Urogynecologic Surgical Mesh:

Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse

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July 2011

I. EXECUTIVE SUMMARY

In October 2008, the FDA issued a Public Health Notification (PHN) to inform clinicians and patients of adverse events related to urogynecologic use of surgical mesh, and to provide recommendations on how to mitigate risks and how to counsel patients. Following the *PHN*, the FDA continued to monitor the outcomes of urogynecologic use of surgical mesh. A search of the FDA's Manufacturer and User Device Experience (MAUDE) database from the last 3 years (January 1, 2008 - December 31, 2010), identified 2,874 Medical Device Reports (MDRs) for urogynecologic surgical meshes, including reports of injury, death, and malfunctions. Among the 2,874 reports, 1,503 were associated with pelvic organ prolapse (POP) repairs, and 1,371 were associated with stress urinary incontinence (SUI) repairs.

The FDA also conducted a systematic review of the scientific literature to learn more about the safety and effectiveness of POP and SUI using surgical mesh. The FDA determined that (1) serious adverse events are NOT rare, contrary to what was stated in the 2008 *PHN*, and (2) transvaginally placed mesh in POP repair does NOT conclusively improve clinical outcomes over traditional non-mesh repair.

The FDA is providing this update to advise the public and the medical community of complications related to transvaginal POP repair with mesh. The FDA plans to convene an advisory panel meeting of outside experts in September 2011 to discuss these findings and the types of clinical studies necessary to better assess the risks and benefits of using mesh to treat POP and SUI. In addition FDA is considering regulatory changes that may improve our understanding of the safety and effectiveness of this device.

The FDA continues to evaluate the effects of using surgical mesh for the treatment of SUI and will report about that usage at a later date.

II. OVERVIEW

Surgical mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists [1].

Surgical mesh has been used since the 1950s to repair abdominal hernias. In the 1970s, gynecologists began using surgical mesh products indicated for hernia repair for abdominal repair of pelvic organ prolapse (POP), and in the 1990s, gynecologists began using surgical mesh for surgical treatment of stress urinary incontinence (SUI) and transvaginal repair of pelvic organ prolapse (POP). To do so, surgeons cut the mesh to the desired shape and placed it through a corresponding incision. Over time, in response to a perceived demand in the surgical community, manufacturers developed mesh products specifically designed for SUI and POP. In 1996, the FDA cleared the first surgical mesh product specifically for use in SUI, and in 2002, the FDA cleared the first surgical mesh product specifically for use in POP. Over the next few years, surgical mesh products for transvaginal POP repair became incorporated into "kits" that included tools to aid in the delivery and insertion of the mesh. Surgical mesh kits continue to evolve, adding new insertion tools, tissue fixation anchors, surgical techniques, and absorbable and biologic materials.

Surgical mesh products are currently regulated as Class II devices and are reviewed under the 510(k) Premarket Notification Program. The FDA's premarket review of these devices has primarily focused on data supporting the adequacy of mechanical performance and material safety. Bench and/or animal testing have been used to confirm that engineering specifications are met and that the mesh material is biocompatible. Clinical performance data typically has not been used to support clearance for POP or SUI urogynecologic mesh products.

Surgical mesh materials can be divided into four general categories:

- non-absorbable synthetic (e.g., polypropylene or polyester)
- absorbable synthetic (e.g., poly(lactic-co-glycolic acid) or poly(caprolactone))
- biologic (e.g., acellular collagen derived from bovine or porcine sources)
- composite (i.e., a combination of any of the previous three categories)

Most surgical mesh devices cleared for urogynecologic procedures are composed of non-absorbable synthetic polypropylene.

Surgical Mesh for Urogynecologic Procedures

Surgical mesh can be used for surgical repair of SUI and POP. SUI affects an estimated 20-40 percent of women [2]. Treatment may be conservative (such as exercise to strengthen the pelvic floor muscles) or surgical. Surgical repair of SUI can be performed through an abdominal incision, using sutures (Burch urethropexy), or through a vaginal incision, by placing a biologic or synthetic "sling" (e.g., surgical mesh) under the urethra to help prevent urinary loss during physical activity.

Following promising continence outcomes using surgical mesh slings for SUI repair, surgeons began using surgical mesh to augment transvaginal POP repairs. POP occurs when the pelvic floor tissues that hold the pelvic organs in place become weakened or stretched, often from childbirth (see **Figure 1** for normal anatomy). This causes the pelvic organs to bulge (or

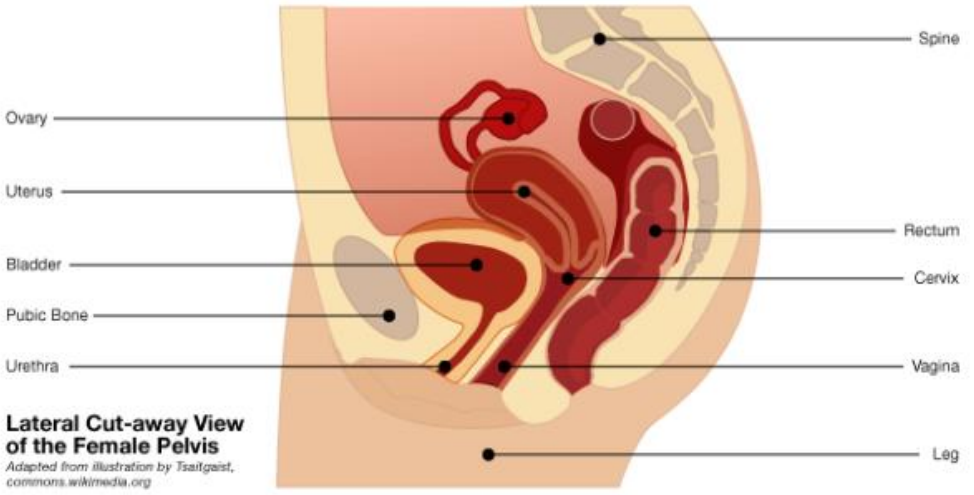


Figure 1.

prolapse) into the vagina. The pelvic organs sometimes prolapse past the vaginal opening, and more than one pelvic organ can prolapse at the same time. The organs involved in POP may include the bladder (cystocele) (**Figure 2**), the uterus (procidentia) (**Figure 3**), the rectum (rectocele) (**Figure 4**), the top of the vagina (apical prolapse) or the bowel (enterocele).

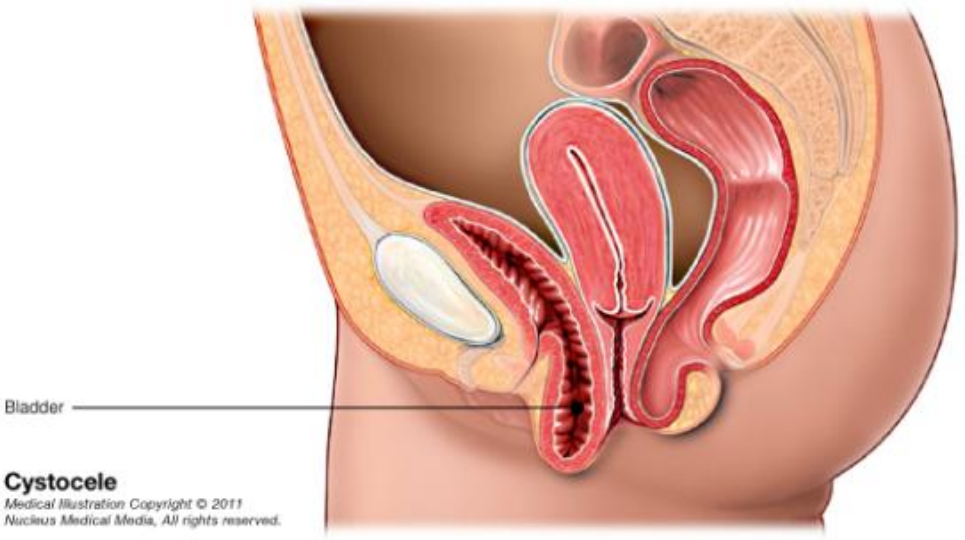
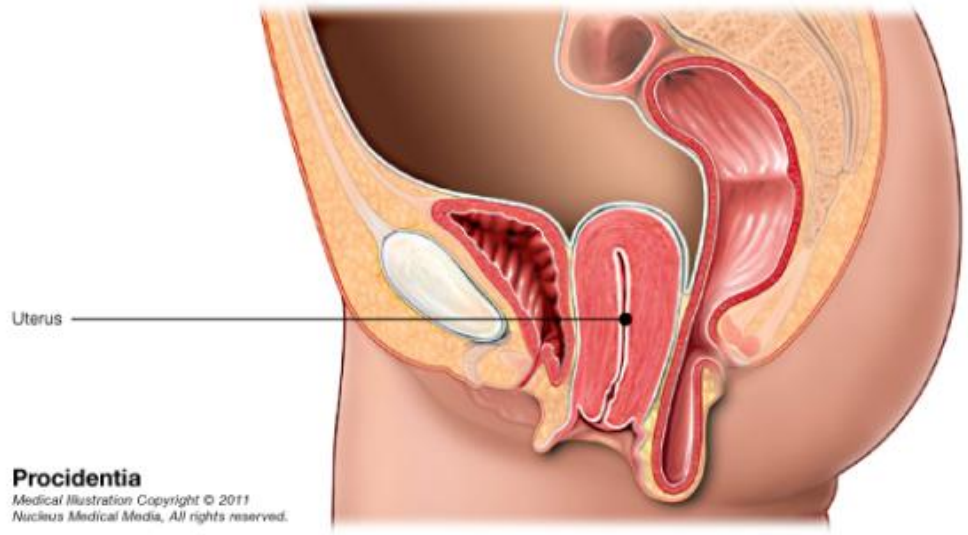


Figure 2.



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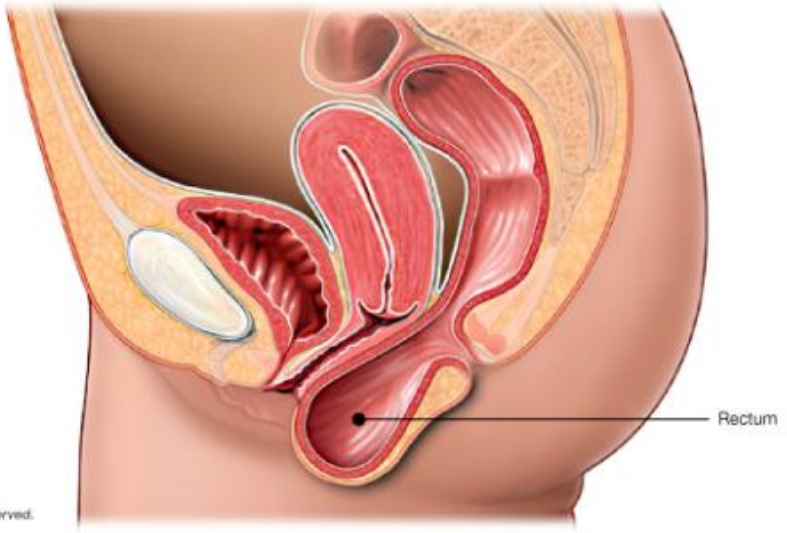

Figure 4.

Some women do not have symptoms from POP, but for others, POP may negatively impact the quality of life by causing pelvic discomfort and interfering with sexual, urinary and defecatory function, as well as other daily activities.

A woman's estimated lifetime risk of POP is 30-50 percent, with 2 percent of women becoming symptomatic [3]. Symptomatic POP can be managed conservatively with either pelvic floor muscle exercises or vaginal inserts to support the prolapsing tissue (pessaries). Surgical correction is also an option, although not all women will have long-term improvement in symptoms from traditional surgical correction without mesh [4]. In total, women have an estimated 11 percent lifetime incidence of surgery to repair POP or SUI [4].

The placement of surgical mesh is intended to increase the longevity of POP repairs. In general, mesh products for POP repair are configured to match the anatomical defect they are designed to correct. Mesh can be placed in the anterior vaginal wall to aid in the correction of cystocele (anterior repair), in the posterior vaginal wall to aid in correction of rectocele (posterior repair), or attached to the top of the vagina to correct uterine prolapse or vaginal apical prolapse (apical repair). Surgical mesh can also be placed through the abdomen (transabdominally) to correct apical prolapse. This latter procedure is known as sacral colpopexy and was described using prosthetic slings in 1974. High success rates were reported in the 1980s [30], and sacral colpopexy has become accepted in the gynecologic community as an effective surgical means to correct POP.

Market data from manufacturers indicate that in 2010 approximately 300,000 women underwent surgical procedures in the United States to repair POP and approximately 260,000 underwent surgical procedures to repair SUI. According to industry estimates, approximately one out of three POP surgeries used mesh, and three out of four of the mesh POP procedures were done transvaginally. For SUI surgeries, over 80 percent were done transvaginally with mesh.

III. SUMMARY OF ADVERSE EVENT REPORTS

The FDA conducted a search of the Manufacturer and User Device Experience (MAUDE) database for medical device reports (MDRs) of adverse events associated with all urogynecologic surgical mesh products received from January 1, 2005 - December 31, 2010. The search identified 3,979 reports of injury, death, and malfunction. Among the 3,979 reports, 2,874 reports were received in the last 3 years (January 1, 2008 - December 31, 2010), and included 1,503 reports associated with POP repairs and 1,371 associated with SUI repairs. The number of MDRs associated with POP repairs increased by more than 5-fold compared to the number of reports received in the previous 3 years (January 1, 2005 - December 31, 2007).

Multiple factors can affect MDR reporting, including increased use of urogynecologic surgical mesh in the clinical community, increased awareness on the potential adverse events associated with mesh after the 2008 *PHN*, an increased number of new POP meshes on the market, or an increase in the number of actual adverse events associated with mesh. Determining the exact cause or causes of the increase is difficult. Regardless, the FDA believes the overall increase in the number of serious adverse event reports is cause for concern.

From 2008 to 2010, the most frequent complications reported to the FDA from the use of surgical mesh devices for POP repair included vaginal mesh erosion (also called exposure, extrusion or protrusion), pain (including painful sexual intercourse known as dyspareunia), infection, urinary problems, bleeding, and organ perforation. There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage and emotional problems. Many of the MDRs cited the need for additional intervention, including medical or surgical treatment and hospitalization. Vaginal shrinkage was not reported in the previous three year period corresponding to the 2008 *PHN*.

Between 2008 and 2010, there were seven reported deaths associated with POP repairs. Follow-up investigation on the death reports revealed that three of the deaths associated with POP repair were related to the mesh placement procedure (two bowel perforations, one hemorrhage). Four deaths were due to post-operative medical complications not directly related to the mesh placement procedure.

IV. REVIEW OF THE LITERATURE

Due to ongoing concerns in the clinical community and the safety signals identified from adverse event reports, the FDA evaluated the peer-reviewed scientific literature to revisit the fundamental questions of safety and effectiveness of surgical mesh for POP and SUI. The literature presented in this document includes all relevant randomized controlled trials (RCTs), all relevant systematic reviews, and a subset of observational studies that presented data on adverse events associated with transvaginal repair of POP using mesh from January 1996 through April 2011. The FDA continues to evaluate the literature for SUI surgeries using surgical mesh and will report on that usage at a later date.

Safety

The literature review identified the following safety concerns with transvaginally placed surgical mesh for POP repair:

- Patients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh [7-9, 15, 16, 19-24].

- Adverse events associated with transvaginally placed mesh can be life-altering for some women [13, 14, 17]. Sequelae (e.g., pain) may continue despite mesh removal.

- Mesh-associated complications are not rare. The most common mesh-related complication experienced by patients undergoing transvaginal POP repair with mesh is vaginal mesh erosion [7-9, 15, 16, 19-24]. Based on data from 110 studies including 11,785 women, approximately 10 percent of women undergoing transvaginal POP repair with mesh experienced mesh erosion within 12 months of surgery [23].

- More than half of the women who experienced erosion from non-absorbable synthetic mesh required surgical excision in the operating room. Some women required two to three additional surgeries [23].

- Mesh contraction, causing vaginal shortening, tightening, and/or vaginal pain in association with transvaginal POP repair with mesh, is increasingly reported in the literature [13, 17].

- New onset SUI has been reported to occur more frequently following mesh augmented anterior repair compared to traditional anterior repair without mesh [12].

- Transvaginal surgery with mesh to correct vaginal apical prolapse is associated with a higher rate of complication requiring reoperation and reoperation for any reason compared to traditional vaginal surgery or sacral colpopexy [20].

- Abdominal POP surgery using mesh (sacral colpopexy) appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh, with the median vaginal mesh erosion rate reported at 4 percent within 23 months of surgery [22].

Effectiveness

The literature review found that while transvaginal POP repair with mesh often restores anatomy, it has not been shown to improve clinical benefit over traditional non-mesh repair, as evidenced by the following key findings:

- Transvaginal apical or posterior repair with mesh does not appear to provide any added benefit compared to traditional surgery without mesh [5-8, 18, 22, 24].

- Only two RCTs compared multi-compartment repair (including apical repair) with mesh to traditional repair, and neither found a significant improvement in effectiveness with

mesh augmentation [7, 8]. A systematic review of vaginal mesh kits for apical repair found they appear effective in restoring apical prolapse in the short-term, but long-term outcomes are unknown [21].

- Although one RCT showed anatomic benefit for posterior repair with mesh, mesh subjects in the trial had less posterior prolapse at baseline than subjects who underwent traditional repair [8]. Three other RCTs that have evaluated mesh augmentation in the posterior compartment did not show an anatomic benefit from using mesh [5, 6, 7].

- There does appear to be an anatomic benefit to anterior repair with mesh augmentation [5, 8, 9-12, 18, 19, 22, 24]. This anatomic benefit may not result in superior symptomatic outcomes or lower rates of repeat surgery for recurrent prolapse compared to traditional POP repair without mesh [26].

- Patients who undergo traditional POP repair without mesh have equivalent improvement in quality of life when compared to patients who undergo transvaginal POP repair with mesh [5, 8, 9, 11].

- Compared to traditional vaginal surgery without mesh, abdominal apical prolapse repair with mesh (sacral colpopexy) results in less recurrent prolapse, although it has not been shown to reduce the rate of repeat surgery for recurrent prolapse [22].

Limitations of Existing Literature

The existing literature has several important methodologic limitations that impact the interpretation of the available data, including:

- The majority of studies use an effectiveness outcome that pertains to ideal pelvic support, which is not necessary for most women to achieve symptomatic relief [26];

- Results reflect both primary and repeat prolapse repairs;

- In most studies subjects undergo various additional POP procedures and/or combined POP-SUI procedures;

- Adverse events are inconsistently defined and reported;

- Many studies are poorly designed and/or conducted, are underpowered, use incompletely documented inclusion/exclusion criteria, have inadequate evaluator masking, and fail to account for variable lengths of patient follow-up; and

- Very few studies extend past 2 years.

V. SUMMARY OF KEY FINDINGS

Based on evaluation of adverse event reports and assessment of the scientific literature, the FDA has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves

clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk.

In particular, these products are associated with serious adverse events, including vaginal mesh erosion (also called exposure, extrusion or protrusion), a complication which can require multiple surgeries to repair and may result in continued sequelae (e.g., pain) even after mesh removal. Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair, particularly for transvaginal apical and posterior repair. While the literature suggests an anatomic benefit to anterior repair with mesh augmentation, this anatomic benefit may not result in superior clinical outcomes, and the associated risk of adverse events should be considered.

Based on these findings, the FDA is considering regulatory changes that may improve our understanding of the safety and effectiveness of these devices and has specific recommendations for patients and healthcare providers below.

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.

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*.

VIII. FDA ACTIVITIES

Safety Communication

The FDA is issuing a new FDA *Safety Communication* that provides an update to the 2008 FDA *PHN*. The *Safety Communication* focuses on transvaginal POP repair with mesh. The objective of the *Safety Communication* is to inform health care providers and patients that the risks of serious complications associated with transvaginal POP repair with mesh are NOT rare, contrary to what was stated in the 2008 *PHN*. This updated communication identifies vaginal shortening, tightening, and/or pain due to mesh contraction as a previously unidentified risk of transvaginal POP repair with mesh, and it provides recommendations for patients and health care providers.

Consideration of Regulatory Changes

The FDA is considering regulatory changes that may improve our understanding of the safety and effectiveness of this device. Considerations include:

- A change in risk classification of mesh used for transvaginal POP repair from Class II to Class III, which would require manufacturers to submit premarket approval applications, including relevant clinical data for these devices.

- Clinical studies to address the risks and benefits of mesh used to treat POP and SUI.
- Expanded post-market monitoring of device performance.

Advisory Meeting

On September 8-9, 2011, the FDA will convene a meeting of the Obstetrics-Gynecology Devices Panel of the Medical Devices Advisory Committee to discuss the safety and effectiveness of transvaginal placement of mesh for POP and SUI procedures. A notice of this meeting was published in the Federal Register.

IX. HOW TO REPORT INFORMATION TO THE FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. The FDA encourages health care professionals and consumers to report suspected problems with surgical mesh to the FDA by filing a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. Device manufacturers must comply with the Medical Device Reporting (MDR) regulations.

X. CONCLUSION

The FDA has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse (POP) based on a review of adverse events reported to the FDA and an assessment of the scientific literature.

In addition to providing an updated FDA *Safety Communication* to promote understanding of the risks associated with transvaginal POP repair using surgical mesh and to encourage informed decision-making by patients and health care providers about the use of mesh, the FDA will convene an Advisory Panel of outside experts to consider clinical studies that may improve our understanding of the safety and effectiveness of urogynecologic mesh.

XI. SOURCES

1. "Surgical Mesh." 21 CFR 878.3300(a). 2010. Print.
2. Kane AR and Nager CW. *Midurethral Slings for Stress Urinary Incontinence.* Clinical Obstetrics and Gynecology. 2008; 51(1): 124-135.
3. Samuelsson EC, et al. *Signs of genital prolapse in a Swedish population of women 20 to 59 years of age and possible related factors.* Am J Obstet Gynecol. 1999; 180(2 Pt 1): 299-305.
4. Clark AL, et al. *Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence.* Am J Obstet Gynecol. 2003; 189(5): 1261-1267.
5. Sand PK, et al. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Am J Obstet Gynecol. 2001; 184(7): 1357-64.
6. Carey M, et al. Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial. BJOG. 2009; 116(10): 1380-6.
7. Iglesia CB, et al. Vaginal mesh for prolapse: a randomized controlled trial. Obstet Gynecol. 2010; 116(2 Pt 1): 293-303.
8. Withagen MI, et al. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. Obstet Gynecol. 2011; 117(2 Pt 1): 242-50.
9. Nieminen K, et al. Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up. Am J Obstet Gynecol. 2010; 203(3): 235 e1-8.
10. Sivaslioglu AA, et al. A randomized comparison of polypropylene mesh surgery with site-specific surgery in the treatment of cystocoele. Int Urogynecol J Pelvic Floor Dysfunct. 2008; 19(4): 467-71.
11. Nguyen JN and Burchette RJ. Outcome after anterior vaginal prolapse repair: a randomized controlled trial. Obstet Gynecol. 2008; 111(4): 891-8.
12. Altman D, et al. *Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse.* N Engl J Med. 2011; 364:1826-36.
13. Caquant F, et al. Safety of Trans Vaginal Mesh procedure: retrospective study of 684 patients. J Obstet Gynaecol Res. 2008; 34(4): 449-56.
14. Aungst M, et al. De novo stress incontinence and pelvic muscle symptoms after transvaginal mesh repair. Am J Obstet Gynecol. 2009; 201: 73e1-7.
15. Rardin, C, et al. New considerations in the use of vaginal mesh for prolapse repair. J Minim Invasive Gynecol. 2009; 16(3): 360-4.
16. Miller D, et al. Prospective clinical assessment of the transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse – 5 year results. FPMRS. 2011; 17: 139-143.
17. Feiner B, et al. Vaginal mesh contraction: definition, clinical presentation, and management. Obstet Gynecol. 2010; 115(2 Pt 1): 325-30.
18. Jia X et al. *Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis.* BJOG 2008; 115: 135-1361.
19. Foon R et al. *Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications.* Int Urogynecol J 2008; 19: 1697–1706

20. Diwadkar GB, et al. *Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review.* Obstet Gynecol. 2009; 113(2 Pt 1): 367-73.
21. Feiner B et al. *Efficacy and safety of transvaginal mesh kits in the treatment of prolapse of the vaginal apex: a systematic review*. BJOG 2009; 116: 15–24.
22. Maher C, et al. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev. 2010; (4): CD004014.
23. Abed et al, *Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review*. Int Urogynecol J, 2011.
24. Sung VW et al, *Society of gynecologic surgeons systematic review group. Graft use in transvaginal pelvic organ prolapse and urinary incontinence.* Obstet Gynecol. 2008; 112(5): 1131-1142.
25. Jia X et al, *Systematic review of the efficacy and safety of using mesh in surgery for uterine or vaginal vault prolapse.* Int Urogynecol J. 2010; 21:1413–1431
26. Chmielewski L, Walters MD, Weber AM, et al. *Reanalysis of a randomized trial of 3 techniques of anterior colporrhaphy using clinically relevant definitions of success.* Am J Obstet Gynecol 2011;205:69.e1-8.
27. Lefranc JP, Blondon J. *Surgery of genital prolapse using the abdominal approach. Experience of the surgery and gynecology department at the Salpetriere Hospital.* J Chir Paris 1983;120(8–9):431–6.

XII. GLOSSARY OF TERMS USED IN THIS DOCUMENT

Anterior repair	surgical repair to correct weakened tissue between the bladder and vagina
Apical repair	surgical repair to correct prolapse of the top of the vagina
Colostomy	surgical procedure in which the healthy end of the large intestine or colon is brought through the anterior abdominal wall to provide an opening for feces to leave the body instead of the rectum
Colporrhaphy	surgical correction of the vagina
Cystocele	prolapse of the bladder into the vagina
Dyspareunia	painful sexual intercourse
Federal Register	the official daily publication for rules, proposed rules, and notices of federal agencies and organizations, as well as executive orders and other presidential documents.
Mesh erosion	mesh that wears through ("erodes") tissue and becomes exposed, also called exposure, extrusion or protrusion
Morbidity	diseased state, disability, or poor health
Pelvic organ prolapse (POP)	bulge of organs/structures surrounding the vagina into the vagina or extending beyond the vaginal opening, caused by laxity of supporting tissue of the vagina
Posterior repair	surgical repair to correct prolapse of the tissue between the vagina and rectum
Procidentia	prolapse of the uterus
Rectocele	prolapse of the rectum
Sacral Colpopexy	surgical correction of vaginal apical prolapse (via abdominal or laparoscopic route) in which mesh is attached to the vaginal apex on one end and the sacrum on the other
Stress Urinary Incontinence (SUI)	leakage of urine during moments of physical activity
Vaginal apex	top of the vagina