

Submission to the Senate Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters

Joint submission by Health Consumers Councils across Australia:

Health Issues Centre (Vic)
Health Consumers Queensland
Health Consumers' Council (WA)
Health Consumers Alliance of SA
Health Care Consumers Association (ACT)
Health Consumers New South Wales

This submission was prepared by Dr Martin Whitely, Manager Policy and Research Health Consumers' Council (WA) with substantial assistance from Carolyn Chisholm from the Australian Pelvic Mesh Support Group, Danny Vadasz of Health Issues Centre (Victoria) and Melissa Fox, CEO of Health Consumers Queensland. The survey cited in this paper was conducted by the Health Issues Centre (Victoria).

31 May 2017

“Women’s voices and their right to safe health care must be at the centre of this Senate inquiry.”

Terms of Reference of the Inquiry

1. The number of women in Australia:
 - a. who have had transvaginal mesh implants;
 - b. who have had transvaginal mesh implants who have experienced adverse side effects; and
 - c. who have made attempts to have the mesh removed in Australia or elsewhere.
2. Information provided to women prior to surgery about possible complications and side effects.
3. Information provided to doctors regarding transvaginal mesh implants and possible complications and side effects.
4. Any financial or other incentives provided to medical practitioners to use or promote transvaginal mesh implants.
5. The types and incidence of health problems experienced by women with transvaginal mesh implants and the impact these health problems have had on women’s lives.
6. The Therapeutic Goods Administration’s:
 - a. role in investigating the suitability of the implants for use in Australia;
 - b. role in ongoing monitoring of the suitability of the implants; and
 - c. knowledge of women suffering with health problems after having transvaginal mesh implants.
7. Options available to women to have transvaginal mesh removed.

About Our Submission

This joint submission is made by the peak health consumer representative organisations in the mainland Australian states and the ACT.¹

We support the submission of the *Australian Pelvic Mesh Support Group* (APMSG). APMSG are a group of more than 800 mesh-injured women originally created on Facebook in 2014. The purpose of the group is to connect with and support mesh-injured women. We also support the individual submissions of the women suffering from the failure of clinicians and their government through the *Therapeutic Goods Administration* (TGA) to ensure their safety.

We encourage the Committee to hear verbal evidence from representatives of the APMSG and as many individual mesh injured women as possible. We would also welcome the opportunity for members of our organisations to provide verbal evidence to the committee.

In 2016 *Health Consumers Queensland* responded to reports by mesh injured women across Australia, and raised the issue with *Queensland Health’s Patient Safety and Quality Improvement Service* (QHPLSQIS). QHPLSQIS subsequently pursued the issue with the *Australian Commission on Safety and Quality in Health Care* (the Commission) and the TGA.

Consequently, the Commission convened an expert reference group with consumer representatives (including *Health Consumers Council WA* and mesh affected women) and held consumer focus groups around the country. The Commission aims to develop guidance for consumers, clinicians and health services on the use of transvaginal mesh products for the treatment of pelvic organ prolapse and stress urinary incontinence including:

- Treatment pathways for pelvic organ prolapse and stress urinary incontinence
- Service models for mesh complications and mesh removal
- Training and credentialing of clinicians who implant and remove mesh for treatment of pelvic organ prolapse and stress urinary incontinence
- Data collection and reporting of device use and adverse events
- Patient decision support tools
- Information for general practitioners.²

We welcome the parallel process of a Senate Inquiry which has the potential to shine the light on the catastrophic failure by Australian clinicians and our medical device regulator (the TGA) to provide evidence-based care and protect women from harm.

We ask the Senate for urgent consideration of our Recommendations (page 15-16), including immediately suspending the use of mesh for prolapse and stress urinary incontinence, due to the severity of complications. The suspension must not be lifted unless and until their safety and efficacy is established.

Our submission draws on numerous sources including surveys facilitated by our organisations and discussions with mesh injured consumers who have participated in forums hosted individually by our organisations or in conjunction with the Commission. A summary of the outcomes forums held jointly with the Commission is available online at <https://www.safetyandquality.gov.au/our-work/transvaginal-mesh/consumer-forums-to-discuss-transvaginal-mesh/>.

To inform our submission, the *Health Issues Centre (Victoria)* in mid-April 2-17 developed and disseminated an anonymous survey via a specific, newly created Facebook page <https://www.facebook.com/UnderstandingPelvicMesh/> which used boosted (paid) posts.

Through this page and various other channels, women were invited to complete a survey which consisted of 12 questions that explored women's experience of mesh, including adverse effects, consent and any remedial treatments.

We have included the de-identified results up until 25 May 2017 of the survey (1750 participants) at Appendix 1 and have discussed survey results (including a sample of comments from participants) where appropriate in the body of the report. *Health Issues Centre (Victoria)* has left the survey open and at the request of the committee is able to provide updated results. *Health Issues Centre (Victoria)* is making a separate submission to the Senate Inquiry based on the experiences of women as gathered through this survey.

We have structured this submission to address each of the terms of reference and finally outline recommendations we hope the committee will endorse. In addition, at Appendix 2 we have provided the links and a very short description of some mesh related internet items in the belief that they may be of some interest to the committee. Due to time and other resource constraints, we have not reviewed their content in detail and do not endorse views expressed in these items or vouch for the accuracy of the information within them.

Terms of Reference 1- The number of women in Australia:

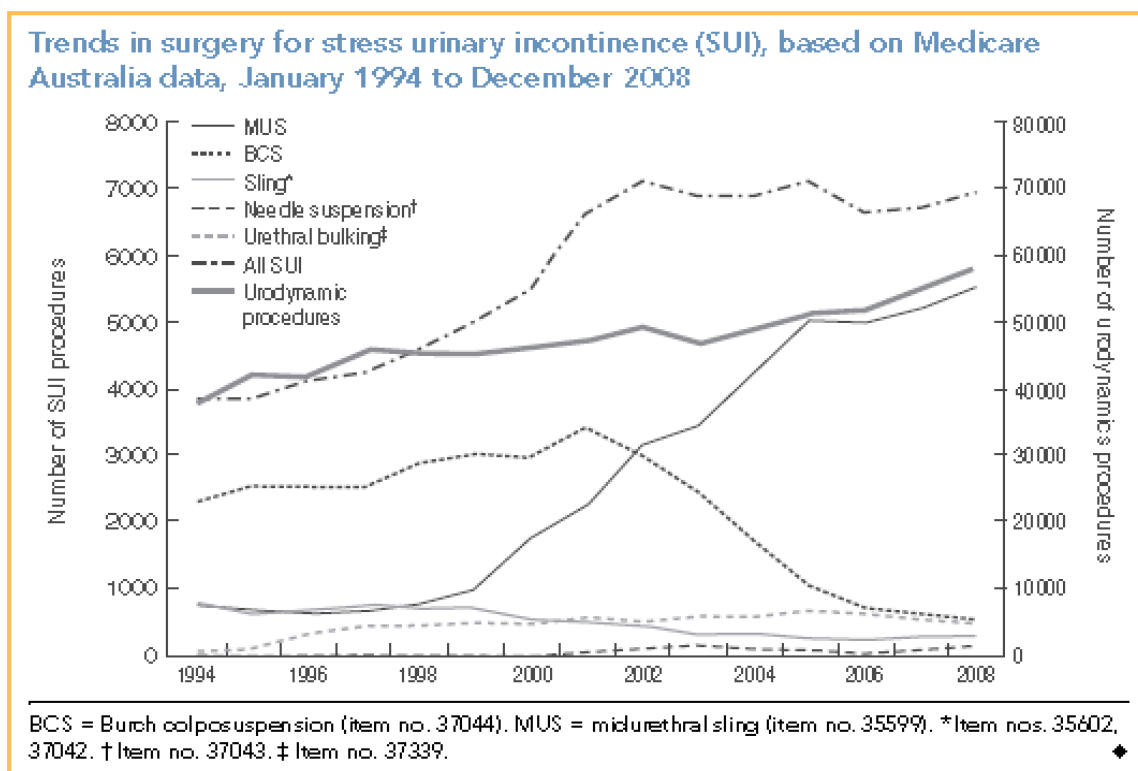
- who have had transvaginal mesh implants;
- who have had transvaginal mesh implants who have experienced adverse side effects; and
- who have made attempts to have the mesh removed in Australia or elsewhere.

The lack of reliable comprehensive public data in relation to the number of treatments and adverse events, and reparative interventions for transvaginal mesh, inhibits the capacity to assess the safety and efficacy of this product. This is a consequence of Australia's inadequate post-market safety monitoring system. Unless accurate information about the number of treatments, adverse events and reparative interventions is routinely collected for all medical devices, pharmaceuticals and alternative medicines, Australian consumers will remain vulnerable.

In the absence of comprehensive data, we suggest the following potential sources of information. **Regarding 1a**, we believe information about the number of devices sold should be readily available from product manufacturers. We note that this may exceed the number of women treated as some mesh devices maybe held in inventories. Additionally, we are aware of some women having "mesh on mesh", with two or three devices in situ.

In addition, as identified in a 2010 letter to the *Medical Journal of Australia*, data from the Medicare Benefit Schedule could provide a supplementary source of information of the number of women with transvaginal mesh implants.³ The letter **included the graph below** and stated that:

Medicare Australia data from 1994 to 2008... show that there was a 75% increase in surgery for stress urinary incontinence over this period, from 4000 to nearly 7000 cases a year, reflecting the increasing popularity of MUSs as a result of lower morbidity and shorter hospitalisation (day surgery).



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In relation to 1b, we note the absence of a national register of all implants prevents the identification of the true injury rates. In addition, we believe that there is likely to be massive under-reporting to the TGA of adverse events. There are several reasons that this is likely including:

- Research indicates that under the voluntary reporting regime for adverse events for medications, only a tiny fraction of adverse events is reported to the TGA.⁴ Adverse event reporting for medical devices is also not mandatory. It is therefore likely massive under-reporting has occurred for transvaginal

mesh injuries.

- Mesh injured women report that initially they are not aware that they have had mesh inserted (due to it being referred to in many ways – surgical sling, TVT, tape, etc.) and/or that the symptoms they are experiencing are mesh-related.
- Mesh-injured women report that some surgeons are reluctant to acknowledge that adverse events may be linked to mesh and are openly resistant to the idea of reporting complications to the TGA (as it is not mandatory).
- Mesh-injured women have commented that to report complications, they have had to obtain their medical records and the serial number of the device inserted into them. It is not clear from the TGA's website that they can still self-report their complication without a device serial number. Some women had little difficulty obtaining this information, but others reported being charged up to \$270 to obtain their records.
- We also consider that the reporting rates of complications would be very low among women with hearing, vision and intellectual impairments and women from culturally and linguistically diverse backgrounds.

We note that in 2011 a *Senate Community Affairs References Committee Inquiry into the Regulatory Standards for the Approval of Medical Devices in Australia* recommended that:

The Department of Health and Ageing introduce mandatory reporting for health practitioners to the Therapeutic Goods Administration on relevant issues, in certain circumstances including problems with medical devices.⁵

We were disappointed with the response from the Commonwealth Government, where they undertook to consult with the Medical Board of Australia on the issue of mandatory reporting.⁶ Action, not consultation was required.

We note that this ignored recommendation is very like the recommendation on mandatory reporting made by the *Consumer Health Forum of Australia* in its' January 2015 submission to the *Review of Medicines and Medical Devices Regulation*.⁷ It is also like a recommendation the *Health Consumers' Council WA* made in relation to pharmaceutical regulation in previous submissions being that the Commonwealth Government:

Make adverse drug event reporting to the TGA for a specified range of serious reactions (suicidal ideation, strokes, psychosis etc.) mandatory and regularly publish full de-identified details on the TGA website.^{8,9}

We also inform the Senate Inquiry that in our efforts to gather information about women's experiences of mesh, we have heard of concerning complications experienced by men who have had mesh inserted for hernia treatment. We think this warrants the further investigation of use of all mesh devices.

In relation to 1c – Please refer to our response to Terms of Reference 7.

Term of Reference 2 - Information provided to women prior to surgery about possible complications and side effects.

Women seeking treatment should have had all non-surgical options explained prior to any surgery. They should also have been advised that there are non-mesh surgical options such as native tissue repair. However, results from Question 3 of our survey found 62% of women who participated in the survey either did not consider they were fully informed (40%), or that they were given some information but 'things did not go as was suggested' (22%).

In Australia, clinicians are considered as having acted negligently if they did not warn a patient of the 'material' risks involved in a proposed treatment (*Rogers v Whitaker*).¹⁰ A risk is deemed material when a reasonable person, in the patient's position would find that information important when making decisions about medical treatment. Unfortunately, the practice of not properly informing consumers of material risks of treatment is so common, that for some treatments it has arguably become the norm.

To address this problem, we draw the committee's attention to the *Australian Government Response to Senate Community Affairs References Committee Report on the role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothèse (PIP) breast implants July 2013*. We strongly endorse recommendation 1 of the committee that:

Rigorous systems put in place to ensure that medical practitioners provide consumers with all the information needed to allow them to give fully informed consent.

Again, we note with disappointment the weak 'hands off' response by the Australian Government to recommendation 1. The response stated:

The Australian Government notes the recommendation, and undertakes to bring it to the notice of the Medical Board of Australia (MBA) for consideration. Codes relating to the conduct of medical practitioners are the responsibility of the MBA. The MBA Good Medical Practice: A Code of Conduct for Doctors in Australia describes the ethical and professional standards that are expected to be met by all doctors registered to practise in Australia. It specifically covers informed consent (section 3.5). Where a practitioner is believed to be acting outside the Code of Conduct, a notification can be made to Australian Health Practitioner Regulation Agency (AHPRA). The practitioner may then be subject to investigation or performance assessment by the Board so that appropriate action can be taken to protect the public.¹¹

Women have reported dissatisfaction with outcomes of AHPRA processes, which have relied on the TGA's assertions that these devices are safe and effective. We do not have a national register of all implants and there are barriers to consistent reporting to the TGA. Therefore, we do not have the evidence in Australia to know the true complication rates in women and whether these devices can be classified as safe and effective.

If the MBA, and its 'code of conduct', and AHPRA processes were working to ensure informed consent we would not have these repeated inquiries finding these failings in informed consent processes.

It is also important to consider the kinds of translation services and written materials in other languages that should be made available to women from culturally and linguistically diverse backgrounds and those with hearing, vision and intellectual impairments so that they are able to make informed decisions and aware of potential side effects.

Term of Reference 3 - Information provided to doctors regarding transvaginal mesh implants and possible complications and side effects.

It is of significant concern that medical device companies have been the primary source of training and information for doctors inserting mesh. This is an inherent conflict of interest as was recognised in 2009, in an article in the *International Urogynaecological Journal* which stated:

While once commercial interests tied to the practice of surgery had little vested interest in the particular operation that was being performed, surgical device manufacturers are now intensely interested in specific procedures. Now that they are in the business of providing operation-specific “kits” for surgical use, potentially huge profits are on the table. Almost everything you need to operate (except good clinical judgment and technical skill) is right there, fresh out of the box—and an increasing number of suppliers want to be the ones to sell you the boxes.¹²

This also raises questions about the skill level of the surgeons performing procedures. Examples include:

- Should this procedure be confined to urogynecologists?
- Should it be limited to surgeons who can undertake a base number of procedures?
- How is it that a medical device company can enroll surgeons to undertake a procedure without any appropriate safety checks and balances conducted by professional associations?

It seems that at the heart of this issue is the fact that the use of mesh, or sling, or transvaginal tape has revolutionised the way surgery is undertaken. From the surgeon’s perspective, surgery is less invasive, day stays are shorter and the holding up of organs (seen as the goal of the surgical procedures for stress urinary incontinence and pelvic organ prolapse) is achieved. The potential for long-term side effects are largely ignored, or deemed by the surgical community to affect an insignificant number of women. We contend that greater emphasis on long-term outcomes for consumers and less emphasis on convenience and short-term patient outcomes is warranted.

We also note that representatives of the APMSG have told us that despite in 2016 the TGA issuing an alert to doctors acknowledging the potential side effects and encouraging increased reporting, the APMSG and its members had not been informed of the contents of the alert by either their doctors or the TGA.¹³ We share the APMSG’s concern that the practice of the TGA relying on doctors to pass on information to patients has not worked to ensure women are able to make informed decisions.

Term of Reference 4 - Any financial or other incentives provided to medical practitioners to use or promote transvaginal mesh implants.

We encourage the committee to investigate this term of reference thoroughly as we are concerned that financial incentives may have driven unsafe treatment practices. We have been informed that there are clinical variations with a higher number of procedures undertaken in Queensland and WA. Although we have not been able to verify this claim, it warrants investigation to determine a) if it is correct, and b) if so what drove this behaviour.

We note that the 2011 *Senate Community Affairs References Committee Inquiry into the Regulatory Standards for the Approval of Medical Devices in Australia* recommendation 18 states:

The committee recommends that the Department of Health and Ageing undertake further work to address the issue of inducements paid by pharmaceutical companies and medical device manufacturers to doctors and teaching hospitals, in line with the Physician Payment Sunshine provisions of the Patient Protection and Affordable Care Act of 2009 in the United States. The definition of inducements should include a commercial interest in a company or device; any cash payments or discounts offered to medical practitioners; and any other gifts provided to medical practitioners.

We are both frustrated and concerned by the response of the Commonwealth Government to recommendation 18, where they agree in principle, and disagree in practice, within the one sentence:

The Australian Government agrees with the recommendation in principle but notes that a legislative framework for ethical conduct of industry in the promotion of therapeutic goods to healthcare professions is not warranted in the Australian context at this time.¹⁴

History has shown us that voluntary self-regulation works only for those practitioners who do the right thing already. Compulsory disclosure of conflicts of interest is required.

Recommendation 18 is similar to a recommendation made in previous Senate submissions from the *Health Consumers' Council WA* that requested that the Commonwealth Government:

Require full public disclosure of pharmaceutical industry funding sources for clinicians, researchers, patient groups, advisory board members and members of committees involved in regulatory and policy development processes.^{15 16}

Although this *Health Consumers' Council WA* recommendation related to pharmaceutical industry funding, it is equally applicable to medical device industry funding.

Term 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 women's lives.

As previously stated we support the submissions of individuals injured and encourage the committee to take direct evidence from the APMSG and as many individual women as possible. The TGA has belatedly recognised the following potential harms:

- punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel (these may require surgical repair)
- transitory local irritation at the wound site
- a 'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation)
- mesh extrusion, exposure, or erosion into the vagina or other structures or organs
- as with all foreign bodies, mesh may potentiate an existing infection
- over-correction (too much tension applied to the tape) may cause temporary or permanent lower urinary tract obstruction
- acute and/or chronic pain
- voiding dysfunction
- pain during intercourse
- neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area
- recurrence of incontinence
- bleeding including haemorrhage, or haematoma
- seroma
- urge incontinence
- urinary frequency
- urinary retention
- adhesion formation
- atypical vaginal discharge
- exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- mesh migration
- allergic reaction
- abscess
- swelling around the wound site
- recurrent prolapse
- vaginal contracture
- vaginal scarring
- excessive contraction or shrinkage of the tissue surrounding the mesh
- vaginal scarring, tightening and/or shortening
- constipation/defecation dysfunction
- granulation tissue formation.¹⁷

Mesh injured women have also reported the following additional side effects:

- Chronic debilitating pain
- Chronic ongoing infections
- Bleeding
- Recurrence of prolapse/SUI
- Tissue necrosis - necrosis cell death as a direct result of irreversible changes caused by injury or disease
- Autoimmune disorders (the mesh is made of polypropylene and releases toxins when in contact with heat)
- Disability (can't sit, stand or walk without pain)
- Sepsis
- Post-Traumatic Stress Disorder
- Anxiety disorder

- Depression
- Suicidal ideation
- Significant out of pocket expenses for reparative treatments.

Participants in the survey *Health Issues Centre (Victoria)* conducted to support this submission reported a range of common adverse events including, abdominal pain, painful sexual intercourse, incontinence and breakdowns of personal relationship (see Question 5 at Appendix 1). Many (65% of those who responded) rated the effects as being 'severe' or 'debilitating' or 'unendurable'. Below we have included a **sample of comments from women who participated in the survey.**

- *Please do anything and everything you can to prevent this stuff being used on any other women. It's time to stop this damage occurring to innocent women.*
- *Women with problems due to these procedures are not being offered professional help to remove these ominous implants, why are we being hidden?*
- *If I was told the truth about what was going to be inserted into me, I would NEVER had agreed. I was told prior to my first surgery that I would feel (and I quote the surgeon) "AS GOOD AS NEW". Every GP since has treated me like I was making it all up in my head and was just there to get painkillers and NOT ONE GP wants to hear anything I have to say about MESH!*
- *When I have days that I can't function without chronic pain I don't want to live anymore. I had chemo only 1 year before mesh implant and I just want to enjoy life but I can't. How can a specialist who knows all the complications of plastic mesh implants insert it and inflict so much pain on patients? He also placed it incorrectly.*
- *3.5 years later, I have to lay in bed for 20 hours a day due to pain. I haven't been able to sit without being in agony since I woke from surgery.*
- *[I] was not told it was a permanent implant, was only told it was a sling, was not given enough facts to make an informed choice.*
- *I haven't experienced any problems at all.*
- *Say no to mesh it is killing us and causing damage that we were not warned of.*
- *Mesh should be banned! Mesh destroyed my life in so many ways. I can't be intimate with my husband ever again I, I can't sit or walk, I can't work! We need to be informed from doctors what the risks are as we are not informed now. Help in Australia needs to be available.*
- *Some of the choices offered in this survey were insufficient. Many women who have had this procedure suffer many problems, some of which can be helped, some of which can never be fixed and some of which are intermittent. One of the biggest problems is finding a doctor who is sympathetic to these issues and who is willing to try to help fix or alleviate the severity of the pain issues.*
- *I had removal in the USA. My pain is still debilitating and I struggle to do the most basic things each day. I have lost my career and my ability to walk, sit or stand. My insurance company does not recognise my disability.*
- *My surgery was done 20 years ago, but I now have major problems with my bladder.*
- *Worst decision of my life.*
- *The remedial treatment and result was only temporary. It seems to be getting worse – particularly after shingles in vagina in Sept 2015. I had my initial operation with mesh implants and tapes in 2006. Up until now, when I have found a specialist who is up to date on all things 'mesh', I have not seen doctors who understand the implications of these procedures. It's very alienating and frustrating, as each 'complaint' that I've been to GP's with over these years has been diagnosed and treated as a separate issue, instead of conditions being caused by the mesh trying to be rejected by my body. A tiring and consuming roundabout that has been going on for years and not understood by those you*

go to seek help. I hope that all medical practitioners and allied health providers e.g. exercise physiologists, yoga teachers, physiotherapists, would become informed of how this mesh mess can affect women, so that they don't give exercises to 'tone the core', which is already too tight!

- *I had no side effect at all*
- *The autoimmune complications of mesh cannot be overlooked. This has the potential to affect 100% of mesh patients. Mesh was never tested for safety in the pelvic area. Mesh that has been removed ALL show degradation, shrinkage, breakage and blackening. The body is reacting to this foreign body and consequences are long term. The use of mesh in the Pelvic area needs to be banned.*
- *I only was able to work out my symptoms were related to mesh because I found a Facebook group. Specialists send me away and told me my mesh was not the problem.*
- *It did fix my problem at the time but [I] was never told of side effects groin pain, auto immune problems. [I] wouldn't have done [it] if I knew it couldn't of been removed*
- *I was never informed about any issues with the mesh, I've only had the mesh in since Sept 2016 so I'm extremely worried about side effects in the future*
- *This product has not only impacted me, but has injured my husband also.*

Term of Reference 6 - The Therapeutic Goods Administration's:

- a. role in investigating the suitability of the implants for use in Australia;**
- b. role in ongoing monitoring of the suitability of the implants; and**
- c. knowledge of women suffering with health problems after having transvaginal mesh implants.**

In 2016, a Cochrane Collaboration systematic evidence review comparing 'Transvaginal Mesh' with 'Native Tissue Repair' concluded:

The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery. While it is possible that in women with higher risk of recurrence the benefits may outweigh the risks, there is currently no evidence to support this position.¹⁸

Writing in *The Conversation* the lead author of the Cochrane Systematic Review Associate Professor Christopher Maher noted, "Gynaecologists should be wary of adopting innovations that have not been fully evaluated by clinical trials. Our patients deserve better studies and, in the absence of evidence, better advice."¹⁹

It is the job of the TGA to evaluate the safety and efficacy of medical devices prior to allowing them to be marketed. The TGA has clearly failed in relation to Transvaginal Mesh. The TGA has belatedly recognised the dangers of these devices. In doing so it implicitly acknowledged its' own failure to ensure the safety of mesh products before they were approved for the Australian market. In August 2014, the TGA issued a press release that stated:

While there may be a benefit in certain patients there is little evidence to support the overall effectiveness of these surgical meshes as a class of products... The TGA undertook a literature search of published materials since 2009. The overall quality of the literature was found to be poor... However, the literature did identify the known adverse outcomes associated with their use... Specifically, the review found that the use of urogynaecological surgical mesh devices for the surgical treatment of stress urinary incontinence and abdominal pelvic organ prolapse repair is adequately supported by the evidence... The TGA review also found that, while adverse events involving these devices are most likely under-reported, the reported complication rate remains low considering many thousands of these mesh devices have been implanted in Australian patients...The TGA review identified inadequate training/experience for implanting surgeons as a factor in increasing the risk of complications.²⁰

Given the paucity of evidence to support their safety and efficacy, why the TGA allowed these devices to be approved for market, is the obvious question. Mesh injured women have also reported dissatisfaction with outcomes of AHPRA processes, which have relied on the TGA's assertions that these devices are safe and effective.

The TGA is not the only national regulator to have failed to ensure the safety of mesh devices. We would encourage committee members to view the five-minute YouTube video *Mesh Misery: Thousands are suffering. Where are the watchdogs?*²¹ The video highlights that the US Food and Drug Administration was similarly ineffective in protecting American Women. We also note that in 2016 California co-led a multistate investigation, including 46 states and the District of Columbia, into Johnson & Johnson's surgical mesh products for women, and is seeking injunctive relief and monetary penalties to ensure that Johnson & Johnson stops its deceptive practices.

Johnson & Johnson put millions of women at risk of severe health problems by failing to provide critical information to doctors and patients about its surgical mesh products," said [Californian] Attorney General Harris. "Johnson & Johnson's deception denied women the ability to make informed decisions about their health and well-being. My office will continue to hold companies accountable for misleading consumers and patients for financial gain."²²

We encourage the committee to monitor the progress of this court action. We note that court actions alleging deceptive practices of pharmaceutical and medical device manufacturers are common in the USA. From 2004 to 2013 in the USA at least \$19.47 billion in fines and settlements have been paid for off-label promotion, fraudulent misbranding and marketing by pharmaceutical and medical device companies.²³ Companies fined

include Johnson & Johnson, GlaxoSmithKline, Abbott, Novartis, Forest, AstraZeneca, Pfizer, Eli Lilly, Bristol-Myers Squibb, and Purdue, most of whom operate in Australia.

In Australia, the TGA are not alone in belatedly recognising the dangers of urogynaecological mesh. Initially in 2007 and again in 2016 the *Royal Australian and New Zealand College of Obstetricians and Gynaecologists* acknowledged there is 'very little robust information is available on the efficacy and long-term safety of polypropylene mesh kits marketed for use in the surgical management of pelvic organ prolapse'.²⁴

We note that the failure of the TGA in relation to gynaecological mesh, follows a string of similar failures by the TGA to fulfil its' mandated role to protect the safety of Australian consumers of medications and medical devices. The TGA's failure in relation to medications including Pradaxa, Vioxx and Atomoxetine have been outlined in detail in two previous submissions to Senate Inquiries by the Health Consumers Council WA.^{25 26}

The TGA also failed to ensure the safety of Poly Implant Prothèse (PIP) breast implants²⁷ and of Articular Surface Replacement (ASR) hips marketed by DePuy Orthopaedics, a subsidiary of the Johnson & Johnson. Widespread and repeated complaints about the deterioration of the metallic replacement hips and the release of toxins into the patient's body caused 'DePuy issued a worldwide recall of the hip in 2010 and voluntarily withdrew it from Australia in 2009, but not before 93,000 patients worldwide, 5,500 of them Australians, had been implanted with the faulty hip'.²⁸ These failures were the catalyst for Senate Inquiries that have highlighted the failings of the TGA, however very little has changed.

It is obvious that Australian consumers have not been able to rely on the Commonwealth Government via the TGA to keep it safe. We express our extreme frustration with the failure of successive Australian governments to implement the recommendations of past Senate inquiries into similar failures. In 2011, the Senate Community Affairs References Committee held an Inquiry into the Regulatory Standards for the Approval of Medical Devices in Australia. The inquiry made specific recommendations of assistance that should be made available to recipients.²⁹ It also made recommendations on how the operations of the TGA could be improved to better protect the safety of medical device consumers (Recommendations 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 13, 14 and 18). We endorse all these recommendations.

Despite these concerns about inadequate regulation we note that recent 'reforms' of approval and safety regulation of pharmaceuticals and medical devices focus on finding faster ways of getting new products to market via streamlined processes including relying on foreign regulators. We are concerned that the TGA has a long history of relying on foreign regulators to guide it when new products are first approved for market but appears not to monitor when overseas regulators place warnings on products.

For example, from January to September 2005 the US FDA issued twenty black box warnings on prescription drugs sold in both the US and Australia. However, the Australian TGA issued warnings for only five of these twenty. In response to a question in a Senate committee, the TGA admitted that it did not monitor the FDA's drug warnings stating:

The TGA does not record which drugs sold in the US, with black box warnings in the US approved prescribing information document, do not carry black box warnings in the Australian prescribing information (P1) document.³⁰

Although this is old evidence of the practice of the TGA ignoring overseas evidence of the dangers of medications, it remains a concern.

The fundamental weakness of TGA processes is that treatment proponents (both medical device and pharmaceutical manufacturers) provide the evidence that the TGA uses to licence and monitor (once brought to market) the safety and efficacy of their products. Treatment proponents are free to determine who conducts their studies, which studies they seek to publish and which are kept private.

This largely self-regulatory process delivers the worst of all outcomes for consumers. They believe that the products like urogynaecological mesh have been through a robust independent TGA process, however in reality the TGA has rubber stamped the treatment proponent's application. The onus has been put on those suffering adverse events to prove they have suffered after market, rather than on the treatment proponents proving their products are safe and efficacious before they are licenced.

Term of Reference 7 - Options available to women to have transvaginal mesh removed.

We note that having mesh inserts is not an easily reversible process. Partial removal of mesh is more routinely offered for mesh-injured women. We are advised by APMSG representatives that from a consumer perspective, partial removal is often seen as worse than leaving the mesh in place as following partial removal the ends of the mesh deteriorate and create additional problems such as infection and re-erosion. Some women have reported undergoing three or four revision operations, whereby small protruding amounts of mesh are removed and then new protrusions of mesh cut through the vaginal wall. In addition, as many of the revision procedures take place in the private sector, some consumers have incurred significant costs.

We have also been informed that several mesh injured women have travelled to the United States of America at considerable expense to be treated by Dr Veronikas who has developed techniques and instruments to remove mesh. Consumers and the APMSG have advocated for surgeons in Australia to be trained and supported to undertake full removal. We also note that access to the only type of screening which can reveal the mesh, 3D/4D scanning with appropriate clinical review of the images, is limited. For example, it is not currently available in WA.

APMSG representatives have also advised us that some women who had their mesh inserted through the private system over ten years ago have found that the hospitals have destroyed their records. These women can't find out what mesh they had inserted and therefore may never be able to have the mesh removed.

Most respondents in our survey (62%) indicated they had sought medical assistance to rectify the problem (see Question 7 Appendix 1). Of those who had remedial action, only a small proportion reported an improved outcome with nearly as many reporting it made things worse (see Question 9 Appendix 1).

Recommendations

For the reasons outlined above we support the call to action by the APMSG and recommend:

1. The suspension of the use of mesh for prolapse and stress urinary incontinence, due to the severity of complications, with the suspension not to be lifted unless and until their safety and efficacy is established.
2. Free medical expertise and help being made to women already injured including access to experienced mesh removal surgeons sourced internationally if necessary.
3. Acknowledgement and ongoing support for adversely affected women. The host organization, format and language of information and promotional materials should be co-designed with affected women and consumer organisations. The support provided should include:
 - i. A consumer help line.
 - ii. Website for women with evidence based information around risks and benefits of treatment options.
 - iii. Recognition and support for women with ongoing incontinence issues.
 - iv. Recognition and support for women with ongoing disability issues and facilitate access to NDIS funding.
 - v. Referral to specialist surgeon who can advise and treat the complications.
4. Explicit and clear warnings to clinicians, patients and families of potential adverse effects of mesh (Including appropriate information for women with hearing or sight impairment or from CALD backgrounds).
5. Full public disclosure of the clinical trials and other evidence used by the TGA in determining that the products were fit for market.
6. Full public disclosure of how the TGA has responded to adverse events reported by women injured through pelvic mesh devices.
7. A broader Senate inquiry into the operations of Therapeutic Goods Administration TGA in relation to its failure to ensure the safety and efficacy of pharmaceuticals and medical devices in Australia.

We call on the Commonwealth Government to:

8. Establish a Gynecological Mesh User Registry along the lines of the Australian Orthopedic Association National Joint Replacement Registry (AONJRR). The purpose of the AONJRR is to 'benefit patients by enhancing the outcome of joint replacement surgery through the provision of comprehensive, quality, validated information'.³¹ A Gynecological Mesh User Registry would fulfill a similar purpose for women suffering from, or concerned about, potential adverse effects. The database should also have a consumer-friendly interface which facilitates women logging in and self-reporting their complications.
9. Consider having a Register for all mesh devices implanted in patients.

In line with previous Senate inquiry recommendations we also call on the Commonwealth Government to direct:

10. Commonwealth Government to legislate to introduce mandatory reporting for health practitioners and pharmacists to the Therapeutic Goods Administration for a range of (yet to be specified) severe adverse events for medications and medical devices.³²
11. Furthermore, we recommend that the TGA regularly publish full de-identified details (not just summaries) of adverse events associated with the use of medications and medical devices on a publicly accessible website.
12. The Department of Health to undertake further work to address the issue of inducements paid by pharmaceutical companies and medical device manufacturers to doctors and teaching hospitals, in line with the Physician Payment Sunshine provisions of the Patient Protection and Affordable Care Act of 2009 in the United States. The definition of inducements should include a commercial interest in a company or device; any cash payments or discounts offered to medical practitioners; and any other

gifts provided to medical practitioners.³³

We also recommend that:

13. There needs to be enhanced participation of consumers in all the TGA processes with a formal place in the assessment for input from consumers and consumer organisations which would form part of the data package used for that assessment in line with international best practice on consumer involvement in health technology assessment. There should be robust consumer participation on all TGA committees with a transparent process for nominating and publication of the results of any such process.
14. In our efforts to gather women's experiences of transvaginal mesh, we have heard of concerning complications experienced by men and women who have had mesh inserted for other conditions. We think this warrants the further investigation of use of all mesh devices.

We repeat that we would welcome the opportunity to attend the Senate Inquiry to provide in-person evidence.

Appendix 1

Results of Survey conducted by *Health Issues Centre (Victoria)* as at 24 May 20217.

Q1 Have you undergone a transvaginal mesh, tape or sling implant as treatment for urinary incontinence or pelvic organ prolapse? (Answered: 1,722 Skipped: 28)

Yes	1,280	(74%)
No	306	(18%)
Not sure	136	(8%)

Q2 Do you continue to have undiagnosed symptoms of chronic abdominal pain or urinary incontinence? (Answered: 359 Skipped: 1,391)

Yes	192	(54%)
No	167	(46%)

Q3 Do you feel you were fully informed before agreeing to the procedure? (Answered: 1,236 Skipped: 514)

Yes	422	(38%)
No	464	(40%)

I was given some information but things did not go as was suggested

241	(22%)
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Q4 Did the procedure satisfactorily resolve your health concerns? (Answered: 1,234 Skipped: 516)

Yes	531	(43%)
No	703	(58%)

Q5 Could you specify any adverse impacts you may have experienced? (Answered: 614 Skipped: 1,136)

Abdominal pain	353	(57%)
Pain during intercourse	344	(56%)
Incontinence	454	(74%)
Breakdown of personal relationship	152	(25%)

Q6 How would you rate this adverse impact? Answered: 673 Skipped: 1,077

Discomforting	226	(34%)
Severe	152	(23%)
Debilitating	202	(30%)
Unendurable	78	(12%)
Not applicable	15	(2%)

Q7 Have you sought medical assistance to rectify the problem? (Answered: 856 Skipped: 894)

Yes	534	(62%)
No	322	(38%)

Q8 Did your doctor/specialist confirm a causal relationship between your symptoms and the mesh implant? (Answered: 510 Skipped: 1,240)

Yes	178	(35%)
No	171	(34%)
Inconclusive	115	(22%)
Not applicable	46	(9%)

Q9 If you were offered remedial treatment, did it change your condition? (Answered: 440 Skipped: 1,310)

It made it better	48	(11%)
It made it worse	45	(10%)
I was told nothing could be done	174	(40%)
It didn't make a difference	173	(39%)

Q10 What is your age? (Answered: 1,335 Skipped: 415)

30-39	57	(4%)
40-49	221	(17%)
50-59	416	(31%)
60-69	453	(34%)
70+	178	(13%)
Prefer to not answer	10	(1%)

Other questions asked were:

11. What is your postcode? – These results were broadly in line with the population distribution across Australia.

Appendix 2

*The internet links (with brief descriptions) below have been provided in the belief they that may be of some interest and use to the committee. They constitute a range of documents from peer reviewed journals through to online unreferenced blog reports and mainstream media 'tabloid' coverage. Due to time and other resource constraints **we have not reviewed their content in detail and do not endorse views expressed in these items or vouch for the accuracy of the information within them.***

Are Surgeons correctly trained? Leading Italian surgeon says mesh used in women's operations has a high rate of complications

<http://www.wisbechstandard.co.uk/news/are-surgeons-correctly-trained-leading-italian-surgeon-says-mesh-used-in-women-s-operations-has-a-high-rate-of-complications-1-4516888>

MAUDE database shows Inaccurate Representation of Mesh-Related Adverse Events and Trends - SAGES Abstract Archives

<https://www.sages.org/meetings/annual-meeting/abstracts-archive/maude-database-audit-shows-inaccurate-representation-of-mesh-related-adverse-events-and-trends/>

A Meta-Analysis Detailing Overall Sexual Function and Orgasmic Function in Women Undergoing Midurethral Sling Surgery for Stress Incontinence. - PubMed - NCBI

<https://www.ncbi.nlm.nih.gov/pubmed/28363810/>

Incidence and Risk Factors for Pelvic Pain After Mesh Implant Surgery for the Treatment of Pelvic Floor Disorders. - PubMed - NCBI

<https://www.ncbi.nlm.nih.gov/pubmed/27773810/>

Mesh and cancer

<https://www.jscomedcentral.com/Surgery/surgery-4-1041.pdf>

2007 Report on complications with SUI slings

http://eu-acme.org/europeanurology/upload_articles/Managing%20Complications%20after%20Midurethral%20Sling%20for%20Stress%20Urinary%20Incontinence.pdf

Inflammatory Response Tied to Vaginal Mesh Complications - Mostyn Perspectives

<https://mostynperspectives.com/2016/08/18/inflammatory-response-tied-vaginal-mesh-complications/>

Pathology of explanted mesh

<http://waset.org/publications/9999333/pathology-of-explanted-transvaginal-meshes>

Nobody knows the true scale of the pelvic mesh scandal - but new figures show it could be as high as almost 40 per cent - News - Wisbech Standard

http://www.wisbechstandard.co.uk/news/nobody_knows_the_true_scale_of_the_pelvic_mesh_scandal_but_new_figures_show_it_could_be_as_high_as_almost_40_per_cent_1_4849954

Transvaginal mesh: let's not repeat the mistakes of the past - Mowat - 2017 - Australian and New Zealand Journal of Obstetrics and Gynaecology - Wiley Online Library

<http://onlinelibrary.wiley.com/doi/10.1111/ajo.12597/full>

Recent FDA Review

<https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/urogynsurgical/mesh/>

NZ Surgical Mesh review

http://www.acc.co.nz/PRD_EXT_CSMP/groups/external_providers/documents/reference_tools/wpc138053.pdf

Detailed Dutch review

<https://www.igz.nl/zoeken/download.aspx?download=Transvaginal+Mesh%3ASerious+Complications+Demand+Cautious+Use.pdf>

Mother forced to spend £4,500 to remove mesh implants | Daily Mail Online

<http://www.dailymail.co.uk/health/article-4463698/Mother-forced-spend-4-500-remove-mesh-implants.html>

Thousands of women await day in court against J&J | NJ.com

http://www.nj.com/healthfit/index.ssf/2017/04/massive_jj_pelvic_mesh_lawsuit_gets_autumn_court_d.html

Jury delivers \$20 million verdict against Johnson & Johnson in local vaginal mesh case - Story | WTXF

<http://www.fox29.com/news/local-news/251407273-story>

Sullivan V Boston Scientific Pelvic Mesh Case Settles on Eve of Trial - Mesh Medical Device Newsdesk

<http://www.meshmedicaldevicenewsdesk.com/sullivan-v-boston-scientific-pelvic-mesh-case-settles-eve-trial/>

Why does the medical establishment fail to take women in pain seriously?

<http://www.newstatesman.com/politics/feminism/2017/04/why-does-medical-establishment-fail-take-women-pain-seriously>

Vaginal mesh left me in agony. When will women's health be taken seriously? | Kath Sansom | Opinion | The Guardian

<https://www.theguardian.com/commentisfree/2017/apr/27/vaginal-mesh-women-health-bladders-bowels-sex-lives-nhs-operations>

The Project Episode Network 10

<https://tenplay.com.au/channel-ten/the-project/extra/season-8/transvaginal-mesh-implants>

BBC documentary about mesh.

<https://www.youtube.com/watch?v=ebmjbcoUHNY&sns=em>

Outrage over mesh prosecution failure | Newcastle Herald

<http://www.theherald.com.au/story/4619798/outrage-over-mesh-prosecution-failure/?cs=303#slide=4>

'A tragedy created by greed'. Mounting pressure for a women's mesh sling operation to be withdrawn - News - Wisbech Standard

<http://www.wisbechstandard.co.uk/news/a-tragedy-created-by-greed-mounting-pressure-for-a-women-s-mesh-sling-operation-to-be-withdrawn-1-4676143>

Hundreds sue NHS over 'barbaric' vaginal mesh implants - BBC News

<http://www.bbc.com/news/health-39567240>

Insight: Down but not out after mesh implant 'whitewash' - The Scotsman

<http://www.scotsman.com/news/health/insight-down-but-not-out-after-mesh-implant-whitewash-1-4409770>

SMH today Woman speaks out over devastating impact of mesh surgery

<https://www.google.com.au/amp/s/amp.smh.com.au/national/health/woman-speaks-out-over-surgery-that-left-her-rotting-from-inside-20170322-gv3ybd.html>

Mesh scandal's Australian backstory | Newcastle Herald

<http://www.theherald.com.au/story/4493496/scandals-australian-backstory/?cs=305#slide=2>

Mum left with 'deadly vagina' that 'BIT' her partner during sex after surgery for stress incontinence went wrong

<https://www.thesun.co.uk/living/3130966/mum-left-with-deadly-vagina-that-bit-her-partner-during-sex-after-surgery-for-stress-incontinence-fears-life-of-celibacy/?CMP=Spklr- -Editorial- -TheSun- -Living- -FBLink- -Quote- -FBPAGE>

Kiwi mum warns of surgical mesh nightmare that destroyed her life | Stuff.co.nz

<http://i.stuff.co.nz/national/health/90433221/kiwi-mom-warns-of-surgical-mesh-nightmare-that-destroyed-her-life>

Regulator quietly reveals pelvic mesh risks | Newcastle Herald

<http://www.theherald.com.au/story/4533002/regulator-quietly-reveals-pelvic-mesh-risks/?cs=305>

Doctor denies being blind to mesh risk | Newcastle Herald

<http://www.theherald.com.au/story/4524242/doctor-denies-being-blind-to-mesh-risk/?cs=305>

30 articles on Medical mesh: Suffering in silence | Newcastle Herald

<http://www.theherald.com.au/story/3795734/medical-mesh-suffering-in-silence/>

Tribunal told mesh device evidence 'very poor' | Newcastle Herald

<http://www.theherald.com.au/story/4462077/tribunal-told-mesh-device-evidence-very-poor/#slide=1>

Polypropylene Resin Not Meant for Human Implants - Mesh Medical Device Newsdesk

<http://www.meshmedicaldevicenewsdesk.com/mesh-polypropylene-resin-not-meant-human-implants/>

ENDNOTES

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- ⁵ Australian Government Response to Senate Community Affairs References Committee Report on The Regulatory Standards for the Approval of Medical Devices in Australia August 2012 [http://www.health.gov.au/internet/main/publishing.nsf/Content/3141B94933949C69CA257BF0001B750C/\\$File/Final%20Govt%20Response_approved%20310812.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/3141B94933949C69CA257BF0001B750C/$File/Final%20Govt%20Response_approved%20310812.pdf)
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- ⁸ Health Consumers' Council of WA, Submission to the Senate Community Affairs Legislation Committee inquiry into the Therapeutic Goods Amendment (2016 Measures No. 1) Bill. (March 2017) Submission 32 available at http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/TGA2016Measure_sNo1/Submissions
- ⁹ Health Consumers' Council of WA submission to the Senate Select Inquiry into Health, (*Licensing and Subsidising Pharmaceuticals in Australia - Reforms needed to deliver Transparency, Safety and Value for Money*) September 2014 <http://www.hconc.org.au/couch/uploads/file/hcc-senate-submission-on-pbs-tga-transparency-reform-september-2014.pdf>
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