Friday, 20th April 2012

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

RE: SUBMISSION TO THE SENATE COMMUNITY AFFAIRS INQUIRY INTO THE ROLE OF THE GOVERNMENT AND THE THERAPEUTIC GOODS ADMINISTRATION (TGA) REGARDING MEDICAL DEVICES, PARTICULARLY POLY IMPLANT PROTHESE (PIP) BREAST IMPLANTS

To Whom It May Concern,

I wish to make a submission to the senate's inquiry into the Therapeutic Goods Administration (TGA) handling of the issues that have arisen concerning the faulty implanted medical breast prostheses manufactured by the French Company Poly Implants Prothese (PIP). I would also like to tell you about my personal journey with PIP implants and how this has and is still affecting my life.

I had a breast augmentation on the 3rd November 2005, performed by , Perth, Western Australia, at which time I was implanted with Poly Implant Prothese (PIP) breast implants.

After watching the 60 minutes program on 11th March 2012, I became concerned that I may have these PIP implants. After an extensive search of my house and old files I located my breast implant card and was devastated to learn that I had PIP implants. I was even more upset to learn that in April of 2010 the implants had been recalled, and yet I had heard nothing from my surgeon or the in Subiaco.

After finding out that I had PIP implants, I went to the Therapeutic Goods Administration (TGA) website to get as much information as I could on the situation. I also took note of the comment that '*Consumers with these silicone gel implants who have concerns should contact their treating breast implant physician for advice and follow-up.'* Once I had collected as much information as I could from the TGA website I contacted my treating physician on 13th March 2012.

On first contact I was told to contact the TGA as that they could not give me any information on the PIP issue, nor could they send me for a referral to have an MRI or ultrasound to have my PIP implants checked. They made me feel as though I had done something wrong and that I was wasting their time with my phone call. When I got off the phone I could not stop crying, I did not call them because I was angry, I called them for advice and support as this surgeon recommended and implanted me with PIP.

Following the lack of success with my surgeon, I contacted the TGA on the Breast Implant Information Hotline. Again no joy there. Although the lady I spoke to on the phone was lovely, and doing her job, she could not give me any further information on where I could go to get an MRI in Perth, or how to go about organizing one. Finally I was told to contact my surgeon again and get them to help.

After three days of feeling lost and confused I made an appointment to meet with my GP. He was fantastic and seemed to be more knowledgeable on the subject than both the TGA and my surgeon and referred me for an ultrasound straight away. After having made such a positive step with my GP I left feeling better about the situation, only to be stonewalled by the company that I had been referred to for my Ultrasound. I tried to make a booking with the company my GP referred me to only to be told by the lady on the phone that their machinery was for people with real issues and that as a PIP screening I would have to wait until they had a cancellation as other people would take priority. I could not believe what I was hearing, and again I was back at square one without any assistance or guidance into the matter. At this point, I chose not to have my ultrasound at that place.

So back to the internet I went, trawling through the entire TGA site, but to no avail. Finally I decided to contact an old friend who had her implants done by the same surgeon. She too had recently found out that she had PIP implants and was going through the same thing. I found out from her that there was a place in Perth that was screening PIP patients and was providing a bulk billed MRI. I saw my GP again, this time for a referral for an MRI.

On 2nd April 2012 I had my MRI. Later that same week I found out that I have intracapsular and extra capsular rupture of the left breast implant, and silicone material in some lymph nodes. This was the lowest point in my journey.

On the 5th April 2012 I became a statistic, one that the TGA may now want to speak with and take notice of.

I am disappointed that the TGA do not believe that there is a bigger picture issue here and that this issue is allowed to continue as it is; it is also hard to believe that the best course of action is the ‘wait and see’ approach. But how long do we have to wait? Do we wait until all women with PIP implants have a rupture? Or do we wait until children who have been breast fed develop health problems in 5, 10 or 20 years? Or do we wait for the TGA to keep testing unaffected, un-ruptured implants out of a single batch, with no cross comparison from other ruptured implants of differing batches?

Today, like me there are many women in Australia who have only recently found out that they have PIP implants and thousands more that still don’t even know that they have them. There are also many scared, confuses and lonely women who have been given no support from the TGA and are being told that although the implants have been recalled there is no need to panic or have them removed; the key issue here is that the implants have been recalled.

I am not naïve to the fact that at some point in my future I may have had to have my implants replaced, but I did trust that the Australian health regulatory bodies had both trialed and tested my implants before they were approved as the ‘quality’ product that I was sold. I feel that the TGA has not made any serious efforts to ensure that surgeons contact their PIP patients; I also feel that if this was any other prostheses like a surgical pin or plate there would be more action taken to ensure all patients were notified and given the best medical treatment available.

The last few months have been incredibly tough on both me and my family. I am anxious, stressed and frightened. I cannot sleep as I can’t stop thinking about the effect that the PIP implants are having and may continue to have on my body. I am stressed about missing work and finding the finances to have my implants removed. Emotionally and mentally I am not coping very well.

I feel that the TGA has been very relaxed in their attitude towards women that have PIP implants and also in their ability to notify, warn and follow up on people living with them. I feel like I have been let down by both my surgeon and the TGA, as without the use of the media and the 60 Minutes program I still would not know that my implants had been recalled.

Today I am living with a ruptured PIP implant inside me and I await an appointment with a new surgeon to schedule my removal. Not replacement. I will forever live with the fear that my faulty implants may have future repercussions on my health.

I thank you for the opportunity to tell you my story, and hope that this sheds some light on the lack of information, awareness and support that women living with PIP implants have received.

Yours sincerely