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Allergan/JNJ: Cancer association with breast implants has 'very little' impact on plastic surgeon community; recalls highly unlikely

by Kimberly Ha and Viral Gandhi in New York

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Allergan (NYSE:AGN) and Johnson & Johnson's (NYSE:JNJ) breast implants are unlikely to be recalled or see decreased use despite an FDA review that suggests a possible association between implants and a rare cancer, plastic surgeons told Pharmawire. The FDA is aware of approximately 60 cases of anaplastic large cell lymphoma (ALCL) among an estimated 5-10 million women who have received breast implants worldwide.

The FDA identified 34 unique published cases of ALCL in women with breast implants, of which 24 implants were silicone-filled and seven were saline-filled. Although the connection has not been definitively established, the agency is requesting that healthcare professionals report cases of ALCL in women with breast implants.

Dr Phil Haeck, president of the American Society of Plastic Surgeons (ASPS), said that ASPS will move forward to run a registry of these patients to take an in-depth look at ALCL cases, along with the FDA. Issues that it is looking to identify include whether there are any differences between breast enlargement versus breast reconstruction, silicone versus saline, or textured versus smooth implants.

He added that the recent news is unlikely to change his practice or recommendations in any way, except disclosure to patients about the associated risk. "There is a higher chance that a woman will be struck by lightning than get this condition," Haeck said. The condition itself was limited to the fibrous capsule, and did not invade the breast tissue, limiting the need for women to undergo surgical removal of the breasts, he added.

Haeck noted that the FDA will have an interim report on the post-marketing studies of various approved products this spring. He added that the ASPS meeting this September in Denver, Colorado will have a panel on this topic.

"The main advantage of this registry is that epidemiologists and statisticians will be on board and it is estimated that it would take about 100 years to prove cause and effect because the numbers are so low," Haeck said. The implants are safe, and patients should be fine as long as they continue to do routine exams, added Haeck.

A spokesperson for Allergan said that the company has been in ongoing dialogue with the FDA and all other regulatory authorities around the world about the reported cases of ALCL in patients with breast implants. "The company also sponsored a scientific advisory committee to independently evaluate reports of suspected ALCL in patients with breast implants and carefully assess and review each case," the spokesperson added.

"We are in ongoing dialogue with the FDA to evaluate the best course of action for health care providers and patients and adjust these recommendations as needed." With regards to a risk management plan, Allergan has had a risk management program in place since gel-filled breast implants were re-approved by the FDA in 2006, the spokesperson added.

Johnson & Johnson did not respond to request for a comment by press time.

Dr Howard Bellin, founder, director, and cosmetic surgeon at CosMedica, who has been practicing cosmetic surgery for more than 30 years, said the recent news will have "very little impact" on how he treats patients.

"It's not brand new information. The FDA has been gathering information over the last couple of years," said Dr Adam Kolker, associate clinical professor at Mount Sinai School of Medicine and an aesthetic plastic surgeon in New York City. Kolker, who also said this announcement will not impact his treatment decisions, estimated that approximately five million women in the world have breast implants, adding that there is no causal relationship between implants and this type of rare lymphoma.

While a recall is unlikely, Kolker said that there are going to be some changes, "without a doubt," from an informed consent perspective. "This type of cancer risk (ALCL) is typically not routinely discussed with patients when they come in to consultations," he noted.

The FDA will not recall these products, said Bellin, who was previously chief of plastic surgery at Cabrini Medical Center. In addition to the two major brands that exist - Allergan and Mentor (a J&J company) - Brazilian-based Silimed is awaiting FDA approval for its implants, Bellin noted.

In 2009, Allergan net sales for the breast aesthetics business were USD 287.5m. Estimated annual sales are 264m for Mentor's product globally, according to analyst reports.

"Women with breast implants who are not showing any symptoms or problems do not need to change their healthcare routine," said Dr William Maisel, chief scientist and deputy director for science at the FDA's Center for Devices and Radiological Health in a media advisory call on Wednesday.

FDA is not recommending the routine removal of breast implants in patients without any symptoms. Given the rarity of ALCL, the FDA would like to collect more information to fully understand the potential link, Maisel noted.

The agency is requesting that physicians report all confirmed all cases of ALCL in women with breast implants to Medwatch, the FDA safety information and adverse event reporting program.

"People with breast implants could get cancer regardless, with or without the implant," said Bellin, who has performed approximately 2500 breast implantations. "It's not something I would pay attention to."

ALCL in women with breast implants may have been underreported due to the indolent nature of the disease in addition to the fact that removal of the scar capsule adjacent to the implant where the cancer is thought to develop is often curative, said Dr Evan Farkash from Massachusetts General Hospital and lead author of one the publications used by the FDA for its analysis. Patients are often diagnosed due to a recurrent seroma or contracture, at which point a keen clinician or pathologist would play an important role in identifying the lesion, he explained.

Farkash added that data on the true incidence of primary breast ALCL in the US is still not clear.

The most complete epidemiologic data comes from the Netherlands, which has a nationwide pathology database, Farkash said. In a study published in the Journal of the American Medical Association in November 2008 titled "Anaplastic large-cell lymphoma in women with breast implants," the authors describe identifying just 11 cases in the Netherlands in 17 years. According to this paper, the odds ratio for ALCL associated with breast prostheses was 18.2. Per the authors, even though preliminary findings suggest an association between silicone breast prosthesis and ALCL, "the absolute risk is exceedingly low due to the rare occurrence of ALCL of the breast."

Seattle Genetics (NASDAQ:SGEN) shares increased 3.3% on Wednesday's news, as the company is one of few developing a specific drug to treat this type of rare cancer. Data presented at the American Society of Hematology last month showed that of the 58 patients who received SGN-35 (brentuximab vedotin) for ALCL, more than half of the patients (53%) had their tumors completely eradicated after they were dosed with the active agent, and a total of 86% had their tumors shrink by half or more, according to an abstract.

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