

Submission for the Senate Inquiry “The regulatory standards for the approval of medical devices”

By: Stuart Cain

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I was given a Johnson and Johnson/De Puy ASR metal on metal hip replacement in June 2007 after a long battle with Osteo-Arthritis (OA), at the time I was 37 years old. This device was recommended to me by my Orthopaedic Surgeon as the best possible device for someone my age because of its ‘longevity’ for someone so young, the fact that it would allow me to maintain an active lifestyle and because it was promoted as the most technologically advanced device of its kind available on the market. As I needed the operation quickly due to a rapidly deteriorating condition I was not given any further information, as a health professional myself, I trusted that the product would do as was explained to me and, working in our (Australia’s) health system I naturally assumed that this would be a fully tested and approved medical device that had the approval of our TGA (Therapeutic Goods Administration).

I commenced having major physical problems with the device in December 2008, this commenced firstly as pain and quickly developed in to a lack of mobility and confidence in the leg to maintain balance. I was also advised to see a Haematology specialist shortly after this as I became more and more anaemic (low red blood cell count in the blood) and this was leading to fatigue, weakness and exhaustion with everyday activities. The only answer at the time that extensive blood testing could come up with was a condition called Macrocytic Anaemia, of which the only recognised cause internationally was heavy metal poisoning. As my Doctor and I didn’t even consider the hip implant as a cause (because why would you question a ‘safe’ medically implanted device), the concern was that this condition was a forerunner to a further more sinister malignancy (Cancer) and that I had to be constantly monitored and tested for when this might occur.

It was only when the media enlightened me to the issues around the dePuy implant and my Orthopaedic Surgeon requested that I have a blood test for Cobalt and Chrommium Ion poisoning as well as a Nuclear Bone Scan to assess the integrity of the implant, that my true situation became clear. I have since not only had the ASR implant replaced with multiple blood transfusions afterwards, I am now looking forward to further surgery on the opposite knee that has collapsed after I relied on it to hold most of my body weight and balance for the time that my hip replacement was failing, but I am also undergoing on-going blood screening to determine the extent of the resolution of the blood poisoning I developed from Cobalt and Chrommium Ion poisoning.

My main submission of concern to this committee is that in June 2007 when I received this implant, the TGA had already been notified around concerns with this medical device (implant) as had the Australian College of Orthopaedic Surgeons. Neither party had officially notified or warned the public of the potential risk to patients of the use of these implants, I am now led to believe that the implant was never officially tested or scrutinised by the TGA in the first place, so why bother having an approval/validation process for medical devices in the first place, and, as more countries internationally began banning the use of this implant, the TGA

maintained their approval for the device and allowed its continued use in Australian patients.

As a senior nurse in a government health facility, I feel that not only has the system that I represent with pride let me down, but it has also let down many hundreds of other Australian patients. I will be living with the effects of this failed device for the rest of my life, given my age, it is a level of doubt that I carry daily and it has also seriously limited my chances of a good quality of life in the future. I implore you as a committee to make sure that this situation does not happen again, and that future generations of Australian patients are never put at risk in such a manner again.

Kind Regards,

Stuart Cain