ACOG Practice Advisory on the FDA's Order that All Manufacturers of Surgical Mesh Intended for Transvaginal Repair of Anterior Compartment Prolapse (Cystocele) stop Selling and Distributing their Products Immediately

On April 16, 2019, the U.S. Food and Drug Administration (FDA) ordered the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse (POP) to stop selling and distributing their products in the U.S. immediately.

It is important to note that the FDA announcement applies only to mesh placed vaginally to treat POP. The FDA order does **NOT** apply to transvaginal mesh for stress urinary incontinence. Additionally, the FDA order does not apply to mesh placed abdominally (sacrocolpopexy via laparotomy or endoscopy) for prolapse repair.

ACOG has followed this issue closely and first issued formal written comments supporting the reclassification (or "upclassification") of surgical mesh for transvaginal POP to a high-risk device at a 2011 meeting of the FDA's Obstetrics and Gynecology Devices Panel of the Medical Devices. More recently, ACOG provided expert testimony at the February 12, 2019 meeting of the FDA Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee on the risks and benefits of transvaginal placement of surgical mesh for POP. ACOG continues to support efforts to improve the safety and effectiveness of surgical options for women with pelvic organ prolapse. ACOG strongly supports continued audit and review of outcomes, as well as a registry for surveillance for all current vaginal mesh implants.

For more information on recommendations for the safe and effective use of vaginal mesh for the repair of POP, see Practice Bulletin #185, "Pelvic Organ Prolapse," developed jointly by ACOG and the American Urogynecologic Society and published in November 2017.

Additional information:

- **FDA press release (April 16, 2019)**: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm636114.htm
- **ACOG Committee Opinion #694, "Management of Mesh and Graft Complications in Gynecologic Surgery,"** developed jointly by ACOG and the American Urogynecologic Society (April 2017) https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Management-of-Mesh-and-Graft-Complications-in-Gynecologic-Surgery
- **AUGS/SUFU Position Statement: Mesh Midurethral Slings for Stress Urinary Incontinence (supported by ACOG)** https://www.augs.org/assets/1/6/AUGS-SUFU_MUS_Position_Statement.pdf
- **ACOG Patient Education FAQ, Surgery for Pelvic Organ Prolapse**: http://www.acog.org/Patients/FAQs/Surgery-for-Pelvic-Organ-Prolapse
- **ACOG video, Pelvic Organ Prolapse**: http://www.acog.org/Patients/Patient-Education-Videos/Pelvic-Organ-Prolapse

- **FDA Urogynecologic Surgical Mesh Implants webpage**: https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/urogynsurgicalmesh/