

Australia: No higher risk from French implants

January 5 2012, By KRISTEN GELINEAU, Associated Press

(AP) -- Australian health officials said they have found no evidence that potentially faulty French-made breast implants are at an increased risk of rupture in Australian women.

An expert panel of the Therapeutic Goods Administration, Australia's medical watchdog, said in a statement late Wednesday that the silicone implants made by the now-defunct French company Poly Implant Prothese - or PIP - have no higher risk of rupture than other <u>silicone</u> <u>implants</u>.

The PIP implants were made with cheap industrial silicone instead of medical grade silicone, and were banned last year in countries around the world after more than 1,000 women in France suffered ruptures.

<u>Health experts</u> across the globe have been trying to determine the health risk and whether to tell women to have the implants taken out. Last month, French officials said women with the implants should have them removed, with the government picking up the tab.

Rohan Hammett, National Manager of the TGA, said in a statement that all implants have a 10 percent risk of rupturing over a 10 year period after insertion. The current rupture rate of PIP implants in Australian women is approximately 0.4 percent, or 37 ruptures out of the 9,054 implants placed in Australian women between 2002 and 2011, Hammett said.



"While these figures are based only on reports to the TGA, this rate remains well within the expected performance of <u>breast implants</u> based on historical and international trend data," Hammett said. "Testing of PIP implants supplied in Australia by TGA in July 2010 indicated that the <u>outer shell</u> of the implant complied with international standards and regulatory requirements for strength and rupture resistance."

Lab testing of the <u>silicone gel</u> in the PIP implants had also indicated the gel was non-toxic to the tissue around the implant even if it does rupture, Hammett said.

"We know that breast implants won't last a lifetime in many women, and rupture is relatively common but the results of <u>laboratory analysis</u> both here and in the UK are reassuring in that even when rupture occurs the risk with PIP implants appears no different to other implants," Hammett said.

Concern over the devices increased after a handful of cases of a rare cancer known as anaplastic large cell lymphoma were found in women who had the PIP implants. Hammett said the TGA had not received any reports of Australian women with PIP implants developing the cancer.

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