SUBMISSION TO THE SENATE COMMUNITY AFFAIRS INQUIRY INTO THE TGA HANDLING OF PIP PROBLEM

To whom it may concern,

I am writing to make a submission to the Senate's inquiry into the Therapeutic Goods Administration (TGA) handling of the issues arising from the faulty implanted medical breast prostheses manufactured by the French Company Poly Implants Prothese (PIP).

I had breast augmentation surgery in December 2007 performed by , Sydney using breast prostheses manufactured by PIP.

Since becoming aware of the problems with the PIP implants, I have suffered a great deal of anxiety, stress and concern for my physical and mental health. News headlines reading "Ticking time bombs" have made it impossible not to panic about the risks to my health and the TGA's information and advice helpline provided me with very little information and no comfort.

surgery did not approach me to let me know of the potential problems and risks once the information about PIP faulty implants became public knowledge. I contacted surgery as soon as I heard about the issues and I have been given a quote for a more qualified surgeon not to the amount of $18,000 for surgery to remove and replace the implants.

Given the potential health risks I am facing because of issues with PIP implant rupture rates and use of low quality silicon, I have no option but to proceed with the surgery. At this time Medicare and my private health fund have not determined how they will provide financial support to cases such as mine. I could be waiting 12 months or more before I could have surgery receive any financial contribution towards the surgery. Right now waiting 12 months for help will not allow me any peace of mind about my health.

I believe that 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