SUBMISSION TO SENATE ENQUIRY

DATED 27TH JULY 2011

ENQUIRY INTO THE REGULATORY STANDARDS FOR THE APPROVAL OF MEDICAL DEVICES

SUBMITTED BY:-

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I would like the Senate Enquiry to accept my submission into the "The Regulatory Standards for the Approval of Medical Devices."

The reason for my submission is that I am one of the thousands of victims of the Johnson & Johnson DePuy ASR hip prosthesis failure. This failure could have been avoided by simple regulatory changes to The Therapeutic Goods Association (TGA) and the National Joint Replacement Registry (NJRR). Because many devices continue to be implanted well after they are seen to be failing badly, the Senate Enquiry also need to be investigating the financial arrangements between some surgeons and the medical suppliers.

At present there are 13 different brands of hip prosthesis showing higher anticipated rates of revision. This high revision (replacement) rate can be directly linked to the low level of testing required by the TGA .The big difference with the ASR was that, even after it was pinpointed as having a high rate of revision by the NJRR, it continued to be used in large numbers. There has never been an implant fail so badly and yet continue to be implanted in such great numbers! How could this happen?

I was a fit and active 63 year old when I had a DePuy ASR total hip replacement in January 2008. In June 2010 after 2 years of pain with continual surgery visits, I was informed by my surgeon that the ASR had been removed from the market.

My surgeon informed me that it was also subject to a high failure rate of around 12%. After examining my X-ray's he said that everything looked good and for me to come back for another check-up in a year's time. I again, as I had many times before, asked him about my thigh and groin pains. His reply was, as before, that I must have a lower back problem. I left the surgery unconvinced and worried! I decided to look on the internet to try and determine what symptoms patients, who had already undergone revisions had experienced before having to have their ASR implants removed. Their symptoms were similar to what I was experiencing. The amount of information on the ASR failure around the world on the internet was staggering. The Metal on Metal hip was leaching Cobalt and Chromium ions into patients' bloodstream in huge quantities. Yet here, there was no public response by the NJRR or the Australian Orthopaedic Association (AOA). What

needs to be kept in mind that at this time in Australia about **400 ASR hip revisions had already taken place,** and surgeons during these revisions, would have seen the effects that leaching Cobalt had in the destroying of flesh and muscles around the implant, and the deterioration of the hip and femur bones. However, not one public word had been uttered. **There had been no attempt to follow up patients, even though this was a serious health issue and the resources were available to them**.

In July 2010, I contacted my local GP and had a test which confirmed cobalt levels 750% more than normal. I contacted my surgeon who dismissed the cobalt levels as a problem but reluctantly agreed for me to have a CT scan and a Nuclear Bone Scan. When he received the results he informed me that I had extensive bone loss from my femur. The result of this was that the stem had become loose and as a result was causing my pain. The hip would have to be removed. It would be a major operation involving my femur being cut open, the stem of the implant removed and then my femur wired together with considerable bone grafts to both my femur and hip to replace bone that had been eaten away. The revision would have to be done as soon as possible as the top of my femur could fracture. I would lose 15% of my mobility for life. In August 2010 the ASR was **voluntarily** recalled by Johnson & Johnson DePuy **nearly four years after the Australian authorities and medical community and specifically the NJRR new it was failing badly and a major health risk.** (Attach 4. Video. British Medical Journal. D.Cohen interviews NJRR's Stephen Graves. "The story of the ASR"). During this time thousands more had been implanted! I had my ASR prosthesis removed in October 2010 in a five hour operation, only two and a half years since I had it put in. The negative effect this has had on my mobility and mine and my family's quality of life has been dramatic!

It was at this stage that I decided to try and find out how DePuy, theTGA, NJRR and the Orthopaedic Association had failed thousands so badly, and what changes should be made so that the ASR incident could not happen again. By December 2009, the NJRR figures already showed 300 revisions had taken place. The figure to date would be close to 500. With some hospitals in the UK having an almost 50% failure rate, the situation here could result in at least 2500 patients needing revision in Australia alone. My costs for the revision and further complication that resulted in being admitted to intensive care with complete renal failure and pneumonia as a result of my revision is in excess of $65,000. More than 5500 Australian recipients of the DePuy hip are at risk. .

In September last year when Shine Lawyers and I went to air on channel 7 to alert patients of the unfolding disaster, the vice president of the Orthopaedic Association was reported in the Courier Mail accusing us of " being alarmist" . The situation now is that one of the most respected Orthopaedic surgeons in the UK is describing this as "the biggest Orthopaedic catastrophe the world has ever seen". (Attach 4. Video. BMJ D. Cohen. Interviews. Dr. T. Nargol).

As you read this, there are victims and their families facing all the risks of major surgery and those who already have had the revision, trying to cope with the deterioration of their mobility and the other health problems associated with having been affected by high Cobalt and Chromium levels. Hip revisions carry greater risks and have worse outcomes than the primary hip replacement. **Revision is not a cure**. The patients mobility will be impacted for the rest of their life and for younger patients the risk of having a third revision in their lifetime increases dramatically, with the third revision bringing greater risks again.

Revisions of the DePuy ASR hip will continue for many years and because of the way this recall has been handled, some patients will never know that the device was recalled or that the pain and suffering they have had to go through was because of a faulty prosthesis. The TGA, NJRR and the AOA have been shown to be reluctant and inadequate in handling the ASR recall. Patients' quality of life and future health will be impacted forever. Mine will also be impacted forever.

To address the terms of reference of the enquiry:

Inquiry reference (a) The role of the TGA in regulating the quality of devices available in Australia.

As the EU changed the classification of implantable devices from Class IIb to Class III last year after a 5 year transition period, it means that manufacturers are ready to supply the EU market now. It would be a simple matter for them to supply us. If we don't change now to Class III, we will be vunerable in having a lower standard of devices listed on the Australian Register of Therapuetic Goods (ARTG.) (Attach 1. AOA submission to the TGA. Proposal 1)

Last year the TGA called for submissions on this regulatory change. One of the submissions was from Johnson & Johnson Medical who while in broad terms accepting the change, wanted at least 4 years to comply! They went on to say that there was no real need for change "There is no evidence of systemic or regulatory failure or of proliferation of unsafe or substandard medical devices or of significant public health concern associated with medical devices in these jurisdictions, " (ie. In countries with a classification IIb) (Attach 2. Page 14). This was from a medical device supplier who only 2 months before had recalled 93,000 ASR hip prosthesis worldwide!

This same submission from Johnson and Johnson Medical (Attach 2 pages 11, 12) show that they would like to rely heavily on "risk management " and "post market surveillance". What this actually means is that manufacturers would like to be allowed to continue supplying clinically untested devices into the market and let the patient take the risks, and then watch and see what happens. **This is the current approach in Australia and agreed upon by the TGA**. If surgeons were required to make patients aware that the prosthesis they were about to implant was untested and that they could not say that it had been shown to be safe, the patients would be horrified. All the parties involved keep to the same doctrine "we have to have a balance between innovation and patients' safety to get new products onto the market". This may be suitable when the patients' condition is life threatening and there **is no suitable alternative** but in the case of hip prosthesis the NJRR reports there are many hundreds of different combinations of prosthesis available. **We need**

to examine the driving force that makes a surgeon choose a particular device without using evidence based criteria. (Attach 1. AOA submission to the TGA. Proposal 1).

On the 20 July 2011 the TGA released its report into it's Transparency Review. One of the recommendations is that patients may benefit if medicine-labeling had to have a "black triangular logo" marking on the label to alert patients that a particular medicine had not been fully tested. This gives the patient the opportunity **not** to be part of the "Post Market Monitoring" system, where they pay to take the risk of untested medicines. At present they do it unknowingly!

This could also be applied to Hip, Knee and Elbow prosthesis where a quality standard could be applied to devices that had been performing well over a period of time, and that a lower quality standard could be applied to poorer performing or new devices to the market. This would possibly be opposed by manufacturers and some surgeons, **but applauded by patients and anyone truly interested in patients care first.**

To contrast this with the present situation, the NJRR state ,that between 2003 and 2007 more than **TWO HUNDRED AND FIFTY** (250) new hip and knee devices were introduced and trialed on the Australian market. **Not one** of these devices performed any better than other well performing devices available. In fact more than **one third performed substantially worse**.
(Attach 4. Video. British Medical Journal. D.Cohen interviews NJRR's Stephen Graves. "The story of the ASR" 14/05/2011)

Did the patients who received these hips and knees realise they were part of a "Post Marketing Monitoring Program" or did they think they were getting a safe and well performing prosthesis?

In the Medical Journal of Australia (1 March 2004) the NJRR reports that in Sweden, which has the reputation of having one of the lowest revision rates in the world ,they had just five (5) prosthesis making up 75% of their implants while the Australian NJRR had six hundred (600) combinations of prosthesis recorded. The situation has not changed! **In 2009 one hundred and fifty four (154) new hip prosthesis combinations were recorded !**

- The classification of implantable medical devices needs to go from Class IIb to Class III

- Consideration should be given to the "labeling" of devices so that a patient knows that the device is safe and has had a low level of revision over a number of years.

- The TGA needs to take a more aggressive role in suspending suspicious devices from the Australian Register of Therapeutic Goods when any patient's health concerns are compromised.

Inquiry reference (b) The cost effectiveness of subsidised devices.

A study of all the new hip prosthesis introduced to Australian during 2008 showed that not only was this new technology potentially **detrimental to patient care but it lead to increased health care costs**. (Attach 1. AOA submission to TGA. Proposal 2).

- We need to have a two year clinical trial period at least , for all hip prosthesis.

Inquiry reference (c) Accuracy of the billing code.

No comment.

Inquiry reference (d) The processes in place to ensure that approved products continue to meet Australian standards.

According to the AOA, there are no standards that define what is required for pre market asessment. (Attach 1. AOA Submission Proposal 1). (Attach 4 .British Medical Journal. D. Cohen interviews Tom Joyce.)

- New standards need to be written for "Notified Bodies".

Inquiry reference (e) The safety standards for devices remanufactured for multiple use.

No comment.

Inquiry reference (f) The process in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices.

The TGA has the power to remove a device from the register under the **"Therapuetic Goods Act -- Sect 41 GL (a)**

The NJRR knew of the failure of the ASR resurfacing device in 2006, as detailed in their 2007 annual report. This report comments on what happened during 2006 and as the NJRR is accurate to approximately six weeks, it is obvious that they would have been alerted to the problems with the device during 2006. There was no action taken until late 2009. During this time surgeons implanted thousands more.

The situation that arose with the DePuy ASR hip recall is that the overseas manufacturer was notified at least 17 times over a period of at least four years dating from late 2006 or early 2007 by the NJRR concerning problems with the implant, (Attach 4. Video BMJ. The Story of the ASR. D.Cohen interviews S.Graves) and then when in August 2010 DePuy issued a recall of 93,000 hips worldwide , they finally contacted Australian surgeons, who were left to contact patients **voluntarily.** There is no absolute way of knowing that all patients were contacted, and anything that has been done, has been done reluctantly and ad hoc, with no concern for patient safety. The situation with metal ion poisoning is that it is time crucial, this pointed out by DePuy and yet some patients have not yet been advised or had necessary Cobalt testing.

If there are any processes there to notify the public and relevant authorities, in the case of the ASR they weren't used or nothing happened at the time that it was needed, to stop the implanting of a dangerous device. The only notification by the TGA to consumers happened the day after the ABC Four Corners Report on the 16/05/2011, **eight months** after DePuy's voluntary recall. If you look at the experience in the UK, (Attach 4. British Medical Journal Video D. Cohen interviews Surgeon Tony Nargol) it will make it clear the effect of the incompetence by the TGA and the NJRR not to remove this device from the market sooner. It is going to result in many more patients suffering, and increased health costs for many years?

Inquiry reference (g) The effectiveness of the current regimes in place to ensure prosthesis with high revision rates are identified and the action taken once these devices are identified.

The NJRR's statistical approach to acquiring, compiling and analysing data as outlined in the video interview by Deborah Cohen with the NJRR's statistician Mr. Phillip Ryan, (Attach 4. Video. BMJ. "Europeans are left to their own Devices") shows that the ability for the NJRR to highlight prosthesis with high rates of revision is impressive. The problem lies with the fact that **too little or nothing** is done with the information to lower revision rates which is primarily what the NJRR was set up to do!

In the current situation with the ASR hip, both the NJRR and the AOA have shown that they do not have the ability or the desire to respond in a way that has patients' health risk as paramount.

If you look at the NJRR year 2010 website report in the section on **"Investigation of Prosthesis with Higher than Anticipated Rates of Revision"**, in the list of **"Primary Total Conventional Hip" "Newly Identified", "Re- identified and still used"** and **"Identified and yet no longer used"**. In these lists there are 27 brands of prosthesis named. However, there are actually 65 combinations of hip and knee prosthesis showing "higher rates of revision" in the 2010 report. The ones that aren't named (38) are still failing at more than twice the rate expected but the concern for patient safety is so low that they will continue to be used and 'monitored' with hundreds more patients put at risk. Nearly all of the **"named"** prosthesis showed unacceptable failure rates before

the two year mark, and yet most continued to be used for years, **and many are still being used** without any action taken. This means that hundreds of Australians have had and will have their health irreparably damaged, their quality of life ruined, and many such as myself will require future care as our health fails because of the results of this inaction! The cost of this to families and the wider community is incalculable and all this time the TGA and the NJRR continue their **"Post market Monitoring Program",** knowing they have the capacity to act, and yet doing nothing. This clearly demonstrates reluctance by the NJRR, which is controlled by the AOA, to restrict the use of clearly failing devices to their colleagues!

By increasing the level of testing of Medical Devices to Class III not only will it lower dramatically the number of devices getting onto these High revision lists but it will immediately lower the cost of health care short and long term in Australia and save Australians from the enormous health risks and traumas that are associated with revision surgery.

The success of the NJRR is attributed to having an almost 100% reporting rate by surgeons and hospitals on primary and revision implants. The reporting is voluntary. This fragile situation needs to be addressed so that the future of the NJRR can never be compromised.

The information supplied by hospitals and surgeons to the NJRR is protected by law. This means that the NJRR, a publicly funded entity has no transparency and is immune from any auditing into its actions or inactions. This should not be allowed to continue.

If you look at the situation that arose with the ASR hip, it was clear from 2006 that the data showed that the resurfacing device was a dangerous device, well known to the NJRR. The chances that their information could be wrong was negligible and yet because of their direct link with surgeons they never instructed their "colleagues" to stop using the device . **The NJRR's assertions that surgeons stopped using the device when it was clear it was a problem, is blatantly untrue.**

- When the NJRR identifies any medical device as having a more than twice the rate of revision, the device should immediately be removed from the ARTG, surgeons advised and be

immediately stopped from implanting the device.

- All patients who have been implanted or **already have had the device revised** should be contacted by the NJRR so that they can be made aware of the problem and then the appropriate medical advice be issued by the **TGA** in conjunction with the NJRR and the AOA.

- The supplying of data by surgeons and hospitals to the NJRR needs to be made mandatory.

- Consideration should be given to having some separation between the NJRR and the AOA.

Inquiry reference (h) The effectiveness of the implemented recommendations of the Health Technology Assessment.

There has been no effect at all looking at recommendation **8. (c)** of the HTA

Inquiry reference (i) Any other related matter.

In line with the government's desire for greater transparency, and following on from the TGA's Transparency Review that has just issued its report, consideration needs to be given to a focused review into the transparency of the NJRR, including the laws that shield it from any form of accountability.

The public have a right to know, not only the full extent of the failure of nearly all of the 250 prosthesis that came onto the market in the 2003---2007 period. The NJRR doesn't report on many of these devices as they don't meet their criteria of "observed years of use". However, they could account for thousands of failed operations and the results are shielded from public scrutiny by the NJRR.

A separate and focused enquiry needs to access this information, not only to look at the increased cost to the health system by allowing so many devices to be listed on the ARTG but also the effect

these implants have had on thousands of people's lives and the reasons they were given for the failures of the device. **Someone needs to be held responsible.** It's almost unimaginable that the head of the NJRR could sit back and watch what has been happening for years without any action.

Referring particularly to the Johnson & Johnson DePuy ASR issue, it is beyond the realms of imagination that by the start of 2009 at the extreme latest, those surgeons who were using this device were not fully aware of the high revision rate and the risks of using this device. The NJRR by its own admission had warned DePuy at least seventeen times, and yet from January 2009 until it was taken off the market late that year, they implanted another 668 devices.

Year and number of ASR Implants in that Year

YEAR	2003	2004	2005	**2006**	2007	2008	**2009**	total
ASR Total	--------	72	510	**898**	1179	1210	**537**	4406
ASR Resurf	41	142	286	**237**	183	147	**131**	1167

Just the sheer number of new implants coming onto the market, 250 over 5 years, (Attach 4. Video BMJ .D. Cohen interviews S.Graves. The story of the ASR), must give even the casual observer some pause to think something is not right. These devices will have had no clinical trials. They were listed on the ARTG to allow them to be tested in Australian patients with total support of the TGA and were enthusiastically implanted by many surgeons who had no evidence of their suitability or any proven advantage over other proven successful devices. The NJRR expertly tracked their failures and did nothing to stop thousands of Australians being injured. **The NJRR admits that from these 250 devices not one advantage to Orthopaedic surgery was made. Many of these devices were metal on metal hip implants which all show higher rates of revision!**

- If no one is held responsible when this Senate enquiry is completed, it will be a disappointing outcome for those Australians who have been injured by the those people who had the

responsibility to protect our safety and hold our health and quality of life paramount , and didn't. I am not just referring to the victims of the ASR , I am referring to all the patients who have been injured by the reliance of the authorities on the" Post market monitoring system "and have not had the courage or the inclination to make the manufacturers of these devices raise the bar of quality higher, but to just allow them to flood the market with large numbers of **clinical untested** medical devices and have them tested in patients who were oblivious to the dangers they were being exposed to!

- A new and more focused enquiry that has the power to look deeply into the actions and inactions of the TGA, NJRR and the AOA.

To Investigate

- The financial connections between medical manufacturers and surgeons.
- The financial arrangement between hospitals and the medical manufacturer.
- All correspondence between Johnson and Johnson, and the TGA and the NJRR with reference to the ASR.
- All correspondence between the NJRR and the AOA with reference to the ASR.
- The outcomes of all other victims of failed implants so that the full extent of the present "post marketing monitoring" system can be understood.
- All TGA Orthopaedic Expert Working Group records and findings on the ASR device during 2007and 2008.
- A point in time when it would be considered reasonable that an Orthopaedic surgeon who was using the ASR device would have known that the device could not be implanted with a satisfactory degree of patients' health and safety. Bearing in mind that there had been seventeen (17) separate calls to the manufacturers concerning its failure rate!
- And determine if some surgeons should be called before an enquiry to explain their actions in the implantation of this device.

Summary

Australians expectations of the TGA are that they would only allow a safe and well performing **implantable** device onto the market. They believe that is what they are there for. They are wrong. The TGA are fully aware that many devices are trials! Australians expectations that a failing medical device would be taken off the market **quickly** to prevent any more damage, as is done in the motor industry , is wrong. Australians expect that all surgeons would be more discriminatory and evidence based into their choice of prosthesis. They are wrong.

If the members of the committee could see the suffering and the pain that the lack of dedication to improving revision rates has caused, they would be appalled. Women whose babies have been born with toxic Cobalt levels, people who are sole carers ,who now find it difficult to walk themselves , people who will never be able to walk properly again unaided and people who have had to have their " hip" completely removed .The scale of suffering that could have been avoided is immense.

The personal effect on myself and my family by the revision of this prosthesis is immeasurable both physically and mentally. The long term damage through the cobalt poisoning is unknown. I suffer almost constant pain that may be with me forever .My wife and I have worked our whole lives to be financially stable and physically healthy so that we could enjoy our retirement years. A large part of what we have worked for is now gone. My health will never be the same, and the prognosis for my newly revised hip is uncertain.

I feel that I speak out for thousands who are also suffering and may not even know that this enquiry is in progress. For us any changes will be too late.

I can only hope that the enquiry can make the right decisions that will change what has been for us a nightmare , into the safe, simple and successful operation it should be for the thousands of people that have to undergo it every year.

Things have to change and there are people who need to be held accountable.