

This is my submission to the senate enquiry into the actions of the TGA on the import and recall of PIP breast implants.

On the 11<sup>th</sup> August 2005 I had breast augmentation surgery at \_\_\_\_\_ Private Hospital; my surgeon was Dr \_\_\_\_\_. He inserted PIP implants 290cc in each breast, this surgery cost me \$7800 in out of pocket expenses. I had this surgery done yes and I don't think as women we should have to justify why we had this operation. But here you go anyway I had this surgery done to boost my self esteem and self image as after having children I felt I was deformed as a woman. I did not feel comfortable in the clothes that I wore every day. This surgery did boost my self-esteem and made me feel whole again.

I am very disappointed in the Therapeutic Goods Administration (TGA) in the way that they have handled this problem. I believe I should have been notified back in 2010 that there was a problem. I am disgusted in the way that the government can run a company in this manner. We as tax payers pay their wages and expect complete transparency in the medical devices that are put into our medical system. Considering that the TGA gets funding from all the pharmaceutical companies wanting their products approved for use in Australia. How much did Medical Vision Australia (not Medical Vision Australia Cosmetics) pay the TGA for approval of use?????

It's very sneaky that medical vision has divided its company less than 24 hours after the French authorities order the removal of all implanted PIP implants in French women. Very convenient for them!!!! Considering on April of 2010 the PIP Company was declared bankrupt Medical Vision KNEW that there was a problem and should have notified the TGA and all of us women that there was a problem.

BUT NO!!! They didn't.

I can't understand why the TGA didn't randomly test PIP implants from the date from the date they were first imported into Australia from September 1999 until December 11 especially after their last fiasco with the artificial hip replacements. This does not look good!

So let me tell you about me....

On 20<sup>th</sup> December 2008 I was admitted to \_\_\_\_\_ Hospital \_\_\_\_\_ with unilateral swelling to my right breast. I was in extreme agony. I was febrile and tachycardia with a CRP of 98. I was very distressing for myself, my partner, children and extended family. I was an inpatient for 14 days over the Christmas and New Year's period. I was denied MRI, CT scan, PICC lines, Ultrasounds, HITH, and fasted for the first three days as it was unknown whether surgery would be necessary as no one knew what was wrong with me.

Being accused of having a bodgey boob job in Thailand was embarrassing and hurtful. My Partner and I were both very scared and felt cheated as we had been told that nothing could happen to these implants as they were cohesive silicone gel and the gel could not move even with a rupture in both of the outer shells.

During my time in hospital I had numerous blood tests that showed raised CRP (inflammation

markers), high dosages of IV antibiotics, numerous PIV insertions, only allowed 4 hours day release on Christmas Day to spend with my children and family.

I had 2 aspirations performed under ultrasound guidance which removed approximately 200mls of cloudy yellow Seroma. Many tests were conducted on them showing mixed inflammatory cells negative cultures and luckily no malignant cells were shown. This news was delivered to me as "we no it's not cancer but we don't know what it is". Can you imagine what it would be like to be told that while you are missing Christmas with your family? I was then discharged and became an outpatient for months after. With weekly specialist appointments and a continuation of the antibiotics.

Since then I have had sore and tender breasts, sore sensitive nipples, sore and swollen joints, rashes over my stomach, breasts, arms, and buttocks, insomnia, extreme fatigue, nausea, heart palpitations, shortness of breath, hair loss, abdominal cramping and severe pain, anxiety, depression, stress and I constantly worry about my health physically, emotionally and mentally.

From my research, experiences, knowledge and hindsight I believe that I have experienced a Gel Bleed from the inferior products and production of PIP implants. I do not know if this will happen again tomorrow.

On the 7<sup>th</sup> of July 2010 Today Tonight ran a segment on PIP implants. The next day I attended the Cosmetic Studio and queried them what I had seen. They told me I was being stupid and irrational and there was no cause for concern, while shooing me out the door they gave me an information sheet regarding the bankruptcy and concerns of the PIP implants. This raised major alarm bells with me, considering the problems I had had back in 2008. I raised these concerns in further discussion with the receptionists, and was dismissed by them and was not able to talk with a Doctor there about my concerns. Even with a follow up appointment I was further referred onto another cosmetic surgeon as Dr [redacted] had conveniently retired around September 2010. Seeing this new surgeon would be at my own expense and was considered a new procedure and not covered in my previous after patient care.

Following the advice from the letter from Cosmetic Studio I attended an Ultrasound at the hospital and they found no apparent loss of integrity in my implants, with my knowledge know this should have been an MRI as this is 94% accurate in the detection of leaks ruptures and bleeds from the implants.

On several occasions during 2010 onwards I have tried to contact the TGA to express my concerns about PIP implants and have been unable to get anyone on the phone who knew what I was talking about. No one there listens. They may hear what I'm saying but no one listens.

I had not had any more contact or updates from the TGA until December 2011 when the international scandal of PIP implants broke worldwide. But I'm sorry but this is a little bit too late for me and my family. The TGA have never been concerned about informing the public about the withdrawal of PIP implants off the Australian market, it's only now that they contain industrial silicone e.g. Baysilone, Silopren and Rhodorsil that they now are concerned on the rupture rate despite Dr's written statements about higher than normal rupture rate years ago and other countries demanding immediate removal of all implanted PIP implants from women.

The breast help line is the biggest load of crap the government has ever setup. The lady I spoke to was uneducated on the breast implants and was just reading off a piece of paper referring me to the

TGA website. I gave the lady a 1-0-1 on pip implants and hoped that she could be more helpful to other women in the same situation.

Why was the media was release such a small segment on their website?

Why was it not in the papers or on other media outlets?

Why do they not have a record of every woman that had these implanted into their bodies on their system so they could advise the by letter or email?

Now it's been advised that that they contain medical grade silicone the TGA are giving the appearance that they are concerned on the rupture rate despite Dr's written statements about higher than normal rupture rate years ago and other countries demanding immediate removal of all implanted PIP implants from women.

The TGA has still failed to mention any health impactions and I find it disgusting that the TGA's sample size for testing is 15 implants (this indicates that testing is not extensive) yet thousands of women have them in their body. I noted that testing is only being conducted on implants that are expired or due to expire soon (based on a ten year life of implant) and that most of them expired 2014 which mean that they manufactured in 2004.

Where are the rest of the implants?

Shouldn't the sample size be bigger?

Where did these implants come from if they were all supposedly all destroyed in 2010 when they were taken off the market?

Are they going to test on explanted implants?

Are they PIPs that they are testing on?

I'm sure if I was to conduct a research I would be laughed out if my sample size was that small. This data they are releasing is flimsy and relying on Drs and patients to report ruptures is and inadequate way to measure the rupture rates. Again this disgusted me, considering my implants are from 2005 and there is no testing on this year and I have medical concerns about this implant.

There is currently no data to support the TGA's claim that these implants are safe, and that a wait and see approach is further doing me harm.

The samples that the TGA's have tested have not been subjected to the same heat, conditions or environment as which they would have been in the human body. From what the media has reported these implants contain such ingredients as **Baysilone**, **Silopren** and **Rhodorsil**, which are components in fuel additives, industrial rubber tubing, mattress filler, and bathroom sealant. To my research these three products, if kept at a cooler temperature are of a high viscosity thus meaning in the human body at temperature of 36.6 degrees Celsius, the viscosity of these products is severely compromised!!!! All of which was NOT intended or approved for use in the human body. The TGA is insistent that these are of no harm to us so why did they remove all non-implanted implants off the shelf?

The TGA should be made to release all of its tests in full and be accountable for allowing such an appalling product into Australia. The kickbacks received by doctors for using this product or allowing it to be approved for use should be made public knowledge and women who have had this implants should be reimbursed and compensated for this terrible outcome of such a faulty product.

Upon further research I have found that in 2000 the PIP Hydro gel was recalled off the market in the U.K as inadequate pre-clinical testing was done on them.

Why did this not raise concerns or alarm bells with our government and TGA authorities?  
Considering PIP implants have been used in Australia since September 1999.

This is most concerning to me. This is a criminal act in itself.

International studies have also shown results as being "PIP implants has a rupture rate disproportionately higher than equivalent devices" but yet the TGA refuses to acknowledge any of these findings. (Berry and Stanek journal of plastic, reconstructive and aesthetic surgery 2012).

On the 26th of October I noted that Medical Vision Australia was still advertising PIP implants on their website. Even though they had been withdrawn off the market 7 months prior. (Don't you think this is a long time to have a withdrawn product on the FOR SALE section still?)

Medical Vision state that they are high cohesivity gel breast implants that are filled with a high cohesive medical grade silicone gel. They gel is a polymer from the VQM Polysiloxans family.

Authorised in France since 2001. The clinical risk due to the filler spreading in the event of a rupture is limited by the gels high cohesivity which makes it easier to remove.

Sound wonderful doesn't it!!!!!!

This is a complete lie.... Where is the party that says they turn to mush and fall apart and "ooze out" silicone into every part of your body? There is no warning on there either that tells you, you may suffer from hair loss, night sweats, rashes over your entire body, inflammation of the breasts and lymph nodes, sore and tender breasts, sore sensitive nipples, sore and swollen joints, insomnia, extreme fatigue, nausea, heart palpitations, shortness of breath, abdominal cramping and severe pain, anxiety, depression, stress, auto immune diseases and maybe even cancer.

I want the product that I thought I was getting in the brochure not the one I got sold!!!

Is the TGA actually going to ever report on all its findings or just the ones that make them look good?

Are the TGA only going to support their findings and not of other countries, doctors, journals and most of all us women who have them in their bodies?

Why is it only now with media coverage that the rupture rate is starting to grow and is now at 250? I am part of an online group and I find it hard to believe that in the whole of Australia that there are only 250 ruptures. We have done a survey on our online group and out of 384 women there are 82 ruptures (double ruptures are not reflected in this number). This is a 20% fail/rupture rate.

Thus leads me to think the TGA is hiding something.

I really don't think Dr Flemming is such a great presentive of the TGA seeming he was the biggest user of PIP implants and is only a glorified GP.

Wouldn't it be in the TGAs favour to get a more qualified surgeon to represent them?

Luckily for men the TGA didn't import the testicular implants or the chest implants that have been reported to be made of the same industrial silicone. I truly believe that if they too were imported into Australia that all the implants made by PIP would have been removed and replaced immediately. Unfortunately this is not the case.

Big thank you to Nick Xenophon for trying to raise awareness of the PIP breast scandal on the 3rd of June 2010 at the Community affair Legislation committee- Health and ageing portfolio- Therapeutic good administration. He tried to bring up the issue of pip recall and said "That the recall

followed an investigation in France and that they are seeking further information.” He also stated that he was unaware of the fraud in France and                      may want to expand testing. Then the subject was changed.

What a load of shit... Why has it taken                      (who was the National Manager of the TGA and just happened to resign 2 days after the PIP scandal came to light in the media) and                      2 years to still be investigating? This is not good enough!!

Until I have my implants removed I live in constant fear of ruptures, and health issues. My husband is fearful also as to what will happen to me. He see’s media reports about health issues associated with the implants. My sister and Aunty also have PIP implants so our family isn’t just dealing with fearing for my safety but for all of our health.

Thank for reading I really hope I get some answers and medical compensation soon