 21 January 2008, Dr Espinet attended upon Mr. House in preparation for his discharge. It was determined that he had generally improved, and whilst he continued to complain of headaches, it was decided that he could be released with prescriptions for Fentanyl patches, Endone and Gabapentin. Mr. House was reportedly able to mobilise at this time. He was booked in for an appointment with Dr Espinet as an outpatient at the Pain Clinic on 1 February 2008. Dr Espinet claims that during this time, he counselled Mr. House as to the risk associated with continuing opioid therapy.

72. In correspondence from Dr Espinet addressed to Dr Seton dated 1 February 2008, he noted that Mr. House had presented to the pain clinic on this date. His initial presenting problems were listed as severe headaches and right foot pain, for which he was prescribed Indomethacin, Gabapentin, Fentanyl Patch (100 mcg/hr) and Endep. Mr. House reported that his headaches had significantly improved and he had a good range of motion, although was still suffering from neck pain. His right foot was also said to have significantly improved, although his ankle was still swollen and painful.

73. Dr Espinet noted in this correspondence that Mr. House's diagnosed conditions were left CO/C1 and C1/C2 joint dysfunction, bilateral facet joint disease at C3/4, and early CRPS of the right foot. To date it was noted that steroid injections, lumbar epidural infusions and Fentanyl patches had been used to treat his condition. On 1 February 2008, further LA/Dextrose injections were carried out to the left C2/3 facet joint, left cervical muscles, right medial malleolus and right posterior tibial nerve. The results of these treatments were that Mr. House was said to have no pain in his neck or right foot. He was booked in to undergo ablation of the facet nerves, tibial nerve and phenol injection under the right medial malleolus.

74. Infusions and Fentanyl patches had been used to treat his condition. On 1 February 2008, further LA/Dextrose injections were carried out to the left C2/3 facet joint, left cervical muscles, right medial malleolus and right posterior tibial nerve. The results of these treatments were that Mr. House was said to have no pain in his neck or right foot. He was booked in to undergo ablation of the facet nerves, tibial nerve and phenol injection under the right medial malleolus.

75. At inquest, Dr Seton stated that he didn't have any concerns prescribing Mr. House with opiate pain medication at this time, partially because of Mr. House's engagement with a pain specialist. He also noted that Mr. House did not appear to be engaging in drug-seeking behaviour and he believed that Mr. House was suffering from the pain he alleged. He described Mr. House as being a '*perpetually unwell person*'.

76. Throughout 2008, Mr. House solely attended the SPD&NMC, predominantly consulting with Dr Seton, to obtain repeat prescriptions for his opiate pain relief medication, which generally consisted of OxyContin 10 – 20 mg tablets, Endone 5 mg tablets and Fentanyl 100 mcg/hr patches. Mr. House would usually request the dosage of medication he required during each consultation.

77. Mr. House also continued to attend upon Dr Espinet at the Pain Clinic as well, where he complained of pain in his neck, spine and ankle as well as headaches. He was administered anaesthetic injections to his C7 facet nerve and right medial and lateral ankle. On 22 December 2008, Mr. House was admitted to the GCH to undergo a number of procedures aimed at treating his neck pain, including a cervical epidural injection into the spine. He was released that day.

78. On 28 December 2008, Mr. House attended upon Dr Seton, whereby his records noted that: "*Running out of ideas refused further analgesia until I get notes ex government health dept review soon with some further info."*

79. When asked about this notation during the inquest, Dr Seton indicated that Mr. House's pain was '*hard to manage*', and that he had to predominantly rely on self-reporting, rather than a physical assessment. On occasions, Mr. House would present crying and complaining of being in a tremendous amount of pain. He would appear to be uncomfortable during most consultations, although was not using a wheelchair at this point in time. It is of interest that it is recorded in Mr House's notes on his first attendance at Dr Seton's practice, Mr House's past medical history and 'condition' is noted to be '2007 MVA – quadriplegia'. And on April 6 2012, when he saw Dr Stephen Clapham, '*in wheelchair following MVA 2007 – hit by car spinal and head injuries…'* It would seem Dr Seton and Dr Espinet made no enquiries of Mr House as to the extent of his recovery from 'quadriplegia' to walking around unaided.

80. Mr House's presentation at hospital and at the rooms of his general practitioners in varying states of serious disability – sometimes using a wheel chair sometimes not - seems to me to be in stark contrast to reality. This is made obvious when one considers the particulars of the police charge that brought him before the Southport Magistrates Court on 28 August 2012 - the day of his death. Mr House had been arrested on an outstanding warrant on a charge of robbery. The circumstances of that charge are that he rode his pushbike from his home to Harvey Norman at Ashmore – a distance of 5kms. He then went into the store picked up a boxed flat screen television, carried it out to where he left is pushbike in the car park and proceeded to attempt to carry it away on his pushbike, presumably home again, before being apprehended by security.

81. In relation to seeking advice from DDU about prescribing to Mr. House, Dr Seton stated that:

…--I must be honest, I – I never ever thought of discussing the matter with DDU…

…To me – my understanding at that particular point was that the DDU would be fully aware of the pain clinic, myself, that we were looking after Mr House and they would be watching and that if he was seeing anyone else or dealing with – you know – doctor shopping or any of these things, they would immediately inform me and say [indistinct] they were unhappy with the dosages based on, you know, what they were aware of.…

82. Dr Seton stated that as Mr. House was under the care of a Pain Specialist, he had assumed that DDU would have been aware of his ongoing treatment with opiate pain medication. However, he never contacted nor was contacted by Dr Espinet to discuss Mr. House's care and treatment.

83. On 2 July 2009, Mr. House presented to the emergency department of the GCH complaining of a headache, as well as chest and arm pain. He underwent a number of tests, including a CT scan, MRI and angiography, following which it was found that his symptoms were likely attributable to a viral illness. During this admission, he was seen by Dr Espinet where he was administered steroid injections. His was noted to be taking OxyContin 30 mg tablets and Endone 5 mg tablets. Despite being booked in to undergo a cervical facet joint ablation, he absconded from the ward for a period of time before discharging himself against medical advice. He was readmitted a short time later where he underwent a number of ablation procedures over the next couple of days. It was noted that Mr. House was suffering from involuntary movements of head and neck, upper limbs and chest. He was provided with physiotherapy and occupational therapy throughout his Hospital stay, which continued for a number of months. He also underwent various investigations and scans, including MRI's of the brain and spine and CT scans of the head.

84. Prior to his discharge from the GCH on 29 September 2009, Mr. House was assessed by Dr Espinet, who noted that he had been requesting 3 hourly Endone from nursing staff, and would become agitated and upset if this was not provided. He noted that there may be an element of addiction to opiates at this time as well as the chronic condition Mr. House was suffering from. On 18 September 2009, Dr Espinet ordered that Mr. House be given a morphine infusion, with his fentanyl patch, OxyContin and Endone to be ceased. He intended to reduce Mr. House's morphine level by 20 mg a day, with a return to oral morphine or methadone instead of OxyContin.

85. Unfortunately, it does not appear that Dr Espinet's intention to commence Mr. House on Morphine Sulphate and cease OxyContin, Fentanyl patches and Endone was communicated to Dr Seton. As such, on 30 September 2009, following a consultation, Dr Seton prescribed him OxyContin 30 mg tablets and Fentanyl patches. When asked during the inquest as to why he had increased

the dosage, Dr Seton speculated that it was likely he did this following an indication from Mr. House that his dose had been increased whilst he was in Hospital.

86. On 8 October 2009, Mr. House's dose of OxyContin was increased once again, and he was prescribed 40 mg tablets following a consultation with Dr Seton. When asked about the basis of this clinical decision during the inquest, Dr Seton stated that it was likely done at Mr. House's request.

87. Following this consultation, Mr. House continued to be prescribed OxyContin 40 mg tablets and Fentanyl patches at regular intervals by Dr Seton. He also continued to engage with Dr Espinet, who whilst aware of Mr. House's return to OxyContin and Fentanyl patches, made no further attempt to transition him to Morphine Sulphate. In fact, in a letter dated 30 October 2009, Dr Espinet indicated that he intended to carry out facet blocks and lumbar epidural injections to address Mr. House's complaints of neck, back and left shoulder pain, and confirmed that his present medication was OxyContin 40 mg tablets and Fentanyl patches.

88. Mr. House subsequently underwent a number of surgical measures aimed at treating his chronic pain, including inter-spinous ligament and facet block, as well as lumbar and thoracic epidural injections.

89. From October 2009, Mr. House was reportedly wheelchair bound. In a letter dated 4 January 2010, Neurologist, Dr Max Williams from the GCH advised Dr Seton that Mr. House was unable to walk due to the effects of propriospinal myoclonus and CRPS involving his left and right lower limbs.

90. Mr. House attended an outpatient clinic with Dr Espinet on 30 October 2009, where he reported that his medications were Fentanyl patches and OxyContin. Whilst he doesn't have a specific recollection, Dr Espinet surmises that he may have assumed that this was simply what his general practitioner had prescribed him.

91. Records from SPD&NMC indicate that in July 2010, Dr Seton wrote to DDU in relation to Mr. House. Whilst he was unable to recall the content of the letter he sent, he postulated that he may have detailed the dosages of the opiate pain medication he was presently prescribed, which he may have done due to the length of time he had been engaged to treat Mr. House's chronic pain.

92. On 18 October 2010, Mr. House was admitted to Hospital for severe pleuritic chest pain. Dr Espinet recalls that his pain control was very difficult and he was getting large amounts of morphine and Endone to control his pain. He was asked to review Mr. House on the ward and provide some possible options for pain

control. He recommended that his OxyContin dose be temporarily increased to 50 mg, whilst reducing his Morphine and Endone dosage. This was the last occasion on which Dr Espinet assessed Mr. House, as he failed to attend a number of future appointments with the Hospital Pain Clinic.

93. On 27 November 2010, Mr. House attended upon Dr Seton following which he was prescribed OxyContin 80 mg tablets and Fentanyl patches. The notations for this consultation state, *'nightmare, asked him to find a new Dr Re care plan and dentist review.'* When asked about this notation during the inquest, Dr Seton stated that he had encouraged Mr. House to take the opportunity to find a doctor that could take over management of his chronic pain and place him on a care plan, as this was not normally something Dr Seton had much cause to do. He further stated:

> *…It's a nightmare for me as a doctor to – to write pain medication that I'm not a specialist in."* Yes? *"---To deal with pain, it's – its – it's very hard to quantify as a doctor and to constantly have a person coming in for pain medication that you don't always fully understand the management of, I – I – I was always uncomfortable and always anxious about dealing with that.*

94. In relation to the increase in dosage of OxyContin, Dr Seton stated that as Mr. House had been taking 50 mg tablets twice a day, he thought it would be safer if he was placed onto one dose in the morning, and one at night, which would equate to a similar dosage.

95. During the inquest, Dr Seton stated that he often spoke to Mr. House about his pain management. He confirmed that he did not suspect Mr. House was drug dependent or engaging in drug seeking behaviour until the end of his engagement with him in 2011.

96. Mr. House continued to be prescribed this level of OxyContin by Dr Seton at regular intervals until August 2011, when he commenced attending various other medical surgeries. He also had a number of admissions to hospital during this period, with a majority of complaints related to chest pain and the need for further opiate pain relief.

97. During one of the last consultations with Mr. House on 16 August 2011, Dr Seton recorded that he had 'no plan' in relation to Mr. House's pain management. At inquest, Dr Seton elaborated that in the three years he had treated Mr. House, he felt they'd achieved very little in terms of managing his chronic pain. With the benefit of hindsight, Dr Seton recognised that it would have been useful to contact DDU to seek advice in relation to his treatment of Mr. House, a practice he now engages in regularly.

98. During Mr. House's final consultation with Dr Seton on 22 August 2011, he alleged that his medications had been stolen. Dr Seton explained to Mr. House that he could no longer care for him, and further recorded that *'fear of drugs on the street and all I do is write meds'.* He also expressed concern as to the amount of analgesia Mr. House was prescribed by the pain clinic at GCH. At inquest, Dr Seton confirmed that he felt he was unable to continue dealing with Mr. House's pain management, and was concerned that he was becoming opiate dependent.

99. Mr. House subsequently started attending Primary Medical and Dental Centre (PM&DC) in Southport. PM&DC operated in a similar manner to SPD&NMC, in that patients were seen by the next available doctor, rather than on an appointments basis. Medical records held by the practice for a patient are made available to each of the general practitioners.

100. Mr. House first consulted with Dr Suzanne Blum at PM&DC on 25 August 2011. She noted his complex medical problems, including his diagnosis of CRPS, chronic headaches and associated spinal issues, which he reported were being treated and managed by the GCH. He was observed to be in a wheelchair and had slurred speech with uncontrolled movements of his lower limbs. Dr Blum noted that the dosage of opiate pain relief medication he was presently prescribed (Fentanyl patches and OxyContin 80 mg tablets) was 'huge'. She subsequently requested his GCH & SPD&NMC records, which were to be for review once received.

101. Mr. House attended upon Dr Blum once again on 29 August 2011, claiming that he had been assaulted and his medications stolen. She recalls that he had cigarette burns to his right hand and arm, a deep cut to his right forearm and deep scratches to his right thigh. Dr Blum 'hesitantly' provided him with prescriptions for the medications allegedly stolen, however, noted that she was uncertain as to his history, and would not prescribe him anything different than that previously provided by Dr Espinet without written advice.

102. On 3 September 2011, Mr. House attended upon Dr Philip Myers at PM&DC requesting further scripts for opiate pain relief medication, which he was provided. Mr. House confirmed that he had missed his appointment with Dr Espinet the previous day.

103. On 8 September 2011, Mr. House attended upon Dr Philip Myers at PM&DC requesting further scripts for opiate pain relief medication. On this occasion, his request was refused given the short duration since his last consultation. Dr Myers claims that he was concerned Mr. House may be misusing his pain relief medication. Over the next two days, Mr. House was able to obtain scripts for Fentanyl patches and OxyContin 80 mg tablets from two different general practices.

104. A further notation in the PM&DC records dated 19 September 2011 by Dr Blum indicates that Mr. House's records from the GCH had been received. Dr Blum noted that Mr. House had cancelled multiple appointments with the Pain Clinic and booking for various procedures. She also notes:

Is obviously abusing medication currently with his multiple requests.

105. Having received the records, Dr Suzanne Blum recalls that she attempted to contact the Pain Clinic at the GCH on a number of occasions, however, was unsuccessful until 19 September 2011. At this time, she was advised that Mr. House had cancelled multiple appointments with the Clinic in 2010, with his last consultation taking place on 30 October 2009. A further appointment with Dr Espinet was scheduled for 7 October 2011.

106. Around this time, Mr. House's Medicare and DDU records confirm that he was regularly attending upon multiple medical practices, sometimes only on a single occasion, to source further scripts for OxyContin tablets and Fentanyl patches, which he was often able to obtain. Unfortunately, his regular treating general practitioners at PM&DC were not made aware of this doctor-shopping behaviour.

107. Throughout September and October 2011, Mr. House presented to the Emergency Department of the GCH complaining predominantly of chest pain. He was reviewed by Dr Espinet on a number of these occasions, and was directed to continue on his current pain medication regime. He continued to attend different general practices at varying intervals in order to obtain scripts for his pain relief medication.

108. Mr. House next consulted with Dr Koriki Love at PM&DC on 13 December 2011, during which he requested, and was provided with, repeat pain medication scripts. During the inquest, Dr Love indicated that he had not seen Dr Blum's previous notation as to Mr. House's drug seeking behaviour, which he acknowledged would have altered his clinical conduct.

109. On 23 December 2011, Mr. House attended upon Dr Jason Blum at PM&DC for treatment of an infected graze on his right leg sustained during a recent camp trip. He also requested repeat prescriptions for Fentanyl patches and OxyContin claiming he had left them at the campsite. Dr Blum refused to provide further scripts for the opiate pain medication, and prescribed antibiotics to treat the infection. In evidence Dr Blum stated that it was his standard practice not to provide further scripts for opiate medication until the patient was due for repeat prescriptions, regardless of whether they claimed that they had lost a previous script.

110. Mr. House attended upon Dr Love once again on 29 December 2011, during which he claimed that he required repeat prescriptions for OxyContin and Fentanyl as his regular treating general practitioner was on leave. He stated that he had attended an appointment with Dr Espinet in October, however, had no correspondence detailing the outcome. Whilst this lack of paperwork concerned Dr Love, he didn't make any further enquiries at the time. He further stated that he didn't have any suspicions in relation to Mr. House, which would have caused him to contact DDU before prescribing the opiate medication requested.

111. Throughout January 2012, Mr. House continued to obtain regular repeat scripts for Fentanyl patches and OxyContin tablets from PM&DC. Concurrently, he also continued to source single scripts for these pain relief medications from other general practices on the Gold Coast. These instances are clearly documented in the DDU records held in relation to Mr. House.

112. On 24 January 2012, PM&DC received a facsimile from DDU, which indicated that Mr. House had attended multiple doctors within the same practice in order to obtain prescriptions for controlled drugs. The practitioners were requested to make contact with DDU should Mr. House present again, and before any further Schedule 8 medications were prescribed. Unfortunately, the correspondence did not indicate that in addition to attending PM&DC, Mr. House was also sourcing Schedule 8 medication from a number of other general practitioners at other practices at the same time.

113. On 4 February 2012, Mr. House attended upon Dr Long at PM&DC. On this occasion, Dr Long contacted DDU to discuss the correspondence recently received, and Mr. House's pain relief medication management. It was confirmed that he was attending upon multiple doctors within the one general practice, and that signs of intravenous drug use had not been observed. Given the intervals at which he was attending the PM&DC were consistent with usage, it was advised that he could continue to be reviewed, and should attend upon the same few medical practitioners. At inquest, Dr Long recalled that during this discussion, DDU didn't express any concern as to Mr. House continuing to be prescribed opiate medication, nor was he advised that Mr. House had attended other general practices. Had he known that this was the case, Dr Long stated that he would not have prescribed him any further Schedule 8 medications.

114. Some four days later, Mr. House was able to obtain a further script for Fentanyl patches from a different medical practice.

115. From 11 February 2012, Mr. House attended upon various doctors at PM&DC at regular intervals to obtain repeat prescriptions for Fentanyl patches and OxyContin tablets.

116. On 11 March 2012, Mr. House attended upon Dr Love seeking further pain medication scripts as he alleged that his residence had been broken into and he was assaulted by two assailants. Dr Love recalls that Mr. House presented with bruises, and appeared to have suffered an assault. Accordingly, Mr. House was provided with repeat script for OxyContin 80 mg tablets and Fentanyl patches.

117. The following day, Mr. House attended upon Dr Love once again, this time claiming that a friend had stolen the repeat scripts he had been provided with the previous day. On this occasion, Dr Love was not inclined to believe Mr. House's story, and decided to contact DDU. DDU advised Dr Love that for future prescriptions, Mr. House was to collect his medication and return his used patch to a specific pharmacy each day after use, which was to continue until his next appointment with Dr Espinet scheduled for 4 May 2012. During the inquest, Dr Love confirmed that based upon his conversation with DDU, he understood their advice to be that he could continue to prescribe Mr. House OxyContin 80 mg tablets, so long as they were dispensed in a controlled manner. He acknowledged that had he been aware that Mr. House was sourcing additional opiate pain relief medication from other general practitioners, this would have altered his clinical decision to continue prescribing him controlled drugs.

118. On 16 March 2012, Mr. House consulted with Dr Michael Long at PM&DC. He noted that Mr. House was not observed to be wearing his Fentanyl patch, which he did not believe was being used. Mr. House claimed that he had suffered broken bones and had been in hospital, however, had no supporting correspondence. Dr Long recorded that Mr. House was engaging in 'drug seeking behaviour' and was only to obtain prescriptions for controlled drugs from Dr Love. Accordingly, he refused to provide Mr. House with any further prescriptions.

119. Nonetheless, Mr. House was able to obtain two further prescriptions for Fentanyl patches from different medical practices prior to his next appointment with Dr Love on 26 March 2012. On this occasion, Dr Love recorded that Mr. House had been compliant with obtaining his medication every three days as previously directed. He subsequently provided him with repeat prescriptions for his regular medications, including OxyContin 80 mg tablets and Fentanyl patches.

120. Mr. House continued to attend upon Dr Love to obtain repeat scripts for his opiate pain relief medication. On 4 May 2012, Mr. House was sent a letter from the GCH Pain Clinic confirming that he had failed to attend a number of appointments, including one scheduled for that day. Mr. House was directed to respond within 14 days of receipt of the letter or would be removed from the appointment list. As he failed to respond, Mr. House was discharged from the Pain Clinic.

121. On 29 May 2012, Mr. House presented to SPD&NMC and then the GCH by ambulance seeking opiate pain relief medication. DDU was contacted and

confirmed that he had been engaged in doctor shopping behaviour, having attended other practices that day seeking Fentanyl patches. It was noted that Mr. House had been observed walking around outside the Hospital and picking up cigarettes. When the attending doctor went to discuss Mr. House's management with senior staff, he absconded from the Hospital.

122. Unfortunately, it does not appear that Mr. House's disengagement and eventual discharge from the Pain Clinic was communicated to Dr Love until 30 May 2012, when during a consultation with Mr. House, he contacted them requesting information. Accordingly, in the interim, he had continued to prescribe Mr. House opiate pain relief medication at regular intervals. The records suggest that Mr. House had dishonestly indicated that he had a future appointment with the clinic in July 2012.

123. On 30 May 2012, Dr Love also contacted DDU, who advised him that Mr. House had been attending upon other medical practitioners at other practices, sometimes on the same day as he consulted with Dr Love, in order to obtain scripts for opiate pain relief medication. Furthermore, since January 2012, he had, on average, been able to obtain 1 x Fentanyl patch 100 mcg/hr and 3 x OxyContin 80 mg tablets daily. Whilst Mr. House denied this was the case, Dr Love advised him that he would not be prescribed any further medications at PM&DC, and was urged to engage with ATODS for professional assistance. At inquest, Dr Love confirmed that this advice was only provided to him by DDU when he spoke to them, and was never communicated by way of any correspondence.

124. On 1 June 2012, Mr. House was taken to GCH by ambulance after he was found collapsed outside his residence suffering from a suspected opioid overdose. Following treatment, it was recommended that he commence the opioid replacement treatment program immediately, and reengage with the chronic pain team. Following admission to the ward, Mr. House absconded and did not return to the Hospital. DDU were contacted and advised of his presentation.

125. On 3 June 2012, Mr. House was returned to the GCH by ambulance with another suspected drug overdose. His sister had allegedly found him unconscious near an empty box of OxyContin, and some recent track marks. He was subsequently transferred to the Robina Hospital, where his care and management was discussed with DDU. Reports from DDU confirmed that he was doctor shopping for opioid medication, which he was likely injecting. It was noted that he was no longer suitable for opioid treatment in a general practitioner setting.

126. Medical records state that Mr. House was not to have any further opioid medication prescribed by the Hospital, unless at the advice of a treating Consultant. Regardless, Mr. House was discharged on 6 June 2012, and

provided with all of his opiate pain medication at the insistent of the discharging doctor.

127. On 12 June 2012, Mr. House was found by Police having fallen from his wheelchair in a public place. Whilst he didn't appear to have suffered any injuries, QAS were called and assisted him back to his residence.

128. On 17 June 2012, Mr. House presented to the Robina Hospital emergency department claiming he had suffered two seizures that day. He was observed to go into withdrawal and requested opiates to treat his pain. The progress notes indicate that he regularly absconded from the ward. He subsequently discharged himself against medical advice.

129. Despite Dr Love's previous refusal to prescribe Mr. House with any further opiate pain relief medication, he attended a consultation with Dr. Fearon at PM&DC on 20 June 2012, where he was able to obtain further repeat scripts. On 3 July 2012, Mr. House was supplied with further repeat scripts by Dr Fearon.

130. On 26 June 2012, Mr. House was found outside the Robina Hospital unconscious in his wheelchair. Following his admission, he regularly absconded from the ward when allowed to leave to smoke a cigarette. On one occasion, he returned suffering from a suspected opioid overdose having been able to obtain a further script for OxyContin from a new general practitioner. It was recognised by treating staff that Mr. House was at a high risk of suffering from accidental self-harm or death though his continual drug use. It was reiterated that he was not suitable for opioid treatment by a general practitioner, and that DDU should be notified if he was provided with any medication by the Hospital.

131. On 28 June 2012, Mr. House discharged himself against medical advice. Later that day, he was able to obtain a further script for Fentanyl patches from a general practitioner in Ashmore.

132. On 3 July 2012, Mr. House was able to obtain repeat scripts for his opiate pain relief medication from Dr Fearon at PM&DC.

133. On 13 July 2012, Dr Fearon was advised by DDU that Mr. House had attended upon other general practitioners in order to obtain opiate pain relief medication, and that he was inclined to overdose. That same day, Mr. House was found in a Hospital ward by security at the GCH. He appeared to be intoxicated from methyl-amphetamine use. A mental health assessment was ordered, and it appeared that he was suffering from auditory hallucinations. A fresh injection site was observed on his arm. Mr. House was subsequently admitted under an Involuntary Treatment Order. He was administered some opiate pain relief medication whilst an inpatient in a controlled manner. He absconded from the

ward a few days after his admission, returning in a wheelchair a day later. Mr. House was discharged on 19 July 2012, and was not provided with an opiate pain relief medication.

134. On 21 July 2012, Mr. House was able to obtain a repeat script for Fentanyl patches and OxyContin 80 mg tablets from a general practice in Varsity Lakes.

135. On 26 July 2012, Mr. House was brought to the GCH by Police on an Emergency Examination Order (EEO) on the basis that he had been expressing suicidal ideation, and was hallucinating. During his mental health assessment, he admitted that he had consumed OxyContin and Fentanyl patches. The EEO was subsequently revoked, and he was discharged to the emergency department for further medical treatment. It was noted that he presented as drug affected. It was planned that he would be observed overnight. In the evening on 27 June 2012, Mr. House had a seizure in the Hospital cafeteria and a code blue was called. He was subsequently treated in the emergency department, during which his GCS started to improve before being discharged.

136. Hospital records confirm that Mr. House was repeatedly offered assistance by ATODS, however, refused to engage with the service.

137. At a subsequent appointment on 31 July 2012, Dr Fearon refused to provide him with any further scripts for opiate pain relief medications given the advice received from DDU. He encouraged Mr. House not to continue to visit several doctors in order to obtain this type of medication.

138. On this same date, Mr. House attended upon Dr Than Tun at the Southport Park Medical Centre, where he was able to obtain repeat prescriptions for all his medications, including OxyContin and Fentanyl patches. On 13 August 2012, Mr. House attended upon Dr Tun again, and was provided with a further script for Fentanyl patches and OxyContin 80 mg tablets.

139. On 20 August 2012, Mr. House presented to the GCH emergency department with an altered state following a suspected opioid overdose. He was subsequently intubated and placed in the intensive care unit. After a mental health assessment and medical review, it appears that he was discharged on 22 August 2012.

140. Later that day, Mr. House presented to the emergency department of the Robina Hospital suffering from a drug overdose. He was intubated and treated, before being transferred to the GCH. Mr. House advised staff that he wanted to leave the Hospital as he owed a lady OxyContin for some ICE previously supplied. He was kept under an order, however, convinced a nurse to allow him to smoke outside, during which he absconded. He returned later that day in his wheelchair.

The treating team concurred that his appearance and behaviour was consistent with recent drug use, and he was required to remain in the Hospital over the weekend.

141. On 25 August 2012, whilst still an inpatient, Mr. House was found by nursing staff in his bathroom acting suspiciously. Droplets of blood were observed on the floor, with a syringe, spoon, lighter and rock like substance present. Police were notified and confirmed that there was an outstanding warrant for his arrest. It was requested that Police be advised when he was due to be discharged.

142. On 26 August 2012, Mr. House requested pain relief from nursing staff, which was refused. He subsequently became violent and hit a wall. Police were called and removed the relevant drug paraphernalia. Mr. House remained as an inpatient. Later that day, he absconded from the ward, returning in the evening drowsy. Naloxone was subsequently administered.

143. On 27 August 2012, Mr. House was discharged from the GCH, during which he was not provided with any opiate medication. Police collected him at 2:30 pm, where he was transported to the Southport Watch house.

144. On 28 August 2012, Mr. House went before a Magistrate before being discharged from the watch house at 1:14 pm. At 2:31 pm, he attended upon Dr Than Tun at the Southport Park Medical Centre where he was able to obtain scripts for OxyContin 80 mg tablets and Fentanyl Patches. It was this medication that Mr. House used shortly prior to his death.

Failures of MRQ in relation to Mr House

145. Based upon Information received from MRQ, the following actions were taken in relation to the monitoring of the dispensing and prescribing of Schedule 8 medicine to Mr. House:

- 12 July 2010: DDU wrote to Dr Seton requesting information about the ongoing prescribing of Mr. House with Fentanyl and OxyContin for chronic pain.

- 20 July 2010: DDU received a “Report to the Chief Executive” from Dr David Seton stating that he was treating Mr. House with Fentanyl patches, 100mcg/hr every 3 days and OxyContin 40mg BD. This treatment regime had been initiated at the Gold Coast pain clinic when Mr. House was reviewed on 30 October 2009. Dr Seton also included information from a referral to the Department of Neurology, Gold Coast Hospital, which Mr.

House attended on the 4 January 2010, at which no alteration was made to his medications for chronic pain.

- 22 July 2010: DDU responded to Dr Seton's report by indicating that he should notify DDU if there as any escalation of dose of Mr. House's analgesics.

- 23 August 2011: A further report was received from Dr Seton stating that he was no longer prepared to prescribe for Mr. House as he had stated that he had medication stolen from his house.

- 17 January 2012- 30 May 2012: Numerous calls recorded from the Enquiry service regarding Mr. House and the following behaviours –

    - Injecting sites identified on his left and right arms;

    - Information indicating that he was not as disabled as he was presenting to various GP (for example, Mr. House would present in a wheelchair but had been seen walking around the local area); and

    - He was attending various GP's requesting pain relief, generally OxyContin tablets and Fentanyl patches.

- 30 May 2012: Phone call received from the GCH Alcohol and Drug liaison service. Mr. House had presented to the Emergency Department requesting medication (OxyContin and Fentanyl), however, did not wait to be seen and left the hospital without waiting for a review.

- 1 June 2012: Phone call received from GCH Drug and Alcohol Brief Intervention Team indicating that Mr. House had been brought in by ambulance and was suspected of having an opioid overdose.

- 3 June 2012: The GCH Alcohol and Drug service notified DDU that Mr House had presented 3 times that week with opioid overdose symptoms and signs.

- 6 June 2012: The GCH Alcohol and Drug service notified DDU that Mr House had been admitted 3 days beforehand with an opioid overdose of his Schedule 8 medicines. He was admitted to ICU and discharged 2 days later. At that time, he was provided with discharge medicine, including OxyContin and Fentanyl.

- 26-27 June 2012: Mr. House was again admitted to the GCH with opioid overdose and continued to abuse medication whilst in hospital (taking extra medication when went out for a cigarette).

- 27 June 2012 - 24 August 2012: Mr. House had a further admission to the GCH for overdoses of a mixture of medications and was treated in the mental health unit on two of these occasions. On discharge from hospital on 24 August, Mr. House was not given any opioids as part of his discharge medication.

146. In relation to Mr. House's prescribing history, MRQ records suggest that:

- Between 1 January 2012 and 28 August 2012, Mr. House saw 20 different doctors. Prescriptions provided during this time were for OxyContin (80mg tablets) and Fentanyl patches (100 mcg).

- Mr. House was averaging 1 x Fentanyl patch daily and 2 x OxyContin tablets daily.

- Mr. House's last prescription was written and dispensed on 28 August 2012, when he received 5 x 100mcg Fentanyl patches and 28 x 80 mg OxyContin tablets. This was 4 days after his final admission to the GCH when he was not discharged with any opioids.

147. In relation to the monitoring of the prescribing and dispensing of Schedule 8 medicines to Mr. House, MRQ noted that:

- All doctors were notified of Mr. House's drug seeking behaviour by fax and during phone calls in early 2012.

- Doctors who called the DDU 24/7 enquiry service were also provided with information as to his controlled drug prescribing. However, not all prescribing doctors contacted DDU before prescribing Schedule 8 medicines to Mr. House.

- DDU recommended that Mr. House be referred to QOTP, however, he refused to engage with the service.

- Multiple health care services on the Gold Coast were involved in managing this patient, including mental health services.

- General DDU recommendations to GP's prescribing to Mr. House were that they restrict the amount of medication provided to him at any one time.

- DDU surveillance and alert processes can only detect patterns of behaviour after prescribing has occurred. Also, there is a time lag in information transmission as prescription data is only transferred on a monthly basis.

- DDU has issued general alerts to the GP community in relation to concerns associated with Fentanyl misuse and also promoting its 24/7 telephone enquiry service.

148. It is evident from the above that despite Mr. House attending upon 20 different general practitioners between 1 January 2012 and 28 August 2012, the only action taken by DDU, as the regulator, was to send correspondence to one general practice in January 2012. No other proactive monitoring or follow up was carried out by DDU in relation to his escalating drug seeking behaviour.

GCHHS Review in relation to Mr House

149. Following Mr. House's death, the GCHHS conducted a comprehensive Root Cause Analysis (RCA), so as to identify any system vulnerabilities related directly to the death, or lessons that could be learnt to improve the delivery of patient care within the health service. Upon a review of the circumstances surrounding Mr. House's death, a number of lessons learnt were identified.

150. I do not propose to set out in detail these changes in these findings, as I am satisfied the recommended changes to work practices have been implemented. It is significant, however, that there continues to be no direct line of communication between MRQ, as the regulator of controlled drugs in Queensland, and a treating hospital, who have the authority to dispense such medication, often in significant quantities.

Changes made to practices by General Practitioners since Mr House's death

151. Consistently, each of the general practitioners, who were involved in Mr. House's pain management expressed some level of regret, with the benefit of hindsight, as to some of the clinical decisions made. Most confirmed that had they been aware that Mr. House was engaged in drug seeking and doctor shopping behaviour, this would have significantly impacted upon their decision to prescribe him Schedule 8 medication.

152. Specifically, Dr Seton indicated that following his engagement with Mr. House, he had made a number of changes to his practices when managing patients

suffering from chronic pain. These changes include engaging with DDU when a patient is commenced on opiate pain relief medication.

153. Dr Seton also noted that since 2011, there had been significant improvements to the communication between the Hospital and general practitioners, including access to specialists involved in the treatment of patients. He stated that information is now often provided electronically, which can then be easily accessed by the doctors within the practice.

154. Dr Love confirmed that he had made substantial changes to how he manages patients with opiate pain relief medication since Mr. House's death. He indicated that he now closely interrogates a patient's record, and will seek clarification and advice from external sources if necessary.

155. Dr Long indicated that since his engagement with Mr. House, he no longer prescribes Fentanyl patches, as they are prone to abuse.

156. Having had an opportunity to consider Mr. House's medical records, Dr Espinet recognised that the dosage of opiates he was prescribed was inappropriate for his conditions. He recognised that there was no coordinated care of Mr. House or an overall management plan across the various specialties involved in his treatment. He also acknowledged that opiates were not recommended for the treatment of musculoskeletal pain or headaches, and he now only uses low dose slow release opiates, which he withdraws from patients after six months, even for those with a definite diagnosis.

157. Dr Espinet highlighted the challenges associated with the under resourced and limited capabilities of the Pain Clinic as of 2008, which prevented him from providing Mr. House with follow up care, and effectively implementing an ongoing management plan. He notes that there was an extreme shortage of public pain management services on the Gold Coast 10 years ago. Mr. House's case has reiterated to him the importance of a coordinated approach with other treating specialists and general practitioners in relation to the care for chronic pain patients. He is now also far more cautious about prescribing opioids. Pivotally, he is of the view, that one specialist needs to take ownership for the management of a patient, to ensure they are provided with a proper pain management program.

158. Dr Espinet also highlighted the difficulties associated with identifying and managing a patient who is suffering from an opiate addiction and/or is opiate dependent. He noted that it is challenging to identify and distinguish between the two conditions, and then act accordingly in the best interests of the patient. He agreed that this would a difficult task for a general practitioner, who was not a

pain specialist, and that targeted education is important to ensure they are aware how to manage pain properly.

General Practitioner Education

159. Dr Seton indicated during the inquest that he had never received any targeted training in relation to the prescribing of Schedule 8 medication or the regulatory environment surrounding such medication. This sentiment was shared by Dr Love and Dr Suzanne Blum.

160. Neither Dr Jason Blum nor Dr Suzanne Blum could recall being provided with information detailing their obligations as a doctor with respect to managing patients with opiate medications from any governing bodies in recent years. Both agreed that targeted education in relation to clinical decisions to be made surrounding opiate prescribing would be helpful, however, firmly thought that real-time prescription monitoring was an important component in a system designed to prevent opiate abuse.

161. Dr Long stated that he had only recently been provided with some targeted training as to prescribing Schedule 8 medication, as well as the regulatory environment aimed at controlling the use of these drugs. He noted that this education was certainly valuable.

162. There was a general consensus amongst the general practitioners, who were called to give evidence during the inquest, that a real-time prescription monitoring system in Queensland would be a pivotal tool in ensuring the effective prevention of the abuse of opiate medication.

Jodie Anne Smith

163. Jodie Anne Smith was 41 years of age at the time of her death. She resided at Upper Coomera with her husband David, and her son Jermayne. Three years before her death, Ms. Smith had been diagnosed with CRPS in her hands and lower limbs after suffering a fall at work in 2009. She had been on WorkCover since that event, and had moved to Queensland around a year later.

164. At around 4:00 am on 19 August 2012, Mr. Smith awoke after falling asleep on a lounge chair. He saw that Ms. Smith had also fallen asleep on the couch. He dozed off again, waking at around 8:30 am. He saw that Ms. Smith was no longer on the lounge, and found her asleep in their bed. He noticed that she was breathing heavily, and at times was snoring. He checked on her again at around 9:15 am, and noted that she was breathing and occasionally snoring.

165. After attending to other household chores, Mr. Smith went to check on Ms. Smith at around 10:30 am. He found her lying face down on the bed not breathing. He immediately called triple 0 before commencing CPR as instructed by the Queensland Ambulance Service ('QAS') operator. An ambulance arrived around 12 minutes later. As no signs of life could be detected, Ms. Smith was declared deceased at 10:53 am.

166. Police subsequently attended the residence and conducted an examination of Ms. Smith's room. They located a substantial number of medications, namely:

Prescribed by Dr Rachid HOMSI, of Mt Druitt MC, Sydney on 13/08/12:

I. Diazepam GA 5 mg tabs – 20 of 50 remaining (1 when required)
II. Zopliclone 7.5 mg tabs – 10 of 30 remaining (1 nocte)
III. OxyContin CR 40 mg tabs – 30 of 40 remaining (1 x 2 per day)

Prescribed by Dr M TADROS of Brygon Creek MC on 20/07/12:

IV. Amitriptyline AF 50mg tabs – 20 of 50 remaining (1 nocte)

Prescribed by Dr SENANAYAKE of Coomera City MC on 13/08/12:

V. OxyContin CR 10 mg tabs – none remaining of 28 tabs (1 x 2 per day as required)
VI. Zopiclone 7.5 mg tabs – 20 of 30 remaining (1 nocte when required)

Prescribed by Dr SRINIVASA of Ormeau MC on 10/098/12:

VII. Antenex 2 Diazepam 2 mg – 5 remaining of 50 (1 daily)

167. Notably, two sets of the prescriptions provided, which both included a script for OxyContin, were dated the 13 August 2012. This is unusual as one of the prescribing doctors is based in Sydney, and the other in Coomera on the Gold Coast. Mr. Smith reportedly told Police that Ms. Smith's Mother would fill prescriptions for her in Sydney, before mailing the medication to her daughter. A statement from Mr. Smith was never obtained by Police.

168. Police also located seven ampoules of Morphine Sulphate, dated 2011, in Ms. Smith's bedside table. Mr. Smith told Police that she had not taken this medication for quite some time.

Post-mortem findings

169. At autopsy, Ms. Smith's cause of death was found to be as a result of the combined effects of myocarditis (as caused by a viral infection) and the ingestion

of a large quantity of medications for Complex Regional Pain Syndrome. Toxicological testing revealed the presence of Diazepam, Temazepam, Amitriptyline, Oxycodone and Zopiclone. Forensic Pathologist, Dr Grace Higgins noted that the level of Amitriptyline and Oxycodone was high, *'especially when taken in conjunction with the other drugs detected, but this woman would have had high tolerance for these drugs*.' Accordingly, Dr Higgins found that, '*the cause of death in this case is probably cardiorespiratory failure, due to the combined effects of viral myocarditis and ingestion of large quantities of medication taken to manage Complex Regional Pain Syndrome*'.

Medical history

170. In 2009, whilst residing in Sydney, Ms. Smith suffered a significant workplace injury, following which she required management by Musclo-Skeletal Physician and Pain Management Specialist, Dr Robert Adler at the Westmead Hospital. Her primary long-term general practitioner since 2002 was Dr Richard Homsi from the Mt. Steward Medical Centre. According to Dr Homsi, she had a complex medical history, with her key clinical problems identified as follows:

- Chronic knee pain;
- Chronic back pain;
- Migraines;
- Chronic skin abscesses (as a result of manifestations of Methicillin-resistant *Staphylococcus aureus,* a 'superbug' which is resistant to many antibiotics. This horrible condition seems to have plagued Ms. Smith for a number of years since a hysterectomy in June 2002); and
- Difficulties with weight control.

171. In September 2009, Ms. Smith was diagnosed with Complex Regional Pain Syndrome (CRPS), the severity of which Dr Adler described as 'horrific'.170 She required hospitalization on a number of occasions, and received a Ketamine infusion. She was prescribed OxyContin 20 mg tablets to assist in managing the pain associated with her condition.

172. In 2010, Ms. Smith relocated to Queensland and commenced attending the Ormeau Medical Centre. She was primarily managed by Dr Ramiah, until his death in August 2011.

173. On 15 July 2010, Dr Ramiah prepared a report to DDU, identifying Ms. Smith's diagnosis of CRPS, for which she was prescribed various medication, including Endone 10 mg tablets, OxyContin 40 mg tablets and Morphine saline solution 30mg/ml. A response was received from DDU on 21 July 2010, which requested further notification if her analgesic requirements 'significantly escalated'.

174. During the course of his engagement with Ms. Smith, Dr Ramiah referred her to Pain Specialist, Dr Mark Tadros. In correspondence addressed to Dr Ramiah, Dr Tadros noted the complexity and severity of Ms. Smith's condition from which she suffers vasomotor and neuropathic pain symptoms consistent with CRPS. He expressed concern as to the dosage of OxyContin she was presently prescribed, and advised that this should gradually be reduced to 20 mg. Ms. Smith subsequently underwent a number of procedures in an attempt to manage her pain, which including extended Hospital admissions. In correspondence dated 20 October 2010, Dr Tadros stated that *'I am not really keen for Jodie to have any more opioids, her pain has been proven to be opioid resistant.'* She subsequently underwent rehabilitation treatment at the St. Vincent's Hospital in Brisbane. Unfortunately, following release from Hospital, and in spite of Dr Tadros' advice, Dr Ramiah prescribed Ms. Smith OxyContin 40 mg tablets, to be taken twice a day.

175. At the same time Ms. Smith was attending upon Dr Ramiah, she regularly sought scripts for opiate pain relief medication and benzodiazepines, often on a one-off basis, from various other local general practices. She appears to have been a consummate doctor shopper, who attended upon various different pharmacies in order to fill these multiple prescriptions in order to avoid detection.

176. On 31 October 2011, Dr Arehalli Srinivasa took over management of Ms. Smith's care at the Ormeau Medical Centre. At this time, she was prescribed Endone 5 mg tablets, in addition to other medication to treat her complex condition. She continued to then be prescribed Endone at regular intervals.

177. On 19 January 2012, Ms. Smith attended upon Dr Srinivasa complaining of continued back pain. She was subsequently changed from Endone tablets to OxyContin 20 mg tablets with the intention of weaning her from this when her back pain subsided. On 22 January 2012, Ms. Smith attended the emergency department of the Robina Hospital where she complained of suffering from back pain for a period of two weeks. She was sent home with a prescription for Oxycodone tablets, Panadeine Forte and zopiclone.

178. On 6 March 2012, her dosage of OxyContin tablets was reduced by Dr Srinivasa to 10mg, before once again being increased on 26 March 2012. The reason for this increase is not clear from the records. Following gastric band surgery, Ms. Smith was returned to Endone tablets only.

179. Unfortunately, without Dr Srinivasa's knowledge, Dr Homsi continued at irregular intervals to engage with and prescribe Ms. Smith opiate medication, including OxyContin 40 mg tablets and Endone 5 mg tablets, despite the fact that she now resided in Queensland. This was often done without consulting with Ms. Smith in person, rather relying solely on a telephone discussion. The scripts for these pain relief medications were then provided to Ms. Smith's mother, who filled them before sending the medication to Queensland. At no time, did Dr Homsi contact Dr Srinivasa to discuss Ms. Smith's management.

180. Dr Homsi claimed that Ms. Smith had sought repeat scripts from him over the telephone whilst she resided in Queensland as she was unable to see a local doctor as she was house bound by her level of pain.183 He expresses regret that he did not identify her as a doctor shopper, and also recognised the inappropriateness of prescribing medication to a patient without a proper consultation.

181. Dr Homsi last personal attendance on Ms. Smith was on 6 July 2012, at which time she advised him that she had been diagnosed with osteoporosis, and that a fracture had been found in her spine. When asked about providing prescriptions to Ms. Smith's Mother on her behalf, he noted that:

> *[25] At no point was I suspicious that the deceased was attending other doctors for the same medications, or that she was a doctor shopper. The deceased's chronic conditions were debilitating and my subjective and objective observations of the deceased supported use of strong pain medications. I was guided in my treatment of the deceased by input from a variety of specialists, including a pain specialist.*
>
> *[26] The deceased's husband often attended with the deceased to many of the consultations over the years of her treatment. We had a good long standing relationship and it was my understanding he was responsible for a large amount of her care at home, and he was given scripts on some occasions as indicated in the medical records. I did not charge Medicare for any service rendered at which the patient did not personally attend.*
>
> *[27] I note that the Coroner has asked whether I gave scripts to the deceased's mother. Again, the deceased's mother was heavily involved in her care and from time-to-time (on two or three occasions no more) I may have given scripts to her Mother to be filled. The giving of scripts to the deceased's husband and mother only occurred in circumstances where I had a good understanding of the deceased's condition and in circumstances where she felt too unwell to attend the surgery.*

182. On 13 August 2012, following a telephone discussion, Dr Homsi provided Ms. Smith with further prescriptions for OxyContin 40 mg tablets. This script was subsequently collected by her mother.

183. Dr Srinivasa expressed dismay that Ms. Smith had consulted with other general practitioners during the course of their engagement. She had no knowledge that Ms. Smith was obtaining medication from other sources. Dr Srinivasa further stated that Ms. Smith never presented as though she was 'doctor shopping', and clearly had a genuine need for pain management medication.

Changes made to practices by General Practitioners since Ms. Smith's death

184. Since Ms. Smith's death, Dr Homsi now refers patients with increasing pain management requirements to pain specialists before commencing opiate analgesia. He also contacts the Prescription Shopping Program if a new patient requests a prescription for opiates or other drugs of dependence. He no longer prescribes the same amount or types of drugs of dependence.

185. Dr Homsi has also participated in a review of his practice with the assistance of the NSW Risk Advisory team from Avant. He has also undergone further relevant training in relation to the prescribing of drugs of dependence.

Vanessa Joan White

186. Vanessa Joan White was 38 years of age at the time of her death. She resided with her partner, Richard Bell at a residence in Labrador.

187. On 18 December 2012, Ms. White was celebrating her birthday with Mr. Bell at home. From around 9:00 am that morning, until 10:30 pm on that day, they were injecting OxyContin on a regular basis about every two hours. Each dose was said to be around 80 mg. It is not exactly clear how each of these administrations occurred.

188. In addition to OxyContin, Ms. White also consumed ½ x tablet of Solian (antipsychotic), one tablet of Silex (antibiotic for pneumonia), one tablet of Murelax (sleeping tablet) and three Vodka Cruisers.

189. Ms. White was reportedly in a good mood that day, although had expressed some despair at being separated from her daughter, who was in the care of the Department of Communities, Child Safety and Disability Services.

190. Ms. White retired to bed at around 11:00 pm, having had her last injection of OxyContin at around 10:30 pm. Mr. Bell remained in the lounge room watching television. He fell asleep waking at around 6:00 am the following day. He went to the bedroom where he found Ms. White unresponsive and not breathing. He immediately called the Queensland Ambulance Service ('QAS'), who attended and declared Ms. White deceased.

Post-mortem findings

191. At autopsy, Forensic Pathologist, Dr Grace Higgins found that Ms. White's cause of death was as a result of multiple drug toxicity. Toxicological analysis of blood samples taken detected a number of substances, including alcohol, Oxycodone (1.3 mg/kg), Diazepam (Valium), Oxazepam (Murelax), Amisulpride (Solian), Benztropine (Cogentin) and Quetiapine (Sequase). It should be noted that Ms. White had not been prescribed Quetiapine (antipsychotic medication) or Oxazepam (anti-anxiety medication) at the time of her death. The level of Oxycodone detected was very high and in the fatal range. The level of Solian detected (14mg/kg) when considered in the context of post-mortem redistribution, is relatively high.

192. Multiple areas of scarring, possibly related to injection sites, were also found on the arms, top of the feet and ankles.

Medical and mental health history

193. Ms. White had a notable medical and mental health history, having been diagnosed with schizophrenia, hepatitis C, low back pain and substance abuse. In 2001, she was involved in a motor vehicle accident, in which she sustained a fractured pelvis.

194. In 2002, Ms. White was admitted to the Princess Alexandra Hospital psychiatric unit with a drug induced psychosis, with a differential diagnosis of Schizophrenia.195 She had been experiencing persecutory ideas, auditory hallucinations and had threatened her friend with a knife. She was admitted involuntarily, and subsequently discharged on 2 May 2012.

195. In May 2005, Ms. White self-referred to mental health services as she was experiencing early psychotic symptoms, including auditory hallucinations. She was commenced on anti-psychotic medication, Solian (Amisulpride) to manage her Schizophrenia.

196. In August 2007, Ms. White was again referred back to mental health services as she was experiencing low level psychotic symptoms, in particular auditory hallucinations. She was 37 weeks pregnant at the time.

197. In April 2009, Ms. White was taken to the GCH with left hip pain, which had worsened over the previous four days.196 No new fractures were found following an X-ray, and it was thought that the pain was muscular.

198. In 2010, Ms. White was diagnosed with a grade 3 L5/S1 anterolisthesis with a suspected high-grade spinal stenosis. On 13 July 2010, Ms. White attended upon Dr Ian Mitchell at the Surfers Paradise Day and Night Surgery complaining of lower back pain following her diagnosis. He conducted an examination, during which he did not find any track marks, and also called the DDU, who confirmed that she had no history of obtaining narcotics. He prescribed her 20 mg OxyContin tablets to be taken twice a day and ordered a CT scan. The scan confirmed the marked anterolisthesis with compression of the openings where the nerves come out from the spinal cord.

199. Dr Mitchell reviewed Ms. White again on 23 July 2010, where he noted that she had been getting lower back pain for the past few months that had come on spontaneously, particularly when she was standing up.199 He referred her to the neurosurgery department of the GCH for surgical assessment. In a subsequent consultation on 2 August 2010, Dr Mitchell noted that she was on the waitlist for an appointment. He refused to provide her with a higher dose of OxyContin at this time, despite her requests, as he did not believe it was clinically necessary. Dr Mitchell also contacted DDU to confirm the dosage Ms. White may have been provided by other general practitioners. He assessed her as having a 'complex chronic medical disorder'.

200. On 4 August 2010, Ms. White attended the Redcliffe Peninsula 7 Day Medical Centre where she consulted with Dr Than.203 She claimed that she had moved from the Gold Coast and that she was using OxyContin for back pain, for which she was awaiting a specialist appointment. Dr Than rang DDU and noted that she was '*not on the program*' (meaning the doctor shopping program) and that it was acceptable for her to be prescribed OxyContin. He subsequently prescribed Ms. White 80 mg OxyContin tablets to be taken twice a day.

201. On 13 August 2010, Dr Than referred Ms. White to an orthopaedic specialist as he was tablets was provided. This was repeated on 25 August 2010. On 8 September, Ms. White claimed that she had lost her specialist referral, which was reissued.

202. On 15 August 2010, Ms. White saw Dr Seton at the Surfers Paradise Day and Night Surgery requesting more OxyContin tablets. Dr Seton refused to provide it, advising her to see Dr Mitchell. She subsequently saw Dr Mitchell the following day and he was suspicious of a needle mark on her right forearm, stating that he would not prescribe her with any more OxyContin if there were any further suspicious marks on her arms.

203. Dr Mitchell saw Ms. White again on 24 August 2010, and noted that she had taken extra OxyContin due to her pain worsening. He continued with the same dose, and advised her not to take any extra doses.

204. On 14 October 2010, Dr Than referred Ms. White to a psychiatrist and again reinforced the need for her to make an appointment with the orthopaedic surgeon. He provided her with prescriptions for OxyContin 80 mg tablets, his last being given on 24 November 2010.

205. On 13 December 2010, Ms. White attended the Bay Medical Centre and saw Dr Russell MacDougall. She requested a script for OxyContin. He subsequently called Dr Than noting that he had been prescribing her OxyContin awaiting a specialist appointment. He confirmed that the last time he had prescribed her OxyContin was on 24 November 2010. Dr MacDougall prescribed her OxyContin 80 mg tablets to be taken twice a day, advising her that this was a once only script. Nevertheless, she attended upon him again on 22 December 2010, seeking OxyContin, which he refused to prescribe.

206. On 27 December 2010, Ms. White saw Dr Mark Jeffrey at the Surfers Paradise Day and Night Surgery, who refused to prescribe her OxyContin as he noted that she as getting this medication from a Dr Than in Redcliffe at a strength of 80 mg. She subsequently saw Dr Mitchell on 30 December 2010, who noted that Ms. White was now regularly seeing her doctor in Redcliffe, however, he was away. She requested a script for 80 mg OxyContin tablets, however, he only prescribed her 20 mg tablets to be taken twice a day. During the inquest, Dr Mitchell agreed that this request did give him some cause for concern.

207. Ms. White last visit to the Redcliffe Peninsula 7 Day Medical Centre was on 31 December 2010, where she was prescribed 60 OxyContin 80 mg tablets by way of an Authority prescription by Dr Karen Flegg.

208. In January 2011, Ms. White started attending Primary Medical and Dental Centre (PM&DC), where she consulted with Dr Suzanne Blum. Notes suggest that Ms. White had been prescribed OxyContin 60 mg tablets at Redcliffe three weeks earlier. Dr Blum contact the Redcliffe surgery and was advised that Ms. White sometimes took one tablet three times a day. Dr Blum subsequently prescribed her OxyContin 20 mg tablets, with advice that she attend her usual doctor for this medication in future. On 7 February 2011, Ms. White showed Dr Blum the CT scan of her spine following which Dr Blum noted that it was the worst case of anterolisthesis she had seen. Dr Blum subsequently wrote a letter to the GCH requesting an urgent review of Ms. White's case.

209. Ms. White was last seen at the Surfers Paradise Medical Centre on 16 February 2011, where she was stressed and loud in the waiting room. She was prescribed Valium to help with her anxiety and psychotic symptoms.

210. On 10 March 2011, Ms. White presented to the PM&DC claiming that she had lost her purse with her medication. Another prescription was issued. She was also observed to be increasingly aggressive with her daughter in the waiting room. On 18 March, Ms. White's pain was so severe that she could not lie flat for an examination. She again lost her prescriptions, in Toowoomba this time, but the doctor refused to re-issue the scripts.

211. In 2011, Ms. White attended upon doctors at the Scarborough Street Medical Centre, which had been prescribing her with Solian since 2005. Dr Mitchell had since moved to this practice, and saw Ms. White on a number of occasions prescribing her with Valium and Solian. On 16 September 2011, Dr Mitchell noted that she had been abusing Valium. The last prescription provided was issued on 15 November 2012.

212. On 3 June 2011, Ms. White was assessed at the Hospital neurology outpatients, where Senior Neurological Surgeon, Dr Poulgrain conducted an examination and ordered an MRI. He then referred her to Dr Stephenson, who could perform the necessary spinal surgery.

213. On 10 June 2011, Ms. White presented to the PM&DC claiming she had lost her referral for the MRI. On 23 June, she presented stating that she had left Coffs Harbour without her medication and requested further scripts. On 18 July, she presented again claiming that she was back from Coffs Harbour and had left her medication on the train. On 18 August, Ms. White presented again claiming that her medication and money had been stolen from her purse. On 28 September 2011, Ms. White again claimed that she had lost her medication and did not offer any explanation as to how it happened.

214. On 6 October 2011, Dr Blum was contacted by the Department of Communities, Child Safety as Ms. White had allegedly assaulted her daughter at the Brisbane Road pharmacy, during which she and her partner appeared to be under the influence of drugs. Ms. White also had bruises on her arms, which looked like puncture marks and there was concern she was injecting OxyContin. Dr Blum was also advised that another doctor had been prescribing her Valium.

215. On 11 October 2011, Dr Blum documented in Ms. White’s medical record that she had not been identified as a ‘doctor shopper’ within the previous 3 months. She was now being prescribed her medications from the pharmacy on a daily basis only. On 28 October, Ms. White denied that she was injecting OxyContin, however, admitted to injecting speed. She was reportedly extremely distressed. Dr Blum noted that it was unlikely that she would be able to cease the OxyContin until her surgery was completed, however, this was a long term aim. Her back surgery was recorded as being a posterior lumbar interbody fusion, which was likely to take place in November or December 2011.

212. On 21 November 2011, medical records from PM&DC suggest that Ms. White reported that her psychotic symptoms were not well controlled, and she was experiencing auditory hallucinations.

216. On 5 December 2011, Ms. White was late to an appointment with the neurosurgeon and her appointment was rescheduled for February 2012. On 22 February 2012, a letter from the neurosurgery department of the GCH, confirmed that her MRI showed the anterolisthesis and also significant bone to bone impaction. She was placed on a waiting list as a category 2 patient.

217. On 27 March 2012, Dr Blum contacted Dr Mitchell to confirm that he had not been prescribing Ms. White OxyContin, however, had provided her scripts for Valium and Solian.217 On 16 August 2012, Dr Blum advised her of the risks associated with taking Valium and OxyContin, and planned to decrease her Valium to two tablets three times a day over the next couple of weeks, and then to try and reduce the amount of OxyContin necessary. The OxyContin prescribed was now being supplied every second day by the pharmacy. On 25 September, it was noted that Ms. White had missed the preoperative MRI appointment.

218. On 17 November 2012, Ms. White accidentally overdosed on OxyContin and Valium tablets, and was found unresponsive on the couch by Mr. Bell. She was taken to the GCH for treatment by ambulance, however, regained consciousness with the assistance of oxygen, following which she became aggressive and abusive. She told them that she had taken 10 OxyContin tablets and 10 Valium tablets, although she denied intentionally trying to hurt herself. Ms. White was transported to the GCH, however, left before she was able to be seen by a doctor. She attended upon Dr Blum the following day, however, failed to mention the overdose. She was subsequently given the full prescription of OxyContin as she stated that she was traveling to Brisbane for the next two weeks. Another full prescription was then given on 2 December, as she was allegedly staying in Brisbane again, however, Dr Blum noted that she was not going to do this again.

219. On 16 December 2012, Ms. White was prescribed the full prescription by Dr Terry Miller from PM&DC, who noted that he intended to speak to Dr Blum about the medications.221 An entry by DDU does indicate that Dr Miller had called them in relation to Ms. White as he was making an enquiry in relation to her prescriptions of OxyContin. This was the final consultation with Ms. White at PM&DC.

General practitioner comments in relation to the treatment of Ms. White

220. Records confirm that Dr Mitchell contacted DDU before prescribing Ms. White opiate pain relief medication. He stated that overall, she appeared to be taking her medications as prescribed within the requisite therapeutic effect. In hindsight, Dr Mitchell recognises that his records in relation to Ms. White could have been

more comprehensive, however, the care he provided was reasonable in the circumstances.

221. In recent times, Dr Mitchell has undergone further training and education in order to improve the quality of the care he provides to his patients, who require opiate pain relief medication. He has also undertaken an audit of all the patients for whom he has prescribed Schedule 8 medications for the past 12 months, and has sought to rectify any deficiencies identified in the audit. He confirmed that he had obtained the necessary authority to prescribe from DDU (MRQ), per the regulatory requirements, in all cases where this was required.

222. Dr Mitchell agreed that further education and training for general practitioners as to the appropriate prescribing of Schedule 8 medications, as well as the regulatory environment, would be beneficial.

Hospital Review

223. Since Ms. White's death, a number of changes have been made to the reporting and recording of patient's presentations at the GCH, which include:

- In 2013, the Acute Care team was redesigned, the outcome of which has been that patients who require medical clearance are identified earlier with the medical clearance process standardized.

- In 2015, a 'Did not wait: Review of patients who DNW for treatment in the ED' was introduce, which outlines the steps for the screening of those who did not wait and in its present form describes the steps to be taken for the management of those people.

- In relation to the prescription of controlled drugs and doctor shopping , a guideline was developed titled '*Guidelines for Narcotic Use in Gold Coast Hospital Emergency Department'*, which in essence stipulates that narcotic pain relief should be avoided if the acute problem is likely to be considered frequent or recurrent. Importantly, emergency department doctors are not to provide replacement or additional scripts to patients unless they have specific authorisation from MRQ. Staff in general are also encouraged to liaise with MRQ and the National Dr Shopper Hotline, as well as utilise VIEWER to identify a patient who may be drug seeking or a frequent attender.

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Daniel Keith Milne

224. Daniel Keith Milne was 40 years of age at the time of his death. He had a long history of significant illicit drug use, which included heroin, and had sporadically attended various drug rehabilitation clinics in the 2 years before his death.

225. Mr. Milne's treating General Practitioner immediately prior to his death was Dr William Bruce Whelan. Medical records suggest that Dr Whelan consulted with Mr. Milne primarily at the Gold Coast Pharmaceutical Support Centre and Broadbeach General Practice. During this time, Mr. Milne was managed for substance dependence with Suboxone. On 4 December 2013, he commenced treating Mr. Milne with fentanyl patches for injuries reportedly suffered during a workplace accident. These injuries were never substantiated.

226. At around 7:45 pm on 12 February 2014, Mr. Milne was located deceased by his flat mates at his Broadbeach residence. He had a syringe in the back of his hand. The Queensland Ambulance Service was immediately called and attended. Despite continued resuscitation efforts, Mr. Milne was declared deceased.

Post-mortem findings

227. The cause of Mr. Milne's death was found to be acute fentanyl toxicity. Toxicological analysis of the post-mortem blood samples taken indicated a fentanyl concentration of 0.037 mg/kg.

228. Both old and recent needle puncture marks were observed on his arms. Old track marks were also visible in his elbow creases. No evidence of significant natural disease was found.

Medical History

226. Medicare and medical records suggest that Dr Whelan was Mr. Milne's primary treating general practitioner at the time of his death. His first consultation with Mr. Milne took place on 22 June 2011 at the Gold Coast Pharmaceutical Support Centre. On this occasion, details of Mr. Milne's history of substance use, mental health diagnoses, occupational and current medications were recorded. It was also noted that Mr. Milne had a takeaway dose of methadone 13 mg/day, and had previously used cocaine and cannabis. No examination notes were recorded. Dr Whelan subsequently changed Mr. Milne from Methadone to 8 mg of Suboxone, which he had to collect daily. Dr Whelan advised DDU of this change.

229. During the course of Dr Whelan's treatment of Mr. Milne, he was prescribed various benzodiazepines, anti-depressants and the anti-psychotic drug,

Quetiapine. To manage his substance abuse and withdrawal, Mr. Milne was prescribed Suboxone and clonidine.

230. On 3 August 2011, Dr Whelan reduced Mr. Milne's dosage of Suboxone to 6 mg.229 On 9 September 2011, at Mr. Milne's request, his dose was again reduced to 5.2 mg. On 21 September 2011, it was further reduced to 4.8 mg daily. On 21 October 2011, Mr. Milne advised Dr Whelan that he for the past 10 days he had reduced his Suboxone to 2 mg daily without suffering from any withdrawals.230 From 31 October 2011, his dose was reduced further to 1.6 mg, which was increased to 2 mg in November 2011 as he reported suffering symptoms of withdrawal. On 8 February 2012, Mr. Milne reported to Dr Whelan that he had used heroin. He was recommenced on 8 mg of Suboxone. This was then reduced to 4 mg two days later.

231. In March 2012, Dr Whelan referred Mr. Milne to Psychiatrist, Dr Jonathan Lichter. Following a consultation, Dr Lichter formed the view that Mr. Milne had symptoms of chronic dysphoria and severe anxiety with a primary diagnosis of ADHD. He continued to treat Mr. Milne's ADHD with dexamphetamine, which was then changed to methylphenidate when reviewed on 10 May 2012. As of May 2012, Mr. Milne was being prescribed 8 mg of Suboxone, which was temporarily increased to 16 mg for a week.

232. In September 2012, Mr. Milne requested that his dosage of Suboxone be reduced. Dr Whelan agreed to reduce the dose to 6 mg for six weeks, and then 4 mg as of October 2012.234 As of January 2013, Mr. Milne was prescribed 5 mg of Suboxone. According to Dr Whelan, in June and October 2013, Mr. Milne presented as settled and stable, and was slowly reducing his dosage of Suboxone. As of December 2013, he was on 2 mg of Suboxone.

233. On 4 December 2013, Mr. Milne attended upon Dr Whelan claiming that five days earlier he had been crushed at work between an asphalt paver and truck causing injuries for which he required spinal surgery. He claimed that he had been treated with Fentanyl at the Hospital. As such, Dr Whelan wrote him a script for Fentanyl patches 100 mcg/hour. The records do not indicate whether Dr Whelan physically examined Mr. Milne, although he claims that he conducted a 'brief clinical examination'. He did not request any further investigations or supporting documentation to verify these alleged injuries. At inquest, Dr Whelan admitted that he did not have access to any documentation from the GCH to confirm Mr. Milne's injuries. He also did not seek the necessary regularly approval from DDU before prescribing Fentanyl to Mr. Milne.

234. During the inquest, when asked why he would prescribe Fentanyl patches to a patient on the QOTP, Dr Whelan stated that he had done so as this is what Mr. Milne had reported he had been provided with by the Hospital. Dr Whelan admitted that in hindsight it was a 'major error in judgment'. When asked about

the QOTP guidelines, which specifically state that clients on Suboxone, who suffer from severe or acute pain will require alternatives to opioids, Dr Whelan admitted that he was aware of these requirements. Nonetheless, he prescribed Fentanyl patches to Mr. Milne on four occasions shortly prior to his death. At no point during any of these consultations did Dr Whelan examine Mr. Milne's arms for track marks.

235. At inquest, Dr Whelan claimed that he had ceased Mr. Milne on Suboxone when he first prescribed him Fentanyl. However, in the medical records, Dr Whelan only advised Mr. Milne to cease Suboxone on 12 February 2014. DDU/MRQ records also show that Dr Whelan subsequently wrote prescriptions for Suboxone on 30 December 2013 and 25 January 2014.

236. Of particular concern during the inquest, Dr Whelan asserted that the Pharmacist he was working with at the Gold Coast Pharmaceutical Support Centre would have him sign prescriptions in bulk for various patients. He admitted that he didn't often look at the scripts he was signing, which had been written by the Pharmacist.

237. Dr Whelan had a further four consultations with Mr. Milne after he reported his apparent workplace injury, the last being on 12 February 2014. During three of these consultations (11/12/13, 17/12/13 & 14/01/14) Fentanyl patches were prescribed. Dr Whelan also prescribed Mr. Milne the medication Lyrica, which is a non-opioid medication used in the management of neuropathic pain. The PBS records suggest, however, that whilst all of the scripts for Fentanyl patches were filled, the Lyrica prescriptions were not.

238. Dr Whelan claims that he requested that the Fentanyl patches he prescribed to Mr. Milne be dispensed every three day, although this is not reflected anywhere in the medical records. There is no suggestion in the medical records that he had any concern about Mr. Milne's use of Fentanyl patches until 12 February 2014, where he is said to have advised him to come off Suboxone progressively.

239. From 21 June 2011 until 12 February 2014, Mr. Milne consulted with Dr Whelan on 35 occasions, however, there are no records of any physical examinations being conducted for 32 of these appointments. Whilst Dr Whelan claims that some of the records may be missing, he also stated that as a QOTP prescriber, he didn't consider it necessary to do a '*formal physical examination'* of a patient.

240. Records were sought from MRQ as to Mr. Milne's prescribing and treatment history in relation to Schedule 8 medicine. Mr. Milne was registered on the Queensland Opioid Treatment Program with Dr Whelan on 23 June 2011. He was listed as drug dependent.

241. There are no entries in the MRQ records, which suggest that Dr Whelan ever contacted them to discuss the prescribing of Fentanyl patches to Mr. Milne, or to notify them of such, despite the requirement to do so.

242. The Gold Coast Pharmaceutical Support Pharmacy dispensed Suboxone sub-lingual tablets or films, 1 mg, to Mr. Milne on 50 occasions from 30 June 2011 until 25 January 2014. On 16 September 2012, he was dispensed 104 mg of Suboxone sub-lingual tablets (1 mg) by the Mermaid Beach Pharmacy on a prescription written by Dr Whelan on 30 August 2012.

243. On 1 May 2011, approval was given for Dr Lichter to prescribe dexamphetamine for Mr. Milne, and on 10 May 2012, this approval was changed to methylphenidate at the doctor's request. Dr Lichter records of the phone call, which took placed on 1 May 2012, notes that he advised that Mr. Milne met the DSM-IV criteria for adult ADD and was prescribed a daily dose of dexamphetamine was 40 mg, which was to be dispensed daily. Furthermore, he had a history of intravenous drug use and was registered on QOTP as managed by Dr Whelan. Regardless, Mr. Milne was dispensed 300 tablets of 5mg of dexamphetamine on 1 May 2012. On 11 and 18 May 2012, he was dispensed a further 100 tablets of methylphenidate as prescribed by Dr Lichter.

244. On 10 April 2014, some 2 months after Mr. Milne's death, MRQ sent a fax to Dr Whelan confirming that they had received information that he was prescribing fentanyl patches to a QOTP client, without prior approval. It was requested that he speak to a senior advisor about '*recent evidence of an increase in drug dependent persons misusing fentanyl patches and injecting products derived from the transdermal patches.'* The fax goes on to state that MRQ, *'counsels extreme caution in prescribing fentanyl transdermal patches to patients where there is any concern about potential drug abuse'.*

245. During the inquest, MRQ Director, Mr. Loveday acknowledged that despite a stipulated two month timeframe for follow up service alerts by MRQ officers in such cases, this did not occur. He agreed that resourcing within MRQ may have contributed to this inability to comply with the stipulated monitoring thresholds. He confirmed that resourcing for MRQ had not changed since 2013.

Changes made to practices by General Practitioners since Mr. Milne's death

246. Following Mr. Milne's death, Dr Whelan stopped working in the area of addiction medicine. He has since retired from medical practice, and cancelled his registration.

247. Dr Whelan has indicated that he has remorse for having made a 'grave error' in prescribing Mr. Milne Fentanyl patches following his reported injuries in December 2013.

Real-Time Prescription Monitoring

Electronic Recording and Reporting of Controlled Drugs

248. Current regulations for Controlled Drugs are stipulated in separate State and Territory medicines and poisons legislation. As outline above, in Queensland, Schedule 8 medicines, such as opioids, are available on prescription only, and have specific restrictions placed on their supply and use because of their dependence forming nature and high levels of misuse (*Poisons Standard).* Regulation for the prescribing, dispensing and monitoring of these drugs rest with each of the individual State Governments.

249. Common across all jurisdictions is a requirement of the Pharmacist to record transactions for all controlled drugs in a register. The monitoring of compliance with this requirement, and the investigation of issues associated with the prescribing and dispensing of these medicines, is therefore significantly dependent upon receipt of the required information from Pharmacists. Manual reporting and non-real time reporting mechanisms, which are used in most jurisdictions, including Queensland, undoubtedly slow this process down and are open to errors and omissions.

250. It is the position of the Australian Government, that:

> *A move from manual to electronic recording and real-time reporting will improve the ability to efficiently monitor the prescribing and dispensing of Controlled Drugs to ensure appropriate access to these medicines. Real-time access to accurate dispensing information will improve the efficiency by which state and territory regulators, prescribers and pharmacists identify problems of forgery, abuse and doctor shopping and improve public health outcomes. Electronic recording will improve the accuracy of efficiency for pharmacist when recording transactions of Controlled Drugs.*

251. On 1 July 2010, the Fifth Community Pharmacy Agreement (Fifth Agreement) was entered into between the Australian Government and the Pharmacy Guild of Australia. This was a five-year agreement that recognised the important part that is played by community pharmacy in primary health care.

252. The Electronic Recording and Reporting of Controlled Drugs (ERRCD) initiative was to be implemented pursuant to the Fifth Agreement. The ERRCD initiative was developed in order to provide a nationally consistent system to collect and report data on the dispensing of Controlled Drugs in real-time, which was intended to complement and support the current controls mandated by the States and Territories, in their role as regulators. It was noted that current manual recording and non-real time reporting mechanisms hinder the ability to effectively

monitor movements of Controlled Drugs promptly, and may be open to errors and omissions. Having access to real-time dispensing information was thought to improve the effectiveness with which State and Territory Health Departments, prescribers, and pharmacists could identify problems of *'forgery, dependency, misuse, abuse and prescription shopping and improve public health outcomes'.*

253. The Commonwealth ERRCD initiative focused on the development of software programs designed to enable a nationally consistent electronic system to collect and report data relating to the dispensing of Controlled Drugs, and real-time access to current information on Controlled Drugs dispensing events for prescribers and pharmacists.265 Specifically, the ERRCD system is said to have been designed to allow access by health practitioners to contemporary information about the following:

- A patient's previous supplies of Controlled Drugs from any hospital or community pharmacy (whether supplied on the PBS or not);
- Supplies of other drugs of abuse potential (whether on the PBS or not);
- The patient's participation in state-run Opiate Dependency Treatment Programs; and
- If there has been repeat presentations, whether the prescriber has been authorised by the relevant state health authority to prescribe drugs of addiction to the patient on an ongoing basis.

254. This information is then expected to be made available to authorised health practitioners as part of the implementation by the States and Territories of the ERRCD.

255. The ERRCD system was intended to be the single source of data for prescribers, pharmacists and State and Territory health departments in relation to Controlled Drugs, specifically the types of medicines dispensed, the person to whom the medicines have been dispensed, and State and Territory authorisations to prescribe Controlled Drugs. Information could be accessed through a secure web interface, which would allow the State or Territory to manage the system and to direct responses as required to automatic alerts that have been raised. Prescribers and Pharmacists could use the portal to access data on Controlled Drugs dispensed to a particular patient, so as to make an informed decision as to what action should be taken.

256. In contrast to e-Health departments, the ERRCD system is not 'opt-in', such as that which was proposed for the Personally Controlled Electronic Health Record.

257. The medicines to be monitored by the ERRCD initiative are Schedule 8 medicines of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP), which have been given legal effect through specific State and Territory legislation. All Controlled Drugs, regardless of whether they are subject to a Pharmaceutical Benefit Scheme subsidy, will be reported by the system. In addition to Schedule 8 medicines, each State and Territory could also possibly use the ERRCD system to monitor other medicines liable to misuse or abuse.

258. Importantly, the Department of Health (Cth) advised that the ERRCD system had been designed to monitor and act upon the ***supplies*** of Controlled Drugs and any other drugs of interest, rather than the ***prescribing*** of those medicines. In practice, this means that authorised health practitioners, including doctors and pharmacists, should be able to view past supplies of target medicines for a particular patient, but not prescribing details, such as prescriptions not yet dispensed. Furthermore, the Department of Health (Cth) notes that:

> *This is a deliberate choice, supported by the implementation of the system – the states and territories. In the view of stakeholders, it is the supply, and potential accumulation of, medicines with abuse potential that is the precursor to the harms seen in cases under investigation, rather than an individual being in possession of numerous prescription for a particular medicine.*
>
> *It is also important to note that even with the availability of the contemporary patient information described above, this data is not intended to make a decision for the health practitioner. Rather, the information is expected to be taken into account by the practitioners in making a clinical decision to prescribe, supply, or otherwise.*

259. The ERRCD initiative also included the development of a Controlled Drug Electronic Register (CDER), which would interface with existing pharmacy dispensing software and assist to enable pharmacists to efficiently meet their statutory obligations to maintain records of Controlled Drugs.

260. The ERRCD system developed was significantly based on the real-time reporting and monitoring system established by the Tasmanian Department of Health and Human Services. The Tasmanian system was licensed and then 'enhanced' by the Commonwealth Government, in order to provide capacity for '*real-time monitoring of Controlled Drug dispensing, and for sharing of information across jurisdictions, as a platform for a national system*'.

261. As of March 2013, the Commonwealth Government's licensing arrangements of the ERRCD system permitted the State and Territory health departments to evaluate the extent to which the system meets current, and future jurisdictional needs. Further enquiries would need to be made by the State or Territory to determine a myriad of jurisdiction specific issues, such as how cross-border sharing of data could be managed, how Controlled Drug data could be migrated

and how automatic alerts for health practitioners might be configured. Accordingly, it was acknowledged that implementation dates would vary state-by-state, as these processes were conducted.

262. The Department of Health (Cth) has provided financial resources to design and develop the ERRCD system software, which as of 2014, was *'built, delivered and operationally ready to be implemented'.* It was the position of the Commonwealth Government that the State and Territory governments, as regulators of controlled drug prescribing and monitoring, then had responsibility for the implementation of the system within each jurisdiction, including the cost. The ERRCD system is not to be used by the Commonwealth Government.

263. In November 2016, due to concern by the Commonwealth government as to the lack of adoption of the ERRCD by some of the States and Territories, a new governance structure was endorsed by AHMAC. This structure recognised the need for the Commonwealth to *'play a coordination role to accelerate implementation enhancements and improve uptake of the ERRCD system by states and territories, while also recognizing the primacy of the states' and territories' responsibility in regulating the use of controlled drugs'.* The new agreed governance model provides for the following:

- Strategic direction and support to manage the implementation and operation of the national ERRCD system;
- Technical coordination for the development, implementation, maintenance, enhancements and ongoing operation of the national ERRCD system;
- Development of an ERRCD implementation roadmap;
- Enabling data transfer from clinical information systems into the national ERRCD system;
- Enabling cross border data-sharing arrangements and data security;
- A mechanism for jurisdictions to consult with the ERRCD system's national host (IT) vendor to deploy any system changes or enhancements as necessary;
- Change management; and
- Transitional and long-term governance arrangements.

264. Pursuant to these arrangements, an ERRCD Implementation Steering Committee, with representatives from the Commonwealth and all states and territories, has been established to *'facilitate state and territory consideration of requirements for the national ERRCD system, and to support jurisdictions adopting ERRCD in the short-term (such as Victoria and Western Australia)'.*

265. Queensland is a party to AHMAC-endorsed ERRCD governance arrangements, which stipulates that the states and territories are responsible for the following:

- Actively engaging in the ERRCD Implementation Steering Committee and the ERRCD Central Management Committee, Technical Governance Office and Change Control Board;
- Contributing to the development of the ERRCD Implementation Roadmap;
- Developing an implementation plan and change management strategy for their jurisdiction;
- Developing the legislative framework to support the implementation of the ERRCD program in their jurisdiction;
- Ensuring that the system, as locally adapted, meets their individual regulatory requirements;
- Contributing to the development of arrangements for data sharing between states, territories and the Commonwealth;
- Undertake an assessment of existing ERRCD System functionality versus individual regulatory requirements;
- Engaging with the ERRCD Implementation Steering Committee to align local ERRCD development with an agreed system development framework/principles prior to implementation of the national system;
- Funding and managing local ERRCD development;
- Providing advice to the Change Control Board to ensure that any enhancements proposed for the national system take appropriate account of jurisdictional regulatory requirements;

- Contributing to the development of a funding framework for the implementation of the ERRCD program; and

- Communicating with and educating prescribers and pharmacists about their roles and responsibilities under the ERRCD program.

266. In November 2016, certain states and territories advised the ERRCD Implementation Steering Committee that they had progressed enhancements to the national ERRCD system. It was agreed by all jurisdictions that an IT gap analysis of the national system be undertaken by the Commonwealth to identify and document these enhancements and determine what may be needed to ensure the system remains nationally consistent as jurisdictions continue to further implement the ERRCD. It was recommended that:

    a. *Migration to a common IT codebase* – whereby functionality and data is migrated into an agreed common IT solution, of which the NSW codebase was recommended as the most appropriate.

    b. *Use of a common codebase for future changes* – future updates and changes can be made to a common codebase to prevent re-emergence of divergent codebases for each state and territory.

267. The Gap Analysis conducted by the Commonwealth only considered the NSW ERRCD and Tasmanian ERRCD versions, as well as the deployment by the ACT of a separate Drugs and Poisons Information System, as these are the only jurisdictions, which have implemented the national system. Based on this analysis, a re-consolidation of the ERRCD system will be undertaken, which is on track to be provided to the states and territories in mid-2017. As of May 2017, the states and territories had access to the reconsolidated version of the NSW codebase for testing purposes.

268. An ERRCD Systems Development Framework and a Real Time Reporting Options Framework was also commissioned by the Commonwealth, which is intended to guide future amendments to the national system and to allow for real-time reporting alerts and functionality within the system. These frameworks were accepted by all jurisdictions through the ERRCD Implementation Steering Committee in January 2017. Despite claims that the real-time reporting capability of the Commonwealth system was still in its infancy, it is claimed that the ERRCD software, as it was developed in 2013, had this portal functionality, which whilst undergoing funded improvements, does allow regulators to access information with a short time lag. The timeframe by which the improvements will be made available is dependent upon when the ERRCD IT roadmap is agreed to and commenced by the states and territories.

269. The Commonwealth is of the view that:

> *The Department will provide a test environment for UAT (User Acceptance Testing) to be undertaken by states and territories. This ERRCD consolidation project work has not compromised the ability of states and territories to access the existing national ERRCD system, as provided under software license agreements in 2013.*
>
> *In the interim, the Department acknowledges that states and territories require the flexibility to enhance and modify the ERRCD system as necessary to meet local legislative and regulatory requirements for controlled medicines. To further assist states and territories take forward their ERRCD system extensions, the Commonwealth, via New South Wales, has provided early access to the enhanced New South Wales ERRCD IT codebase, which is the basis of the re-consolidated ERRCD codebase. Access to this application has been available to all states and territories since 24 May 2017.*

270. An ERRCD IT implementation roadmap has been developed and agreed in-principle by all of the states and territories. This roadmap outlines the sequence of activities to be executed, resulting in a staged delivery of capabilities to the end users of the national ERRCD system, which at this stage, is over a period of two years from the time it is agreed to by all states and territories. However, the implementation requirements for each state and territory can only be determined by the respective jurisdictions, consistent with their specific regulatory requirements.

271. In terms of funding commitments for the national ERRCD system, the Commonwealth has undertaken to provide for enhancements to the current system supporting the scalable and interoperable nationally consistent system. The Commonwealth has also committed to funding further enhancements of the system to allow for real time reporting alert capabilities. It is intended that any additional funding required for further extensions to meet local regulatory requirements will remain the responsibility of the state or territory.

272. The Commonwealth states it intends to maintain an ongoing collaboration with the Queensland Department of Health in relation to the implementation of the ERRCD. It was acknowledged during the inquest that there was an urgency in implementing this real-time prescription monitoring system.

Interstate Response to the ERRCD

273. Since 2012, there have been 20 Victorian coronial findings calling for the implementation of a real-time prescription monitoring system in Victoria. However, as of 2015, Tasmania and the Northern Territory were the only states utilising real-time information software retrieval systems to inform decision making about the prescribing and dispensing of controlled drugs.

274. During an inquest in Victoria in relation to the death of Ms. Anne Brain, Matthew McCrone, the Victorian Department of Health Chief Officer for Drugs and Poisons Regulation provided evidence about Tasmania's Drugs and Poisons Information System – Online Remote Access (DORA), the platform used as part of the fifth agreement initiative, as well as Victoria's progress towards a real-time reporting system. He noted:

- The DORA system works through capturing information on Schedule 8 medicine dispensed in Tasmanian pharmacies, and transmitting it at the time of dispensing to a central storage location where others can view it.

- Although the DORA system was rolled out to all pharmacists and is capturing Schedule 8 drug dispensing information, enabling access to this information is an ongoing process. In 2014, less than half of Tasmania's GP's had direct access to the DORA data when treating patients.

- Implementing a real-time reporting system is far more involved than just putting the software, ERRCD in place. A tender process was conducted seeking a service provider to develop a business case to implement a real-time reporting system in Victoria. This process was finalised in January 2014.

- Privacy issues have been raised, however, in Victoria the real-time reporting system could be effects through subordinate legislation and not an Act of Parliament.

- A range of costs would be associated with implementing the real-time reporting system, including the software, teaching prescribers and dispensers how to use it, maintaining the underlying IT infrastructure, leasing or purchasing the computer servers that store the data, maintaining the software, sharing data and information between states, dealing with Schedule 8 medicine applications, monitoring prescriber compliance with permit conditions, and acting upon the hugely increased amount of drug dispensing information suddenly available to the department.

- The expense to be incurred by Victoria would be substantially more than that of Tasmania.

- It is critical that a national standard for data collection on drug dispensing events is used so information shared is the same across the country.

- Implementation of a real-time prescribing monitoring system in Victoria would save lives and 'everyone' supports the need for such a system.

275. In September 2015, Australia's peak medicine, pharmacy and consumer bodies, including the AMA, MSIA, RACGP, the Pharmacy Guild of Australia and the Consumers Health Forum of Australia collectively wrote to the Australian Health Minister and all State and Territory Health Ministers imploring them to work collaboratively to urgently implement a national system for the ERRCD. The letter noted that:

> *This system will provide clinicians with a crucial tool, enabling them to work with patients in a more collaborative and informed way to address the serious problem of addiction to some of these Controlled Drugs. Each of our organisations has been advocating for the ERRCD and we have agreed to work together to ensure that it is implemented expeditiously.*
> *…*
> *Consumers, general practitioners, physicians, pharmacists and the medical software sector consider the ERRCD system to be a crucial clinical support and intervention tool to help practitioners manage the prescribing, supply and management of drugs of addiction, and to prevent harm from inappropriate use of prescription drugs.*
>
> *We call on all jurisdictions to agree on a clear implementation plan and timetable for a national ERRDC system at the next COAG Health Council meeting, and to remove any roadblocks to achieving this outcome.*

276. These peak bodies recognised that without a crucial clinical tool like the ERRCD, avoidable deaths involving prescription medicines will continue to occur at an alarming rate.

277. In the 2016-2017 State Budget, the Victorian Government announced a $30 million commitment to rolling out a real-time prescription monitoring software system to over 1900 medical clinics, 1300 pharmacies and 200 hospitals throughout Victoria. Additional counselling and addiction treatment services are also to be established, as well as training and support packages to medical practitioners and pharmacists.

278. In support of this initiative, the Victorian Minister for Health, The Hon Jill Hennessy, issued a media release on 25 April 2016, titled, *Real-time Prescription Monitoring Will Save Lives,* which recognised that:

> *With more people losing their lives each year in Victoria from overdoses of prescription drugs than those dying in road accidents, a real-time prescription monitoring system has the potential to prevent the deaths of up to 90 Victorians over the next five years.*
>
> *Many prescription overdoses result from people "prescription shopping" from multiple doctors and pharmacies. Without a centralised monitoring system, this often goes undetected with tragic results.*

> *A real-time monitoring system will help our medical clinics, pharmacies and hospitals better identify prescription drug seekers earlier, before their addiction escalates into serious harm.*

279. In further factsheets released by the Victorian Real-time Prescription Monitoring Taskforce, it is recognised that real-time prescription monitoring enables doctors and pharmacists to make supported and informed clinical decisions in relation to the safe treatment of their patients by providing them with up to date medication supply history of certain high risk medicines. It is noted that:

> *The increasing harms and deaths from the misuse of prescription medicines is a growing major public health concern in Victoria. In 2015, there were 330 Victorian drug overdose deaths involving pharmaceutical medicines, higher than the number of overdose deaths involving illicit drugs, and higher than the road toll.*

280. The software system to be introduced in Victoria allows pharmacy dispensing records for certain medicines to be transmitted in real-time to a centralised database, which can then be accessed by medical practitioners and pharmacists during a consultation.

281. The Western Australian Department of Health have also expressed an intention to overhaul the current pharmaceutical monitoring system by replacing the current MODDS with a modified ERRCD. The WA Health Chief Pharmacist, Mr. Neil Keen stated that *'the ERRCD will improve transparency of medication history, support informed clinical decision making, reduce inappropriate prescribing, limit potential for doctor shopping and assist in rapid identification of at-risk individuals who may benefit from referral to drug treatment or other interventions as required'.* Transition to the new system is expected to be completed by 2018, with training and support to be made available to pharmacists and prescribers as implementation progresses.

Queensland Department of Health's Response to the ERRCD

282. As of 3 April 2013, the Department of Health was examining implementation of the ERRCD. It was recognised that this system would allow 'real-time' reporting of controlled drug prescriptions and eventually direct access to general practitioners to verify a patient's controlled drug prescription history. An initial business requirements and gap analysis was conducted of the ERRCD by MRQ via the Health Service Information Agency.304 According to the Department, it became *'readily apparent during the course of this process that there were going to be significant challenges in implementing the system in Queensland and implementing a national system, in the absence of the Commonwealth or some other entity taking on the role of coordinating the development, implementation, maintenance and upgrades to it'.*

283. Concerns were raised as to whether MODDS could continue to operate with the ERRCD, and how the information stored on it could be transferred to the ERRCD. However, the Controlled Drug Reporting and Monitoring System Gap Analysis document, dated 10 July 2014, states that:

- A total of 263 requirements were assessed with MODDS meeting 67% of the total requirements and 88% of the mandatory requirements. ERRCD met 32% of the total requirements and 46% of the mandatory requirements.

- The resources available to assess the ERRCD have limited the ability to conduct a thorough gap analysis. After utilising the resources available it is not possible to draw a conclusion as 19 % of the total requirements could not be assessed against ERRCD.

- It is recommended that Queensland Health take the necessary steps to obtain further information regarding the ERRCD solution to enable a thorough assessment to be undertaken.

284. Nonetheless, MRQ Director, Mr. Loveday confirmed during the inquest that no further information was provided at that time in relation to the ERRCD.

285. In addition, a previous review of the Tasmanian real-time prescription monitoring system was undertaken by representatives of MRQ in 2014, who identified a number of shortfalls with its adaptability to the Queensland prescription landscape. Accordingly, no further steps were taken by the Department of Health to implement or incorporate the ERRCD, or develop a separate real-time prescription monitoring system for use in Queensland.

286. The Department submits that the subsequent further actions undertaken by the Commonwealth government in November 2016 with respect to the ERRCD transpired after the Queensland Minister for Health proposed and promoted the Commonwealth facilitating and developing a costed proposal for the implementation of real-time prescription monitoring system, as an agenda item at the Council of Australian Governments Health Council meeting on 6 November 2015. Nonetheless, the Department maintains that there is substantial work still to be done by the Commonwealth to progress a national approach to real-time prescription monitoring.

287. While noting that evidence of increased prescriptions of opioid analgesic medications have been linked to problems of misuse, dependence and overdose, is still emerging in Australia, Chief Health Officer, Dr Janette Young supports the need for real-time prescription monitoring in Queensland. It is

acknowledged that a real-time system will improve regulatory compliance and public health outcomes in relation to the use of controlled drugs. Dr Young further points out that the misuse of prescription medication requires a multi-layered response, with real-time monitoring being but one of the important tools in a complex matrix of factors. It is suggested that improving the responsiveness of its telephone service, improving surveillance and monitoring processes and the timeliness of the investigative and enforcement processes are also vital tools.

288. Given the recent updates undertaken by the Commonwealth Government, the Director-General of the Department of Health has provided in-principle support to the implementation of the ERRCD system in Queensland, and intends to develop a business case and Cabinet Budget Review Committee bid to seek appropriate funding from the Treasury for real-time prescription monitoring for the 2018-2019 financial year. In the Draft Project Initiation Document developed for this purpose, dated April 2017 it is recognised that:

> *The purpose of the implementation of a real-time reporting system is to improve regulatory compliance and public health outcomes in regards to the use of controlled drugs.*
>
> *Real-time prescription monitoring is one of the 16 specific recommendations made by the Health Ombudsman, and recommends the review of Queensland Health's options for the introduction of a real-time prescription monitoring (RTPM) system in Queensland and the subsequent development of a business plan to progress the implementation of a RTPM system.*
>
> *The Commonwealth Department of Health's Electronic Reporting and Recording of Controlled Drugs (ERRCD) can potentially deliver these outcomes and this document outlines the Queensland Department of Health plans to investigate, develop and implement the national solution to meet these outcomes.*

289. One of the assumptions made in the Draft Project Initiation Document is that *'prescription transaction volume of approximately 2 million prescriptions per year, >150,000 per month will continue to grow at a rate of <15 per cent.'* It was acknowledged by the Department that it was envisaged that this rate would continue to grow.

290. The Draft Project Initiation Document also includes a draft funding plan for implementation of the ERRCD in Queensland.320 This plan envisages that at a cost of around four million dollars, implementation will not be complete until 2022. When this timeframe was challenged during the inquest, Mr. Loveday reiterated that this was an estimate only, and that the business case would look at the most 'expeditious solution'. He also noted that the real-time reporting components of the system could potentially be achieved in a shorter period of time.

291. However, concerns have recently been raised by the Department as to the suitability of the ERRCD system in Queensland, and the lack of access to data as to the updated codebase. Whilst login details for a test version have been

provided, no supporting user documentation has been provided. During the inquest, Mr. Loveday stated:

> *We have concerns, based on the way the current regulatory system is being implemented within ERRCD. We're not clear that it's going to be suitably able to be translated to Queensland. We also have concerns that it's not been tested with any real-time reporting information, in terms of script volumes going into it to populate a database of people, to do the matching of those people, to identify those people and produce appropriate records, which is really the key capability of that system.*

292. During the inquest, Mr. Loveday and Dr Young agreed that should the Department determine that the ERRCD was not a suitable system for use in Queensland, then consideration would be given as to the possible developments that could be made to MODDS to make it a real-time reporting system, or whether a hybrid of the ERRCD and MODDS could be created for use in Queensland.

OHO Investigation Report

293. Following a number of complaints made to the Office of the Health Ombudsman (OHO) in relation to the inadequate prescribing, dispensing and monitoring of Schedule 8 medications in Queensland, a systemic investigation was launched reviewing the appropriateness and effectiveness of the current regulatory system for scheduled medicines as it applies to health services.

294. The relevant portions of the investigation report titled, '*Undoing the knots of constraining medicine regulation in Queensland'* ('the Report'), which was published in November 2016, are summarised below.

Regulatory framework

295. Based upon the submissions provided by MRQ to the Health Ombudsman, it was determined that the activities and functions of the regulator fall into the following four groups:

- Administration of licenses and approvals, including the Queensland Opioid Treatment Program – MRQ staff undertaken management of licenses and approvals to manufacturers, wholesalers, individuals (including health practitioners) and other entities to manufacture, distribute, sell, provide treatment with, conduct research with, or use scheduled medicines and poisons. MRQ also provide administrative oversight of the QOTP.

- Provision of clinical support and advice – MRQ has responsibility for providing, via a confidential telephone enquiry service, clinical support and

advice to health practitioners to ensure appropriate use of Schedule 8 medicines.

- Data processing, monitoring and analysis – MRQ staff undertaken processing of Schedule 8 medicine prescription data from pharmacies, including data quality assurance, as well as surveillance and analysis of dispending data to identify inappropriate use of Schedule 8 medicines.

- Enforcement of regulatory non-compliance – MRQ staff undertaken enforcement activity in situations of regulatory non-compliance, including investigation and prosecution of alleged offences under the Health (Drugs and Poisons) Regulation 1996.

296. In 2014, MRQ staff received and processed information on more than 2 million prescriptions for Schedule 8 medicines from more than 1000 pharmacies. They also received more than 5000 reports of treatment with a Schedule 8 medicine for longer than 8 weeks.

MODDS data

297. According to MRQ, 50% of dispensing data is visible in MODDS within two to three weeks of the dispensing event, although some data does not appear until as many as six weeks after the dispensing of the Schedule 8 medications.

298. Having considered MRQ's criteria, the Health Ombudsman noted the following perceived limitations, including:

- Examination of the surveillance alerts for monitoring of dispensed prescriptions with a high daily drug dose indicates that it does not monitor high drug doses for ALL Schedule 8 drugs each month, only either a targeted drug by the month, or psychostimulants as a group. This results in drug dosage for each targeted drug being actively monitored only twice a year at most.

- *Feedback:* Director General of the Department of Health advised that the Department of Health does not consider more frequent monitoring would be an effective use of surveillance resources as a longer timeframe is required to identify patterns of prescribing.

  In response, the Health Ombudsman indicated that he was *'supportive of the need for public health surveillance and action to address potential drug misuse and abuse in this area, but am also of the view that this further serves to demonstrate the multiplicity of disparate functions and purposes that MRQ endeavours to deliver'.*

- While self-administration of Schedule 8 medicines is prohibited under the Health (Drugs and Poisons) Regulation 1996, it seems that MRQ only review MODDS data every two months to detect prescriptions dispensed where the prescriber and recipient are the same.

- MRQ noted in their submission to the Health Ombudsman that the threshold for identifying cases for follow-up, which involved prescription shopping patients is adjusted on a monthly basis if necessary by MRQ staff depending on the number of cases initially identified for potential follow-up. The Health Ombudsman noted in response that, *'the use of inconsistent thresholds, depending on the volume of work, is concerning.'* In response, the Director-General of the Department of Health claims that there was no accepted definition of doctor shopping, as such, there was no set criteria on which surveillance was conducted. MRQ are presently involved in a research venture with UQ to define high-risk drug seeking behaviour to improve monitoring.

- MRQ indicated in its submission to the Health Ombudsman that it considered non-compliance with s.84A (4) of the Health (Drugs and Poisons) Regulation 1996, which requires a dispenser to report immediately to MRQ dispensing requests for Schedule 8 medicines that appear to be for amounts more than reasonably necessary, or more frequently than reasonably necessary, is *'minor non-significant non-compliance'* raising *'limited health and safety concerns'.* In response, the Health Ombudsman noted that he could not comprehend why this would be considered low risk given Schedule 8 medications, particularly opioids, were commonly implicated in overdose deaths across the country.

- During the Health Ombudsman's investigation, MRQ are said to have acknowledged that it does not routinely monitor compliance with s.120 of the Health (Drugs and Poisons) Regulation 1996, which requires a prescriber to notify MRQ if they are providing lengthy treatment (more than 8 weeks) to a person with a Schedule 8 medicine. The reason provided for this failing was the structural limitations in developing appropriate and meaningful queries. Furthermore, MRQ indicated that their monitoring activities targeted high-risk patients and that there was no evidence that long-term prescribing of Schedule 8 medicines represents any significant health risks.

- The Health Ombudsman's investigation highlighted that MRQ are unable to undertake any monitoring activities based on the type of practitioner involved.

299. In response to the restrictions identified, the Health Ombudsman recognised the limited resources available to MRQ, and as such, acknowledged that within the limits of current resources, the present level of compliance monitoring was reasonable.337 However, he further noted that:

> *...I am of the view that based on the information gathered during my investigation, the current scope and level of monitoring undertaken by MRQ in isolation is insufficient to protect the health and safety of the public. I note that the introduction of a real time prescription monitoring system has been suggested for some time as a method for improving capacity to monitor access to Schedule 8 medicines.*

Enforcement

300. MRQ indicated during the investigation that their monitoring and enforcement activity was based on a risk matrix, which involves examining the non-compliance identified and determining the level of risk associated with this conduct. The enforcement activity subsequently undertaken is done so in a graduated approach, which most commonly takes an advisory or educational form. This usually involves providing written correspondence to health practitioners informing them of the issue identified through surveillance claims, which frequently relates to patients consulting with multiple practitioners to access Schedule 8 medicines. In 2014, 1000 letters were sent for this purpose. The Health Ombudsman notes that the effectiveness of this as a 'risk management strategy' is clear. Further concern was raised as to the high volume of letters sent with no timely follow up by MRQ.

301. Between 2010 and 2014, MRQ instigated on average only 3 to 4 investigations per year into the prescribing or dispensing practices of health practitioners. In addition, only 9 prescribers had their endorsements cancelled in the same time period, with another 8 voluntarily surrendering their endorsements. The Health Ombudsman notes that given MRQ only has 1 investigator in the current structure, it is not surprising that such a small number of investigations are conducted per year. When contrasted with the 50 open investigations held by OHO in 2014-15 in relation to the prescribing of Schedule 8 medications, and the more than 50 notifications made to AHPRA in relation to inappropriate prescribing/dispensing practices, the Health Ombudsman expressed concern as to the *'capacity of MRQ to interrogate the information in MODDS and identify at-risk practitioners'.*

302. The Health Ombudsman further notes that:

> *My impression is that the focus of MRQ, in line with that of its predecessor, is on improving clinical outcomes through education and advice rather than monitoring, investigating and enforcing compliance with legislative requirements. While education and advice are worthy outcomes, it appears that a large part of the functions assigned by MRQ under the Health Act 1937 and its subordinate legislation are not being fully and effectively performed.*

303. The Health Ombudsman subsequently recommended that it would be a more effective use of MRQ's current resources to focus on the monitoring of the MODDS data, and to develop and implement clear thresholds on how to escalate a matter appropriately, where the initial advice and education provided is seen to be ineffective in achieving compliance.

304. It should be noted that during the course of the coronial investigation MRQ advised that since 2010, the following number of partial and full cancellations in relation to a practitioner's prescribing rights have been actioned by MRQ:

- 10 health practitioners with full endorsement cancellations subsequent to investigations;
- 3 health practitioners with partial cancellations or variations to their endorsements subsequent to investigations;
- 17 health practitioners who have voluntarily surrendered their endorsements subsequent to investigations;
- 5 health practitioners where endorsement action has been taken following an investigation.
- 2 health practitioners have retired subsequent to investigations.

305. At inquest, MRQ Director, Mr. William Loveday disagreed that the number of partial and full cancellations for this period was low, reiterating that such an action was the last resort taken by MRQ against a general practitioner.

Agency roles

306. Whilst MRQ have primary responsibility for the administration of the *Health Act 1937,* other agencies, such as QPS, AHPRA and HHS public health units, also play a key role, particularly in relation to Schedule 8 medicines.

307. The Health Ombudsman noted that from the information provided, there was a lack of clarity regarding each of the different party's involvement in regulating Schedule 8 medicines in Queensland, particularly given the functions performed by each often overlap and intercept. There are few formal cross-agency agreements held by MRQ, which effectively define the roles and responsibility of each of the agencies. Furthermore, the Health Ombudsman found that there was

insufficient clarity regarding the role and responsibilities of MRQ, or any other agency, involved in the regulation of Schedule 8 medicines.

308. Further concern was raised with the Health Ombudsman as to MRQ's failings to alert OHO as to serious concerns regarding the prescribing practices of some practitioners in relation to Schedule 8 medicine, despite being aware of this conduct for an extended period of time. A *case example* provided in the Report demonstrates that MRQ delayed in taking action against a practitioner for almost 18 months, who on 273 occasions breached requirements to prescribe Schedule 4 and 8 medications to a drug dependent person without prior approval. A further 12 months then lapsed before the practitioner's authorisation to prescribe Schedule 4 and 8 drugs was cancelled. OHO were only notified of this practitioner's behaviour some 2 years after the initial non-compliance.

309. The Health Ombudsman expressed concern about this lack of timely referral or sharing of information with OHO, which causes a significant delay in the assessment of the risk the practitioner may pose, as well as the implementation of any risk mitigation strategies necessary to protect public health and safety.

310. Similarly, the Health Ombudsman expressed concern that MRQ had made a very small number of referrals to AHPRA, particularly when contrasted with the letters sent expressing concern over Schedule 8 medicine prescribing and dispensing behaviour. In fact, since 2012, the number of referrals had noticeably dropped each year.

311. The Health Ombudsman subsequently recommended that the Director-General of the Department of Health establish a committee to undertake a thorough review of the roles and responsibilities of MRQ, in light of the role played by other agencies in regulating Schedule 8 medicines. Consultation with relevant stakeholders should be undertaken during the course of the review. He made a number of recommendations to be carried out by the Director-General, including:

    - Consider the development of formal agreement setting out a clear statement of shared purpose and agreed roles and responsibilities of each of the agencies.

    - A review of current resourcing levels to determine the resources required for MRQ to appropriately perform its functions.

    - Identify trigger points for information sharing and referral between agencies.

- Direct MRQ to review its compliance and enforcement framework and to undertake a current risk assessment of work practices, including surveillance thresholds and criteria, at regular and prescribed intervals.

312. In relation to the recommendations made, the Director-General of the Department of Health confirmed that a formal response would be provided at a later stage. It was also indicated that MRQ had recently established a set of policies and procedures to improve its administration of legislation, which includes a mechanism by which work practices were regularly reviewed.

313. The Health Ombudsman reiterated his view that MRQ's failure to develop and maintain appropriate operational guidance documentation presented a significant risk of inconsistent monitoring practices and decision making, as well as reduces the transparency of the operations of the agency. As such, he recommended that all existing documentation of the policies and procedures be reviewed, and a consolidated and current version be developed.

New proposed legislative framework

314. The Department of Health has proposed new legislation to protect *'the public from the health risks associated with inappropriate access to, and use of medicines, poisons and therapeutic goods*' and to minimise '*the risk that medicines and poisons can be diverted for unlawful purposes'.*

315. It is the understanding of the Health Ombudsman that the Department intends to repeal the current legislation, including the *Health Act 1937,* the Health Regulation 1996 and the Health (Drugs and Poisons) Regulation 1996, and replace it with new legislation, the key objective of which will include the following:

- Protect the public from the health risks associated with inappropriate access to and use of medicines, poisons and therapeutic goods.

- Minimising the risk that medicines and poisons could be diverted for an unlawful purpose.

- Adopting a contemporary approach to regulating medicines, poisons and therapeutic goods in Queensland that introduces a more responsive and outcomes-focused regulatory framework.

- Streamlining the regulatory controls governing medicines, poisons and therapeutic goods to reduce the associated regulatory costs for industry, consumers and government.

316. The Health Ombudsman notes that he is very supportive of the objects of the proposed Medicines, Poisons and Therapeutic Goods Bill 2015, particularly:

    (a) To ensure persons who are given the authority to deal with the substances have the necessary competencies to do so safely.

317. Whilst the draft Regulations were not available for consideration at the time of the Report, he notes that *'any extension of authority to new groups of people for prescribing, supplying and/or administering scheduled medicines must be accompanied by adequate training and education, as well as oversight'.*

Real-time prescription monitoring

318. The Report notes that there has been particular interest in the implementation of real-time prescription monitoring in response to the increasing number of Schedule 8 medicines dispensed in Australia, and the related cases of harm as a result of the misuse of these medicines.

319. The National Pharmaceutical Drug Misuse Framework for Action 2012-15, identified the introduction and implementation of an online, real time medication management tool that would provide access to information on patients' medication usage to prescribers, dispensers and regulators. It was argued that the real-time system could effectively identify the following:

- Irregularities in treatment such as excessive prescriptions amounts and early repeat dispensing.
- Drug seeking by individuals attending multiple prescribers and pharmacies, hospitals, specialists and other settings.
- Whether purportedly lost prescriptions had been filled.
- Patterns of dispensing, which may suggest fraudulent activities undertaken to obtain medicines.
- Identify patterns of problematic prescribing or dispensing.

320. Having considered the information obtained during his investigation, the Health Ombudsman concluded that MODDS is not presently an effective support for either practitioners' clinical decision making, or the action of regulatory bodies, such as MRQ. He highlighted that the dispensing data of Schedule 8 medicines is not presently provided in real-time in Queensland, and as such, the regulator

is not able to respond immediately to issues or concerns that arise, particularly in relation to the provision of up to date information to practitioners, who make enquiries in relation to a patient. Accordingly, preventative action by way of notifications to prescribers and dispensers of potential Schedule 8 medicine abuse, is currently unable to be taken or may be delayed.

321. In relation to the limitations of MODDS, the Health Ombudsman noted the following:

- It currently relies on the prescriber/dispenser to form a suspicion prompting a request for information from MRQ about an individual. Prescribing information is not routinely checked for all patients, or even for high-risk patient groups or high-risk prescribing.

- Access to the system and the significant data stored is restricted to MRQ.

- MRQ are not required to share or report information that may be of significance to another agency.

- QPS have advised that there is no opportunity to obtain information from MRQ via alerts received through MODDS, which would otherwise assist in their investigations of drug-related offences. Currently, Police are only able to obtain information by way of a warrant.

322. The Ombudsman noted that most stakeholders, consulted during his investigation, favoured a real-time prescription monitoring system. Specifically, it was noted that:

- AHPRA submitted that '*any system that raises relevant alerts in real time would be advantageous. It is AHPRA's experience in Queensland that by the time concerns are raised about an individual's use of, prescribing of or dispensing of schedule 8 medicines, there could have been a lengthy period of abuse or of inappropriate prescribing or dispensing.'*

- Pharmacy Guild of Australia – *There is a need for real-time monitoring/reporting…*

- QPS – *It is recognised that a national system, such as the Electronic Recording and Reporting of Controlled Drugs would assist prescribers and pharmacists in the management of patients with a therapeutic need for controlled drugs while information prescribers about potential 'at risk' patients and suspicious behaviour.*

- Hospital and Health Service – *A national database of all Schedule 8 prescribing and dispensing including non-PBS and public hospital dispensing that integrates with medical officer prescribing software and pharmacist dispensing software at the point of care, must be mandatory for all prescribing and dispensing health practitioners and consumers.*

323. It was further noted that RACP and RACGP had both recommended the adoption of a real-time reporting system to operate nationally.

324. In the United States of America, Prescription Drug Monitoring Programs (PDMP), which are similar to that of a real-time prescription monitoring system, have been operating in each state in response to a nationwide concern as to the growing abuse and misuse of prescription medication. These reporting programs are used to identify prescription shopping, as a patient care tool and to identify clinicians with patterns of inappropriate prescribing and dispensing of controlled medicine. It has been found that these PDMP's are effective in reducing the time required for drug diversion investigations, changing prescribing behaviour, reducing prescription shopping, and drug abuse.

325. Reference was also made to the success of Queensland's Project Stop, which is a real-time monitoring web based tool developed by the Queensland branch of the Pharmacy Guild of Australia for the tracking of pseudoephedrine sales. The data collected through this tool is able to be accessed and monitored by law enforcement agencies, as well as health regulators looking for inappropriate patterns of use. The success of this system saw it rolled out nationally following a funding agreement with the Australian Government in 2007.

326. Given the ERRCD, MRQ considered a review of their business processes and MODDS to determine whether any changes were required, and how these may then be achieved. Documents were provided to the Health Ombudsman from MRQ in relation to this review, and it seems he concluded that in order for an informed business decision to be made about the real-time monitoring of Schedule 8 medicines, further analysis of MRQ's business requirements and MODDS, as well as gaps with the business requirements and the ERRCD, was necessary.364 It was noted that no cost analysis was included as part of the review, and as such, the assessment was considered to be incomplete.

327. The Health Ombudsman did indicate that MRQ had suggested during the course of the investigation that modifications to MODDS so as to incorporate real-time information were being considered, as opposed to adopting the ERRCD. He further noted that there had not been any budget allocation by the Department of Health for the implementation of the ERRCD, nor a cost analysis completed to enable a business case to be prepared. He notes that the absence of a technical solution does not appear to be an issue as there are currently a number

of software alternatives, in addition to the current ERRCD, available from private sector companies.

328. The Ombudsman noted that in delivering an effective real-time prescription monitoring system, the following factors should be considered and explored:

- *Collaboration:* It is essential that there is collaboration between government bodies, professional health groups, and consumer group.

- *Workforce development:* Workforce development for prescribers and dispensers will play a key role in the success of any real-time prescription monitoring system. It is suggested that early engagement with professional clinical and pharmacy groups, as well as other key stakeholders, may assist to identify opportunities for better infrastructure and skills to support the prescribers and dispensers communicating to patients about addiction and mental health. Support and training for primary clinicians will be a key factor in ensuring that any real-time prescription monitoring system is successful.

- *Broader regulatory scope:* Consideration as to whether the prescribing and dispensing information in relation to Schedule 4 drugs should also be included in any real-time prescription monitoring system.

- *Data capture:* There is also an opportunity to capture information relevant to the Pharmaceutical Benefits scheme, Repatriation Pharmaceutical Benefits Scheme and other private prescriptions (all data which is not currently captured by MODDS). Inclusion of this information may provide a more complete picture of a patient and prescriber's client usage when reporting and identifying trends. It was recognised that increased resourcing for regulators may be required to facilitate a response to the additional information.

- *Resourcing and capacity:* The possible impact on other health services. Referral pathways to specialist services need to be considered and established while ensuring services have the capacity to respond to the potentially large number of patients, which may be identified by the introduction of real-time reporting.

- *Pain management trends*: Specific attention will need to be paid to the management of chronic pain. It was recognised that chronic pain is a considerable health issue and often results in the high use of opioids. The system needs to prevent stigmatisation and be capable of identifying the difference between patients who may be prescription shopping and

patients being treated for long-term chronic and complex conditions under the management of multiple practitioners.

- *Improved prescribing:* A real-time reporting system would also highlight concerns regarding the prescribing practices of practitioners. AHPRA noted in submissions provided to the Ombudsman during his investigation that detecting problematic prescribing was often difficult, and that by the time concerns were raised about an individual's use, prescribing or dispensing of Schedule 8 medicines, there could have been a lengthy period of abuse, or of inappropriate prescribing or dispensing.

329. The Ombudsman also expressed his support for the practice currently engaged in by regulatory units in other States, who meet regularly to discuss the status of business assessments considering whether to implement the ERRCD or another real-time prescription monitoring system.

330. Finally, the Ombudsman recommended the introduction of a real-time prescription monitoring system would:

> *…have significant benefits for the effective and efficient monitoring of the prescribing and dispensing of schedule 8 medicines in Queensland, as well as schedule 4 medicines if possible. A RTPM would also help to manage risks to the health and safety of the public created by the inappropriate prescribing or unlawful dispensing of such medicines.*
>
> *In order to achieve the best possible outcome for Queensland, consultation should occur with key agencies and stakeholders such as MRQ, my office, AHPRA and the national boards, law enforcement agencies, the Pharmacy Guild of Australia, the AMA and with consumer groups.*
>
> *It seems clear that the move towards a RTPM to date has been at various times affected by a variety of issues and changing priorities. Nevertheless, technically the system itself is within reach. Complexities include possible significant impacts on legislation, resourcing, health service delivery, workforce development and education, and the interactions and effects on stakeholders. All of these will require further thought and exploration.*
>
> *It is evident to me that a real-time monitoring system is both feasible and essential to assist in the effective and efficient management of the prescribing and dispensing of schedule 8 medicines in Queensland and Australia.*

331. The Ombudsman recommended that the Director-General of the Department of Health expeditiously review Queensland's options for the introduction of a real-time prescription monitoring system, as well as the subsequent development of a business plan to progress the implementation of the real-time system.

332. The Health Ombudsman concluded that the current Queensland regulatory system for the prescribing and dispensing of Schedule 8 medicines contains a number of weaknesses, which creates an unacceptable risk that these medicines could be misused and accessed inappropriately, which presents an ongoing danger to the public. He recognised the complexity of the clinical social and practice issues, which coupled with the overlap in the regulatory and policy functions of many agencies, necessitates the need for substantial interagency collaboration and communication. Under the present system, this necessary collaboration and communication requires considerable development.

333. Furthermore, the Health Ombudsman found that the regulatory system in Queensland must have the capacity to source and analyse data in a timely manner to enable an effective response to emerging issues, and to efficiently manage the public health and safety risk. While the current data able to be collected by MRQ is valuable, there are substantial limitations.

334. The Health Ombudsman reiterated that a real-time prescription monitoring system in Queensland needed to be progressed as a matter of urgency.

335. The following five formal recommendations were made by the Ombudsman:

I. Legislative complexity

It was recommended that the Director-General of the Department of Health do the following:

- Continues to actively consult with stakeholders on the proposed new framework for the regulation of medicines, poisons and therapeutic goods in Queensland, particularly in relation to the prescribing and dispensing of Schedule 8 medicines.

- Take into account the issues identified in the report when considering the proposed new legislation.

- Work with stakeholders following the introduction of the new *Medicines, Poisons and Therapeutic Goods Act*, to ensure they are aware of their obligations under the new legislation.

- MRQ continues to strengthen its work with QPS to ensure adequate guidance is provided about the misuse of scheduled medicines and the implications.

- Considers recommending to the Queensland Minister for Health to propose that amendments are made to the National Law to require practitioners to

disclose to their national board if they have been charged or convicted of an offence under relevant drugs and poison legislation in any jurisdiction.

II. Roles and responsibilities

It was recommended that the Director-General of the Department of Health do the following:

- Establish a committee to undertake a review of the roles and responsibilities of MRQ in light of the roles and responsibilities of the other agencies involved in regulating Schedule 8 medicines. Representation from key stakeholders should also be reflected in the Committee. The review should consider (i) whether MRQ should
- maintain each of its functions, including monitoring, (ii) which agency in the regulatory environment is best placed to take the lead role in relation to each function, (iii) the identification of shared performance indicators, reporting arrangements and outcomes (where possible); and (iv) the creation of appropriate governance arrangements to support decision-making and performance monitoring.

- Depending upon the outcome of the review, it was also recommended that consideration be given to developing and documenting a formal agreement setting out a clear statement of shared purpose and agreed roles and responsibilities for each of the agencies, including AHPRA, MRQ, OHO, QPS and CCQ.

- Furthermore, steps are taken to ensure that these agencies regularly communicate to their staff about their roles.

- Review current resourcing levels and determine the resources required for MRQ to appropriately perform its functions.

- Identifies trigger points for information sharing and referral between agencies in consultation with key agencies, including MRQ, AHPRA and OHO:

- Directs MRQ to review its compliance and enforcement framework and to undertake a current risk assessment of work practices, including surveillance thresholds and criteria, at regular, prescribed intervals.

III. Policies and procedures

Recommended that the Director-General of the Department of Health directs MRQ to review its existing documentation and develop consolidated and current authoritative version of all policies and procedures.

IV. Communication and collaboration

Recommended that the Director-General of the Department of Health direct an expeditious review of Queensland Health's options for the introduction of a real-time prescription monitoring system in Queensland and the subsequent development of a business plan to progress the implementation of a real-time prescription monitoring system.

V. Real time prescription monitoring

Recommended that the Director-General of the Department of Health direct an expeditious review of Queensland Health's options for the introduction of a real-time prescription monitoring system in Queensland and the subsequent development of a business plan to progress the implementation of a real-time prescription monitoring system.

Further Action Undertaken by the Queensland Department of Health

336. Pending the development and implementation of a real-time prescription monitoring system in Queensland, the Department considers that an improvement to its telephone access system via a proposed 13S8INFO telephone enquiry service to be delivered by the Department's Health Contact Centre (HCC) from 8am until 8pm, 7 days a week, will assist. This service will be hosted by the HCC allied health team, which consists of telephone counsellors and a team leader (nursing officers or health professionals) who will manage calls. Complex matters and requests for approvals to prescribe will be transferred directly to MRQ Senior Clinical Advisers during business hours. If a call is made outside MRQ business hours or an MRQ Tier 2 Clinical Adviser isn't available, HCC staff will request that the doctor call back in business hours or send a referral email from the 13S8INFO email address to MRQ to prompt a call back.376 Marketing will be provided to relevant stakeholders to promote use of the service.

337. In 2017, a *S8 Monitoring Strategy* was developed to replace the *Surveillance Alerts,* and consists of nine indicators, reported monthly with specific follow up steps conducted if non-compliance has not been addressed.378 These indicators include prescribing controlled drugs without approval to patients registered on the QOTP, prescribing higher doses of controlled drugs without an approval, and assisting to identify potential drug dependent patients. The new proposed thresholds are as follows:

- *Doctor shopping*: threshold now six doctors and six prescriptions over a three month period, with reports run monthly.

- *Patient registered on the QOTP and obtaining Schedule 8 medicine scripts*: surveillance alerts reduced from two months to one month.

- *High dose without an approval:* surveillance alerts previously run each month, and now monthly outside an approval.

338. The Strategy also articulates the actions to occur in the months following the detection of a non-compliance, which are as follows:

- *Month 1:* written advice provided to practitioner about potential non-compliance and actions required.

- *Month 2:* if non-compliance continues, escalation to Senior Clinical Advisor for discussion with the practitioner.

- *Month 3:* if non-compliance continues, escalation to either Senior Medical advisor or to MCHTU for investigation.

339. Furthermore, the Department of Health has made the following further changes:

- MRQ has been organisationally restructured into five separate units to manage the breadth of medicines regulation and legislative work. MRQ itself remains the primary administrator of the regulation of controlled drugs with the Health (Drugs and Poisons) Regulation 1996. A separate compliance unit, the Medicines Compliance and Human Tissues Unit (MCHTU), will now undertake compliance work under the Regulation.

- The Department is currently reviewing the overall regulation of Schedule 8 drugs in conjunction with the Queensland Office of the Health Ombudsman (OHO).

- MRQ is currently developing new business practices to improve its surveillance and monitoring activities.

- MRQ is working with higher dispensing volume Pharmacies to upload information on a more frequent basis.

340. A number of system enhancements have also been made, and are continuing to be made to MODDS, which include:

- A redesign of the Dispenser (Pharmacy) table, aimed to ensure uploads of Schedule 8 medicine data is uploaded more regularly and within the stipulated monthly timeframe.

- MRQ has been organisationally restructured into five separate units to manage the breadth of medicines regulation and legislative work. MRQ itself remains the primary administrator of the regulation of controlled drugs with the Health (Drugs and Poisons) Regulation 1996. A separate compliance unit, the Medicines Compliance and Human Tissues Unit (MCHTU), will now undertake compliance work under the Regulation.

- The Department is currently reviewing the overall regulation of Schedule 8 drugs in conjunction with the Queensland Office of the Health Ombudsman (OHO).

- MRQ is currently developing new business practices to improve its surveillance and monitoring activities.

- MRQ is working with higher dispensing volume Pharmacies to upload information on a more frequent basis.

341. A number of system enhancements have also been made, and are continuing to be made to MODDS, which include:

- A redesign of the Dispenser (Pharmacy) table, aimed to ensure uploads of Schedule 8 medicine data is uploaded more regularly and within the stipulated monthly timeframe.

- The creation of a Pharmacy Ownership Module, which enables the recoding of registered pharmacists and pharmacies they own.

- The automatic identification and voiding of a duplicate electronic prescription.

- Automated sex code allocation, which allows for great efficiency in identifying and matching patients in the system.

- A redesign of the system to allow for system alerts to undertake quality assurance of records provided by pharmacies.

- Improvements to the generation of treatment approval correspondence.

- To address the increasing number of prescriptions being written, a Medicare Number and a unique identifier are being introduced into the MODDS system.

342. At this stage, it is not anticipated by the Department that the monthly upload timeframe of information from dispensers to MODDS will be lessened, although some preliminary analysis as to whether this could be achieved is being undertaken.384 Given the limitations of the system, however, it is not anticipated that the timeframes could be reduced to less than 24 hours.

343. It was acknowledged by the Department during the inquest, however, that the improvements, which had been made by MRQ to MODDS, the internal regulatory structure and the 24/7 telephone enquiry service, were not sufficient to address the concerns associated with the increase in opioid prescribing in Queensland.386 It was agreed that a real-time prescription monitoring service was crucial in addressing and managing these increasing risks to the community.

344. Mr. Milne's circumstances highlight that despite the previous threshold for a surveillance alert being two months for those registered on the QOTP, it was in fact four months since the first prescription was issued, and tragically two months after his death, before MRQ corresponded with his treating general practitioner. This delay was acknowledged by Dr Young, where she noted that *'the resourcing of MRQ was such that alerts were undertaken on a three monthly basis'.* Despite the resourcing in MRQ not having changed since 2014, she claims that the alerts now being run monthly will facilitate a more timely provisions of information to general practitioners. Mr. Loveday also reiterated that MRQ was investigating possible business process improvements, which may potentially be able to expedite monitoring practices.

My Health Record

345. During the inquest, the Queensland Department of Health cited the Commonwealth Government's *My Health Record* (MHR previously known as the *Personally Controlled Electronic Health Record)* as a potential source for health practitioners, which would allow them access to a patient's complete medical history and treatment episodes across various facilitates and settings in real-time. The MHR is facilitated by the Australian Government to operate as on online platform, which is intended to enable a more efficient and effective

treatment of patients by various health practitioners assisted by a patient's ability to access and manage their own records.

346. The MHR is an 'opt out' system, which may contain a patient's prescription medication history, Medicare claim history, immunisation records, clinical summaries, as well as specialist referrals and letters. Patients are able to add various information, such as allergies, personal health noted and current medications. Relevantly, for the purpose of this inquest, MHR users are able to customise and set access controls to restrict who is able to see the information, and can cancel their record indiscriminately.

347. The Office of the Australian Information Commissioner (OAIC) '*regulates the handling of personal information under the My Health Record system by individuals, Australian Government agencies, private sector organisations and some state and territory agencies'.*

348. In relation to personal electronic health records, the Australian Medical Association (AMA) have noted that any such records must contain *'core clinical information that is accurate, reliable and comprehensive'.* The usefulness of such records clinically will inevitably be limited by the content, accuracy and accessibility of the information recorded. Certainly, any concern as to the completeness of the records and the accuracy of the information contain therein would '*undermine the confidence of the user'.*

349. The AMA note that the MHR does not include every aspect of a patient's medical record, and as such, will not replace this completed document. Given this limitation, it cannot be realistically relied upon by a health care provider to make clinical care decisions, as it is not necessarily complete nor accurate. The AMA recommended that the MHR, *'could benefit from and contribute to initiatives to make the range of existing information systems across the health care sector interoperable. A fully functional shared EMR should be aligned with current clinical workflows and integrate with existing clinical software'.* Accordingly, it is suggested that the MHR would be most effective if it is part of a coherent and integrated health system.

General Practitioner Education in relation to Opioids

350. For general practitioners to maintain specialist recognition and consequent vocational listing with Medicare Australia, as well as recognition by AHPRA on the specialist register, all medical practitioners are required to meet the standard for Continuing Professional Development (CPD) set by the relevant AMC accredited college, which in this case is RACGP. Medical Practitioners who are not on the vocational or specialist register must complete a minimum of 50 hours CPD per year and may choose a self-directed program.

351. RACGP offers a wide range of multimodal educational programs for general practitioners. The activities provided in the Quality Improvement and Continuing Professional Development (QI&CPD) program are purported to reflect current technology and best practice in the delivery of education, training, and to recognise individual needs of doctors such as their working hours, locations and preferred learning styles.

352. RACGP is also a recognised CPD auditor for AHPRA. The QI&CPD program offered by RACGP streamlines the administration of this requirement for its participants throughout the triennium period and in times of audit. The professional development activities, accredited services and compliance are recognised by AHPRA, GPA Accreditation Plan and AGPAL as approved evidence of complying with legislative requirements set by these professional bodies.

353. At present, there are no sanctioned QI&CPD education programs or workshops delivered face to face in Queensland for general practitioners in relation to pain management, or the treatment of patients with Schedule 8 medications. However, there are five online activities accredited by the RACGP relating to opioid use that are accessible to general practitioners nationally.

354. At inquest, RACGP confirmed that there were no plans to provide any additional incentives to general practitioners to undertake any targeted pain management and opioid prescribing courses, despite the fact that it was recognised that general practitioners play a primary care role in managing these patients.

Education Provided to GP's by MRQ

355. In relation to the education provided to general practitioners when prescribing Schedule 8 medicines by MRQ, an information kit is provided, which includes general information about the prescribing of opioids, details of the 24/7 telephone enquiry service, information resources and signs for displaying in a practice setting.

356. Information and details are also provided by way of the Department of Health's webpage. MRQ staff also provide practitioners with information about doctors' legal obligations and the 24/7 Telephone Enquiry Service through direct interactions and presentations in various forums.

Expert Opinions

357. Expert opinions were subsequently sought from Forensic Medical Officer, Dr Don Buchanan, Pain Medicine Specialist, Dr David Gronow and Pharmacist, Dr Esther Lau, in relation to the issues associated with the prescribing, dispensing

and monitoring of Schedule 8 medicines in Queensland, as highlighted by the circumstances of each death. A summary of their findings and recommendations are detailed below.

Review by Forensic Medical Officer

358. In preparation for the joint inquest, Forensic Medical Officer, Dr Don Buchanan was requested to consider the circumstances of each death, including previous advice received from the Clinical Forensic Medical Unit, and comment on any apparent issues associated with the care and treatment provided, as well as any broader systemic concerns.

<u>William House</u>

359. On 2 October 2013, Dr Buchanan provided a report for the purposes of the coronial investigation. Dr Buchanan concluded that Mr. House developed a chronic pain condition that required various measures to relieve his pain, including localised pain relieving injections and opiate medication. He began to abuse his opiate medication at the expense of making himself available for ongoing management of his chronic pain and assessment of his drug dependence. Like many of these patients, Mr. House was manipulative and untruthful in his consultations with the various medical practitioners; however, a lack of an integrated approach to his care meant his treatment outcomes were not optimised.

360. Dr Buchanan notes that integrating hospital services with general practice is a difficult issue, as patients are free to visit any general practitioner. A hospital discharge summary that is sent to a nominated general practitioner will not of course be available to another GP practice. This creates issues with continuity of patient care generally; however, it is particularly so when a patient deliberately seeks out different GPs in order to obtain opiate medication.

361. Dr Buchanan notes that, as all opiate medication is ultimately dispensed by a pharmacist, whether in public or private practice, collection of this data in real time and making it available electronically to regulators and health practitioners should provide an adequate solution to this ‘doctor-shopping’ behaviour. This is what the Commonwealth’s Electronic Recording and Reporting of Controlled Drugs (ERRCD) undertakes to achieve, allowing medical practitioners in both the public and private sectors to optimise the care of the drug dependent patient. Further details as to the specific of the ERRCD and the implementation status is outlined further below.

362. Dr Buchanan is of the view that an integrated hospital approach involving the emergency department, ICU, ATODS, mental health and the persistent pain team, with improved documentation and compliance with procedures, should see demonstrably improved outcomes for this difficult group of patients. A database

that monitors the dispensing of opiate medication in real time around Australia and across the public-private divide will provide an additional and essential resource in ensuring that these outcomes are optimised. This will similarly enhance the overall quality of care and safety for these patients by providing access to the patient's opiate prescribing history of both public and private health sector health practitioners.

363. Having subsequently considered the recommendations made by the GCH following the RCA, and the implementation of each of these changes, Dr Buchanan is satisfied that the actions taken sufficiently address the concerns he raised.400 He does note, however, that the iPharmacy integration is yet to be actioned. It should be highlighted that the Viewer portal has since been launched by the Department, which provides consolidated clinical information about each patient who received treatment or care at a Queensland Health facility, which can be accessed by general practitioners generally.

364. Dr Buchanan notes that there has been significant work done to improve co-ordination and service delivery to alcohol, drug and mental health patients across the GCHHS, as well as developing referral and management pathways for patients presenting with persistent pain management requirements.

Jodie Anne Smith

365. Forensic Medical Officer, Dr Anne-Marie Swain was asked to consider the circumstances of Ms. Smith's death. Having considered Ms. Smith's medical and PBS records, Dr Swain noted that she was clearly a consummate 'doctor shopper', who attended numerous doctors in order to obtain prescriptions for opiates, benzodiazepines and non-benzodiazepine sleeping tablets. Over a period of three years, Ms. Smith obtained prescriptions from 20 different doctors on one occasion only, with four different doctors only twice. She then tended to have the prescriptions filled from the different doctors at different pharmacies even when she was filling the prescriptions on the same day. Records confirmed that she often had multiple prescriptions dispensed in a single day.

366. Dr Swain considered the prescribing practices of a majority of the doctors who treated Ms. Smith in the few years before her death. She found that the overwhelming majority of doctors appear to have acted responsibly in their management of her condition. As such, she did not recommend any further investigation be carried out into the prescribing practices of the doctors involved in Ms. Smith's care and treatment.

367. Dr Swain closely considered the prescribing practices of Ms. Smith's three most regular general practitioners; Dr Homsi, Dr Ramiah and Dr Srinivasa. In relation

to Dr Ramiah, Dr Swain found that in a majority of instances, the treatment provided to Ms. Smith was reasonable in the circumstances. Although she did raise some concern as to a decision by Dr Ramiah to prescribe Ms. Smith high doses of opiates following a successful weaning off of Oxycodone during a hospital admission, she did acknowledge that overall he made significant and appropriate attempts to manage Ms. Smith's difficult condition.

368. Ms. Smith consulted with Dr Srinivasa on 13 occasions from 31 October 2011. During this time, he actively decreased the amount of oxycodone prescribed to Ms. Smith and attempted to change her to a sustained release oxycodone tablet. Overall, Dr Swain notes that the treatment provided by Dr Srinivasa to Ms. Smith was reasonable.

369. Unfortunately, at the time of Dr Swain's review, Dr Homsi had not been asked to provide a detailed statement as to his treatment and care of Ms. Smith. It should be noted that none of Ms. Smith's regular treating general practitioners were aware that she was attending three different medical centre simultaneously (and still obtaining prescriptions from Dr Homsi).

370. Dr Swain noted that 'doctor shopping', inappropriate prescribing practices, the misuse of prescription medication, dependence on prescription medication are multifactorial and complex problems, for which there are no simple solutions. She recommended that input be sought from a number of health professionals including, a general practitioner, specialist in pain and addiction medicine and a pharmacist.

371. Having considered the circumstances of Ms. Smith's death, and Dr Swain's report, Dr Buchanan confirmed that he agreed with the conclusion that she was a prescription shopper and that the individual treatment provided by various doctors was largely appropriate. Collectively, he highlights that the practitioners were unfortunately unaware that she was attending other medical practices.

372. In relation to Dr Homsi, Dr Buchanan raises significant concern as to his practice of providing further scripts for various medications without consulting with the patient in person. He is of the view that this behaviour is below the standard reasonably expected of a medical practitioner.

373. Dr Buchanan also reiterates that it is concerning Dr Ramiah recommenced Ms. Smith on opiate medication following her release from Hospital, particularly given the advice of Dr Tadros. He also notes that the only correspondence received from DDU in relation to Ms. Smith was that dated 21 July 2010, in response to Dr Ramiah's correspondence.

374. Dr Buchanan is of the view that Ms. Smith's care would have benefited from the various general practitioners, with whom she consulted, being made aware that she was seeking similar medications at other practices. As such, real-time monitoring of Schedule 8 medications within and across jurisdictions of both private and PBS prescriptions would likely have detected her behaviour and enabled appropriate action to have been taken.

Vanessa Joan White

375. Forensic Medical Officer, Dr Don Buchanan subsequently conducted a review of the circumstances of Ms. White's death. He noted that there would have been an additive effect of all of the medications found by the toxicological testing, which would have enhanced or aggravated the overall toxic effect.

376. Dr Buchanan found that Ms. White's medical records clearly paint the picture of a patient who, following her initial prescription for OxyContin in 2010, continued to obtain it by prescription in increasing amounts and concentrations, and with increasing frequency, up until her death. That being the case, Ms. White clearly suffered from a genuine spinal injury, which would have caused her excruciating pain. Although she had been referred to the GCH for surgery, there was delay in such a procedure being carried out, which could, at least in part, be attributed to Ms. White's failure to attend a number of outpatient appointments.

377. Most of Ms. White's treating general practitioners, being aware of her substance abuse history, contacted DDU to make the requisite enquiries about her Schedule medicine history. As she never achieved the status of a 'doctor shopper', it appears to have supported the ongoing treatment of Ms. White's back pain with opiate medication. Continued checks with DDU seemed to support this ongoing treatment plan whilst Ms. White was awaiting her back surgery.

378. Dr Buchanan notes that it would have been helpful for Ms. White's medical practitioners to have been aware of her admitted overdose on 17 November 2012. As she left before being assessed by the doctor, no discharge letter was prepared and sent to her general practitioner. He notes that had an episode been lodged with DDU at least, this would have been reported to Dr Miller when he contacted DDU before prescribing her OxyContin on 16 December 2012.

379. Dr Buchanan confirmed that he was satisfied that the subsequent changes made by the GCH following Ms. White's death, addressed the concerns raised surrounding her presentation shortly before her death.

Daniel Keith Milne

380. Forensic Medical Officer, Dr Nelle van Buuren conducted a review of the care and treatment provided to Mr. Milne prior to his death. Dr van Buuren notes that

opioid dependence is often a chronic relapsing condition, the clinical management of which encompasses not only routine and safe medical practice and prescribing, but also advocacy and understanding of challenging behaviour.

381. Having considered all of Mr. Milne's medical records, history and cause of death, Dr van Buuren raises significant concern as to the clinical decisions and prescribing practices of Dr Whelan. Around the time of his death, Mr. Milne was prescribed buprenorphine, fentanyl and quetiapine by Dr Whelan. Dr van Buuren notes that both fentanyl and quetiapine have the potential for diversion for intravenous use, however, there is no record to suggest that this possibility was considered by Dr Whelan, or discussed with Mr. Milne. Furthermore, the injury cited by Mr. Milne, for which he was prescribed fentanyl patches, was never investigated or confirmed by Dr Whelan. It is not evident from the medical records that he examined Mr. Milne to determine how the injuries or pain incapacitated him, such that he would require opioid analgesics. Whilst Dr Whelan has subsequently claimed that he saw bruising, Dr van Buuren notes that given this was the only substantiated injury, fentanyl patches were not an appropriate first-line analgesia.

382. Dr van Buuren further highlights that of the 35 consultations recorded, 32 of these do not indicate whether any physical examination was conducted by Dr Whelan. On the last four consultations, during which Dr Whelan prescribed fentanyl patches, there is no evidence to suggest that he conducted an examination of Mr. Milne. Had this been done, he may have noted the old and possibly new track marks found at autopsy. As such, Dr van Buuren notes that despite Dr Whelan's experience in managing substance dependent patients, he did not perceive Mr. Milne's reported, unsubstantiated injury and request for fentanyl patches may have been an indication that he had relapsed.

383. Dr van Buuren further concludes that the co-prescribing of Suboxone and fentanyl patches to Mr. Milne was inappropriate. There is no supporting information, despite Dr Whelan's claim to the contrary, that he ever instructed Mr. Milne to cease using Suboxone once he commenced fentanyl, particularly given he continued to prescribe Suboxone.

384. Accordingly, Dr van Buuren concludes that Dr Whelan's treatment of Mr. Milne was a significant departure from the accepted professional standards and would merit review by OHO.

385. In relation to the monitoring and conduct of MRQ, Dr van Buuren notes that, whilst they have the capacity to identify unsafe prescribing practices by QOTP prescribers, and notify them of such, the fax sent to Dr Whelan in relation to Mr. Milne is dated some 18 months after the first script for Fentanyl was dispensed. This is also 15 months after the last script was dispensed (and his death). Whilst Dr van Buuren recognises that there is about a month delay in MRQ receiving

information from pharmacies about the dispensing of Schedule 8 medicines, this still leaves a 17 month delay since the first script, and 14 months since the last script, before a fax was sent to Dr Whelan in relation to his prescribing practices. Had a more timely communication been sent, it may then have been of clinical benefit.

386. It should be noted that the date on the DDU correspondence included in the records considered by Dr van Buuren was incorrect, and should have been 10 April 2014, some two months after Mr. Milne's death.

387. Dr Buchanan agrees with the conclusions reached by Dr van Buuren. He notes that this case highlights *'the need for real-time monitoring of S8 medicines to inform timely regulatory action'.* During the inquest, he agreed that it was concerning that the only correspondence generated by MRQ was some two months after Mr. Milne's death, despite the fact that he had been prescribed Fentanyl patches over a four month period.

388. Dr Buchanan further reiterated that the decision by Dr Whelan to prescribe Mr. Milne Fentanyl patches, particularly without any supporting documentation from the Hospital or ordering any further investigations be carried out, was '*hard to understand*'.

Dr Buchanan's recommendations

389. Having considered the circumstances of Mr. House, Ms. White, Ms. Smith and Mr. Milne's deaths, Dr Buchanan notes that it is clear that the current monitoring system in place is not optimal. He notes that the MODDS system does not effectively support health practitioners' clinical decision-making or actions by regulatory bodies, such as MRQ, as it does not provide an immediate response to issues, which arises, or provide up to date information to practitioners.409 He notes that in the case of Mr. Milne, a timelier warning from DDU/MRQ may have changed the tragic outcome. Accordingly, Dr Buchanan vehemently supported the need for the urgent introduction of a real-time prescription monitoring system, preferably in a nationally consistent manner.

390. Dr Buchanan reiterates that these deaths highlight the urgent need for prescribers and dispensers to be alerted to potential misuse in real-time, so that preventative and corrective measures can be taken immediately, reducing the risk to the patient and the community.

391. During the inquest, Dr Buchanan agreed that effective monitoring and regulation of the prescribing and dispensing of these drugs of dependency is crucial in managing the associated risks posed to the patient and the community. This is

especially so given patients are not registered to a single general practitioner, and can attend upon any general practice for a consultation.

392. Dr Buchanan also expresses the view that public hospitals should be included in any real-time prescription monitoring and reporting of Schedule 8 medications. He acknowledged, however, that the addition of Viewer portal, which will be accessible by general practitioners, will be a good tool, which assists in moving towards an integrated approach to patient care.

393. Dr Buchanan recognises that the new *S8 Monitoring Strategy* put in place by MRQ is certainly a more proactive approach to managing non-compliance with the regulatory requirements in a shorter timeframe. However, he notes that the inability to alert prescribers and dispensers to potential misuse in a timely fashion means preventatives or corrective action is unavailable or delayed, with potentially significant clinical consequences.

394. In relation to the new telephone enquiry service offered by MRQ, Dr Buchanan is of the opinion that it is problematic that access to senior clinical advisors is only available in business hours. Furthermore, it seems that there is a general lack of awareness amongst practitioners as to the availability of the service, which limits its effectiveness. He acknowledged, however, that the proposed ad campaign, which was scheduled to commence in April 2017, as to the availability of the service to be undertaken by the Department of Health was positive.

395. Again he notes that real-time monitoring at least allows general practitioners to be provided with up to date information on Schedule 8 medications 24 hours a day.

396. Dr Buchanan also reiterates the need for general practitioners to be provided with education and information as to the regulatory environment that directs Schedule 8 medicine prescribing, which he suggests should be provided by the Royal Australian College of General Practitioners.

397. Whilst Dr Buchanan acknowledged that the improvements made recently by the Department of Health to the timeframe for which the data is collected for MODDS were positive, he still was of the view that real-time prescription monitoring for general practitioners is essential in effectively managing and mitigating the misuse of opiate medication.

Review by Pain Specialist

398. The Director of the Sydney Pain Management Centre, Dr David Gronow, a Pain Medicine Specialist also provided an expert opinion as to the care and management provided to Mr. House, Ms. Smith, Ms. White and Mr. Milne, as well

as consideration of the current systemic issues evident in relation to the prescribing, dispensing and monitoring of drugs of dependence in Queensland.

William House

399. Having considered Mr. House's medical history and treatment, particularly in the few years before his death, Dr Gronow noted that there did not appear to be any overall pain management plan in place. Rather, his dosage of opioids was simply increased.

400. In Dr Gronow's opinion, Mr. House was on an *'inappropriate dose of opiates for inappropriate conditions'.* He states that opiates are not recommended for the management of chronic long-term musculoskeletal pain nor for headaches. Whilst they may be indicated for the management of diagnosed acute musculoskeletal pain, this should only be in the short-term, for a maximum of six months. Dr Gronow notes that the recommended maximal dose for non-cancer pain is between 80-100 mcg morphine equivalent per day, and for a general practitioner initiating slow release opiates 40 mg morphine equivalents per day.

401. Dr Gronow highlighted that in the community, Mr. House was able to attend upon multiple different doctors, both in the same and different general practices. At times, MRQ were contacted and provided advice about his multiple prescriptions, and he was found by others to be engaged in doctor shopping, following which he was refused prescriptions, however, this was not the 'usual pattern'. It appears, in Dr Gronow's opinion that the general practitioners treating Mr. House relied upon correspondence from Dr Espinet to confirm that he was on the opiates they then prescribed. Unfortunately, there was no feedback provided to Dr Espinet as to his suspected abuse or the efficacy of the opiates by these practitioners.

402. Furthermore, Dr Gronow highlights that the cues Mr. House may have been abusing opiates were not communicated to other members of the treating team. He further notes that it appears Mr. House had developed opioid induced hyperalgesia, which is common in patients who are taking more than 100mg morphine equivalent per day (Mr. House's morphine equivalent per day was approximately 600mg per day). Dr Gronow opines that this would have accounted for Mr. House's perception of suffering from increasing pain despite increased opiate intake.

403. Dr Gronow recognised that Mr. House was a manipulative patient, who was difficult to manage. However, he notes that identifying these patients is important, as is '*putting in place appropriate barriers to change their behaviour to reduce self-harm…'* which he acknowledged would be hard for a general practitioner without the involvement of a pain service'.

404. In the community, Dr Gronow states that there was inappropriate prescribing of opiates to Mr. House, including increasing quantities and early repeat scripts. He notes that it was unfortunate Mr. House was not transferred onto a drug, such as Suboxone, when it was suspected that he had become addicted.

Jodie Anne Smith

405. Dr Gronow notes that it is 'extraordinarily unusual' for a general practitioner to continue to prescribe opiates without reviewing a patient, and also assuming that they had not sought medical attention in the State that they now reside. He also expressed concern that Dr Homsi had provided opiate prescriptions to a relative, given normal practice would be to hand over care to a local general practitioner.

406. Dr Gronow notes that Ms. Smith's case highlights the willingness for some general practitioners to provide opioid scripts to patients where there is no direct therapeutic relationship. When a patient presents to an unknown doctor requesting a script for opiates, the options can be to refuse the request or check the validity of their reason by contacting their general practitioner and the DDU, and only then to provide it if appropriate, with enough simply to cover the days before the patient was able to return to see their normal prescriber.

Vanessa Joan White

407. Dr Gronow notes that in Ms. White's case, a patient with a known substance abuse history, was prescribed opiates, which were dramatically increased without any assessment of their efficacy or compliance. Furthermore, there was no coordination of her management, with a lack of direction within single general practices highlighted.

408. Dr Gronow also notes that Ms. White's case highlights the willingness of some general practitioners to prescribe opiate medication to patients.

Daniel Keith Milne

409. Dr Gronow expresses surprise and concern Dr Whelan's decision to prescribe opiates to a patient, who was a known substance abuser, especially as there was no attempt to conduct an adequate assessment of the need for opiates, or consideration as to the use of non-opiate analgesia.434 In his view, the choice to use Fentanyl and the dose was inappropriate. Dr Whelan clearly did not following the 4As of opiate prescribing, namely: analgesia, activity, adverse effects and aberrant behaviour.

410. At inquest, Dr Gronow stated:

"*I think it is amazing one would even consider giving such a drug. At such dose-…I (have no) way of knowing what the thinking was, but sometimes, it's thought that, you know, because you're on Suboxone that they're going to be tolerant of their medication, but he wasn't on a high dose of Suboxone."*

General issues and coronial recommendations

411. Dr Gronow noted, having considered the circumstances of each of the deaths, that there was a '*lack of understanding of the role of opiates in management of chronic pain*'. There appears to have been a general assumption that opiates can be used without impunity and at high doses, without an understanding or acknowledgement of the risks or benefits. None of the patients had been provided with a plan as to how to manage their opiate use, and the dosage prescribed, nor to assess their ongoing clinical needs.

412. In relation to the regulatory monitoring presently available in Queensland, Dr Gronow notes that it is retrospective, and appears to only identify a patient who may meet a certain criteria once an enquiry is received. It does not appear that there is any ability for the current system to be proactive, which allows patients to obtain excessive scripts from multiple general practitioners. In the cases considered, unless initiated by a general practitioner by way of an inquiry with DDU, feedback from the regulator was not timely if provided at all.

413. Dr Gronow is of the view that there would be benefit in improving the communication of patients attending hospitals, mental health units, and drug and alcohol services to the community where there is use of high doses of opiates or evidence of a patient having substance abuse. He notes that the early identification of all prescribers to a patient would be helpful.

414. Dr Gronow supports the introduction of a real-time prescription monitoring system in Queensland, which he believes should be made available at the time the doctor is writing the prescription to alert the doctor of the presence of prior prescriptions and dosages. Episodes of attempts to obtain prescriptions for controlled medication need to be recorded, as well as those actually prescribed. Dr Gronow further submits that the monitoring system should also be made available to the pharmacy to prevent the prescription being dispensed.

415. Dr Gronow further notes that education for general practitioners, which provides them with the necessary skills to manage patients appropriately with opiate medication, could assist to prevent misguided prescribing of drugs of dependence. In addition to further undergraduate education in relation to chronic pain, Dr Gronow submits that more active education needs to be provided to current practicing general practitioners.

Review by Pharmacist

416. Pharmacist, Dr Esther Lau, who is presently a Lecturer and Course Coordinator at the Queensland University of Technology, was requested to provide an expert opinion as to the issues associated with the prescribing, dispensing and monitoring of drugs of dependence in Queensland from a pharmaceutical perspective, considering the particular circumstances of Mr. House, Ms. Smith, Ms. White and Mr. Milne's deaths.

William House

417. In relation to Mr. House's clinical care and treatment, Dr Lau highlighted the following concerns

- Fragmentation of information available to the general practitioners and Hospital as to his medication.

- Mr. House's uptake of appropriate management of drug misuse was poor. Despite ongoing issues and concerns with his opioid use, there are little options provided to prescribers as to how this can be managed in conjunction with Mr. House's persistent pain.

- Prescribers found Mr. House to be a difficult patient to manage.

- A general lack of communication and collaboration between general practitioners and specialists as to Mr. House's care and management.

- Lack of compliance with regulatory requirements and resources by general practitioners.

- There was a fragmentation of information in relation to the dispensing of Schedule 8 medicine. As dispensing systems and data between pharmacies are not linked, even if they are affiliated or owned by the same proprietor, it is not possible to identify any unusual doctor shopping behaviour.

- As only medicines dispensed under the Pharmaceutical Benefits Scheme will appear in the information provided from the Prescription shopping information service, private scripts are not captured. Pharmacists are not able to access information from the PSIS, as they do not have prescriber numbers.

Jodie Anne Smith

418. Dr Lau cited the following concerns as to the clinical care and management of Ms. Smith:

- Ms. Smith was requesting prescriptions from different doctors across different practices in both Queensland and New South Wales, often only on one occasion preventing continuity in care and transparency in information flow.

- The provision of scripts for drugs of dependence without the patient attending upon the doctor.

- Ms. Smith presented to different prescribers at different practices, at times on the same day, requesting prescriptions for drugs used in the management of insomnia.

- Ms. Smith's uptake of appropriate management of persistent pain was poor.

- The amount of morphine prescribed to Ms. Smith was well beyond the recommended daily dose (which is 80-100mg for non-cancer pain).

- It appears that prescribers deviated from the advice of specialists to cease opioids.

- Ms. Smith presented multiple prescriptions from different doctors for the same medicine to be dispensed on the same day at different locations and different pharmacies.

- Ms. Smith did not trigger the threshold for being identified as a doctor shopper.

- There was a disparity in records between MRQ and those held by the prescribers.

<u>Vanessa Joan White</u>

419. As with Mr. House and Ms. Smith, Dr Lau found that there was fragmentation in the information available to those involved in her care, with Ms. White requesting and on occasion obtaining prescriptions from multiple doctors across multiple practices concurrently. Similar concerns as to issues associated with intravenous drug use and Ms. White's unwillingness to engage with services offered, made it difficult for general practitioners to effectively manage her care.

420. Furthermore, issues associated with the limited prescribing and dispensing information available to pharmacies and shared between different pharmacies was cited by Dr Lau as a concern. Ms. White attended upon multiple different pharmacies to fill her prescriptions, which would have been unknown to others she may have attended.

Daniel Keith Milne

421. Dr Lau raised the same concerns as that cited by Dr Buchanan and Dr Gronow, as to Dr Whelan's decision to prescribe Mr. Milne fentanyl patches, without appropriately verifying his alleged injury, particularly given he had a significant substance abuse history. She also noted that he did not complete a treatment report to DDU prior to commencing a drug dependent person with a drug of dependence.

General issues and coronial recommendations

422. Dr Lau notes that the current system, as it is designed, is intended for one patient, who requires drugs of dependence medicines, to be managed by one prescriber, and ideally to have their medication dispensed from one pharmacy. However, the system in its present state is unable to detect, in a timely manner, the prescribing of drugs of dependence by a number of different general practitioners, often at concurrent times.

423. Dr Lau also highlighted that there is a general fragmentation of information between different health care providers, regulators and other agencies at present. This is exacerbated if a patient choses to attend different practitioners or different pharmacies to have their prescriptions dispensed. Dr Lau also noted that the fragmentation of data due to pharmacy dispensing systems not being linked was a concern, which allowed a patient, who chose to attend different pharmacies to fill different prescriptions to do so without detection.

424. Dr Lau also raised concern as to the fragmentation of data held by the regulator, as well as the delay in the applicable data being provided to MRQ. She further notes that the records received by MRQ can potentially be incomplete, as those administered by hospitals are not captured in the system.

425. In relation to the actions to be undertaken to address the systemic issues identified given the circumstances of each of these deaths, Dr Lau suggests the following:

- The introduction of a real-time prescription monitoring system in Queensland, which captures medicines prescribed and dispensed.

Consideration needs to be given to ensure that this system can be integrated with prescribing and dispensing software, regulatory and monitoring authorities, and ideally other electronic record systems.

- Introduce resources for facilitating better patient uptake of appropriate management of chronic pain, and other conditions, which require the use of drugs of dependence medicines.

- Introduction of approximate morphine equivalent doses to prescribing and dispensing systems so the prescriber and pharmacist acknowledge the doses of opioids being prescribed, particularly when high doses are initiated or prescribed, or when patients are being changed between opioids.

- Increased awareness and education for healthcare professionals, to ensure awareness and understanding of the role of MRQ, availability of resources and support for managing complex and difficult patients taking drugs of dependency medicines, or medicines with a potential for misuse.

- Increased awareness and education for patients living with persistent pain around expectation and treatment goals.

426. Dr Lau agrees that the introduction of a real-time prescription monitoring system in Queensland would greatly assist to prevent deaths caused by drugs of dependence medicine, and would also help to rectify some of the fragmentation in the information presently available to the various healthcare settings and agencies. Dr Lau is also of the view that allowing Pharmacists access to information held by the PSIS may be helpful to further reduce the present information disintegration.

Further Non-Party Submissions

427. During the course of the coronial investigation and inquest, the Australian Medical Association (AMA) and the Royal Australian College of General Practitioners (RACGP) provided further comment in response to the concerns raised about opioid prescribing, dispensing and monitoring in Queensland.

AMA submissions

428. In response to an invitation to comment on the issues to be considered during the inquest, AMA stated the following:

"*It is the view of AMA Queensland that a real-time prescription monitoring (RTPM) system is urgently needed in Queensland. We have been advised that the Queensland Government is in negotiations with the Commonwealth, who is leading the implementation of a national system of prescription monitoring. It is AMA Queensland's understanding that the implementation of a national system is many years away, with some time frame we have been privy to suggesting a minimum of four years at best.*

AMA Queensland is deeply concerned that such a time frame will see countless more vulnerable patients die due to issues of drug dependency. This is why, following the traffic death of Katie Lee Howman and the subsequent Coroner's report into her death in 2015, AMA Queensland established an internal working group of doctors who have experience within the field of addiction medicine to consider what could be done in the interim until a national system is established.

Under the current system, pharmacists in Queensland must manually upload data to the Monitoring Drugs of Dependence System (MODDS) at the end of each calendar month. Although the MODDS system is quite comprehensive in the data it captures, clearly a monthly update is an insufficient timeframe when trying to prevent people from doctor shopping.

AMA Queensland believes that a series of progressive steps as part of a broader approached could be recommended by the Coroner to begin to shorten the time frame so that within the space of three years we have moved to a state-wide system of real time monitoring, which could operate until such time that the national system is in place.

Firstly, AMA Queensland must stress that real time prescription monitoring currently has an insufficient evidence base to demonstrate its effectiveness. We strongly believe in evidence based policy, and while prima facie the move to a real time prescription monitoring system seems to be a good idea, there are potential pitfalls which a review of evidence would be able to account for.

We are aware that Tasmania recently undertook a trial of a real time prescription monitoring system, however, to the best of our knowledge, the review if the trial has not yet been made available. AMA Queensland believes that it would be beneficial for the Queensland Government to find some way of accessing that data, and then using it as a basis for our own system.

Once that data has been reviewed, we would recommend to the Coroner that a recommendation be made to initially establish a memorandum of understanding between the Queensland Government's Medicines, Regulation and Quality (MRQ) unit and pharmacies to develop a system that could reduce the delay from one month to no more than 24 hours…

With the MOU in place, the Queensland Government would be free to implement a software-based solution, which would begin the move to a state wide real time monitoring system. By working with medical software manufacturers to implement an update to their software, pharmacists could scan prescriptions in real time into the MODDS system and doctors would be able to access this data directly from their desktop.

This system could then operate within Queensland until the national system is established."

429. At the inquest, Chair of the AMA Queensland Council of General Practice, Dr Richard Kidd, confirmed that opioid misuse was a worldwide growing problem. He noted that almost four Australians die from an overdose every day, and a majority of those deaths are linked to prescription medications. Australians are the second highest users of prescribed opioids, codeine and morphine in the world, with the number of prescriptions provided increasing.

430. Dr Kidd reiterated the urgent need for the implementation of a real-time prescription monitoring system, which he described as a 'fundamental tool' required to address the growing problem.

431. Dr Kidd referred to the success of the Tasmanian real-time prescription monitoring system, DORA, which as of March 2017, had reportedly greatly reduced the doctor-shopping phenomenon within the State. Dr Kidd also agreed that the international evidence, particularly from the USA, suggests that real-time prescription monitoring reduces doctor-shopping practices and also changes some practitioners prescribing behaviour.

432. Dr Kidd implored the Australian States to develop a real-time prescription monitoring system as soon as possible in collaboration with one another and national leadership.461 He maintained that AMA are concerned as to the length of time it may take for the ERRCD system to be implemented in Queensland, given the number of deaths that will occur in the interim.

433. In relation to the present monitoring system available in Queensland, Dr Kidd indicated that MODDS is inefficient, and the lag experienced from the delay of uploading of information is concerning. He also highlighted that the present system, whilst providing information to MRQ, does not automatically provide details directly to prescribers, which inevitably leads to delays in intervening and addressing any concerning behaviour.

434. Dr Kidd confirmed that AMA are of the view that pending implementation of the ERRCD in Queensland, an interim real-time reporting system needs to be introduced. Whilst he recognised the limitations CHO, Dr Young cited, he maintained that it was AMA's position that it could be achieved in a short timeframe if the government takes leadership and prioritizes the matter. He describes the Department of Health as having *'chosen to wait and see what the rest of Australia does'* rather than proactively addressing the increasing issue within the State.

435. Dr Kidd acknowledged that a reduction in the reporting timeframe of MODDS to 24 hours 'really soon' would be a 'big improvement'.467However, he expressed concern that should changes to MODDS be made at the expense of implementing a real-time prescription monitoring system then this would not effectively address the increasing risk posed by opioid misuse in Queensland.

436. Dr Kidd agreed that should the Department of Health decide not to implement the ERRCD, AMA would advocate for the urgent introduction of a real-time prescription monitoring system of another type in Queensland.

Department of Health's response to AMA submissions

437. In response to the submissions made by AMA, the Department is of the view that the timeframes provided are not realistically achievable for a number of reasons, including:

- There is still considerable work to be undertaken from the Commonwealth's perspective. The CDOH has yet to release a consolidated and updated code base for the ERRCD. It is still developing costing and governance models.

- There needs to be agreement and support for stakeholders and policy positions of the ERRCD.

- Appropriate business re-design and resource requirements will need to be available to MRQ to manage the ERRCD.

- Training and education of stakeholders will be required to manage clinical and ICT issues of the ERRCD.

- Legislative support for new regulatory requirements will be necessary to implement the ERRCD.

  An assessment will be required of the role of, and the need to maintain the MODDS database within the ERRCD implementation. There may be a requirement for an increase in the scope of the data migration.

- The extent of the prescribing information which can be captured within the system needs to be analysed.

- It is important to ensure that restrictions are not placed on those who have a need for the medications being monitored. In order to achieve this, the system will need to be able to distinguish between those patients who may

be prescription shopping and those who are receiving multi-disciplinary treatment for chronic or complex medical conditions.

- It is important that any automated warning system is not over burdensome so as to create 'warning fatigue'.

- There will need to be increased staffing and business requirements of the Department in the administering process and facilitating compliance.

- The commitment to implement a real-time reporting system will involve an incremental increase and increase in maturity level of the reporting system, as modelled by the progress of other States to date.

- Investigations will need to be undertaken of the possibility of leveraging new software features/functions and software testing from other jurisdictions.

438. Whilst it was recognised by the Department that a real-time system available to general practitioners is a vital initiative, significant investment is required. Whilst awaiting the ERRCD, which should have this capacity, the Department is of the view that improved telephone access system enquiry service, will allow doctors to get better and timelier access to clinical and regulatory advice in these matters.

RACGP Submissions

439. In relation to the ERRCD, in December 2014, RACGP released a discussion paper calling for the urgent implementation of the ERRCD system for prescription drug management. In March 2015, RACGP renewed calls for the immediate rollout of a real-time prescription drug database, given the alarming number of people dying from prescription drug overdoses. RACGP President, Dr Frank Jones Stated:

> "*Across Australia far too many people are dying from prescription drug overdoses and the real tragedy is that a large number of these deaths could be avoided if GPs had access to a national real-time prescription drug database.*
>
> *It is difficult for GPs to determine where prescription drug abuse is happening because GPs sometimes have limited access to a particular patient's medication history. Patients may visit a regular GP and then attend other doctors as a transient patient to obtain more prescription drugs, so called 'doctor-shopping'.*
>
> *The lack of adequate monitoring strategies is severely hindering a GPs ability to protect their patient's safety."*

440. During the inquest, Chair of the RACGP Queensland, Dr Edwin Kruys reiterated that RACGP continued to support the immediate implementation of a real-time

prescription monitoring system. He noted that the current monitoring system in Queensland is lacking, with a deficiency of useful feedback and information being provided to general practitioners as to what a patient has been prescribed. He cites the success of the Tasmanian real-time prescription monitoring system, which has '*stopped drug-seeking behaviour but has also increased awareness of GPs and prescribers around opioid prescribing and the risks and issues associated with it*'.

Previous Queensland Coronial Recommendations & Departmental Response

441. Previous Queensland coronial inquests have touched upon issues associated with the monitoring of controlled drugs in Queensland.

442. Most recently, the inquest into the death of Katie Howman in 2015, as convened by Coroner Christine Clements, considered the death of a nurse in Toowoomba as a result of an opioid overdose. During the course of the coronial investigation it became clear that Ms. Howman had engaged in extensive doctor-shopping behaviour in order to obtain opioids. Whilst it appears that this was first done to manage pain suffered as a result of a range of medical conditions, Ms. Howman soon became dependent. The fentanyl she injected, which ultimately caused her death, was thought to have been unlawfully appropriated through her work at the Critical Care Ward of the Toowoomba Base Hospital.

443. Coroner Clements subsequently made the following recommendation:

> **Recommendation 2**
> *It is strongly recommended that there be statutory change to enable real time access to relevant prescription and doctor attendance history. It is noted the New Zealand model forwards information of concern out to the treating doctor rather than relying on the doctor contacting the information service. No doubt there would be ways to accommodate privacy issues while still safeguarding patients from harm and the abuse of a publically funded resource. These matters should be urgently investigated and considered by the government.*

444. On 12 September 2016, the Minister for Health responded to Coroner Clement's recommendation as follows:

> *The Department of Health implemented the coroner's recommendation when it investigated and considered real-time reporting.*
>
> *The Department provides a prescription drug monitoring system, 24 hour/seven day a week telephone enquiry service for medical practitioners; however the information is not updated in real time.*
>
> *Queensland Health supports real-time reporting and has proposed to the Commonwealth Government that the Commonwealth lead a process to develop a fully costed nationwide project to allow uniform development of such a system*

across all states and territories. Appropriate changes to Health (Drugs & Poisons) Regulation 1996 will need to be made to enable real-time reporting as there is currently no timely reporting mechanism to meet the compliance requirements. In the meantime, Queensland Health is investigating the enhancement of the medical practitioner telephone enquiry service and increasing the frequency of dispensed prescriptions from community pharmacies.

Interstate Coronial Recommendations

445. To date, there have been in excess of 21 coronial inquests conducted interstate, which have considered issues associated with the misuse of Schedule 8 medications, and the shortfalls of monitoring measures currently available. Resoundingly, Coroner's have called for the introduction of a real-time prescription monitoring system.

446. A summary of some of the pertinent inquests and recommendations made are provided below.

Inquest into the death of James, Victorian Coroners Court (5181/09)

447. James was 24 years of age at the time of his death. He had a troubled life, suffering from depression, anxiety and insomnia. He subsequently developed an addiction to prescription medication, which he was unable to satisfy or overcome. He was found deceased by Police after his father requested that they conduct a welfare check. Many prescription medications, as well as a used syringe, were located in his residence.

448. James' addiction to prescription medication saw him engaging in extensive doctor-shopping behaviour. Medicare records disclose that in the three years prior to his death, James had attended 19 different doctors, who prescribed him medications through the PBS. The medications were then dispensed at 32 different pharmacies. Furthermore, there was evidence to suggest that James had obtained large quantities of medications that were not recorded on PBS. James' cause of death was found to be combined drug toxicity.

449. Coroner Olle noted that none of the 19 doctors or 32 pharmacists involved in James' care, had the benefit of real-time prescription monitoring. He was of the view that the circumstances of James' death highlighted the urgent need for a real-time system to be implemented.

450. Accordingly, Coroner Olle recommended the Victorian Department of Health implement a real-time prescription monitoring program within 12 months, in order to reduce deaths and harm associated with prescription shopping. It was recommended that the Victorian Government to convene a steering committee to oversee the implementation of the real-time prescription monitoring program

in Victoria. Also that the Victorian Government to develop a contingency plan to implement a Victorian-based real-time prescription monitoring program in the event that the anticipated ERRCD does not address a number of specific criteria, including a focus on public health rather than law enforcement, recording of all prescription medications and facilitating the ability of the Department of Health to monitor prescribing and dispensing to identify behaviours of concern.

451. In response to these recommendations, the Victorian Department of Health claimed that they were leading the national response to pharmaceutical drug misuse through the development of the National Pharmaceutical Drug Misuse Strategy, which focuses on the development of a national system of real-time medication histories to prescribers and dispensers, along with strategies to enhance good prescribing practices and to support the roles of pharmacists.

452. In relation to real-time prescription monitoring, the Department of Health expressed the view that for such a system to reach its full potential, it must be nationally implemented. The Department undertook to continue to engage with the Commonwealth government in relation to the development of the ERRCD. The Coroner's recommendation that all prescription medications should be included was not supported by the Department, as this would affect operational capacity requirements without equivalent public health benefits.

453. Dr Adrian Reynolds, the State-wide Clinical Director of the Tasmanian Department of Health and Human Services also responded to the recommendations and findings made by Coroner Olle in this inquest. He clarified a number of issues raised in relation to the DORA system developed, which was in use in Tasmania at the time of the inquest. Obviously, the ERRCD was yet to be developed and rolled out to the States.

454. Dr Reynolds expressed the view that he was hopeful all jurisdictions would agree to a nationwide real-time system rather than a nationwide system, in which each jurisdiction managed this data within its borders, which was not then made available to all other jurisdictions on a clinical basis, with appropriate safeguards. Dr Reynolds also highlighted issues associated with the shortage of Addiction Medicine specialists in Australia.

<u>Inquest into the death of Kirk Ardhern, Victorian Coroners Court, April 2014</u>

455. In the inquest into the death of Kirk Ardhern in the Victorian Coroners Court in April 2014, Coroner Jamieson made various recommendations and comments, including:

- Nearly two years after the Victorian Department of Health indicated that it was engaging with the Commonwealth on ERRCD initiative, Victoria is still without a real-time prescription monitoring system to assist in

addressing the harms and deaths associated with pharmaceutical drug misuse and inappropriate prescribing and dispensing of pharmaceutical drugs. He noted that there was no question that the present system lacked sufficient rigor. A comment made by Coroner Olle in a previous inquest noted that if the Victorian Government was relying on the Commonwealth Government to deliver a national real-time prescription monitoring system, it might be *'waiting for an extended period or even indefinitely while preventable harms and deaths from prescription shopping continue to occur'*. It was noted that had a real-time prescription monitoring system been in place, this would have allowed the medical practitioners involved in Mr. Ardhern's care and treatment to identify the medications he had been provided with from other general practitioners.

- Coroner Jamieson recommended that Victorian Department of Health: *"explore options for implementing a Victorian real-time prescription monitoring system to prevent ongoing harms and deaths associated with pharmaceutical drug misuse and inappropriate prescribing and dispensing of pharmaceutical drugs. As there is practically no discernible publicly available information regarding the status of the ERRCD initiative and Victorian progress towards implementing real-time prescription monitoring".*

- Coroner Jamieson recommended that within three months the Victorian Department of Health should create a page on its website regarding real-time prescription monitoring, the ERRCD system and other related topics. Transparent, continuous disclosure of progress would assist a broad range of stakeholders, including peak medical and pharmacy bodies, Coroners and Victorian public.

456. In response, the Victorian Department of Health commissioned a business case to explore the options and present recommendations to the Minister regarding the possible establishment of a real-time prescription monitoring system in Victoria.

457. In October 2017, the Victorian Parliament passed the *Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Bill 2017,* which established the use of a real-time prescription monitoring system state wide, to be known as SafeScript. SafeScript is designed to enable doctors, nurse practitioners and pharmacists to access a patient's prescription history by way of an up-to-the-minute database. It will also monitor all Schedule 8 medicines, as well as other high risk prescriptions, including all benzodiazepines.

458. An investment of $29.5 million has been made by the Victorian Government to implement real-time prescription monitoring in Victoria. Over the course of the next year, software for the SafeScript system will be built, with further public consultation to take place. The system is expected to be rolled out in a phased approach in late 2018. Once in place, it will be mandatory for all prescribers and

pharmacists to check the system before writing or dispensing a prescription for a high-risk medicine, with only limited exceptions.

Inquest into the deaths of Christopher Salib, Nathan Attard, Shamsad Akhtar, NSW Coroners Court, June 2014

459. In the case of Mr Sahib, Deputy State Coroner Forbes noted that:

> *Mr. Salib's case highlights the fragmentation of the care inherent in the medical system, as well as the urgent need for a real-time prescribing system. Furthermore, it also highlights the need for a general practitioner, who is seeing a new patient, to be able to speak to a treating doctor before prescribing addictive medication. The experts also identified that a further measure, which may have been of assistance in this case was the identification of a single clinician with overall responsibility for Mr. Salib's treatment and management, with ready identification of other clinicians, who also have a significant responsibility.*

460. Deputy State Coroner Forbes subsequently made a number of recommendations, which include:

- That the NSW Department of Health consider steps to be taken to implement a real-time web based prescription monitoring program availability to at least, pharmacists and general practitioners within 12 months, which records the dispensing of all Schedule 8 medications in NSW, provides real-time prescription information to all prescribers and dispensers throughout NSW, and facilities the NSW Department of Health to monitor the dispensing of these medications and to identify behaviours of concern, with an expected completion date of 36 months.

- NSW Department of Health consider including all benzodiazepines within the aforementioned program.

- NSW Department of Health consider what if any additional steps can be taken to educate pharmacists and general practitioners on the ability to report inappropriate prescribing to the Pharmaceutical Services Unit, Ministry of Health (NSW).

- Consideration should also be made as to imposing a requirement that a doctor should not commence prescribing a Schedule 8 drug or a benzodiazepine to a patient without making enquiries to verify the patient's prescribing history, or if not practicable, such support should be limited to that which is necessary until the prescribing history can be obtained;

- The Pharmacy Guild of Australia, the Pharmaceutical Society of Australia and the Royal Australian College of General Practitioners liaise with a view

to promoting the use pf staged supply and other means to reduce the risk of the misuse of prescription medication; the use of supervised administration of medication in a pharmacy; and developing education modules on lawful options available to respond to suspected misuse of prescription medications.

- That the Royal Australian College of General Practitioners (RACGP) develop a short clinical guideline for use by general practitioners, regarding the management of chronic non-cancer pain, prescription of benzodiazepines and opioids, the circumstances in which the use of private and repeat prescriptions may be appropriate as well as the available resources.

- That RACGP consider developing a clinical governance framework for General practices and general practitioners to address the rising problem of prescription drug abuse in Australia.

- That RACGP consider including various opioid prescribing and pain management related topics within their continuing professional development requirements for general practitioners.

Analysis of the Coronial Issues

The findings required by s. 45 of the Coroners Act 2003

461. In accordance with section 45 of the *Coroners Act 2003* ('the Act'), a Coroner who is investigating a suspected death must, if possible, make certain findings.

William House

462. Based on the evidence presented at the inquest, I find:

a. The identity of the deceased person is William House;

b. Mr. House died following a drug overdose at his residence in Southport;

c. The date of Mr. House's death was 28 August 2012;

d. The place of Mr. House's death was his residence at Meron Street, Southport; and

e. The cause of Mr. House's death was as a result of acute fentanyl toxicity in a man with epilepsy.

Jodie Anne Smith

463. Based on the evidence presented at the inquest, I find:

a. The identity of the deceased person is Jodie Anne Smith;

b. Ms. Smith died following a drug overdose at her residence in Upper Coomera;

c. The date of Ms Smith's death was 20 August 2012;

d. The place of Ms Smith's death was her residence in Upper Coomera; and

e. The cause of Ms. Smith's death was myocarditis and the ingestion of large quantities of medication to manage complex regional pain syndrome.

Vanessa Joan White

464. Based on the evidence presented at the inquest, I find:

a. The identity of the deceased person is Vanessa Joan White;

b. Ms. White died following a drug overdose at her residence in Labrador;

c. The date of Ms White's death was 19 December 2012;

d. The place of Ms White's death was her residence in Labrador; and

e. The cause of Ms White's death was multiple drug toxicity.

Daniel Keith Milne

465. Based on the evidence presented at the inquest, I find:

a. The identity of the deceased person is Daniel Keith Milne;

b. Mr Milne died following a drug overdose at his residence in Broadbeach;

c. The date of Mr. Milne's death was 12 February 2014;

d. The place of Mr. Milne's death was his shared residence in Broadbeach; and

e. The cause of Mr. Milne's death was acute fentanyl toxicity.

Consideration of Inquest Issues

466. The tragic circumstances of Mr. House, Ms. Smith, Ms. White and Mr. Milne's deaths highlight the broad systemic issues present in relation to the prescribing, dispensing and monitoring of Schedule 8 medicines in Queensland. The findings demonstrate the significant limitations of the current available monitoring system for the prescribing and dispensing of drugs of dependence. Coupled with the increasing issues of opioid dependence, doctor-shopping and inappropriate prescribing behaviour of some medical practitioners, these regulatory weaknesses have undoubtedly contributed to the marked increase in the number of deaths associated with the misuse and abuse of Schedule 8 medicines in Queensland.

467. Mr. House, Ms. Smith and Ms. White's cases exemplify the challenges faced by general practitioners in managing a patient with severe and genuine non-malignant chronic pain. It may seem reasonable to prescribe opiate pain relief to a patient with a chronic condition or who is suffering from severe pain, particularly if other treatment options are exhausted or ineffective. However, in patients that have coexisting addiction issues their drug dependence may be difficult to identify and manage. If patients like Mr. House, Ms. Smith or Ms. White present with a debilitating condition, requesting strong opiate pain relief may appear reasonable, rather than drug seeking behaviour. Assessments of high risk patients are further complicated by 'doctor shopping' and 'shared care arrangements', both of which involve multiple practitioners and specialists. These were certainly issues that were experienced by a number of the general practitioners involved in the care Mr. House, Ms. Smith and Ms. White.

468. Each of these deaths highlight the need for prescribers and dispensers to be alerted to potential misuse of Schedule 8 medicines by a patient in real-time, so that preventative and clinically meaningful measures can be taken to immediately reduce the risk to the patient and community. It is evident from the circumstances of each of these deaths, which was emphasized by Dr Gronow and Dr Buchanan, that the present regulatory monitoring in Queensland is, by virtue of the capabilities of the MODDS system and resourcing, retrospective rather than proactive, with follow up largely not provided in a timely manner, if at all. As such, patients are able to obtain excessive scripts from multiple practitioners before any meaningful intervention can take place, as largely occurred in each of the cases considered during the inquest.

469. There is a consensus view between the experts engaged for the purpose of this inquest, the general practitioners involved in the care of each of the deceased, and prominent external agencies, such as the AMA, RACGP and Pharmacy Guild of Australia, that there is an urgent need for the immediate introduction of a real-time prescription monitoring system in each State. This sentiment has also been expressed in numerous interstate coronial inquests. It is clear that a real-time system will improve regulatory compliance and public health outcomes in relation to the use of controlled drugs.

470. Whilst the Department acknowledges the need for such a system in Queensland, it seems that they view a national system, such as the ERRCD, as the preferable means by which this could be implemented. Whilst a nationally consistent real-time prescription monitoring system would unquestionably be preferable, further delays as to the implementation of the ERRCD, or another real-time system, in Queensland cannot continue. The timeframes provided by the Department as to implementation of the ERRCD, should it be deemed suitable, is five years. The number of deaths that will occur in the interim whilst implementation is taking place, or another system is developed, is alarming. Coronial statistics indicate an annual death toll from prescription opioids approaching 1500 people each year and increasing. It is recognised by peak medical bodies and experts that without a crucial clinical tool, like the ERRCD, avoidable deaths involving prescription opioid medicines will continue to occur at an alarming rate.

471. Given the growing epidemic associated with opioid misuse, the States and Territories need to take responsibility for addressing the increasing issues associated with the prescribing, dispensing and monitoring of drugs of dependence. This is certainly a commitment the Victorian and Western Australian Governments have made by way of the development and implementation of a State real-time prescription monitoring system based upon the ERRCD. Extensive funding has been allocated in each of these States to ensure such a program can be introduced as soon as possible.

472. The measures that have been put in place by MRQ in recent times, including the improvements to MODDS, the introduction of the *S8 Monitoring Strategy*, and the changes to the telephone enquiry service, whilst positive, are not sufficient to address the flaws in the present monitoring system, nor a suitable substitute for a real-time prescription monitoring system in Queensland. Such improvements still do not enable prescribers to be alerted to potential misuse in a timely fashion, so that preventative action can be taken, and the significant clinical consequences avoided.

473. The circumstances of these deaths also highlight the general fragmentation of information between different health care providers, regulators and other agencies under the current regulatory system. It is evident that real-time prescription monitoring will support more collaborative case management

amongst general practitioners, specialists and other agencies involved in a patient's care and ongoing pain management.

474. In addition to the absence of effective regulation and monitoring of these medications in Queensland, it seems that there is also a lack of effective independent and mandatory clinical education and support provided to general practitioners as to appropriate prescribing practices of Schedule 8 medicines. Clearly, comprehensive and independent clinical general practitioner education in Queensland will be a necessary component of any plan to effectively address the increasing opioid epidemic. A number of the doctors who treated Mr. House, Ms. Smith and Ms. White have expressly stated that they had not been provided with any specific education in relation to the prescribing of controlled drugs, particularly opioids. Effectively enhancing the general clinical competence of medical practitioners in the prescribing of Schedule 8 medication though independent and mandatory education programs, will undoubtedly assist in reducing the often inadvertent, and unfortunately widespread, inappropriate prescribing and dispensing practices of general practitioners.

475. Furthermore, increased awareness needs to be provided to healthcare professionals as to the regulatory environment in which Schedule 8 medicines are prescribed, including the role of MRQ, and the availability of resources and support for managing complex and difficult patients taking controlled drugs.

476. It has been the implementation of a real-time prescription monitoring system in Queensland, coupled with further clinical education, will assist doctors to identify and respond appropriately to 'red flags' that appear during the course of their assessment of a patient. This will undoubtedly facilitate more safe and meaningful intervention and treatment. The circumstances of Mr. House, Ms. Smith, Ms. White and Mr. Milne's death clearly highlights the significant risks associated with general practitioners making clinical decisions about the use of drugs of dependence without sufficient collateral information.

477. It is clear that the current regulatory system for the monitoring of the prescribing and dispensing of controlled drugs in Queensland is flawed, and does not adequately manage the risk posed to patients and the community. MODDS is not presently an effective support for either practitioners' clinical decision making, or the action of regulatory bodies, such as MRQ.

478. I repeat the recommendations of all the Coronial jurisdictions in Australia and all of the professional bodies representing stakeholders, that real-time prescription monitoring be introduced as a matter of urgency. It is no longer credible of governments to raise financial restraints as an excuse for not doing so. The savings to the PBS by drastically reducing the number of opioid prescriptions and to Medicare would go a long way towards offsetting the cost of implementation. The statistics show a prescription transaction volume of

approximately 2 million prescriptions per year, >150,000 per *month* which will continue to grow at a rate of <15 per cent.' It was acknowledged by the Department that it was envisaged that this rate would continue to grow. Also, the pharmaceutical industry has had in place real time prescription monitoring for some other drugs for years, so it is hardly ground breaking innovation.

479. It is apparent that integrating Hospital services with general practices and specialists is difficult, particularly as patients are free to attend upon any medical practitioner. The Viewer portal now in use will certainly assist to ensure that general practitioners have access to relevant clinical information from the Hospital.

480. Nonetheless, integration of any real-time prescription monitoring system to be put in place in Queensland would need to include the public and private hospital services. As was submitted by Dr Buchanan, any database that monitors the dispensing of opiate medication in real-time around Australia or in Queensland, and across the public-private divide, would provide an additional and essential resource in ensuring that the outcomes for applicable patients are optimised.

Recommendations in accordance with s. 46

481. Section 46 of the Act provides that a coroner may comment on anything connected with a death that relates to:

a. Public health and safety,

b. The administration of justice, or

c. Ways to prevent deaths from happening in similar circumstances in the future.

482. Having considered the evidence presented at this inquest, the recommendations made by Coroners in other jurisdictions, and the submissions made by various professional bodies, I make the following recommendations:

I. Queensland Department of Health

(a) In order to reduce the deaths and harm associated with opioid misuse, the Queensland Department of Health should urgently consider and determine how a real-time prescription monitoring system can be implemented in Queensland at the earliest opportunity, but certainly within the next two years. A determination as to whether the ERRCD is a suitable system to be utilised should be made without delay. If so, the plan to implement such a system,

and the necessary changes to legislation and other regulatory requirements, needs to be actioned urgently. A business plan to progress the implementation of a real-time prescription monitoring system in Queensland, either the ERRCD or a separate hybrid or new system, needs to be developed, and appropriately funded as a priority. A plan to transition to a real-time prescription monitoring system in Queensland should aim to be completed within two years, in line with other States. If such a scheme is adopted by some states but not all, this would lead to border-hopping and would have a catastrophic effect on the state or states concerned.

(b) The Queensland Department of Health should urgently consider what additional steps can be taken to educate general practitioners and pharmacists as to the scope and functions of MRQ, particularly the availability of advice as to appropriate prescribing practices. Incidences of over-prescribing of opioids, once this education campaign has been completed should be dealt with by professional disciplinary bodies, by regulation.

(c) The Queensland Department of Health to consider the suitability of resourcing currently provided to MRQ in order to appropriately perform their regulatory functions in a proactive manner, particularly given the timeframe changes as stipulated in the new *S8 Monitoring Strategy*.

II. The Commonwealth Department of Health

(a) That the Commonwealth Department of Health liaise urgently with all state governments to speed up the introduction nationally of the ERRCD; and

(b) That consideration be given to legislating the banning of the promotion of prescription opioids to health practitioners by drug manufacturers.

III. Other agencies

(a) The Royal Australian College of General Practitioners to urgently consider what further measures and programs can be introduced through their continuing professional development requirements for general practitioners, to improve education and standards of care in relation to the prescribing of Schedule 8 medicines, and chronic pain management.

(b) The Pharmacy Guild of Australia, the Pharmaceutical Society of Australia and the Royal Australian College of General Practitioners to liaise with a view to promoting the use of staged supply and other means to reduce the risk of the misuse of prescription medication.

Exercise discretion of the coroner to refer in accordance with s. 48(4)

483. Section 48 of the *Coroners Act 2003* gives a Coroner discretion to refer information about a person's professional conduct to the relevant professional disciplinary body if the Coroner reasonably believes the information might cause that body to inquire or take steps in relation to the conduct. Having regard to the definition of 'disciplinary body' under s48 (5) of the Act, the disciplinary body for a health practitioner is the relevant Board.

484. I make no referral pursuant to s. 48 of the *Coroners Act 2003.*

I close the inquest.

James McDougall
Coroner
Southport
21 May 2018