TEXAS JURY FINDS ETHICON TVT-O DEFECTIVE, <u>AWARDS \$1.2 MILLION</u>

On April 2, 2014, a Dallas, Texas jury returned a verdict finding that Ethicon's TVT-O device for the treatment of stress urinary incontinence is defective, and awarded \$1.2 million in compensatory damages to the plaintiff, Linda Batiste. The verdict followed a 3-week trial at which the plaintiffs demonstrated, through internal Ethicon documents, and deposition testimony from key Ethicon medical and research and development witnesses, that Ethicon was well-aware of multiple defects in the mesh used in the TVT-O system, as well as unreasonably dangerous aspects of the procedure to surgically implant the TVT-O device.

The jury heard striking evidence, including testimony from plaintiffs' experts indicating that the mesh material, originally developed in 1974 for the treatment of hernias, degrades and deteriorates inside the human body, leading to the loss of particles of the polypropylene material, leading to a diffuse inflammatory reaction and pain. The jury also saw a promotional video sponsored by Ethicon, in which Ethicon consultant Todd Heniford, M.D. was promoting an alternative mesh construction that would be lighter weight, less dense, and less likely to cause the severe foreign body reaction, inflammatory reaction, contraction, and erosions and exposures that are the signature injuries caused by the defective mesh. In the video, Dr. Heniford is seen banging explanted heavyweight mesh that was covered in hard fibrotic tissue, on a table. Dr. Heniford commented during the video that there is essentially no reason to ever use a heavyweight mesh in the human body. Ethicon was unable to provide any satisfactory explanation for why it would continue to use the heavyweight prolene mesh in the TVT-O, despite knowledge of the many severe complications associated with implanting this prolene heavyweight mesh in the human body.

This trial is one of thousands in state and federal courts around the United States, and is a critical verdict for multiple reasons. Most important, the TVT-O is touted by Ethicon, and its paid consultants, as well as medical societies influenced by Ethicon and Johnson & Johnson, as the "gold standard" for the treatment of stress urinary incontinence. This verdict demonstrates that an impartial jury, having heard evidence that has not been publicly available, and certainly has not been disseminated within the medical community, that the device is in fact defective, and far from a "gold standard." The jury also heard compelling evidence that the TVT-O and the closely related TVT device to treat stress urinary incontinence became the "gold standard" through heavily funded, strategic marketing, including paid consultants who infiltrated and had significant influence over the professional societies that adopted this unsupported position.

Numerous trials are scheduled throughout the United States on a going-forward basis, and it is expected that this will be the first of many verdicts against Johnson & Johnson and Ethicon for their marketing of unsafe, defective pelvic mesh devices. In June, Adam Slater, Esq. of Mazie Slater Katz & Freeman, LLC, will be going to trial against Ethicon and Johnson & Johnson in Missouri State Court, based upon severe, permanent injuries suffered by a Missouri woman who was implanted with both the Prolift and Prolift +M pelvic mesh devices for the treatment of pelvic organ prolapse. The injuries suffered in that case include severe contraction and erosion of the mesh, severe pain and dyspareunia, and the need for multiple operations to remove and revise mesh, as well as to attempt to reconstruct her damaged pelvis. One operative report actually refers specifically to the fact that a surgeon attempting to remove the mesh found the mesh to be "rock hard." Adam Slater, Esq. was lead trial counsel in Gross v. Ethicon, the first pelvic mesh trial against Ethicon and Johnson & Johnson, which resulted in an \$11.1 million verdict, which included \$7.76 million in punitive damages.