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Media coverage of FDA breast implant update a total bust

By ACSH Staff — June 23, 2011

Ever since the FDA finally approved silicone gel breast implants in 2006, the procedure has grown in popularity; nearly 400,000 breast enlargement or reconstruction procedures were performed in the U.S. in 2010 alone. While confirming [1] that silicone gel-filled breast implants are safe and effective when used as intended, the FDA emphasized that women should fully understand the risks prior to considering silicone gel-filled breast implants for breast augmentation or reconstruction. The report noted that these implants are likely to need additional surgery within ten years to address what the FDA deemed to be frequent complications, which include: implant wrinkling, asymmetry, scarring, pain, and infection at the incision site.

But according to ACSH advisor Dr. Jack Fisher, professor emeritus of surgery and former head of the Division of Plastic Surgery at UC San Diego, the FDA continues to equate re-operation with complication; many women elect to return for some revision of surgery, like a minor scar revision which the FDA would list as a complication. Thus their frequent use of the word 'frequent.'

The FDA is working to revise safety labels for breast implants following a review of data from several post-approval studies that breast implant makers Allergan and Johnson & Johnson s Mentor were required by the agency to conduct. Preliminary two-year data was obtained for only 60 percent of the participants in one study, while data for only 21 percent of the study population was available in another review, but Dr. Fisher believes that demanding the study of 80,000 women represented an unprecedented invasion of privacy, explaining the large number of dropouts.

ACSH's Dr. Gilbert Ross is slightly confused as to why this lackluster story was covered so breathlessly by so many news media outlets in the first place; as he puts it, There is nothing new in this report, nothing that should be surprising to doctors or patients. He observes that women with breast implants, or those who are thinking about getting them, should be no more concerned about the procedure now than they were before reading this report. Any complications associated with the surgery should be discussed between the doctor and patient, since surgeons should be aware of all these well-known issues.

ACSH s Cheryl Martin points out that the report may simply have been released as an update on the post-market surveillance of breast implants, which the agency had itself mandated. This may have only amounted to a routine announcement, but the media probably got a little carried away with their coverage of the issue.

Links

[1] http://www.reuters.com/article/2011/06/22/us-fda-implants-idUSTRE75L3NA20110622