

I understand that submissions for the the Senate Inquiry into TGA handling of the PIP Implants should have been received by the 20<sup>th</sup> April but I was unaware on the 20<sup>th</sup> April that I had PIP implants. It was after this date that the staff from the surgeon's office phoned to inform me. I feel I really need to inform you of my situation.

In July 2006 I had breast reduction mammoplasty surgery and implants inserted which I now know to be PIP Implants by Dr .

In June 2009 I went to my GP because I had a lump in my left breast and under my right armpit and hardening and soreness. My GP sent me for an ultrasound and referred me to Dr for follow up.

In November 2009 I had surgery to remove and replace implant and remove lump from left breast, the surgeon said she did not remove lumps from armpits, locate in both right and left armpits because of long term implications.

In February 2011 I became very ill and was admitted to hospital the diagnosis at the time was pancreatitis. Further investigation by the surgeon Dr located a tumour in my bile duct./head of pancreas. The surgeon then referred me for follow up to Professor .

In March 2011 Professor performed a Whipples' Procedure, (an operation I would not wish upon any person) to remove the tumour and surrounding organs to ensure no cancer was left. No amount of recovery will ever restore what I have lost.

In April 2012 I went to my GP as I have been experiencing pain, swelling, lumps and hardness in my right breast. He referred me to the surgeon for follow up. I had made my appointment to see the surgeon again on the 9<sup>th</sup> May, but before my appointment I received a phone call from Dr surgery informing me I had PIP Implants and should consult the surgeon about these. I advised I have already made an appointment as I have problems already with my implants.

I will be having surgery to remove my implants on the 8<sup>th</sup> June as there is definitely something wrong with them. This comes with great financial hardship.

I am absolutely sick to the stomach and the mind, I cry every time I think about it which is all the time. To think that all my health problems could be related a product that was unfit to be distributed for sale let alone implanted into peoples bodies

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I believe the TGA has mismanaged this issue and has failed in their duty of care and responsibility to the Australian women who have been affected. The product was recalled from sale in 2010 in Australia by the TGA due to European, particularly French government, concerns that the material used in PIP implants' manufacture was not of a medical grade silicone and rupture rates were extraordinarily high.

The TGA made to declare the PIP implants a health risk that warranted removal. If the product is safe enough to be left in our bodies in the TGA's opinion, why have they stopped the sale of the device for new procedures? The regulatory bodies of other advanced Western societies such as the UK, France, Germany and the USA have announced that the product is not safe. They have not only recommended urgent removal but have paid for the cost of surgery and replacement of the medical device. What is the TGA doing about this ?

The testing procedures used by the TGA are insufficient numbers to give any sort of accurate observation of the integrity of the product. Of the thousands of Australian women who are affected, only a few have had the suspect implants explanted, ruptured or unruptured, and of these only an even smaller amount have had these implants sent to the TGA for testing. Advice from the TGA has not

made it mandatory for surgeons to send the potentially faulty explanted device off for testing. This places the responsibility, and the cost, on Australian women for collecting the data that could help the TGA determine how many women could still be at risk.

Many Australian women today do not know they have PIP implants and are unaware that they are potentially at risk. In my case, I had no idea what brand of implant I had at the time of my initial procedure. I simply had faith in my surgeon and in the Australian health regulatory bodies. The TGA has not made serious efforts to instruct all surgeons that used the PIP device to contact their patients.

This information all highlights a lack of concern and responsibility for the health of Australian Women in the TGA's handling of this issue. Given the risks to my health and the financial and mental strain that is being placed on my family and myself, I would expect a lot more support from Australia's public health service.

Sincerely