FORM 37

Rule 60(1)

FINDING INTO DEATH WITH INQUEST

Section 67 of the ***Coroners Act 2008***

Court reference: 5241/08

Inquest into the Death of MICHAEL WILLIAM GLEDHILL

Delivered On:	17 FEBRUARY 2011
Delivered At:	MELBOURNE
Hearing Dates:	23 SEPTEMBER AND 22 OCTOBER 2010
Findings of:	CORONER K. M. W. PARKINSON
Place of death/ Suspected death:	80 LOCHIEL AVENUE, EDITHVALE, VICTORIA 3196
Counsel Assisting:	SENIOR CONSTABLE REMO ANTOLINI
Appearances:	MS ELIZABETH MCKINNON FOR MR TRIFON SAMARAS
	MR NEIL MURDOCK FOR DR DAVID MILECKI

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Section 67 of the ***Coroners Act 2008***

Court reference: 5241/08

In the Coroners Court of Victoria at Melbourne

I, KIM PARKINSON, Coroner

having investigated the death of:

Details of deceased:

Surname: GLEDHILL
First name: MICHAEL
Address: 80 LOCHIEL AVENUE, EDITHVALE, VICTORIA 3196

AND having held an inquest in relation to this death on 23 September and 22 October 2010 at Melbourne

find that the identity of the deceased was MICHAEL WILLIAM GLEDHILL

and death occurred on 23rd November, 2008

at 80 Lochiel Avenue, Edithvale, Victoria 3196

from: MIXED DRUG TOXICITY (HEROIN, METHADONE & DIAZEPAM) IN A MAN WITH CORONARY ARTERY ATHEROSCLEROSIS

1. An inquest was conducted into the death of Mr Michael William Gledhill on 23 September and 22 October 2010. The following witnesses gave evidence in the proceeding: Dr David Milecki, Medical Practitioner, Mr Trifon Samaras, Pharmacist, Mr Stephen Marty, Registrar of the Pharmacy Board of Victoria and Mr Mathew McGrone, Manager Drugs and Poisons, Department of Human Services (Victoria). After the conclusion of the evidence, written submissions were filed on behalf of Dr Milecki and Mr Samaras.

2. Mr Michael William Gledhill was born on 12 May 1971 and he was 37 years of age at the time of his death. He resided at 80 Lochiel Avenue, Edithvale. Mr Gledhill had a history of substance abuse, including intravenous heroin use and was a participant in the methadone treatment program at the time of his death. He was employed in the heavy drilling industry, working interstate and sometimes in remote or country areas.

3. He was treated by his General Practitioner, Dr David Milecki and since November 2003 had been a registered participant in the methadone drug treatment program. His methadone prescriptions were dispensed by a regular pharmacist, Mr Trifon Samaras of the Guardian Pharmacy in Chelsea.

4. Methadone is a prescribed drug pursuant to Schedule 8 of the Drugs, Poisons and Controlled Substances Act 2006. The supply of methadone is regulated under the Drugs, Poisons and Controlled Substances Act 1981 and Regulations 2006. Medical Practitioners and Pharmacists prescribing or dispensing pharmacotherapy (methadone and buprenorphine) require approval from the Drugs and Poisons Reference Group (DPRG) of the Department of Health (Cwlth). Its prescribing and dispensing is regulated by that Act and there are professional practice guidelines issued by professional bodies and by the health or community services departments of both the State and Commonwealth.

5. Methadone is usually dispensed by the pharmacist to the patient, at the pharmacy where it is ingested under the supervision of the pharmacist. This enables supervision of consumption as well as ensuring no adverse reaction or combination with other substances. A practice known as take away doses exists by which a stable patient may be allowed to take home doses a limited number of days per week, often weekends. This measure is largely for the convenience of the patient.

6. Mr Gledhill was usually prescribed 38mg of methadone daily. He was authorised by his doctor, for take away doses on a regular basis and had recently been authorised a high level of take away dose (10 days) in April, June and August 2008, when he was working interstate. He had explained to his doctor that it was inconvenient for him to attend at a pharmacy interstate and that he did not want his employer to be aware that he was on the methadone program. (This appears of itself problematic, when he was an employee engaged in heavy drilling operations, although this matter is outside of the scope of this inquiry).

7. On 13 October 2008, he attended a consultation with Dr Milecki and advised that he was travelling to Queensland the following day to undertake further drilling work and that he again sought a long-term prescription for take away methadone doses. In view of the reported short time frame for departure, Dr Milecki's evidence was that there was no time to consider a referral to a provider in Queensland. Consequently, he decided to authorise take away doses for the entire period. Dr Milecki wrote a prescription for 76mg methadone daily in suspension liquid (Exhibit 4). This represented double the usual daily dosage and this was discussed with Mr Gledhill as being for convenience of handling and transporting.

8. Whilst Dr Milecki and Mr Samaras stated that they regarded him as a stable patient, the evidence is that Mr Gledhill had been recently arrested by police for possession of heroin and that he had been taken to hospital for a suspected overdose. Apparently, there is no mechanism for reporting his arrest for possession or attendance at the hospital to the general practitioner, or to the dispensing pharmacist. Neither the medical practitioner, nor pharmacist were aware of these matters and took Mr Gledhill at his word that he was not otherwise using.

9. He did not in fact leave for Queensland that next day. On 26 October 2008, he collected fourteen double doses from the Guardian Pharmacy, which was sufficient methadone for 28 days supply. The dosage was not dispensed into individual containers identifying the daily dosage accurately. For convenience of handling 14 bottles were supplied, each bottle (Exhibit 5), contained a double dose of the usually prescribed daily amount.

10. Whilst the evidence is that Mr Gledhill understood that he was to take only half of the amount in the bottle, the labelling of the bottle was inaccurate as it described the contents as "one daily dose". The level of methadone (76mg) contained in each container was double his usual prescribed dosage.

11. He left Victoria, on 26 October 2008, to travel to a work site in Queensland. What mechanism was used to store the methadone during the course of the travel is not clear. During that time, he self-administered the methadone, apparently without incident. He returned to Melbourne on 22 November 2008.

12. On Sunday 23 November 2008, a friend Mr Paul Bradshaw, attended at Mr Gledhill's home and discovered Mr Gledhill unresponsive on the floor in the bedroom. He was unable to be resuscitated. Located on the floor in the bedroom was a used hypodermic syringe, a spoon and a cigarette lighter. Mr Gledhill was observed to have a track mark on his arm consistent with recent intravenous drug use. Also located near Mr Gledhill were two bottles of the earlier dispensed methadone oral solution 200ml/76mg, one empty and one nearly full. The police reported no suspicious circumstances.

13. Family and friends report that whilst Mr Gledhill had some difficulties emotionally in the past, he was at the time of his death fully employed and had some stability in his life. He was pleased to have returned to Melbourne. There were no indications in any of the evidence that Mr Gledhill had intended to take his own life.

14. An autopsy was conducted by Dr Melissa Baker, Forensic Pathologist with the Victorian Institute of Forensic Medicine. Dr Baker reported that the cause of death was mixed drug toxicity. She commented:

"Toxicological analysis of urine revealed the presence of 6-monoacetylmorphine and morphine, consistent with the recent use of heroin. Methadone and diazepam (along with its metabolic nordiazepam) were also detected in blood. All of these drugs cause central nervous system depression. There was evidence of bronchopneumonia involving most lung lobes. This is a common finding in death due to drugs causing respiratory depression where there has been a period of unconsciousness prior to death. Post mortem examination showed significant single vessel coronary artery atherosclerosis with up to 80% stenosis of the left anterior descending coronary artery."

15. There was no evidence of any injuries that may have caused or contributed to death. The toxicology report identified the following drugs present in post mortem specimens: 6-monoacetylmorphine Urine 0.1mg/L, Morphine total Urine 8.2mg/L, Codeine total 0.04mg/L, Methadone Blood ~ 0.6mg/L, stomach ~6.8mg, Diazepam ~0.1mg/L and Nordiazepam (Blood) ~ 0.2mg/L.

16. The compound 6-monoacetylmorphine at 0.1mg/L was detected in post mortem urine. Heroin is converted to morphine within minutes of injection via the intermediate compound 6-monoacetylmorphine. 6-monoacetylmorphine was detected in post mortem urine and the toxicologist reported that having regard to the short half-life of that compound, this would indicate usage of heroin within 6 hours of death.

17. Morphine at the levels detected has the capacity to depress respiratory function, more so when combined with other drugs such as methadone and benzodiazepines, such as Diazepam.

18. Counsel for Dr Milecki and Mr Samaras, submit that there is no evidence to enable a finding that the methadone, its labelling or its multiple dispensing, contributed to the cause of death and submit that it was a peripheral and background matter to that of the ingestion of heroin.

19. Whilst it is unclear whether Mr Gledhill had exceeded the prescribed methadone dosage (he was not measuring the dose and was apparently drinking it directly from the bottle), the forensic pathologist has reported that it is the combination of the substances, which has caused the death in this case. I accept that this is so.

20. It is not possible to identify with certainty the degree to which the methadone acted to cause or contribute to the death in a setting where heroin was being used in combination with diazepam, each known for their capacity to suppress respiratory function. However, I am satisfied having regard to the pathology and toxicology reports that the methadone was a contributing factor in this death.

21. Mr Gledhill had been apparently relatively stable on the methadone program for sometime. In the context of the existence of a take away regime, the decision by Dr Milecki to facilitate Mr Gledhill's participation in that regime was of itself not unreasonable. It is unclear whether any intervention by substance testing would have been useful in identifying any ongoing illicit substance use by Mr Gledhill and no information from other sources such as police or emergency units was available to Dr Milecki to assist in determining appropriate management.

22. Whilst the evidence does not satisfy me that the mislabelling or form of dispensing of itself caused or contributed to the death in this case, there are however serious public health concerns arising from this practice which are appropriate for comment.

23. I am satisfied that Mr Michael William Gledhill died as a result of mixed drug toxicity in circumstances where his respiratory function was depressed as a result of the effects of the heroin he injected and the methadone and diazepam he had consumed. He was likely further compromised by his pre-existing and significant coronary artery disease. There is no evidence to suggest that the death was anything other than accidental. I do not find that any person or persons contributed to his death.

I make the following comment(s) connected with the death including matters relating to public health and safety and (including any notification to the Director of Public Prosecutions under 67(3) of the Coroners Act 2008)

24. Mr Gledhill died as a result of mixed drug toxicity, including methadone. Two specific public health and safety issues arose in this case. They relate to (1), the inaccurate description of the prescribed amount, mislabelling of the medication dosage and bottle contents and the manner of packaging of same, and (2), the appropriateness and safety of Mr Gledhill being able to acquire multiple doses of the prescribed substance methadone, for the purpose of self administering over a long period of time and to transport that Schedule 8 drug interstate in large quantities.

25. As to (1), the inaccurate description of the prescribed dose mislabelling and multi dose packaging, the evidence is that it is not good medical or pharmacology practice to inaccurately describe the dosage on the prescription or labelling of a medication.

26. Drugs and poisons regulations require accurate description in prescribing and accurate labelling of medication upon dispensing. See Drugs, Poisons and Controlled Substances Act 1981 and Drugs, Poisons and Controlled Substances Regulations 2006.

27. The guidelines for dispensing state that each daily dose should be prepared separately and the label should include the following: "contains a single daily dose of methadone to be taken on (date) and dose to be taken by (name of patient)".

28. Whilst I accept Dr Milecki's evidence that it was the convenience of the patient in transporting the methadone, and the desire to facilitate his rehabilitation program that motivated the practice, these motives fail to account for the broader public interest.

29. Mr Samaras, the Pharmacist, explained his reasoning for adopting this dispensing method after querying it with the patient, on the basis that he was simply following the prescription as directed by the doctor. All professionals have an obligation to comply with proper and appropriate practice in their discipline and there appears to be a lack of recognition of public health considerations in the practice adopted in this case.

30. As to (2), whilst there is no prohibition upon an authorised prescribing medical practitioner directing take away dosage, regulatory authority guidelines provide criteria as to the circumstances in which allowing take away dosage is appropriate. These include the following guidelines issued by the Department of Human Services (Victoria) and by the National Expert Advisory Committee on Illicit Drugs under the auspices of the Commonwealth Department of Health and Ageing.

- Policy for Maintenance Pharmacotherapy for Opioid Dependence (2006) (Vic) ("the department of Human Services Guidelines").
- National Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence (2003) (Cwlth).

The Pharmacy Board of Australia also produced publications updating practitioners upon current practice and developments.

31. There is a presumption apparent in the legislation (methadone being classified as a Schedule 8 Drug requiring a permit to prescribe) and the regulatory mechanisms and guidelines that the provision of methadone comes with a level of supervision of the patient and that there ought to be satisfactory arrangements for secure storage and transport.

32. These presumptions are to be ascertained by reference to the Department of Human Services Guidelines (pages 23-29 and page 50), which nowhere provide for more than five take away doses per week and no single supply exceeding three take away doses and only for a highly stable patient. The guidelines also propose drug testing from time to time, inquiry as to the manner in which the drugs are to be stored and provision for transfer of the program interstate. The guidelines are recommended best practice and are not mandatory or subject to regulatory supervision or enforcement. Such practices are also articulated in the Commonwealth Guidelines.

33. These guidelines are an attempt to insure against a number of concerns, including the very circumstance of combined use, which has arisen in this case. They are:

- that the recipient might combine the drugs with other substances, illicit or otherwise;
- that the dosage may potentially be exceeded; and that persons other than those for whom the medication is prescribed may be able to access the drug.

34. Drug addicted persons are often difficult patients with complex needs. It is apparent that there is a necessity in a context of treatment on a methadone program that some degree of trust and acceptance of the word of the patient necessary, otherwise the program would become too rigid and too cost prohibitive. However that said, the information provided by substance abusers is not always reliable and it is a great leap of faith and reckless to the issue of public health and safety to place such large quantities of methadone in the hands of a drug addicted person to take out into the community and to be transported interstate.

35. A serious question relating to public health and safety also arises as to the appropriateness of providing for take away dosage at such a level and for such a long period of time. Whilst counsel submit that there is no legislative prohibition against such practice, the evidence of the expert clinician, Mr Marty, satisfies me that such levels of take away dosage are not anticipated or provided for in the practice guidelines issued to medical practitioners or pharmacists. It is apparent and readily understandable from the documents, that the guidelines anticipate alternative arrangements for dispensing will be made in the event that a patient is unable to attend the regular dispenser and not that large quantities of methadone will be provided as take away.

36. The guidelines do not specifically identify who is responsible for the oversight of matters such as administration of dosage and safe storage or what steps are required to be taken to ensure safety prior to take away doses being allowed. To leave the decision making, administration and storage arrangements solely in the hands of the addicted person seems to be an approach, which is fraught with risk, given the unreliability often associated with persons suffering with substance addiction.

37. That very lack of supervision and regulation of the storage and transportation arrangements is, in my view, an extremely dangerous practice, which has the potential to result in death or serious injury to the patient and to persons other than the patient, in particular children. The practice would appear to be more dangerous when large quantities of take away doses are made available.

38. Neither Dr Milecki nor the pharmacist, had knowledge of recent illicit drug use by Mr Gledhill. Clinicians administering and managing patients on methadone maintenance programs would be assisted by receiving information relevant to the management of their patient's progress

such as information as to suspected illicit substance use or arrest for same. Similarly, it would seem reasonable that a medical practitioner receive information from other health services, where a patient on the methadone program has been resuscitated for drug overdose.

I make the following recommendation(s) connected with the death under s72(2) of the Coroners Act 2008:

1. That the responsible regulatory authorities, The Department of Human Services (Victoria) and the Department of Health (Victoria), establish a clear mechanism of supervision of the safety arrangements for take away dosage of methadone.

2. That there be a prohibition upon take away methadone dosage unless responsible regulatory authorities, the Department of Human Services (Victoria) and the Department of Health (Victoria), are satisfied that safe storage arrangements are in place in the premises in which the drug is to be stored.

3. That the responsible Minister/s give consideration to legislative amendment if necessary to enable the implementation of appropriate levels of supervision and safety arrangements.

4. That the responsible Minister/s give consideration to legislative amendment if necessary to enable the provision of health information, such as overdose events or drug related arrests, to the General Practitioner supervising a patient's pharmacotherapy program such as the methadone maintenance program.

5. I direct that a copy of these findings be provided to: The Honourable Nicola Roxon MP, Minister For Health (Commonwealth); The Honourable Mr David Davis MLC Minister for Health (Victoria); The Honourable Ms Mary Wooldridge MP, Minister for Community Services Victoria; The Secretary, Department of Human Services (Victoria); The Secretary, Department of Health (Victoria); The Health Practitioner's Board of Australia (Victoria); The Pharmacy Board of Australia (Victorian Branch); The Medical Practitioners Board of Victoria; The Pharmacy Guild of Australia (Victorian Branch) and The Australian Medical Association (Victorian Branch).

Signature:

Coroner K.M.W. Parkinson

Date: 17 February 2011