TVM Manufacturers' Temporary Reprieve from Losses via Safer Alternative Design

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Dr. Greg Vigna

SANTA BARBARA, CA, UNITED STATES, September 11, 2020 /EINPresswire.com/ -- A majority of jurisdictions across the country requires evidence that a feasible safer alternative design existed that would have prevented the alleged injury or substantially reduced the risk in order for a victim to prevail on a design defect theory. This is referred to as the safer alternative design in product liability law. If there is no evidence of a safer alternative design, or if evidence of a safer alternative design is rejected by the court, the Plaintiff can still succeed in their claim if there is proof that the manufacturer failed to provide reasonable warnings of a foreseeable risk of harm in the Instructions for Use—sometimes called the IFU or product label.

Ethicon and other manufacturers of the transvaginal mesh devices are having occasional success in pretrial motions as cases with erosion type injuries that have been remanded from the Transvaginal Mesh (TVM) Multidistrict Litigation in West Virginia are occasionally being lost at the Summary Judgment stage of the litigation. The courts in these cases are sometimes disregarding evidence of a safer alternative polypropylene mesh design that would have prevented the erosion type of injury or reduced the risk of injury.

The above scenario is exemplified in Willet v. Johnson & Johnson & Ethicon. In that case Ms. Willet was referred to Dr. Michael Woods, a pelvic floor surgeon and consultant for Ethicon, who implanted the Prosima device to treat Ms. Willet's pelvic organ prolapse (POP). Injuries included an erosion into the bladder and a total of 13 procedures was endured by Ms. Willet for complications related to the device. Dr. Zipper, the Plaintiff's expert, in his expert report offered a safer alternative design that included allographs (biological grafts), native tissue repair, and a Prosima device made with Ultrapro (Prosima-M) which is a lighter, larger pore mesh than the mesh used in Prosima. The Court ruled that native tissue repair and allographs are not relevant as they do not represent an alternative design because native tissue repair is a different

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procedure and the allograph wasn't a different design but a different product. As it relates to the Prosima-M, the Court ruled that Dr. Zipper's opinion regarding using Ultrapro as a safer alternative design was not reliable as there was a "complete lack of scientifically adequate evidence to support a reliable expert opinion."

This was a fatal blow to the Plaintiff's case given that the failure to warn regarded an erosion injury that was warned of in the IFU and Dr. Woods testified that Prosima "worked" for his patients.

Greg Vigna, MD, JD, national pharmaceutical injury attorney, practicing physician, and Certified Life Care Planner, "This is a brutal outcome given that no POP device is on the market at this time after being banned by the FDA on April 16, 2019. Our position is much different in case in which we represent victims of neurological injury. These neurological complications are specific to each device and these injuries are usually far more serious than erosion injuries. There are several safer alternative polypropylene devices to prevent these specific injuries. We believe these devices are also trash devices but we legally may be required to differentiate one trash device from another given the difference in the severity and frequency of catastrophic injuries they cause."

Most courts that require a safer alternative design will look at the feasibility or reasonableness of an alternative design by looking at the following factors: 1) The usefulness and desirability of the product, 2) The magnitude and probability of the foreseeable risks of harm, 3) The type and quality of the instructions and warnings accompanying the product, 4) The nature and strength of consumer expectations, 5) The advantages and disadvantages of the product as it was alternatively designed, 6) The cost of the alternative design, 7) The effects of the alternative design on longevity, maintenance, repair, and aesthetics, 8) The technological feasibility, 9) The safety of the alternative design, and 10) The alternative design protects against the type of harm suffered by the plaintiff and the harm imposed on the community as a whole.

Dr. Vigna adds, "To date we haven't lost a failure to warn claim for our neurologically injured clients even when faced with implanters who are paid consultants. The failure to warn claims are very strong in earlier implant cases from the Multidistrict Litigation as the warnings were so inadequate. They still are inadequate.

Dr. Vigna concludes, "We believe that by focusing on the neurological injuries and representing only the most injured, we can prevent the already artificial safer alternative design landmines resulting in cases being thrown out on Summary Judgment. We aim to get to verdict for our clients on the design defect claim understanding that we still believe we have a viable failure to warn claim on the specific neurological injury even with new implant cases. There is a roadmap

for litigating transobturator (TOT) slings, mini-slings that insert into the obturator membrane and retro public slings. That said, experts are differentiating between devices as to the risk and magnitude of neurological injuries they are known to cause."

The Vigna Law Group targets the below TOT slings and mini-slings that cause pudendal and obturator neuralgia:

Ethicon: TVT-O, Abbrevo
Boston Scientific: Obtryx, Solyx
Coloplast: Aris, Altis

The Vigna Law Group targets the below retropubic slings that cause ilioinguinal neuralgia and Complex Regional Pain Syndrome:

Boston Scientific: Advantage Fit
Ethicon: TVT, TVT Exact
Coloplast: Supris

Dr. Vigna is a California and Washington DC lawyer who focuses on catastrophic neurological injuries caused by transvaginal mesh devices including pudendal neuralgia, obturator neuralgia, ilioinguinal neuralgia, and Complex Regional Pain Syndrome. Dr. Vigna represents clients with these diagnoses filed throughout the country with Martin Baughman, a Dallas, Texas firm. Ben Martin and Laura Baughman are national pharmaceutical injury trial attorneys in Dallas, Texas.

To learn more on the anatomical basis for TOT injury or irritation to the obturator and pudendal nerve and the treatments of obturator and pudendal neuralgia click here: https://vignalawgroup.com/ebooks/pelvic-mesh-pain/#page=59

Click here for a FREE BOOK on Vaginal Mesh Pain : https://vignalawgroup.com/publications/
For articles, video resources, and information visit the Pudendal Neuralgia Educational Portal (https://pudendalportal.lifecare123.com/) or https://tvm.lifecare123.com/.
Click here for information regarding sling related complications:
https://tvm.lifecare123.com/slingebook.html

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