

# **Senate Inquiry: Number of women in Australia who have had transvaginal mesh implants and related matters inquiry.**

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August 1st 2017

I am writing this submission to the senate on behalf of my mother who was unknowingly inserted with a transvaginal mesh implant whilst undergoing surgery for a vaginal hysterectomy in May 2009. Having resided with my mother since this procedure, I can personally attest to the physical and emotional trauma this device has caused her. Moreover, the Australian government and medical communities procedures, regulations and resources, have been ineffective in informing my mother and patients like her of the risks and complications linked to these devices prior and post surgery. Furthermore, the limited medical services and support currently available to support women implanted with these devices is inadequate and deplorable.

Two weeks ago my mother became aware through hospital records that while in surgery for a vaginal hysterectomy a transvaginal mesh device was inserted. My mothers legal and ethical rights, to provide informed consent for this device were ignored. Prior to surgery my mother was not informed a medical device was being implanted, nor was she informed prior or post surgery about possible complications associated with this medical device. Had my mother been provided with this information she would have never consented to this procedure. Since researching the complications associated with these implants my mother has sought medical advice to determine the devices condition and possible removal options. After receiving a referral from her General Practitioner for a 3d/4d translabial ultrasound and despite living in one of Australia's largest cities we have struggled to obtain this ultrasound as numerous hospitals and organisations have refused to administer this for her. To obtain this ultrasound my mother will have to travel interstate at a considerable financial cost. Unfortunately, my mothers difficulties in seeking medical information regarding her mesh implant and obtaining a translabial ultrasound appears to be a common struggle amongst other women throughout Australia. To support women like my mother deal with the emotional and physical trauma associated with these mesh implants and access appropriate medical services, I recommend a hotline/advice line be set up. This hotline could provide specific counselling and medical support, including links to experienced surgeons and mesh experts willingly to treat women with these devices throughout Australia. In addition. I also recommend a specialised website be developed that is similar to Headspace and Beyond Blue. This website could provide accurate information on complications and symptoms associated with mesh devices, links to support services including counselling and medical professionals that are mesh specialists, printable resources detailing mesh device complications. This website would a valuable resource in informing and supporting women and family members that have had medical mesh devices inserted or considering having a medical mesh device inserted. This website could also become a valuable tool in raising awareness amongst medical professionals like General Practitioners of the risks associated with those medical devices.

In terms of the number of women with complications as a result of transvaginal mesh, I fear that there are many more women like my mother who are unaware they have been implanted with a mesh device and therefore unable to link their symptoms, including urinary infections, bleeding and chronic pain to complications associated with these devices. To protect women and men in the future who have medical devices implanted, the government must create a database or register that links a patient name and Medicare number with the implemented device batch number and serial code. This way alerts like those issued by the Food and Drug Administration in terms of mesh implants in 2008 and 2011 could have been sent directly to those individuals impacted. Having a

database or register would also allow the Therapeutic Goods Association to monitor and track complications associated with specific devices and their batch numbers. I find it incomprehensible that medical devices inserted into the human body in Australia are not registered in a database. Even companies that produce electrical goods register and record customer details for warranties and are legally obligated under consumer affairs to refund customers if their goods are faulty. However, companies that produce medical devices for insertion into the human body are not obligated to provide warranties or compensation if customers encounter complications. This leaves individuals impacted by these medical devices no other alternative than to seek legal action to be reimbursed for financial costs occurred for medical treatment in addressing complications linked to these devices. In terms of changes to the policy regarding transvaginal mesh and other medical devices, the Therapeutic Goods Association has a Duty of Care to the Australian population to approve products that have been rigorously tested and monitored through long term trials. Therefore, the Therapeutic Goods Association must disclose to the public evidence used in declaring any medical devices fit for the Australian market.

In regards to information that was presented to my mother prior to her surgery, the surgeon failed to inform my mother on multiple occasions that a mesh device was being or had been implanted. My mother informed me that in her initial consultation with the surgeon she only discussed having a vaginal hysterectomy. In the week prior to my mothers hysterectomy I witnessed her receiving a phone call from the surgeons secretary requesting her participation in a trial that the surgeon was undertaking involving a new vaginal hysterectomy procedure. According to the secretary, this procedure would result in quicker healing time along with regular follow up appointments. At no time in this conversation did the secretary mention to my mother that this trial involved inserting a mesh device. At the end of the phone call my mother politely declined to be part of this trial. However when my mother attended her first follow up appointment the surgeons secretary billed her for her appointment. Having worked in Health Insurance my mother questioned these charges. The secretary informed my mother that these costs were associated to her trial and that she could claim her money back from Medicare. My mother again explained to the secretary that she was not part of the trial. Despite declining to be part of a trial over the next four years the surgeons secretaries continued to send my mother numerous questionnaires and left numerous messages for her to complete these questionnaires. However, not once in these four years did the surgeon contact my mother to inform her that she had a mesh implanted or to inform her of new warnings that were issued by the Food and Drug Administration over her implants.

Although, it is legal for medical practitioners to receive financial incentives from medical companies, my mothers case highlights the ethical dangers of how research for a medical company can override a patients treatment options and choices. In terms of financial incentives my suggestion is that if a surgeon or medical practitioner receives financial incentive from a company, legally they should be required to disclose the full financial details of this incentive to their patient. Furthermore, if the patient agrees to treatment following these disclosures then all services provided and associated with the patients treatment including medical practitioners, hospital and theatre fees and follow up surgeries must be donated. Moreover, companies that create these devices and surgeons who implant and trial these devices with financial incentives need to be financially responsible for the medical expenses incurred in diagnosing and correcting complications associated with these devices. It is unfair that the financial burden of complications linked to these medical devices be transferred the patient, Health insurance Companies and Medicare.

As my mother was unaware until recently that she was implanted with a transvaginal mesh, she was unable to link many of her health symptoms over the past ten years to complications associated with her device. However, after reviewing the Therapeutic Goods Association list of complications I have realised that she has suffered from numerous complications. The first complication my mother encountered and reported following her hysterectomy was constant vaginal bleeding. In an effort to stop the bleeding the surgeon on two occasions administered silver nitrate internally. This procedure was extremely painful and failed to cease the vaginal bleeding. Unfortunately for the past ten years my mother has continued to experience and been forced to live with vaginal bleeding. In addition to vaginal bleeding my mother has had constant urinary infections that require regular antibiotics. Having to seek medical treatment for these infections makes my mother highly anxious. She often feels ashamed and embarrassed at having to be tested for another urinary infection, believing that the Doctor will assume that her hygiene is the cause for these infections. These infections also require regular absences from work. Two years ago I become so concerned over my mothers lack of energy and the severity of her infections that I suggested she seek diagnostic testing from specialists to determine if she had a Thyroid disorder or another medical condition. Following extensive testing from specialists my mothers results were inconclusive. This was particularly difficult period for my mother as she felt her symptoms were dismissed by medical experts. In addition my mother has experienced over the last ten years chronic groin, hip and leg pain. I have lost count of the number of times a witnessed my mother cry out in pain from leg spasms and cramps. In the past few years my mothers pain become so severe that she was forced to stop exercising and ceased being able to walk for long periods. In an attempt to diagnose and address this pain my mother received both physiotherapy and osteopathy treatment. Two years ago following numerous ultrasounds, x-rays and MRI scans my mother was diagnosed with bursitis and given cortisone injections. Despite treatment my mothers bursitis progressed into a gluteal tear requiring specialised surgery and two months off work that was undertaken two weeks ago.

I have little doubt that my mothers health symptoms reported on in this submission are the result of complications linked to mesh devices. I believe that my mothers legal rights and ethical rights of informed consent, fidelity and do no harm were dismissed and ignored by the medical company that produced her device, the surgeon who implanted the device and the Therapeutic Goods Association who approved this device for the Australia market.

I also wish to thank the senate for providing me with the opportunity share my mothers experiences and provide recommendations to support women and families impacted by these devices.