Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2014 - 2015, 22 October 2014

Ref No: SQ14-001255

OUTCOME: 7 - Health Infrastructure, Regulation, Safety and Quality

Topic: Poly Implant Prothese Breast Implants

Type of Question: Written Question on Notice

Senator: Xenophon, Nick

Question:

I refer to concerns raised with my office regarding the apparent failure of the TGA to provide information at the Senate Inquiry into the role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants. I refer to two letters provided to the Inquiry dated 2008, written by Dr Daniel Fleming, past President of the Australasian College of Cosmetic Surgeons and current member of the TGA Advisory Committee on PIP breast implants, to Australian distributor Medical Vision Australia (attached). In these letters Dr Fleming outlines his concerns about the PIP breast implant brand and allegations of Medical Vision Australia falsifying data on a PIP breast implant trial. The second letter notes Dr Fleming's resignation as the Principal Investigator of the PIP breast implant study and his advice that he would be contacting the TGA, Bellberry and other investigators to inform them of his concerns. Did Dr Fleming contact the TGA about his concerns in 2008, as stated in the letter? Did he contact the TGA later down the track? If so, what action did the TGA take when they were notified by Dr Daniel Fleming in 2008, that there were problems with PIP breast implants and allegations of fraud conducted by the Australian sponsor/distributor Medical Vision Australia?

Answer:

It should be noted that the concerns Dr Fleming raised in 2008 were not in relation to the Poly Implant Prothese (PIP) breast implants that were recalled in Australia in April 2010. Dr Fleming's concerns were in relation to a clinical trial for Titanium Coated Breast Implants. The trial was to determine the rate of capsular contracture in 1,500 breast augmentation patients receiving silicone gel breast implants with a smooth surface titanium coated shell. The implants were manufactured by PIP and supplied by Medical Vision Australia to implanting surgeons participating in the trial. These implants were not, and have never been, on the Australian Register of Therapeutic Goods (ARTG).

The Therapeutic Goods Administration (TGA) was made aware of Dr Fleming's concerns in relation to the Titanium Coated Breast Implants in 2008. While the product was not on the ARTG, the TGA had granted access to doctors and patients under the Special Access Scheme (SAS) for use in the clinical trial, which was approved by the Bellberry Human Research Ethics Committee. In August 2008, following Dr Fleming's concerns and an independent

report of the results of the trial from the Bellberry Human Research Ethics Committee, the TGA did not approve any further SAS applications for the Titanium Coated Breast Implants. The report by the Bellberry Human Research Ethics Committee also led to the trial ceasing on 15 August 2008. Dr Fleming indicated that he was satisfied with the result.