URGENT SUBMISSION UPDATE FOR THE SENATE INQUIRY IN TO THE REGULATORY STANDARDS FOR MEDICAL DEVICES.

By: Stuart Cain
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To the members of the Senate Inquiry,

I had previously submitted a statement to this inquiry and unfortunately my situation has changed dramatically in the past weeks and I think this is very pertinent to the questions your committee is considering. As previously described I received a Johnson and Johnson ASR total hip replacement in June 2007 which consequently failed causing multiple medical problems for me and was revised under agreement with Johnson and Johnson (de Puy) and Crawford and Co. in November 2010 in Brisbane. I am a 42 year old man with a family who works as a Nurse Educator in Public Health.

On September 29, 2011, at my home in Brisbane, I was in the process of standing from a chair when I experienced an excruciating pain in my right hip, the one that had been revised in the previous November (2010). I was completely unable to weight bear on my right leg, was enduring pain unlike anything I had experienced in the past and was rapidly loosing all mobility in the leg. After emergency x-rays I was admitted back in to hospital for further investigations, these included Nuclear Bone Scans and MRI. It was discovered that the femoral shaft of my implanted device had snapped in two pieces with no visible break in my own femoral bone. I had spent a week in hospital at this stage, in a wheelchair as I had now lost the use of my right leg and had uncontrollable pain. The surgeons that reviewed me in this time were unable to explain to me how it was possible for a Titanium shaft within my femoral bone to break with no trauma involved with the bone, it was continually mentioned to me that this was very unusual without trauma and they were also very concerned that as I had already received 2 hip replacements that it may be too difficult to repair. The diagnosis that I was given was a catastrophic failure of the right total hip replacement.

Fortunately I was able to successfully undergo surgery on Saturday October 8 and after 4.5 hours of surgery I now have received my last possible hip replacement and have had my femoral bone wired together to repair the damage caused through the removal of the ten month old implant that had broken. The main cause of concern for me, and I think a very relevant issue for this inquiry is what the surgeons discovered upon performing the osteotomy (splitting of the bone to access the interior of it) to separate my femoral bone to remove the broken elements of my previous implant. There was an approximately 10cm area within the bone that had developed severe necrosis (tissue death) as a result of metalosis caused by the original ASR implant degrading whilst it was insitu as there was no visible degradation on the surface of the ‘new’ implant I received in November 2010. This ‘dead’ area had not allowed my new implant to grow or adhere to the bone, this allowed the femoral stem to have flex which in the course of time caused it to snap in half. I also had to undergo 4 blood transfusions post-surgery to try to assist me to recover even a low Haemoglobin level, this was directly related to the Anaemia that I developed as a result of having the ASR implant in my hip in the first place. This was effectively a time bomb that was ticking away within my leg, it would eventually fail and as there is no other way to determine

the extent of metalosis within the bone (except for regular bone biopsies which are not a standard follow up procedure for hip replacement patients), this is now a risk that I have come across, but more importantly, potentially there are many other Australian patients out there who could be unknowingly in the same situation.

As a result of this, I can never undergo a further hip replacement procedure, the surgeon, despite his best efforts can not guarantee that there will not be further metalosis based necrosis developing in the future, the damage that has been done to my femoral bone means that any further surgical options are very limited for me. My age means that my future is considerably uncertain, it appears that I will be suffering on-going health problems for the rest of my life, my ability to continue working in my profession is questionable and this places an enormous amount of pressure on my family and I. A further concern is the risk to the many other patients across Australia who have had complications from the ASR hip implant, I am hopeful that this is an event particular to my situation, however the numerous surgeons that I have spoken to feel that this will be the first of many complications as a result of the ASR implant. The only way that this can be diagnosed in patients is for them to undergo regular bone biopsies, this has inherent risks for this patient group as they routinely have weaker or damaged bones as a result of their implant surgery and is very costly and would drain already stretched health resources.

My surgeon has alerted me to the fact that he notified Johnson and Johnson as soon as he diagnosed the issue (on October 5, 2011) as they had 'provided' the revision in November 2010. He was very surprised that they felt that this was 'not their problem' and that 'they would be having nothing to do with any repair surgery or on-going care'. This to me typifies the attitude of a major health company who has made an error in the supply of a faulty piece of equipment, their complete disregard for the patients that they are presumably responsible to and their on-going efforts to distance themselves from what is becoming a very messy situation. I believe that this company would do well to actually sit down with patients like me and explain how it will make sure that this never happens to anyone in the future and also to, at the absolute very least, offer some sort of apology for completely altering the course of the rest of my life.

To this point in my recovery I am facing a very uncertain future, I am unable to plan when I can return to work placing enormous economic pressure on my family, I am not even guaranteed whether or not I will ever re-gain even majority usage of my right leg, and, I will be forever filled with the doubt that at any day, doing any movement I will suffer a further catastrophic failure of my implant. Every medical expert that I have spoken to believes that the best possible outcome that can be achieved has been achieved, however they also agree that in the future I will suffer from further complications that will eventually mean I will be unable to use my right leg and that I will be in a wheelchair.

I implore you to further consider this evidence in your discussions and I hope that I have been able to provide a patient's view of the implications of the Johnson and Johnson ASR hip implant, the risks that the TGA, among others, have put Australian patients under by allowing approval of this obviously faulty product and then not acting quickly enough when it was obviously harming Australian patients, and the

potential cost to the health system, patients and private health funds that the on-going issues with these implants are going to cause.

Thank you for your time and I hope that this updated submission is able to further enlighten the committee in to what ordinary Australians are suffering as a result of these medical devices.

Kind Regards,

Stuart Cain
17/10/11