



CORONERS COURT OF QUEENSLAND

FINDINGS OF INQUEST

CITATION: Inquest into the death of Timothy John

TITLE OF COURT: Coroners Court

JURISDICTION: Brisbane

FILE NO: 2013/1356

DELIVERED ON: 14 September 2017

DELIVERED AT: Brisbane

HEARING DATES: 29 September; 21 – 22 November 2016

FINDINGS OF: Mr John Hutton

CATCHWORDS: Coroners; Inquest; suicide; smoking cessation; Varenicline; Champix; Chantix; neuropsychiatric symptoms; precautions; product label; Consumer Medicine Information leaflet; Product Information document; routine forensic toxicology screening

REPRESENTATION:

Counsel Assisting: Mr Peter De Waard
(Coroners Court of Queensland)

Counsel representing Phoebe Morwood-Oldham (Mother of the deceased): Mr Adrian Braithwaite
(instructed by Jones of Russo Lawyers)

Counsel representing Pfizer Australia Pty Ltd: Mr Daniel Wallice
(instructed by DLA Piper Australia)

Counsel representing Dr Oliver Yang: Mr Andrew Luchich
(instructed by MinterEllison)

Table of Contents

INTRODUCTION.....	1
FINDINGS REQUIRED BY S. 45	2
FINDINGS ON THE ISSUES.....	2
Whether Champix contributed to Timothy's death	2
The adequacy of the care provided by the deceased's General Practitioner when prescribing Champix in the circumstances.....	2
The adequacy of the product labelling and instructions provided with Champix in relation to potential adverse neuropsychological effects	3
RECOMMENDATIONS.....	3
EVIDENCE, DISCUSSION AND GENERAL CIRCUMSTANCES OF DEATH.....	4
Timothy's background	4
Timothy's commencement of Champix.....	13
Timothy's death.....	23
Autopsy results.....	23
Does Champix increase the risk of suicide?	24
Did Champix contribute to Timothy's death?	27
Did Dr Yang provide adequate care when prescribing Champix to Timothy?.....	28
The adequacy of Champix product labelling and instructions (and recommendations).....	29
Warnings on the Champix packaging	30
Consumer Medicine Information leaflet.....	30
Product Information document.....	31
Other recommendations	32
Introduction of routine screening for Varenicline by forensic pathologists	32
A change to practices by prescribers.....	32

INTRODUCTION

1. Timothy John died through suicide on 17 April 2013 at 22 years of age.
2. I initially finalised this matter via 'chamber findings' on 12 May 2014. However, Timothy's mother applied to the State Coroner on 28 May 2014 to have the findings set aside because she considered that the cause of her son's death was an adverse and known reaction to Champix.
3. The State Coroner, Mr Terry Ryan, conducted a review of the matter and made some initial enquiries, including obtaining an opinion from the Clinical Forensic Medicine Unit. On 20 May 2015, the State Coroner directed me to re-open the investigation. I conducted extensive further enquiries, including:
 - a. Requesting further toxicology testing of Timothy's blood samples;
 - b. Gathering Timothy's medical records from a range of institutions, and reports from treating medical practitioners;
 - c. Obtaining records from the (then) Health Quality and Complaints Commission;
 - d. Requesting responses from Pfizer Australia Pty Ltd, the Therapeutics Goods Administration, the U.S Food and Drugs Administration, MIMS Online, and the Pharmacy Guild of Australia;
 - e. Obtaining a peer review report from an experienced General Practitioner;
 - f. Obtaining an expert report from a tobacco treatment specialist; and
 - g. Obtaining statements from Timothy's mother and brother.
4. I held an inquest from 21 – 22 November 2016. A comprehensive brief of evidence was compiled and distributed to the parties and I heard oral evidence from the following witnesses:
 - a. Ms Phoebe Morwood-Oldham (Timothy John's mother);
 - b. Dr Oliver Yang (Timothy John's General Practitioner);
 - c. Dr Robert Kable (an experienced General Practitioner who conducted a peer review of Dr Yang's care); and
 - d. Associate Professor Colin Mendelsohn (a Tobacco Treatment Specialist from the Australian Association of Smoking Cessation Professionals).
5. These findings address the following issues (and other related issues), which were identified at a Pre-Inquest Conference on 29 September 2016, namely:

- a. The findings required by section 45(2) of the *Coroners Act 2003*; namely the identity of the deceased person, how, when and where he died, and what caused his death;
- b. The adequacy of the care provided by the deceased's General Practitioner when prescribing Champix in the circumstances;
- c. The adequacy of the product labelling and instructions provided with Champix in relation to potential adverse neuropsychological effects; and
- d. Whether any recommendations can be made to reduce the likelihood of deaths occurring in similar circumstances or otherwise contribute to public health and safety or the administration of justice.

FINDINGS REQUIRED BY S. 45

6. Pursuant to s. 45(2) of the *Coroners Act 2003* (Qld), I find:

- | | |
|--------------------------------------|--|
| a. <i>Identity of the deceased</i> – | The deceased person is Timothy John. |
| a. <i>How he died</i> – | As per the circumstances outlined below. |
| b. <i>Place of death</i> – | Timothy died at 29 Oakville Street, Runcorn, in the state of Queensland. |
| c. <i>Date of death</i> – | Timothy died on 17 April 2013. |
| d. <i>Cause of death</i> – | The medical cause of Timothy's death was hanging. |

FINDINGS ON THE ISSUES

Whether Champix contributed to Timothy's death

7. I find that Champix contributed to Timothy's death. However, I am unable to determine the level of contribution that Champix had on Timothy's death due to his pre-existing mental health condition.
8. My reasoning is outlined in paragraphs 154 - 157.

The adequacy of the care provided by the deceased's General Practitioner when prescribing Champix in the circumstances

9. I find that Dr Yang did not provide adequate care to Timothy when prescribing Champix.

10. If Timothy's family had been informed by Dr Yang (or by warnings on or within the Champix packaging) about the need for Timothy to stop taking Champix and to contact a doctor immediately if he exhibited neuropsychiatric symptoms, it is likely that his family would have taken appropriate earlier action, and it is possible that Timothy's death may have been avoided.
11. My reasoning is outlined in paragraphs 159 - 162.

The adequacy of the product labelling and instructions provided with Champix in relation to potential adverse neuropsychological effects

12. I find that certain aspects of the product labelling and instructions provided with Champix are inadequate and some improvements can be made.
13. My reasoning and recommendations for improvement are outlined in paragraph 163 – 167.

RECOMMENDATIONS

14. Section 46 of the *Coroners Act 2003* (Qld) provides that a Coroner may comment on anything connected with a death that relates to public health or safety, the administration of justice, or ways to prevent deaths from happening in similar circumstances in the future.
15. I recommend that:
 - a. Pfizer Australia Pty Ltd (and Pfizer Incorporated), in consultation with the Therapeutic Goods Administration, make improvements to the Champix product labelling, Consumer Medicine Information leaflet and Product Information document (as outlined in paragraphs 163 - 167);
 - b. The general practice community take note of this case and ensure that before prescribing Champix to a patient, they provide direct advice to an appropriate family member, carer, or friend about the need to monitor the patient and for the patient to cease Champix and see a doctor immediately if they exhibit neuropsychiatric symptoms. If a patient is unwilling to consent to inclusion of a third party, consideration should be given to not prescribing the drug to the patient; and
 - c. All State and Territory forensic pathology services follow Victoria's lead and conduct routine toxicology screening for Varenicline in relation to suicides and suspected suicides.

EVIDENCE, DISCUSSION AND GENERAL CIRCUMSTANCES OF DEATH

Timothy's background

16. In order to determine whether Champix contributed to Timothy's death, it is first necessary to have a thorough understanding of his background.
17. Timothy was born on 25 February 1991 in Brisbane. He resided at his family home with his mother and father at Balonne Street in Runcorn.
18. About two weeks after his birth, Timothy's parents separated. His mother was given sole custody of Timothy and his older brother, Peter. His mother worked as a Special Education teacher to support them. She had a very close relationship with her boys. Timothy's father's involvement in Timothy's life was described by his mother as 'occasional'.
19. In 1996, Timothy began year 1 at the age of five at Warrigal Road State School. His mother was working at the same school. Timothy started tennis and he was described by his mother as 'very sporty'.
20. In 2000, when Timothy was in year 4 and nine years of age, he moved schools to Runcorn Heights State School, because the school was closer to their home.
21. In 2001, when Timothy was in year 5 and 10 years of age, he moved schools again. This time to St Laurence's College in South Brisbane.
22. In 2003, when Timothy was in year 7 and 12 years of age, he was allegedly subjected to bullying at school. He told his mother that the reason for the bullying was that she wouldn't let him play rugby. On one occasion, Timothy was allegedly punched in the head and concussed. Timothy's mother complained to the police, but Timothy told his mother that it only made the bullying worse.
23. Timothy became a State tennis player and was doing well at school until year 8. In 2004, when Timothy was in year 8 and 13 years of age, he started drinking and smoking, unbeknown to his mother.
24. In late 2005, when Timothy was in year 9 and 14 years of age, he was suspended from school and received a warning from the police for bringing a knife to school. He subsequently moved schools to Macgregor State High School.
25. It was at this time that Timothy appears to have joined an Asian gang at Garden City in Brisbane. In his 'auto-biography' (that he wrote during an Adolescent Drug and Alcohol Withdrawal Service intake at the Mater Children's Hospital on 10 April 2007), Timothy stated that when he went to Macgregor, he made friends fast but it was with the popular group. He came to know 'gangsters' and 'hoodlums' from Garden City and became close with them because they would 'back him up in a fight'.

26. In December 2005, just after Timothy finished year 9, Timothy's mother had a 'stroke of luck'. She won an RSL Art Union prize, which included a house at Burleigh Waters and \$200,000 in gold bullion. She sold the prize house at Burleigh Waters but kept the electronic gadgets for Timothy.
27. Timothy wrote in his autobiography that after his mother won the house at the coast, for the first time in his life, he had money. He was 'the happiest a person could be'. He was 'popular, rich, and strong with backup' (referring to his gang). He 'had a family that loved him'.
28. However, in February 2006, when Timothy was in year 10 and just before he turned 15, there was an unfortunate turn of events. The Plasma TV that Timothy's mother had kept for him from the prize house 'blew up' and caught their family home on fire. They lost their home and all of their life possessions. They were insured, but under-insured.
29. Timothy's family were forced to move in with a family friend, in cramped conditions, for a few weeks until his mother was able to purchase another house at Oakville St in Runcorn. At this time, Timothy broke up with his girlfriend and began dating her friend. He became withdrawn, and began 'wagging school' and 'hanging out' with his gang at Garden City. His mother spoke with the school Principal about it and took Timothy to the school office each morning, only to receive an automated text message from the school later each morning that he was absent from school.
30. It would appear that as a result of the circumstances of the house fire, Timothy developed anxiety. He told his mother that he felt anxious inside buildings and needed to get out of the 'four walls'. He was fearful that the computer labs at his school would also catch fire. He also became anxious around strangers and different situations. Although the family had some support from a local priest and a family friend, Timothy and his family did not take up the family counselling that was offered to them, nor did Timothy seek medical help for his condition.
31. Timothy left home around this time, at the age of 15. His mother had deposited \$40,000 into his bank account after her RSL winnings, partly to pay for new furniture in his bedroom. Instead, Timothy withdrew all of the money, allegedly with the help of one of his friend's mothers, and 'went on a bender'.
32. Timothy reflected about this period of time in his auto biography:

It didn't seem in the so called real world that I had lost everything, but in the mind, body and spirit I had. I watched it all burn right in front of my eyes, but I couldn't cry. I didn't want people to think I was weak, so I masked it as if nothing had happened.

In my mind at that point, I was blind. I thought my gang was all I had left. I wasn't there for my family when they really needed me most. Instead, I would try to be around my gang 24/7. They were my support, my

protectors, the people that were there for me. They meant everything. Popularity, the group, the gang. I spent money on them.

At this point I left home so I could be with the gang 24/7. They had no arguments. They saw dollar signs and the money evaporated. I was left with nothing but a gangster in a house, a prison if you will. I had so many enemies because of the monstrosities I had committed and no back up. No guards, no money. Nothing except court cases coming out of my ears... I felt like slitting my throat so often because of what I [had] done to others and my blood, the people who love me the most. I think because I don't want people to remember me, I wish I never existed, that there is no trace of my ever being born. Who knows maybe this is all a dream and I am already dead just stuck in hell. I wait for the day I awake and all this shit comes to an end.

33. In April 2006, Timothy was charged by the police for alleged assault. His ex-girlfriend reported him for allegedly stealing her watch, which his mother stated she saw her give to him as a gift when he had lost his watch in the house fire. Timothy's medical notes indicate that he reported to his doctor with injuries on 24 April 2006 after an altercation with a 'known female'.
34. Timothy's mother alleges that his ex-girlfriend and her two brothers were involved with a Lebanese gang. They came around to their new house in Runcorn on two occasions. The first time, Timothy wasn't home and they allegedly threatened to rape her. The second time, they came around and allegedly assaulted Timothy. Timothy's ex-girlfriend then alleged to the police that she was the one who was assaulted.
35. In mid 2006, Timothy moved back home and returned to Macgregor State School in an attempt to finish year 10. However, he was allegedly involved in a fight at school and he was suspended from school soon after. His mother decided that he was better off in a vocational program and enrolled him in a TAFE mechanical and engineering pre-apprenticeship program.
36. In December 2006, Timothy's original family home was rebuilt and they moved back in. Timothy's mother stated that he seemed happier and more settled there.
37. In early 2007, Timothy's mother sent him off to boarding school at Scots College in Warwick to get him away from 'undue influences' in Brisbane. However, Timothy only lasted there for around seven weeks. He was leaving the school grounds and going to the local hotel, returning to school intoxicated. Timothy was suspended from school. Although he was entitled to return, his mother decided not to send him back.
38. On 23 March 2007, Timothy's mother took him to see a General Practitioner, Dr Aboobaker Khatree, at the Beenleigh Road Medical Centre in relation to his drinking issues at school. She requested that he be sent to the Belmont Hospital for treatment. Dr Khatree referred Timothy to the Mater Hospital. The reason for the referral was noted as an 'alcohol and smoking problem'. However, in oral evidence at the inquest,

Timothy's mother stated that she was not aware at that stage that Timothy had also been smoking.

39. From 10 – 19 April 2007, at the age of 16, Timothy was admitted to an inpatient program for detoxification at the Mater Children's Hospital Adolescent Drug and Alcohol Withdrawal Service (ADAWS).
40. According to Timothy's Mater Children's Hospital medical records, he reported on 13 April 2007 that he had not disclosed the full extent of his alcohol and drug use during his intake because his mother was present. He reported:
 - a. Drinking a minimum of 2 – 6 cans of mixed spirits or beer daily;
 - b. Binge drinking every 3 – 4 days with 1 – 1.5 x 750mL bottles of spirits;
 - c. Smoking 4 – 6 'cones' of marijuana most weekends; and
 - d. Using ecstasy 'fairly regularly'.
41. Timothy was adamant that he wanted this information to be kept confidential from his mother and it is clear from his mother's evidence during the inquest that she has no awareness of this.
42. There is also mention in the intake documentation that Timothy talked about suicide but it was noted that this was a 'cry for help rather than an attempt'. Again, Timothy's mother had no awareness of this. Timothy had never spoken to her about suicide.
43. As part of Timothy's treatment at the Mater Children's Hospital, he commenced seeing a Psychiatrist, Dr Deborah Weins. Dr Weins stated that she conducted a mental health and addiction review for Timothy. However, her role was to advise and support him in his battle with substance misuse, not to treat possible psychiatric conditions. Timothy told her at the time that he had become involved in substance misuse from year 8 and was asked to leave school for fighting and carrying a knife (although I note that this actually occurred late in 2005 whilst Timothy was in year 9). He became involved with local gangs, which provided an identity and aggression outlet. Dr Weins is of the belief that Timothy's forensic issues followed from there.
44. Dr Weins stated that Timothy had a lengthy history of problems with anger made worse by substance abuse. He had a hostile/dependent relationship with his mother, which he worked on and which had improved over time. Dr Weins stated that between April and September 2007, Timothy's behaviour had improved.
45. After Timothy's discharge from the Mater Children's Hospital, Timothy's mother took three months long service leave to help him settle back into his normal life.

46. Timothy attended a volunteer program named 'Headspace' once a week, and he enrolled in TAFE, in order to finish year 11 and 12 of his schooling. However, he did not complete his studies. It would appear that he had become fearful after seeing his ex-girlfriend at the Logan TAFE campus and another person involved in a Lebanese gang, who had just been released from jail. This person had allegedly demanded protection money from Timothy. Timothy did not wish to be caught up in all of that again.
47. On 29 May 2007, Timothy was tried in the Brisbane Children's Court for charges of assault in company, grievous bodily harm in company, and theft of a mobile phone. Timothy's mother stated that they were able to prove that Timothy had not stolen his ex-girlfriend's watch and so all of the charges were dropped as well.
48. On 12 June 2007, Timothy's mother took him to the Beenleigh Road Medical Centre to see her preferred General Practitioner, Dr Brett Fordyce, for a referral to a psychiatrist. She stated in oral evidence that the reason she did this was for his alcohol issues. Timothy was referred to Dr Robert Bell, a psychiatrist specialising in addiction. The referral letter refers to 'depression' as the reason for the referral. However, Timothy's mother denies that Timothy had depression. She stated that it was her understanding it was Dr Fordyce's practice to note 'depression' down as the reason for all of his referrals to psychiatrists and that he had done this for her after Timothy's death also when she wished to speak with Dr Bell about her son's death.
49. Dr Weins stated that in September 2007, Timothy had found out that the man he believed to be his biological father was not. Dr Weins noted that this destabilised Timothy within a few months of the news. However, Timothy's mother stated in oral evidence that she never noticed any difference in Timothy in relation to this news. She had been placing newspaper ads in New Zealand to find a family contact due to losing the information in the house fire, as Timothy wished to travel to New Zealand to find his biological father. Timothy never did locate his biological father before he died.
50. On 10 October 2007, Timothy's mother informed the ADAWS and Headspace Programs that their program had been a success. She informed them that Timothy had transformed, he had made positive changes, and his communication has greatly improved. She stated that she wished she had before and after photos both of Timothy and his bedroom, which was now neat and tidy.
51. However, on 16 October 2007, Timothy's mother advised ADAWS that he had 'fallen back in with his gang'. Dr Weins stated that at this time, Timothy had relapsed to alcohol and marijuana. Dr Weins was of the opinion that this later appeared to fuel his paranoia around gang involvement.
52. On 5 December 2007, Timothy's mother advised ADAWS that he had seen a number of Lebanese gang members known to him outside a 'Fitness First' gym and that it had worried him to the point where he had asked her to drive through a red light and to collect him from Headspace

earlier than usual. The gang members were allegedly brothers of Timothy's ex-girlfriend who were drug dealers.

53. On 5 August 2008, Timothy reported to the Headspace program in a 'disguise'. It was noted that he had long hair under a cap and sunglasses. He informed the staff that he did not wish to be recognised by old gang members. Timothy was noted as having presented with a faint smell of alcohol under his breath but he was not intoxicated. In oral evidence, Timothy's mother questioned the accuracy of the Headspace notes because she does not remember Timothy ever having long hair or wearing sunglasses.
54. Timothy's mother also took exception to the term 'paranoia', which Dr Weins had used to partially describe her son's behaviour at the time. In her view, Timothy's fears around gang involvement were genuine and real. She had also been personally subjected to threats by these people, so she knew they were real. This would appear to be correct. Timothy could perhaps more accurately be described at the time as 'anxious'.
55. In 2009, Timothy moved to Adelaide. Whilst in Adelaide he was charged by police with assault and other related offences. He later returned to live with his mother in Brisbane.
56. On 22 March 2010, Timothy went in to the Beenleigh Road Medical Centre to see a General Practitioner, Dr James King. The medical notes indicate that Timothy was diagnosed with Chronic Bronchitis and Urticaria (hives). Timothy advised Dr King at that time that he had stopped smoking.
57. On 25 March 2010, Timothy's mother took him in to see another General Practitioner, Dr Robert Fordyce. The reason for the visit is recorded in Dr Fordyce's notes as 'PTSD'. Timothy was referred once again to his psychiatrist, Dr Robert Bell. The referral letter states that the reason for referral was 'depression'. Dr Fordyce also wrote a letter for Timothy indicating that he required distance education due to a medical condition. Timothy's mother stated that the medical condition being referred to was 'anxiety'. As before, Timothy's mother denies that Timothy was suffering from depression. She explained in oral evidence that this was just Dr Fordyce's general practice. She stated that the reason for the referral to Dr Bell was to obtain a report for the purposes of Timothy's upcoming court proceedings.
58. Timothy saw Dr Bell on six occasions in 2010. Dr Bell stated that although he had previously diagnosed Timothy with a 'major depressive disorder', he was at that time of the opinion that Timothy's ongoing problem was more one of anxiety. He stated that Timothy did not require medication. His treatment was more focused around therapy and support.
59. Timothy's mother stated in oral evidence that although she never went in with Timothy to his appointments with Dr Bell, she had been advised by Dr Bell that he was treating Timothy for addiction, not depression or a major depression disorder. She was, however, aware that Timothy had anxiety. She was under the impression that Timothy had initially been

given antidepressant medication for his anxiety but that he was taken off the medication because he couldn't get his thoughts together and the medication made him stutter.

60. From August 2010 to February 2012, Timothy undertook his schooling via distance education. He attended classes once a week and his progress was monitored by a family friend. Timothy's mother advised that he did end up completing year 11, but not year 12. He also obtained a certificate 1 in Information Technology.
61. From February until Christmas 2012, Timothy commenced helping his mother with volunteer work at a political party. During the other two days that his mother would volunteer, they would go out together for lunch and a drive. Timothy's mother stated that she did not notice any concerns regarding Timothy's mood or behaviour during this time. He was quite happy.
62. At the end of 2011, Timothy moved out of his mother's house and into his brother's house in Runcorn. It was around this time that Timothy's mother first became aware that Timothy had been smoking. This is because he had fainted one day whilst using Nicorette spray. He never used the spray again. Timothy's mother is of the understanding that Timothy first started with the aid of Nicorette patches, then gum, then spray. However, she seemed confused as to the order, during her oral evidence. In any event, it would appear that Timothy had tried a number of things to reduce his smoking. He successfully reduced his smoking down from around a packet a day to around seven cigarettes a day.
63. Sometime in 2012, Timothy changed his last name by deed poll. Timothy's mother stated that he did this because he was embarrassed about his (non-biological) father. She alleges that on one occasion, Timothy's father had asked him to pretend that he was his older brother and had been driving, so that his father didn't get booked for drink driving. She also alleges that Timothy had been asked by his father to steal things from a bike shop where they had worked together.
64. In early September 2012, Timothy attempted to move back to Adelaide because he wanted to be more independent. However, he was only in Adelaide for two days, before he flew back to Brisbane. Timothy's mother has advised that whilst in Adelaide, Timothy reported details of his previous gang association to the Australian Federal Police and to Centrelink. He provided evidence of the gang structure and the people involved. The next evening, Timothy phoned his mother and told her that he thought that someone was coming to get him. His mother advised him to call the police, so he did. When the police arrived, they asked him if he had anything in his possession that he shouldn't have and he told them he had two knives under his mattress. Timothy's mother explained in oral evidence that she was actually with Timothy when he had earlier purchased the knives in Sydney. They were not typical knives. They were a set of two and he was interested in them. Timothy spent the night in prison in Adelaide.

65. Upon his return to Brisbane, Timothy told his mother that whilst he in Adelaide overnight, he got drunk and someone injected him with amphetamines. Timothy's mother believed him because she saw a large lump on his arm and she was of the belief that the direction and location of the needle mark indicated that he would not have injected himself.
66. On 22 September 2012, Timothy's mother took Timothy in to the Beenleigh Road Medical Centre to see a General Practitioner, Dr Suong Hoang. The medical notes indicate that the reason for the visit was that Timothy's mother had found him after he had fallen off a two-metre balcony whilst intoxicated the night before. Timothy could not remember what had happened and he was not sure whether he had lost consciousness.
67. On 26 September 2012, Timothy's mother took him in to the Beenleigh Road Medical Centre to see a General Practitioner, Dr Oliver Yang. This was the first time that Dr Yang saw Timothy but he later became Timothy's preferred doctor. Dr Yang referred Timothy to his psychiatrist, Dr Bell. In the referral letter, Dr Yang stated that the reason for the referral was regarding the diagnosis and management of "mixed depression, anxiety and drug abuse". Timothy's mother stated that she asked for the referral due to Timothy's issues with anxiety, alcohol, and drugs (referring to the Adelaide incident only). She denied that Timothy had depression.
68. On 28 September 2012, Timothy once again began seeing his psychiatrist, Dr Bell. Dr Bell stated that Timothy advised him that he had moved back to Adelaide in an attempt to start a new life but he "started using both amphetamines and cannabis on a regular basis". He was also facing criminal charges. He had returned to Brisbane to live with his mother to address his problems. In oral evidence, it was clear that Timothy's mother was not aware of the true nature of Timothy's drug use, as reported by Timothy to Dr Bell. She questioned how Timothy could have been regularly using amphetamines and cannabis in Adelaide if he was only there for two days. However, it would appear that his drug usage was not just confined to his time in Adelaide and Timothy's mother was perhaps somewhat naive as to the true extent of Timothy's drug abuse.
69. On 6 March 2013, Timothy again went into the Beenleigh Road Medical Centre and saw Dr Yang, but this time in relation to his blood results. The results indicated that he had an abnormal liver function. According to Dr Yang's notes, Timothy reported to him that he had used a lot of drugs such as Amphetamines and Cocaine but the last time he used drugs was in September 2012.
70. On 14 October 2012, Dr Bell admitted Timothy to the Belmont Private Hospital to undertake an intensive Cognitive Behaviour Therapy. The reason was to help address Timothy's drug use issues, as well as his underlying and long-standing anxiety symptoms. By this time, Timothy was 21 years of age. He attended the program for three weeks.
71. Upon admission to the Belmont Private Hospital, the medical notes indicate that Timothy advised a Registered Nurse that four to five years

earlier, he had attempted to overdose on panadol because “life was really bad”. This is confirmed by Timothy’s response in his pre-admission documentation dated 1 October 2012, where he indicated that he had previously attempted suicide and that he “tried to kill himself by taking heaps of pills”. Timothy was assessed by the nurse as seeing self-harm as an “act of self-soothing”. However, he advised that he had never done this in the past. When this information is interpreted in conjunction with the autobiography that Timothy wrote whilst in ADAWS, it seems clear that the trigger for these thoughts and possible suicide attempt was the house fire, his anxiety, and his abuse of alcohol and illicit drugs.

72. Timothy’s mother stated in oral evidence that she did not know anything about her son’s past suicide attempt and she had never noticed any marks or indication that Timothy was self-harming (other than the night before his death). She stated that Timothy was “very particular about the way he looked”.
73. Timothy’s Belmont Private Hospital admission notes provide a useful snapshot of how he was feeling at the time of admission. Timothy indicated that in the two weeks leading up to his admission, he was a nervous person all of the time, he felt down in the dumps and could not cheer up most of the time. He did not feel calm or peaceful at any time, he felt let down most of the time, he was a happy person a little of the time, and he felt tired most of the time. Timothy rated his feelings as follows: he felt scared without any good reason, he felt he was using a lot of nervous energy, he felt down hearted and blue, he found it hard to wind down, he was in a state of nervous tension, and he found it difficult to relax.
74. Timothy’s mother stated in oral evidence that from her perspective, Timothy could have had these feelings going into the Belmont hospital program because he was going into the program against his will. She explained that although he was 21 years of age, he was still living with her at the time, and she wanted him to do the program. “There was no choice”.
75. On 2 November 2012, upon discharge from the Belmont Private Hospital program, Timothy again rated his feelings. The majority of his scores were markedly lower than on admission. According to the Cognitive Behavioural Therapy Program Self-Assessment, Timothy had reduced his anxiety levels from ‘extreme severe anxiety’ to ‘moderate anxiety’; his depression levels from ‘severe depression’ to ‘mild depression’; and his stress levels from ‘moderate stress’ to ‘mild stress’.
76. Dr Bell stated that Timothy had an unremarkable stay in hospital and felt a great deal of benefit from the program. The discharge plan was for Timothy to follow up in Dr Bell’s rooms. However, Timothy did not attend any of his appointments with Dr Bell after discharge.
77. Timothy’s mother stated that after the Belmont Hospital program, it was “like someone had waved a magic wand over him”. He wasn’t drinking (except a limited amount on social occasions), he had quit drugs, and he had cut down on his smoking. Timothy went back to volunteer work with

her at the political party and was working really well. He started going to church with her every Sunday. He was no longer 'drifting'. He had goals, which included a fixation on getting a job, and to get some stability again in his life.

78. Timothy's mother's evidence about Timothy's determination is supported by a letter that Timothy gave to her for Christmas in 2012. Timothy wrote:

Mum

I love you more than anybody else. You truly are the best Mum in the world. I have been a disappointment and a bastard the last couple of years; and what [unreadable] me the most; is the fact that I've [unreadable] you so much. I can't afford to give you a worth while present this year so instead I'm going to give you a promise. I promise you Mum, that this year I will fix my life and do you proud. I promise you Mum that I will try my best to be a good son and not some wanna be crook. I love you Mum.

79. On 18 January 2013, Timothy's mother took him in to the Beenleigh Road Medical Centre to see Dr Yang. The purpose of the visit was to address Timothy's dust mite allergy so that he could get a job. Dr Yang put Timothy onto a desensitization treatment program, which began on 30 January 2013, and required Timothy to come in once per week for injections.
80. Later on 18 January 2013, Timothy binge drank (according to information he provided to Dr Yang on 6 March 2013). Timothy advised Dr Yang on 6 March 2013 that this was the last time he binge drank. Timothy's mother confirmed this in oral evidence. She explained that this occasion was an exception because it was her birthday and they were celebrating on the night in question.

Timothy's commencement of Champix

81. On 3 April 2013, Timothy saw Dr Yang in relation to his weekly desensitisation treatment.
82. Timothy's mother stated in oral evidence that she did not go into the Beenleigh Road Medical Centre but they discussed his appointment afterwards. Her recollection is that Timothy had told her that Dr Yang had discussed with him how the desensitisation treatment was going and asked him whether there was anything else he was having troubles with. Timothy told his mother that he felt like he had to say something so he informed Dr Yang that he was having difficulty giving up smoking. Timothy advised his mother that Dr Yang told him that he had medication for that but he had to get permission to give it to him and to come back the next week and he would give it to him.
83. There is no mention in Dr Yang's notes on 3 April 2013 about Champix or Timothy's desire to quit smoking. Dr Yang stated in oral evidence that he didn't think the discussion occurred at this time because it is not his

practice to advise patients about Champix and then prescribe it one week later. He usually prescribes Champix on the same day as the consultation as it only takes him a few minutes to phone for approval before prescribing the drug.

84. It is possible that a discussion about quitting smoking between Dr Yang and Timothy began on 3 April 2013 but nothing really turns on this evidence. It is clear that Timothy was motivated to quit smoking by 10 April 2013. He had tried other drugs such as Nicorette gum and spray, with some success. He had reduced his smoking from approximately 20 cigarettes a day to seven cigarettes a day whilst on the Nicorette spray. However, he had not able to reduce his smoking to zero and he experienced an episode of fainting when taking the Nicorette spray. He was seeking an alternative solution to help quit smoking entirely.
85. On 10 April 2013, Timothy saw Dr Yang again. Dr Yang's notes for that appointment are as follows:

Surgery consultation recorded by Dr Oliver Yang on 10/04/2013

*1 desensitization
2. asks for champix
never took Champix before
he told me that he still has anxiety
but not suicidal or homicidal
lives with his brother who does (sic) not smoke*

I explained that Champix may make his psychiatric symptoms (sic) worse, and he needs to cease the medication and see a doctor if this is the case

The patient expressed his understanding of this

*Diagnosis:
Smoking cessation*

*Reason for visit:
Smoking cessation*

*Actions:
Prescription printed: Champix Starter pack 0.5mg x 11; 1mg x 42
Tablet(Varenicline) 1 As directed*

86. Dr Yang has provided an explanation of this appointment on four occasions: in a letter to the Health Quality and Complaints Commission (in response to a complaint made by Timothy's mother) dated 5 February 2014; in a letter to the State Coroner (responding to a request for information) dated 22 January 2015; in a self initiated statement to me dated 14 November 2016; and in oral evidence at the inquest on 21 November 2016.

87. In his letter to the Health Quality and Complaints Commission and his first

statement to the State Coroner, Dr Yang provided the same summary of the care he provided. He stated as follows:

- a. On 10 April 2013, Timothy requested a script for Champix, having expressed his desire to quit smoking;
 - b. Timothy stated that he had a diagnosis of PTSD for a number of years;
 - c. Despite the diagnosis of PTSD, there were no details in relation to the diagnosis or management on his file;
 - d. Timothy had not been prescribed Champix in the past;
 - e. Prior to prescribing the Champix to Timothy, Dr Yang indicated that the medication may have an adverse effect on his mood and behavior and may increase the likelihood of mental illness;
 - f. Timothy indicated on questioning that he had no suicidal thoughts or ideation. He lived with his brother and did not live alone;
 - g. Dr Yang discussed with Timothy options for smoking cessation and the requirement to undertake smoking cessation counseling;
 - h. As Champix was not contraindicated in Timothy's circumstances, Dr Yang prescribed the medication; and
 - i. Dr Yang advised Timothy of the potential adverse effects and indicated that if he experienced any adverse effects such as mood changes, he was to cease the medication and present for review. Timothy acknowledged these instructions and understood the side effects and directions.
88. In his statement to me, Dr Yang advised that he only had a limited recollection of the particular consultation. He had therefore reviewed Timothy's medical records held by the Beenleigh Road Medical Centre in order to provide an additional statement. Dr Yang provided the following additional information of relevance:
- a. Dr Yang first saw Timothy on 26 September 2012, when he provided a referral letter to a psychiatrist, Dr Robert Bell, for the management of Timothy's mixed depression, anxiety and drug use;
 - b. That whilst discussing Champix with Timothy on 10 April 2013, Dr Yang reviewed the Champix Product Information contained in 'MIMS Online'. MIMS Online is a comprehensive online reference tool that provides medical practitioners with a wide range of information relating to Australian medicines. He recalled that MIMS Online stated that Champix may have some adverse effects on the patient's mood and behavior and may exacerbate a patient's mental illness. However, it did not state that Champix was contraindicated for patients such as Timothy with a history of mental illness;

- c. Given Timothy's history of depression and anxiety, Dr Yang was reluctant to prescribe Champix, as he was concerned about the potential adverse effects. He therefore questioned Timothy about his current mental health. Timothy advised that he suffered from anxiety. Timothy's records indicated a previous history of depression and anxiety; and
 - d. Timothy appeared motivated to cease smoking and psychiatrically well at the time.
89. During oral evidence, Dr Yang provided further relevant information, as follows:
- a. He had not read the 'Psychiatric Symptoms' section of the Champix Product Information, as reproduced in MIMS. This was due to time constraints. His usual practice was to read the contraindications *only*, to ask a patient about their medical history, and to review their medical records on the screen;
 - b. He could not remember whether he reviewed Timothy's medical records in relation to his mental health conditions prior to prescribing Timothy with Champix. He recalled that Dr Fordyce had mentioned to him that Timothy had been diagnosed with PTSD. He was also aware that Timothy had taken amphetamines in the past. He was not sure whether he would have referred to other letters from specialists within Timothy's medical record;
 - c. If he had seen Timothy's medical record indicating that Timothy had a prior history of depression, anxiety and drug abuse, it would not have made any difference to his decision to prescribe Timothy with Champix. This is because his understanding was that Timothy's mental state was stable and there were no recent suicidal attempts. He based this on Timothy's responses at the time, as well as his previous consultations with Timothy, where on the few occasions that he saw him, Timothy had been stable. Timothy rarely mentioned anything to him about mental problems;
 - d. He had prescribed Champix, on average, to around 10 patients per year. Usually the patients asked for Champix by name. Of those 10 patients, on average, around three to four patients would have pre-existing mental health issues;
 - e. His usual practice was to recommend Champix as a first option to patients without mental illness. For patients with mental illness, he would recommend smoking cessation drugs like chewing gum or patches first, unless they specifically asked for Champix;
 - f. Despite his belief that Timothy's mental health was stable, Dr Yang was reluctant to prescribe Champix to Timothy because he was of the opinion that a patient with mental illness had a higher chance of adverse effects. However, Timothy specifically requested Champix;

- g. The reason he asked Timothy whether he was suicidal or homicidal was not because he had read about this in the Champix Product Information (as reproduced in MIMS). His questioning was based on his memory and training as to the questions he needed to ask patients before prescribing the drug;
- h. He was aware that a pre-condition for the prescription of Champix under the Pharmaceutical Benefits Scheme was that the patient had to enter into a 'comprehensive support or counseling program'. However, he considered that he had done this by providing his initial advice to Timothy about the possible adverse effects of the drug and to cease taking it and to see a doctor if he experienced any issues;
- i. As a result of not reading or familiarising himself with the direction in the Precautions section of the Champix Product Information (as reproduced in MIMS), Dr Yang was unaware of the need to:
 - 1. Alert Timothy's family to monitor him for neuropsychiatric symptoms; and
 - 2. Advise Timothy's family that Timothy should stop taking Champix and contact a doctor immediately in such circumstances.

Dr Yang could not recall whether he was aware that Timothy had a close relationship with his mother. He stated that he made enquiries as to whom Timothy was living with due to his mental health training. His understanding was that if a patient was living with someone else, it was usually safer for the patient;

- j. He assumed that the Champix Consumer Medicine Information, designed to provide important information to patients, was included in the Champix box. He was surprised and concerned to learn that patients had to either ask a pharmacist to print a copy out for them, or they would need to access the document on the Internet; and
 - k. In terms of follow up, his usual practice was to either advise patients to come back two weeks after starting Champix, or two to three weeks before they finished the first pack. He expects patients to make the appointments themselves. He did not make a follow up appointment for Timothy and he accepted that he did not have a structured follow up plan or structured counseling/support regime in place for Timothy.
90. Timothy's mother stated that she waited for Timothy in the car whilst he attended the appointment with Dr Yang on 10 April 2013. After the appointment, Timothy gave her his script for Champix and said that Dr Yang had told him that he could see that Timothy had PTSD and an anxiety disorder and that the medication might increase his anxiety. Timothy and his mother both agreed that Timothy wasn't experiencing any anxiety at the time and they weren't worried about this. Timothy

made no mention that he could become suicidal. It would also appear that Timothy did not mention anything about the need to stop taking Champix in the event that his anxiety increased.

91. They later drove to the pharmacy and Timothy's mother went in to pick up the Champix whilst Timothy remained in the car. However, the pharmacist didn't have Champix on hand and had to order it in. Later that afternoon, Timothy's mother gave Timothy's brother, Peter, money to pay for the medication and Peter picked up the Champix from the pharmacy. Peter brought the Champix home and Timothy's mother asked him whether the pharmacist said anything about the medication to him. Peter advised that the person at the counter said nothing. Timothy's mother had a look at the box to see what it was all about. She did not open the box, nor did they know to get the Consumer Medicine Information leaflet from the Internet.
92. Timothy commenced taking his first tablet between 3:30 and 4:00pm on 10 April 2013. He continued to take a tablet each day in the afternoon / evening before bed.
93. On 14 April 2013, day five of the medication regime, Timothy commenced taking two tablets of Champix a day (as required). He took one tablet in the morning when he woke up and one tablet before going to bed.
94. The first sign of Timothy exhibiting unusual behaviour, in hindsight, was on 15 April 2013, day 6 of the Champix medication regime. Timothy and his brother, Peter, went to their mother's house to get some tape so that Timothy could tape his door, due to Timothy's concern that someone might come into his room. Timothy did not feel safe. They found some duct tape at their mother's house and they went home.
95. Timothy's mother stated that at the time, this did not seem strange to her. Although Timothy's condition had been stable since the Belmont Private Hospital program, she had been used to dealing with Timothy's past anxiety and Timothy had told her that his anxiety might increase with the Champix. She made the point she had dealt with much worse than that before.
96. The next day, on 16 April 2013 at about 5:30pm, day 7 of the Champix medication regime, Timothy's mother received a phone call from Timothy's brother, Peter. Whilst Peter was on the phone, Timothy punched the chest of drawers beside the phone and broke it. Peter told her that Timothy was angry, so she spoke with Timothy and asked him to come over to her house. They went over to her house and she cooked them some dinner. Timothy and Peter spent the night at their mother's house.
97. After dinner, Timothy's mother had a shower and retired to her bedroom for the night. Peter later knocked on his mother's door and nodded his head in the direction of Timothy's room. Timothy was sitting on a cushion on the floor at his bedroom door, with an electric chainsaw that he had retrieved from the garage. The electric chainsaw was sitting in Timothy's lap and plugged in.

98. Timothy's mother asked him what was happening. Timothy said that people were coming to get him. Timothy's mother reassured him that no one was coming to get him, but if they were, she would protect him. She sat down behind him, unplugged the chainsaw and put it down on the floor in front of Timothy. She wrapped her arms around Timothy and stroked him, whilst reassuring him that she would keep him safe. Timothy was tensing his muscles and kept saying: "they're coming to get me. Mum help me."
99. Timothy's mother stated that she thought about calling the ambulance but knew that Timothy would react adversely to strangers (based on her previous experiences of Timothy's anxiety around strangers and new situations, after their family home had burnt down in 2006). She was concerned that if Timothy was frightened, he might lash out at the ambulance officers. She asked Timothy whether he wanted her to call a doctor for him but he said no. She just held him for hours. At about 3:00am on 17 April 2013, Timothy relaxed his body and became very calm. Timothy's mother went back to her bedroom.
100. Timothy's mother explained in oral evidence that the chain saw incident was "off the scale" compared to anything that Timothy had ever done before. However, she was expecting that his anxiety would increase with the Champix due to their earlier discussion and she considered that this was the "bottom line" in terms of the effect Champix would have on him and that he would improve from there.
101. At about 6:00am on 17 April 2013, day 8 of the Champix medication regime, Timothy's mother made him some breakfast. She later drove him back to his house, so that he could change his clothes and she could take him to the Beenleigh Road Medical Centre for his desensitisation injections.
102. Timothy was wearing a singlet top during the drive to his house, and his mother noticed that he had some red welts on his left arm. The welts were from his wrist up to around his shoulder area. She was concerned about the welts because they appeared different to the rashes he would get from his dust mite allergy. She asked him about the welts and Timothy told her that he had been picking at his arm. Whilst Timothy's mother was concerned about this, she did not suspect that he was suicidal. She explained in oral evidence that this was because Timothy was otherwise calm and he was no longer worried that someone was going to come and get him.
103. Timothy got changed into a long sleeve shirt at his house and they drove to the Beenleigh Road Medical Centre for his appointment at about 9:00am. Timothy's mother explained that although she did not go in with him for his appointment and was concerned about the red welts, she was comforted by the fact that she knew that Timothy would have to remove his shirt for his desensitisation injections. She was therefore of the belief that this issue would be raised with Timothy's doctor.

104. Timothy's mother stated that before Timothy went in for his appointment, she told him that he "had to see the doctor". She said this because she was aware from previous occasions that although an appointment was always made with the doctor for the desensitisation injections, sometimes he would only see the nurse.

105. Timothy's medical record for his consultations at the Beenleigh Road Medical Centre on 17 April 2013 are as follows:

*Surgery consultation recorded by Dr Oliver Yang on 17/04/2013
Desensitization injection*

*Reason for visit:
Desensitization injection*

*Surgery consultation recorded by Sr N on 17/04/2013
Desensitization injection*

*Reason for visit:
0.8ml s/c desensitization given*

106. Dr Yang stated in his letter and first statement to the State Coroner that he saw Timothy on 17 April 2013 for desensitization injections after having started the Champix. He stated that Timothy did not say anything about his mental health status. He presented normally, with no apparent signs of stress.

107. In his statement to me, Dr Yang added that his consultation with Timothy on 17 April 2013 was brief. He did not discuss Champix with Timothy. However, if Timothy had raised any concerns or issues about his mental health, he would have made a note in his medical records about that fact and otherwise dealt with the issue further.

108. In oral evidence, Dr Yang stated that:

- a. He wasn't quite sure why, in the context of having concerns a week earlier about prescribing Champix to Timothy with a mental illness, that he didn't ask him how he was going with the Champix on 17 April 2013; and
- b. He thought that maybe this was because he had asked Timothy to see a doctor if he felt unwell. However, he acknowledged that he could have elicited information from Timothy as to how he was progressing and that usually a doctor would not just rely on a patient to tell them how they are.

109. Timothy's mother stated that she waited in the car for Timothy whilst he attended his appointment for around 15 – 20 minutes before Timothy returned. When Timothy returned to the car, her first question to him was whether he saw the doctor and he advised her that he had not. She got out of the car and went into the Beenleigh Road Medical Centre (with Timothy following behind her) to ask if he could see a doctor. She stated

that she spoke to one of the three receptionists that were there. She could not recall the receptionist's name but it was the "older lady with dark hair". She stated that she advised the receptionist that she would like to see Dr Yang. However, she was informed that she couldn't because Dr Yang was fully booked. She then said to the receptionist that it was "urgent", but did not say why. Timothy's mother explained that she did not consider enquiring as to whether another doctor at the Medical Centre was available because she had some bad experiences with other doctors at the surgery in the past and that she and Timothy trusted Dr Yang. She didn't consider making an appointment for the next day either because she figured that she would look after Timothy during the day and then re-assess how she was after that. Although she was concerned about Timothy, there was no urgency in her mind at the time because his behaviour from the night before had ceased and she was at no stage aware that Timothy was suicidal.

110. Timothy may well have advised his mother that he did not see a doctor on 17 April 2013. This was possibly because the consultation he did have with Dr Yang was only brief and there was no discussion about how he was tracking with the Champix. However, it is clear that there was in fact a brief consultation with Dr Yang.
111. During cross examination by Dr Yang's legal representative, Timothy's mother stated that she thinks she also asked for Dr Fordyce when she went into the Beenleigh Road Medical Centre and was told that Dr Yang was not available. This is because Dr Fordyce was her doctor of choice and she also trusted him. She thinks that she was told that Dr Fordyce was fully booked too. She conceded to perhaps not using the word "urgent" when requesting the doctor's appointment because at that stage she was not concerned that Timothy was suicidal. Timothy's mother was also questioned about why she had never mentioned that she went back into the Medical Centre to ask to see Dr Yang until her statement prior to the inquest. Timothy's mother explained that her statement was a summary of events and although it took her three days to make the statement, with the assistance of a Coronial Support Unit Police Officer, she found the whole process very difficult emotionally and the statement did not mention everything that was discussed, or all of the events.
112. Nothing really turns on this aspect of the evidence. Even if Timothy's mother did ask for a doctor's appointment, it is clear that she did not explain the reason for the appointment and that she was not at that stage concerned that Timothy was suicidal. Had she have been concerned that Timothy was suicidal and explained the reason for her concern to the receptionist and still not been granted a doctor's appointment, it would have been a different story.
113. Following the inquest hearing, I directed the police to take a statement from Senior Registered Nurse (Sr) N in relation to her consultation with Timothy on 17 April 2013. Ms N provided a statement dated 29 December 2016.

114. Ms N stated that she did not recall all the details of her consultation with Timothy on 17 April 2013 but she did recall certain things from the day. She believed that Timothy would have seen Dr Yang prior to her attending the treatment room where she would have prepared whatever injection was required on the day. From memory, Timothy was having a desensitization injection. After every injection, the patient was required to stay and be monitored for 30 minutes.
115. Ms N did not recall what Timothy was wearing on the day, however, if he had been wearing a long sleeve shirt, her process for the injection would have been to have him undo a couple of the top buttons and pop the shirt off the top of the shoulder. She does not recall which arm the injection was in but she would usually just ask the patient which arm they wanted the injection in.
116. Ms N stated that she did not observe any markings or injuries to Timothy's arms. Had he been wearing a short sleeve shirt and she did notice injuries, she would have spoken to Timothy and then sent him back in to see the doctor. She recalled that on the day Timothy was a quiet patient but nothing that would make her believe there was a problem or any cause for alarm.
117. It was revealed during the my enquiries that Ms N was dismissed from the Beenleigh Road Medical Centre 11 months after Timothy's death, although Ms N did not mention this in her statement. The Beenleigh Road Medical Centre reluctantly disclosed two Incident Reports relevant to Ms N's dismissal although they claimed that they could not see how they were possibly relevant to the inquest. The first Incident Report contained an allegation that Ms N had recorded scores on a patient's chart in relation to a 'mini mental state examination' on 22 August 2013, yet Ms N had not asked the patient any questions in relation to the examination. The second Incident Report contained details of a patient complaint on 27 February 2014 about Ms N's clinical competence, demeanour, and professionalism. It should be stressed that these are untested allegations. However, the first Incident Report in particular does raise a concern about the reliability of Ms N's statement in relation to her consultation with Timothy on 17 April 2013.
118. Notwithstanding this concern, Ms N's evidence in relation to the procedure she would have followed when administering Timothy with the desensitisation injection, in the context of him possibly wearing a long sleeve shirt, is credible and consistent with general medical practice. It is likely that in those circumstances, Timothy would have sought to hide the red welts on his left arm from Ms N by offering his right arm for the injection. This could have possibly been because Timothy was embarrassed and/or not wanting to be quizzed by a nurse he did not have a close relationship with about potential self harm the night before.
119. Later on 17 April 2013, Timothy and his mother and brother went on a family drive to the Gold Coast, at Timothy's request. Timothy's mother stated that she drove and Timothy sat in the front seat, so that she could keep an eye on him. They went to see some prize homes (similar to the

one they had previously won through the RSL). Timothy commented that he would like to build a house in Pimpama and live there some day. They picked up some lunch and sat on the beach for a while. Timothy's mother and brother stated that Timothy seemed upbeat, even making a joke about a girl who had walked past them a few times.

120. Timothy then developed a headache, so they decided to drive home. On the way home, they stopped off at a pharmacy to buy some nurofen. Later during the drive, Timothy commented about a car he thought he had recognised from their drive to the coast. He thought the work van had the same number plate. His mother explained that work vehicles can sometimes be registered together and they can have consecutive number plates. Timothy seemed to accept this explanation and the van turned off the highway and was not mentioned again.
121. Timothy later asked his mother during the drive home whether he should stop taking the Champix as it was making him "feel strange". She told him that if it was helping him to give up smoking, then maybe he should keep taking it.

Timothy's death

122. Timothy's mother dropped him and his brother off at their house at around 3:00pm on 17 April 2013. Timothy's brother had an afternoon sleep until around 4:30pm. He awoke to find Timothy hanging by an electrical cord under the outside back patio of their house.
123. Timothy's brother phoned 000 and then cut his brother down with a knife. The ambulance arrived soon after at about 4:41pm and declared Timothy deceased.
124. Police located a small statue of a child wrapped in a hand in Timothy's pocket. In another pocket, there was a pocket knife and a digital voice recorder which contained the following message:

"Mum I love you with all my heart and Peter you're the best brother I could ask for. I know this doesn't make sense right now but it's for the best trust me. I'm losing my mind. I'm going crazy. I love you both."
125. Police noted scratch marks and a scratch in the shape of the letter 'F' on Timothy's left inner-forearm. They noted that the injuries seemed fairly old but the letter 'F' still had a scab in the making.
126. The police investigating officer, Constable Aaron Christoffel from the Acacia Ridge Police Station, submitted a report to me dated 17 April 2013. There were no suspicious circumstances noted and the conclusion was that Timothy had committed suicide.

Autopsy results

127. An external examination was performed on 18 April 2013 by a senior forensic pathologist, Dr Beng Ong. Routine toxicology testing was also conducted. The Toxicology Certificate of Analysis was issued on 20 May 2013. Dr Ong issued his Autopsy Report on 31 July 2013.
128. On 24 July 2015, I requested further testing of Timothy's blood samples for Varenicline (Champix).
129. An amended Toxicology Certificate of Analysis was issued on 14 October 2015. Varenicline was detected at a non-toxic level (ie. the expected therapeutic range). A sub therapeutic level of ibuprofen was also detected. Dr Ong produced an amended Autopsy Report to take into account the updated results on 26 October 2015.
130. Dr Ong noted that there was a ligature mark present nearly circumferentially around Timothy's neck. Dr Ong was of the opinion that the orientation was consistent with being caused by hanging. The ligature mark was in keeping with it being caused by the accompanying computer cord. There was no evidence of third party involvement.
131. In addition to the ligature mark, Dr Ong noted other signs of recent injuries, as follows:
- a. Faint longitudinal abrasions (about 10) on the front of the left wrist and forearm with variable lengths ranging from 1 to 12cm; and
 - b. An abrasion in the shape of the letter 'F' on the mid front of the left forearm. The vertical limb of the 'F' was 4cm long, while the horizontal limbs were 3cm long each.
132. After the inquest hearing, I requested Dr Ong to comment on the timing of the injuries on Timothy's left forearm and wrist.
133. Dr Ong produced an amended Autopsy Report dated 6 December 2016 to address my enquiry. He noted that timing is notoriously difficult to assess in the post-mortem period based on appearance. However, it is his opinion that these injuries were recent and could have been inflicted near the time of death (up to about 24 hours before death).
134. Dr Ong was of the opinion that the cause of Mr John's death was:
- 1(a). Hanging

Does Champix increase the risk of suicide?

135. 'Champix' is the Australian product name for the drug Varenicline. The US equivalent product name is 'Chantix'. It is a prescription medication that can help adults (18 and over) quit smoking by reducing craving and withdrawal symptoms. It is believed to achieve this by activating certain receptors in the brain and blocking nicotine from attaching to them.

136. An American global pharmaceutical company named 'Pfizer Incorporated' manufactures the drug. According to Pfizer Incorporated, the drug is approved in more than 100 countries and has been prescribed to over 20 million patients worldwide. 'Pfizer Australia Pty Ltd' introduced the drug to the Australian market in 2007. According to the records held by the Therapeutic Goods Administration, there were 2.8 million scripts written by health professionals in Australia alone between 2008 and 2014.
137. Patients usually take Champix for a period of 12 weeks. The Champix starter pack lasts for the initial four weeks and a patient is required to go back to the doctor for the next eight-week subscription. Sometimes medical practitioners extend the initial 12-week period by a further 12 weeks to increase a patient's chances of quitting smoking in the longer term.
138. Clinical studies suggest that Champix is one of the most effective drugs to assist people to quit smoking. A patient who takes Champix is reportedly up to three times more likely to remain a non-smoker one year later, compared to a person who does not take Champix.
139. The benefits of Champix, where it is successful in assisting patients to quit smoking, are clear. According to Dr Mendelsohn:
 - a. Smoking is said to kill around 15,500 Australians each year and is the largest preventable cause of death and disability in Australia; and
 - b. Continuing smokers are said to lose 10-12 years of their life.
140. There are, however, like most drugs, potential adverse effects associated with Champix.
141. A number of post marketing reports have identified incidences where smokers using Champix have experienced serious or clinically significant neuropsychiatric adverse events. Examples include: mood changes (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, panic, suicidal ideation, suicide attempt and completed suicide.
142. Between January 2008 and 3 December 2016, Pfizer Australia Pty Ltd has recorded 5,227 adverse events in relation to Champix. These post-marketing reports are reported voluntarily from a population of uncertain size and often lack medically important information, including the presence of co-morbid conditions and concomitant medications as well as length of treatment. They cannot therefore be reliably used to estimate the frequency of events or establish a causal connection to drug exposure. They are, however, a 'signal'.
143. A National Coronial Information System report that I obtained for the purposes of this inquest has revealed that between 2008 and 2014, there were 58 *known* suicide cases Australia wide where the deceased was taking Champix. This data is likely to underestimate the number of suicide cases potentially associated with Champix in Australia because, with the

recent exception of Victoria, forensic pathologists do not routinely test people who have died through suicide for Varenicline. The data set is therefore incomplete and again, they merely provide a 'signal'.

144. The current state of affairs is that among the more valid study designs (pooled analyses of placebo controlled trials or large controlled observational studies), the evidence has been that Varenicline either does not cause increased suicide outcomes, or if it does, the effect is relatively small.
145. Just prior to this inquest, the results of the 'EAGLES' (Evaluating Adverse Events in a Global Smoking Cessation Study) were released. To date, this is the largest smoking cessation clinical trial in patients without and with a history of psychiatric disorder.
146. The EAGLES study was a randomized, blinded, active and placebo controlled clinical trial, which was conducted by Pfizer in collaboration with GlaxoSmithKline. The study was conducted at the request of, and designed in consultation with, the U.S Food and Drug Administration and European Medicines Agency (the equivalent organisations to Australia's Therapeutic Goods Administration).
147. The trial was the first and largest to compare the safety and efficacy of Chantix / Champix, bupropion and nicotine replacement patches. The study pool included approximately 8,000 smokers, with and without a history of psychiatric disorder. The trial was designed to compare the risk of clinically significant neuropsychiatric adverse events of these smoking aids over 12 weeks of treatment, and to determine whether smokers with a history of psychiatric disorder are at greater risk of developing clinically significant adverse events compared to smokers without a history of psychiatric disorder.
148. In the cohort of patients without a history of psychiatric disorder, Chantix / Champix was not associated with an increased incidence of clinically significant neuropsychiatric adverse events.
149. However, in the cohort of patients with a history of psychiatric disorder, there were more clinically significant neuropsychiatric adverse events reported with Chantix / Champix, compared to the non-psychiatric cohort.
150. There was a risk increase of 2.7% for those taking Champix / Chantix compared to the placebo. There were also risk increases of 2.2% for bupropion, and 0.4% for transdermal nicotine.
151. Neuropsychiatric events of a serious nature were reported in 0.6% of Chantix / Champix treated patients with 0.5% requiring psychiatric hospitalisation. In placebo-treated patients, serious psychiatric events occurred in 0.6%, with 0.2% requiring psychiatric hospitalisation.
152. Dr Mendelsohn stressed that the increase in risk associated with patients with a history of psychiatric disorder taking Champix was not 'statistically significant' in scientific terms, due to the limited pool of patients in the

study. Because of this, he also explained that the study could not rule out an increase in risk of up to 4%.

153. The end result though is that Champix does in fact increase the risk of suicide in patients such as Timothy, with a history of a psychiatric disorder, compared to people attempting to quit smoking without a medical aid.

154. It is therefore important to closely monitor people with a history of psychiatric disorders, such as Timothy, whilst they are taking Champix.

Did Champix contribute to Timothy's death?

155. I find that Champix contributed to Timothy's death because:

- a. According to Timothy's psychiatrist, Dr Robert Bell, he had a history of major depressive disorder and anxiety. This therefore placed him within the cohort of patients proven by the EAGLES study to have a higher risk of suicide whilst quitting smoking with the aid of Champix, compared to quitting smoking without an aid;
- b. Timothy's symptoms stabilised when he completed the three week intensive Cognitive Behaviour Therapy program at the Belmont Private Hospital on 2 November 2012;
- c. At the time of taking Champix, Timothy no longer had a substance misuse problem. The last time he used illicit drugs was in September 2012 and the last time he binge drank was during a one off event on 18 January 2013. Further, toxicology testing did not identify any alcohol or illicit drugs in his system at the time of death;
- d. It was not until eight days after Timothy commenced the Champix medication, that Timothy's psychological condition deteriorated significantly, to the point that he suicided;
- e. The only other time that Timothy may have previously attempted suicide (potentially through an attempted overdose of panadol) was in the context of a traumatic event in his life (his family home burning down), unstable depression and anxiety, and alcohol and drug abuse;
- f. Timothy presented to his General Practitioner, Dr Yang, on the day that he was prescribed with Champix (10 April 2013), in a stable condition, and without suicidal ideation. Dr Yang was a doctor that Timothy trusted and it is unlikely that he was being dishonest; and
- g. Previous attempts to quit or reduce his smoking with Nicorette patches gum and spray had only resulted in low-level changes to his behaviour (mild agitation and aggression and an episode of fainting whilst on the spray).

156. I do not accept Pfizer's submission that there is no reliable evidence to reach a conclusion that Champix contributed to Timothy's death. Champix was more than just a present factor; it appears to have been a contributing factor.
157. I note Timothy's mother's submission that there is a direct correlation between the prescription of Champix to Timothy and a significant and quick decline in Timothy's mental stability, which resulted in his death. Whilst this may be so, I cannot rule out the possibility that Timothy's pre-existing mental health conditions also resurfaced, independently of the Champix, and also contributed to his death.
158. For this reason, I am unable to determine the level of contribution that Champix had on Timothy's death.

Did Dr Yang provide adequate care when prescribing Champix to Timothy?

159. I find that Dr Yang did not provide adequate care to Timothy when prescribing Champix to him because:
- a. Dr Yang did not read or familiarise himself with the 'Precautions' section of the Champix Product Information (as reproduced on page 4 of MIMS at the time);
 - b. As a consequence of not reading or familiarising himself with the Precautions section of the Champix Product Information, Dr Yang was not aware of the need to, and did he make any enquiries as to the practicality of:
 - i. Alerting Timothy's family to monitor him for neuropsychiatric symptoms; and
 - ii. Advising Timothy's family that Timothy should stop taking Champix and contact a doctor immediately in such circumstances;
 - c. Although Dr Kable and Dr Mendelsohn advised that it was not common for the general practice community to provide such information to a patient's family, this does not mean that the failure of Dr Yang to do so in these circumstances was adequate. I understand the practical difficulties of achieving this in situations where patients do not consent to family involvement, and I also understand that Timothy was an adult. However, Timothy was not even asked about the possibility of family inclusion. It would not have been impractical for Dr Yang to make enquiries with Timothy about this. Timothy attended the appointment alone but he informed Dr Yang that he was living with his brother. There were options reasonably available to Dr Kable to include Timothy's family. For example, he could have delayed the prescription until Timothy's brother (or another nominated family member such as his mother)

attended, or he could have phoned Timothy's family member whilst Timothy was there;

- d. Dr Yang held concerns about prescribing Champix to Timothy due to his mental health condition and his awareness that this could increase risk, yet he did not put in place a structured follow up plan for Timothy. He instead relied on Timothy to make a follow up appointment, and to identify if he needed to see a doctor; and
 - e. If the pre-arranged desensitisation injection appointment that Timothy had with Dr Yang on 17 April 2013 was intended also to be his Champix review, then the review was inadequate. I accept that Timothy was an adult capable of raising concerns and that he did not appear to be in distress, but Dr Yang should still have made a reasonable attempt to elicit information from Timothy about how he was going with the Champix. This is especially so given that he held concerns about prescribing Champix to Timothy the week before as a result of his mental health condition.
160. It is not possible to conclude whether a formal follow up appointment and/or specific questioning by Dr Yang on 17 April 2013 would have changed the outcome for Timothy. It is possible that Timothy might not have advised Dr Yang about the difficulties he was experiencing, even if asked.
161. What is clearer to me though, is that if Timothy's family had been informed by Dr Yang (or by warnings on or within the Champix packaging) about the need for Timothy to stop taking Champix and to contact a doctor immediately if he exhibited neuropsychiatric symptoms, it is likely that his family would have taken appropriate earlier action, and it is possible that Timothy's death may have been avoided.
162. This highlights the importance of prescribers advising patient's family, friends, or carers, if possible, about the precautions before the patient is prescribed Champix. It also highlights the importance of ensuring that the precautions are more readily available with the Champix packaging.

The adequacy of Champix product labelling and instructions (and recommendations)

163. Important consumer safety information relating to Champix is provided on the packaging itself and in two main documents produced by Pfizer:
- a. A six page 'Consumer Medicine Information' (CMI) leaflet designed for patients; and
 - b. A more detailed and technical 20 page 'Product Information' (PI) document, designed for medical practitioners.

Warnings on the Champix packaging

164. It is my view that simply referring to the Consumer Medicine Information and its availability on the Champix packaging is inadequate. I recommend that:

- a. The Champix packaging contain an alert about when to immediately cease taking Champix and to see a doctor. This is important information that should be upfront.

Consumer Medicine Information leaflet

165. I have identified inadequacies in the Consumer Medicine Information Leaflet and I recommend the following changes:

- a. The Consumer Medicine Information leaflet should be included within the Champix packaging.
 - i. It is acknowledged that the Therapeutic Goods Administration seems to be moving towards alternative methods of accessing such documents such as the 'app' called 'Medsearch' which is available to download on smartphones and tablets. These are encouraging additional safeguards. However, it is still my view that it should not be left to a patient to have to request a pharmacist to print out the leaflet or to have to go to the Internet to access this important information.
 - ii. Some patients will not have Internet access or access to smart phones or tablets. Many pharmaceutical companies in Australia provide Consumer Medicine Information leaflets within their drug packaging. Pfizer also does so in the U.S. in relation to Chantix, so the issue of keeping the Consumer Medicine Information up to date has obviously been overcome. One way to mitigate against the issue of currency is to advise at the top of the Consumer Medicine Information leaflet that it is current, as at a certain date and to check with a doctor or pharmacist, or to access an Internet page, to determine whether it has been updated.
 - iii. The history of amendments to the Champix Consumer Medicine Information suggests that although emphasis has changed on certain warnings over the years, the substance has remained the same. To not include the Consumer Medicine Information within the Champix packaging raises an unnecessary barrier to ensuring that patients and their families have ready access to important information that can potentially save lives.
 - iv. Also, some patients will not know to ask, or feel uncomfortable asking a pharmacist for the Consumer Medicine Information leaflet. Pharmacists are required to exercise their professional judgement in terms of their oral advice to patients when dispensing prescription drugs but they may not always do so, and in some cases such as Timothy's, the patient is not the person who necessarily picks up the drug from the pharmacist.

- b. The guidance within the Consumer Medicine Information leaflet that “[i]t is important to keep taking Champix for the full 12 weeks and not to stop taking it or change the dose without checking with your doctor” has the potential of causing confusion when compared to the guidance of when to immediately cease taking Champix and to see a doctor. This aspect of the guidance within the Consumer Medicine Information should be refined;

Product Information document

166. I have identified inadequacies in the Product Information document and I recommend the following changes:

- a. The Product Information document should be amended to include practical guidance as to how a medical practitioner should alert and advise the family of a patient about the relevant precautions. There should also be a brief explanation as to why this is important.
 - i. I do not agree with Pfizer’s submission that this should not be done because it would arguably trespass on the role of general practitioners.
 - ii. I accept Pfizer’s submission that there is no ‘one size fits all’ and that is why a range of scenarios should be addressed within the Product Information document. For example:
 - 1. Should a medical practitioner rely on a patient to convey the Champix precautions to their family where the medical practitioner assesses that the patient is competent to do so?
 - 2. Should the medical practitioner delay prescribing Champix to a patient until they bring in a relevant family member?
 - 3. What should a medical practitioner do where a patient is socially isolated?
 - 4. What if a patient insists on confidentiality in relation to their mental health condition, their smoking addiction, or their decision to quit smoking?
 - 5. Also, why should this guidance be confined to family? The guidance for Chantix in the U.S includes ‘friends’ and ‘carers’;
- b. The Product Information document should be amended to include guidance to medical practitioners about the need to put structured follow up plans in place when prescribing Champix, particularly for patients with a history of psychiatric disorders.
- c. The Product Information should be amended to provide more clarification around what a ‘comprehensive counselling and support

program' entails. Such a program is a pre-requisite before Champix can be subsidised under the Pharmaceutical Benefit Scheme for good reason. The reason is to provide support to patients to successfully quit smoking. It will of course have the added benefit of monitoring a patient's welfare. The anecdotal evidence is that this requirement has become a 'tick and flick' exercise for some medical practitioners. In Dr Yang's case, he considered that it was a one off exercise.

167. I accept Pfizer's submission that the above changes could be dealt with by healthcare professionals in the Royal College for General Practitioner's Guidelines. However, it remains my view that these issues should be addressed first in the central Product Information document.

Other recommendations

Introduction of routine screening for Varenicline by forensic pathologists

168. I recommend that all State and Territory forensic pathology services follow Victoria's lead and routinely screen for Varenicline in relation to suicides and suspected suicides.

169. My understanding is this can be achieved at no extra cost due to the technology currently in place. This will create a national data set, which will still only provide a 'signal', but may assist in terms of a closer examination of the extent that Varenicline can be linked to suicide in the future.

A change to practices by prescribers

170. I also recommend that the general practice community take note of this case and ensure that before prescribing Champix to a patient, they provide direct advice to an appropriate family member, carer, or friend about the need to monitor the patient and for the patient to cease Champix and see a doctor immediately if they exhibit neuropsychiatric symptoms. If a patient is unwilling to consent to inclusion of a third party, consideration should be given to not prescribing the drug to them.

I offer my condolences to Timothy's family and friends.

I close the inquest.

John Hutton
Coroner
Brisbane

14 September 2017