Consumer group questions review of breast implants

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(AP) -- Consumer safety advocates are questioning the Food and Drug Administration about seemingly incomplete and erroneous data used to affirm the safety of silicone breast implants last year.

The FDA concluded last summer that the silicone-gel implants are basically safe as long as women understand they come with complications. More than one in five women who get implants for breast enhancement will need to have them replaced within five years, the agency's report concluded.

In August, an outside panel of physicians affirmed the FDA's decision that the devices should remain available for both breast enhancement and reconstruction.

But the National Research Center for Women and Families says the FDA did not present information that showed women reported lower emotional, mental and physical well-being after implantation. Additionally, the group questions why figures presented by the FDA appear to show implant complications declining over time. The implants are known to fail over time.

"This shows problems with the data, since the complication rates are reported to be cumulative and should therefore stay the same or increase over time," states Diana Zuckerman, the group's president, in a letter to the head of FDA's medical device division.

Most of the FDA's data on the safety and effectiveness of breast implants comes from long-term studies conducted by the two U.S. manufacturers of the devices, Allergan Inc. of Irvine, Calif., and Mentor, a unit of Johnson & Johnson, based in New Brunswick, N.J.

When the FDA reviewed the initial applications for the devices in 2005, women using Allergan's implants scored lower on nine out of 12 quality-of-life measures, including mental, social and general health. Women did report higher scores on measures of sexual attractiveness-body esteem.

Women implanted with J&J's implants also scored worse on measures of physical and mental health. In the 11-page letter, Zuckerman questions why that information was not presented at FDA's public meeting in August.

"Breast implants are widely advertised and promoted as a way to increase women's self-esteem and positive feelings about themselves," said Zuckerman, in an interview with the Associated Press. "But the implant companies' own data, which the FDA made public in 2005 but ignored last year, shows the opposite."

Silicone gel breast implants have traveled a long, winding regulatory path at the FDA over the last 20 years. The FDA banned the silicone-gel type in 1992 amid fears they might cause cancer, lupus and other diseases. For more than a decade, only saline-filled implants were available. But when research ruled out most of the disease concern with silicone, regulators returned the implants to the market in 2006 - with the requirement that manufacturers continue studying patients to see how they fare long-term.

When the FDA revisited the devices' safety last year they relied on eight and 10-year follow-up data from J&J and Allergan, respectively. This followed up on similar data submitted in 2005.

Breast implants are known to rupture and break down over time. But Zuckerman points out in her letter that the company data seem to defy this trend, with complication rates falling over time.

For instance, Allergan's reported rate of swelling among patients fell from 23 percent in 2005 to 9 percent reported in 2011. Rates of scarring similarly fell from 8 percent to 4 percent.

"This again raises questions about the accuracy of reporting, and whether patients with complications were excluded from the 10-year sample," writes Zuckerman.

FDA staffers did not immediately respond to a request for comment Thursday. Representatives for J&J and Allergan also did not respond to requests for comment.

The questions about FDA's review of breast implants come amid a wave of recalls and warnings over similar devices across Europe and South America. The implants from French company Poly Implant Prothese are being pulled from the market amid fears they could rupture and leak silicone into the body.

French investigators say the now-defunct company used cheap industrial silicone, not medical-grade silicone, and that more than 1,000 women in France have had one or two implants burst. French health officials have agreed to pay for an estimated 30,000 women in France to have the implants removed.