IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2010 003699

FINDING INTO DEATH WITH INQUEST

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

Inquest into the Death of: Phillip George BLACK

Delivered On:	20 February 2015
Delivered At:	Coroners Court of Victoria 65 Kavanagh Street Southbank Victoria 3006
Hearing Dates:	12 and 13 November 2012
Findings of:	Coroner Paresa Antoniadis SPANOS
Representation:	Mr M. STANTON of Counsel, instructed by Ms F. Riani of Galbally and O'Bryan Lawyers, appeared on behalf of Mr Black's family.
Police Coronial Support Unit	Leading Senior Constable T. CRISTIANO, assisting the Coroner

I, PARESA ANTONIADIS SPANOS, Coroner,

having investigated the death of PHILLIPP GEORGE BLACK

and having held an inquest in relation to this death at Melbourne

on 12 and 13 November 2012:

find that the identity of the deceased was PHILLIPP GEORGE BLACK

born on 14 April 1981, age 29

and that the death occurred on 25 September 2010

at 23 Lydia Avenue, Campbellfield, Victoria 3061

from:

I (a) COMBINED METHADONE, DIAZEPAM AND CLONAZEPAM TOXICITY IN A MAN COMMENCING A METHADONE MAINTENANCE PROGRAMME

in the following circumstances:

BACKGROUND AND PERSONAL CIRCUMSTANCES[1]

1. Phillipp George Black was a 29-year-old man from Jeparit, 70 kilometres north of Horsham, the middle child of Kevin and Heather Black. Mr Black's parents separated when he was about 15 years of age. Mr Black moved with his mother to Melbourne while his younger brother, Steven, remained with their father in Jeparit. By this time, his older sister, Nicole, was living independently.

2. The fragmentation of Mr Black's family was unsettling for him. In his sister's estimation, he *did not know where he fit in*, a situation exemplified, or perhaps compounded, by his frequent relocations between his parents' homes.[2]

3. Since his teenage years, intermittently, Mr Black had used illicit drugs and medications not prescribed to him. In his early twenties, Mr Black's drug use escalated, he joined a negative peer group and came to the attention of police.[3] As a result of criminal offending related to his drug use, he spent a significant period in prison. His family remained supportive

[1] This section is a summary of facts that were uncontentious, and provide a context for those circumstances that were contentious and will be discussed in some detail below.

[2] Exhibit C.

[3] Exhibit C.

throughout his incarceration, and observed Mr Black's determination to lead a productive and law-abiding life on his release from prison.[4]

4. By 2008, after his release from prison, Mr Black had obtained a forklift driver's licence and secured full-time employment,[5] first with Belkompt and later with the Australian Brushware Company [ABC].[6] His usual hours of work were weekdays between 6am and 2pm, with occasional overtime.[7] Mr Black helped his brother obtain work with the same employer.

5. In about October 2008, Mr Black disclosed to his family that he was using illicit drugs, particularly heroin. His sister commented that the signs of his drug use were *obvious* from his *mental state and actions*.[8] Mr Black's family were concerned about him and supportive when he told them that he wanted to address his drug dependence by commencing Methadone Maintenance Therapy [MMT].[9]

6. Mr Black's mother took him to Panch Health Service where he consulted Dr Parmjit Kaur.[10] Dr Kaur prescribed a starting methadone dose of 40mg per day to be dispensed at the Campbellfield Discount Drug Store[11] and Mr Black commenced MMT on 9 October 2008.[12]

7. Whilst on MMT, Mr Black lived with family in Melbourne and continued to work and contribute to household expenses.[13] He commenced a long-distance relationship with Ms Jennifer Cook, who he had met in Jeparit.[14] Mr Black reportedly told his sister that although methadone sometimes made him feel drowsy and produced other side effects, he was not craving or using illicit drugs.[15] He also told her that he did not want to remain on the MMT too long, in case he found it difficult to cease the program.[16]

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[4] Exhibit C.

[5] Exhibit C.

[6] Coronial Brief of Evidence (Statement of Steven Black).

[7] Coronial Brief of Evidence (Statement of Steven Black).

[8] Exhibit D.

[9] Exhibit C, Coronial Brief of Evidence page 172ff (Methadone Maintenance Therapy records 2008-9).

[10] Exhibit C.

[11] Coronial Brief of Evidence, page 186.

[12] Coronial Brief of Evidence, page 178.

[13] Exhibit C.

[14] Exhibits A and B.

[15] Exhibit C.

[16] Exhibit C.

8. Dr Kaur continued to manage Mr Black's MMT and reviewed his progress monthly.[17] By January 2009, he was titrated to a daily maintenance dose of 70mg of methadone.[18] In April 2009, in consultation with Dr Kaur, Mr Black started to gradually reduce his methadone maintenance dose, until he stabilised on a daily dose of 30mg in June 2009.[19] Mr Black's last dose of methadone was 28mg, dispensed on 8 July 2009.[20]

9. In October 2009, Mr Black secured his own rental accommodation, which he shared with his brother until August of the following year.[21] The brothers continued to work together at ABC, where Mr Black was reportedly particularly well regarded.[22] Mr Black and Ms Cook continued to visit one another when their schedules permitted and made plans to live together.[23]

10. According to his brother Steven Black, and corroborated to some degree by Ms Cook, in about March 2010, Mr Black started to use heroin and the amphetamines 'speed' and 'ice' *occasionally*.[24] Mr Black's family and Ms Cook all expressed their impression that Mr Black was open and honest with them about the extent of his illicit drug use.[25] In Steven Black's estimation, his brother's drug use was *nowhere near the same level* as it had been in 2008.[26]

11. In April 2010, following a period of lethargy and excessive consumption of sugary drinks,[27] Mr Black was hospitalised in Horsham and diagnosed with Type 1 diabetes and Hepatitis C,[28] the latter attributed to his history of intravenous drug use. It appears that Mr Black did not require/receive any treatment in relation to Hepatitis C. However, management of his diabetes required subcutaneous insulin injections four times a day and review by endocrinologist, Dr

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[17] Coronial Brief of Evidence pages 55-72 (Medical Records maintained by Dr Kaur).

[18] Coronial Brief of Evidence pages 178-185 (Methadone Dispensing Records maintained by Campbellfield Discount Drug Store).

[19] Coronial Brief of Evidence pages 55-72 and 178-185.

[20] Coronial Brief of Evidence page 173 and 185.

[21] Coronial Brief of Evidence (Statement of Steven Black) and Exhibit C.

[22] Ibid.

[23] Exhibits B and C.

[24] Coronial Brief of Evidence (Statement of Steven Black), Exhibit B and Transcript pages 5-6.

[25] Coronial Brief of Evidence (Statement of Steven Black), Exhibits B, C and D.

[26] Coronial Brief of Evidence (Statement of Steven Black).

[27] Exhibit B and C.

[28] Coronial Brief of Evidence page 82 (Medical Records maintained by Dr Wimbury of Lister House Clinic).

Yeo.[29] On review in September 2010, Dr Yeo noted that Mr Black was managing his diabetes well but that he had reported some mild hypoglycaemic episodes in the early morning and following exertion at work in the afternoon.[30] Dr Yeo also noted Mr Black's expressed intention to address his illicit drug use by re-commencing MMT.[31]

12. In about mid-August 2010, Ms Cook and her daughter moved in with Mr Black at his home in Campbellfield. On Ms Cook's observation, Mr Black use half a gram of heroin or speed about twice a week.[32]

13. In September 2010, Mr Black disclosed to Ms Cook and his family that he intended to recommence MMT. Mr Black's family were shocked by his announcement.[33] Steven Black reportedly told his brother that he did not believe MMT was warranted given his *level of use* and that he could abstain by using will power. Mr Black apparently explained that he doubted he had the strength of mind to abstain without MMT and was concerned that his drug use *may escalate out of control.*[34]

14. On 23 September 2010, Ms Cook went with Mr Black to Flemington Medical Centre where Mr Black consulted the sole general practitioner, Dr Noah Diner, while Ms Cook remained outside.[35] Dr Diner prescribed a starting methadone dose of 40mg per day to be dispensed at the Campbellfield Discount Drug Store.[36] Later that day, Mr Black's first daily dose of methadone was dispensed and consumed under the pharmacist's supervision at 3.30pm.[37] Ms Cook noticed that Mr Black appeared drowsy after taking methadone.[38]

15. The following day, 24 September 2010, Mr Black went to work where his brother formed the impression that he was *stoned.*[39] Mr Black appeared drowsy, *on occasions falling asleep*

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[29] Coronial Brief of Evidence pages 136-163 (Medical Records maintained by Dr Kabat of Epping Healthcare).

[30] Coronial Brief of Evidence page 147 (Dr Yeo's letter reporting to Dr Kabat).

[31] Coronial Brief of Evidence page 147 (Dr Yeo's letter reporting to Dr Kabat).

[32] Exhibit B and Transcript pages 5-6.

[33] Exhibit C.

[34] Coronial Brief of Evidence (Statement of Steven Black) and Exhibit D.

[35] Exhibit B.

[36] Coronial Brief of Evidence, page 167 and 170.

[37] Coronial Brief of Evidence, page 170.

[38] Exhibit A.

[39] Coronial Brief of Evidence (Statement of Steven Black).

while seated on the forklift while loading, and his speech was slurred.[40] Mr Black's condition reportedly worsened over the course of the day.[41]

16. After work, Mr Black went home and told Ms Cook that he continued to feel the effects of the previous day's methadone dose.[42] Nonetheless, Mr Black presented to the pharmacy for his second methadone dose with his partner. The second dose of methadone was dispensed and consumed under the pharmacist's supervision at 2pm on 24 September 2010.[43]

17. After doing some errands together, Mr Black and Ms Cook returned home. From about 7.30pm they watched television from a mattress in the lounge room. Within two hours, Mr Black was asleep. Some time later Ms Cook also fell asleep. At about midnight on 25 September 2010, Ms Cook woke up, turned off the television and had a brief conversation with Mr Black. Both were awake again at about 3am when Mr Black complained of feeling cold. Ms Cook snuggled up to him and they both went back to sleep.[44]

18. A little before 7am on 25 September 2010, Ms Cook woke up and found Mr Black unresponsive. She telephoned emergency services and commenced cardio-pulmonary resuscitation.[45] A short time later, ambulance paramedics arrived and confirmed that Mr Black was deceased. The police were also called to the house and commenced the coronial investigation of Mr Black's death.

19. On 29 September 2010, Forensic Pathologist Dr Linda Iles, from the Victorian Institute of Forensic Medicine [VIFM], performed a post-mortem examination or autopsy on Mr Black's body. Dr Iles also reviewed the circumstances of death as reported by the police to the coroner and post-mortem CT scanning of the whole body and provided a written report of her findings. Although Dr Iles found evidence of early acute bronchitis and bronchopneumonia at autopsy, she noted that none of her anatomical findings accounted for Mr Black's death.[46]

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[40] Coronial Brief of Evidence (Statement of Steven Black).

[41] Coronial Brief of Evidence (Statement of Steven Black).

[42] Exhibit A.

[43] Coronial Brief of Evidence, page 170.

[44] Exhibit A.

[45] Exhibit A.

[46] Exhibit G.

20. Although there was no toxicological evidence of excessive insulin, Dr Iles noted that hypoglycaemia can rarely be excluded at post mortem as a cause or contributor to the death of a person with diabetes.[47]

21. Routine post-mortem toxicological analysis detected 0.2mg/L of methadone (and its metabolite at 0.02mg/L), 0.1mg/L of the benzodiazepine diazepam, and 0.02mg/L of 7-aminoclonazepam (metabolite of the benzodiazepine clonazepam).[48] Dr Iles noted that each of these drugs are central nervous system depressants.[49] She observed that notwithstanding that individual tolerance to methadone varies markedly, it is well established that those commencing MMT are particularly vulnerable to the central nervous system sedating effects of the drug.[50] And, while the benzodiazepine concentrations detected were *relatively low*, it was impossible to exclude the possibility that these drugs also contributed to Mr Black's death.[51] Dr Iles' findings suggested that Mr Black's death was as a result of central nervous system mediated depression of respiratory function.[52]

22. Accordingly, Dr Iles advised that it would be reasonable to attribute Mr Black's death to combined methadone, diazepam and clonazepam toxicity in a man commencing a methadone maintenance programme.[53]

INVESTIGATION – SOURCES OF EVIDENCE

23. This finding is based on the totality of the material the product of the coronial investigation of Mr Black's death. That is the brief of evidence compiled by Constable Julie Hose of Broadmeadows Police and Leading Senior Constable Tania Cristiano of the Police Coronial Support Unit, the statements, reports and testimony of those witnesses who testified at inquest and any documents tendered through them, and the final submissions of Counsel. All of this material, together with the inquest transcript, will remain on the coronial file.[54] In writing this

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[47] Exhibit G and Transcript pages 62-3.

[48] Exhibit G.

[49] Exhibit G and Transcript pages 60-61, 64 and 66.

[50] Exhibit G.

[51] Exhibit G and Transcript pages 60-61 and 64-67.

[52] Exhibit G and Transcript pages 60-61, 64 and 66.

[53] Exhibit G.

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

finding, I do not purport to summarise all the material and evidence, but will refer to it only in such detail as is warranted by its forensic significance and in the interests of narrative clarity.

PURPOSE OF A CORONIAL INVESTIGATION

24. The purpose of a coronial investigation of a *reportable death* is to ascertain, if possible, the identity of the deceased person, the cause of death and the circumstances in which death occurred.[55] The *cause* of death refers to the *medical* cause of death, incorporating where possible the *mode* or *mechanism* of death. For coronial purposes, the *circumstances* in which death occurred refers to the context or background and surrounding circumstances, but is confined to those circumstances sufficiently proximate and causally relevant to the death, and not merely all circumstances which might form part of a narrative culminating in death.[56]

25. The broader purpose of any coronial investigations is to contribute to the reduction of the number of preventable deaths through the findings of the investigation and the making of recommendations by coroners, generally referred to as the *prevention* role.[57] Coroners are also empowered to report to the Attorney-General in relation to a death; to comment on any matter connected with the death they have investigated, including matters of public health or safety and the administration of justice; and to make recommendations to any Minister or public statutory authority on any matter connected with the death, including public health or safety or the administration of justice.[58] These are effectively the vehicles by which the prevention role may be advanced.[59]

26. It is important to stress that coroners are not empowered to determine the civil or criminal liability arising from the investigation of a reportable death, and are specifically prohibited from including in a finding or comment any statement that a person is, or maybe, guilty of an

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[55] Section 67(1) of the *Coroners Act 2008*. All references which follow are to the provisions of this Act, unless otherwise stipulated.

[56] This is the effect of the authorities – see for example *Harmsworth* v *The State Coroner* [1989] VR 989; *Clancy* v *West* (Unreported 17/08/1994, Supreme Court of Victoria, Harper J.)

[57] The 'prevention' role is now explicitly articulated in the Preamble and purposes of the Act, cf: the *Coroners Act 1985* where this role was generally accepted as 'implicit'.

[58] See sections 72(1), 67(3) and 72(2) regarding reports, comments and recommendations respectively.

[59] See also sections 73(1) and 72(5) which requires publication of coronial findings, comments and recommendations and responses respectively; section 72(3) and (4) which oblige the recipient of a coronial recommendation to respond within three months, specifying a statement of action which has or will be taken in relation to the recommendation.

offence.[60] However, a coroner may include a statement relating to a notification to the Director of Public Prosecutions if the coroner believes an indictable offence may have been committed in connection with the death.[61]

FINDINGS AS TO UNCONTENTIOUS MATTERS

27. In relation to Mr Black's death, most of the matters I am required to ascertain, if possible, were uncontentious from the outset. His identity and the date and place of death were not at issue. I find, as a matter of formality, that Phillipp George Black born on 14 April 1981, aged 29, died at 23 Lydia Avenue, Campbellfield, Victoria 3061, on 25 September 2010.

28. Relying on Dr Iles' findings at autopsy and advice, I find that Mr Black died as a result of combined methadone, diazepam and clonazepam toxicity in a man commencing a methadone maintenance programme.

FOCUS OF THE CORONIAL INVESTIGATION AND INQUEST

29. In common with many other coronial investigations, the primary focus of the coronial investigation and inquest into Mr Black's death was on the circumstances in which he died. Specifically, the adequacy of the clinical management and care provided by general practitioner, Dr Noah Diner, to Mr Black in relation to opioid dependence treatment. Although Mr Black presented to Dr Diner only once – on 23 September 2010 – it is convenient to consider the three distinct phases of that consultation separately, namely:
    a. The clinical assessment for treatment with methadone;
    b. Setting Mr Black's initial methadone dose; and
    c. Arrangements for clinical review.

30. It is also necessary to provide the context for the consultation on 23 September 2010 and Mr Black's commencement on methadone, by outlining the regulatory context in which methadone and other opioid dependence treatments are prescribed, and the rationale for that regulatory framework as elucidated by those expert witnesses heard at inquest.

[60] Section 69(1).

[61] Sections 69 (2) and 49(1).

METHADONE & THE REGULATORY FRAMEWORK OF OPIOID DEPENDENCE TREATMENT

31. Methadone is a synthetic opioid with a long-acting analgesic effect and a relatively gradual onset of analgesia compared with other opioids.[62] In Victoria, methadone is regulated[63] under the *Drugs Poisons and Controlled Substances Act* 1981 and can only be legally obtained by prescription from health professionals having a permit to prescribe it. Health professionals must, in turn, complete mandatory training in pharmacotherapy and drug addiction provided by the Victorian Department of Health, in order to obtain a permit to prescribe methadone for opioid replacement therapy.[64] The Therapeutic Goods Administration authorises methadone for two purposes - as an opioid substitute to treat opioid (particularly heroin) dependence[65] and as an analgesic for treatment of chronic, severe non-opioid analgesic resistant pain.

32. On receiving a permit to prescribe methadone, a health professional prescribing methadone for pharmacotherapy must also complete an Application to Treat an Opioid Dependent Person with Methadone or Bruprenorphine[66] for each patient and must submit it to Drugs and Poisons Regulation [DPR][67] of the Department of Health for approval before treatment can commence. An approval to prescribe methadone to a particular opioid dependent patient is returned to the health practitioner with advice that s/he treat the patient in accordance with DPR policies and national clinical guidelines.[68]

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[62] Like all opioid analgesics, methadone can be addictive.

[63] Methadone is a Schedule 8 controlled drug under the *Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons* meaning that its manufacture, supply, distribution, possession and use is regulated to reduce its abuse, misuse and the risks that individuals who use it develop a physical or psychological dependence on it.

[64] There are limited exceptions, such as doctors treating patients in hospital, oncology, palliative care or pain clinic patients.

[65] The use of methadone as an opioid substitution therapy includes both detoxification from opioid dependence and maintenance treatment to prevent relapse; it is generally referred to as 'opioid pharmacotherapy'. Doctors are require by the Drugs Poisons and Controlled Substances Act to 'take all reasonable steps' to ensure a therapeutic need exists before prescribing scheduled drugs.

[66] Buprenorphine is an opioid, a semi-synthetic derivative of thebaine. It is a mixed agonist–antagonist opioid receptor modulator that is used to treat opioid addiction in higher dosages, to control moderate acute pain in non-opioid-tolerant individuals in lower dosages and to control moderate chronic pain in even smaller doses. Buprenorphine has the advantage of being a partial agonist; hence negating the potential for life-threatening respiratory depression in cases of abuse.

[67] At the time of Mr Black's death, the DPR was known as the Drugs and Poisons Regulation Group.

[68] Exhibits I and F.

33. The Victorian Policy for Maintenance Pharmacotherapy for Opioid Dependence [the Policy] was formulated by the DPR in consultation with the Drugs of Dependence Advisory Committee. The version of the Policy applicable at the time of Mr Black's death was that published in 2006. The Policy is not intended as a comprehensive clinical guide and, its authors state, that it should be read in conjunction with the National Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence [the Guidelines]. The Guidelines, last updated in 2003, are based on national and international research literature, previously published guidelines and clinical experience with the use of methadone in Australia following rigorous review.[69]

34. At inquest, I had the benefit of hearing evidence from the Chief Officer of Drugs and Poisons Regulation, Matthew McCrone. He stated that the requisite pharmacotherapy training was delivered to health practitioners by a clinical body and focussed on the national clinical guidelines, basic pharmacology of the drugs involved and *the sort of things prescribers need to be aware of in prescribing safely.*[70] Of interest, prescribers are not required to participate in 'refresher' or on-going training in pharmacotherapy after their initial mandatory training.[71]

35. Mr McCrone clarified that although permits to treat are expressed as being conditional upon adherence to the Policy and the Guidelines, adherence to the Policy and Guidelines is not *a rule*[72] and that the Department of Health does not have an *enforcemen*t role[73] or a role in specifically monitoring that pharmacotherapy prescribers comply with the Policy and the Guidelines.[74] Mr McCrone, and the other experts appearing at the inquest, acknowledged the role that a prescriber's clinical judgement necessarily played in her/his management of patients.[75] Nonetheless, Mr McCrone stated that he expected prescribers to follow the Policy and the Guidelines, and that any departure from these be made with caution and on a sound

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[69] The Guidelines have been endorsed by the Australian Professional Society on Alcohol and other Drugs and the Royal Australasian College of General Practitioners.

[70] Transcript page 132.

[71] Transcript page 133. However, Mr McCrone noted that medical practitioners are required to undertake 'continuing professional development' in order to maintain their registration.

[72] Transcript page 134.

[73] Transcript page 133.

[74] Transcript page 133. Usually, it seems, that the DPR only 'communicates' with practitioners (through standard forms) when the prescriber applies for a permit to treat an opioid dependent patient.

[75] Transcript pages 133-134 (Mr McCrone), Transcript page 148 (Professor Drummer) and Transcript page 120 & 122 (Dr Frei). Mr McCrone specifically stated that dosing was a "clinical matter" (page 137).

clinical basis.[76] Experts Dr Matthew Frei, Clinical Director of Turning Point Alcohol and Drug Centre, and Forensic Pharmacologist and Toxicologist, Professor Olaf Drummer of VIFM who gave evidence at inquest, also expressed this view.[77]

36. The rationale for regulatory framework in which methadone is prescribed, and the expectation that the Policy and Guidelines will be observed, arises from methadone's pharmacokinetic properties. Methadone users face a particular risk of toxicity and death due to:

    a. the relatively slow onset of analgesia (30 minutes after administration),

    b. the peak plasma concentration being reached between one and five hours after administration,

    c. the duration of methadone's analgesic effect (four to eight hours), and

    d. its long and unpredictable elimination half-life in the body (between 15 and 150 hours).[78]

Thus, in the first three to four days of ongoing dosing, even while taking therapeutic doses as prescribed, patients are at particular risk of toxicity and death. Additionally, as methadone is slow-acting, it may reach toxic levels some hours after administration without any prior warning or other indication. The margin between a therapeutic and a toxic dose of methadone can be very narrow in an individual patient, and impossible to predict with any certainty.[79]

THE GUIDELINES

37. The Guidelines contain information intended to ensure that health practitioners prescribe MMT appropriately and safely. Section 2 of the Guidelines, entitled "Entry into Methadone Treatment", contains advice about establishing a clinical basis for MMT – a diagnosis of

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[76] Transcript 134.

[77] Transcript pages123 and 148.

[78] The difference between the period of analgesic effect and the elimination half-life of methadone is a potential cause of methadone toxicity. For example, if a patient is self-medicating for analgesic effect at a rate faster than methadone is cleared from the body, methadone can accumulate to toxic levels. The unpredictability of methadone's half-life in the body can also lead to accumulation to toxic levels.

[79]For example, as quoted in the toxicologist's report, *"Recommended doses that can be tolerated depend on the degree of tolerance and the duration of use...Blood concentrations of methadone in patients receiving daily doses of methadone overlap considerably the blood concentrations in deceased apparently dying form methadone toxicity."* Coronial brief of evidence pages 44-45.

opioid dependence – by eliciting information about the extent of drug use, drug tolerance, withdrawal symptoms and other indicia of drug dependence from the patient so that the practitioner can determine the patient's level of neuroadaptation to opioids.[80]

38. Section 2.2 of the Guidelines advises practitioners assessing a patient's suitability for MMT to conduct and document a *comprehensive* assessment of her/his drug use, medical, psychological and social conditions, previous treatment history and current treatment goals.[81] The importance of obtaining corroborative evidence of medical history and, especially, drug use and evidence of drug dependence, through physical examination and urinalysis, is emphasised as a means of enhancing the accuracy of clinical assessments.[82]

39. Section 3 of the Guidelines provides information about initial and maintenance methadone dosing. The first methadone dose *should be determined...based on the severity of dependence and level of tolerance to opioids.*[83] Clinicians are warned that even a comprehensive examination will provide (only) an *indication* of the patient's level of opioid tolerance, not *predict it with certainty.*[84] A period of observation of a patient at a time when s/he is experiencing withdrawal symptoms may resolve uncertainty about a safe starting dose.[85]

40. The overriding message contained in this section of the Guidelines is one of caution. The Guidelines warn clinicians against relying on *history alone* and encourage them to minimise uncertainty about opioid tolerance to the extent possible by *making every effort to communicate with* other practitioners who have treated the patient in relation to addiction and general health issues.[86] Clinicians are also encouraged to consider when and where dosing will occur, when the patient last used opioids and the concomitant use of alcohol or benzodiazepines when setting the initial dose.[87] Clinicians are advised to dose new patients with caution and if possible, to observe all patients three or four hours after their initial

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[80] Neuroadaptation refers to the process whereby the body compensates for the presence of a chemical in the body so that it can continue to function normally.

[81] Coronial Brief of Evidence, page 272 (the Gnidelines).

[82] Coronial Brief of Evidence, page 272 (the Guidelines).

[83] Coronial Brief of Evidence page 278 (the Guidelines).

[84] Coronial Brief of Evidence page 278 (the Guidelines).

[85] Coronial Brief of Evidence page 278 (the Guidelines).

[86] Coronial Brief of Evidence page 278 (the Guidelines).

[87] Coronial Brief of Evidence page 278 (the Guidelines).

methadone dose.[88] The reason for this cautious approach is explicitly stated in the Guidelines as being that fact that deaths in the first two weeks of MMT have been associated with doses as low as 20mg per day, with most deaths occurring at doses of 40 to 60mg per day.[89]

41. In addition to comments about review/observation within hours of the initial methadone dose, the Guidelines advise that patients be observed by the dispensing pharmacist prior to each daily dose and reviewed by an experienced clinician or the prescriber at least once, but preferably twice, in the first week of treatment to assess their intoxication from methadone. The Guidelines state that the patient, and their friends/family, should be warned about the signs and symptoms of methadone overdose.[90] Regular reviews of the patient by the prescriber should continue throughout MMT, including the use of urinalysis, but may be less frequent once the patient has stabilised and has demonstrated compliance with MMT.[91]

42. Throughout Sections 2 and 3 of the Guidelines, in particular, are checklists[92] and text boxes exhorting practitioners to *EXERCISE CAUTION* with patients, especially those who are *at high risk of polydrug use [or have a] history of reduction in opioid tolerance [or] concomitant medical problems"*[93] or when prescribing a starting dose of methadone of *30mg or more.*[94]

CLINICAL ASSESSMENT FOR TREATMENT WITH METHADONE

43. Dr Diner is a sole practitioner and, as at the time of the inquest, had worked in general medical practice for 20 years.[95] Dr Diner stated that he received his mandatory training in pharmacotherapy 20 years earlier and had been prescribing methadone to opiate dependent

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[88] Coronial Brief of Evidence page 278 (the Guidelines).

[89] Emphasis added. Coronial Brief of Evidence page 278 (the Guidelines).

[90] Coronial Brief of Evidence page 290 (the Guidelines).

[91] Coronial Brief of Evidence page 278 (the Guidelines).

[92] See for instance, the checklist guide for clinical interview "Key Features of the Assessment" at page 9 of the Guidelines on page 273 of the Coronial Brief of Evidence.

[93] Coronial Brief of Evidence pages 258-317 (the Guidelines). I have omitted reference to other "high risk' categories of patients identified in the Guidelines – persons dependent upon alcohol and those with psychiatric illness – as these are not applicable to Mr Black's circumstances.

[94] Coronial Brief of Evidence page 278 (the Guidelines).

[95] Dr Diner's practice does not use an appointment system and is open on weekdays between 9am and 12pm and 2-5pm and on Saturday mornings from 9-11.30pm; see Transcript pages 19-20 and 71.

patients since then.[96] He had not undertaken any additional addiction-related training in the interim but received clinical magazines, circulars and attended medical conferences periodically, to remain abreast of developments in general practice.[97] Dr Diner conceded that he had not read the Guidelines in *a while*[98].

44. Unsurprisingly, when he gave evidence at inquest, Dr Diner had no independent recollection of his consultation with Mr Black some two years earlier.[99] His evidence was limited to the information contained in contemporaneous patient notes[100], a statement prepared with reference to those notes in February 2011[101], and generalisations about what he would ordinarily discuss[102] with prospective MMT patients. Dr Diner conceded that he did not write everything down during consultations when he was *busy*[103] or being *lazy*.[104]

45. Dr Diner agreed that the clinical assessment of a patient seeking entry to MMT should be comprehensive.[105] He estimated that his first and only consultation with Mr Black lasted for about 20 minutes.[106] Dr Diner noted that Mr Black reported a 10-year history of intravenous heroin use, had ceased MMT 12 months earlier, was injecting half a gram of heroin per day in addition to injecting 'ice' and 'speed'[107] and wanted to resume MMT.[108] Mr Black disclosed that he was taking insulin for diabetes, had been diagnosed with Hepatitis C and that he drank alcohol, and smoked tobacco, socially.[109] During his physical examination, Dr Diner observed injection sites in the crook of Mr Black's left arm.[110]

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[96] Transcript pages 19-20.

[97] Transcript page 20.

[98] Transcript page 47.

[99] Transcript page 23.

[100] Exhibit F.

[101] Exhibit E.

[102] Transcript page 39.

[103] Transcript page 36.

[104] Transcript page 39.

[105] Transcript page 72.

[106] Transcript page 99.

[107] Exhibit E.

[108] Exhibit F.

[109] Exhibits E and F.

[110] Exhibits E and F.

46. Dr Diner observed, as did Dr Frei, that it was *not uncommon for patients to embellish their drug use,*[111] in order to obtain a high initial dose of methadone and thereby minimise the symptoms of heroin withdrawal.[112] However, while Dr Frei emphasised the limitations inherent in clinicians relying on self-reported drug use and how these could be minimised[113], Dr Diner testified that he had to take at face value whatever Mr Black told him about his drug use.[114] Dr Diner conceded that the injection sites he observed on Mr Black's arm were the only corroboration of any aspect of Mr Black's account of intravenous drug use.[115]

47. The tenor of Dr Frei's evidence was the importance of information gathering with a view to ensuring that the clinician has a reliable basis on which to exercise clinical judgement about a patient's need for MMT, his/her tolerance to opioids (or neuroadaptation) and methadone dosing and review.[116] In contrast, Dr Diner expressed the view that he did not think anyone can assess a patient's neuroadaptation, *that there are no tests you can do in a consulting room that [are] going to suddenly tell you how somebody's neuroadapted.*[117]

48. Although Mr Black had disclosed *poly*substance use, Dr Diner did not document the reported frequency of Mr Black's amphetamine use, nor is there any evidence that he asked about the use of drugs other than those nominated by Mr Black. Dr Diner explained these gaps in the history he obtained by stating that amphetamine/stimulant use was not relevant to his MMT assessment as they are not opioids/significant respiratory depressants,[118] and that it was clear to him that Mr Black attended his clinic to address his opioid addiction.[119]

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[111] Transcript page 30.

[112] During my investigation, and at inquest, there was conflicting evidence about Mr Black's reported heroin use and what he hoped to achieve by seeking medical help. Mr Black appears to have given Dr Diner one account and his family and partner, another. This, of itself, is not surprising. However, I note that Dr Diner did not document any discussion with Mr Black about his treatment goals, merely that he *"want[ed] to go back on the [methadone] program"* (Exhibit F) and his evidence that he usually respected a patient's wishes about his/her choice of drug to treat opioid dependence (Transcript page 25). Had a discussion about treatment goals occurred, and had Mr Black disclosed that he wanted medical intervention to block the effects of opioids and so prevent his heroin use escalating out of control as his family believed, Dr Diner's evidence suggests that another therapeutic course would have been more appropriate, that is buprenorphine (Transcript pages 53-54 and 52).

[113] Transcript page 109 and 114.

[114] Transcript page 30.

[115] Transcript page 81.

[116] See generally Exhibit H and Transcript pages 105-131.

[117] Transcript page 81. Professor Drummer made a similar observation , see Transcript page 148.

[118] Transcript page 77.

[119] Exhibits E and F.

49. In contrast, Dr Frei observed that a patient's disclosure of poly-substance use should suggest a number of things to a clinician, in particular, the need for further inquiry.[120] For example, Dr Frei stated that intravenous use of more than one substance could suggest that injection sites observed on physical examination may not relate to recent heroin use. Similarly, he stated that it is generally known by clinicians that there is a high incidence of benzodiazepine use amongst both heroin and amphetamine users (the latter using benzodiazepines sedating effects to counteract the stimulant effects of amphetamines), and that the concurrent use of benzodiazepines and methadone increases a MMT patient's risks of adverse outcomes.[121]

50. Dr Diner did not attempt to confirm which drugs, if any, Mr Black used or had used recently, through urinalysis. He explained that urinalysis only demonstrated the presence or absence of drugs, not the recency, frequency or quantity of a patient's drug use.[122] Moreover, to await urinalysis results before commencing MMT was likely to deter patients from commencing the program.[123] In his view, it was important to minimise the harms to which heroin users were exposed when using heroin by *striking while the fire is hot*"[124] and commencing MMT when patients are motivated to cease illicit drug use.

51. Dr Frei conceded that urinalysis screening prior to MMT commencement was not a common practice among clinicians. He also acknowledged that there was a risk that opioid dependent patients would *drop out* if faced with delays to commencing MMT.[125] However, Dr Frei noted that the lack of urinalysis results was a *barrier*[126] to clinicians having *full knowledge* of[127] a patient's drug use and so caution, particularly when setting the initial methadone dose, was warranted.[128]

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[120] Transcript page 126.

[121] Transcript page 126 and the Guidelines.

[122] Transcript page 31. Dr Diner conceded that the use of benzodiazepines can place a MMT patient at additional risk of adverse effects (Transcript page 82). He did not know that Mr Black used benzodiazepines (Transcript page 84). Dr Diner was not aware that the Guidelines suggested clinicians obtain specialist advice about MMT if they patient used poly-substances (especially where benzos were involved).

[123] Transcript page 54.

[124] Transcript page 32.

[125] Transcript page 106.

[126] Transcript page 106.

[127] Transcript page 106.

[128] Transcript page 125.

52. Dr Diner did not attempt to inquire of Mr Black's treating physicians (or by blood test) whether his diabetes was well managed, and whether this condition or Hepatitis C had compromised his liver function before initiating MMT. Dr Diner acknowledged that diabetes and Hepatitis C are chronic conditions that can affect liver function and are therefore relevant considerations given that methadone is metabolised in the liver.[129] He stated that he *would have considered*[130] these conditions, but had placed greater emphasis on Mr Black's account of his drug use.[131] Dr Frei acknowledged that Mr Black's chronic conditions would not necessarily preclude him from MMT but were another reason for the clinician to exercise caution, and conduct regular reviews.[132] Dr Diner had not been aware that the Guidelines recommended contacting a patient's other doctors to obtain corroboration of significant aspects of their medical history.[133] Dr Diner said that it was *impractical*[134] to contact other practitioners because patients rarely recalled their names[135] and he was *too busy*.[136]

53. Dr Diner did not attempt to confirm, or otherwise inquire about Mr Black's reported MMT treatment with the previous prescriber.[137] Dr Frei indicated that it would have been *preferable* to do so even though the previous prescriber's notes would have limited utility given the passage of time between Mr Black's MMT episodes.[138] Dr Diner conceded that it would have been easy for him to obtain the previous prescriber's name, even if Mr Black was unable to provide it, by telephoning the Department of Health.[139]

54. Dr Diner stated that he does not ordinarily ask patients whether they are accompanied to consultations.[140] He did not know that Ms Cook was in the waiting room during his

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[129] Transcript page 55.
[130] Transcript page 68.
[131] Transcript pages 55 and 68.
[132] Transcript page 125.
[133] Transcript page 78.
[134] Transcript page 78.
[135] Transcript page 39.
[136] Transcript page 79.
[137] Transcript page 75.
[138] Transcript page 108.
[139] Transcript page 80.
[140] Transcript page 46.

consultation with Mr Black.[141] Dr Diner conceded that Ms Cook may have been able to provide information about the extent of Mr Black's drug use and that he could have communicated methadone's potential adverse effects to her as a precaution.[142] Dr Diner stated that he was not aware that the Guidelines suggested that, where possible, prescribers warn a patient's family or friends about the possible side effects of MMT.[143] He indicated that generally, if the patient had previously received MMT, he would not bother to highlight what to expect, and the effects of methadone.[144]

55. Mr Black did sign a "Methadone/Bruprenorphine Programme Contract and Consent Form", countersigned by Dr Diner, that outlined the goals and conditions of the program, including regular urinalysis, and warned of drowsiness and the risks of increased methadone intoxication, toxicity, respiratory failure and death, if opioids, sedatives or alcohol were used concurrently.[145] Mr Black was not provided with a copy of this document, or any other written information, to remind him of the risks associated with MMT, especially on commencement.[146]

56. Dr Frei observed that while information brochures about MMT, including side effects and risks, were readily available from governmental and non-governmental organisations, they were not always supplied by prescribers.[147] Dr Diner's clinic did not provide patients with such brochures in 2010.[148] Dr Frei noted that it was *normal practice* to provide patients with written information or a brochure about MMT.[149] He considered information sheets useful for patients and their family/friends because there is a lot of information to absorb at the outset, especially about the potential dangers of MMT, and testified that *obviously the implications of that information are very significant.*[150]

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[141] Transcript page 46.

[142] Transcript page 46.

[143] Transcript page 75.

[144] Transcript page 75.

[145] Exhibit F.

[146] Transcript page 98.

[147] Transcript page 130.

[148] Transcript page 40.

[149] Transcript page 112.

[150] Transcript page 130.

INITIAL METHADONE DOSAGE

57. At inquest, Dr Diner acknowledged that methadone is a potentially toxic drug and *one of those drugs that you don't know how it's going to affect somebody*[151] so care should be taken when prescribing it.[152] He confirmed that he was aware of the *start low and go slow* principle recommended in the Guidelines as the appropriate approach to methadone dosing.

58. Dr Diner stated that when determining Mr Black's initial methadone dose, he considered Mr Black's self-reported intravenous use of half a gram of heroin per day and the presence of injection marks.[153] Dr Diner also stated that he drew on his own clinical experience. In his view, the *majority of people with the sort of use [described by Mr Black] need a lot more [than 40mg] to get them stable.*[154] In his evidence he emphasised that he had *treated thousands of addicts over the 20 years, it's not like I've seen one or two in my life and I've just picked that number because I thought it was a great number to start on.*[155]

59. Accordingly, Dr Diner fixed Mr Black's initial methadone dose at 40mg per day, the highest initial dose permitted, applied for a permit to Treat an Opioid Dependent Person with Methadone as required, and wrote Mr Black a prescription for one month's supply of methadone.[156]

60. Both Dr Frei and Professor Drummer rejected Dr Diner's dosing decision because it departed from the Guidelines and did so, in their opinions, without a sound clinical basis.[157]

61. Professor Drummer indicated that the purpose of methadone dosing is to avoid any undue risk of toxicity when replacing heroin with methadone while minimising the effects of withdrawal that would be experienced by the patient if the methadone dose were too low.[158]

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[151] Transcript page 35.

[152] Transcript page52.

[153] Dr Diner stated that urinalysis results – even if they detected benzodiazepines – would "probably not" influence his methadone dosing practices (Transcript page 33). He said that he would advised patients that it's "not good" to mix particular drugs, like benzodiazepines, but remarked that "they're buying [benzodiazepines] on the streets anyway, if they want to" (Transcript page 34).

[154] Transcript page 29.

[155] Transcript page 32.

[156] Coronial Brief of Evidence.

[157] Exhibits H and J and Transcript pages 123 and 148.

[158] Transcript page 143.

62. Professor Drummer stated that injections sites are not strong evidence of heroin use.[159] He observed that, irrespective of the quantity and regularity of the patient's heroin use, in and of itself, doesn't equate with significant tolerance to heroin, so in his view it is safer to start at a lower dose and then titrate the dose to the patient's requirements.[160]

63. Professor Drummer noted that the evidence available at inquest suggested that Mr Black *was either not using heroin at all in the recent weeks to months prior to his death, or [using] very occasionally.*[161] It appeared to him that Mr Black had *little or no tolerance to heroin and was at great risk of developing methadone-caused respiratory depression at doses above 20mg.*[162]

64. Dr Frei's analysis and conclusion was similar to that of Professor Drummer. He acknowledged that significant weight was placed on the history provided by the patient, even though it may be unreliable. However, Dr Frei opined that an initial methadone of 20 to 30mg per day would have been preferable, and safer, given the *absence of reliable indicators of high levels of opioid neuroadaptation* in Mr Black's presentation to Dr Diner.[163]

65. Both experts observed that the risks of methadone overdose are reduced if the prescriber commences the patient on a low dose and monitors her/him more regularly than not.[164]

REVIEW

66. Dr Diner gave evidence that he would ordinarily tell patients commencing MMT to return for review *after two doses if the dose is not holding [them] or if it's too much.*[165] He would also advise patients to inform the dispensing pharmacist if they experienced drowsiness and that the pharmacist should be the patient's *first port of call if there were issues.*[166]

67. When it was suggested to him at inquest that this description of his usual practice amounted to less of a practitioner-driven clinical review than one placing the *onus back on the patient,* Dr

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[159] Transcript page 142.

[160] Transcript page 143.

[161] Exhibit J.

[162] Exhibit J.

[163] Exhibit H and Transcript page 120.

[164] Transcript page 156 and Exhibits J and H.

[165] Transcript page 35.

[166] Transcript page 40.

Diner responded, *they're not children where you have to hold their hand ... whether they come to see me is up to them.*[167] Dr Diner added the observation that *a lot of patients don't want to ... go back to the doctor if they don't have to, especially this cohort ... they see a lot of this as a waste of their time.*[168]

68. Dr Frei gave evidence that the MMT patient review practice Dr Diner described was unusual.[169] In his experience, normal clinical practice and practice that accorded with the Guidelines, indicated clinical review of new or re-commencing MMT patients, prior to the third methadone dose.[170] Moreover, if a weekend intervened to prevent review at that time, commencement of MMT should be delayed, or the initial dose limited to the *lower end of doses* recommended by the Guidelines.[171] Dr Frei testified that if a high commencement dose, that is one above 30gm, was clinically appropriate, the patients should be reviewed three or four hours after their initial dose, and prior to their third dose.[172] Dr Diner considered review four hours after a patient's initial methadone dose was *impractical.*[173]

69. Dr Frei recommended that short prescriptions be written for MMT patients to improve the prospect that they would attend for clinical review.[174]

70. Professor Drummer echoed Dr Frei's comments, emphasising the importance of *regular follow up until the patient is responding well and [shows] no significant side effects that might lead to adverse outcomes.*[175]

CONCLUSIONS

71. The <u>standard of proof for coronial findings</u> of fact is the civil standard of proof, on the balance of probabilities, with the *Briginshaw* gloss or explication.[176] The effect of the authorities is

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[167] Transcript page 90.

[168] Transcript page 90.

[169] Transcript page 110.

[170] Transcript page 109 and Exhibit H.

[171] Transcript page 109.

[172] Transcript page 123.

[173] Transcript page 45.

[174] Transcript page 110. Dr Diner stated that he sometimes wrote short prescriptions to encourage patients to return for review but did not write one for Mr Black because he lived 20 minutes away from the Flemington Medical Clinic (Transcript page 36).

[175] Transcript page 143.

that Coroners should not make adverse findings against or comments about individuals, unless the evidence provides a comfortable level of satisfaction that they caused or contributed to the death.

72. Having applied the applicable standard to the available evidence, I find that:

a. At the time of his death, Mr Black had relapsed to the extent that he was an occasional user of opioids and other drugs of dependence.

b. During his consultation with Dr Diner, Mr Black over-stated the frequency and quantity of his heroin addiction, in order to persuade Dr Diner to commence him on MMT.

c. The clinical interview Dr Diner conducted with Mr Black, as recorded in the patient notes, was perfunctory. Absent from that record is any discussion of Mr Black's treatment goals, specific details about his non-opioid drug use, and any corroboration, or attempt to obtain corroboration, of his opioid use beyond the observation of injection sites on his arm.

d. Dr Diner's decision to set Mr Black's initial methadone dose at 40mg per day was not clinically sound. That decision appears to have been unduly influenced by Dr Diner's personal experience as a clinician and informed by his patient's poorly substantiated self-report of opioid use.

e. Dr Diner failed to make appropriate arrangements for the review of Mr Black's initiation into MMT, particularly in light of the fact that the initial dose he prescribed was the maximum permissible dose.

f. At the time of his consultation with Mr Black, Dr Diner was unfamiliar with many of the most clinically significant provisions of the Guidelines.

72. I accept, and endorse, the expert evidence provided by Professor Drummer, Dr Frei and Mr McCrone, that methadone prescribers should not depart from the Guidelines without a sound clinical reason. I find that neither Dr Diner nor his methadone prescription practices, had

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

appropriate regard for the Guidelines and so, tragically, the known and grave risk the Guidelines are in place to avert, was realised.

73. I find that Mr Black died from combined methadone, diazepam and clonazepam toxicity in the setting of his recent commencement on a methadone maintenance programme, and that sub-optimal clinical management by Dr Diner caused or contributed to his death.

RECOMMENDATIONS

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

1. That the Royal Australasian College of General Practitioners reminds its members who are methadone prescribers of the need to regularly review the National Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence to ensure that their practice accords with those guidelines, unless there is a sound and documented clinical basis for departure.

2. That Drugs and Poisons Regulation (Department of Health and Human Service, Victoria) and its Drugs of Dependence Advisory Committee considers amending the Victorian Policy for Maintenance Pharmacotherapy for Opioid Dependence, to include a mandatory requirement that health practitioners prescribing methadone comply with the National Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence, unless there is a sound and documented clinical basis for departure.

3. That Drugs and Poisons Regulation and its Drugs of Dependence Advisory Committee considers amending the Victorian Policy for Maintenance Pharmacotherapy for Opioid Dependence, to include a mandatory requirement that health practitioners prescribing methadone complete ongoing training in relation to the Victorian Policy for Maintenance Pharmacotherapy for Opioid Dependence, and the National Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence, at regular intervals, and that compliance be audited.

4. That the Australian Health Practitioner Regulation Authority considers the circumstances in which Mr Black died, and takes whatever action it seems appropriate in relation to Dr Diner.

For the purposes of Recommendation 4 above, I direct that the Principal Registrar provide a copy of this finding, the coronial brief and the inquest transcript to the Australian Health Practitioner Regulation Authority.

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

Mr Black's family

Dr Noah Diner, Flemington Medical Clinic

Dr Frei, Clinical Director, Turning Point Alcohol and Drug Centre

Mr Matthew McCrone, Chief Officer, Drugs and Poisons Regulation, Department of Health and Human Services

Drugs of Dependence Advisory Committee (Victorian)

Professor Olaf Drummer, Victorian Institute of Forensic Medicine

Senior Sergeant Jenette Brumby, O.I.C. Police Coronial Support Unit

Royal Australasian College of General Practitioners

Royal Australasian College of Physicians – Addiction Medicine

Australian National Council on Drugs

Signature:

PARESA ANTONIADIS SPANOS
Coroner
Date: **20 February 2015**

Cc: Manager, Coroners Prevention Unit