# Recent FDA Action
# Source: AUGS.org

In the summer of 2011, the FDA issued a Statement of Concern regarding the use of transvaginally placed mesh used to correct POP and stress urinary incontinence. The concern was based on a significant increase in reported complications from 2008 to 2010 as compared to the previous 5-year period. This information came from the Manufacturers and Users Device Experience (MAUDE) database, which is known to be under reported by surgeons who are not required by the FDA to report complications. Admittedly, this complication increase could be explained by the large increase in procedures performed (approximately 75,000 in 2010). The FDA also stated that their concern was increased because of some long-term, life-altering complications, such as chronic pain and sexual dysfunction.

The FDA also performed a review of research on these procedures and concluded that there was not enough evidence to support mesh use over existing native tissue repairs. They did admit that more benefit with mesh might be seen if the patient groups were followed for longer periods of time. All of the reviewed research was from one year post-surgery follow-up studies.

The FDA held an investigative public meeting in August 2011, which included presentations from women who had undergone the mesh procedures with good and bad outcomes, various “medical experts,” representatives from professional societies including ACOG, AUA, AUGS, SUFU, and SGS, representatives from the companies that manufacture and sell the mesh products, and other interested parties. Litigation attorneys were present.

An expert panel discussed the issues (pros and cons) and the FDA made its determinations. It was concluded that there was not yet enough data to support that, for these transvaginal mesh procedures for POP, risk was greater than benefit, and because there were many good outcomes and subgroups of patients who apparently had favorable stories to share that most of the mesh products should not be taken off the market. It was decided that the approval process for new mesh products would change and require that the manufacturers conduct and report on additional research for traditional repairs with longer durations of post-surgery follow up and that certain mesh products in existence would need varying degrees of research based on their outcomes. It was also recommended that placement of

transvaginal mesh for pelvic organ prolapse should be used cautiously by experienced surgeons with
extensive training in pelvic surgery.
On January 4, 2012, the FDA announced that they would be requiring additional research to address
specific safety and effectiveness concerns related to surgical mesh devices for POP and single-incision
mini-sling devices for stress urinary incontinence. The research collected from these studies will enable
the FDA to better understand the safety and effectiveness profiles of these devices. Updates on the
research will be available on the FDA website and made public as it becomes available.