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

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 had breast augmentation surgery on the 27th of October 2008 performed by Dr in Sydney using breast prostheses manufactured by PIP. I have since had the suspect breast implants removed by the same surgeon and replaced with another safer brand of implant. Thankfully the extracted implants were not ruptured however I had them sent off for clinical testing due to legal advice.

I believe that the TGA has mismanaged the issue from the outset and have failed in their duty of care and responsibility to the Australian populace who are affected by this issue. I will examine why I have come to this conclusion and also wish to state that this has caused significant stress on my person and on my family, arising from the fact that these implants could have had an extremely adverse affect on my health and well being, not to mention the financial hardship placed upon me with regards to what I believe necessary cost of removal and time away from work due to recovery from the procedure.

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, yet the TGA made no move to have the product deemed a health risk that warranted removal. If the product is safe enough to be left in our bodies in the TGA's opinion, why stop the sale of the device for new procedures. This does not make sense, either the product is safe or it is not safe, and going by the opinions of the regulatory bodies of other advanced Western societies such as the UK, France, Germany and the USA the product is not safe and thus they have not only recommended urgent removal but have paid for the cost of surgery and replacement of medical device.

The testing procedures used by the TGA are not in sufficient numbers nor in a sufficient broadness of batch 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 handful 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 due to the fact surgeons are reliant upon advice by the TGA which has been static if not blasé, and thus are not overly enthusiastic to have the explanted devices clinically tested by them. My own experience of this lack of action by the TGA was that my particular surgeon was not concerned enough about the product to insist that the product he removed from my person be sent to the TGA for testing. I had to in fact insist that I keep the explanted PIP implant devices and send them to be clinically analysed privately by the Law firm representing the potential class action that may arise because of this fiasco. The TGA is so blasé about the potential dangers of the PIP implants, that they have not made it mandatory for surgeons to send the potentially faulty explanted device off for testing.

Many Australian women today do not know they have the PIP implants and are unaware that they are potentially at risk, this fact although hard to believe is plausible as many people are not media savvy, are not consumers who are aware what implant they have. 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 make it essential that all surgeons that used the PIP device contact their patients, in my case I had made the first call to my surgeon after observing the PIP issue in the news media. I contacted the TGA in January 2012 to alert them to the fact that surgeons are not always contacting past patients with PIP implants, they told me this was not their responsibility and that I should take the matter up with the relevant Doctors association; so much for their concern of public health.

Lastly, I wish to highlight the woeful attempt by the TGA to provide an information and advice Hotline. The phone was answered by a registered nurse which was a good sign, but then things went downhill from there. The nurse was reading from an information sheet and had no real insight into the problem and was mainly concerned with directing me to the TGA website for more irrelevant information and was not able to answer any substantial questions such as where in Sydney could I have an MRI examination for my suspected breast rupture. My 14 year old son armed with a laptop and Google could and did accurately provide more helpful information than the half dozen or so times I called the hotline. All the while being sick with worry and not knowing what it was that I had implanted. News headlines reading “Ticking time bombs” and adding to a very stressful situation. Perhaps I should be grateful that the TGA’s hotline did not palm off this seemingly insignificant (for the TGA) problem to a third world call centre, at least registered Australian nurses answered the phone even though they had no information that could not be found on the TGA’s website. Again, a huge lack of effort by the TGA.

The above points all are evidence of the ineptitude of the TGA’s handling of this issue, this had contributed to my feeling of emotional and financial distress and hardship I have undergone. As a single mother with 2 kids, I fear for my health, fear for my life and most importantly my children’s well being.

Yours faithfully