Private Healthcare Australia
Better Cover. Better Access. Better Care.

Unit 17G, Level 1, 2 King St, Deakin ACT 2600
T (+61) 2 6202 1000
F (+61) 2 6202 1001
www.privatehealthcareaustralia.org.au
ABN: 35 008 621 994

Hon Dr Michael Armitage
CHIEF EXECUTIVE OFFICER

Committee Secretary
Senate Standing Committees on Community Affairs
Parliament House
Canberra ACT 2600

Dear Committee Secretary

Thank you for the opportunity for Private Healthcare Australia to participate in your Committee's inquiry into the *role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese breast implants*.

Private Healthcare Australia (formerly the Australian Health Insurance Association) represents 23 private health funds, which collectively insure approximately 95 per cent of the 12.1 million Australians who hold some form of private health cover.

Private Healthcare Australia is concerned that this Inquiry is taking place so soon after the Committee's 2011 inquiry into the regulatory standards for the approval of medical devices in Australia. The Committee made sound recommendations following that Inquiry and the Government is encouraged to implement those recommendations as soon as is practical.

Private Healthcare Australia wishes to reiterate that the fundamental concern with the role of the TGA regarding medical devices is that the Administration does not make assessments of devices on the basis of clinical outcomes beyond statements supplied by the sponsor of the product. This is a significant deficiency in respect to the TGA's regulatory role and one which leaves patients exposed to a lower standard of care.

Private Healthcare Australia believes it is important that the TGA undertakes clinical testing of all prostheses and devices itself, or arranges for independent clinical testing to be undertaken, before the devices can be approved for use in our health care system.

When a prosthesis or device fails, a second operation is frequently required, at considerable inconvenience to the consumer, resulting in an inefficient use of resources within the health system. It is estimated by the National Joint Replacement Registry that approximately 10 per cent (or around 6,000) joint replacement procedures in Australia are revisions, meaning consumers have to undergo the same procedure twice, usually in a short space of time.

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The failure of the TGA to implement recommendations from both the recent Senate inquiry and those contained in the Australian Health Insurance Commission submission to the Committee at the time, has resulted in more devices being allowed to continue to be listed on the Australian Register of Therapeutic Goods, with only poor evidence to support their use.

The Committee will be interested to note that Private Healthcare Australia is aware of 513 instances of PIP breast impacts being surgically implanted into Australian women in the private system in recent years. In most instances, these women have undergone traumatic mastectomies following a cancer diagnosis and treatment within the private care system.

Private Healthcare Australia would welcome the introduction of a regulatory system that assesses the safety, effectiveness and value of devices against existing products and that prohibits the use of poorly performing prostheses.

Yours sincerely

HON DR MICHAEL ARMITAGE
CHIEF EXECUTIVE OFFICER

20 April 2012