AUGS Issues Statement Opposing The Restriction Of Surgical Options For Pelvic Floor Disorders

The American Urogynecologic Society (AUGS), the leading professional organization dedicated to the treatment of pelvic floor disorders, issued a position statement today strongly opposing restrictions that ban surgical options for the treatment of pelvic organ prolapse (POP), including transvaginal surgical mesh cleared for use by the U.S. Food and Drug Administration (FDA). Individualized treatment decisions should be made between patients and their surgeons, with the goal of providing the patient with the best, most effective therapy based on each patient's specific clinical need.

POP is a condition that occurs when the normal support of the vagina is lost, resulting in sagging or dropping of the vagina, uterus, bladder and rectum. As the prolapse of the vagina and uterus progresses, women can feel bulging tissue protruding through the opening of the vagina. The FDA first cleared the use of transvaginal surgical mesh for the treatment of POP in 2002. During such surgeries, a piece of synthetic mesh is implanted through the vagina to support the prolapsed organs.

In July 2011, the FDA released a safety communication and white paper on transvaginal surgical mesh to highlight the potential benefits and risks associated with this therapy. Since that time, a few groups including a state medical organization, a healthcare system and a malpractice insurance company have considered restricting or have banned its use. Such restrictions were never the intent of the FDA safety communication nor do they represent the findings of the FDA Advisory Panel.

"Women should have all treatment options made available to them. The decision of what surgical option is right for a patient should be left between the patient and her surgeon without outside interference or limitations," said Anthony G. Visco , M.D., Division Chief of Urogynecology at Duke University Medical Center in Raleigh-Durham, N.C., and President of AUGS. "A ban on mesh would have a chilling effect on research in this area and would severely limit the advancement of science and future innovations that could significantly help women."

The AUGS position statement notes that it is essential for patients and their surgeons to have access to a full range of both non-surgical and surgical options and to have an open discussion during the informed consent process regarding the likely benefits as well as the potential risks of all options. In some instances, transvaginal mesh for POP may be the most appropriate surgical option, such as in high-risk patients with recurrent prolapse or those with medical conditions where a more invasive and lengthier procedure may be more dangerous.

AUGS is the leading professional organization dedicated to the treatment of pelvic

floor disorders, especially POP and stress incontinence, and its members are working closely with the FDA, the National Institutes of Health (NIH) and the American College of Obstetrics and Gynecology (ACOG) to develop robust mechanisms to continue to monitor the safety and effectiveness of transvaginal surgical mesh.

AUGS recently developed two credentialing guidelines for POP procedures, one for transvaginal mesh surgery and the other for sacrocolpopexy. These guidelines encourage hospitals and health systems to establish processes to credential and audit surgeons who perform these types of urogynecologic procedures. To achieve the best clinical outcome, it is important that surgeons are properly trained in these procedures. The AUGS credentialing guidelines provide specific recommendations for surgical training and ongoing maintenance of skills.

In addition to adopting the credentialing guidelines at the local and state levels, AUGS recommends the following over-arching strategies:

- Establish a broad group of trained pelvic floor reconstructive experts to review cases and complications of both mesh and non-mesh prolapse repair.
- Ensure appropriate resources and patient management systems are implemented to identify and manage both mesh and non-mesh related complications.
- Track both surgeons and specific products being implanted, as these may each influence efficacy and complications.
- Mandate a standardized informed consent process for mesh placement.

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