SENATE COMMUNITY AFFAIRS COMMITTEES

The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants

Written submission by: (PIP breast implant patient)

I am an Australian woman who has been deeply impacted on a physical, psychological and financial level since having my breasts augmented with PIP breast implants in March 2010 (less than 3 weeks before the Australia wide recall) in Brisbane, Australia.

In this submission, I will refer mainly to the following Terms of Reference:

> d) the impact of PIP breast implant failures on Australian patients;
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> e) the procedures the TGA has in place to assess the risk to Australian patients if devices in Australia are the subject of warnings or withdrawals overseas;
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> f) the procedures the TGA has in place to communicate device information (including withdrawal information) to the general public, with a focus on affected patients.

Physical impact of defective PIP breast implants

Prior to March 2010, I was a fit, healthy woman, happily able to work in my full time job plus my part time job teaching aerobics. I was also able to care for my family which included my two young sons. Within weeks of getting fitted with the PIP breast implants in March 2010, my health started deteriorating with my symptoms getting progressively worse over 22 months, to the end point where I was unable to function normally. My initial symptoms included extensive hair loss, chronic fatigue and general malaise, bowel/stomach issues, severe headaches and rashes. The rashes were initially red and scaly and started off around my chest and then extended across my neck and down both arms to my hands – when the redness and scaliness subsided, the pigmentation was taken out of the skin, leaving me with many white patches all over my upper body. A few months later, I started to experience severe arthritic pain in my knuckles and knees which progressed to the point where my knuckles are now permanently swollen and disfigured. I also experienced ongoing swollen lymph glands in my neck, pain around the implants and in my armpits, night sweats, numbness in my toes, fingers and lip, dizziness, breathlessness, heart palpitations and mental confusion. In the 22 months since my breast augmentation with the PIP breast implants, I became unable to work full time, I was also unable to keep teaching my aerobics classes and my husband was forced to take over the majority of the care of our two young sons .

As I became more and more unwell, particularly from June 2010, I was put under the care of many medical specialists including a Rheumatologist. Many of my blood tests were abnormal including elevated CRP levels, elevated ANA levels and elevated anti-thyroid antibodies: the abnormal results were mostly inflammatory and autoimmune in nature – though the doctors kept telling me that my results were ‘atypical’ and ‘unusual’. In June 2011, I was hospitalised with severe infections and inflammation around both implants. My symptoms included grossly swollen and painful breasts around both implants concurrent with extremely high temperatures and lymphangitis into the

axilla. During my hospitalisation I was treated with IV antibiotics and after discharge, I undertook long term treatment with oral antibiotics. Every time I finished the oral antibiotics, the infection around the breast implants reoccurred, until the infectious specialist that had been treating me since my hospitalisation in June 2011, recommended the removal of the PIP breast implants. My PIP breast implants were removed in January 2012. I was refused replacement implants due to medical contraindications relating to the chronic infection around both PIP breast implants. Testing on the removed scar tissue surrounding the PIP breast implants revealed chronic inflammation and the presence of synovial metaplasia. Ultrasounds of my lymph nodes at the time of removal showed several reactive lymph nodes in the left axilla. My removed PIP breast implants had changed colour from a normal translucent colour to a milky grey white colour and the consistency seemed very liquid and loose instead of the expected cohesive "gummy bear' consistency.

My health status today, even with the PIP breast implants being removed, is compromised. I am on daily medication for my autoimmune symptoms of which my treating doctors have said that I will suffer from forever, now that they have been 'triggered'. The medication I am on has further risks to my health, including the possibility of serious eye problems in the future.

Financial impact of defective PIP breast implants

I am now left with medical bills approximately $25,000 consisting of $10,000 from the original PIP breast implant surgery, $8,000 from the removal of the PIP breast implants and $7,000 of medical expenses from being treated for PIP breast implant related ill health over the past 22 months (hospitalisation from infections around implants, medication, specialist fees, etc). I believe that I should be reimbursed my original surgery costs of $10,000 as I was supplied with a defective product as evidenced by the TGA recall in April 2010. I also believe I should be reimbursed for the removal surgery costs of $8,000 as it was to remove a defective product. I also believe I should be reimbursed the $7,000 of medical expenses that I incurred over the past 22 months from symptoms caused by defective breast implants that have made me very ill. Doesn't the Federal Trade Practices Act, which was the applicable act in force when these PIP breast implants were provided, give me a guarantee that products and services purchased in Australia must meet a basic need of quality and performance and must be free from defects? Why have my rights not been protected?

My health has declined to the point where I am unable to perform my full time and part time jobs and I have experienced a major loss of income which has had a devastating impact on my family's financial status.

Psychological impact of having defective PIP breast implants

I have been left with grossly disfigured breasts that are stretched and empty from the initial implant surgery and have two very large noticeable horizontal scars, each approximately 10cm long from the implant removal surgery. The plastic surgeon who performed the removal surgery strongly recommended that I seek psychological treatment to assist me cope with the mental trauma of my breast disfigurement.

The anxiety and stress that my family and I have suffered from my declining health, cannot be underestimated. My health started deteriorating quite quickly from March 2010 and I started seeking medical treatment from June 2010. My life since then has mainly consisting of being bed

ridden at home or in hospital, trying to find the energy to attend the many medical appointments that were scheduled by my treating doctors. My health had declined so badly, last year I had to be taken into my appointments at my Rheumatologist's clinic, in a wheelchair hooked up to an IV drip, as I was an inpatient at a hospital at the time with infection/inflammation around the PIP breast implants.

Some of my worst memories over the past 22 months is seeing the anguish in my young children's eyes when I was admitted to hospital again and wasn't able to be at home for days at a time. My husband has had to be the main source of income for our family over this time, as well as the main carer for our young children. He has also had to care for me on a day to day basis and take me to my medical appointments and to and from the hospital whenever I was admitted. I feel so ashamed that my husband has not only witnessed my health decline, but also had to become my carer when he already had so many commitments with his work and his new role of main carer of our children. Our marriage has been greatly affected by this.

Adding to my anxiety during this time, was the differing approach by the TGA on the seriousness of the PIP breast implant situation compared to other countries such as France. I became aware towards the end of 2011, that the French government advised women to have the PIP implants removed. I attempted to get information from the TGA on the PIP breast implant situation and I felt that I was given limited and incorrect information and very little to no support.

My experiences with the TGA

I believe that the TGA were purposely downplaying the seriousness of the defective PIP breast implants. The first indication I had of this was when the TGA initially reported very low rupture rates of the PIP breast implants based on incomplete and insufficient data from a voluntary reporting system. Yet the TGA used these inaccurate rates as 'evidence' that PIP breast implant rupture rates were similar to rupture rates of other breast implants.

Earlier this year, I joined a support group for Australian women with PIP breast implants. I spoke to many women from this group and discovered, not only a confirmed rupture rate of approximately 20% amongst these women, but that many were also suffering from similar symptoms to me, particularly the extensive hair loss, chronic fatigue, rashes and joint pain. A smaller number of women had also been hospitalised with grossly swollen breasts relating to infection/inflammation from the PIP breast implants. In addition, I was advised that an Australian Plastic Surgeon, , was also experiencing a 20% rupture rate from his PIP patients. So I was aware that there was a real problem with the PIP breast implants including an unacceptable rupture rate and many women suffering distressing symptoms (with or without rupture).

I submitted an 'adverse event to a medical device' form to the TGA in January 2012 yet, except for a standard email acknowledgement of receipt, I was not asked for further details until April 2012, when I was sent a letter requesting that the TGA contact my treating doctors for further information of my symptoms. This delay is unacceptable, particularly when the TGA were advised in the 'adverse event to a medical device' form that I was so ill from the PIP breast implants, I had been hospitalised.

I found the TGA Breast Implant Hotline to be completely unhelpful – I called it several times since it was established only to hear a nurse on the line reading from a TGA press release 'that there is insufficient evidence" to do anything and 'not to worry". Even after I advised the hotline nurse that I was so sick from the PIP breast implants I had been hospitalised and suffering daily symptoms such as breathlessness and heart palpitations, the only advice I got was "to see my doctor".

Finally, I am greatly concerned that there is information publicly available that suggests that the PIP breast implants were on a 'worldwide alert' for some time before the Australian recall in April 2010 and that there are many anecdotal reports from overseas and Australian plastic surgeons that the PIP breast implants were not performing to the standard of other breast implants. I am also aware from the FDA website that the FDA refused to approve PIP breast implants due to serious concerns about the manufacturing practices of the PIP manufacturer.

This information leads me to believe that I have suffered needlessly because the TGA should not have approved the PIP breast implants in the first place and/or should have had more stringent monitoring processes in place to identify when medical devices such as breast implants are not meeting approved standards.

Request to appear before the committee

I would appreciate the opportunity to appear before the committee to provide further details on my interactions with the TGA, Federal and State health departments, plastic surgeons, cosmetic surgeons, medical practitioners and medical industry representatives since the PIP breast implants were recalled in April 2010. I am happy to do this at my own expense.

Yours sincerely