



Submission to Senate Community Affairs References Committee

I am writing this submission as a result of my personal experience of the effects of transvaginal mesh implants.

Name and contact details

Name [Redacted]

Address [Redacted] **Date of Birth** 26.9.1962

[Redacted] **Contact number** [Redacted]

NSW 2100 **Email address** [Redacted]

State Queensland **Postcode** [Redacted]

Terms of Reference 1: The number of women in Australia who have been impacted

1. Have you or a family member had a transvaginal mesh implant? Yes No

self 2008 & 2009

If Yes, please share your experience:

after 1st operation. 2nd operation to try & "fit" the first one. excruciating pain for a long time

It ruined my life as I knew it. It did not repair the bladder prolapse and caused damage to more body parts and my mental health. It incapacitated me at a critical time as a mother of young children, and as a wife. There are many things I can no longer do or attempt to do; lost opportunities, horrendous medical expenses, bouts of depression chronic pain + discomfort + continuing bladder prolapse issues. . . . just to mention a few parts of my dreadful experience!

2. Have you or your family member experienced adverse side effects as a result of the transvaginal mesh implant? Yes No (full details are provided at Terms of Reference 5, below)

If Yes, please share your experience:

- mesh erosion, nerve pain, chronic inflammatory "foreign body" response

- depression + anxiety, ruined sex life, marital issues with an almost failed marriage, continuing bladder prolapse inability to exercise which lead to issues around being overweight

- painful sex, unable to do any "bearing down" type activities, ~~was~~ could run or jog because of discomfort,

etc - these are the main ones -

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3. Have you or your family member had the mesh removed or made attempts to have the mesh removed in Australia or elsewhere? (full details are provided at Terms of Reference 7, below)

Yes

No

If Yes, please share your experience:

I had three surgeries to remove the mesh - pretty much at least died due to the blood loss and mess that the surgeon found when he opened me up for the first removal operation. The surgeon is now retired - removal was done at [redacted] - 2010 - [redacted]

4. Do you have any suggestions or recommendations about changes to laws, policy and practices in relation to transvaginal mesh implants or similar products?

Nothing should be able to be put in a person's body as an implant unless thorough clinical trials are done where it is visible about who is funding & managing the trial. It should be statistically significant and not approved purely because it was approved in U.S or E.U. there should be a national register where it is recorded ~~for~~ for each patient, all devices/serial numbers etc that have been inserted in the patient's body. Then patients will know what is in their bodies and have a way to be contacted should defects/alerts be issued.

It isn't ~~how~~ about how many "failures" of the devices that is key, it is the extent of the damage that is done that is most relevant. The "outcomes" need to be setup so that "acceptable" is not just a number... it needs qualitative measures of success.

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Terms of Reference 2: Information provided to women prior to surgery about possible complications and side effects

1. What information was given to you or your family member prior to surgery to implant the transvaginal mesh?

A pretty brochure and a promise of an operation that, after 6 weeks, would return me to "normal" functioning and aesthetics regarding the bladder prolapse ... absolute misleading rubbish!

2. How was this information provided to you? (eg. brochures, verbally, websites)

brochure + specialist's "sell" on the procedure.

3. Do you have any suggestions or recommendations as to what information you think women should receive before they receive a transvaginal mesh implant?

they should have told me that class actions were already starting in the US (2008) before I allowed them to put this "rubbish" in my system/body. (I only found out after I had the operations + had problems (independently))
they (surgeons) should have to be audited on how many procedures (of specific types) they have done and what the outcomes were - provide facts so patients can get their ^{own} reliable information.

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Terms of Reference 3: Information provided to doctors regarding transvaginal mesh implants and possible complications and side effects

1. What is your experience of doctors' knowledge of transvaginal mesh implants, complications and side effects?

GP's ^{generally} do not have a clue about the surgery to implant ^{in terms of} what can go wrong and how to help patients get the mesh out. It is easy to put the stuff in but a nightmare to remove as the skills required for removal are highly specialised and there are few surgeons able to do the removal safely.

2. Have you found information about transvaginal mesh including complications and side effects that your doctor (GP or specialists) was not aware of?

Plenty — !! — class actions
- effects of polypropylene in the body
- foreign body reactions
- nerve damage because of method of implanting
- mental health issues when it goes wrong

3. Do you have any suggestions or recommendations about what information you think doctors should be provided with in relation to transvaginal mesh?

Doctors need to NOT be persuaded by pharmaceutical companies, that mesh is a good idea. Mesh should not be suggested until so much more independent research is done to make ^{Dr's/} people fully aware of what it can do when it doesn't work

4. How could women adversely affected by transvaginal mesh implants tell their stories to doctors?

Have a compulsory webinar which doctors must view/attend where they can be educated by women who have stories to tell about their mesh experience so that they know ~~how big~~ the depth and variations of the problem

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Terms of Reference 4: Any financial or other incentives provided to medical practitioners to use or promote transvaginal mesh implants

1. Do you know of or do you have evidence of incentives being provided to medical practitioners to use or promote transvaginal mesh implants?

yes - but I can't prove it - only
heresay from a nurse who was on the
hospital's theatre nurse team for the surgeon
who did by initial implant.

2. Do you have any suggestions or recommendations about the provision of incentives to medical practitioners for using or promoting transvaginal mesh implants?

Incentives are immoral! They should not be allowed
in any situation regarding people and their health.
Pharmaceutical companies should be randomly
audited to see if they are directly or indirectly
(holidays, travel) trying to influence doctors & surgeons to use
their products

Terms of Reference 5: The types and incidence of health problems experienced by women with transvaginal mesh implants and the impact these health problems have had on their lives

1. This is the opportunity to tell your and/or your family member's story about how transvaginal mesh implants have affected you and your family. These impacts do not have to be limited to health issues but may also extend to issues around relationships, finances, employment or any other part of life that has been affected.

Implant - [redacted] Aug 2008 + revision April 2009
Ex plant - April 2010 + July 2010 + Oct 2010
I was a vibrant, optimistic confident financially secure sexually active
intelligent, well-travelled fit, optimistic, trusting, proud, attractive,
industrious, capable, athletic, self-confident woman, aged 46,
when I had the first of 5 (five) operations related to
the "repair" of a ~~sta~~ moderate to severe bladder prolapse. At this
time I had been happily married for 8 years, had three healthy
children (9/2002, 4/2004 & 8/2006, aged 6, 4 and 2 at time of first operation)
and had started (in 2006) a successful business with my husband.
We had finished having children and I wanted to
find a way to repair the damage to my pelvic floor

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after a trauma (foetus delivery-related) occurred in 2002.
With the delivery of our first child. The damage left me with
a moderate-severe bladder prolapse. I just wanted to
be restored to normal anatomy in aesthetics and function.

After seeing several specialists I was confidently assured that
the Prolift bladder mesh would solve my issues (in 6 weeks)
and that if there were any issues they would be minor
and could be easily corrected in a day surgery.

This was not the case - Besides the ordeal of the first
surgery which failed I went through a second ~~major~~ surgery
(with the same surgeon) which also failed. ~~the two~~

I then sought a different surgeon to remove the mesh over
3 more major surgeries. I am now worse off, (physically)
than I was if I had have just left the prolapse of the bladder
alone. And also worse off ~~financially~~ in many more ways as

well - Some of the main areas are listed below. ~~And the~~
extent of the "all-round-damage" is so profound that there is not
enough space to write it all down.

PHYSICAL

- extreme pain + discomfort during operations + "recovery"
- continuing pain
- sexual dysfunction + pain + discomfort
- bladder dysfunction + pain + discomfort
- abnormal aesthetics of vulva
- scars to vagina, pain in vagina, pain in pelvic region
- unable to jog, run, perform body movements which require
"bearing down" eg pilate's, digging, pushing,
lifting, water-skiing, squatting, gardening,
- continued bladder prolapse issues
- incontinence issues
- bladder infections
- scars on torso from surgical incisions
- immune system lowered/compromised due to reaction to polypropylene
foreign body response

NTAL

7/14

DEPRESSION

ANXIETY

LOSS OF BODY CONFIDENCE + feeling like a sensual woman

LOSS OF SELF-ESTEEM, feeling damaged + ruined

LOSS OF SENSE OF MY AUTHENTIC SELF - doubt trust people and what they say

- feeling limited in what I am capable of dealing with physically + emotionally
- feeling ashamed and angry about what has happened to me and what's been lost
- unsure of myself and my relationships (esp incl. my marriage)

- feeling "stuck"

- grief of missing experiences with husband + children as kids grow up + I was absent

- worry and stress that my absence from not participating in my children's lives (when I was recovering)

having and recovering from the operations may have had a negative impact on them, which may become evident later

- grief/sadness over the loss of ^{not} being the mum that I wanted to be ~~and couldn't~~ as I could only "observe" from the sidelines over many years

- feelings of disgust + immorality to the medical/pharmaceutical profession

- Stress of trying to be brave and "get on with life" when in significant pain and discomfort.

- Lack of privacy at home when we have had to engage live-in help

- stress created by wanting to avoid intimacy and sex because of the self-loathing of what I have been left with

- feeling angry that I feel like my world is "small" and "limited" compared to how I felt about my options before the operation; etc!!

Financial

8/14

① * out of pocket expenses from the operations
tens of thousands of dollars

② * cost of paying for help at home to
- look after children
- run/manage household
- do chores etc.
tens of thousands of dollars

③ * ~~opportunity~~ Cost of me not being able to
work in our business → pay some one to do
my job
→ tens of thousands

* opportunity cost of me not developing
& implementing expansion plans
for our business - meant business
didn't grow in the size and rate
that we had planned. →
\$100,000's ~~that~~ not
realised

* house renovation not finished because
the money went on ①, ② + ③ above

* Funds needed to pay for help to
clean out/re-organise home since it wasn't
done for 4 years + problem kept getting bigger
(during surgery years) \$10,000 - 00

Relationships

9/14

- Marriage breakdown
 - loss of intimacy
 - my anger + frustration
 - stress on husband trying to hold everything together
 - financial stress
- Kids having to not have their mum active, present and loving them as a regular - hands-on parent has lead to stress + anxiety for them (and who knows what else as they were all very young when I was "absent")
- ~~disconnections~~ bonding experiences ~~either~~ "stolen" so relationships have suffered
- stress on family and friends who have worried about us given time to try and help and donated to us. This has made us feel quite indebted to many friends + family members.

In Summary,

Unless a "mesh gone wrong" happens to you, it is hard to document how far reaching the negative effects are. 10/14

The promise of a sure-fire, 6 week "fix" for my bladder prolapse was the worst decision of my life, and I consider myself a well-educated, sophisticated person.

I trusted the medical profession who allowed themselves to be corrupted by the ~~the~~ immoral code of ethics of the pharmaceutical companies.

So many women's lives have been ruined, marriages have broken up, children have had to learn and accept having a "distant" mother, who will never be the mother they should have had.

I am luckier than most as I can "manage" around my issues. Some women

are crippled physically, emotionally, financially + socially and it should never have been allowed to happen to one woman, let alone the thousands that are suffering. It should NEVER be allowed to happen again!

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SHINE LAWYERS

RIGHT WRONG.

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Terms of Reference 6: The Therapeutic Goods Administration's (TGA) role in a) investigating the suitability of the implants for use in Australia; b) ongoing monitoring of the suitability of the implants; and c) knowledge of women suffering with health problems after having transvaginal mesh implants

1. What experience have you had with the TGA?

limited - tried to lodge a complaint /
~~for~~ adverse reaction but it was
too complicated / impersonal.

2. What do you think of the current work the TGA is undertaking in this area?

I don't know what they ~~are~~ doing.
I would want them to not rely upon the standards
of other countries... we need proper checks +
measures of our own in Australia.

3. What is needed to improve the work of the TGA in this area?

Have an easier, more technologically sophisticated
way to lodge concerns. ~~Be can~~ Have a social
media presence so people can see alerts / concerns
more easily, especially if they are considering
a surgery requiring implants or ^{new} medications.

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4. Are there other government agencies (apart from the TGA) who could or should have a role in this?

GOVT SUPPORT to families where mother/father can't do "home duties" and help needs to be supplied or hired.

ETHICS COMMITTEE - scrutinising how pharmaceutical companies "market" their products.

- Patient ADVISORY UNIT → collects ^{+ publishes} data from surgeons about what operations they have done, what implants they use, what outcomes are generated. Then potential patients' can check surgeons credentials and track record for themselves - objectively!

currently no way a patient can be sure they are not being misled about a surgeon's experience.

5. In your opinion, is there anywhere (in Australia or internationally) that does a good job in these areas?

don't know

6. Do you have any recommendations about changes that might be needed to laws, policy and practices in relation to regulation of medical devices in Australia?

No device should be available until thorough clinical trials for the material ^{used} + functionality of the devices are done, in a "scientifically significant" clinical trial, run under a transparent framework, over a longer time frame.

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Terms of Reference 7: Options available to women to have transvaginal mesh removed

1. What is your experience of trying to have transvaginal mesh removed?

Three surgeries - ~~nearly~~ extremely dangerous first surgery, - massive blood loss potential nightmare dissection of the mesh "mess" entangled in major organs. Two more surgeries followed to remove more mess & try & repair with Surgisis - biological graft

2. Do you know of anywhere (in Australia or internationally) where it is easier for women to have mesh removed?

no - maybe U.S. not here in Australia -

3. Do you have any recommendations or suggestions about what would make it easier for women seeking to have mesh removed in Australia?

Have the pharmaceutical companies be forced to ^{pay for} send surgeons overseas to get trained properly to attempt to remove it. Have govt support patients + pay for O.S repair since T.G.A. has failed as Medical system

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Are there any final comments you would like to make?

I try not to dwell in the past and it is very painful, sad and gut-wrenching to re visit the details of how this decision (to try to fix a bladder prolapse with [REDACTED] mesh) ~~ran~~ ran my life, my husband's life, and my kids' lives, into a ditch. I have slowly been crawling out of that ditch, over many years, trying to rebuild my life and my family member's lives. I will never be the woman, wife, mother, friend, daughter, sister or human being that I envisioned for myself and have had to learn how to manage anger, loss, grief, stress, frustration, pain and discomfort on a daily basis. My authentic self has been "stolen" by some pretty disgusting human beings who are at the heart of deceiving patients, doctors + govt bodies - all in the name of monetary profits.

Submissions can be made to the Committee in writing by 31 May 2017 and should be sent to the Committee Secretariat contact:

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patients, doctors + govt bodies - all in the name of monetary profits.
May they rot in hell.

If you would like more time to finalise your submission, an extension can be requested by emailing the secretariat at community.affairs.sen@aph.gov.au or telephone on 02 62773515.