Products Liability Law Daily Wrap Up, TOP STORY—DESIGN AND MANUFACTURING DEFECTS—4th Cir.: Ethicon's appeal of $3.2 M transvaginal mesh verdict rejected, (Jan. 27, 2017)

Products Liability Law Daily Wrap Up

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By Pamela C. Maloney, J.D.

A $3.2 million jury verdict returned against Ethicon in the first multidistrict litigation case involving the company's allegedly defective transvaginal mesh device that went to a jury was upheld by the U.S. Court of Appeals for the Fourth Circuit based on a finding that the patient had presented sufficient evidence to support the jury's determination that the device contained a design defect and that the manufacturer failed to carry its burden of showing that it was protected from liability under the unavoidable unsafe product exception to §402A of the Restatement (Second) of Torts. The court also rejected the manufacturer's claim that a new trial was warranted because the district court erred in failing to instruct the jury on the unavoidable unsafe product exception and in excluding four pieces of FDA evidence (*Huskey v. Ethicon, Inc.*, January 26, 2016, Motz, D.).

A month after the surgical implantation of a TVT Obturator System (TVT-O)—a mid-urethral sling that uses heavy-weight laser cut polypropylene mesh manufactured by Ethicon, Inc—the patient's physician noticed during an examination that the mesh on the right side of her vagina was eroded and that the erosion was the source of the pain she had been experiencing. When alternative treatments for the patient's complications failed, she underwent a second surgery. Despite that surgery, the patient continued to experience constant pelvic pain exacerbated by physical activity and had reoccurring stress urinary incontinence (SUI), bladder pain, dyspareunia, and sacroiliac joint pain.

The patient and her husband filed a products liability against Ethicon, Inc. and Johnson & Johnson (collectively Ethicon), presenting four claims for consideration by the jury: (1) strict liability for defective design; (2) strict liability based on failure to warn; (3) negligence; and (4) loss of consortium. The jury returned a verdict in favor of the patient on all of her claims, and awarded her $3,070,000 in compensatory damages and $200,000 to her husband for loss of consortium. Prior to the verdict, Ethicon had moved for judgment as a matter of law, which was granted only as to punitive damages. After the jury verdict, Ethicon's renewed motion for judgment as a matter of law or, in the alternative, for a new trial, was denied [see *Products Liability Law Daily's* August 20, 2015 analysis] and Ethicon appealed.

Design defect. In support of its motion for judgment as a matter of law, Ethicon argued that the patient had failed to prove that the TVT-O contained a specific design flaw, as opposed to proving a general complication resulting from implantation. However, the patient's three experts, one of whom was a former Ethicon employee, had all agreed that because of the body's propensity to treat polypropylene mesh as a foreign material, it was best to minimize the amount and weight of the polypropylene that was present in the mesh. They also agreed that the patient's symptoms were a reaction to the mesh and could not be attributable to any other cause. Drawing all inferences in the patient's favor, the jury could have reasonably concluded from the exert testimony that use of a heavyweight quantity of polypropylene mesh in the TVT-O constituted a design defect that caused the patient's inflammation and pelvic pain. Therefore, Ethicon was not entitled to judgment as a matter of law on the patient's strict liability design defect claim or on the negligent design claim.

Having resolved the design defect claim in favor of the patient, the court found it unnecessary to address Ethicon's challenge to the jury's findings on the failure to warn claim. Further, because the husband's loss of consortium claim was derivative of the patient's claim, the court did not need to address Ethicon's challenge to the jury's finding on that claim either.

Unavoidably unsafe product exception. Whether a product qualifies as unavoidably unsafe under the exception to liability embodied in comment k to §402A raises a question of fact on which the product manufacturer bears the burden of proof. In this case, a jury reasonably could have found that the TVT-O did not meet the parameters of the exception based on testimony by the patient's experts that: (1) the greater quantity of mesh used in the TVT-O increased the chance that a patient would experience an adverse foreign body response; and (2) had Ethicon use lightweight mesh, the TVT-O would have remained effective and would have reduced a patient's risk of an adverse response. Because the jury could have concluded that Ethicon could have designed its device using lightweight mesh without sacrificing without sacrificing performance and, therefore, comment k did not shield Ethicon from liability.

Jury instructions challenge. Ethicon argued that it was entitled to a new trial because the district court improperly refused to instruct the jury on comment k. In turning aside this objection, the Fourth Circuit again observed that in order to show that a product fell within comment k's protection, the manufacturer had to prove that the product's marketing and use were fully justified notwithstanding the unavoidably high degree of risk which it involved. The only difference between the requested comment k instruction and the design defect instruction outlining the unreasonably dangerous product requirement was that the comment k instruction shifted the burden of proof to the manufacturer. In light of the fact that Ethicon failed to produce sufficient evidence to prove that its device was an unavoidably safe product, as discussed above, the failure to provide an instruction that shifted the burden to Ethicon in this case would not likely have provided the company with a more favorable outcome. Thus, the district court did not abuse its discretion in denying Ethicon's motion for a new trial on this ground.

Evidentiary challenges. In the alternative, Ethicon claimed it was entitled to a new trial because the lower court improperly excluded multiple pieces of evidence involving the FDA, specifically: (1) evidence of the TVT-O's compliance with the FDA's Section 510(k) evaluation process; (2) evidence that a 2011 FDA Advisory Committee deemed mesh slings, including the TVT-O, to be safe and effective; (3) a 2013 published guidance, which reported the Advisory Committee's conclusions; and (4) the regulatory history of the Prolene suture, an Ethicon product that contains the same polypropylene as the TVT-O's mesh.

Addressing each exclusion in turn, the Fourth Circuit first ruled that evidence of TVT-O's compliance with the 510(k) process, which focused on the equivalence between the product in question and an older one while only tangentially examining the safety of the product going through the process, would cause a battle of the experts over the robustness of the 510(k) process and, as such, risked confusing the jury. The court previously had ruled on this issue in *Cisson v. C.R. Bard, Inc.* —a bellwether case from a related MDL—and found no basis in Ethicon's argument that TVT-O's 510(k) compliance process actually did focus heavily on safety to distinguish this case from its exclusionary holding in *Cisson*.

With regard to the FDA Advisory Committee's examination of the risks and benefits of surgical mesh and the FDA's guidance policy, which was based on the Committee's study, the court upheld the trial court's decision to admit the underlying studies, but to exclude FDA's review of those studies. The agency did not use its own analysis of the TVT-O to reach a conclusion regarding the safety and efficacy of the device; it simply opined on work done by others. The admission of the underlying studies enabled Ethicon to obtain most of the probative value of the evidence without the risk of usurping the jury's role in determining whether the patient had proven her claims. In addition, admission of the FDA guidance had the potential for confusing the jury between what the FDA had opined that other literature had to say about the safety of the device and what the FDA itself had found about the TCT-O's equivalence to an earlier device. Given the potential for jury confusion, the district court did not abuse its discretion in excluding this evidence.

The lower court also did not err in excluding evidence of the regulatory history of Prolene sutures because that evidence could divert the focus away from a determination about the defectiveness of entire device the patient received to a determination of the role that the sutures or other components of the TVT-O might have played. Ethicon had been permitted to introduce evidence of its robust safety record, including evidence with regarding to the safety of its Prolene sutures. Thus, Ethicon had been able to provide the same information that would

have made up the core of the probative value the regulatory history without bringing in the potentially negative effects of that evidence.

The case is No. 15-2118.

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Companies: Ethicon, Inc.; Johnson & Johnson

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