Commentary on the FDA Safety Communication released July 13

On July 13, 2011, the FDA issued a safety communication update, intending to inform patients and healthcare providers that "serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse are not rare". Subsequent to that release, there has been an explosion of media and litigatoryexploitation of this subject and unfortunately has placed inappropriate targets of controversy onto many of the procedures that have proven safety and are the current standards of care in our field of expertise. This commentary is meant to provide our patients with an understanding of the position of Dr. Babin and Dr. McKinney at Athena Women's Institute for Pelvic Health. It is our position that vaginal mesh augmentation is a valuable option in specific circumstances and one that the women we treat deserve to have available to them. It is also our position that the use of mesh augmentation in sacralcolpopexy and incontinence are the current proven standard of care. The American Urogynecologic Society in its response to the FDA notification states "No one approach for mesh placement has been proven to be superior in all cases and there may be particular circumstances when the placement of transvaginal mesh is appropriate", therefore they too support the use of mesh in prolapse surgery. Both doctors Babin and McKinney have used mesh for many years in their practice with excellent outcomes and have reported many of their results in the peer reviewed medical journals and will continue to use mesh when indicated, with the appropriate informed consent of potential risks as well as alternatives. Without it, they could not get the cure rates they do and they have seen no increase in overall complications when compared to "traditional" surgery without mesh. They support the FDA notification in regards to patients being adequately informed, given all risks/benefits and alternative choices and ensuring that surgeons have adequate training and experience that are performing these procedures. They make themselves readily available to their colleagues and patients to assist with any issues or concerns regarding mesh complications secondary to their extensive expertise in the field. They continue to partner with other thought leaders in the field of Female Pelvic Medicine to pursue additional research to fully understand the value and risks of all newer surgical procedures.

The FDA's safety communication regarding mesh placed vaginally for pelvic organ prolapse (i.e. cystocele, rectocele and vaginal vault prolapsed) reported on complications arising after placement of surgical mesh through a vaginal approach to treat patient for pelvic organ prolapse over the past several years. The notification reported on 1,503 complicationsover the past 3 yrs which is less that 1% of the procedure involving placement of vaginal mesh. They noted that mesh placed transvaginally was associated with adverse events including erosion through the vaginal tissue, pain, infection, bleeding, pain with intercourse, organ perforation during the surgery and urinary and bowel problems. Many of these complications may require further surgery and may not resolve with further surgery. They stated that there has been an increase in complications reported due to more mesh surgery being completed. The Safety Communication pertains to the transvaginal placement of mesh for treatment of pelvic organ prolapsed and NOT the gold standard use of mesh placed abdominally or laparoscopically (i.e.

sacralcolpopexy) for prolapse or mesh used in slings for urinary leakage. They concluded that most cases of prolapse may not need mesh to successfully treat prolapse such that the risk of mesh could potentially be eliminated. It is important to understand that this conclusion is a very controversial one. It certainly depends on what "most" means, i.e. most surgeons who treat advanced prolapse, recurrent prolapse, and patients at high risk of failure from "traditional" surgery would not agree with this statement as research has shown a MUCH higher cure rate with mesh in these groups.

The development of vaginal mesh kits for surgical management of prolapse came about as an extension of other highly successful procedures involving mesh, including the Sacral Colpopexy (abdominal placement of mesh), the TVT sling (mesh sling for treatment of SUI), as well as the use of mesh in general surgery for the treatment of abdominal mesh hernias. At the present time, the use of mesh to treat stress urinary incontinence by placing a thin band of mesh beneath the mid-urethra and exiting either behind the pubic bone (egretropubic mid urethral sling) or through the thigh (egobturator sling) are considered the standard of care and research over the pass two decades have shown that they are both safe and effective. Likewise, as mentioned above, the use of a polypropylene mesh attached to the vaginal walls through an abdominal incision and attached to the sacrum (just above the tailbone), during a procedure known as a Sacral Colpopexy has been an accepted treatment for pelvic organ prolapse for over 50 years.

There has been, understandably, a significant amount of confusion and misunderstanding about pelvic floor mesh in general since the FDA report. It is important for patients to understand the differences between the various procedures involving mesh, especially since many of the gold standard operations include the use of extensively tested mesh as mentioned above. It is equally as important to understand that the FDA did not take the mesh off the market, nor did it recall any of the mesh products. It was a Notification to patients and surgeons that these complications were being reported and to suggest a more intensive evaluation of use. NO surgery is risk free. Prolapse and Incontinence surgery without mesh carries very similar risks to surgery with mesh only with the addition of higher failure rates. Afterall, this same mesh has been utilized in abdominal hernia repairs and routine suture materials for many decades with a good safety profile. Therefore, this shows that it is NOT the mesh that is the problem, it is how it is placed, in whom it is placed and how it heals once in place. The SAME exact mesh is used in these procedures on the same vaginal tissues and it has been shown to have minimal risk of infection, rejection and is very well tolerated and gives the benefit of higher cure rates compared to non-mesh surgery. There are multiple published studies totaling thousands of patients that show excellent results with minimal complications when mesh is placed vaginally for prolapse;however, all of these studies were completed by very experienced surgeons and surgical experience seems to be KEY in good outcomes and minimizing complications. Prolapse surgery, whether mesh is used or not, is advanced surgery and extra training and expertise is critical to obtaining good outcomes in patients.

Over the past several years many companies have made mesh "kits" for prolapse surgery and trained many new surgeons on their use; therefore, the numbers of these surgeries being performed escalated quickly and in many cases by non-specialists. It is important to remember that even in the most experienced hands complications of surgery arise but in fewer percentages of patients. Recently, there were modifications and improvements to the kits such as eliminating external needle passes through the

groin and buttock and making the mesh lighter and less reactive in the tissue and these improvements have helped resolve many of the issues surrounding mesh augmentation. The FDA and societies such as the American Urogynecology Society (AUGS) have recommended improved training, credentialing and monitoring by hospitals and departments on who should be completing these procedures, which will also help decrease complications. The American Association of GynecolgicLaparoscopists (AAGL, a leading organization in the field of Gyn Surgery) recently issued a statement in response to the FDA notification which is very consistent our views while also challenging some of the FDA's findings. They feel that in the conclusions the FDA did NOT take into the most critical factor in surgical outcomes, i.e. surgical experience and that the FDA also did not include many studies in the literature that showed excellent outcomes with mesh that were completed by very experienced surgeons.

Athena Women's Institute for Pelvic Health maintains a large patient database of women in whom we have performed these procedures, and we are continually reviewing our results. Our physicians have been and continue to be involved in clinical research in this area. In general, our data suggests a largely positive experience, and high patient satisfaction. We are diligent to report any unusual problems directly to the FDA.. In our opinion, our research should focus on proper patient selection, how best to get surgeonsappropriate training , as well as identifying optimal anchor points for the mesh procedures.

Finally, Dr. Babin and Dr. McKinney are experts not only in the placement of vaginal mesh but in the evaluation and management of women who have experienced complications from transvaginal mesh procedures, including the surgical revision or removal of such devices. If you are such a women, we would encourage you to schedule an appointment with one of our physicians for a consultation regarding your treatment options.