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From: Branch Neil **On Behalf Of** News
Sent: Friday, 3 October 2014 2:12 PM
To: jmccarthy@fairfaxmedia.com.au
Subject: TFS [SEC=UNCLASSIFIED]

From a spokesperson for the TGA:

A TGA review of urogynaecological surgical mesh devices such as the TFS device has concluded that the use these devices for the surgical treatment of stress urinary incontinence and abdominal pelvic organ prolapse repair is adequately supported by the evidence.

However, due to the poor quality of the studies undertaken, the evidence to support the use of these meshes for transvaginal pelvic organ prolapse repair, particularly posterior repair, is not well established.

Therefore, the TGA is currently reviewing all such devices included on the ARTG. All TGA cancellations of devices included on the ARTG are published on the TGA website.

Background:

- The ARTG entry for the TFS incontinence prosthetic mesh was supported by clinical evidence for stress incontinence and vaginal prolapse. The vaginal prolapse evidence comprised an article published in the International Urogynecology Journal in 1998 (Int Urogynecol J(1998) 9:19-27).

- There was a systematic review of intravaginal slingplasty vs tension-free vaginal tape procedures for stress urinary incontinence which was conducted by the Australian Safety and Efficacy Register of New Interventional Procedure – Surgical (ASERNIPS) in 2001.
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Media Unit
Australian Government
Department of Health inc the TGA

Office for Sport
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: Joanne McCarthy [mailto:jmccarthy@fairfaxmedia.com.au]
Sent: Friday, 3 October 2014 8:32 AM
To: Anthony Hobbs
Subject: re TFS

Dear Dr Hobbs,

My name is Joanne McCarthy and I am a journalist with the Newcastle Herald.
In the past few weeks, since the NSW Medical Council's suspension of gynaecologist Dr Richard Reid, I have written a number of articles about medical procedures and medical devices relating to prolapse in women.
I have been forwarded material gained under FOI from the TGA in relation to the processes followed which allowed TFS onto the Australian market.
Can I confirm that:

1. TFS was registered based on material supplied to the TGA about IVS and TVT use for stress incontinence?
2. Can I confirm that a formal review of the IVS and TVT material referred to poor quality evidence, and spoke of the need for a randomised clinical trial?
3. Can I confirm that the material before the TGA was for IVS and TVT relating to stress incontinence, and not prolapse treatment, yet TFS was used by a number of Australian surgeons, including Dr Reid and Dr Peter Petros, for prolapse surgery and treatment?
4. Is it reasonable to conclude that TFS has been used in Australia to treat women for prolapse, without any formal assessment of either the device or the procedures, or their potential risks to women?
5. What is the status of TFS at the moment, given the number of women now taking action against doctors, and reviews by other specialists raising serious concerns about TFS and the procedures relating to it?

Thank you. Joanne McCarthy.

Joanne McCarthy
Senior Journalist, Newcastle Newspapers
jmccarthy@fairfaxmedia.com.au

m 0419 977 330 | t 02 4385 2534

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