Inquiry into The Regulatory Standards for the Approval of Medical Devices

Summary

I, was implanted with a DePuy hip resurfacing device at in Adelaide on 26th November 2008.

My recovery following the surgery was slow and painful during the first six weeks post-op.

From then I became ill with a whole range of different general symptoms and my hip remained sore, the pain increasing with time and the hip began "clicking and crunching".

I consulted many different Doctors over the following fifteen months as I attempted to discover what was causing my general malaise.

At no time did I consider that my worsening illnesses may be attributable to the hip implant.

At no time did my Surgeon suggest my illness could be related to the hip implant.

Following a television current affairs programme, my partner and I realised that 'Heavy Metal Poisoning (Cobalt and Chromium)" seemed to account for all of the symptoms I had experienced between the day of my operation and then.

I arranged for an appointment with my GP and for a Cobalt and Chromium blood test.

The results revealed extremely high levels of Cobalt and Chromium toxicity in my blood.

I then attended for my next scheduled follow-up appointment where I informed the replacement surgeon of my blood test results.

Further blood tests were arranged and the results showed a significant increase in the already enormous level of toxicity in my blood.

then refused to see me again and referred me to the for assessment and possible treatment at some time in the future.

Since that time I have been refused all orthopaedic treatment in South Australia

Realising that the part needed to be revised urgently, my partner attempted to locate a Surgeon somewhere in the world who was willing to operate and remove the device.

Eventually a Surgeon in Melbourne contacted us and I travelled to Melbourne, where the implant was removed on 11th November 2010.

The damage to my bone and soft tissues was horrendous and extensive.

This meant that a Total Hip Replacement was required as described in the operation notes.

Follow-up blood tests have indicated a dramatic reduction in Cobalt levels, but Chromium levels remain extremely high and static to the present time.

I am at this stage, despite medical expectations, still alive. I have been told that my death from the damage caused by the level of Cobalt and Chromium toxicity in my body will be horrific and will occur sooner rather than later. My partner and my family are extremely distressed.

The use of this faulty part has had devastating consequences on my life and on the lives of my loved ones. If the part had been properly tested, approved as a result of that testing, and monitored to ensure satisfactory performance, my life would be totally different. My initial operation was undertaken to restore full functionality to my hip and to remove the source of pain, giving me a vastly improved quality of life. Unfortunately for me, the opposite is true. How did this happen?

This series of events outlined above raises many questions relevant to the Terms of Reference of this enquiry, which I will address below.

The role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia;

The Australian public believe that the Therapeutic Goods Administration is in place to protect the public from exposure to faulty parts, dangerous products and hazardous substances.

The original device implanted in my right hip in 2008 was an approved product. Like any other product approved by the TGA, the Australian public expect that it has been extensively tested by the TGA and found to be safe to enter the Australian market. I expected that this was true for the part used in my hip resurfacing operation.

It is my understanding that this particular part has been in use since 2003. I also understand that there has been a higher than usual dislocation rate in Australia over several years as reported to the National Joint Registry.

The processes in place to ensure that approved products continue to meet Australian standards;

Firstly, are there any Australian Standards when it comes to joint prostheses and other medical devices? My understanding is that many of these devices, if not all of them, receive automatic

approval by the TGA if they have been approved by overseas regulatory agencies. This sets up a situation where there has never been a real focus by the TGA on a particular device and therefore any ongoing monitoring of performance is likely to be equally ineffective.

What we have here is a circular loop where, if a device can somehow circumvent a testing regime and achieve approval in one jurisdiction, it has an unimpeded journey throughout the world market due to automatic acceptance policies of other regulatory bodies such as the TGA.

I believe this to be the case in relation to this particular part which was grandfathered in to FDA approval in the USA under an arrangement which allows substantially similar devices which do the same job as a previously approved device to be FDA approved without testing.

In the case of joint replacements there needs to be a close monitoring and investigative relationship between the TGA and the National Joint Register. While joint dislocation may be the only situation reported to the National Joint Register, it is now obvious that dislocation, pain and swelling may indicate more far-reaching underlying problems.

The processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices;

I believe that the manufacturer and design team were well aware that this particular product was not performing to acceptable standards from late in 2004. Certainly there is ample evidence to suggest that it was well known by 2006.

According to the Four Corners programme "Joint Reaction" screened earlier this year, the revision rate for this part in Britain is at 49%.

What are the responsibilities incumbent upon manufacturers and distributors of parts which indicate failure beyond the acceptable range to notify authorities such as the TGA of potential problems? Also, what is the role of the TGA to notify the general public of these faulty or recalled devices?

The effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified;

Why was a faulty, high risk part allowed to be implanted into a healthy, active 43 year old woman?

Obviously, current arrangements are not working effectively.

Any other related matter.

What happens to all the bone tissue removed from patients in a production line business model such as at the in South Australia? Harvested for Dental implant surgery perhaps?

Why is it that some substances, devices and parts which have been removed from the market overseas due to their hazardous consequences are still available for unrestricted use in the Australian marketplace?

Why is it so difficult for patients with the defective part to arrange to firstly, see an orthopaedic surgeon and secondly, have the faulty part removed ?

Why is it that the indicative level of Cobalt in Australia has become 20 nmol/L whereas in the rest of the world it is 2 – 7 nmol/L?

Why is Cobalt Poisoning simply NOT RECOGNISED in Australia?

The general public believe the TGA is in place to protect them from faulty products – THE TGA HAVE FAILED US.

Why was this allowed to happen to me?

There are potentially thousands of Australians suffering from the side-effects of joint replacement surgery without ever knowing the cause. This must have cost the Australian Public millions of dollars in medical budgeting. Many patients have probably died as a direct result of heavy metal poisoning from their joint prostheses. This must not be allowed to continue. What can be done to stop this.