

Submission to the Inquiry into Regulatory Standards for Approval of Medical Devices

My wife's left hip was replaced by a surgeon in Adelaide with a DePuy ASR hip in October 2007. Replacement of her right hip followed in April 2008. She was a fit and healthy 70 year old when she first received her DePuy ASR hip replacement.

On a five month holiday to France, Germany and England in 2006, she experienced trouble walking, sparking an investigation into the cause (upon our return home). Medical investigations indicated that she required hip replacement surgery.

She recovered from her operation very well and hasn't needed any walking aids.

Her first indication that there were any problems with her hip replacement was in March 2009, with symptoms appearing only 17 months after her left hip was replaced. She experiences a lot of pain in her hip and often needs a heat pack on her neck due to pain.

Her hair has been impacted as well, and at times she suffers short term memory loss. For example, when wanting to visit the craft shop at Eaglehawk she didn't realise she had forgotten where it is located, and turned left instead of right.

The other day, we were at the shop for her to have an ultrasound and x-ray. She had to visit the ladies – and after being in there for an extended period was called to her appointment. After some searching, she was found a substantial way down a long corridor. She had accidentally exited through another door and become lost.

She can no longer drive, because of her restricted neck movement. She is completely dependent on me. She cannot walk long distances or quickly and has trouble with gardening, an activity she loved.

She has also had to give up reading, in part because of the strain on her neck. She can now only look at short magazine articles and illustrations.

When she first started getting aches and pains, she visited a physiotherapist and on their recommendation had her left shoe built up in an effort to improve her posture. We were concerned that some of her symptoms these are comparable to early signs of dementia – but she has been tested three times with no medical evidence of dementia.

Subsequently, she visited numerous other medical and allied health professionals seeking assistance for her symptoms. These include:

- Many visits to [redacted] . Both [redacted] and [redacted] , including:
 - [redacted]
 - [redacted]
- A neurologist
- A spinal clinic at [redacted]
- A private physiotherapist
- A GP
- A psychologist



As pensioners, we paid the gap to access these services quickly.

We only learnt of the DePuy ASR hip's withdrawal from the market at annual review with her original surgeon in South Australia on October 10th 2010.

After the 4 Corners program highlighted these problems as being widespread we immediately alerted doctor in . As the initial surgery had been in Adelaide, we went to a doctor in who ordered tests: results were received on 23 May indicating problems with hip – with a very high concentration of both chromium (normal is 10-100 H nmol/L, had 565 H nmol/L) and cobalt (normal is 0-20 H nmol/L, had 1285 H nmol/L).

Subsequently, in July we visited the surgeon who performed the initial hip replacement operation in Adelaide. We took the pathology report with us indicating the very high concentration of toxic metals.

This surgeon told us not to worry about blood toxicity, as this alone was not significant enough to warrant revision surgery. He mentioned he had twelve other patients in a similar position. The surgeon in Adelaide provided a referral to a different, closer surgeon whom is now seeing in Melbourne.

Further investigation has proven does need revisionary surgery. will be undergoing revisionary hip surgery on her DePuy ASR hip replacement on 3 October 2011.

Johnson and Johnson are picking up the cost. is registered with them for the cover of medical expenses.

Full details of our experience have been sent to Shine Lawyers and we have met with them face to face on 19 September in Brisbane. They are pursuing a class action for clients over pain and suffering expenses, out of pocket expenses and, if employed, loss of income.

It is probably hard to prove emphatically that other pains that has suffered over this time (other than her hip) have been exacerbated by high blood metal, but for someone who was always active, it makes you wonder. Since March 2009, has had to continually take paracetamol daily to help in her relief, another imposition she has not had to rely on in the past.

These problems have taken away the quality of life we expected in retirement.

We request the inquiry consider how long-term research can be undertaken, including into:

1. What the long-term effects on patients with a DePuy ASR hip will be?
2. When the DePuy ASR hips are replaced, will the symptoms disappear?
3. Will all DePuy ASR hips eventually have to be replaced?
4. At what level do cadmium and chromium become toxic?