

Supplementary Submission To The Senate Enquiry

Dated 17th October 2011

Enquiry Into The Regulatory Standards For The Approval Of Medical Devices

Submitted By:

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I would like to thank the committee for allowing me to make a further submission to the enquiry.

Since the first sitting of the enquiry the 2011 NJRR annual report has been published. I would like to draw the attention of the committee to the Supplementary Report on “Investigations of Prosthesis with Higher than Anticipated Rates of Revision”

When prosthesis have reached this stage of the report, they have already been scrutinised very closely by an expert panel of surgeons and NJRR staff . They remove any from the list that are failing because of reasons not connected to the prosthesis. Once they hit this list their performance rarely gets better, just worse.

It must be kept in mind that many of these are performing worse than the ASR !! Some with failure rates of 20% or more !!

As at 31st December 2010 there were 13 **“newly identified and still used”** brands of hips failing. These had been implanted into 3,842. patients. Some will have worse outcomes than the ASR.

Also there were 11 **“re-identified and still used”** brands of hip failing .These had been implanted into 5,574 patients.

The figures above do not include the ASR. As the 24 prosthesis named are still being used, the figure would be much higher now! Even though they are performing worse than the ASR, no action seems to have been taken either by the TGA, NJRR or the AOA.

There are also 18 **“identified and no longer used”** prosthesis that were put into 6,951 patients . One of these prosthesis has a failure rate of 25.4% over ten years. The ASR is in this group and is conspicuous in that it accounts for 4,081 of the total ,most of the other 17 are in the low hundreds. Why was its use taken up so quickly and in such great numbers and never stopped being used by surgeons until they couldn't get it any more !!

This is a total, as at December 2010 of 16,367 patients out in the community walking around with prosthesis that have been identified as having more than double the normal failure rate!!

This figure will be a minimum figure as it does not include most of the patients who have had their hips already removed from the 42 “named” Prosthesis and it also does not include “ Resurfacing Hips“ that are also failing. The results of which can be seen in the annual report.

Using the TGA’s insulting analogy that we ,the victims, are ” flat tyres” we can assume from the figures in the NJRR report that we have many more unnecessary “flats” to come!

The revision rate figure that these failure rates are compared to is an inflated figure. It is an average of all the prosthesis failures , both good and not so good! If the registry used an average of the failure rates of the best performing prosthesis and used it as the comparison to the “**Identified with High Anticipated Failures**” prosthesis figures, the situation would look much worse! Nobody wants to set the bar too high and alert the public to the deplorable results.

This year the report identified 330 new femoral cup and acetabular cup combinations than last year. An over 20% increase in one year. This makes assertions that we operate a “choice” based system laughable. If the AOA, NJRR and the TGA aren’t embarrassed and ashamed ,they should be. **The whole situation is out of control and the patients are paying the price!**

It is no wonder that Dr. Armitage is less enthusiastic about more “**post market monitoring**” and is more concerned with stopping these prosthesis getting to the market by “**pre market clinical trials**”.

When you investigate the figures above for yourself ,I am sure you will be alarmed. I would like to think that you could enlist someone such as Mr. Phillip Ryan from the NJRR who is the main statistician for the registry, to go through what I have found to be a terribly upsetting and appalling set of facts. Perhaps he can verify what I am putting before you.

If the facts are verified then not only does the TGA have a wider case to answer , but also Surgeons, who continually keep putting in all these different types of prosthesis with no clinical evidence as to their suitability

and, in many case the opposite of it . They have escaped any sort of scrutiny at this time by the enquiry or the media , hiding behind the NJRR whose directors salary is paid by them.

When high failing prosthesis are identified by their own colleagues ,they do not stop using them. WHY ?!

When the committee is evaluating the time line between the TGA and the NJRR to ascertain who new what and when with regards to the ASR situation, it is important to remember that the NJRR has updated information on a monthly basis ,not an annual one!

If the NJRR saw a spike in the resurfacing hips failure in 2006 then as a registry whose sole purpose is to track these “outliers” as every months figures were received, you would expect that the data should have been made available to the TGA well before the annual report was done . It is surely incompetent to track these figures on a monthly basis and not take further action.

Before the committee releases its findings I would like to ask it to view the “4 Corners” and the “Tony Nargol” videos once again and to be aware that there are thousands more patients and their families suffering besides those with the ASR. The system is a failure and we need new people like Dr. Armitage to help rebuild it. We cannot rely on the TGA and the NJRR as they have been the architects of what we have now! Early revision of a hip is a mentally and physically debilitating procedure with the patient never recovering fully, and the only ones to blame are the TGA, NJRR and Surgeons!!!!

I hope that I have been of some help to the committee.

Sincerely Mr. R.Lugton