EXCERPTS from FDA REPORT on MESH

Part VI. RECOMMENDATIONS FOR PATIENTS

The FDA recommends that women considering surgery for pelvic organ prolapse:
Before surgery:

- Be aware of the risks associated with transvaginal POP repair.
- Know that having a mesh surgery may increase the risk for needing additional surgery due to mesh-related complications. In a small number of patients, repeat surgery may not resolve complications.
- Ask their surgeons about all POP treatment options, including surgical repair with or without mesh and non-surgical options, and understand why their surgeons may be recommending treatment of POP with mesh.

After surgery:

- Continue with annual and other routine check-ups and follow-up care. Patients do not need to take action if they are satisfied with their surgery and are not having complications or symptoms.
- Notify their health care providers if they develop complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after the last follow-up appointment.
- Let their health care providers know if they have surgical mesh, especially if planning to have another related surgery or other medical procedures.
- Talk to their health care providers about any questions or concerns.
- Ask their surgeons at their next routine check-up if they received mesh for their POP surgery if they do not know if mesh was used.

Part VII. RECOMMENDATIONS FOR HEALTH CARE PROVIDERS

The FDA encourages health care providers to:

- Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.
- Choose mesh surgery only after weighing the risks and benefits of surgery with mesh versus all surgical and non-surgical alternatives.
- Consider these factors before placing surgical mesh:
- Surgical mesh is a permanent implant that may make future surgical repair more challenging.
- A mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications.
- Removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain.
- Mesh placed abdominally for POP repair may result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
- Inform the patient about the benefits and risks of non-surgical options, non-mesh surgery, surgical mesh placed abdominally and the likely success of these alternatives compared to transvaginal surgery with mesh.
- Notify the patient if mesh will be used in her POP surgery and provide the patient with Information about the specific product used.
- Ensure that the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data.
- Continue to follow the recommendations provided in the 2008 PHN.

U.S. Food and Drug Administration

"EXCERPTS FROM FDA'S STATEMENT ON THE TRANS-VAGINAL PLACEMENT OF MESH."

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