Coroners Act 1996
[Section 26(1)]

Western *Australia*

RECORD OF INVESTIGATION INTO DEATH

Ref No: 15/13

I, Barry Paul King, Coroner, having investigated the death of ***Wendy Elaine Osborne*** *with an inquest held at the* ***Perth Coroner's Court, Court 51, CLC Building, 501 Hay Street, Perth,*** *on* ***23 April 2013****, find the identity of the deceased person was* ***Wendy Elaine Osborne*** *and that death occurred on or about* ***1 July 2010*** *at* ***81 Crawford Road, Maylands,*** *as a result of* ***early bronchopneumonia complicating combined drug toxicity*** in *the following circumstances:*

Counsel Appearing :

Emily Winborne assisting the Coroner

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INTRODUCTION

1. On 11 June 2010 Wendy Elaine Osborne (the deceased) attended her doctor, Dr Andrew Stewart of Swan Street Surgery in Yokine, complaining of back pain.
2. The deceased had been regularly seeking Dr Stewart's help for about 2 years, primarily for psychiatric and substance abuse issues.
3. On this occasion, Dr Stewart referred the deceased for a CT scan which revealed that she had suffered a disc protrusion in her lower back.
4. Initially Dr Steward prescribed an anti-inflammatory. On 18 June 2010 he prescribed a stronger anti-inflammatory and oxycodone tablets.
5. On 25 June 2010 Dr Stewart prescribed 50mcg/h (microgram per hour) patches of transdermal fentanyl (fentanyl).
6. On 29 June 2010 the deceased again attended Dr Stewart, who increased the prescription of fentanyl to 75mcg/h patches.
7. On 30 June 2010 the deceased was at home with her 12 year old son. She was severely intoxicated. In the evening, the deceased's son removed a fentanyl patch and put the deceased to bed with a hot water bottle.
8. The deceased went to bed but got up at about midnight, had a shower and went back to bed.
9. When the deceased's son awoke the next morning, he found the deceased in bed with no signs of life.
10. A post mortem examination established that the deceased had died from bronchopneumonia as a result of an overdose of fentanyl.
11. An inquest into the deceased's death was held with the stated purpose of examining the potential dangers of doctors prescribing fentanyl patches and to raise the awareness of doctors and the public about those dangers.

12. The evidence received at the inquest included a folder of documents obtained by Senior Constable Eric Langton, the police officer investigating the death, and oral evidence by Senior Constable Langton.

13. Those documents included a report with addendum by Professor David Joyce, a specialist in clinical pharmacology and toxicology, and two reports by Dr Stewart.

14. Professor Joyce and Dr Stewart also attended the inquest to provide oral evidence.

EVENTS PRECEDING THE DEATH

29. On 11 June 2010 the deceased attended Dr Stewart, the general practitioner whom she had been seeing regularly for the past two years. She was complaining of acute sciatic pain.

30. Dr Stewart initially prescribed the deceased Naproxen, a non-steroidal anti-inflammatory, and referred the deceased for a CT scan. A CT scan carried out on 16 June 2010 revealed that the deceased had a paracentral disc protrusion at the L4/L5 level of her spine. The protrusion appeared to contact the L5 nerve root.

31. On 18 June 2010 Dr Stewart prescribed Indomethacine, a strong anti-inflammatory, and one 5mg oxycodone tablet per night.

32. On 25 June 2010 the deceased told Dr Stewart that the oxycodone was insufficient to control her pain overnight, so he prescribed 50mcg/h fentanyl patches.

33. On 29 June 2010 the deceased returned to see Dr Stewart who increased the dosage of fentanyl to 75mcg/h patches.

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[6] Exhibit 1, Tab 20 p220-221
[7] Exhibit 1, Tab 3 p.5, Tab 20 p196

34. On 30 June 2010 the deceased appeared to Angus as dopey and, at times, confused. She spent a large part of the day sleeping.

35. In the late afternoon or early evening Angus rang his father, Steve Gummow, because he became concerned for his mother. She could hardly stand, yet she wanted to go out in the car to get something to eat. Mr Gummow asked Angus to put the deceased on the phone, which he did. The deceased, who sounded a bit dozy but intelligible, told Mr Gummow that she just needed some sleep and that she would not be going out. Mr Gummow told Angus to let the deceased sleep and that she would be alright.

36. Later in the evening Angus rang the deceased's mother, Joan Osborne, to ask her to speak to the deceased who was mumbling so badly that Angus could not understand what she was saying. Mrs Osborne asked the deceased how she was doing but could get no sensible reply from her.

37. Mrs Osborne then spoke again to Angus to ask if he thought that they should call for an ambulance. Angus replied that his mother had told him that she did not want to go to hospital.

38. Mrs Osborne told Angus to put the deceased in bed with a hot water bottle and keep her warm. She asked Angus if the deceased had one or two pain relief patches on her. Angus said that he could only see one, and that he had taken it off and thrown it into the bin.

39. When Senior Constable Langton spoke to Angus on 22 September 2011, Angus recalled taking the patch off, and thought that it was from the left side of the deceased's abdomen, but said that he had not looked to see if there was another patch there.

40. After Angus put his mother to bed, he slept on her bed with her until about midnight when she awoke saying that she was cold. He helped her into the shower and then got a hot water bottle for her while she was in the shower.

41. The deceased stayed in the shower for 5 or 10 minutes, and went back to bed. Angus did not see her apply another fentanyl patch. He stayed with her while she fell asleep then went to his own bed.

THE MORNING OF 1 JULY 2010

42. Angus arose around 7.30am on 1 July 2010 and went to check on his mother. He found her unresponsive in a similar position to that which he had left her the night before, but she had vomit around her nose and mouth and was cold to touch.

43. Angus called Mrs Osborne and St John Ambulance Service. The latter instructed him to get the deceased out of bed and to conduct chest compressions. Ambulance officers arrived within minutes, but the deceased displayed no signs of life.

44. The deceased had a 75mcg/h fentanyl patch applied to the left side of her abdomen.

45. There were two unopened 50mcg/h patches and three unopened 75mcg/h patches found at the deceased's home indicating that she had used one more of each prescription than she was supposed to have used.

POST MORTEM EXAMINATION

46. A post mortem examination was conducted by Chief Forensic Pathologist Dr C T Cooke.

47. Dr Cooke found congestion of the lungs and discolouration of the heart muscle. Microscopic examination showed early bronchopneumonia in the lungs.

48. Dr Cooke noted that a toxicology analysis carried out as part of the post mortem examination showed a very high level of fentanyl and two prescribed medications at therapeutic levels. He noted that these agents have a combined sedating effect which may result in impairment of consciousness, coma and death. In

an impaired state of consciousness, it is possible to develop a build up of fluid in the lungs with consequent bronchopneumonia.

49. Professor Joyce relied on the toxicology analysis to conclude that the opioid toxicity was the cause of death.[8] His view was that, though there were other medications which could have interacted with the fentanyl, practically all of the toxic potential lay with the fentanyl.[9] He told the Court that the blood and liver concentrations of fentanyl found in the deceased were within the range that has caused fatality.[10]

50. Of concern to Professor Joyce was the apparent lack of proper explanation for the high concentrations found in the deceased given the dosages that she had been prescribed. He postulated two possibilities: either the deceased applied more than one patch at once, which still would not be sufficient in his view to explain the concentrations, or the release of the fentanyl by the patch was dramatically increased by an event such as the heating of the patch.[11]

51. Professor Joyce stated that, in a number of cases of deaths arising from overdoses of fentanyl, he had been struck with the degree of elevation of the post mortem concentration of the drug compared with the dose prescribed to the patient. He suspected that it had something to do with the physiology of fentanyl clearance during the hours of dying.[12]

THE FENTANYL PRESCRIPTION

52. Dr Stewart stated that, when prescribing the deceased fentanyl, he informed her about the symptoms that it was expected to control and about the common and serious side-effects that can occur. He stated that he always counselled her not to exceed the

[8] t.20
[9] t.15
[10] t.20
[11] t.19
[12] t.20

prescribed dose, but that her track record was not always to adhere to this advice.[13]

53. Dr Stewart indicated in oral evidence that a lot of his prescribing habits are guided by the MIMS manual. His other understanding and usage is from his personal experience and the experience of other clinicians, including pain specialists.[14]

54. The MIMS Abbreviated Prescribing Information relied upon by Dr Stewart in 2010 (the MIMS) relevantly provided the following direction:

> Contraindications: … ; initial doses > 25mg/hr
> …
> Precautions: … external heat; drug alcohol abuse (monitor for misuse, abuse, addiction); … ; opioid naïve (esp with noncancer pain);
> …
> Dose: Opioid naïve (initiate with low dose opioid equiv. Durogesic less than or equal to 25 mcg/hr): initial max 25 mcg/hr; may titrate up or down by 12 or 25 mcg/hr every 3 days.[15]

55. Dr Stewart first prescribed fentanyl to the deceased at a dose of 50mcg/h after having prescribed oxycodone at 5mg per night for a week. It is apparent that he did not comply with the contraindications information in the MIMS since the initial dose was greater than 25mcg/h.

56. However, it appears that, in relation to the issue of determining the appropriate dose, it is at least arguable that by virtue of taking the 5mg oxycodone, the deceased was not deemed to be opioid naïve since that dose was less than or equal to an opioid equivalent of 25mcg/h of fentanyl. That reading of the MIMS is supported by the MIMS Full Prescribing Information then available.[16]

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[13] Exhibit 1, Tab 12
[14] t.29
[15] Exhibit 1, Tab 20
[16] Exhibit 1, Tab 20

57. Nonetheless, by prescribing the deceased an initial dose of fentanyl greater than 25mcg/h, Dr Stewart was not complying with the information provided in the MIMS.

WARNING ABOUT HEAT

58. Dr Stewart did not tell the deceased about a possible danger of applying heat to the patch, as he was not aware of it himself.[17] When asked how he could not have been aware of it when a superficial search of the internet revealed that hazard, Dr Stewart indicated that he could not be aware of changes that did not appear in the MIMS.

59. When taken to the MIMS reference to the potential hazards of exposing fentanyl patches to heat and the recommendation to warn patients to avoid exposing patches to external heat sources, Dr Stewart said that he did not find that reference clinically helpful since it refers to an experimental model that says there could be an issue relating to heat.

60. I found this aspect of Dr Stewart's testimony somewhat unsatisfactory, but it is fair to say that the MIMS warning in relation to heat is not as prominent as it could be.

THE DECEASED'S ABUSE OF PRESCRIBED MEDICATION

61. Another matter with respect to Dr Stewart's prescription of fentanyl to the deceased was his awareness that she had a history of abusing prescribed medication. In addition to the warning in the MIMS Abbreviated Prescribing Information shown above, the MIMS Full Prescribing Information of 1 March 2009 contained the following warning:

> Drug and alcohol dependence and potential for abuse. Use of Durogesic (the product name for fentanyl transdermal patches) in combination with alcoholic beverages and/or other depressants can result in increased risk to the patient.

[17] t.38

> Durogesic should be used with caution in individuals who have a history of drug or alcohol abuse, especially if they are outside a medically controlled environment. Fentanyl can be abused in a manner similar to other opioid agonists. Abuse or intentional misuse of Durogesic may result in overdose and/or death. Patients at increased risk of opioid abuse may still be appropriately treated with modified release opioid formulations; however, these patients will require monitoring for signs of misuse, abuse or addiction.[18]

62. Despite his intimate knowledge of the deceased's history of alcohol abuse, medication overdoses and unreliable self-medication, Dr Stewart did not take any steps to monitor the deceased's use of the fentanyl patches apart from telling her that if she had any problems she should contact him.

63. Dr Stewart said that, in some cases involving irresponsible patients, he provided single samples of medications and had the patients return to him after they had tried the medication in order to ensure that there would be no problems. But, he said, he did not have samples of every medication, implying that such a course would not have been convenient with a fentanyl prescription for the deceased.

64. Dr Stewart considered that the deceased's apparently reliable use of the weaker opioid tramadol in the previous year for pain associated with treatment for bladder retention issues indicated that she was unlikely to misuse fentanyl. It is worth noting that the consultation notes for the deceased at Dr Stewart's practice show that Dr Stewart had also prescribed tramadol for the deceased in 2007 without any apparent problem.

WERE THE PRESCRIPTIONS REASONABLE?

65. Professor Joyce had earlier been provided with most of the documents in the folder compiled by Senior Constable Langton.

[18] Exhibit 1, Tab 20, p4

He provided a report in which he analysed the circumstances leading up to the deceased's death, and he addressed the issue of how she came to have a fatal concentration of fentanyl.[19]

66. At the inquest, Professor Joyce was asked about the appropriateness of Dr Stewart's prescriptions. Professor Joyce noted that it would only take a couple of days to assess whether oxycodone was being tolerated, so if a patient were not responding to a dose after 48 to 72 hours, that would be the time to increase the dose.

67. He considered that the decision to introduce fentanyl after the ineffectiveness of oxycodone was reasonable, but that the 50mcg/h dose of fentanyl was an unusually high starting dose beyond the recommendation. He also considered that the interval between the 50mcg/h dose and the 75mcg/h dose was shorter than usual. In both cases, Professor Joyce's view was that the decision to make the prescription required compelling reasons.

68. The dosage of oxycodone was only 5mg per night, which Professor Joyce considered would engender only a small degree of tolerance to opioids.[20]

69. However, Professor Joyce noted that the fact that the deceased had been using 50mcg/h fentanyl patches for four days or so would have provided Dr Stewart with reassurance that that dose did not carry a risk to the deceased, so that a higher dose might be reasonable. That view was supported by the MIMS, which indicates that dosage adjustment can occur every three days after the initial application.[21]

70. Professor Joyce was asked about the ambiguity in the directions in the MIMS. His view, which I accept, is that the prescription of fentanyl by doctors at the time of the deceased's death was

[19] Exhibit 1, Tab 17
[20] T.16
[21] Exhibit 1, Tab 20

generally guided by the MIMS, but not a detailed knowledge of it. Instead, a doctor would be guided by the information as he or she understood it, filtered through the advice of experts and his or her own experience.

71. According to Professor Joyce, there was a shift in the medical practitioner's culture of prescribing potent opiate drugs. Up until 10 or 12 years ago, such drugs were not prescribed for chronic pain except for that relating to cancer. There was then a phase where the use of opioids was 'culturally permissive' for about five years until doctors re-learnt that opioids were not safe for use in chronic non-cancer pain and that they carried a significant risk of lethality. At the time of the deceased's death, doctors were just emerging from a phase of believing that these drugs were more benign than they were.

72. Professor Joyce said that, in the last five years, the medical profession has come to understand that fentanyl patches and another transdermal patch (containing buprenorphine) have a limited utility and that they should be be prescribed only to patients with moderate to severe chronic pain who have been taking regular daily around the clock narcotic pain relief for longer than a week and are considered to be opioid tolerant. Opioid tolerant patients are those who have been taking at least 60mg of morphine or 30mg of oxycodone daily for a week or longer. The patients must avoid exposing the patch to excessive heat, and the directions for prescribing and using such patches must be followed exactly to prevent death or other serious side effects from overdose.[22]

73. It is worth noting that the U.S. Food and Drug Administration drug alert update of 21 December 2007 for fentanyl commenced with the following:

[22] t.23-24

> This update highlights important information on appropriated prescribing, dose selection, and the safe use of fentanyl transdermal system.
> In 2005 the FDA issued a Public Health Advisory and Information for Healthcare Professionals that emphasized the appropriate and safe use of the fentanyl transdermal system (fentanyl patch), marketed as Duragesic and generics. Despite these efforts FDA has continued to receive reports of death and life-threatening adverse events related to fentanyl overdose that have occurred when the fentanyl patch was used to treat pain in opioid-naïve patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patches too frequently, and exposed the patch to a heat source.

74. As to prescribing of fentanyl to a patient who, like the deceased, was not responsible with prescriptions, Professor Joyce noted that such patients are always a great problem in prescribing opioid drugs. He said that the counsel of perfection would be to supervise the drug treatment entirely, but that it is simply impractical for most patients. Most typically, a doctor deals with the risk by trying to get the patient to understand the risks and to appreciate how carefully the patient must comply with the treatment.[23]

75. Dr Stewart explained his decision to prescribe 50mcg/h fentanyl to the deceased on 25 June 2010. He said that he had prescribed 25mcg/h patches in other cases but did not do so with the deceased because he considered that such a dosage would be insufficient for the deceased's level of pain. He was aware that the MIMS recommended that a lower dosage of fentanyl should be used given that the deceased had been taking only 5mg of oxycodone per night for the previous week, but he took into account the fact that the deceased had previously used tramadol

[23] t.17

as well as dextropropoxyphene and oxycodone without perceived side effects.[24]

76. Dr Stewart considered increasing the oxycodone dosage or switching to a slow release oxycodone. One issue for him was the risk of overdose if he prescribed the deceased with oral medication.[25]

77. Dr Stewart said that he maintained that 50mcg/h was an appropriate prescription at the time. He had to decide whether to start with 25mcg/h or 50mcg/h, and he made a clinical decision that 25mcg/h would be ineffective for analgesic control.[26]

78. He said that he had started other patients on 50mcg/h fentanyl patches where they had had a pre-usage of a narcotic in the lead up to it.

79. As to the change from 50mcg/h patches to 75mcg/h patches, Dr Stewart disagreed that the change was unusually quick given the context of what he had used before and in the context of what can be recommended through the MIMS recommendations; that is, that a steady state of analgesia can be reached within 24 hours. He said that his basis rule for assessing side effects was to wait a minimum of three days before making a change.[27]

80. As somewhat of an aside, Dr Stewart's report of 11 November 2010 contains the sentence 'When last seen on 29th June 2010, she (the deceased) reported adequate pain control on her fentanyl patch (75mg/1hour) and with concurrent use of the N.S.A.I.D. (Indocid suppositories 100mg).'

81. The sentence is inconsistent with Dr Stewart's evidence and with common sense given the prescription of 75mcg/h on 29 June 2010. It is also inconsistent with the consultation notes obtained from Dr Stewart's practice which indicate that the deceased's

[24] t.34
[25] t.33
[26] t.41
[27] t.38

history on 29 June 2010 was that she was 'better on fentanyl than endone (oxycodone) not quite enough', and that the plan was for 'Fentanyl 75mcg/hour Patches 1 every 3 days'. Dr Stewart was unable to provide a reason for the sentence.

82. It is likely in my view that the sentence contains two inadvertent errors. It seems that the word 'adequate' was intended to be 'inadequate', and the figure '75' was intended to be '50'.

83. Dr Stewart was asked about his experience in prescribing fentanyl. He said that he had prescribed it 12 or 14 times over a 10 year period. He said that when he first started prescribing it, he would have always exhibited the most cautious approach to its initiation, but that approach changed over time so that he began to regard the MIMS as being the most cautious end of the usage. He had used fentanyl and other opioids beyond the recommendations on a case by case basis.[28]

84. To a large extent, Dr Stewart's experience reflects Professor Joyce's description of the shift from cultural caution to cultural permissiveness, though Dr Stewart was not aware of a change of that latter position by 2010.

85. From an objective view with the benefit of hindsight, it appears that Dr Stewart's prescriptions of fentanyl to the deceased were inappropriate. The initial dosage of 50mcg/h was too high, there was too short a time before the increase of the dosage to 75mcg/h and, given the deceased's history of prescription drug abuse, close monitoring of her condition was warranted. A warning about applying heat should also have been given.

86. However, in the context of the prescribing culture which existed at the material time with respect to fentanyl, it is difficult to conclude that Dr Stewart's care of the deceased was unreasonable. This is so even taking into account Dr Stewart's

[28] t.40

awareness of the deceased's previous abuse of prescription medication.

DID THE PRESCRIBED DOSAGE CAUSE THE DEATH?

87. As noted earlier, Professor Joyce noted that the deceased died from opioid toxicity from fentanyl, but he also commented on the apparent inconsistency between the amount of the deceased's prescriptions for fentanyl and the elevated levels of fentanyl found in the toxicological analysis. The blood concentration of fentanyl in the deceased was well above the concentration expected in a person of the deceased's weight who was using a 75mcg/h fentanyl patch.[29]

88. Accepting, as I do, Professor Joyce's opinions in relation to this issue, the question arises as to whether the amounts of fentanyl prescribed by Dr Stewart to the deceased were sufficiently high on their own to have caused her death, taking into account the relatively low amounts of opioids she had been taking in the week of so before she started on the fentanyl.

89. Professor Joyce was asked whether there was an explanation for the toxicity. He expressed the view that one possibility was that more than one patch had been applied at one time, but in his view even that would not explain on its own the concentrations that appear to have been present in the deceased after her death.

90. He thought that a second possibility was that heat had been applied to the patch, which could have substantially increased the rate of release of the drug.

91. Professor Joyce could not say whether the application of heat to the deceased from the shower after the patch had been removed would have had any effect, but as noted there was evidence that the deceased had gone to bed with a hot water bottle.

[29] Exhibit 1, Tab 17, p8

92. Professor Joyce was asked about the possible effect of the deceased having replaced a patch at a time earlier than prescribed. He said that no research had been done to find out how much of the dose was lying in the skin after a patch had been removed, and the patches are produced to systematically release, so he doubted that an early replacement of a patch would affect the dosage.

93. However, the current MIMS Prescribing Information for fentanyl contains the following statement:

> A pharmacokinetic model has suggested that serum fentanyl concentrations may increase by 14% (range 0-26%) if a patch is applied after 24 hours rather than the recommended 72-hour application.

So the possibility exists that, by changing her fentanyl patches early, the deceased increased the dosage she otherwise would have received.

94. The problems associated with the issues here are compounded by the evidence relating to the fentanyl patches found on the deceased prior to and after her death. There is no cogent evidence that the deceased had applied more than one patch at once.

95. It is apparent that Angus removed one patch from the left side of the deceased's abdomen on the night before she died, yet there was one there the following morning when the deceased was found. It may be that Angus failed to see that there were two patches when he removed one, but that seems unlikely given what he told Mrs Osborne about seeing only one.

96. It is also possible that the deceased applied a fresh patch at some stage after Angus removed the old patch, but that too seems improbable given her state and Angus' advice to Senior Constable Langton that he did not see the deceased put on another patch in

circumstances where he would likely have been able to see it occur.[30]

97. In the end, I am unable to determine with any degree of confidence how the deceased came to have the fatal concentration of fentanyl. It follows that I cannot determine whether the prescribed dosage itself was sufficient to lead to that result.

98. It does appear, as already mentioned, that the dosage was excessive given that the deceased would not have had much opioid tolerance when the fentanyl therapy began. However, the fact that the deceased had used 50mcg/h patches for four days without apparent problems suggests that the dosages were not lethal on their own.

99. It seems likely that the effect of the already high dosage was exacerbated by the application of heat from a water bottle provided to the deceased with the best of intentions. It may also have also been possible that the deceased entered the shower with a fresh patch on her abdomen and thereby applied heat to it, though that possibility was not sufficiently explored in evidence and remains speculation. And it may be that, in changing her patches prematurely, the deceased increased her dosages. One or any combination of these possibilities may have had an effect, but it is not now possible to know.

CURRENT PRESCRIBING OF FENTANYL

100. As noted, Professor Joyce considered that the culturally permissive era of fentanyl prescription has evolved back to a culture of caution in which doctors follow guidelines more appropriately reflecting the balance of risk and benefit from opioids.

[30] Exhibit 1, Tab 2

101. Dr Stewart said that he has prescribed fentanyl on two occasions since the deceased died. He was not asked about the details of those occasions.

102. In his view, the prescribing of fentanyl by doctors has lessened in the last 12 months in Australia because of the availability of other options in the form of oral medications. He said that he had been made aware of the potential hazards associated with fentanyl in the last six months.

103. Despite that welcome evidence, in my view it is appropriate for steps to be taken to ensure so far as is practicable that medical practitioners are aware of the potential dangers of prescribing fentanyl.

104. As it appeared from the evidence provided at the inquest that the MIMS is a common source of guidance for prescribing doctors, I considered whether would be appropriate for that service to ensure that its product information (or prescribing information) for fentanyl contain strong unambiguous warnings of the hazards associated with it. In particular, the apparent deeming of a person who has been taking opioids less than or equal to 25mcg/h of fentanyl to be opioid tolerant might be rectified.

105. Following the inquest, the Court contacted the company responsible for the MIMS, MIMS Australia Pty Ltd, which explained through its lawyers that the prescribing information published in the MIMS is governed by the Therapeutic Goods Administration Act 1989 (Cth) under which intending sponsors of medicine in Australia (usually the manufacturer or distributor) are obliged to provide prescribing information which must be approved by the Therapeutic Goods Administration (the TGA) and published on the TGA website before the medicine can be supplied in the Australia market. That TGA-approved prescribing information is reproduced in the MIMS, and an abbreviated

version consistent with the approved information is also provided as noted. Changes cannot be made to the prescribing information without the approval of the TGA.

106. The Court also contacted the TGA, which indicated that it is not currently considering any change to the product information for Durogesic as it does not have any evidence that inappropriate prescribing of Durogesic in opioid naïve patients is a significant issue in Australia. The TGA said that it continuously monitors reports relating to the safety of medicines available in Australia and would consider requiring the sponsor of Durogesic to make changes to the product information should such evidence become available.

107. Notwithstanding that advice from the TGA, I make the following recommendation with the apparent anomaly identified in paragraphs 56 and 104 above in mind.

RECOMMENDATION NO.1

The Therapeutic Goods Administration consider changing the product information for fentanyl transdermal patches to ensure that it contains no potential anomalies.

108. In addition, assuming that the product information in future does not contain any anomalies, I make the following recommendation.

RECOMMENDATION NO.2

Medical practitioners ensure that, in prescribing fentanyl transdermal patches, they follow closely the relevant prescribing directions.

FINDINGS AS TO THE CAUSE AND MANNER OF DEATH

109. The evidence makes clear that the deceased died as a result of bronchopneumonia as a complication from an overdose of fentanyl, and I so find.

110. There is no evidence to suggest that anyone other than the deceased applied the fentanyl patches to her skin.

111. Given that the deceased appeared to have no adverse effects from the dosage of 50mcg/h of fentanyl for about four days, it is unlikely that the prescription of 75mcg/h patches in itself was sufficient to have caused the deceased's death.

112. For the deceased to have had the concentrations of fentanyl found in her when she died, it is likely that she had applied more than one patch at once and/or had done something else, such as applied heat to the site of the patches, in order to have raised the fentanyl levels to a toxic level. It is also possible that, by applying new patches within less than 72 hours, the deceased raised the dosage she was prescribed.

113. Despite the deceased's history of alcohol and drug overdoses in the context of suicidal ideation, there is no evidence to suggest that she intended to take her life through the misuse of fentanyl patches.

114. In these circumstances, I find that the deceased died as a result of Accident.

B P KING
CORONER

3 July 2013