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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]

[redacted]

State Victoria **Postcode** 3153

Date of Birth 29/05/1962

Contact number [redacted]

Email address [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

If Yes, please share your experience:

I had a transvaginal mesh implant in December 2000, for a bladder and vaginal prolapse. I also had a hysterectomy at the same time, as advised to by my treating specialist. Due to severe side effects, I had my mesh removed in August 2001, and then, because of worsening bladder symptoms, the specialist replaced the mesh. The side effects of this just got worse.

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

If Yes, please share your experience:

Since Dec 2000 I have had another 12 surgeries to try and rectify problems. I have had severe abdominal pain, have had erosion of the mesh through the vaginal wall twice, have had my mesh removed and then replaced. I had mesh have ongoing pain, bladder problems, bowel problems, vaginal problems, and have not been able to work. It has been over 16 years. I was 38 years old at the time of my initial surgery.

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:

August 2001 - mesh removed in Melbourne
December 2001 - mesh replaced
Several surgeries over the years for bladder / bowel problems - attempted to remove further mesh at that time.
July 2014 - Sydney - further surgery to attempt to remove remaining mesh.

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

I was told that the procedure had only been around for about five years, (maybe in the USA) and no long term studies had been completed, but that every surgery had been highly successful and this was a much better alternative to any old fashioned surgery for bladder and other prolapse. Obviously, this was not the case.

I do not believe I was fully advised on the product used, or the possible complications. Had I been given the correct advice, I would not have had the surgery in the first instance. My life has never been the same.

I believe longer trial periods for such products should be had. When adverse symptoms present in a patient, these should be reported immediately, for every case, and the companies involved advised, so as to investigate and follow up the causes, and if be, remove the product from use until further research is done.

If this had have happened in the instance of the mesh implants, many thousands of women would have been spared the pain and suffering years later.

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?

Regarding the TVT sling mesh, my specialist said it was the surgery preferred by him as it was a far superior product to use for my health problems: stress incontinence, bladder prolapse, vaginal prolapse and pelvic floor problems.

He said it was a new method that in his experience, surpassed the older methods.
I asked about long term prognosis of this new method. He replied he could not see 10 years into the future and he had only been using the method for approx 2 years. He said the product had only been around about five years (not sure if the specialist was talking about in Australia or the USA, he didn't say) but that by his experience there were no reported side effects, and was a safe and far better product that any of the old fashioned procedures used. He said he was confident this would prove successful for me. My specialist said all accounts of TVT sling procedures had been very successful.

He did not offer any other alternative.

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

Verbally.

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

I don't think they should receive a transvaginal mesh implant... full stop.

But if things in the future improve, everyone should have the opportunity to be given correct information. This should include a discussion with your doctor, medical brochures with side effects mentioned (as with all pharmaceutical products), websites to be directed to and personal reviews given by patients, both good and bad.

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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?

As explained in Terms of Reference 2, I do not believe my doctor knew very much at all about the mesh implants, complications and side effects. When I was going through all the problems I was having as a patient of his, he would not admit there was any fault with the mesh, but that it was just my body reacting to it. My situation should have been a warning sign to him, and to other doctors - if it had been reported.

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

Yes. It has been many years since my surgery and there is a lot of information available now.

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

Doctors should be given correct information by the pharmaceutical companies, and thoroughly make themselves aware of all aspects of the product. There should be online doctor's forums to discuss the use of and outcomes of use for any product, between those in the medical professions. Then a doctor needs to decide for him/herself if this product should be used by him or his patient.

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

If there was an online forum for doctors to converse about products, there should also be a patient area on the site to comment on outcomes of products. This is where patients can tell their stories, and doctors can be more informed of potential problems with their patients in the future. It would also make new patients more aware of the good and the bad outcomes of products. (maybe a star rating)

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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?**

No. But I do know that this has happened in the past with other pharmaceutical or medical products, so it would not surprise me.

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

I know in the past, doctors who saw medical reps from companies, would often choose a product based on the incentive given. My own experience of this has been in the dental field with reps given preferences based on their company incentives.

I do not believe any company should provide incentives for any product used; that the product should prove itself on its merits and the experience the doctor / patient has with the product. I believe incentives should be illegal.

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.**

I wouldn't know where to start - I have so much information written down from past experiences. My problems started in Dec 2000 from the time of my original surgery, and have continued until this day. I have had many tests, surgeries, medications, and seen many, many specialists in the gyno, uro, colo-rectal specialities. My family has suffered with me always being sick. My children have grown up with a mother who has spent so much of her time in bed. My intimate relationship with my husband no longer exists. I cannot work because of my medical issues, which has caused financial problems. The costs for treatment for my pain and other symptoms is ongoing. I have spent tens of thousands of dollars out of pocket for treatment, after private health insurance claims. My last surgery cost $8000+ out of pocket. I cannot plan anything without wondering if I am going to be able to accomplish the task I have planned, due to "flare-ups" I have at any given moment. I have missed out on so many family and social activities due to my symptoms. I suffer from anxiety and other psychological problems, and am on medication for this. I have been told there is nothing that can be done to help me, that further surgery will just cause more problems and is too difficult, and that I have to learn to live with my symptoms. I have been shoved and pulled from one doctor to the other, with ongoing referrals, given no hope for help in the future.

I can provide so much more information, but find it difficult to write about here.

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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?

None

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

Any positive work for the outcome of patients is good. Very late though. Should have been started years ago.

This is the role of the TGA - What happened?
"The TGA is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose. These include goods Australians rely on every day, such as vitamin tablets and sunscreens, through to goods used to treat serious conditions, such as prescription medicines, vaccines, blood products and surgical implants.
The regulation of medical devices includes:
classifying the medical device based on different levels of risk to the user
assessing compliance with a set of internationally agreed essential principles for their quality, safety and performance
implementing appropriate regulatory controls for the manufacturing processes of medical devices
including the medical device in the Australian Register of Therapeutic Goods
Once available for supply, medical devices are subject to monitoring by the TGA. This monitoring includes a comprehensive adverse event reporting programme."

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

I cannot answer this, as I don't have a lot of knowledge on what the TGA is doing in this area at the moment. I do think that something should have been done a lot earlier than now. This mesh has been around for many years with many people affected greatly by its use. People should have been able to have a voice a long time ago. Maybe the TGA needs to address their own internal affairs and find out why this sort of thing has happened, which seems to be directly against what the TGA represents.

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

I don't know, but I would imagine the medical boards and pharmaceutical industries should have some role in this. The Australian Law Reform Commission could look into changing some of our laws in regard to the medical and pharmaceutical industries to prevent these things from happening in our country.

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

I would not know enough to comment on this.

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?

My comments above cover this.

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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?**

Original surgery Dec 2000. Mesh removed Aug 2001. Caused worse problems with bladder incontinence than before original surgery. Mesh replaced Dec 2001. (much information can be given for time between Aug and Dec 2001 and reasons behind replacement).
Had many surgeries for complications to bowel, bladder and vagina between years 2001 and 2014. At these times surgeons tried to remove as much mesh as they could, but only little bits at a time, if any. In July 2014 underwent 5 1/2 hours surgery in Sydney (I am from Melbourne), with Dr [redacted] to remove the mesh from my pelvis as well as repairs to bladder, bowel and vagina. This was a very painful procedure and I spent two weeks in hospital. Dr [redacted] was not able to remove any mesh, as it was too deeply imbedded in the flesh and scar tissue.

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

No I do not.

I had heard Dr [redacted] was the only hope for removing mesh, and I heard a few women testify of his work and having their lives return to normal. I saw Dr [redacted] speak at a Seminar, and I was very excited that someone might be able to help me finally find an answer to the medical mess I was in. I made an appointment for a consultation with Dr [redacted] and in a couple of days I was in hospital having surgery. Unfortunately for me, and probably the length of time since my original surgery, and all the surgeries leading up to this, Dr [redacted] surgery was not successful in removing any mesh from my body.

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

To have the support of the medical profession.

It would be a lot easier if the medical profession was advised on such issues, so as to let their patients know where they could go for help. If there are people in the world, who specialise in the procedure of mesh removal, then patients should have a right to know. Doctors who throw their hands up and say there is no hope, have a responsibility to know where help is available and what can be offered to their patients.

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Are there any final comments you would like to make?

A lot has happened to me over the past 16 1/2 years. I have been told by doctors that what has happened to me has been "a disaster", a "bloody mess", and "should never have happened". For many years doctor after doctor covered for each other, not wanting to admit to me the medical issues I had were the result of the mesh surgery. I was even told by one specialist, after a cystoscopy, that he was to refer me to another surgeon - someone who was new to the country and wasn't affiliated with other doctors of the same profession as yet, and that this doctor would give me an honest answer to my questions.

It has been a very frustrating, painful experience, which I believe should have been looked into a lot sooner. I guess for me, this is my life now, and I can only imagine what life would have been like had I never had the TVT mesh sling put into my body.

I have much information that you might feel you could use in this investigation, including the years spent seeing specialists, surgeries, medications and outcomes. I ask you to feel free to contact me in the future if you would like further information.

Thank you for allowing me to participate in this inquiry.

Sincerely,

[redacted]

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

Committee Secretary
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Parliament House
Canberra ACT 2600

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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.