Products Liability Law Daily Wrap Up, EVIDENTIARY ISSUES—MEDICAL DEVICES—S.D.W. Va.: $2 million jury verdict survives challenge by mesh implant manufacturer, (Jan. 21, 2015)

By Kathleen Bianco, J.D.

Challenges to a jury verdict finding the manufacturer of a mesh implant used to treat pelvic organ prolapse liable for damages arising from complications suffered by a patient after the product had been implanted did not warrant a new trial, according to a federal district court in West Virginia (*Cisson v. C.R. Bard, Inc.*, January 20, 2015, Goodwin, J.).

Background. Donna Cisson filed a product liability action against C.R. Bard, the manufacturer of the Avaulta Plus Posterior Biosynthetic Support System (Avaulta Plus), alleging claims based on design defect and failure to warn. The Avaulta Plus is a synthetic mesh product used to treat pelvic organ prolapse in women. Cisson had the product implanted in May 2009. After the device was implanted, she experienced severe complications, including pain, scarring, and inflammation. In 2011, Cisson had the device removed; however, the arms of the device could not be removed and she continues to suffer from pelvic pain and discomfort. Following a trial, a jury awarded Cisson $250,000 in compensatory damages and $1,750,000 in punitive damages. At the conclusion of the plaintiff's case, Bard filed a motion for judgment as a matter of law, which was denied. Bard now seeks a new trial, arguing that certain evidentiary rulings at trial deprived it of a fair trial.

Specifically, Bard contended that a new trial was warranted because the district court erred by excluding evidence of Bard's compliance with the Federal Drug Administration's 510(k) process, admitting the Material Safety Data Sheet (MSDS) into evidence, and allowing Cisson to assert that the manufacturer should have performed pre-market human clinical testing without the support of competent expert testimony. Furthermore, Bard asserts that the court's causation ruling was unfair.

New trial. When entertaining a motion for a new trial, federal law requires that a district court determine whether the verdict was against the weight of the evidence, based upon evidence which was false, or a miscarriage of justice. The moving party bears the burden of proving that no rational jury could have rendered the verdict. In support of its motion, the manufacturer put forth several arguments. First, the manufacturer asserted that the exclusion of evidence regarding the manufacturer's compliance with FDA regulations prevented it from presenting an adequate defense. The court rejected this assertion, declaring that the compliance evidence was not relevant because it did not establish the safety of the product. Moreover, the court opined that the potential probative value of the 510(k) evidence was substantially outweighed by the risk of confusing the issues and misleading the jury.

The manufacturer also contended that the court had erred when it allowed the plaintiff to submit the Material Safety Data Sheet into evidence. The manufacturer raised a myriad of arguments on this issue, none of which the court found to be meritorious. Accordingly, the court concluded that the admission of the MSDS had not resulted in a miscarriage of justice warranting a new trial.

Finally, the manufacturer raised objections to the jury instruction on causation, the submission of the design defect claims to the jury, and the admission of testimony on premarket human clinical testing. Based on the manufacturer's arguments and the available evidence, the court held that none of these alleged errors constituted a "substantial" error warranting a new trial.

The case is Civil Action No. 2:11-cv-00195.

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Companies: C.R. Bard, Inc.

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