



MAGISTRATES COURT of TASMANIA
CORONIAL DIVISION



Record of Investigation into Death (Without Inquest)

Coroners Act 1995
Coroners Rules 2006
Rule 11

I, Stephen Raymond Carey, Coroner, having investigated the death of Deearne Joan Barnes
Without holding an inquest

Find That:

- Deearne Joan Barnes (Ms Barnes) died between 9 and 14 December 2010 at Tolosa Street in Glenorchy;
- Ms Barnes was born in Hobart, Tasmania on 10 February 1957 and was aged 53 years at the time of her death; she was a widow and had two adult daughters; and
- Ms Barnes died as a result of mixed drug toxicity.

Relevant Background Material:

Ms Barnes suffered from numerous longstanding physical and psychological conditions.

In affidavits provided by family to this investigation, it appears that Ms Barnes's health deteriorated circa 1996, a time coinciding with her husband committing suicide. She also suffered a back injury in the mid 1990s resulting in physical limitations, chronic pain and future surgeries. In this context, depressive symptoms, alcohol and prescription drug misuse and abuse were increasingly observed by her family.

Over several years prior to her death, Ms Barnes's psychological condition resulted in multiple hospital and clinic admissions. She had a history of recurrent major depressive episodes and was diagnosed with personality disorder, obsessive compulsive disorder and substance use disorder.

Evidenced from 2007 were a number of hospital admissions involving self-destructive behaviour, including both accidental and apparently intentional drug overdoses. Evidence provided to this investigation by family members suggests that Ms Barnes would deliberately overdose on prescription medications and subsequently contact them to advise them of her actions. She would also combine prescription medications with alcohol, producing associated overdose reactions. She therefore presented with long-term known risks.

The most recent admission for a drug overdose prior to her death was in May 2009 when she overdosed on medication supplied by her treating psychiatrist, Dr Veronica Lewinski.

It is clear that Ms Barnes was known by medical practitioners (including Dr Lewinski) to abuse prescribed medications, taking more than the prescribed amounts and to request specific medications and medications at increased quantities.

Ms Barnes was admitted to numerous substance abuse programs. The most recent admissions to the Hobart Clinic prior to her death were October 2009, March 2010 and June 2010. It was during the October 2009 admission that Dr Lewinski commenced her on the methadone programme for pain management. In a report provided to this investigation Dr Lewinski states that she *'...had a number of worried moments about Deearne, especially earlier in the year (2010) when she seemed out of control, substance abusing and very isolated...'*

In late 2009 and early 2010 Ms Barnes had multiple hospitalisations and surgical procedures relating to her bowel, abdomen and infections. She was also diagnosed with degenerative arthritis. Following each hospital stay a care plan was instigated with Hobart District Nursing Services to provide nursing and domestic support to her. Twice daily medication assistance was also instigated during critical periods where she required assistance managing her medications.

In October 2010, Ms Barnes had a hip replacement. Following this surgery it appears that her physical condition and pain levels significantly improved. It appears she advised both Dr Lewinski and her District Nurses that she was pain free and wished to manage her own medications. Dr Lewinski reported that *'...I thought that the worst was over and that she was on her way to recovery; nonetheless recognising that it would not be as straight forward as she believed it would be'*.

Circumstances Surrounding Death:

About 4:00pm on 9 December 2010, Ms Barnes returned home with her groceries. She was assisted by her neighbour to carry the shopping bags into her residence. This was the last occasion she was seen by anybody.

In the afternoon of 14 December 2010, Ms Barnes's neighbour went to the residence to check on her welfare, as he had not seen her for a number of days. He was unable to elicit a response. Concerned about her welfare the neighbour contacted police who, shortly after, entered the unit and observed Ms Barnes lying on the lounge room floor, deceased.

It was noted by police that there were unpacked grocery items on the kitchen table and a Coles shopping receipt dated 9 December 2010. One shopping bag contained rubbish, including several empty medication boxes and blister packets. Further prescription medications, at various stages of use, were located in the kitchen and main bedroom with numerous empty medication packets in a wheelie bin and recycle bin outside the unit. The police determined that there were no suspicious circumstances surrounding the death.

A post-mortem examination was conducted by Forensic Pathologist, Dr Donald Ritchey. He determined (with the assistance of a toxicological report) that the cause of Ms Barnes's death was mixed drug toxicity (venlafaxine, methadone, amitriptyline, quetiapine and diazepam). Dr Ritchey commented that significant contributing factors were atherosclerotic coronary vascular disease, obesity, borderline obsessive compulsive personality disorders and history of previous prescription overdose.

Toxicology of a post-mortem blood sample revealed:

"desmethylvenlafaxine – 10 mg/L : potentially fatal; methadone – 0.6 mg/L : therapeutic/toxic/fatal; amitriptyline – 0.8 mg/L : greater than therapeutic; nortriptyline – approximately 0.8 mg/L : refer amitriptyline; quetiapine – 1.3 mg/L : greater than therapeutic; diazepam – present; less than 0.05 mg/L : sub-therapeutic; nordiazepam – present : refer diazepam; temazepam – present ; refer diazepam; oxazepam – indicated : refer diazepam".

In his affidavit Dr Ritchey stated:

“Toxicology testing of samples obtained at autopsy revealed the presence of multiple prescription drugs at potentially fatal, toxic and greater than therapeutic concentrations. All of the drugs were strong central nervous system depressants.”

Dr Ritchey interpreted the above results and determined that the central factor contributing to Ms Barnes’s death was mixed prescription drug toxicity (overdose). He reports that he based his opinion on the findings at the scene, suggestive of overdose, in addition to the post-mortem blood concentrations and history of previous prescription overdose. Dr Ritchey further noted that the presence of severe coronary artery atherosclerosis could, under different circumstances, be sufficient to cause death and undoubtedly was a significant contributing factor.

Expanding upon the possible link between the toxic drug mix and the severe coronary disease, the Coronial Division medical consultant Dr Tony Bell comments upon the position in which Ms Barnes was found that:

“The collapsed state appears to be that of a sudden cardiac death rather than sedative drug overdose. The combination of the cardiac effects of the drugs and the coronary artery disease certainly could cause ventricular fibrillation and death.”

However, whatever the mechanism, I accept Dr Ritchey’s conclusions and opinion that the central factor causative of Ms Barnes’s death was mixed prescription drug toxicity.

Findings & Comments:

As part of this coronial investigation, family have expressed concerns in relation to the amount of medications that Ms Barnes was prescribed. Certainly the scene where Ms Barnes was discovered is suggestive of a large quantity of prescribed medication.

It is evidence that in the two years prior to her death, Ms Barnes was under the care of a number of medical practitioners. She had multiple major surgical procedures for physical conditions in major hospitals. Concurrently, Ms Barnes also had clinic admissions relating to substance abuse, including an overdose on prescribed medications.

This is a complex case where prescribing was required for pain management on a background of psychological conditions and ongoing history of substance abuse and prior overdoses. Those circumstances demanded specialist involvement in particular in the areas of pain management and addiction medicine. Dr Lewinski appears to have been ill prepared to deal with this complex presentation.

Of concern, in the context of known substance abuse and concern in relation to Ms Barnes’s management of medication, is the substantial amount of empty packages of methadone and diazepam that were located on the kitchen bench. These packages were dispensed in late November and early December 2010 and were prescribed by Dr Lewinski. A reconciliation of dispensed drugs, dosage instructions and drugs found at the premises indicate as follows:

Methadone	30 missing	50 remaining
Desmethylenlafaxine	18 missing	28 remaining
Valium (diazepam)	50 missing	0 remaining
Quetiapine	0 missing	114 remaining
Amitriptyline	0 – 20 missing	0 remaining

As part of this investigation a report was provided by the Pharmaceutical Services Branch (PSB), Department of Health and Human Services. Information provided in this report shows that psychiatrists from the Hobart Clinic advised PSB in May 2010 that Ms Barnes was an overdose risk. As a result, a further authority was issued to Dr Lewinski on 31 May 2010 containing conditions relating to her prescribing of methadone. The conditions required that Ms Barnes's prescription was posted to the one nominated pharmacy, the medication dispensed to the patient on a daily basis and take-away doses only given to the patient on days when the pharmacy was closed. When such a condition is imposed on authorisations issued to medical practitioners, it is the prescriber's responsibility to ensure that this is endorsed on all prescriptions. The conditions are mandatory and not voluntary.

From 8 October 2010 Dr Lewinski prescribed methadone to Ms Barnes as follows:

22 October 2010 – 120 tablets (dispensed at the Hobart Private Pharmacy)
25 November 2010 – 20 tablets (dispensed by the Augusta Road Pharmacy)
2 December 2010 – 120 tablets (dispensed by the Augusta Road Pharmacy)

As part of this investigation, the prescriptions dispensed by Augusta Road Pharmacy in the weeks prior to Ms Barnes's death were obtained. It is clear that Dr Lewinski had not endorsed the conditions of the authority on the prescriptions of methadone. Ms Barnes received 140 methadone tablets in the two week period before her death. Of note is that there was a break in the prescription of methadone between 22 October 2010 when prescribed by Dr Lewinski and 25 November 2010 when again prescribed by Dr Lewinski. During this time she had been an inpatient at Hobart Private Hospital and on discharge on 16 November was prescribed paracetamol and Panadeine forte by Dr Dunbabin as replacement for methadone. Within the above two week period, Ms Barnes was also dispensed diazepam that was prescribed by Dr Lewinski having falsely stated to and been believed by Dr Lewinski that she had not been prescribed diazepam upon discharge from Hobart Private Hospital.

Given that there was a clearly established history that showed that Ms Barnes was at risk of overdose and was not complying with dosage instructions on her medication, the failure of Dr Lewinski to both comply with the mandatory conditions on the prescribing and also her apparent failure at any time to conduct a risk evaluation and take mitigating steps addressing those risks, is profound. Such risk evaluation and necessary changes to prescribing protocol was particularly necessary following the known incidents of overdose or misuse Dr Lewinski was aware of, and also at any other time that Dr Lewinski believed there was a material risk of misuse.

Additionally, the above outline establishes that Ms Barnes had ceased methadone at discharge (and likely pre-discharge) from the Hobart Private Hospital on 16 November 2010 and replacement medication of paracetamol and Panadeine forte commenced. Methadone was next prescribed by Dr Lewinski on 25 November 2010 together with diazepam (which was additional to that prescribed upon discharge). Given the period of non-use of methadone, Ms Barnes would have rapidly developed a significantly reduced tolerance to that drug. An Australian Government publication in 2003 relating to the Clinical Guidelines and Procedures for the use of methadone warns that:

“When methadone doses are missed for 3 or more days, tolerance to opioids may be reduced placing patients at risk of overdose when methadone is reintroduced.”

Re-introduction after an interrupted period was recommended as follows:

- *“One day: no change.*

- *Two days: if no evidence of intoxication (alcohol, benzodiazapams or other CNS depressants): administer normal dose.*
- *Three days: Administer half dose.*
- *Four days: Recommend at 40mg or half dose whichever is lower.*
- *Five days or more: regard as new induction.”*

These recommendations also highlight a need for careful consideration as to involving opioid dependent persons in detoxification programs. The number of failed attempts by Ms Barnes raises for consideration what means were used to determine her suitability for such programs and what process was in place to monitor and control her medication and alcohol use subsequent to discharge. I am advised that experience shows that given the reality that drug dependence and addiction is a chronic relapsing and remitting disorder and that relapses are common, offering withdrawal management to patients who have demonstrated active opioid dependence in the period leading up to the detoxification can in fact impose a significant risk on the patient. This flows from the substantially lowered tolerance to the opioid medication which upon relapse exposes the patient to no small risk of serious opioid toxicity, even death.

This risk is magnified if that patient is also consuming alcohol, benzodiazepines, major tranquillisers or other psychotropic medications. It is suggested that medically assisted withdrawal management (detoxification) ought to only be provided to those patients who have demonstrated over a significant period of time that they are stable users of opioid medication and who are assessed as ready for that challenge. This is the practice of the Alcohol and Drug Services in Tasmania and although recognising reasons for that approach it does leave somewhat of a conundrum of how to deal with chronic opioid abusers and misusers. In relation to those being prescribed opioid medication for chronic non-cancer pain (CNCP) the answer lies in multi-discipline pain management programs to lessen over time the patient's need for and belief that they need such medication.

Dr Lewinski provided a report to this coronial investigation that included an outline of consultations and prescribing in the month prior to Ms Barnes's death. In two of the three consultations in this period, Dr Lewinski supplies information that she warned Ms Barnes in relation to her abuse of medication:

“...I warned her that if she abused medication she would be restricted to weekly or daily pickup. I did however give her a script for methadone 10mgm ii bid and diazepam 5mgm tds” (appointment 1 December 2010)

“...I informed her that she was not capable of managing her own medication at this time and that I would direct all further scripts to the pharmacy...” (appointment 8 December 2010)

This belief by Dr Lewinski highlights the real danger to which Ms Barnes was exposed by the ongoing failure of Dr Lewinski to comply with the prescribing condition already imposed in relation to the methadone and her failure to consider an overall risk mitigation strategy in respect to Ms Barnes's medication regime.

During this period, Ms Barnes indicated that she wished to cease the methadone program and asked Doctor Lewinski to prescribe valium (diazepam). During the appointment on 8 December 2010 Ms Barnes requested admission to the Hobart Clinic to discontinue her methadone. Dr Lewinski and Ms Barnes '*...agreed to do this at a more appropriate time, not over the holiday season.*'

Ms Barnes had a long complex history of psychiatric illness, physical illness resulting in pain and long-term medication use which led to misuse and addiction. Dr Lewinski either failed to realise or failed to give proper weight and consideration to the fact that prescription drug addiction is a chronic neurobiological disease characterised by impaired control over drug use, compulsive use, and continued use despite harm and cravings. The recent history of Ms Barnes ought to have highlighted to Dr Lewinski that such drug dependence is a chronic and relapsing condition. In Ms Barnes's case there was a clearly demonstrated need to break this cycle and not merely return to the highly questionable prescribing regime after each episode of misuse or abuse of those prescriptions or detoxification endeavour.

There were a number of formal interventions in an attempt to break the cycle but all failed. Ms Barnes was let down at the end by her principal treater, Dr Lewinski. Dr Lewinski failed to conform with the conditions that were applicable to the authority granted to her in May 2010 allowing the continuation of the prescription of methadone. Those conditions obliged Dr Lewinski to mail the prescription to a nominated pharmacy and for the medication to be issued daily. There was a measure of control over her medication regime during the period that she was receiving home assistance from the Hobart District Nursing Service following discharge from hospital on 16 November 2010 through until early December 2010. At this time there appeared a positive interval where, after her most recent surgery, she demonstrated a positive attitude, seemed to be in less pain and wished to move forward by taking control of her own drug management; she impressed both Dr Lewinski and the Hobart District Nursing Service staff with her apparent positive outlook.

There is no objective assessment, however, to support this positive attitude apparently displayed by Ms Barnes. It is also contradictory to the comment by Dr Lewinski that she believed Ms Barnes was not capable of managing her own medication. Unfortunately, due to the unremitting nature of her drug addiction and the past history of relapses such positive attitude could be given little weight. Comments of District Nursing Service staff to that effect ought to also have been given little weight as there is no evidence that the relevant staff were aware of the long history of drug and substance misuse by Ms Barnes, or that this conclusion was supported by any form of risk minimisation assessment. A prescriber dealing with a patient with a history of medication misuse ought not to rely upon opinion from others as to the ability of the patient to safely manage their own medication, unless such person has full knowledge of the patient's relevant history, has had the opportunity to observe the patient over a significant period of time during which the patient has self-managed medication, and these observations produce a positive result on an appropriate risk mitigation assessment. In this period Ms Barnes's medication was released from the pharmacist in weekly packs, collected by a community carer and provided daily to Ms Barnes. However, during this time there were hospital visits where she was also prescribed medication and at least one documented occasion when she obtained an additional prescription of diazepam, falsely stating that she had not received that medication upon release from hospital. Dr Lewinski describes herself as naïve in her acceptance of assurances from Ms Barnes concerning her ability to self-manage her medication. Unfortunately, an objective assessment (albeit in retrospect) identifies a significant shortfall in the professional performance of Dr Lewinski in her treatment of Ms Barnes. In particular she:

- Failed to give proper weight to the significant history of drug abuse and overdoses by Ms Barnes, as demonstrated by hospital admissions in the period of years prior to her death, and in the doctor's clinical decisions concerning the prescribing of medication.
- Maintained, over a significant period of time, a prescribing regime involving opioid medication in combination with other central nervous system depressant medication, without any evidence of having considered a more appropriate pain management process.

- Failed to recognise the particular risks imposed upon Ms Barnes by the nature and mix of prescribed medication.
- Failed to ensure she had an up-to-date and accurate record of medication being prescribed to Ms Barnes, especially upon hospital admissions.
- Failed to abide by the condition imposed upon her authority to prescribe opiate medication; that is to be limited to daily issue to the patient.
- Failed to engage with other appropriate specialists, e.g., addiction medicine and pain management, in order to settle upon a treatment regime that exposed less risk of a fatal event due to drug toxicity.
- Failed to recognise her lack of experience or knowledge in respect of such a complicated case as Ms Barnes, which made it imperative that other professional assistance be sought.

However, Ms Barnes, tragically, was only one of the hundreds of people who have died in similar circumstances over recent years. Despite clear evidence of the dangers that exist and the increased attention this is given to professional development and training of prescribers, the use of opioids with other prescribed and non-prescribed substances continues to remain a major issue in Australia, whether associated with addiction or not. National Coronial Information System (NCIS) information illustrates:

“There are 806 oxycodone related deaths, with a significant increase in the 11 year period from 21 deaths in 2001 up almost 7 fold in 2011 (139 deaths). Most deaths were caused by combined drug toxicity (63.4%) or oxycodone toxicity alone (11%).”(Pilgrim JL et al, “An Update on Oxycodone: Lessons for death investigators in Australia”, Forensic Sci, Med and Pathol (2015); 11(1): 3-12).

The Australian Atlas of Healthcare Variation published in late 2015 by the Australian Commission on Safety and Quality in Health Care (and available online at <http://www.safetyandquality.gov.au/atlas/>) has confirmed what staff from the Pharmaceutical Services Branch were already well aware of, and that is that Tasmanian doctors are prescribing a range of analgesic and psychotropic drugs well in excess of the rates of prescribing on average, across our nation. By way of example, this report reveals that Tasmanian doctors are prescribing opioid medications at 34% above the Australian average, antidepressant medications for those 17 years and under at 20% above the national average and at 38% above the average for those 18 to 64 years of age; anxiolytic medications for those 18 to 64 years of age at 50% above the average, anxiolytic medications for those 65 years and over at 44% above the average; medicines for treating ADHD in those 17 years and under at 23% above the national average and GP mental health plans at 6% below the national average. The rate of prescribing of these medicines across Australia is suggested to be already far too high so one can readily see how much work needs to be done in Tasmania to better understand and address this human distress and dysfunction in ways other than prescribing potent analgesic and psychotropic medications. These medicines have a role in medicine but sadly, when used injudiciously, they often deliver too little even in the way of symptomatic relief; relief that is often only short lived and may either contribute to or cause substantial health and human problems.

Although opioid prescribing remains at very high levels in respect of complaints of chronic pain, advice provided to me is that although strong evidence supports the use of opioids in acute or cancer pain, palliative care and opioid dependency/addiction therapy, there is reliable, consistent evidence that the effectiveness of opioids in patients with persistent non-cancer pain is weak. I commend to all primary prescribers the summary of the approach to the safe and effective use of opioids in chronic non-cancer pain (CNCP) outlined in the

Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists document “Recommendations Regarding the Use of Opioid Analgesics in Patients with Chronic Non-Cancer Pain” (published as PM01 2015 at <http://fpm.anzca.edu.au/documents/pm1-2010>). This document summarises both international and Australian findings that highlight the clear risks versus benefits of opioid use for CNCP. Persistent pain usually presents with biological, psychological and social environmental factors. Safe and effective management of persistent non cancer pain requires effective assessment and management of all of these factors. Prescribers and the general community must be educated as to the known multiple risks and limited benefits associated with opioid prescription in circumstances of CNCP.

The following summarised comments from the above paper highlight the extent of the problem within the community:

- Population studies show that people maintained on long-term opioid therapy for CNCP describe more troublesome pain and greater functional interference than people not on opioids.
- A recent Australian population study of a cohort of patients on long-term opioid therapy found two-thirds were unemployed or receiving government benefit and almost one half were on low income. It also found that 80% of the cohort reported multiple pain conditions, 50% significant depression, 50% suicide ideation, over 50% had a history of childhood abuse or neglect and over 30% had an alcohol use disorder.
- Use of high pain severity using a 0 – 10 verbal numerical rating scale alone provides a poor basis for selecting patients for opioid treatment as these are known to be influenced by multiple psychological and contextual matters. I am advised that unfortunately, the experienced and observant clinician knows that self-report is not a reliable basis in isolation for clinical monitoring and assessment of benefit, risk and harm when it comes to analgesic and psychotropic medicines and to people who are struggling to cope with mental illness, psychological distress, chronic pain or drug-related effects including drug toxicity or drug withdrawal. Pain is what a patient says it is, however, the underlying causes are more complex than self-report. Pain management is accepted as a patient or human right but this must follow on from a proper clinical assessment as to how this is best achieved. When patients self-report benefit, it may be the affect modulating effects, the euphoria or the opioid withdrawal symptom relief rather than analgesia per se, but clinicians do not commonly probe and adduce this level of clinical detail. Rather, more commonly, they will just accept the patient’s word.
- Patients with mental health and substance abuse problems are more likely to be prescribed chronic opioid therapy.

It is manifestly clear on the basis of current knowledge that opioid pharmacotherapy cannot be considered to be the core component of the management of CNCP, and that passive receipt of opioid therapy is a distraction from the need to address all factors that are influencing the patient. It is the multi-modal non-pharmacological interventions delivered by a range of health professionals (psychologists, physiotherapists, nurses, occupational therapists) that must play a more prominent role in the clinical management of persistent non-malignant pain into the future. Sadly, the patients who are drug focussed and perhaps ‘chemical coping’ will often not engage in these other treatment modalities even where they are more readily accessible. It has been described that patients using opioid medication for pain management fall within a spectrum: from adherence, to chemical coping, followed by abuse and then addiction. In short chemical copers are those who become focussed on drugs to address their complaints.

Treatment of CNCP is best addressed by collaboration between the patient, the primary health care provider (GP) and, where necessary and available, by liaison with and referral to a formalised pain management entity. There is a Persistent Pain Service (PPS) based at the Royal Hobart Hospital providing a multi-disciplinary resource to assist those patients who wish to engage with the service. This engagement can be problematic as it is reliant upon the patient understanding what can be provided and having realistic expectations as to outcomes. This engagement may be more positive if patients were educated as to the limited likely benefit of opioid therapy in isolation and were given stark warnings as to the risks and known limited benefits of that approach. Additionally, if the prescribing of opioid medication in respect of CNCP was restricted to accord with scientifically proven guidelines then it is likely that affected patients would be more likely to engage with a multi-disciplinary regime for pain management. Given the extent of the continued inappropriate prescribing of opioid medication in relation to CNCP, the limiting of such prescribing to cases where the patient has engaged with a multi-discipline pain management program ought to be considered. An appropriate pain management program needs to be tailored to address the relevant issues of a particular patient. However, it may involve input from pain management specialists, addiction specialists, appropriately qualified nurse practitioners or registered nurses, psychologists, physiotherapists, occupational therapists and other allied health practitioners who not only have the knowledge and skills but also are motivated to work in this complex and challenging area of health care. I am advised that the PPS at Royal Hobart Hospital is working to capacity and is unable to provide effective service to the North and North West of the State. There is currently no multi-disciplinary pain management service in those areas and there is clearly a need for such service if we are to address the ongoing problems (which include death) of long-term opiate prescribing for CNCP.

Although recognising that the present Government has embarked on a plan for the future insofar as health services within this State are concerned (Delivering Safe and Sustainable Clinical Services: White Paper, June 2015), this Paper contains incorrect foundational facts in relation to current pain management services in the State, for example:

- The PPS at the Royal Hobart Hospital does not provide a State-wide referral service as it is not funded to do so, and
- The Launceston General Hospital has no acute or persistent pain management service.

The White Paper correctly records that there are no pain management services at the North West Regional Hospital or at the Mersey Community Hospital.

Whilst recognising the overall funding issues associated with the provision of health care generally, there is clearly a regional inequity in the provision of pain management services in Tasmania and also a lack of a State-wide co-ordinated approach to this topic. Given the clearly established health risk of over prescribing or inappropriately prescribing of opioid therapy, there needs to be a co-ordinated State-wide approach to deal with CNCP which must include:

- Available options State-wide; that is, provision of a co-ordinated pain management service;
- Community education and knowledge;
- Prescriber education and knowledge;
- Prescriber support from specialist staff in pain management and addiction medicine; and

- Prescription control measures.

The current lack of a comprehensive and co-ordinated pain management service also extends to addiction medicine support. I am advised that the Alcohol and Drug Services presently provides a limited consultation liaison service at the Royal Hobart Hospital and even less at the major hospitals in the North and North West of the State. Community teams from the Alcohol and Drug Services are located in Hobart, Launceston and Ulverstone, with some outreach to remote areas, operating programs principally designed to treat prescription opioid dependence often in tandem with a range of other drug problems, including those related to the use of benzodiazepine medications, cannabis, alcohol and amphetamine type stimulants. It is further reported that there is presently a serious gap in the degree of shared care support Alcohol and Drug Services is able to provide to GPs in the community who find themselves in difficulty managing the complexity of co-occurring CNCP, substance abuse disorders, mental health problems and social problems.

In relation to State-wide availability of persistent pain services, there requires to be a mapping of all public and private sector services so as to develop an effective pain management service delivery model. The issue of qualified specialist staffing to a PPS remains an issue not only from funding of positions but also the relevant training and qualifications required. I am advised that Commonwealth Department of Health funding was available for specialist training programs in pain medicine in the periods 2014 through to 2016 but unfortunately insufficient suitable applicants were attracted. My understanding is that sustainable staffing at the PPS at the Royal Hobart Hospital has been partially realised; however, there is an ongoing shortfall in providing resident regional specialists in the North and North West of the State. I recommend that endeavours to attract and train appropriate medical practitioners continue in order that these services can be established and sustained. The White Paper envisages that regional pain management clinics will be under the clinical direction of a "specialist medical practitioner with sub-speciality training in pain medicine". This is clearly a lesser qualification than a Specialist "Pain Medicine Physician" as recognised by the Australian Health Practitioner Regulation Authority, but no details are provided as to precisely the training and qualification meant by "sub-speciality training". Perhaps this can be designed to encompass a "General Practitioner with special interest". Before advancing the creation and staffing of these pain management programs the necessary qualifications and experience of these key staff needs to be settled. It is recommended that a minimum level of competence is defined for such medical practitioners involved in the clinical management of pain management programs and that a clear process is established to enable close liaison with qualified specialist services to ensure that all Tasmanians are able to receive appropriate, contemporary, safe and effective patient care. Any co-ordinated model for pain management developed during the White Paper implementation must ensure the Alcohol and Drug Services is structured so as to be able to provide clinical guidance and assistance in respect to addiction not only in hospital settings and PPSs but also to primary care providers as and when required. Staffing difficulties are also reported in relation to providing Alcohol and Drug Services support throughout the State. In particular, it has been extremely difficult to recruit and retain addiction medicine specialists. Given the advice that I have received that there are only approximately 100 FTE addiction medicine specialists in practice within Australia and currently 23 doctors in training this difficulty is unlikely to be alleviated by seeking specialist physicians. I recommend that other options be considered to fill the gap, perhaps general practitioners with "sub-specialist training" in addiction medicine to correspond with the pain management proposed model in the White Paper. Finding the resource in other areas such as appropriately qualified and experienced nurse practitioners working under general clinical supervision could be another option deserving of consideration. The clear community need highlighted by the investigation cannot allow a continuing situation where the Alcohol and Drug Services has only one doctor (experienced but not a specialist in addiction medicine) covering the entire North and North West of the State. Given the limited number of pain management and addiction medicine specialists presently available and the unlikelihood of this situation improving in the near future some sustainable alternate option needs to be developed as reliance on short-term

fixes, such as locum appointments, has previously been shown to be a significant expense to a challenged health budget.

I recognise that since the date of Ms Barnes's death, much has been done to address some of the issues highlighted by this investigation. In particular the Tasmanian Department of Health and Human Services (via the Pharmaceutical Services Branch ("PSB")) developed and implemented a real time prescription monitoring program which monitors the dispensing of Schedule 8 opioids and the benzodiazepine, alprazolam. The first stage was to install a real time reporting system (DAPIS) in pharmacies to capture information and dispensing of target drugs and transmit this electronically to the PSB. The real time reporting system was installed in all Tasmanian hospital pharmacies in 2009 and was progressively rolled out to community pharmacies from that date. It is now operating in over 90% of community pharmacies. This system allows staff at the Pharmaceutical Services Branch to monitor dispensing events in order to identify anomalies such as a person dispensing excessive quantities of target drugs or target drugs being dispensed to a person from multiple prescribers. The system therefore guards against "Doctor Shopping" i.e. seeking prescriptions from multiple doctors, but cannot directly protect a patient from over prescribing or inappropriate prescribing. This aspect lies with the level of knowledge and professionalism of the prescriber.

It is recognised that the PSB, within the limit of their resource, continue endeavours to educate, counsel, and facilitate peer support and attempt to negotiate changes in prescribing practices with individual practitioners. If necessary they have, and perhaps given the necessary support ought to use more readily, their powers to remove or restrict prescribing rights or refer practitioners for disciplinary investigation.

Clearly, PSB would need additional resourcing, especially in the area of staffing, if this system were made compulsory or a higher level of vetting of prescribing were to be provided. The ultimate value of this system is to use it not just as a data capture tool but to provide staff to oversee prescribing in order that intervention could occur when prescribing was noted not to be in conformity with safe medical practice. This may involve input from appropriately qualified staff from Alcohol and Drug Services upon issues of addiction or toxicity risk. Present staffing allows only the oversight of identified high-risk patients and the detection of flagrant mis-prescribing and over-prescribing.

The second stage was the implementation of the Drugs and Poisons Information System Online Remote Access (DORA) interface which enables prescribers and dispensers to view online and in real time the drug dispensing history for a patient as stored in the real time reporting system. The DORA interface was installed in Department of Health and Human Services administered hospitals, pharmacies and clinics in 2011 and offered to community pharmacies and general practice at the same time. I understand that approximately half of the pharmacies and half of general practices in Tasmania are able to access DORA. A recent analysis of overdose deaths during the period 2005 to 2013 has identified that overdose deaths involving pharmaceutical opioids have dropped from 32 per year representing 66.7% of all overdose deaths in 2007, to 15 deaths, representing 37.5% of overdose deaths in 2013.

The operation of both of these systems may well have assisted in the clinical management of Ms Barnes. Given the positive effects of these systems, it is my recommendation that consideration be given to mandating that both the primary prescriber and also the dispensing pharmacy of any opioid medication in circumstances of the treatment of CNCP, may only do so if they have access to and use these systems whenever prescribing or dispensing opioid medication.

Although beyond the scope of this investigation, having noted the concern expressed at the high level of prescribing of opioid medication nationally, I encourage ongoing development

and implementation of national programs that may assist and also within Tasmania complement DAPIS and DORA. Those programs are:

- Personal Controlled e-Health Record (PCEHR), and
- Electronic Reporting and Recording of Controlled Drugs (ERRCD).

It is formally recommended that the prolonged use of opioid medication in relation to CNCP only be permitted to be prescribed where it is part of a structured pain management program, be it formal via a PPS or structured and overseen by the prescribing general practitioner. A patient's involvement in any pain management program or multi-disciplinary endeavours is voluntary. It is reported that a significant number of persons to whom such programs or options are suggested refuse or fail to engage in these alternatives. It must be made clear that such alternatives do not mean a person is immediately withdrawn from medication but rather it is a means to address the multi-dimensional nature of chronic pain and allow weaning from opioid medication. The dangers associated with prolonged opioid medication use, especially with other CNS depressants, have been clearly established. The alternative to engaging in a structured pain management program must not be the prescription of medication in isolation. If a unimodal rather than multi-modal approach is allowed then any opioid prescribing must come with appropriate risk management and boundary setting for the patient. A systematic review of opioid response after 6 months of therapy in 25 non-randomised case series showed weak evidence of modest analgesic benefit and inconclusive data in regard to improvement in physical function and quality of life (Noble M. et al, "Long-term opioid management for chronic non cancer pain, Cochrane Database of Systematic Reviews 2010, Issue 1). Population studies show that people maintained on long-term opioid therapy for CNCP describe more troublesome pain and greater functional interference than people not on opioids (Erikson J. et al, "Critical issues on opioids in chronic non-cancer pain: an epidemiological study, (2006) Pain 125: 172-79).

The scientific material that I have been referred to makes it very clear that prolonged use of opioid medication with or without other medication in isolation of other multi-disciplinary input into addressing the multi-dimensional aspects contributing to chronic pain cannot be accepted as appropriate clinical practice. Given the advice I have received that inappropriate prescribing is still occurring in respect of patients with CNCP, my recommendation is that the prescribing of opioid medication in such circumstances be further controlled by authorising such prescribing (after a certain initial period) only in circumstances where the patient has formally agreed to engage in and whilst participating in a recommended multi-disciplinary pain management process in which the pharmacotherapy is a component of that process.

It is recognised that all of this leads back to the primary prescriber, the GP, who has the primary responsibility for most people seeking assistance for chronic pain. Not only must GPs accept (having been given the knowledge and scientific data) evidence-based prescribing practice for opioid medication, they also need assistance to deal with issues that will arise. There needs to be a system, properly resourced, that is readily available to provide GPs with information, guidance and support from appropriate specialists in pain medicine and addiction medicine.

Medical practitioners require knowledge, skills, attitudes and competencies to manage the issues highlighted by this case. They need ready access to specialist liaison and support coupled with regulatory control that mandate prescribing restrictions or direct prescriber behaviours. Finally, they need the availability of other multi-disciplinary options in dealing with a patient complaining of CNCP. This supports the previous recommendation that there be a State-wide co-ordinated approach to the treatment of CNCP.

The stark reality is that in all cases such as this, the start point is the decision made by the primary treater to prescribe opioid medication. In terms of co-morbidity, patients presenting

with CNCP and/or alcohol and drug presentations are significantly more likely to present with a psychological co-morbidity. These may include emotional distress, a diagnosable psychiatric disorder, such as an anxiety disorder and/or depression, and/or related psychological factors such as catastrophizing, fear avoidance and or low self-efficacy. All of these issues may affect the pain experience, disability, engagement with health care providers and outcomes, including an increased risk of opioid prescribing and higher opioid dose prescribing. It is recognised that there are significant issues that impact on the GP that need to be recognised by those GPs, and addressed by them with support options available.

Safe prescribing practice must not only be highlighted in initial medical training but must be ongoing throughout a GPs period of practice. Ongoing scientific research has highlighted the inappropriate use of opioid medication over a long period in cases of CNCP and it is of concern that PSB report numerous incidents of inappropriate prescribing still occurring. A primary prescriber who maintains the long-term prescribing of opioid medication especially in conjunction with other CNS depressants to counter complaints of CNCP without addressing the multi-dimensional aspects of that presentation and involving a multi-disciplinary approach can now be shown to be failing to conform to evidence based medicine. The scientific evidence is available to show the failings that led to the death of Ms Barnes. The medical profession must ensure that this evidence is not only made available to members but that those members change their perhaps historical prescribing practices in order to comply with the current scientific position. Government is obliged to ensure there are support measures in place to allow GPs to adopt this scientifically based approach to treating CNCP. Once the information and knowledge is circulated and support measures are in place, inappropriate prescribing must be addressed by regulatory restriction or even professional disciplinary action.

The information that I have been provided indicates that in respect of prescribing for CNCP, GPs in Tasmania fall across the range from: compliance with current evidence based approaches, through to those struggling due to such things as lack of knowledge, time or skills to deal with interpersonal conflict with patients, to those who steadfastly refuse to alter historic prescribing practices.

Promoting and eventually ensuring a safe and effective prescriber performance in pain, addiction and opioid prescribing is a complex matter. However, just because it is a complex issue is no justification for not taking forceful and positive action to address this significant social issue, which at best will become entrenched or at worst continue to grow. Although inappropriate prescribing of medication would not occur unless a medical practitioner wrote a prescription, the onus and responsibility involves more than that. There is a clear onus upon Governments to support those prescribers by taking steps to educate the community as to unrealistic expectations of analgesic medications for CNCP and to support primary prescribers by providing a structure or process that allows them to deal with patients with CNCP in a holistic manner. One could start with ensuring that medical practitioners can offer the time needed to identify and address the multi-dimensional aspects of CNCP, which presently is constrained by directed consultation times and time based payment systems. Modern GP practice creates limits on a GP's time with a patient, there are difficulties seeing the same prescriber, and perceived gaps in the continuity of information, observations, and clinical picture of a patient between consultations, especially as to prescribing considerations. In addition, the resources necessary for a primary provider to deal with a patient with CNCP must be established, as outlined previously, in the need for a co-ordinated State-wide pain management structure.

However, work needs to continue to ensure that undergraduate medical training focusses on present day scientific evidence concerning the use of opioid medication in relation to CNCP. Professional bodies must ensure similar training is provided to those practicing to ensure their prescribing takes into account the current scientific information, that they appreciate the nature of pain as a bio-psychosocial entity, that they conform to the Universal Precautions in prescribing, that they fully appreciate the risks and benefits of opioids in CNCP, that they are

aware of and in relevant cases undertake risk stratification and commensurate management strategies, and they closely monitor and review the use of opioids (including trials) and are prepared and able to conduct opioid weaning.

Professional development needs to ensure that prescribers have the skills to deal with demanding, aggressive and chemical coping patients. A process must exist for a prescriber unable to deal with such a patient to refer them on rather than merely complying with the patient's demand. They need to be able to explain CNCP and the limited role of opioid medication and benefits of the multi-disciplinary approach.

I am informed that there are still negative attitudes that perpetuate the inappropriate prescribing of opioid medication, usually in conjunction with benzodiazepines. These include:

- Wishing to keep the patient engaged;
- Prescribing as a risk management approach as the patient would otherwise obtain the medication illegally;
- Not engaging in risk management strategies as it is not for them to police use;
- Choosing not to rely upon the extensive literature concerning the harms of long-term and high dose opioid therapy; and
- Dealing with a complaint of pain as a symptom or number in isolation and not by comprehensively assessing pain as a bio-psychosocial entity.

These attitudes merely perpetuate or accentuate the major social health issue of inappropriate opioid medication use.

I recognise that flowing from the Tasmanian Opioid Review 2012, the DHHS has continued to engage with, support and lead State-wide Opioid Risk Reduction via its various operational entities. These strategies seek to improve the safe and effective clinical use of opioids. I encourage the continuation of these strategies which to date have included education on pain management during undergraduate medical training, postgraduate hospital placement and GPs in practice, together with offering the opportunity for telephone contact for specific advice from specialists in pain management and addiction medicine.

This case also highlights the care needed to be taken in prescribing any medication with the onus upon the prescriber to be aware of and take into account the adverse effects of: individual drugs, a cumulative effect from multi-drug use, and the potentiation of adverse effects due to medication-medication interactions. As a Coroner of many years' experience I am dismayed by the significant number of cases where the cause of death is concluded as "multi-drug toxicity". In the majority of cases these arise as a result of the ingestion of various prescription medications. The investigation in relation to those cases (as with this matter) deals with determining whether the death was accidental or not. Given the known risks, I suggest that it is time that a Coronial investigation in such matters (where there is no evidence of deliberate overdose) not accept the alternative as accidental. "Accidental" infers that the death was unexpected and unavoidable. Use of terms "deliberate " or "accidental " overdose have the effect of suggesting the patient as the principal agent associated with the adverse event and or the death was not preventable and or that an increased risk of death was not predictable. Focussing upon the overdose can obscure direct or contributory causes in relation to the medication prescribing itself. I conclude in relation to the death of Ms Barnes that the medication prescribing in light of her past history and the nature of the drugs involved was arguably both likely and avoidable. Far too commonly there appears to be a situation develop where multiple medications are prescribed over time and there is a lack of any record where a prescribing medical practitioner actually takes the time to stand back and

look at the prescribing record or to have someone more experienced or expert look at the prescribing record and identify a time to start again or to simplify the medication regime. This is not meant as a direct criticism to the medical practitioners who, once again, have at the forefront, their wish to assist a patient with reported symptoms. However many cases I have dealt with seem to be dealing with circumstances as a result of a long history of medication being prescribed for one thing or another when a patient reports symptoms, medication is prescribed, they return and report symptoms, medication is prescribed – there does not appear to be a built-in safety valve to consider the cumulative effect over time of these various medications, or the possible inter-relationship of the various medications.

It is clear that the incidence of adverse drug reactions increases with the number of medications used. Additionally, the more drugs a patient is exposed to, the more likely they are to be prescribed inappropriately (Stienman M. et al, “Polypharmacy and Prescribing Quality in Older People”, J Am Geriatrics Soc, 54(10):1516-23 (2006)). The key issue in poly-pharmacy is whether each drug has been prescribed appropriately, both individually and in the context of the patients total medication exposure, risk of drug interactions, comorbidities, physiology and quality of life. Proper prescribing requires regular review of the medication regimen to assess the indication, therapeutic aims, dose, efficacy and safety.

The medication prescribed to Ms Barnes exposed her to significant risk of death by reason of:

- Combined sedative effect of a number of CNS depressants, methadone, diazepam, Quetiapine, amitriptyline, valproate and des-methyl-velaxine.
- Overdose death by allowing self-regulation of opioid medication.
- The combined use of methadone and benzodiazepam is a known high-risk. The Tasmanian Opioid Review 2012 (National Drug and Alcohol Research Centre (2012), A Review of Opioid Prescribing in Tasmania: A Blueprint for the Future: University of NSW) noted at p 65:

“Deaths associated with benzodiazepine use have continued to increase over the past decade. This is a significant concern, particularly since almost all of the deaths resulted from ‘multiple drug toxicity’. The findings were translated into recommendation 4.1.5:

‘The prescribing of opioids, where patients are prescribed benzodiazepines and or are ingesting alcohol in excess of national guidelines is to be actively discouraged.

Recommendation to discourage co-prescribing of opioids and benzodiazepines and to discourage prescribing opioids where there is current alcohol use.

There appears to be few benefits, if any, to long term benzodiazepine prescribing for chronic pain or any of its common comorbid conditions. The combination of these two drugs is a significant contributor to overdose deaths amongst IDUs and chronic pain patients. If the prescribing of both of these drugs is indicated, the patient must be made aware of the serious risk of adverse events; the importance of complying with the medication regimen; and advised not to use any other CNS depressants (especially alcohol)”.

- Methadone was reintroduced after a period of abstinence without any apparent consideration as to loss of tolerance and the increased risks of adverse effects in the re-induction phase.

- Exposure to risk of serotonin syndrome; this is a toxic state resulting from excess serotonin in the nervous system causing mental, autonomic and neuromuscular changes. It is usually but not always caused by the concurrent use of two or more drugs with serotonin effects one of which is likely to be a serotonin reuptake inhibitor. In this case the serotonin reuptake inhibitor des-methyl-venlafaxine was prescribed with other drugs associated with serotonin syndrome, i.e., amitriptyline, methadone and valproate.
- Methadone is noted to prolong the cardiac QT interval. Caution is warned when using with other drugs that prolong the QT interval. In particular the MIMS entry for methadone states "...*extreme caution is necessary when any drug to have the potential to prolong the QT interval is prescribed in conjunction with methadone...*". Quetiapine comes with a warning against use in known cardiovascular disease: "*Causes cardiac QT prolongation and it is reported that its use should be avoided in combination with drugs that are known to prolong the QT interval.*"
- Valproate inhibits the metabolism of both diazepam and tricyclic antidepressants.
- MIMS provides caution for the use of des-methyl-venlafaxine and amitriptyline in persons with cardio vascular disorders.

The above analysis of the medication regime provided to Ms Barnes indicated that the central cause of her death i.e. the drug toxicity whether it caused fatal sedative effects, or an adverse cardiac event or serotonin syndrome was something that was possibly avoidable had the prescriber considered the clear risks of the prescribed medication regime. This is further highlighted by prescribing medication with clear cardiac effect warnings where there is no evidence that the state of Ms Barnes's cardio vascular system was considered and at autopsy was shown to be compromised.

I have received submissions questioning the use of Quetiapine. The drug was approved in 2008 and PBS subsidised for schizophrenia and bipolar disorder (and associated mania/depressive episodes). It has gained non-subsidised approval for treatment resistant depression and generalised anxiety disorder. Quetiapine use grew 82% from 2008 to 2011. It's "off-label" use has become a cause of concern. It is reported as one of the most common drugs taken in overdose and is the most documented antipsychotic on the street. Jonathan Brett, Staff Specialist, Clinical Pharmacology and Addiction Medicine, Royal Prince Alfred Hospital in an article "Concerns about Quetiapine" (Australian Prescriber (2015), 38(3), 188-90) reports:

"There is little evidence to support many of the off-label uses of quetiapine. Indications with particularly poor evidence include anxiety, insomnia, post-traumatic stress disorder, personality disorders, behavioural and psychological symptoms of dementia and substance misuse."

...

Quetiapine appears to be the most documented antipsychotic brought and sold illicitly on the street. There are also numerous case reports of abuse and dependence".

I endorse his conclusion that:

"Quetiapine has proven safety and efficacy when used for its approved indications. However, there are concerning increases in the rates of off-label

prescribing for indications with limited evidence. Adverse outcomes are most likely to occur in already vulnerable populations such as older people, those with mental health problems and substance misusers. Prescribers should therefore be cautious when considering a prescription for quetiapine for an off-label indication”.

One process that not only can educate the patient and prescriber but also provide enhanced regulation of the prescribing of opioid medication is the formal Application for Authority to Prescribe completed by the prescriber and forwarded to PSB. The *Poisons Act 1971* provides by section 59E that such form should contain the information in section 59E and “contain such information relating to the medical history and treatment of the patient as the Secretary requires”. The form has been the subject of redevelopment over 2 years and has been revised with input from specialists in pain medicine, addiction medicine and general practice. There has also been State-wide consultation and I am informed that the revised form is in the final stage of development with a roll-out to occur this year. I have examined the current draft form and am impressed by how it will require engagement by the prescriber and patient and will of itself be a risk and need assessment tool and will also outline all relevant information to the patient. I endorse the intent of this new form to:

- Be educational and improve prescriber knowledge and understanding;
- Promote and support effective bio-psychosocial assessment;
- Support safe and effective decision making in opioid prescribing;
- Improve informed consent for patients regarding the risks and benefits of opioid use as part of a comprehensive management approach;
- Provide for a patient contract if required; and
- Improve the information available to the PBS and its expert advisory panel and thus improve decision making and advice to prescribers.

I recommend that any needed resources be made available to ensure that this revised form is able to be issued for use as soon as possible. The process of completing this form will address information that current day scientific knowledge indicates should form part of any opioid prescribing decision.

Recommendations & Comments:

In summary my formal recommendations are:

1. That Government and medical professional bodies ensure that prescribers are aware that the current scientific knowledge indicates:
 - There are significant risks of adverse events with chronic opioid therapy, and where opioids are used in combination with other drugs. Those risks include but are not limited to sedation, serotonin syndrome, cardiac arrhythmia and death.
 - Opioids have a limited role in treating CNCP with little evidence of long-term benefit. Tolerance to opioids and opioid induced hyperalgesia further complicate the use of opioids in CNCP.
 - Central sensitisation and tolerance can occur within 4 weeks.

- Different pain types/mechanisms exist (nociceptive, neuropathic, neuroplastic, central sensitisation) requiring assessment and management tailored to the individual patient's circumstances and specific diagnosis.
 - The risk of chemical coping and abuse, misuse and addiction is significant.
 - Comorbid conditions, e.g., anxiety and depression, complicate patient management with the use of opioid medication.
 - The known risks of opioid use and limited benefits provided in CNCP mandates a risk-benefit approach to prescribing opioids in CNCP.
2. Primary prescribers be provided with available support options when treating patients with CNCP including:
- A co-ordinated and integrated pain management system providing formal and informal pain management options, advice and support from pain management and addiction medicine specialists.
 - The availability of multi-discipline support to deal with the multi-dimensional aspects of chronic pain: e.g., psychologists, physiotherapists, nurses, occupational therapists.
 - Allowing within the Medicare costing structure of a GP visit, appropriate recognition of the extra time needed to deal with a complaint of CNCP, which allows the treater to deal with the complete picture rather than focussing upon the symptom of pain as a number alone.
 - Consideration of a funding model (similar to community mental health plans) to provide multi-discipline support for CNCP.
 - Professional development in regard to developing skills to deal with demanding, aggressive and chemical coping patients. Also a process to allow referral of such patients to a prescriber or specialists who has those skills if required.
3. Prescribers and patients are informed that opioid pharmacotherapy cannot be considered to be the core component of the management of CNCP and the passive receipt of opioid therapy is a distraction from the need to address the multi-factorial concept of chronic pain.
4. In implementing the White Paper recommendations for State-wide pain management services an early determination is made as to the required qualification, experience and competence required of a medical practitioner to satisfy the criteria of "*specialist medical practitioner with sub-speciality training in pain management*".
5. Any co-ordinated model for pain management developed during the White Paper implementation ensures that the Alcohol and Drug Services is structured so as to be able to provide clinical guidance and assistance in respect to addiction issues to hospitals, PPSs, primary prescribers and the PSB.
6. That there be a continuation of the required funding for the employment of pain management and addiction specialists and that consideration be given to providing the required clinical support by use of suitably qualified medical or nurse practitioners to fill the current and projected need.

7. Government assist medical professional bodies in efforts to educate the general community as to the current state of scientific knowledge, highlighting the limited role and benefits of opioid medication in cases of CNCP and the concurrent risks of long-term use of opioid medication for CNCP. That such community awareness also highlights the benefits of a multi-disciplinary approach to CNCP.
8. Medical professional bodies highlight to their members the dangers associated with poly-pharmacy. In particular, prescribers must ensure that medication is prescribed appropriately, both individually and in the context of the patient's total medication exposure so as to protect against drug interactions. Action by way of regular review of a patient's medication regime is required to ensure prescribing is appropriate and it remains appropriate and safe.
9. The PSB Protocol for Opioid Prescribing (2009) be revised in light of and in order to reflect the current state of scientific knowledge concerning the prescribing of opioid medication in general and in particular with respect to CNCP.
10. In order to address the continued inappropriate prescribing of opioid medication in respect of CNCP, consideration be given to:
 - Limiting (after a specified period) such prescribing only to those patients who have engaged with a form of multi-disciplinary pain management program where pharmacotherapy is but a component of that process.
 - Limiting such prescribing to prescribers who have access to and use DORA in those circumstances and that dispensers use DAPIS and DORA.
 - Removing the prescribing rights of opioid medication from those prescribers shown to have prescribed other than in accordance with accepted scientifically based clinical practice or alternatively limit the authority to prescribe, in those circumstances, to those who have endorsed that recommended clinical practice and undertake to comply with it.
 - Providing additional resources for increased staff at PSB so as to allow oversight of the prescribing of opioid and other targeted medication so as to identify prescribing that is not in conformity with safe medical practice.
 - Developing a protocol that allows assessment of those incidents of prescribing apparently not in conformity with safe medical practice and to allow intervention in such cases either informally or formally by way of prescribing tight restrictions or professional disciplinary action. Such protocol would need to be developed in association with the Ombudsman in order that issues as to patients' rights could be addressed.
11. That the Government work with the appropriate medical and allied health specialists to implement the recommendations outlined at pages 82 - 106 in the National Drug and Alcohol Research Centre (2012), A Review of Opioid Prescribing in Tasmania: A Blueprint for the Future: University of NSW.
12. That future coronial investigations relating to "combined drug toxicity" not be limited to a consideration of whether the ingestion of those drugs (in particular prescriptions drugs) was done with intent to self-harm; with the alternative that any overdose was accidental. Focusing upon the overdose itself does not permit a clear determination of the underlying issues and identification of direct, contributory or systemic causes of the death. The coronial investigation should consider:

- Whether the prescribing of the medication was appropriate and safe;
 - Whether proper consideration was given to the adverse effects of individual drugs, any possible cumulative effect from multi-drug use, or the adverse effects due to medication/medication interactions; and
 - Whether the fatal outcome, given the history of the patient, the nature and effects of the medication upon the patient, the physical and psychological condition of the patient, was in fact likely and avoidable if that medication regime had been objectively assessed against likely risk versus the efficacy of the poly-pharmacy.
13. Government and medical professional bodies objectively assess the efficacy of Quetiapine when used “off-label” rather than for its formal approved use with Schizophrenia and Bipolar Disorder (and associated mania/depressive episodes). Limited evidence exists as to its effectiveness when used “off-label” and there has been a startling increase in its involvement in fatal overdoses and illicit use. The social benefits of widespread use of this drug need to be assessed against the increased rates of misuse and illicit use. Noting the resourcing issue that this creates it is further recommended that in the interim Quetiapine and benzodiazepines, “z drugs” and “gaba drugs” such as gabapentin be made reportable drugs that require authority under section 59E for prescribing in circumstances where the patient has been reported or diagnosed as drug dependant or drug seeking/coping.
 14. The application for authority to prescribe opioid medication (*Poisons Act 1971*) which is currently under revision needs to be completed and introduced for use without delay. Any required resources for that task must be provided as this process has the potential to modify the prescribing habits of primary prescribers and to increase the understanding and appreciation upon this topic by the patient.
 15. Consideration is given as to standardisation of the various terms and phrases used in relation to reporting the misuse of prescribed medication. I am advised there is evidence of inconsistency in definitions related to substance use over time between countries, medical organisations, clinicians, legislation and lawyers. Many terms such as addiction, substance abuse, substance dependence and dependence are often used interchangeably. This uncertainty and lack of precision may not only confuse health professionals and lead to an imprecise clinical picture on a patient but it also hinders the collection, correlation and analysis of data on this topic which negatively impacts upon research findings.

In order to achieve a consistent, safe and effective clinical use of opioids, the key challenge is to translate current, very clear scientific knowledge and recommendations into clinical practice. I encourage the continuation and expansion of endeavours to date in order that the approach incorporates:

- Education and knowledge needs of all prescribers in particular addressing the knowledge/practice gap.
- Reinforcing to all prescribers the need to adhere to recognised Uniform Precautions in prescribing (Gourlay D.L. et al, “Universal Precautions in Pain Management”, *Pain Med* 2005; 6(2): 107-12).
- Adherence to the guidance on opioid prescribing provided in the Review of Opioid Prescribing in Tasmania: A Blueprint for the Future 2012 at p 58 and following.
- Support mechanisms available to prescribers who require such assistance, e.g., expert advice and support from specialists in pain medicine and addiction medicine.

- State-wide equity of access to multi-disciplinary care for the clinical needs of patients.
- The creation of an environment that encourages and supports, and where necessary mandates and enforces safe and effective clinical practice through regulatory or legislative means.

Finally there were no circumstances surrounding Ms Barnes's death that indicated that any other person was involved.

Although a number of substances were found in her system at extremely high concentrations, there is no evidence to suggest that Ms Barnes overdosed in a deliberate act to end her own life. Reports from family and health professionals indicate that in the weeks before her death, following her hip replacement, she was in reasonably good spirits. As explained in these findings I do not simply conclude that the alternative finding was accidental as this denotes that the fatal outcome was unavoidable.

I express my appreciation of Dr M Sarma, Staff Specialist – Pain Management, RHH, Dr A Reynolds, Clinical Director, Alcohol and Drug Services, DHHS and Mr P Boyles, Chief Pharmacist, Pharmaceutical Services Branch, DHHS (and his predecessor Mr J Galloway) for their assistance to me in this investigation.

I convey my sincere condolences to Ms Barnes's family.

Dated: 25 May 2016 at Hobart in Tasmania.

Stephen Carey
Coroner