QUEENSLAND COURTS

OFFICE OF THE STATE CORONER

NON-INQUEST FINDINGS OF THE INVESTIGATION INTO THE DEATH OF KAREN WILLIS

CITATION:	**Investigation into the death of Karen Willis**
TITLE OF COURT:	Coroner's Court
JURISDICTION:	Southport
FINDINGS OF:	Mr James McDougall, Coroner
CATCHWORDS:	**CORONERS: Asian herbal weight-loss medication, Slimming Factor, Sibutramine, cardiac issues.**

Counsel Assisting: Ms Rhiannon Helsen, Office of the State Coroner

Mrs Karen Willis was 45 years of age at the time of her death.

On 14 December 2011, Mrs Willis complained to her husband, Mr Kelvin Willis, of indigestion and mild chest pain after having been at work for around four hours that day. Sometime after 5:30pm, she went to lie down. Mr Willis remained watching television until approximately 8:45pm. When he retired to bed, he noticed that Mrs Willis wasn't breathing. He called the Queensland Ambulance Service (QAS) immediately before requesting assistance from his next door neighbour, Mr Leon Dyson. Mr Dyson attended and commenced CPR for around 15 minutes until the QAS arrived. Unfortunately, Mrs Willis was unable to be revived.

Mrs Willis had no known medical conditions at the time of her death and was not taking any prescribed medications. Two months prior to her death, however, she had commenced using an Asian herbal weight-loss tablet called *Slimming Factor* (also known as Easy Trim, Que She and Chinese Herbal Diet Pills), which she had obtained over the internet. It is unknown how many tablets Mrs Willis was consuming prior to her death. The product information sheet provided with the tablets, which was written in Chinese, recommended an initial dose of one tablet daily for a period of two days before beginning to take two tablets daily.

Autopsy findings & toxicological testing

A full internal and external autopsy was conducted on 15 December 2011 by Pathologist, Dr Grace Higgins. It was found that Mrs Willis suffered from moderate coronary atherosclerosis, pulmonary oedema and enlarged lymph nodes adjacent to the liver. Histological examination showed patchy myocardial scarring, reactive changes in the enlarged lymph nodes, and inflammatory changes in the liver and lungs. Initial toxicological analysis of femoral blood samples taken was found to be negative for alcohol, but positive for fenfluramine (0.25mg/kg), ephedrine/pseudoephedrine (0.01mg/kg) and ibuprofen.

The cause of Mrs Willis' death was deemed to be undetermined at the time of autopsy as further testing of the weight-loss tablets and toxicological samples needed to be conducted. It was suspected that the tablets likely contained other ingredients (toxic drugs) not listed on the packet nor detected by routine toxicological analysis.

Forensic Pathologist, Dr Dianne Little, initially reviewed Mrs Willis' case in July 2012. She noted that Mrs Willis' heart was normal sized although there was single vessel coronary atherosclerosis (approximately 75% narrowing of the right coronary artery). Mild abnormalities were seen in some of her other major organs, but none that would be expected to cause sudden death.

The detection of fenfluramine at a level within the reported therapeutic range for those regularly using the weight-loss tablets was found. However, there was no evidence at autopsy of the potentially adverse consequences of fenfluramine (valvular heart disease and pulmonary hypertension).

With the information available at the time of the autopsy, it was Dr Little's opinion that it was not possible to give a definite cause of death.

The toxicology laboratory subsequently developed a method for detection of sibutramine and re-analysis of the femoral blood samples was undertaken. In addition to the previous substances located, sibutramine was also detected at a level of approximately 0.001mg/kg.

Testing of the weight-loss tablets Mrs Willis had consumed was also conducted. It was found that they contained caffeine, sibutramine, fenfluramine, propranolol, nifedipine and phenolphthalein (indicated).

In a subsequent report provided by Dr Little regarding the results of the further toxicological testing conducted, she notes that a recently published paper titled, *Two fatalities associated with Sibutramine*[1]*,* describes two deaths in individuals who had ingested sibutramine, both of whom had co-existing heart disease. The blood levels detected in these cases were 0.49ng/ml and 0.27ng/ml. The level detected in Mrs Willis was approximately 0.001mg/kg (equivalent to 1ng/ml), which is considerably higher than the two published cases.

Sibutramine has amphetamine-like effects on the heart, causing it to be beat more rapidly and causing blood pressure to rise. Such stimulants can precipitate a fatal cardiac event, often an arrhythmia, particularly if there is underlying heart disease, such as the coronary artery atherosclerosis found in Mrs Willis' case.

Based upon the extra information, which has now been obtained, it is Dr Little's opinion that it would be reasonable to give the cause of Mrs Willis' death as sibutramine ingestion in a woman with coronary artery atherosclerosis.

Information from the Therapeutic Goods Administration (TGA)

On 23 December 2010, the TGA issued a safety advisory alert in relation to the *Slimming Factor* weight-loss capsules. The alert states that some Australian consumers had purchased this product over the internet. The product claims to be 100% herbal in origin. As *Slimming Factor* had not at the time been assessed by the TGA for quality, safety, or efficacy it could not be legally supplied in Australia. It was noted that TGA laboratory analyses had confirmed the presence of the substance sibutramine, fenfluramine and phenolphthalein in the product. The Alert further states that sibutramine was previously a prescription-only medication in Australia until it was withdrawn in October 2010 due to safety concerns, particularly in patients with a history of cardiovascular disease.

The alert advised consumers who had purchased *Slimming Factor* weight-loss capsules to cease using them and discard any remaining product. Consumers were reminded to use extreme caution when purchasing medicines over the internet as the products may not meet the same standards of quality, safety and efficacy as those approved by the TGA for supply in Australia, and may contain unauthorised and potentially harmful ingredients.

On 1 May 2012, a letter was sent to the TGA advising of the availability of the tablets for purchase in Australia. The TGA subsequently confirmed that the *Slimming Factor* was not listed on the Australian Register of Therapeutic Goods (ARTG), which is required before a product can be lawfully sold in Australia. The information supplied was subsequently forwarded on to the appropriate section of the TGA for action.

On 2 December 2013, the TGA issued an alert confirming that the distributor of the *Slimming Factor* weight-loss tablets had initiated a recall of the pills (also known as Easy Trim, Que She and Chinese Herbal Diet Pills) as they pose a serious health risk. The alert notes that the tablets had been distributed as herbal weight-loss supplements via the Melanotan 2 Facebook page. Testing by the TGA has found that these products contain medicines not referenced on the product label.

The alert confirms that *Slimming Factor* tablets should not be taken as they may be harmful and can cause symptoms including headaches, dizziness and dry mouth. These tablets were

[1] Jarvis, H & Gill J, Academic Forensic Pathology, 2 (4), pgs 370-373.

illegally supplied in Australia, as they are not listed on the ARTG and as such have not been assessed by the TGA as required under Australian law. The manufacturer of these tablets was also not approved by the TGA.

Consumers were advised to stop taking any *Slimming Factor* tablets they may have and to ensure the rest were disposed of safely by their local Pharmacist.

Conclusion

Having considered the results of the further toxicological testing conducted and Dr Little's findings, I am satisfied that Mrs Willis died as a result of ingesting sibutramine whilst suffering from underlying heart disease, namely coronary artery atherosclerosis. Mrs Willis ingested sibutramine as a result of her use of the *Slimming Factor* Asian herbal weight-loss tablets, which she had obtained over the internet. Although this product was marketed as a herbal supplement, the further testing of the tablet's contents clearly show this not to be the case, and the tablets contain a number of toxic substances, which are potentially harmful.

Prior to Mrs Willis' death, the *Slimming Factor* tablets were the subject of a safety advisory alert by the TGA. Since then, the tablets have been recalled as they have been found to pose a serious health risk to consumers. It is clear that the tablets were illegally sold in Australia and had not been sanctioned properly by the TGA to ensure their quality and safety.

Given the recall now in effect and the steps taken by the TGA to ensure the public is aware of the risks and dangers of taking the supplement, I am of the view that there are no further issues, which require investigation. As such, I propose to close the coronial investigation without proceeding to inquest.

Mr James McDougall
Coroner
Southport
12 February 2014