Products Liability Law Daily Wrap Up, TOP STORY—MEDICAL DEVICES—4th Cir.: First transvaginal mesh multidistrict litigation jury verdict survives appeal , (Jan. 15, 2016)

Products Liability Law Daily Wrap Up

Click to open document in a browser

By Mary Damitio, J.D.

A jury verdict that awarded a patient $250,000 in compensatory damages and $1,750,000 in punitive damages for injuries caused by an implanted transvaginal mesh medical device was not unconstitutionally excessive, the U.S. Court of Appeals for the Fourth Circuit ruled, affirming various evidentiary rulings by a federal district court in West Virginia. The district court properly allowed the injured patient to present a warning letter into evidence to show that the device manufacturer acted unreasonably when it ignored warnings about a material used in its product (*Cisson v. C.R. Bard, Inc.*, January 14, 2016, Gregory, R.).

Mesh implant. In May 2009, the patient had the Avaulta Plus transvaginal mesh medical device (device) implanted to treat pelvic organ prolapse and stress urinary incontinence. The device was developed and marketed by C.R. Bard, Inc. (Bard). After the procedure, the patient developed an “adhesion band” of scar tissue that ran across her vagina that was taut and caused her pain. Her surgeon resected the mesh and she later saw another doctor who attempted, but could not, remove the entire device from her body.

The patient filed suit claiming that the device caused her to lose sexual feeling and resulted in severe pain during intercourse. At the time she filed suit, Bard was already facing several actions relating to the device and her case was added to the other cases in the multi-district litigation (MDL) against the manufacturer. Bard won summary judgment on a variety of the patient’s claims, but her design defect, failure to warn, and loss of consortium claims proceeded to trial, which resulted in the first jury verdict for the MDL cases.

Trial evidence. The patient presented expert testimony relating to the device’s design defects, which resulted in mesh degradation, inflammation, and the development of rigid scar tissue. She also presented evidence that the manufacturer ignored warning signs about the device after it received a material data safety sheet (MSDS) indicating that polypropylene, which was a material used to make the mesh in the device, should not be used in short- or long-term human implantations. Additionally, internal emails were presented showing that Bard executives were aware of the MSDS and that they prevented their suppliers from learning about the warnings.

Jury award. A jury awarded the patient $250,000 in compensatory and $1,750,000 in punitive damages (see *Products Liability Law Daily*, October 21, 2013, analysis). Per Georgia law, the punitive damages were split, with 75 percent going to the State of Georgia and 25 percent going to the patient. Bard appealed and the patient cross-appealed on the split of the punitive damages.

510(k) compliance. The district court (see *Products Liability Law Daily*, January 21, 2015, analysis) did not abuse its discretion when it excluded Bard’s evidence that the device manufacturer complied with the FDA’s premarket clearance process under Section 510(k) of the Food, Drug and Cosmetic Act (FDC Act) because it was of little or no evidentiary value as the process did not amount to a safety regulation that required device manufacturers to comply with established design standards.

Additionally, Georgia products liability law requires the court to use a “risk-utility” test for products liability claims that includes balancing the risks inherent in a product design against the product’s utility. The court properly determined that the admission of the 510(k) process evidence would have turned the case into a “mini-trial” about the process and Bard’s disclosures. That mini-trial would have, in turn, resulted in a battle of the experts that would have mislead the jury and confused the issues, by inflating the importance of Bard’s 510(k)

compliance, and distracted the jury from its real question of whether the design was unreasonable based on its dangers versus the costs required to avoid them.

MSDS. While the district court erred in ruling that the MSDS fell within one of the exceptions to the hearsay rule, it did not err in allowing it to be offered into evidence because the patient used the document only to establish that Bard received a warning and either ignored it or withheld it from other parties. Additionally, even if she used the MSDS for its truth, it did not prejudice Bard because it was used to show that the company's conduct was unreasonable and that none of the testimony addressed whether polypropylene was actually dangerous or caused the patient's injuries.

Although the patient's trial counsel made a "problematic" remark about the document that seemed to indicate that it was more reliable than expert testimony, such a statement was not sufficient to prejudice the manufacturer and require a new trial. It was one statement in a lengthy trial, and the patient presented sufficient evidence demonstrating that the polypropylene in her body was degraded, which provided the jury with a more "compelling" reason to conclude that the material contributed to her injuries.

Jury instruction. The district court properly gave jury instructions that did not require causation to be proved by expert testimony that was stated to a "reasonable degree of medical certainty" because in Georgia medical implant cases, causation can be established through medical and non-medical evidence. The patient presented "ample" evidence through expert and non-expert testimony for the jury to determine that the design of the device caused her injuries.

Not excessive. The punitive damages award, which was seven times more than the compensatory damages, was not constitutionally excessive because the district court (see *Products Liability Law Daily*, January 21, 2015, analysis) found that they arose from Bard's misconduct that resulted in the patient's injuries and that its conduct was reprehensible.

The Georgia statute that requires 75 percent of any punitive damage award arising from a products liability judgment to be paid to the state did not violate the Fifth Amendment's Takings Clause because the patient did not establish that she had a property interest in the punitive damages award.

The case is No. 15-1102.

Attorneys: Henry G. Garrard, III (Blasingame, Burch, Garrard & Bryant, PC) for Donna Cisson. Melissa Foster Bird (Nelson Mullins Riley & Scarborough, LLP) for C.R. Bard, Inc.

Companies: C.R. Bard, Inc.

MainStory: TopStory EvidentiaryNews DesignManufacturingNews DamagesNews MedicalDevicesNews MarylandNews NorthCarolinaNews SouthCarolinaNews VirginiaNews WestVirginiaNews