Senate Enquiry

PIP Implants

From a Patients Perspective.

I decided to have breast implants for cosmetic reasons only. This was due to dissatisfaction with my body image, particularly after breast feeding both of my children which had left me in much worse condition than ever. I never wanted it to be conspicuous that I had this surgery, I just felt I wanted something that made me look and feel more feminine. I am very tall at 185cm and have battled with self esteem surrounding my body my whole life. I was looking forward to having this done. It was something I had always thought I'd do for myself after I had looked after my babies needs.

On November 05th 2007, I visited a local Plastic Surgeon to discuss the option of breast implants. Firstly, I would like to say that I had been considering saline implants due to adverse media surrounding problems with silicone in the past. From the outset I was steered away from saline implants and really sold/talked into the silicone implants because they supposedly had no issues anymore and all those problems were a thing of the past. I do not recall my initial preference ever being taken seriously and in hindsight I should have taken more time to consider things further.

However, as it was, I came across these professionals who seemed so confident in the fact that these implants were state of the art and I explicitly recall during the appointment that the surgeons assistant took me into the consulting room next to the Dr's after he had sized me up and showed me the PIP implants. At this time she told me that she herself was getting these implants, further cementing the message to me that these were the wise choice.

I was asked to participate in a clinical trial approved by the TGA for the PIP Titanium implants. I was told that these implants would be worth thousands more , in fact the brochure I was supplied by the surgery and still hold says that they were being supplied at 50% off the retail price for the trial (even though further documents state that they can offer no inducement to get you to participate,is this not inducement by making it sound even more like a great deal). It was explained to me that the reason they were going to be worth so much was because they were believed to reduce or stop the impact of capsular contracture. Capsular Contracture is really the only condition which was discussed with me at the surgery, of course then with the fact that these implants were likely to stop this phenomenon which was at that point misunderstood.

I clearly remember asking about the life of the implants and the response was that I may have to replace them in 15 years, more for the look, so to think about coming back at that time to see if they were still visually pleasing. At the same time I was told that these days, women probably wouldn't need to replace them even at 60 as again, the actual implant failing was barely a risk at all.

So all in all, at 35 years of age at the time, I really didn't think that there would be any immediate risk to me, particularly of rupture, believing that the odds were probably that I would be in my 60's thinking about this! All I wanted to know was would I look natural and would anyone know straight away what I had done, as really I needed this to be something private for me.

I was won over by the sales pitch and felt excited about what I had been told by the surgeon and his assistant and their assurances that I would certainly feel much better about myself after having the surgery. I asked if I could get my surgery in the December, but was informed that there was a long wait at that time of the year and possibly I may have to wait until the new year.

I was given literature from the surgeon, which I still have in my file. It all points to benefits of the proposed reduction of capsular contracture. According to the medical notes which I have recently acquired from the surgeon, I was shown a powerpoint presentation (content not specified) and given an ASPS brochure. I'm not sure what this ASPS brochure is, its not in my file today. It also refers to ISC access. I'm not sure what this is, though I do recall having a look at an internet site at the time, which had medical information re this procedure. I was only given access temporarily so I was warned I had to ensure I looked through the content quickly. From memory this site contained information re capsular contracture and other possible side effects of the surgery. I have also in my file my log in details for the site, however it no longer appears to exist www.acapal.com/gps. I was given a Patient Information Sheet Protocol QA 04/2006 regarding the study and both myself, the surgeons and the companies obligations under the studies. This refers to the risk being that I may not get the additional benefits implied.

I received a call from the surgeons rooms within a few days of my initial appointment saying that they could get me in for surgery the following week as they had a cancellation. I had to call them back and let them know immediately I had spoken with my husband as otherwise I would lose the spot. Of course, I had been impressed with what I had been told and so decided to take the plunge immediately.

The following week I went in for the surgery and everything went well. I woke up very happy with the outcome and pleased with my decision.

I had a couple of the follow up visits with the surgeon, as per my schedule with the trial and have copies of the surgeons records which I recently requested. I note that the follow up Protocol was not followed in full. The surgeons notes indicate that I did not arrive for a follow up appointment on 19/11/2008, however if indeed I had a follow up appointment and missed it, which may be the case as there was months between each visit, there is no record from myself or the surgeon indicating that they attempted to follow me up to finalise the study. According to the information booklet, I should have had appointments with the surgeon at 3,6,12 and 24 months post-op. Only the 3 and 6 month visits were undertaken and at these times there is record that I and the surgeon had noted some stiffness in my breasts. I also recall advising the surgeon that I had numbness in the underside of the left breast and it was indicated to me that this was just the nerves and would repair in time. Note that the numbness is still present and also note that the surgeon has not recorded this in my follow up notes. Again in general I have been happy with the results and have not questioned until now the lack of follow up with the procedure.

In 2008, and since then, I have sought advice from my GP for a number of unexplained health issues. These include losing my hair in 2008 at the back of my head, a circle completely bald which started around the size of a twenty cent piece when I noticed it and ended up being around 6cm in diameter. My doctor told me I had alopecia, unexplained and can't be treated. I was given a steroid treatment, however was told that really these treatments are not effective and that if the hair loss continued I could look into other treatments. Thankfully the hairloss did stop, however it took the

best part of a whole year for the hair to grow back. This was a period of great embarrassment for me Around the same time, I also started getting spasms in my right eye. This has been an ongoing problem through to now. The doctors have put it down to a neurological problem, cause unknown, but as it has not gotten much more extreme, just very irritating, it is something I have been just putting up with since. I do have a referral to see a neurologist which I have not attended yet, as I got it not long before the airing of the Sixty Minutes show.

The Sixty Minutes program came as a shock to me on 11/03/2012. I had missed the media attention prior to this surrounding PIP breast implants. Of course I went and checked my file at home and was just dismayed to find that this was what I had in my body and no-one had bothered to inform me. It has occurred to me that perhaps all of the little irritable things that have been happening with my body could be related to it trying to tell me something is wrong. I have also been feeling old and tired for want of a better expression, of course you never really think it could be related to these wonderfully safe implants you have in your body!

The next morning I called my surgeon's office and was sent an MRI referral form so we could check them.

Unfortunately my MRI has shown that my left implant is in fact ruptured. At this stage no-one knows how long it has been ruptured for, but in that time I wonder how much damage has been done to my body, both in the short and long term.

I am yet to see a surgeon as I am waiting for a referral to come through from my GP, whom I only saw this week. I have decided not to go back to my original surgeon because on reflection I have questioned why I hadn't been informed of the problem long before Sixty Minutes went to air. I was told by my surgeon that they had computer problems and had not been able to contact every one of their patients and that others had complained of the same. I find this a very poor explanation from all involved when my contact details have always been the same and two years have passed since the medical industry were informed of the product recall. A product surely would not be recalled and deemed unsafe for future use if it had been safe in the first place. Therefore I question that the TGA, the government and the surgeons themselves would not feel it is fit to inform people as a mandatory course of action when something like this happens. I have also been shocked by the surgery's "nothing to do with us" attitude about the faulty goods supplied.

In the weeks since finding out about the rupture, I have barely slept. I have been researching the implants and what consequences this may have, I have questioned how our medical providers, government and the TGA could have failed thousands of women in this way.

Firstly, they have failed us by not having adequate checks on products which are going to be placed inside the human body. How can it be that every piece of literature I hold clearly states that the filling in these implants is TGA approved, when in fact it is not. According to Trade Practices, goods must be fit for the purpose for which they are intended, be as described and industrial grade silicone was certainly not the appropriate contents for these implants.

Secondly they have failed us by not having adequate record keeping requirements in place, neither in the local surgeries or at a mandatory centralised reporting agency so that if this does happen, individuals affected can be informed as matter of course and make their own judgements with

appropriate medical advice as to the course of action from there. I for one, would have had the implants removed years ago had I known they had problems and may have avoided a rupture which I have now which will mean a more complicated surgery and recovery.

Thirdly, I feel that the disclosure requirements of the medical industry is obviously lacking when I have joined a group of other women who have had similar stories to me... that they have been deceived and mislead into believing that a product or service was safer than reality, that a product was more superior than reality, that the life of the product was so much longer than reality, that no responsibilities or advice are put on patients or medical staff as to follow up care recommendations to ensure that something like this cannot happen. Deception and misleading information is still the same to the end user whether it was intended or not.

I personally work in the banking sector. It does not matter if a client is mistreated intentionally or not, it is the treatment that counts at the end of the day and how it affected the client. If a client is induced into a product which does not meet their needs, or have the functionality that has been advised or implied, then the laws are very clear on who is at fault and who must pay or compensate to rectify the problem.... the supplier.

Why would this not apply to professional services such as medically. And why is it that no-one seems to have to take any responsibility to us as the consumers?

As far as I can see, thousands of unsuspecting women including myself were sold a product which did not meet appropriate standards. The items were not fit for the purpose for which they were intended. Consumers have been left having to undergo costly rectification surgery, costly both financially and emotionally. Many women have reported health issues with these implants, rupture rates are quite obviously higher than ever expected by the TGA due their lack of appropriate reporting standards, this has immediate consequence to the patients with further surgery required, time off work, time unable to look after their families as has been my case. Emotional stress, anger, confusion and anxiety is a huge part of this because every woman I am in contact with has now the same fear, what are the long term consequences, some are asking if they have harmed their own children, all of us are asking how can something like this happen in this day and age. There is no excuse for it.

At the end of the day, this shouldn't have happened and it wouldn't have happened if the government and the TGA had appropriate standards in place.

The message given to me today on writing this submission is- its not the TGA's fault, its not the surgeons fault, its not the governments fault.

I would like someone to sit back and consider the submissions of the women who have been victims of this – its certainly not their fault!