



CORONERS COURT OF QUEENSLAND

FINDINGS OF INVESTIGATION

CITATION: **Non-inquest findings into the death of SJM**

TITLE OF COURT: Coroners Court of Queensland

JURISDICTION: South Eastern Region, SOUTHPORT

DATE: 22/08/2016

FILE NO(s): 2012/2356

FINDINGS OF: James McDougall

CATCHWORDS: prescribed medication; Doloxene; narcotic pain relief; benzodiazepines; prescribing practices

Counsel Assisting, Ms Rhiannon Helsen, Coroner's Court of Queensland

Background

SJM was 57 years of age and resided with his wife at Bundall. He had a history of alcohol abuse, depression, type 2 diabetes, gout, insomnia and anxiety related issues for which he was being treated with a number of different medications by his long-time general practitioner, Dr JB. Dr JB and SJM were also friends.

In the days prior to his death, SJM had been suffering from the flu and had a fever. He appeared to be on the mend, however, on the evening prior to his death he suffered from a bout of diarrhoea.

On 8 July 2012, whilst having his breakfast with a houseguest, SJM became drowsy and started to slur his words. He woke his wife up at some time before 7:45 am, and appeared to be confused. She sent him back to bed as she thought he was too sick to be wondering around. His wife subsequently went out returning to the residence shortly before 9:00 am. She checked on SJM at around 10:00 am, at which time he appeared to be sleeping. When she checked on him again at midday, he was not breathing. The Queensland Ambulance Service ('QAS') were called and she commenced cardiopulmonary resuscitation. Despite further resuscitation efforts by QAS paramedics, SJM was unable to be revived and was pronounced deceased at 12:30 pm.

A number of different medications were subsequently located at SJM's residence and in his vehicle. These included Doloxene, a narcotic pain reliever and Alprazolam and Temazepam, which are benzodiazepines used to treat anxiety and sleeping issues.

All of the medications located were prescribed by Dr JB, with some dating back to 2009. Several packets, however, were dated 21 June 2012, some 17 days prior to SJM's death.

Autopsy examination

An autopsy was performed by Pathologist, Dr Dianne Little on 10 July 2012. A number of histology and toxicology tests were performed.

Toxicological testing of samples taken at autopsy detected the analgesic drug propoxyphene (Doloxene) at a blood level of 3.1 mg/kg, which is within the reported fatal range of 1-17 mg/kg. Dr Little notes that although this drug may go through post-mortem distribution, during which the blood levels may become falsely elevated after death due to leaching of the drug into the blood from other tissues, this problem is less pronounced with peripheral blood samples (as with the femoral vein blood taken in this case) than with samples of blood from the heart. The level of propoxyphene in the liver was 34 mg/kg, which is within the reported fatal range of 7.3-119 mg/kg and supports the diagnosis of a fatal level of propoxyphene. The toxic effects of propoxyphene include coma, convulsions, respiratory depression, low blood pressure and cardiac arrhythmias.

Toxicological analysis also detected the presence of Alprazolam at a blood level of 0.15 mg/kg, which is at the lower end of the reported fatal range of 0.12-2.1 mg/kg. The level of Alprazolam in the liver was 0.5 mg/kg, which is well below the reported fatal range of 2.4-9.2 mg/kg. Temazepam was also detected at a blood level within the reported therapeutic range.

Upon internal examination, the heart was found to be enlarged and dilated, with minimal degenerative disease in the main coronary arteries. Degenerative change was observed in the small artery branches within the heart muscle, a phenomenon that can be seen in diabetic patients. It was noted that the presence of this heart disease would have put SJM at an increased risk of developing fatal complications of the aforementioned drugs toxic effects.

Inflammation of the air passages was also found with a positive PCR for Influenza A. Dr Little expressed the view that this respiratory infection is unlikely to have played a significant role in the cause of SJM's death.

The cause of SJM's death was found to be mixed drug toxicity, with the predominant drug being propoxyphene.

Statement of General Practitioner, Dr JB

In a statement provided by Dr JB for the purpose of this coronial investigation, he notes that his last consultation with SJM was on 21 June 2012. He asserts that the medical conditions for which he was providing treatment to SJM at the time of his death, were as follows:

- Chronic lower back pain associated with degenerative disc disease;
- Type 2 diabetes;
- High Cholesterol;
- Hepatitis C with minimal abnormality of liver function tests; and
- Insomnia and 'stress' related to financial and business worries.

Dr JB states that SJM had given up regular drinking 'a long time ago'.

At the time of his death, SJM's was being prescribed:

- Galvument 50 mg/1000 mg twice a day for Type 2 diabetes;
- Crestor 20 mg 1 daily for Hypercholesterolemia;
- Doloxene 100 mg 1 capsule 4 times a day (max of 6) for back pain; and
- Temaze 10 mg 2 tablets at night for insomnia.

According to Dr JB, his reasons for prescribing Doloxene to SJM are as follows:

- SJM was familiar with this medication.
- It controlled his back pain and was considered a safe alternative to other medication.
- Other options tried, such as codeine and paracetamol combinations, had side effects and the potential to irritate his liver.
- Non-steroidal anti-inflammatory medications were ineffective in controlling his symptoms.
- Strong opioid pain medication was inappropriate for his degree of pain.

Dr JB states that he usually prescribed SJM the equivalent of 180 tablets of Doloxene a month, and that this would usually be in the form of 60 tablets with two repeats to minimise excessive use. He expressed concern regarding the possibility of SJM developing a tolerance and dependence to the medication, which he claims were discussed during each consultation.

Dr JB states that SJM had been issued with a medication reduction plan in February 2012, and he was referred to a Psychologist on 4 June 2012. Dr JB recalls that during his last consultation with SJM, he admitted to taking eight Doloxene tablets a day. He was subsequently instructed by Dr JB to keep a diary of his medication use.

Clinical Forensic Medical Unit review

On 14 May 2014, a Forensic Medical Officer (FMO), was requested to conduct a review of SJM's medical history. In doing so, the FMO reviewed various coronial documents, including

SJM's medical records, the findings of the autopsy report, the Form 1 prepared by the police and letters of concern provided by SJM's wife. The FMO subsequently provided a comprehensive report detailing her review.

Medical History

In relation to SJM's medical history, the FMO noted the following relevant information:

Paradise Centre Medical Centre records

- SJM attended the Paradise Centre Medical Centre from April 1999 until January 2012. All of his consultations were with Dr JB. On average, SJM saw Dr JB between 7 and 14 times a year.
- Records from the Paradise Centre Medical Centre document the following medical conditions:
 - 1997 – Hepatitis C (referred to liver specialist)
 - 2001 – Type 2 Diabetes (blood tests ordered and monitored)
 - 2004 – Insomnia
 - 2005 – Lumbar back pain
 - 2009 – High cholesterol
 - 2009 – Metabolic syndrome
- During this time, Mr JB addressed SJM's chronic health conditions, such as diabetes and hepatitis, as well as attending to emergent issues, such as episodes of gout and fractured ribs.
- The FMO noted, however, that the majority of consultations related to or involved SJM's insomnia, back pain, anxiety, substance abuse of drugs and/or alcohol, and family concerns. On a number of occasions, there was no reason given for the consultation other than to prescribe benzodiazepines, sleep inducing, and/or narcotic pain relieving medication.
- Dr JB started prescribing benzodiazepines (Temazepam) for SJM on 14 May 1999, which was his second visit, when he complained of difficulty sleeping.
- Dr JB first prescribed a narcotic pain reliever (Panadeine Forte) for SJM on 30 July 1999, when he complained of post-operative pain following a haemorrhoid operation two days previously.
- Dr JB first prescribed Doloxene for SJM on 25 March 2002, following a fracture to his forearm two days previously.
- The prescription history for benzodiazepines, hypnotics (sleep inducing agents), and narcotic pain relievers, are as follows:
 - 1999 – 16 of 21 prescriptions written
 - 2000 – 11 of 14 prescriptions written
 - 2001 – 8 of 12 prescriptions written
 - 2002 – 16 of 18 prescriptions written
 - 2003 – 1 of 1 prescription written
 - 2004 – 10 of 15 prescriptions written
 - 2005 – 20 of 21 prescriptions written

- 2006 – 24 of 24 prescriptions written
 - 2007 – 36 of 39 prescriptions written
 - 2008 – 39 of 39 prescriptions written
 - 2009 – 38 of 43 prescriptions written
 - 2010 – 42 of 45 prescriptions written
 - 2011 – 47 of 48 prescriptions written
 - 2012 – 1 of 1 prescription written
- SJM's medical records included several pages under the title, 'Previous Prescriptions' which documented in a list format the medications, which were prescribed by Dr JB on a particular date for the period of 14 May 1999 until 6 January 2012. The FMO subsequently cross referenced these prescriptions to the dates Dr JB had consultations with SJM. She found that there were many instances where drugs of dependency medications appeared on the list and were prescribed on a particular date without there being a computer record documenting a consultation or the prescribing medications for that date in the progress notes themselves. Generally, these instances followed shortly after a consultation where drugs of dependency had also been prescribed.
 - Recently in 2010, Dr JB prescribed SJM Doloxene and/or Temazepam on 6 occasions without a consultation. These prescriptions were provided within days of a documented consultation where prescriptions for these drugs had already been issued. In 2011, Doloxene and/or Temazepam were prescribed on 7 occasions without a consultation and within days of a previous prescription being provided.
 - Over the 13 years that Dr JB saw SJM, he documented the following concerns he had about substance abuse issues:
 - 1999
 - (i) 14 October, advised on appropriate use of medication. Prescribed Temazepam.
 - 2007
 - (i) 17 July, long counselling on dependencies. Prescribed Doloxene and Temazepam.
 - 2008
 - (i) 19 August, basically stopped drinking, using Doloxene as calmativ. Prescribed Doloxene and Temazepam.
 - (ii) On 10 December, going OK has some dependence. Educate on treatment and nature of condition. To make drug diary. Prescribed Doloxene and Temazepam.
 - 2009
 - (i) 20 October, mental health issues regarding excessive alcohol intake.

- 2010

- (i) 30 March, psychologically has settled down but takes too many Doloxene. Prescribed Doloxene, Temazepam and Panadeine Forte.
- (ii) On 27 May, absolute last script for Doloxene. Prescribed Doloxene, Temazepam and Stilnox. On 22 June, chronic problem. Prescribed Doloxene and Temazepam.
- (iii) On 17 August, discuss substance abuse. Doloxene average eight/per day, Temazepam four to six/per day, and Stilnox one at night. Prescriptions written for Doloxene, Temazepam and Stilnox.
- (iv) On 29 October, noted SJM was going to China for 10 weeks [only traveling for 10 days not weeks]. Anxiety disorder, has substance dependence. Temazepam changed from three at night to two at night, and Doloxene. Prescriptions added for Oxazepam 30mg twice a day and Xanax.

- 2011

- (i) 27 January, discuss reducing medication. Prescriptions for Doloxene, Temazepam and Stilnox.
- (ii) 14 April, discuss drug. Prescriptions for Doloxene, Temazepam and Stilnox.
- (iii) 29 April, Doloxene eight in morning, Zolpidem one at 10, Temazepam six. Anxiety disorder and substance abuse. Prolong counselling. Prescriptions for zolpidem one at night, Temazepam 10 mg two at night, and Doloxene.
- (iv) 7 June, has lost prescriptions he claims. Under considerable stress from financial loss. To reduce medication. Treatment plan medication diary reduction strategy. Temazepam ceased, prescriptions for Doloxene and Alprazolam.
- (v) 22 July, has successfully reduced a lot of medications, according to diary just using

Temazepam. Long counselling on relapse prevention. Prescription added for Temazepam.

- (vi) 29 July, under a lot of stress from court case. Anxiety disorder. Alprazolam and zolpidem ceased. Prescriptions for Doloxene and Temazepam.
- (vii) 30 September, still hasn't resolved legal problems and family problems. Not suicidal. Discuss medications. Prescription for Temazepam (which was increased from two a night to two or three a night) and Doloxene.
- (viii) 9 December, has attempted to withdraw from Doloxene, has weakness, lower back and knee pains, fatigue and decreased appetite. Prescriptions for Doloxene and Alprazolam.
- (ix) 30 December, sleep disturbances has improved, still has problems with Doloxene. Advised about lifestyle and priorities in life. Temazepam ceased. Prescriptions for Doloxene and Alprazolam.

- 2012

- (i) 6 January, discuss problems with medication.
- Dr JB wrote referrals to specialists or allied health practitioners regarding SJM on a number of occasions. In these, he did not include Doloxene as a current medication.
 - Dr JB completed a mental health plan regarding SJM on 20 October 2009. He documents that the reason SJM presented was to change his alcohol use and compliance with medication. In the medical consultation notes, Dr JB indicates that SJM has mental health issues regarding excessive alcohol intake and does not document any medication compliance issues.
 - Dr JB documented the diagnosis as anxiety and excessive alcohol use due to anxiety. He documented the use of sleeping tablets and that SJM had a very poor sleep pattern. He did not document the use of Doloxene.
 - A Mental Health Treatment plan was completed by Dr JB on 29 October 2010, in which he records that SJM's problems are anxiety, stress and 'unspecified'. Dr JB documented that SJM suffered from alcohol abuse and that he had normal sleep. The record of patient consent documented that SJM understood that the aim of the referral was to assist Dr JB in addressing his issues of anxiety, depression and alcohol, however, the document was not signed by

either Dr JB or SJM. SJM's significant dependence on Doloxene and benzodiazepines was also not noted.

- In a review of the Mental Health plan on 22 July 2011, Dr JB notes that SJM had reduced his intake of alcohol with less binges and that he was to continue his regular counselling.

Niecon Plaza Medical Centre records

- From February 2012 until June 2012, SJM attended the Niecon Plaza Medical Centre. He had eight consultations with Dr JB during this time.
- During a consultation on 4 February 2012, Dr JB noted that SJM had problems with medication dependence with Doloxene and Alprazolam, which they were slowly reducing. He prescribed Doloxene 100 mg 1-2 four times a day as needed, which is an increase from the amount he was prescribing SJM at the Paradise Centre Medical Centre.
- Dr JB saw SJM on the following further occasions in 2012:
 - 3 March, prescriptions written for Alprazolam and Doloxene.
 - 22 March, discuss use of medication. Prescriptions written for Doloxene and Alprazolam.
 - 10 April, Prescriptions written for Doloxene and Alprazolam.
 - 1 June, issues with pain killers. Prescriptions written for Doloxene and Temazepam after ceasing Alprazolam.
 - 4 June, has gout. Prescriptions written for Doloxene.
 - 21 June, Doloxene eight a day in divided doses for lower back pain and joint pain. Takes Temazepam at night. Discuss use of drugs to keep track of medications issued with pain. Generally doing better. Prescriptions written for Doloxene and Temazepam.

Information about the medications prescribed to SJM

In her report, the FMO provided relevant information regarding the medications supplied to SJM by Dr JB.

Benzodiazepines

Diazepam, Temazepam, Oxazepam and Alprazolam, all of which Dr JB prescribed to SJM at some time, belong to a group of drugs known as benzodiazepines. Benzodiazepines are central nervous depressants and are able to act as sedatives or hypnotics. They are used to treat insomnia, anxiety, muscle spasm, epilepsy and mania, among other conditions.

The function of the specific drugs which were detected in SJM's blood samples tested at autopsy are as follows:

- (i) Temazepam: A sleeping drug. It is only available on prescription and is supplied in 10 mg tablets intended for oral administration on a once nightly basis. The recommended dose is 10 to 30 mg at night. Temazepam was previously available in a 20 mg capsule, which Dr JB prescribed to SJM until April 2004. Temazepam should be used as adjunctive therapy for the short term treatment of insomnia. The recommended duration for treatment is 2 to 4 weeks.
- (ii) Oxazepam: Short-term relief of anxiety symptoms, and in acute alcohol withdrawal. It is also used as a hypnotic. It is only available by prescription in the form of 15 mg and 30 mg tablets. Oxazepam is also a metabolite of Temazepam. As Dr JB had not prescribed SJM Oxazepam since 2010, its presence in the samples taken at autopsy was likely to be as a result of his ingestion of Temazepam.
- (iii) Alprazolam: Used to treat anxiety and panic disorder. It is only available for prescription in the form of 0.025mg, 0.5 mg, 1 mg and 2 mg tablets. Daily dosages for anxiety is between 0.5 mg and 4 mg per day and on average about 6 mg for Panic Disorder, although in rare cases up to 10 mg/day may be necessary. The main effect of Alprazolam on the nervous system is sedation, producing a decrease in tension and anxiety, with drowsiness, slurring of speech, and muscle incoordination occurring at higher levels.

The FMO notes that the use of Benzodiazepines can lead to physical and psychological dependence even at recommended doses. The risk increases with higher doses and longer term use. Temazepam and Alprazolam have the potential to be abused and caution should be used in prescribing it to those who are addiction prone or have a known history of drug and/or alcohol abuse. Caution is recommended if Alprazolam is co-administered with propoxyphene, which can interfere with the Alprazolam's metabolism, thereby increasing its concentration and effect. The sedating effects of Temazepam and/or Alprazolam are additive if co-administered with other central nervous depressants, such as narcotic pain relievers and/or alcohol, and should be avoided.

Propoxyphene or dextropropoxyphene (Doloxene)

Propoxyphene is a weak narcotic drug and is used as an analgesic for mild to moderate pain. It is a central nervous system depressant. Propoxyphene is available as 100 mg capsules on prescription only. The recommended dose is 100 mg or one capsule every four hours as necessary up to a maximum of 600 mg a day. It is intended to be used for the relief of mild to moderate pain in patients who are not able to be adequately treated with other pain relievers.

Propoxyphene is broken down in the liver to an active metabolite norpropoxyphene, which has less central nervous system depressant effects than its parent drug. Propoxyphene and norpropoxyphene have local anaesthetic effects including on the heart, with the latter having the greater effect. This can lead to heart conduction defects and heart beat abnormalities and can cause sudden death.

The relatively long half-life (the time taken for 50% of the amount present in the body or a body compartment, such as the blood to be eliminated) leads to accumulation with chronic use, thus increasing the risk of a toxic reaction.

Propoxyphene causes euphoria and a sense of wellbeing and therefore is associated with abuse and chronic use. Tolerance and dependence, both physical and psychological, is seen with Propoxyphene. The drug has resulted in the death of a large number of persons in Australia and overseas. Its toxicity results from a combination of respiratory depression and its local anaesthetic effects on the heart.

Propoxyphene is contraindicated in patients who may be at risk of concomitant use of alcohol and in patients with abuse potential or history of alcohol or substance abuse. It is strongly recommended that patients taking Propoxyphene on a chronic basis should have a renal function blood test and an ECG performed at baseline at least every 3 months to monitor for increased risk. Additionally, Propoxyphene should be prescribed with caution to patients taking tranquilisers, antidepressants, or other central nervous system depressants, due to the additive depressant effects of these conditions and the risk of sudden death.

Consideration of statement of Dr JB

The FMO also considered the statement provided by Dr JB for the purpose of the coronial investigation. Relevantly, she noted the following:

- In his statement, Dr JB omitted to mention that SJM had been his long-time patient.
- He claims that SJM had given up regular alcohol use a long time ago. However, on 20 October 2010, Dr JB completed a Mental Health Plan and documented that SJM consumed six standard drinks three to four times a week. It was noted that SJM was concerned about his drinking and the reason for his presentation was to change his alcohol use.
- In the progress notes in the medical records from Niecon Plaza Medical Centre, Dr JB has not documented any cause or association for SJM's back pain, in particular that it was the result of degenerative disc disease. The records from the Paradise Centre Medical Centre indicate that SJM has back pain, but does not suggest a cause or association for this. The FMO notes that in the thirteen years SJM was seeing Dr JB, there was no documentation that he examined his back or spine, or that he referred him for any radiological investigations or a specialist to ascertain the cause of his chronic back pain
- There is no indication in the medical records from Niecon Plaza Medical Centre that suggested SJM was only to have six Doloxene tablets a day.
- Dr JB commenced prescribing Doloxene for SJM in March 2002, to assist with a fractured bone in his forearm. He continued to prescribe Doloxene for SJM up until his death. The first mention of SJM suffering from back pain wasn't until 26 July 2012. Medical notes indicate that SMJ continued to complain of back pain during a number of consultations in 2007, 2008 and 2009, which suggests that Doloxene was not adequately controlling his back pain, contrary to Dr JB's assertions.
- On 19 August 2008, Dr JB documented in the medical notes that SJM had basically stopped drinking and was using Doloxene as a calmativie. The FMO notes that this is not an indication for its use, and suggests that at the time, SJM was not suffering from back pain.

- Dr JB continued to prescribe Doloxene to SJM up until 21 June 2012. At the time, it was documented that SJM was taking eight Doloxene a day, in divided doses for lower back and joint pain. The FMO notes that this exceeds the recommended daily dose of six a day.
- From the medical notes it appears that Dr JB was aware that SJM had alcohol and other substance abuse problems involving central nervous system depressant medications.
- When Dr JB first prescribed SJM Doloxene on 25 March 2002, there was no documentation to suggest that he had suffered side effects from Panadeine Forte. On 9 December 2002, Dr JB prescribed Panadeine Forte for SJM when he complained of a toothache. One day later he prescribed Doloxene although no indication was documented for it. There is no indication in the medical records that SJM suffered any side effects from Panadeine Forte.
- The FMO was unable to find any documentation in the medical records from Paradise Centre Medical Centre or Niecon Plaza Medical Centre that Dr JB prescribed non-steroidal anti-inflammatory medication for SJM's complaint of back pain.
- The FMO examined the medication Police seized from SJM's residence, which indicated the following:
 - Temazepam: 10 mg x 100 tablets dispensed on 7 June 2012, with instructions to take two at night. As such, the bottle should have lasted SJM 7 weeks. Dr JB wrote SJM another prescription for Temazepam on 21 June 2012, only two weeks later.
 - Alprazolam: 2 mg x 50 tablets was dispensed on 7 June 2012.
 - Doloxene: 100 mg x 100 capsules dispensed on 21 June 2012, as 10 boxes each containing 10 capsules.
- The FMO also considered a PBS Patient Summary for SJM, from 1 March 2010 until 8 July 2012. There were no prescriptions for Doloxene, Temazepam, Alprazolam or Zolpidem recorded. This indicates that the prescriptions Dr JB was writing for these tablets was by way of a private prescription.
- The FMO noted that the prescribing of 100 tablets of Doloxene at a time was not consistent with Dr JB's assertion that he usually prescribed 60 tablets at a time, with two repeats to the equivalent of 180 capsules a month. With a private prescription, SJM could have obtained all of the capsules at once. In the FMO's view, if Dr JB had wanted to minimise the use of Doloxene, a prescription for much smaller amounts could have been written with no repeat, and SJM been asked to present for prescriptions at shorter intervals.
- Dr JB wrote prescriptions for Doloxene on 1 June 2012, 4 June 2012 and 21 June 2012. If all of the prescriptions had been written for 100 capsules, SJM could have obtained 300 capsules in a three week period. If SJM took 8 tablets a day (which exceeds the daily recommended dose) as Dr JB documented on 21 June 2012, he would have required 168 tablets in that timeframe.

- The FMO is of the view that there is no information in the medical notes provided by Dr JB, which supports his assertion that he tried to minimise SJM's use of Doloxene over the 10 years that he prescribed it to him.
- In relation to Dr JB's claim that he had concerns regarding SJM's tolerance and dependence on Doloxene, which he discussed in each visit, the FMO notes the following:
 - After prescribing SJM Doloxene in 2002, Dr JB saw him at the Paradise Centre Medical Centre on 96 further occasions.
 - The first any concerns in regard to dependencies was documented by Dr JB was on 17 July 2007, which is some 5 years after he had first prescribed Doloxene.
 - Further documentation is made of drug issues and dependencies, excluding alcohol, on 12 occasions from 2008 until January 2012. At Niecon Plaza Medical Centre, Dr JB saw SJM on 8 occasions, 4 of which he noted concerns regarding drug use.
 - According to the medical notes, after commencing SJM on Doloxene in 2002, Dr JB only discussed his concerns regarding dependency with him on 17 occasions of the more than 100 times he saw him.
- In response to Dr JB's claim that he issued SMJ with a medication reduction plan in February 2012, the FMO notes the following:
 - On 4 February 2012, Dr JB did document that SMJ had a problem with dependence on Doloxene and Xanax and a 'medication reduction plan' is mentioned, although no other details are provided.
 - When Dr JB saw SJM a month later on 4 March 2012, he prescribed the same dosing regimen of Doloxene and Xanax. There is no documentation in regard to the medication reduction plan.
 - Dr JB continued to prescribe Doloxene as per the previous dosing regimen to SJM, in March 2012, April and June. On 21 June 2012, which was the last consultation, Dr JB documented that he was to 'keep track of medications issued with pain'.

Importantly, the FMO stated that the use of Doloxene, particularly in doses higher than the recommended dose of a maximum of 600 mg or six capsules a day, when combined with other central nervous system depressants put SMJ at risk of an accidental drug related death. In the MIMS Annual 2002, which is when Dr JB started prescribing Doloxene for SJM, a contraindication to prescribing dextropropoxyphene was the current use of alcohol. Additionally, the MIMS Annual 2002 cautioned against prescribing dextropropoxyphene for

patients prone to dependency or use of alcohol in excess. It was also noted that use of dextropropoxyphene in excessive doses, either alone or in combination with other central nervous depressants including alcohol, was a major cause of drug related deaths. Despite it being contraindicated, Dr JB prescribed Doloxene to SJM and also prescribed it in combination with other central nervous depressants, such as Diazepam, Temazepam, Panadeine Forte, Zolpidem and Alprazolam.

Consideration of Next Of Kin concerns

The FMO was also asked to consider the concerns raised by SJM's wife in her correspondence regarding the coronial investigation. Those concerns were addressed throughout the FMO's report.

Concerns with Dr JB's prescribing behaviour

The FMO notes that Dr JB prescribed SJM with Temazepam for over 13 years. The use of benzodiazepines, including Temazepam and Alprazolam, can lead to physical and psychological dependence, even at the recommended dose. The risk increases with higher doses and longer term use. Temazepam and Alprazolam have the potential to be abused and caution should be used in prescribing it to those who are addiction prone. From Dr JB's medical notes, it appears that he was aware that SJM was prone to dependency and abuse with prescribed medications and that he had abused alcohol in the past.

Dr JB prescribed Temazepam to SJM to treat insomnia. It is not recommended for long term use, with the duration of treatment stipulated by the manufacturer as 2 to 4 weeks. The FMO notes that Dr JB did not appear to explore any underlying causes for SJM's insomnia or its nature.

Apart from the Mental Health Plan completed on 20 October 2010, there was no other documentation in the medical notes, which suggests Dr JB advocated additional therapies or alternatives to medication for the treatment of insomnia. The FMO opines that a referral to a psychiatrist, and/or addiction specialist could have been of benefit in a person with a long history of Temazepam use, as in SMJ's case. Whilst abrupt withdrawal of Temazepam in a person who is dependent on this medication would not be recommended, other strategies, such as reducing the dose over a number of weeks, or slowly tapering down the dose could have been employed. Restricting the number of tablets prescribed and only providing enough for a limited time could be used in conjunction with slowly reducing the dose.

Alprazolam is indicated for the short-term symptomatic treatment of anxiety. In the medical notes provided by Dr JB, there is no documentation to suggest that SJM had a diagnosis of a panic disorder. He was first prescribed Alprazolam on 29 October 2010, at which time Dr JB noted that he suffered from an anxiety disorder and 'substance dependence'. He was last prescribed Alprazolam on 10 April 2012.

Alternatives to benzodiazepines for the treatment of anxiety include antidepressant medications, which are generally safe, effective and not addictive. Dr JB stopped prescribing Alprazolam on 29 July 2011, and instead prescribed an antidepressant. However, on the 1 September 2011, the antidepressant was ceased and Alprazolam was restarted at a higher dose than previously provided.

The FMO notes that a referral to a specialist psychiatrist and/or psychological treatment could have been of benefit in a person who does not respond to short-term anti-anxiety medications, as was the case with SJM.

Doloxene is contraindicated in patients who may be at risk of abusing alcohol or have a history of substance abuse, as SJM did. As the drug causes a sense of euphoria and wellbeing it is often associated with chronic use and abuse.

Dr JB prescribed Doloxene for SJM from March 2002 until June 2012. It was commenced when he had a fractured forearm and prescribed at most visits, including the last visit shortly prior to SJM's death. Back pain was not mentioned in the medical notes until 26 July 2006. There was no documentation at that visit, nor any other visit, that Dr JB clarified the reason for SJM's back pain or examined his back or spine. It does not appear that he ordered any radiological investigations or made a referral to an orthopaedic specialist for assessment. Furthermore, there is no documentation in the medical notes that Dr JB discussed alternatives to Doloxene with SJM, such as simple non-narcotic pain relievers and/or anti-inflammatory medication. There is also no documentation to suggest that Dr JB discussed any additional therapies or alternatives to medication, such as regular gentle exercise or physiotherapy. The FMO notes that a referral to a pain specialist or an addiction specialist could have been of benefit in a person with long term dependence and over use of Doloxene, as in SJM's case.

The FMO expresses that view that it seems unusual that Dr JB did not include Doloxene in the list of medication included in SJM's Mental Health Plan completed on 20 October 2009, particularly, given medication compliance was one of the goals of the plan and Dr JB had expressed concern about dependency on two previous occasions.

The FMO notes that she is unable to explain why there are multiple instances where Temazepam, Doloxene and Zolpidem were prescribed on a particular date, however, there is no matching record in the computer generated progress notes.

In conclusion, the FMO states that the combination of several central nervous depressants taken together is known to increase the risk of drowsiness, excess sedation, respiratory depression, coma and eventual death. In SJM's case, the inclusion of Doloxene on a long term basis in a person known to overuse this medication, also carried the additional risk of cardiac arrhythmias and sudden death.

Actions taken by the Australian Therapeutic Goods Administration in relation to Propoxyphene (Doloxene)

Propoxyphene has been banned from use in Europe, the United Kingdom, New Zealand, and the United States due to concerns regarding fatal overdoses and heart arrhythmias.

In Australia in 2012, the Minister for Health and Ageing decided to cancel the registration of Di-Gesic and Doloxene ('the Products'), both of which contain dextropropoxyphene, on the basis that the safety and efficacy of the Products for the approved indications were unacceptable. However, the pharmaceutical company who makes the drugs, Aspen Pharmacare Australia Pty Ltd appealed this decision to the Administrative Appeals Tribunal of Australia ('the Tribunal').

On 15 June 2012, the Tribunal handed down its review of the Minister's decision as documented in *Aspen Pharmacare Australia Pty Ltd and Minister for Health and Ageing* [2013] AATA 649. Having considered the expert evidence provided and submissions from all the parties, the Tribunal determined that the Products were analgesic for mild to moderate pain, that the safety of the Products in therapeutic doses was similar to other weak opioids and not unacceptable, and that there was a subset of patients (those who require pain relief with a weak opioid but are unable to tolerate other weak opioids, such as codeine and tramadol) for whom there was no currently available and suitable alternative to dextropropoxyphene for mild

to moderate pain.¹ However, the Tribunal also made findings that dextropropoxyphene has been used for the purpose of deliberate suicide and that there were greater than usual risks of accidental overdose with the Products compared to other analgesics because of the relatively small variation between amounts prescribed for therapeutic use, and the amount sufficient to create a risk of serious adverse harm and even fatality.²

The Tribunal rejected the Minister's submission that the Products could be removed from the Australian Registrar of Therapeutic Goods with little or no concern because their removal would only negatively impact on a small handful of people. The Tribunal concluded that the quality, efficacy and safety of the Products would not be unacceptable provided that conditions under s.28 of the *Therapeutic Goods Act 1989* could sufficiently minimise the risk associated with their use, particularly the risk of overdose and the risk of self-harm.

Ultimately, the Tribunal found that the decision of the Minister should be set aside, and that Di-Gesic and Doloxene should remain on the Australian Registrar of Therapeutic Goods, with conditions imposed on its use. In an information bulletin published on 10 October 2013, the Therapeutic Goods Administration ('TGA') confirmed that it would not be appealing the AATA's decision to the Federal Court.

On 10 October 2013, new conditions on the registration and supply of dextropropoxyphene-containing pain killers Di-Gesic and Doloxene took effect. The conditions imposed by the Tribunal requires the sponsor to have arrangements in place designed to ensure that doctors and dentists sign a new Prescriber Confirmation form when prescribing Di-Gesic and Doloxene, confirming that they:

- Are aware that the medicine is only approved for use in patients not able to be adequately treated with other mild pain-killers.
- Have considered the contraindications for the medicine outlined in the product information and have explained them to the patient at the time of prescribing.
- Have considered any recent changes to the patient's clinical presentation or biochemical status.
- Have warned the patient at the time of prescribing about appropriate use of the medicine.
- Are satisfied at the time of prescribing that the patient's history does not indicate that the patient is at risk of accidental or intentional self-harm.

The conditions also require the Sponsor to have arrangements in place designed to ensure that the signed Prescriber Confirmation form is presented to the pharmacist dispensing these medications before supplying them to the patient. The conditions also provide for the auditing of pharmacies to ensure that the new forms are collected as required.

On 7 November 2013, the TGA approved variations to the Product Information documents for Di-Gesic and Doloxene. Within 30 days of this approval, the Sponsor was required to write to doctors, dentists and pharmacies advising when to start using the new form when prescribing Di-Gesic and Doloxene.

¹ *Aspen Pharmacare Australia Pty Ltd and Minister for Health and Ageing* [2013] AATA 649 at [2].

² *Aspen Pharmacare Australia Pty Ltd and Minister for Health and Ageing* [2013] AATA 649 at [2].

Family concerns

During the course of the coronial investigation, SJM's wife has raised a number of concerns regarding the circumstances of her husband's death, particularly the prescribing behaviour of Dr JB, who was also a personal friend. In particular, she expresses concern regarding the prescribing of large quantities of Doloxene to her husband, despite knowing that he had become dependent on the medication. She questions the soundness of Dr JB's decision to prescribe Doloxene at all, given SJM's medical history, which includes sustaining a head injury in 2011 and 2010, a history of alcohol addiction, previous seizures, and hepatitis.

SJM's wife also states that she was unaware her husband suffered from back pain, as she had no knowledge of him sustaining a back injury and he did not complain of any pain to her.

I have considered all the concerns and matters raised by SJM's wife during the course of the coronial investigation, when reaching my conclusions regarding SJM's death.

Referral to the Office of the Health Ombudsman

Following receipt of the FMO's report detailing Dr JB's concerning prescribing practices, particularly in relation to Doloxene, I referred the matter to the Office of the Health Ombudsman (OHO) for further consideration pursuant to its mandate to promote professional, safe and competent practices by health practitioners.

Conclusion

SJM was 57 years of age at the time of his death. He died as a result of mixed drug toxicity, predominantly propoxyphene (Doloxene), a narcotic pain relieving medication. At autopsy it was found that the level of Doloxene in SJM's blood sample was within the reported fatal range. Other notable medications, including Temazepam and Alprazolam, were also detected. It is known that the effects of Temazepam and/or Alprazolam are additive if co-administered with other central nervous depressants, such as narcotic pain relievers like Doloxene.

It is clear from the medical records I have obtained during the course of my investigation that SJM was treated by one general practitioner, Dr JB, for a period of 13 years. During this time, a majority of the prescriptions provided for SJM were for Doloxene and Temazepam. Dr JB continued to prescribe Doloxene to SJM for a period of 10 years, even though he was aware of SJM's history of alcohol abuse, which was clearly contraindicated to its use. Dr JB made little attempt to wean SJM from this medication, despite the fact that he knew SJM had become dependent upon it, and was using it in amounts well outside the recommended dosage.

SJM was prescribed Doloxene in combination with other central nervous system depressants for a prolonged period of time, which significantly increased his chance of sudden death. It is widely known that there have been many deaths associated with the accidental ingestion of excessive amounts of Doloxene in combination with such medication. Regardless, Dr JB continued to prescribe this dangerous concoction of medication frequently and in amounts that would enable misuse.

There is no evidence on the medical records provided that Dr JB made any attempt to ascertain the cause of any of SJM's medical complaints, for which these medications were continually prescribed. At no time during the 10 years SJM was prescribed Doloxene did Dr JB explore any alternatives to such medication, or make an appropriate referral to a pain specialist for assessment and management of SJM's chronic back pain.

I share the concerns expressed by the FMO in her comprehensive report regarding Dr JB's prescribing behaviour, and as such, have referred this matter to OHO for the appropriate assessment and disciplinary action.

Given the referral I have made to OHO, I am of the view that there are no further issues, which require investigation. As such, I propose to close the coronial investigation without proceeding to inquest.

James McDougall
South eastern Coroner
12 August 2016