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FDA safety signal on ALCL and breast implants

Australian Society of Plastic Surgeons (ASPS) today commented on the release overnight of a “Safety Communication” from the Food and Drug Administration (FDA). The FDA announcement refers to a possible association between breast implants and anaplastic large cell lymphoma.

ASPS President Peter Callan said, “We welcome the safety communication from the FDA. Patients, consumers, surgeons and all health care practitioners need clear information to assist them to make informed decisions”, he said.

Peter Callan said, “Anaplastic large cell lymphoma (ALCL) is an extremely rare form of cancer. In May 2009, ASPS was alerted, by one of its members, to a possible link between ALCL and breast implants. We immediately informed the Therapeutic Goods Administration (TGA) in Australia, the equivalent of the FDA in America”.

The TGA is the Australian body responsible for making decisions in relation to the safety of medical devices and to inform the public and health practitioners of its findings.

“In Australia, ASPS is aware of five reported cases of ALCL which may have a possible association with breast implants”, Mr Callan said.

“While the global incidence is small in relation to the millions of breast implant procedures performed each year, patients are entitled to be aware of all possible risks before making a decision about any procedure”, he said.

“We alerted the TGA in May 2009. Since then we have also had discussions with the FDA and kept a close watch on the issue”, Peter Callan said.

“There is no recommendation to withdraw breast implants from use or have them removed”, Mr Callan said.

“Given the low incidence of ALCL in women who have had breast implants, today’s communication from the FDA should not alarm anyone who has had a breast implant procedure. If patients have any concerns we suggest they consult with their doctor”, Mr Callan said.

Australian Society of Plastic Surgeons maintains a Breast Implant Registry (BIR). It is a voluntary register. Patients who have recorded their implant data with the BIR can ring ASPS on 1300 851 157. The FDA has also recommended that a breast implant registry be established in the United States.

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