SENATE COMMITTEE INQUIRY

THE ROLE OF THE GOVERNMENT AND THE THERAPEUTIC GOODS ADMINISTRATION (TGA) REGARDING MEDICAL DEVICES PARTICULARLY POLY IMPLANT PROSTHESE (PIP) BREAST IMPLANTS

Summary

The information provided in this document relates to my experiences with:

- the Government and
- the TGA

regarding medical devices:

1. 1984 – 2001. No record of brand but Plastic Surgeon #1 (PS #1), Melbourne, stated Dow Corning or Heyer Schulte most likely

2. PIP silicone gel breast implants Plastic Surgeon #2 (PS #2), Sydney

3. McGhan silicone gel breast implants PS #1, Melbourne

which were placed in my body for purposes of reconstruction following bilateral mastectomies.

On 1 November 2006, silicone gel breast implants were finally removed from my body (PS #1), Melbourne.

Supporting documents attached to this document include copies of:

I. TGA Independent Patient Use (IPU) Application Form completed by PS #2, dated 8 May 2001

II. TGA Therapeutic Goods Act (1989) – Exemption from Registration to PS #2, dated 8 May 2001
Notice of approval under Section 19(1)(a)
Individual Patient Use (IPU)

III. Principles of Ethical Conduct (4 pages)
National Statement on Ethical Conduct in Research Involving Humans – June 1999

IV. 21 November 2011, letter from to National Manager TGA, (2 pages)

V. 29 November 2011, e-mail from , FOI Coordinator, Office of Legal Services, TGA, to with attachment (FOI fact sheets 12 and 13 - 7 pages)

VI. 30 November 2011, e-mail from : to National Manager TGA,

VII. 2 December 2011, e-mail from , FOI Coordinator, Office of Legal Services, TGA, to , with attachment letter (3 pages)

FACTS RELATING TO THIS SUBMISSION

Approximately 200 000 reports of adverse health effects from breast implants have been reported to the US Food and Drug Administration since 1985 (Lykissa and Maharaj 2006).

A 1993 US Congress report reveals that only approximately 5 percent of adverse reactions are reported to the FDA.

It was not until 2007, some 23 years after breast implants were initially placed in my body, that I was first made aware of the existence of the Government body known as the TGA; the regulator of silicone breast implants.

By way of background, I trained and practised extensively as a Registered Nurse and subsequently held management positions in a number of speciality areas including Operating Theatre, Intensive Care, Surgical Nursing, Midwifery and Occupational Health. In 1993, I established my own business writing enterprise.

Prior to initial implantation, PS #1 told me that silicone was just silicone and that it didn't do anything. He told that it was present in our bodies from food and medications and that it was contained in a number of commonly-used cosmetics.

He assured me breast implants were safe and that they would likely last a lifetime. I had no reason to doubt him.

Within two years of initial implantation, I experienced serious health problems which continue to this day. Over time, it was suggested my silicone gel breast implants might be to blame. It was recommended that, because they had been in my body for seventeen years (17) they should be removed and replaced.

Relevant experience with the TGA regarding Poly Implant Prosthese (PIP) Breast Implants

In 2001, PIP implants were used to replace those which had been in my body 17 years. I foolishly placed my trust in PS #2 who assured me he could make all the necessary arrangements to replace my initial implants. At operation, both previous implants were found to have ruptured.

I did not learn of the brand of implants placed in my body at that time until 2006 when I was required to complete a questionnaire to go in with a number of my specimens which were being sent to the USA for analysis.

When PIP implants were placed in my body in 2001, I had no knowledge whatsoever that PIP implants were not entered onto the Australian Register of Therapeutic Goods (ARTG) and that PIP implants could not be legally supplied in Australia except on an Individual Patient Use basis ...

'where it can be shown that the patient has a demonstrated clinical need for the unapproved silicone gel-filled breast implant, that the patient is likely to benefit from the use of the unapproved silicone gel-filled breast implant, and that no approved silicone gel-filled breast implant is suitable.' *TGA Breast Information Booklet 4th edition.*

This booklet was not ever provided to me, nor was I ever notified that it could be viewed on the TGA website.

At no time was I warned that silicone breast implants were considered 'High Risk' devices.

In 2001, prior to surgery to replace my ruptured implants, I unwittingly signed the hospital generic 'consent to surgery' form. As it later transpired, my consent was anything but informed.

In 2011, some ten years' after this surgery, in an effort to find out the specific content of my silicone breast implants, I made a number of applications to the TGA for documents under the Commonwealth *Freedom of Information Act 1982.*

Among the documents disclosed to me were two documents which caused me a great deal of distress.

I had not previously sighted either of these two documents, and had no knowledge of their existence.

DOCUMENT 1

Copy of TGA Independent Patient Use Application Form

and

DOCUMENT 2

Copy of TGA Therapeutic Goods Act (1989) – Exemption from Registration
Notice of approval under Section 19(1)(a)
Individual Patient Use (IPU)

I have attached copies of both these forms. Against my moral and ethical judgment, I have withheld PS #2's identification.

The information provided by PS #2 on Document 1 differed from his advice both to my GP and to me.

Document 2, the TGA's formal notice of approval to implant unapproved devices into my body, was subject to six conditions.

Not one of these conditions was disclosed to me, and not one of them was met by PS #2.

I was so outraged at the gross misconduct of PS #2, I sought legal counsel. I was warned not to defame him. Had it been Nuremburg during the 1940s, defamation would have been the least of his worries. He'd have been hung by the neck, along with all those other doctors who were found guilty of human experimentation without the subject's consent.

PS #2 had violated both my bodily integrity and my autonomy.

Let's just look closely at what PS #2 actually did to me.

He arranged for me to be taken to a hospital operating theatre. There, he picked up a scalpel, cut open my chest and, **without my knowledge or my consent**, he implanted two devices into my body which could not legally be supplied in this country without an approval which was subject to six conditions.

PS #2 failed to tell me:

1. of any clinical need to implant me with unapproved devices
2. the devices could not be legally supplied in this country
3. he had completed an individual patient use application form on my account
4. there were other suitable silicone breast implant options than PIP
5. how I could possibly benefit from the use of an unapproved device
6. he had received an approval notice from the TGA
7. the approval was subject to six conditions
8. anything about these conditions which included that 'the use of the device shall be regarded as experimental.' He did not bring any of the conditions to my attention, nor did he, himself, meet even one of the conditions of that TGA form of approval

On 30 January 2012, I contacted the National Health and Medical Research Council and obtained a copy of the Statement on Human Experimentation (attached). I had previously not ever sighted this document.

I believe the TGA failed me by not having adequate procedures in place to ensure that my CONSENT to the surgical procedure would be INFORMED. Had I been afforded full and frank disclosure of the facts, there is no possibility (particularly with my medical background) I would have consented to the surgical procedure.

The TGA is responsible for the quality, safety and efficacy of medical devices, yet, without any communication with me, the very individual they were supposed to protect, they gave their approval to an unscrupulous PS #2 to place illegal devices into my body without insisting on written confirmation back from me that:

a. I was aware of the degree of risk

b. that I had read and understood **all** of the conditions of approval, including the fact the use of the devices being placed into my body would be regarded as experimental and

c. that I had given **informed consent**

One of the conditions was that I accept responsibility for the outcome of the therapy. The only profitable outcome of the therapy was PS #2's income; paid upfront by me before he would proceed.

Given the serious nature of the approval conditions, I cannot understand why the TGA did not operate within an accountability-based framework.

I recently heard the Hon David Davis, Minister for Health and Minister for Ageing in Victoria, speaking to the media, "The Government will not sit by if patient safety is threatened." Isn't it time government rhetoric became reality?

Relevant experience with the TGA regarding McGhan silicone gel breast implants

On 26 March 2003, I underwent further surgery. Extensive capsule formation around the PIP implants had caused an embarrassing deformity necessitating their removal and replacement.

McGhan silicone gel implants were used for the replacement surgery.

Within a very short time, I began to experience more troubling physical symptoms, but was told they were all 'in my head'. I later learned it is very common for sick breast implanted women to be labelled 'crazy'.

I sought referral to an experienced and highly regarded psychiatrist who was unable to find any psychological cause for my symptoms. He determined and provided a written report that the symptoms were in my body; not in my mind.

On 1 November 2006, by which time my health was rapidly deteriorating into a downward spiral, I had the implants finally removed. After explantation, my condition deteriorated even further but I learned it is a common phenomenon for symptoms and their severity to multiply following implant removal.

I consulted with four different specialists in this country, but none had any experience in managing the side effects of silicone breast implants.

I travelled to the USA where I consulted with an internationally recognised expert in the diagnosis and treatment of environmental and workplace diseases. He had treated in excess of a thousand sick breast implanted women. After I had undergone exhaustive testing over several weeks, he told me that objective findings demonstrated I was reacting to toxins released from my silicone breast implants. He stated that I was a near-perfect fit to the profile. He claimed that though opposition to the introduction of a foreign body with multiple chemical contaminants into the human breast via a surgical procedure is an unpopular position, for him it is the only tenable position.

He told me that I might start to feel a whole lot better around five to seven years after explantation but he doubted I would ever enjoy the good health that was mine before breast implants had been placed in my body. He had concerns regarding progression to muscle disease and his concerns have since been realised.

I am aware that detoxification programs are available to rid the body of certain chemical compounds but, before I put any further substances into my already ailing body, with a likelihood they might do more harm than good, I need to find out exactly what had been used in the manufacture of both the shell and the gel of my silicone implants so that an individual, highly specific detoxification protocol may be tailored for me.

It is considered very bad medicine to continue treating symptoms in the absence of a diagnosis.

Throughout 2011, I made one after another application to the TGA for documents under the Commonwealth *Freedom of Information Act 1982*, but each of my requests was refused. I requested Internal Review following one decision, but the TGA remained steadfast with their determination not to disclose the documents I had requested.

I wrote to the TGA's National Manager (letter attached).

A TGA representative advised me of my review rights but, as I had already failed in my previous review attempt, I thought it futile to make any further review requests.

In Victoria, we still await the appointment of the FOI Commissioner. At a Federal level, I understand FOI reforms have stalled.

I e-mailed the National Manager (e-mail attached).

Until I can find out what had been placed in my body, I have no chance of healing.

I would like to know why the TGA allows potentially dangerous chemical compounds to be placed into the bodies of Australian women without their consent. Breast implant manufacturers need to trade their secrets for human health.

Perhaps the breast implant manufacturers are worried about litigation and the ultimate cost to them when the link is ultimately established between these chemical compounds and breast implants.

Currently, no woman in this country can give informed consent to silicone gel breast implants whilst she is denied full and frank disclosure of exactly what is being placed in her body.

SUBMISSION RECOMMENDATIONS FOR THE GOVERNMENT AND THE TGA

1. The TGA maintain an up-to-date breast implant register for ALL breast implant recipients in this country
   The register should include copies of implant recipients' signed consent forms which include details of **all** the provided information on which they based their consent
   The register information be available to patients on application
   The register be used for statistical purposes which will not contain any identifying information

2. The TGA issue a warning statement in regard to the safety of medical devices manufactured with silicone which has been catalysed with hexachloroplatinate. This chemical catalyst is used for the manufacture of silicone gel breast implants and silicone-envelope saline-filled breast implants. The medical literature states that no person should come into contact with a liquid or solid containing hexachloroplatinate

3. The TGA's ARTG approval process undergoes urgent reform so that it protects the health and safety of thousands of Australian women, is no longer a threat to public safety, and allows full and frank disclosure regarding the devices to existing and intended recipients

4. The *Freedom of Information Act* undergoes urgent reform so that women who experience serious health problems after having implants are not denied the ability to receive a proper diagnosis and treatment because they are unable to find out what exactly chemicals were placed into their bodies

5. The TGA maintains an up-to-date *Breast Implant Information Booklet* and make it compulsory for all surgeons undertaking breast implant surgery in this country to distribute the booklet to all prospective breast implant recipients

6. The TGA improve its testing facilities in order to conduct random testing of imported products to ensure compliance both with approval conditions and international standards

7. The TGA make public announcements regarding any adverse reports relating to silicone gel breast implants. The March 2010 PIP scandal did not gain 'hot topic' status around the world until December 2011. In April 2010, the TGA removed PIP implants from the ARTG, yet no public announcement was made to Australian PIP implanted women to warn of the scandal, and of the reported increase in rupture rate of PIP implants

8. The Government is fully aware of the impact on its economic obligations of the long-term adverse effects of silicone breast implants

9. Effective immediately, the TGA should cease their practise of allowing devices regarded as experimental to be placed into the bodies of women in this country