

FORM 38

Rule 60(2)

REDACTED FINDING INTO DEATH WITHOUT INQUEST

Section 67 of the Coroners Act 2008

Court reference: 5260/09

In the Coroners Court of Victoria at Melbourne

I, PARESA ANTONIADIS SPANOS, Coroner,

having investigated the death of:

Details of deceased:

Surname: A
First name: D
Address: Craigieburn, Victoria 3064

without holding an inquest:

find that the identity of the deceased was DA was born on the 6th June, 1967

and death occurred on the 6th November, 2009

at 246 Carrick Drive, Gladstone Park, Victoria 3043

from: 1(a) ISCHAEMIC HEART DISEASE
1(b) CORONARY ARTERY ATHEROSCLEROSIS

Pursuant to Section 67(2) of the **Coroners Act 2008**, an inquest into the death was not held and the deceased was not immediately before the person died, a person placed in custody or care; but there is a public interest to be served in making findings regarding the following circumstances:

INTRODUCTION

1. DA was a 42-year-old married father of three who resided with his family at Craigieburn. Mr DA worked as a forklift driver until 2004. When he left he undertook a short course in antenna installation, purchased a franchise and, in 2008, started his own business installing antennas using a Victorian registered business name of "The Antenna Mob".

2. On 6 November 2009, Mr DA was working on the roof of premises occupied by Mr Francesco and Mrs Rosaria Marchese at 246 Carrick Drive, Gladstone Park. The roof was a standard single storey pitched tiled roof. At about 6.15pm Mrs Marchese saw Mr DA fall head

first from the roof, landing on backyard paving. There were no guard rails set up to prevent Mr DA falling from the roof.

3. Mr Marchese Junior who had just arrived at the house, came to Mr DA's assistance. He found him bleeding from a head wound, and initially taking deep wheezing breaths. When he stopped breathing, Mr Marchese Junior attempted cardiopulmonary resuscitation until the arrival of ambulance paramedics a short time later. They took over, initiating advanced cardiopulmonary resuscitation. Despite these measures, Mr DA died at the scene without regaining consciousness.

THE PURPOSE OF A CORONIAL INVESTIGATION

4. The primary purpose of a coronial investigation of a *reportable death*¹³ is to ascertain, if possible, the identity of the deceased person, the cause of death and the circumstances in which the death occurred.¹⁴ The practice is to refer to the *medical* cause of death incorporating where appropriate the *mode* or *mechanism* of death, and to limit investigation to circumstances sufficiently proximate and causally relevant to the death, and not merely circumstance which might form part of an open-ended narrative culminating in the death.¹⁵

5. Coroners are also empowered to report to the Attorney-General on a death they have investigated; the power to comment on any matter connected with the death, including matters relating to public health and safety or the administration of justice; and the power to make recommendations to any Minister, public statutory authority or entity on any matter connected with the death, including recommendations relating to public health and safety or the administration of justice.¹⁶ These powers can be invoked to advance another purpose of the coronial investigation, the *prevention* of similar deaths in the future.¹⁷

¹³ Section 4 of the Act requires certain deaths to be reported to the coroner for investigation. Apart from a jurisdictional nexus with the State of Victoria, the definition of a reportable death includes all deaths that appear "*to have been unexpected, unnatural or violent or to have resulted, directly or indirectly, from accident or injury*" and perhaps more pertinently, deaths that occur "*following a medical procedure where the death is or may be causally related to the medical procedure - and a registered medical practitioner would not, immediately before the procedure was undertaken, have reasonably expected the death.*"

¹⁴ Section 67 of the Act.

¹⁵ See for example *Harmsworth v The State Coroner* [1989] V. R. 989; *Clancy v West* (Unreported decision of Harper, J in the Supreme Court of Victoria, 17/08/1994.

¹⁶ Sections 72(1), 72(2) and 67(3) of the Act regarding reports, recommendations and comments respectively.

¹⁷ Under previous legislation the *Coroners Act 1985*, the prevention role was considered implicit, whereas in current legislation the **Coroners Act 2008**, it is explicitly articulated in the the Preamble - "*... to contribute to the reduction of the number of preventable deaths ...*" and the Purposes which include "*(c) to contribute to the reduction of the number of preventable deaths ... through the findings of the investigation of deaths ... and the making of recommendations by coroners;*"

6. The coroner's role is not to determine criminal or civil liability arising from the death under investigation. Coroners are specifically prohibited from including in a finding or comment any statement that a person is, or may be, guilty of an offence.¹⁸

INVESTIGATION

4. Police and WorkSafe Investigators attended the scene and commenced their investigation of the circumstances surrounding Mr DA's death. This finding is largely based on their investigations and the brief of evidence compiled by one of the attending police officers Detective Senior Constable Isaac Papadopoulos, from Hume Crime Investigation Unit, Victoria Police. The brief includes a statement from the WorkSafe investigator verifying that there were no guard rails set up to prevent Mr DA falling from the roof, and no guard rails or other protective equipment relative to working at a height found in his vehicle. The initial impression was that Mr DA's death was work-related, and that he had died from injuries sustained when he fell from the roof.

MEDICAL CAUSE OF DEATH

5. An autopsy was performed by Forensic Pathologist Dr Justin Du Plessis from the Victorian Institute of Forensic Medicine (VIFM) who also reviewed the circumstances as reported by the police and postmortem CT scanning of the whole body undertaken at VIFM. Dr Du Plessis summarised his anatomical findings as "ischaemic heart disease due to severe triple-vessel coronary artery atherosclerosis, scalp laceration and multiple superficial skin abrasions, sternum and rib fractures and right anterior chest incision." Dr Du Plessis advised that the fractures and incision in the chest region were consistent with advanced cardiac life support measures taken by the paramedics.

6. He characterised the scalp laceration and skin abrasions as superficial injuries consistent with peri-mortem injuries sustained from a drop from a height and expressed the opinion that they did not cause or contribute to death in the setting of Mr DA's established ischaemic heart disease. Dr Du Plessis described ischaemic heart disease as a common cause of sudden death and a condition where there is an inadequate supply of blood to the heart muscle, in this case caused by the severe narrowing of three of the coronary arteries by atherosclerosis.

MEDICAL HISTORY

7. As is documented in the brief of evidence compiled by the police, Mr DA had a significant cardiac history, despite his relative youth. In 2007, Mr DA began complaining to his wife that he was constantly short of breath. As he did not have a regular doctor, he attended a local general practice and, after initial investigations, was referred to the Northern Hospital where a stress ECG was undertaken in late April 2008. This was positive after only six minutes which was potentially dangerous. Mr DA failed to attend a follow-up appointment in May.

¹⁸ Somewhat paradoxically, if a coroner *believes* an indictable offence *may* have been committed in connection with the death, the matter must be referred to the Director of Public Prosecutions, and the fact of such a referral may be referred to -Sections 69, 49(1).

8. He attended an appointment with Consultant Cardiologist Dr Larry Ponnuthurai at the Northern Hospital on 8 October 2008. It appears that he did not seek any further medical attention for his cardiac condition in the interim. After review, Dr Ponnuthurai advised him to start taking Aspirin immediately and explained the necessity for coronary angiography to exclude myocardial ischaemia.

9. On 16 October 2008, Mr DA underwent a left ventricular and coronary angiogram which demonstrated severe left main and triple vessel disease and overall low-normal systolic dysfunction. The plan was for coronary artery bypass graft surgery and aggressive risk factor management. Discharge medications were daily Aspirin, Metoprolol, Atorvastatin, Ramipril and GTN patches, as required. With the possible exception of Aspirin, it is not clear that Mr DA took any of these medications. He was reviewed by a Cardiology Registrar at the Northern Hospital on 29 October 2008 who advised him not to carry out any work except light clerical work while awaiting his bypass graft surgery, for which he was on a waiting list at St Vincent's Hospital.

10. Mr DA was reviewed by Cardiothoracic Surgeon Mr Andrew Newcomb at St Vincent's Hospital on 5 November 2008. Mr Newcomb discussed the risks and benefits of surgery and alternative therapy, and advised that both the risk of operative mortality and the risk of major complications were of the order of 1-2%. Mr DA was booked as a Category 1 patient in the public hospital and in due course scheduled for surgery on 15 December 2008. However, in early December 2008, Mr DA telephoned to cancel his scheduled surgery. There is no record that he returned to Northern Hospital or St Vincent's Hospital or sought any other mainstream medical treatment for his cardiac condition after this time. According to Mrs DA, her husband was terrified by the surgery and refused to consider it.

ALTERNATIVE THERAPIES - "ANGIOPRIM"

11. At about the same time that he cancelled the surgery, Mr DA started researching alternative therapies via the internet. He located the company Angioprim¹⁹ situated in Las Vegas, U.S.A. which purportedly supplied natural remedies for treating cardiovascular conditions. The product Angioprim claimed to be an "advanced chelation formula" for the removal of "unwanted calcium and metals". The active ingredients of the product as stated on the website included the amino acids lysine, cysteine and a synthetic amino acid termed caysine.

12. The following specific health claims made by Angioprim were located within emails retrieved from Mr D's computer and/or formed part of the directions for use -

- *Primary cleaning after a recent heart attack or heart surgery and with a known blockage of 25% or associated symptoms. Use 9-12 bottles in 18-24 days.*

¹⁹ See www.angioprime.com. While the product is described as "Angioprim" on the website bearing the same name and in emails between Mr DA and the supplier, its packaging bore the name "Sparkle" and for postal/importation purposes it was labelled as a "Mineral Remover".

- Major cleaning for blockage of 30-60% with pain in chest, legs, arms, back or face. Use 20 bottles. Increase use of mixture depending on severity of blockages.
- Ultimate cleaning for severe blockage 60-100% may require 24-36 bottles. Mix 1 bottle of Angioprim with 16oz juice. Take whole mixture daily.
- One bottle of Angioprim is a two day supply and is mixed with 24oz of your choice of orange, tomato, pineapple or apple juice. Do not use V8, cranberry juice, colas or sports drinks to mix Angioprim as they have metals and will prevent cleaning.
- Repairing damaged arteries requires Vitamin C totalling 2000mg, three times a day with meals.
- Minerals are metals and need to be avoided. Angioprim will not conflict with most prescribed medication. Take meds after meals.

13. According to Mrs DA, shortly after her husband started using Angioprim in late 2008, he started losing weight, looked healthier and was generally feeling better. His breathing was improving and he claimed the Angioprim product was working for him. Consistent with this state of affairs, is the following email sent by Mr DA to his Angioprim supplier on 23 September 2009, some six weeks before his death -

"... I purchased your product last November ... I have taken it as explained and really restricted myself from fatty and oily foods and I still do till today, eat very healthy. the problem is still there when I go for short walks I get light headed and chest pains and I can not do anything phsyical. it seemed to have done something for a while but looks like I am back to where I started before I took your product, could you please let me know what is the next step, because I have not achieved anything at this moment, thank you and look forward to hearing from you..."

He received the following email reply on 26 September 2009 -

"... Just send me an email and I will send you some Angioprim for free. It sounds to me like you have a stubborn blockage, and I think we can still lick this thing. It is not unusual for someone like yourself to feel a little better, but not be all the way there. If you have more questions call and I will walk you through the process."

14. Police investigations established that the Angioprim product was shipped to Mr DA from the supplier in the U.S.A. by post in packaging describing it, presumably for customs and importation purposes, as a "Mineral Remover". Each individual vial was labelled "Sparkle" and contained a clear liquid substance.²⁰

ACCESSING MEDICAL ADVICE & TREATMENTS VIA THE INTERNET

15. Whilst Mr DA's right to refuse surgery and reject mainstream medical treatment in favour of alternative or complementary therapies is not at issue, the circumstances surrounding his death

²⁰ Attached to this Finding (Attachment A) is a photo of unused bottles of Angioprim/Sparkle found at Mr DA's home after his death and the postal package as received from the U.S. Supplier.

raise an important public health and safety issue - namely, the apparent ease with which he was able to access treatment and (arguably) medical advice via the internet in an environment which is effectively unregulated.

16. Research conducted by the Coroners Prevention Unit (CPU)²¹ indicates that Angioprim and the Angioprim website have come to the attention of the Food and Drug Administration (FDA) of the U.S.A. with a warning letter sent to the maker of the product in January 2005 threatening enforcement action. In that letter the FDA characterised Angioprim as a "drug" as it was intended for use in the cure, mitigation, treatment or prevention of disease²² and was being marketed in violation of the Federal Food, Drug and Cosmetic Act. Furthermore, as a "new drug" it could not be marketed without prior FDA approval which would in turn require scientific data submitted by a drug sponsor to demonstrate that the drug is both safe and effective.

17. In October 2010, the FDA issued a consumer warning about the marketing of unapproved "chelation" drugs. Although Angioprim was not specifically mentioned in the warning, the following excerpt is salutary -

"...The FDA says the companies have not proven their products are safe and effective in treating autism spectrum disorder, cardiovascular disease, macular degeneration, Parkinson's disease or any other serious illness ... FDA compliance expert ... says [they] are preying on people made vulnerable because of serious illness ... Although some of the products are marketed on the Internet as dietary supplements, by law they're unapproved drugs and devices because they claim to treat, mitigate, prevent or diagnose disease."

18. At my request, the CPU sought submissions from seven stakeholder agencies or organisations²³ with regard to the regulation of products of this type including their importation, health claims and product licensing; any efforts undertaken to raise awareness in the community of the risks of sourcing medical advice from "non-mainstream" internet sites (excluding information provided by government agencies or reputable clinical sources); and any efforts undertaken to raise awareness in the community of the risks of self-medication with "complementary" medicines without appropriate medical supervision or as an alternative to conventional medical treatments.

19. Four submissions were received in response. They were from the Chief Health Officer for Victoria, the Therapeutic Goods Administration (TGA), the Australian Customs and Border Protection Service (Customs) and the Australasian Integrative Medicines Association (AIMA). I wish to formally thank them for their interest and contribution to this investigation which has informed the comments and recommendations which follow.

²¹ The Coroners Prevention Unit is a specialist service for coroners created to strengthen their prevention role and provide them with professional assistance on issues pertaining to public health and safety.

²² See paragraph 22 below for analogous definition in the Therapeutic Goods Act 1989.

²³ Australian Customs and Border Protection Service, Australasian Integrative Medical Association, Chief Health Officer (Victoria), Office of Health Services Commissioner (Victoria), Royal Australasian College of Physicians, Royal Australasian College of General Practitioners, and Therapeutic Goods Administration (Commonwealth).

20. Customs advised that they work closely with the TGA to control the import of specific therapeutic goods and medicines as identified by the TGA. High risk drugs and therapeutic substances controlled through the *Customs (Prohibited Imports) Regulations 1956* may not be imported without a permit from the TGA. If these goods are detected at the border without a permit, they will be seized by Customs. Customs and the TGA also work closely to stop the importation of other therapeutic goods or medicine, such as prescription medicines, that are not prohibited under the Customs regulations but breach the *Therapeutic Goods Act 1989*. In the six months leading to December 2010, Customs made 42 seizures under the *Therapeutic Goods Act 1989*, at the direction of the TGA. However, as regards Angioprim, as it comprised amino acids, Customs understanding was that it was not to be proscribed under either the Customs (Prohibited Import) Regulations 1956 or the Therapeutic Goods Act 1989.

21. The TGA is a unit of the Commonwealth Department of Health and Ageing responsible for administering the Therapeutic Goods Act 1989. Therapeutic substances must be entered into the Australian Register of Therapeutic Goods (ARTG) and their therapeutic claims assessed by the TGA. Angioprim is not included in the ARTG. Under the Act, a "therapeutic good" is defined as one to be taken or likely to be taken for a "therapeutic use" which includes preventing, diagnosing, curing or alleviating disease, ailment or injury. Under this definition Angioprim would be regarded as a therapeutic good if supplied in Australia. The TGA can only take action if, the therapeutic substance is supplied through an Australian supplier and, conversely, has no jurisdiction where the supplier is offshore.

22. The TGA website contains information on the risk of importing unregistered goods and was updated in February 2011 with information cautioning anyone intending to purchase therapeutic goods over the internet. People are advised to consult their family doctor, prior to purchasing goods and to be aware of outlandish claims about a therapeutic goods capabilities.

23. The Chief Health Officer for Victoria advised of a number of online strategies employed by the Department of Health (DOH) addressing the risk of sourcing of medical information or medicines online. The "Better Health Channel" (BHC) is an online health information service which targets mainly consumers. It provides a number of fact sheets alerting consumers to the dangers of disreputable information and medical claims on the internet. The BHC has been HONcode certified.²⁴ The DOH further advises that its future plan regarding online health information include initiatives such as syndication arrangements with other websites to publish quality assured content; the use of social media engagement with consumers (eg Facebook) and new content addressing the purchasing of health products online published by the BHC.

24. The Australasian Integrative Medicine Association (AIMA) is an independent not-for-profit organisation of individual medical practitioners seeking to provide whole person medical care by integrating evidence-based complementary medicine with mainstream medicine. In March 2011, the AIMA published a position paper entitled "Advertising & Claims Made by Sponsors: Sourcing medical advice and non-pharmaceutical 'therapeutic' products from overseas and internet sources." AIMA's position was summarised in that paper as follows -

²⁴ The DOH advises that there is an international code of conduct and certification process for online health information called HONcode. Websites which have passed certification are allowed to use the HONcode trust mark.

- AIMA is committed to the integration of safe and evidence-based complementary medicine/therapies into the mainstream and as the peak body representing medical and health practitioners.
- AIMA appreciates the concerns involving the inappropriate manufacturing, licensing, importation and claims made by manufacturers, particularly from overseas sources as advertised on many internet sites, and discourages the community from sourcing and purchasing products from overseas.
- AIMA is keen to raise awareness amongst the community and health professionals about inappropriate importation of products from overseas and claims made by manufacturers, and the importance of Good Manufacturing Practice, high quality standards already set in some countries such as the TGA in Australia.

CONCLUSION

25. I find that Mr DA died from ischaemic heart disease secondary to coronary artery atherosclerosis, in circumstances where he had known severe left main and triple vessel atherosclerosis, had refused coronary artery bypass graft surgery in the preceding twelve months and had chosen to access alternative unsubstantiated treatment via the internet to the exclusion of mainstream medical and surgical treatment.

COMMENTS:

Pursuant to Section 67(3) of the **Coroners Act 2008**, I make the following comment(s) connected with the death:

1. While Mr DA died from natural causes and not as a result of injuries sustained when he fell, his death highlights once again the dangers inherent in working at a height without appropriate guard rails or other safety precautions. These dangers are well known and well-publicised by WorkSafe Victoria.
2. The circumstances surrounding Mr DA's death also highlight the dangers and risks of sourcing and using medical information and therapeutic products obtained online from suppliers and manufacturers who may be without accreditation, and on the basis of unsubstantiated claims about the product's efficacy.
3. While the broader issue of regulation of the internet is well beyond the scope of this investigation, it is clear that there is a need to protect consumers by alerting them to these dangers and risks. The agencies which made submissions were able to outline the initiatives they employ, on the part of Customs to prevent importation of such goods, and on the part of the other agencies by using their own websites and through the development of fact sheets, to alert consumers to the dangers and risks of sourcing medical information and products online. They are to be commended for doing so and commended to continue doing so as this is an area of public health or safety which is rife for exploitation.

RECOMMENDATIONS:

Pursuant to Section 72(2) of the **Coroners Act 2008**, I make the following recommendation(s) connected with the death:

1. Recognising that the agencies or organisations invited by the CPU to make submissions have different remits and jurisdictions and different target audiences, I would recommend that the Chief Health Officer for Victoria/the Department of Health consider sponsoring the joint development of a public education campaign about the dangers and risks of sourcing medical information and products online involving all the relevant stakeholders.

DISTRIBUTION LIST

The family of Mr D A

The investigating officer, Detective Senior Constable Isaac Papadopoulos, c/o O.I.C., Hume Crime Investigation Unit, Victoria Police

Dr John Carnie, Chief Health Officer, Department of Health, Victoria

Dr Rohan Hammett, National Manager, Therapeutic Goods Administration

Mr Michael Carmody, Chief Executive Officer, Australian Customs & Border Protection Service

Dr Zena Burgess, Chief Executive Officer, Royal Australasian College of General Practitioners


Dr Steve Hambleton, President, Australian Medical Association

Ms Janelle Lamont, Executive Officer, Australasian Integrative Medicine Association

Director, Centre for Drug Evaluation and Research, Office of the Centre Director, Federal Food and Drug Administration, United States of America

Signature:




Coroner Paresa Antoniadis SPANOS
Date: 20th September, 2011