Exclusion of Alternative Causation Theories A Must In Texas Product Actions

by Deborah E Lewis

The Court of Appeals for the Fifth District of Texas' recent opinion in *Johnson & Johnson v. Batiste*[1] is just another example of the import Texas higher courts place on a plaintiff's obligation to rule out alternative causes of personal injuries allegedly caused by a product. Certainly in the context of implantable medical devices, *Batiste* provides a "teachable moment" to counsel of the critical need to spend extra time gathering and understanding a patient's complete medical and surgical history. In such a thorough review of this information often lies the evidence that makes or breaks a product liability case.

Most agree that many factors influence a patient's response to medical and surgical treatment, including familial history and genetics, other maladies and current or prior treatment, compliance with a physician's orders, etc. With a surgically implanted medical device, additional risks may exist either from the insertion of the device itself during the surgical procedure or the fact there is now a foreign object within the body to which the body may react. These are some of the facts that came to light in *Batiste*.

Plaintiff Batiste, with a complex medical and surgical history[2], including a history of nine abdominal surgeries, sued Johnson & Johnson and Ethicon, Inc. for injuries allegedly sustained following the surgical insertion of a TVT-Obturator ("TVT-O") medical device to treat stress urinary incontinence. Plaintiff alleged injury from the device's tape made of polypropylene mesh, which tape goes through the vaginal wall, through an opening of the hip bone, and out to the inner thighs. She attributed her groin, pelvic, vaginal and urethral pain to the TVT-O. Before jury deliberations, Plaintiff non-suited her manufacturing and negligence claims against Johnson & Johnson and Ethicon, leaving only design and marketing defect theories. Plaintiff contended that the TVT-O's design defect lay in its: 1) heavyweight mesh and small pores, 2) mechanical cut, rather than laser cut, mesh causing the mesh to curl, fray and rope, and 3) mesh degradation and loss of particles. *Id.* at *3.

Despite having medical experts who testified at trial on these three defective design theories, the appellate court explained, with much detail, how and why Plaintiff failed to present legally sufficient evidence an alleged design defect of the TVT-O was a producing cause of her injuries[3] . Key to the court's conclusion to reverse and render the trial court's judgment was Plaintiff's failure to provide expert testimony that excluded alternative causes of Plaintiff's various areas of pain.

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[1] 2015 WL 6751063 (Tex. App. – Dallas, November 5, 2015)

[2] Plaintiff's medical and surgical history included two C-sections, two open abdominal procedures, five laparoscopic procedures, two strokes, spinal disease necessitating four lower back surgeries, neck surgery, heart attack with a stent placement in her femoral artery, COPD due to smoking, diabetes, diabetic neuropathy, peripheral vascular disease, gout, shingles, arthritis, clitoral cyst, groin cyst, and prior history of abdominal, back, hip and leg pain.

[3] Because there was no legally sufficient evidence of a design defect that was a producing cause of her injuries, the court determined it did not need to address appellants' other points of error, including the rebuttable presumption pursuant to Tex. Civ. Prac. & Rem. Code Ann. §82.008(a) that a manufacturer is not liable for injuries from an alleged design defect if the manufacturer establishes the design complied with mandatory safety standards or regulations promulgated by the federal government or federal agency.

Plaintiff's medical expert ruled out some, but not all, possible causes of injuries and pain. For example, with respect to Plaintiff's contention the mechanical cut of the mesh caused it to curl, fray and rope which caused the erosion of the mesh into her vagina[4], her medical expert failed to rule out other potential causes of the mesh erosion into her vagina such as poor healing due to her smoker status, vaginal atrophy, infection, placement of the mesh too close to the vaginal wall, and the closing of the vagina over the mesh failing to "hold up". *Id.* at *7. Likewise, with respect to her contention the curling, fraying, and roping of the mechanically cut mesh caused urethral pain[5], Plaintiff's expert failed to rule out damage to the urethral area from the surgical procedure itself (passage of a sharp trocar through the body) as a cause of Plaintiff's urethral pain. *Id.* Because the failure to disprove alternative theories of causation makes an expert's testimony speculative and conclusory, this was a key factor in the court's conclusion there was no evidence that curling, fraying or roping of the mesh was a cause-in-fact of Plaintiff's urethral pain. *Id.* at *8, *citing Wal-Mart Stores, Inc. v. Merrell,* 313 S.W.3d 837, 840 (Tex. 2010) (an expert's failure to explain or adequately disprove alternative theories of causation makes the theory speculative and conclusory); *Kia Motors Corp. v. Ruiz,* 432 S.W.3d 865, 878 (Tex. 2014).

For her theory the mesh had a design defect because it was heavyweight with small pores and caused groin pain[6], again Plaintiff's expert identified as a possibility, but failed to exclude, damage to the area from the surgical procedure itself (passage of the sharp trocar through the area - obturator foramen) as causing Plaintiff's groin pain. *Id.* at *10. The expert further failed to rule out or discuss Plaintiff's diabetic neuropathy as a cause of her pelvic pain, and failed to rule out or discuss her interstitial cystitis as a cause for her pelvic and groin pain. *Id.* at *11, fn. 13.

The Court noted that Plaintiff had to prove a specific defect in the TVT-O, and not merely the medical device itself, was the producing cause of her injuries. *Id.* at *11. In other words, complaints, complications and injuries may be due, not to a defect in the medical device, but simply because the medical device gets implanted into the body as in this case. In fact, it was undisputed that the insertion of devices like the TVT-O could cause complications, including the very injuries – erosion, groin, pelvic, and urethral pain – about which Plaintiff complained. *Id.*

Texas law is replete with opinions holding that an expert must rule out and exclude other plausible causes of injury to establish causation, otherwise such expert opinions are speculative and unreliable.[7] Harsh as some may see it, establishing causation in the context of a case involving a medical device can be overwhelming and/or difficult because a plethora of factors (both medical

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[4] Notwithstanding evidence generally that the polypropylene mesh could cause vaginal erosion, there was no evidence, immediately after its surgical removal, the mesh inside Plaintiff had curled, frayed or roped. *Id. a*t *7.

[5] The expert's testimony that the "sling" caused pain did not link any curling, fraying or roping of the mesh to the urethral pain. *Id. a*t 8.

[6] Additionally, the expert's testimony failed to link the groin pain to the small-pore size or the weight of the mesh. Instead, the expert's testimony supported an argument the groin pain was due to the placement of the sling arms near a nerve. *Id.* Likewise, the expert's testimony failed to connect Plaintiff's pelvic pain to the pore size or weight of the mesh, thus there was insufficient evidence to support the finding that the mesh pore-size or weight caused Plaintiff's pelvic pain. *Id.*

[7] *See E. I. DuPont Nemours & Co., Inc. v. Robinson,* 923 S.W.2d 549, 558-59 (Tex. 1995); *Merrill Dow Pharmaceuticals v. Havner,* 953 S.W.2d 706, 711-12 (Tex. 1997); *TXI Transp. Co. v. Hughes,* 306 S.W.3d 230, 237 (Tex. 2010); *Transcontinental Ins. Co. v. Crump,* 330 S.W.3d 211, 218 (Tex. 2010); *Kia Motors Corp. v. Ruiz,* 432 S.W.3d 865, 878 (Tex. 2014).

and surgical) must be considered, examined, and addressed by a medical expert. If plausible alternative causes of injuries cannot be ruled out and excluded with reasonable medical certainty, a plaintiff's case for personal injuries against a medical device manufacturer on theories of product defect may not be successful.

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