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Jeanette Radcliffe
Secretary
Senate Community Affairs References Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Via email to: community.affairs.sen@aph.gov.au

Dear Ms Radcliffe

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

I thank the Senate Community Affairs References Committee's for its invitation to provide a submission on the above inquiry matter.

Since 1 January 2012, there have been five confirmed complaints made to Queensland's health complaints agency relating to procedures involving transvaginal/urogynaecological surgical mesh implants— four to the Office of the Health Ombudsman (OHO) since it commenced on 1 July 2014, and one to the former Health Quality and Complaints Commission prior to this date (later transferred to the OHO).

The reasons for mesh implantation differed across the five complaints: three noted pelvic organ prolapse, one noted incontinence, and one noted both pelvic organ prolapse and incontinence. In one complaint, mesh implantation was used to treat an unsuccessful native repair of pelvic organ prolapse.

In looking at the surgical outcomes contained in these five complaints, outcomes included recurrent infections, incontinence, and ongoing pain as a result of mesh erosion (including lodgement of mesh in pelvic organs). Due to the nature of the complaints, independent clinical advice was sought was sought in four of the five cases: the use of mesh was noted to be an appropriate intervention in all cases.

Moreover, in each clinical advice obtained, the clinician stated that the reported outcomes were known complications of surgical mesh implantation and, in all but one of the four clinically reviewed cases, the independent clinician confirmed that the consent process used with the patient was adequate (the fifth matter was referred to the Australian Health Practitioner Regulation Agency, where the Medical Board determined there were no issues with the practitioner's performance).

The above cases represent a small number of matters, with the outcomes experienced by the complainants determined to be unrelated to the performance or conduct of the respective practitioners. It is clear the use of transvaginal/urogynaecological surgical mesh for repair of prolapse and incontinence is contemporary practice, albeit with known side effects.

Unlike AHPRA, my office's remit is confined to determining whether there has been an issue with the performance or conduct that has given rise to a serious risk to the health and safety of the public. As a result, these few cases offer a limited perspective on this issue.

Nevertheless, in seeking to understand the safety of transvaginal/urogynaecological surgical meshes as medical devices, and whether their application is wholly appropriate, the Committee may wish to seek answers to the following from relevant agencies:

- Given the requirement for practitioners to ensure patients understand the risks associated with procedures, could there be a large contingent who have experienced negative outcomes as a result of mesh insertion but have not reported their experience because they 'knew there was risk' of a poor result?
- Should transvaginal/urogynaecological surgical meshes be employed as broadly as they are; or should they be reserved as an intervention used when other approaches, such as native tissue repair, have been unsuccessful?
- What role, if any, has information or other forms of communication from the manufacturer played a role in the use of transvaginal/urogynaecological surgical mesh becoming contemporary practice?
- Is further, more specific, training required to ensure that patient selection processes are optimum to reduce instances of negative outcomes?

I look forward to reviewing the Committee's report at the Inquiry's conclusion. In the meantime, if my office can be of further assistance, please do not hesitate to make contact with me.

Yours sincerely

Leon Atkinson-MacEwen
Health Ombudsman