

**Senate Community Affairs Committee**

**ANSWERS TO ESTIMATES QUESTIONS ON NOTICE**

**HEALTH AND AGEING PORTFOLIO**

**Budget Estimates 2013-14, 5/6 & 7 June 2013**

**Question: E13-178**

**OUTCOME:** 1 - Population Health

**Topic:** Medical Devices – Product Liability Insurance for Consumers

**Type of Question:** Hansard Page 59, 6 June 2013

**Senator:** Xenophon

**Question:**

[Considering that “there have been literally thousands of women affected by the PIP breast implant debacle...”] – “Is the government looking at a way of ensuring that this does not occur again to other medical consumers who are left high and dry where the company has collapsed and there is no insurance policy in place?”

**Answer:**

There is no requirement under the *Therapeutic Goods Act 1989* for sponsors to hold product liability insurance and the Therapeutic Goods Administration has no role in a sponsor company's insurance arrangements. The Government is unaware of any regulator globally that requires sponsors of devices to hold insurance cover.

Australian companies involved in the manufacture and supply of medical devices are subject to regulation by two main Commonwealth regulators in relation to their business activities.

The regulators are:

- The Australian Competition and Consumer Commission, which has functions under the *Competition and Consumer Act 2010* aimed at ensuring that there is fair competition between businesses and enforcing consumer rights established under this legislation; and
- The Australian Securities and Investments Commission which administers the requirements of the *Corporations Act 2001* (the Act), in particular in relation to the obligations of directors of companies and by taking action in relation to conduct prohibited under the Act.