

FDA sees possible cancer risk with breast implants

January 26 2011, By MATTHEW PERRONE , AP Health Writer

(AP) -- Federal health officials said Wednesday they are investigating a possible link between breast implants and a very rare form of cancer after reviewing a handful of cases reported over the last 13 years.

The [cancer](#), known as anaplastic large cell [lymphoma](#), attacks [lymph nodes](#) and skin and has been reported in the [scar tissue](#) which grows around an implant. The [Food and Drug Administration](#) is asking doctors to report all cases of the cancer so the agency can better understand the association.

The agency is aware of just 60 cases of the disease worldwide among the estimated 5 million to 10 million women with breast implants. The agency reviewed the scientific literature going back to 1997 along with information provided by international governments and manufacturers.

Most of the cases were reported after patients sought medical care for pain, lumps, swelling and other problems around the surgical site.

Breast implants come in both saline and silicone-gel filled formulations and are marketed in the U.S. by Allergan Inc. and Johnson & Johnson's Mentor Corp. Those companies will be required to update the labeling for their products to reflect the cancer cases.

"Women should monitor their breast implants and contact their doctor if they notice any changes," the agency said in a statement.

The FDA pulled silicone breast implants off the market in 1992, saying manufacturers had not provided medical data showing their safety and effectiveness. At the time, there were worries about a connection to a variety of diseases, including cancer and lupus. Alarming cases of ruptures added to the concern.

But in 2006 the agency returned the implants to the market after most studies failed to find a link between silicone breast implants and disease.

The approval came with conditions, including a requirement that the companies complete 10-year studies on women who have already received the implants to study leaks, as well conduct new decade-long studies of the safety of the devices in 40,000 women.

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