Vigna Law Group Position Statement: FDA WAS DUKED on risks of mid-urethral slings

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SANTA BARBARA, CA, UNITED STATES, November 9, 2022 /EINPresswire.com/ -- “Despite mid-urethral slings entering the United States market in 1998 the FDA has been fed deceptive studies that were designed to miss the long-term complications that result in vaginal, groin, and abdominal dissection to remove the injury causing plastic mesh. Well, the long-term complication risks are in, and they are bad for the women in the United States and the World. All we can do is sue the manufacturers and the doctors who implant them. That is what we are doing” ...Greg Vigna, MD, JD, National Pharmaceutical Injury Attorney

> All we can do is sue the manufacturers of these devices and the doctors who implant these devices. Merely picking these devices off the shelf is malpractice. ”
>
> *Greg Vigna, MD, JD*

April 16, 2019 FDA: Considerations about Surgical Mesh for SUI

1) “Erosion of mesh slings through the vagina is the most commonly reported mesh-specific complication from SUI surgeries with mesh”

2) “The safety and effectiveness of mini-slings for female SUI have not been adequately demonstrated. Presently, it is unclear how mini-slings compare to multi-incision slings with respect to safety and effectiveness for treating SUI”

3) The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year.

4) The long-term complications of surgical mesh sling repair for SUI that are reported in the literature are consistent with the adverse events reported to the FDA.

5) Longer follow-up data is available in the literature, but there are fewer of these long-term studies compared to studies with one-year follow-up.

Facts:

At 15-years, the most common indications for surgery to remove the mesh are for complications

that involve pain, EROSION INTO ORGANS, EROSION INTO THE URETHRA, FISTULAS, and other serious complications other than for EROSION INTO VAGINA or for URINARY RETENTION. (Female Pelvic Medicine & Reconstuctive Surgery, Volume 28, Number 4, April 2022)
14.9% of women have pain in the groin or thigh after standard mid-urethral slings at three years, with 4.6% requiring any type of painkiller (New England Journal of Medicine, 386; 13, March 31, 2022)
14.1% of women have pain in the groin or thigh after single-incision mini-slings at three years, with 7.6% requiring any type of painkiller (New England Journal of Medicine, 386; 13, March 31, 2022)

Mini-slings Dyspareunia was reported in 11.7% in the mini-sling group compared with 4.8% in the mid-urethral sling group. (New England Journal of Medicine, 386; 13, March 31, 2022)

Vigna Law Group Position: FDA was duked as to the rate of complications

-There are no rates mentioned in the FDA Statement past 1-year because of the utter lack of reliable studies provided by manufacturers as their studies were at best Mickey Mouse.

-Ongoing registries for the newly implanted women are required for the safety of women because of the ongoing failure of defense manufacturers to provide reasonable post-market surveillance of their products and reasonable clinical testing of their products. Mickey Mouse studies of the past are over.

-Women must be appraised in writing of the risk at 7.9% at 15-years to require surgically remove all or a portion of the mesh for complications at this rate of risk is increasing; half of these surgeries are after two years; multiple surgeries may be required for management of complications; and outcomes include disabling pain and substantial impairment of sexual function which are not uncommon.

Greg Vigna, MD, JD concludes, “All we can do is sue the manufacturers of these devices and the doctors who implant these devices. Merely picking these devices off the shelf is malpractice. There is plenty of data in the complaint files in the Multidistrict Litigation and it is time for these files to be opened to review. Manufacturers had reasons to know as to the frequency, severity, and latency of complications that require surgical removal of these devices from unknowing women. Manufacturers failed to provide adequate warning for women across the world for monetary gain. Doctors are on the hook as well as there is plenty of data in the public purview.”

Symptoms of neurological injury from mid-urethral slings include:
1) Groin pain
2) Hip pain
3) Inability to wear tight pants
4) Clitoral pain or numbness

5) Severe pain that makes vaginal penetration impossible
6) Tailbone pain
7) Anorectal pain
8) Painful bladder
9) Pain with sitting

Dr. Vigna is a California and Washington DC lawyer who focuses on catastrophic injuries and the neurological injuries caused by transvaginal mesh devices including pudendal neuralgia, obturator neuralgia, ilioinguinal neuralgia, and complex regional pain syndrome. Ben Martin and Laura Baughman are national pharmaceutical injury attorneys in Dallas, Texas.

To learn more on the anatomical basis for TOT complications including obturator and pudendal neuralgia and the treatments of obturator and pudendal neuralgia click here.

Read our FREE BOOK on Vaginal Mesh Pain.

For articles, video resources, and information visit the Pudendal Neuralgia Educational Portal or visit https://tvm.lifecare123.com/.

Click the following link for information regarding sling related complications:
https://tvm.lifecare123.com/slingebook.html

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