Products Liability Law Daily Wrap Up, DESIGN AND MANUFACTURING DEFECTS—MEDICAL DEVICES—S.D.W. Va.: Jury verdict, including punitive damages, stands in mesh implant products liability action, (Oct. 21, 2013)

By Kathleen Bianco, J.D.

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 was supported by sufficient evidence to survive a motion for directed verdict, according to a federal district court in West Virginia (*Cisson v. C.R. Bard, Inc.,* October 18, 2013, Goodwin, J.).

Background. Donna Cisson filed a products liability action against C.R. Bard, the manufacturer of the 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 $1,175,000 in punitive damages. At the conclusion of the plaintiff's case, Bard moved for judgment as a matter of law, which the judge deferred. Bard renewed its motion at the close of its case, and a ruling on that motion was again deferred. After the jury verdict was reached, Bard renewed its motion for judgment as a matter of law, arguing that the plaintiff had failed to prove design defects related to the size of the mesh pores or the use of polypropylene. Furthermore, Bard asserted that the warnings that it had provided were adequate. Finally, Bard challenged the assessment of punitive damages, arguing that they were not permissible because Bard had complied with federal regulations and industry standards.

Design defect. As to the design defect claim, the plaintiff alleged three separate defects in the product, including the use of the arms on the device, the size of the pores in the mesh, and the use of polypropylene. Under Georgia law, in order to prevail on a products liability claim, the plaintiffs were not required to prove each alleged defect that had caused an injury, they were merely required to show that the device had not operated as intended and was the proximate cause of the plaintiffs' injuries. As such, because the defendant conceded that sufficient evidence existed to send one of the alleged defect claims to the jury, it was not entitled to judgment as to the design defect claim.

Failure-to-warn claims. Under Georgia law, a failure to warn claim must demonstrate the following: (1) the defendant had a duty to warn, (2) the defendant breached that duty, and (3) the breach caused the plaintiff's injury. In cases of medical devices, a manufacturer does not have a duty to warn end users of the product, instead the manufacturer must warn the patient's doctors. Here, the court concluded that the defendant had a duty to warn the plaintiff's doctor about the dangers associated with the device. Additionally, the court found that the plaintiff had presented sufficient evidence to allow the jury to find that the duty had been breached by the manufacturer's failure to inform the doctor about the use of polypropylene, the higher risk of complications due to the presence of the porcine sheet, and that the inadequate pore size increased the risk of inflammation and scarring. Finally, based on the testimony of the plaintiff's doctor, it was determined that had the appropriate warnings been given, the doctor would not have implanted the product in the plaintiff. As such, the court opined that there was sufficient evidence for a jury to find that the defendant's failure to warn the plaintiff's doctor about the dangers associated with the product had proximately caused the plaintiff's injury. Thus, the defendant's motion for judgment was denied.

Punitive damages. The defendant challenged the punitive damages award, arguing that its compliance with federal regulations and industry standards precluded such damages. While this is generally true, if a plaintiff can show by clear and convincing evidence that the manufacturer engaged in a deliberate course of conduct which knowingly endangered those using the products, punitive damage may be available. The plaintiff was able to show such conduct in regards to the defendant's blatant disregard for the warnings against the use of polypropylene resins in medical applications involving permanent implantation in the human body. Plaintiff

submitted evidence demonstrating that the defendant not only ignored the warnings given to it by the polypropylene manufacturer, but consciously employed subterfuge to procure the resin from the manufacturer, who would not have provided it otherwise. Based on the evidence, the court asserted that a reasonable jury could infer that the defendant had acted with an entire want of care and a conscious indifference to the consequences of its actions. Accordingly, the awarding of punitive damages was reasonable.

The case number is 2:11-cv-00195.

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Companies: C. R. Bard, Incorporated

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