Products Liability Law Daily Wrap Up, DESIGN AND MANUFACTURING DEFECTS—MEDICAL DEVICES—S.D.W. Va.: $3.2M verdict stands in transvaginal mesh device injury suit, (Aug. 20, 2015)

Products Liability Law Daily Wrap Up

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By Mary Damitio, J.D.

A $3.2 million jury verdict against Ethicon, Inc., a transvaginal mesh device manufacturer, remained standing after a district court found that exceptional circumstances did not exist to warrant the overturning of the jury's findings. The claimants presented sufficient evidence to demonstrate that the device was unreasonably dangerous and that Ethicon failed to provide sufficient warnings about the use of the device in active women; therefore, the jury's findings in favor of claimants on the basis of defective design, failure to warn, negligence, and loss of consortium should remain undisturbed (*Huskey v. Ethicon, Inc.*, August 19, 2015, Goodwin, J.).

Background. In February 2011, Jo Huskey underwent a surgical implantation of a TVT Obturator System (TVT-O), a polypropylene-based transvaginal mesh device that was manufactured by Ethicon, Inc. A month later, her physician noticed that the mesh on the right side of her vagina was eroded. The erosion persisted for months, causing Huskey to experience pelvic pain and pain during sexual intercourse. She underwent revision surgery that did not correct the mesh erosion. Huskey then saw another physician who recommended removing the mesh, but stated that it could not be fully removed due to its placement in the obturator space. Huskey had another surgery, during which her physician was able to remove six centimeters, which the physician described as a "chronically infected space." Since the surgery, Huskey has continued to experience constant pelvic pain that is exacerbated by physical activity and has had reoccurring SUI, bladder pain, dyspareunia, and sacroiliac joint pain.

Lawsuit. Huskey and her husband filed suit against Ethicon, Inc. and Johnson & Johnson (collectively Ethicon) in September 2012 , alleging that Jo suffered injuries as a result of the use of the TVT-O. Huskey's case was part of the Ethicon, Inc. MDL, MDL 2327, which was the largest Multidistrict Litigation (MDL) matter in the country with over 26,000 individuals cases relating to the use of transvaginal surgical mesh devices that were used to treat pelvic organ prolapse (POP) and SUI. Her case was also the first in the MDL to go through a jury trial.

Jury verdict. At the conclusion of trial, Huskey presented 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 Huskey on all of her claims and awarded her $3,070,000 in compensatory damages and $200,000 to her husband for loss of consortium. At the end of Huskey's case, Ethicon moved for judgment as a matter of law, which was granted in part as to punitive damages. After the jury verdict, Ethicon renewed its motion for judgment as a matter of law or, in alternative for a new trial.

Judgment as a matter of law. The court denied Ethicon's motion for judgment as a matter of law because a reasonable jury could find in favor of Huskey on all of her claims. In particular, the evidence relating to the defective design was so strong that it was capable of sustaining the verdict on its own.

Design defect. Huskey presented sufficient evidence such that reasonable jury could find Ethicon liable for defective design. The court rejected Ethicon's arguments that comment k of the Restatement (Second) of Torts §402A barred Huskey's design defect claim. Comment k exempts from strict liability claims products that are "unavoidably unsafe." Manufacturers of products that have been prepared properly, marketed, and labeled will not held liable for strict liability in association with the use of such products.

Ethicon was required to show that the risks of the TVT-O were "fully justified" by the products usefulness and desirability. However, Ethicon failed to demonstrate that the TVT-O was unavoidably unsafe. Huskey presented

evidence of the TVT-O's risks, including the danger that the mesh can degrade, shrink, contract, deform, and result in a forging body reaction that results in chronic inflammation. Additionally, physician testimony also demonstrated that removing the mesh does not always correct the problems and can result in scarring, irritation to nerves, and leftover mesh that cannot be removed. Huskey presented evidence that the TVT-O's risks outweighed its benefits and that the risks could have been avoided by minimizing the amount of mesh used. Therefore, a reasonable jury could have concluded that the TVT-O's risks outweighed its benefits and that, as a matter of law, it could not be considered an unavoidably unsafe product so as to exempt Ethicon from liability under Comment k.

Unreasonably dangerous. Huskey also presented sufficient evidence from which a jury could have found that the TVT-O was unreasonably dangerous. Under the risk-utility test, the jury must weigh the design's utility and benefits against the risks of harm that it creates. If the likelihood of harm outweighs its utility, then the product is considered to be unreasonably dangerous. Huskey presented evidence that TVT-O's risks could have been mitigated.

Design defect. While Illinois law, which was applied by the court, does not require a claimant to point out a specific defect in order to establish liability, Huskey did identify several specific defects in the TVT-O that proximately caused her injuries. She presented evidence that the product's defects including: the tendency of the mesh to erode; the use of laser-cut mesh; the placement of the TVT-O in the obturator space; and the use of heavyweight mesh. As a result, a reasonable jury could have found in favor if Huskey on the design defect claim.

Failure to warn. Huskey also presented sufficient evidence to demonstrate that her physician would have acted differently if she had been warned of the risks of the product's use by active women.

Negligence. A reasonable jury also could have concluded that Ethicon was negligent based on the evidence that the company had knowledge of the risks of the TVT-O and it failed to provide adequate warnings.

Preemption. As it had at the summary judgment stage, the court rejected Ethicon's argument that Huskey's claims relating to mesh degradation was preempted by federal law. Ethicon argued that Huskey's claims were preempted because the Prolene suture component of the TVT-O satisfied the FDA's premarket approval process. However, the court concluded that preemption can result from the FDA's premarket approval of a medical device, but not its component parts. Therefore, the fact that a component of the device was approved was irrelevant to the preemption claims.

New trial. Ethicon's motion for a new trial also was denied because the court found that the verdict was not against the clear weight of the evidence. The court likewise rejected Ethicon's remaining arguments relating to evidentiary and expert witness admissions.

The case is No. 2:12-cv-05201.

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Companies: Ethicon, Inc.; Johnson & Johnson

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