Products Liability Law Daily Wrap Up, TOP STORY—MEDICAL DEVICES—N.D. Ind.: Punitive damages reduced in pelvic mesh case from $25M to $10M, (Aug. 9, 2018)

Products Liability Law Daily Wrap Up

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By David Yucht, J.D.

Although a woman injured by the implantation of a vaginal mesh proved her failure to warn and design defect claims against the product's manufacturer, she was not entitled to the full measure of punitive damages awarded to her by the jury deciding her case, a federal district court in Indiana ruled, finding the amount awarded in punitive damages to be excessive and unreasonable. Although the court let stand the $10 million award for compensatory damages, it reduced the punitive damages award by $15 million, from $25 million to $10 million (*Kaiser v. Johnson & Johnson*, August 8, 2018, Simon, P.).

A patient alleged injuries by a mesh product, the Prolift Pelvic Floor Repair System, which was implanted in her vagina to treat pelvic organ prolapse. The product was designed and manufactured by defendants Johnson & Johnson and Ethicon, Inc., which is a wholly owned subsidiary of Johnson & Johnson. The patient filed suit against the manufacturers. After a trial, the jury found in the patient's favor on her failure to warn and design defect claims. The jury awarded $10 million in compensatory damages and $25 million in punitive damages. The manufacturers filed a motion contesting the verdict, seeking judgment as a matter of law or a new trial, in the alternative; or, alternatively still, a remittitur of the jury's damages award. The court denied this motion in its entirety except as to the remittitur of punitive damages.

Failure to warn. The court determined that there was enough evidence to sustain the verdict and prevent the ordering of a new trial on the patient's failure to warn claim. The manufacturers argued that there was insufficient evidence that the patient's surgeon was not adequately warned of the device's risks because the surgeon failed to read the product information before implantation which, according to the manufacturer, made the lack of warning irrelevant under the learned intermediary doctrine. However, the court noted that the surgeon testified that he had read this information multiple times, followed it when implanting the device, and that it influenced his decision to implant the device in this patient. The surgeon also testified that once he learned of the frequent complications from this device, he began recommending against vaginal mesh implantation.

The court also was not swayed by the manufacturers' argument that the product's warnings were sufficient because risks associated with the device were fully disclosed in literature and commonly known to pelvic floor surgeons. Both the patient's surgeon and her expert witness testified that these risks were not widely known when the patient was implanted with the device.

Design defect. The court upheld the jury's verdict favoring the design defect claim and determined there was no reason to grant a new trial. First, the court ruled that the manufacturers were not entitled to a state of the art presumption under Indiana law. The Indiana Products Liability Act (IPLA) allows for a defendant to avail itself of a rebuttal presumption that its product was not defective if it was designed and manufactured "in conformity with the generally recognized state of the art applicable to the safety of the product at the time the produce was designed, manufactured, packaged, and labeled." Courts have defined "state of the art" to mean "the best technology reasonably feasible." The court noted there was no evidence of Prolift's specific safety record at the time it was brought to market, thereby leaving the manufacturers without evidence to warrant the rebuttal presumption and jury instruction on state of the art. Thus, they could not show they were entitled to judgment as a matter of law on the issue. The court next stuck by its earlier finding that proof of a safer alternative design is not an element of a design defect claim under Indiana law, noting that "the Indiana Supreme Court squarely rejected any such requirement based upon the language of the IPLA."

Furthermore, the court held that the patient established that the vaginal mesh was defective and that it caused her injuries. The jury believed the statements by the patient's experts and witnesses. As this was not unreasonable, the court declined to set aside the jury's verdict on this basis.

Preemption. The manufacturers argued that because Food and Drug Administration (FDA) regulations required a manufacturer to submit a new premarket notification before marketing a new or changed device, state tort laws for design defect were preempted. The trial court noted that Congress did not intend to abrogate state product liability design defect claims for medical devices. The process cited by the manufacturers was intended only to maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents and included the possibility that device manufacturers would have to defend themselves against state-law claims. The manufacturer's argument was based on recent case law which only applied to generic pharmaceutical labeling and not to medical devices.

FDA procedures. The court also rejected the manufacturer's argument that it should have been allowed to present evidence concerning FDA medical device approval procedures. The court determined that this evidence only would have confused the jury and required extensive trial time to explain, so any probative value was outweighed.

Jury instructions. Moreover, the court was unimpressed by the manufacturers' assertion that the court's failure to warn and causation jury instructions were flawed. The judge's instructions accurately reflected Indiana law and the manufacturers' proposed additions would not have prevented juror confusion, but instead likely would have heightened confusion by implying elements and requirements which were not strictly elements of the patient's claims.

Compensatory damages. The court denied the manufacturer's request for a remittitur of the jury's compensatory damages award because the award was neither "monstrously" excessive nor the product of passion or prejudice. The court noted that although the injuries here consisted primarily of pain and suffering which were difficult to monetize, the patient produced persuasive evidence that the pain and agony that she experienced daily from the mesh continued to be debilitating. She endured a second painful surgery in an effort to have the mesh removed, but much of it still remained in her body. For these injuries, the jury determined $10 million was appropriate. The court found that although this sum was larger than many other serious personal injury cases, it was not "monstrously excessive" when compared to awards in other vaginal mesh cases. The fact the jury's award was higher than those in many other cases did not make it improper. Moreover, the fact that the jury awarded more than the consumer's attorney requested did not affect the court's ruling because the jury's award was only slightly larger than the seven to nine million dollars counsel requested.

Punitive damages. Finally, the court ruled that punitive damages were appropriate in this case. Counsel for both the manufacturers and the patient agreed that the New Jersey Punitive Damages Act governed this issue. The court noted that under New Jersey law, punitive damages were appropriate when a manufacturer was aware of the serious health hazards created by its product but failed to warn users. There was evidence that the manufacturers were aware of the problems associated with their mesh product but chose to launch it anyway, and that after further problems arose once the product was on the market, they continued to market it without disclosing these risks to surgeons.

However, the court found the punitive damages award was excessive and unreasonable, and, therefore, it granted the manufacturers' motion for remittitur of the jury's $25 million punitive damages award. Although the manufacturers are both multi-billion dollar corporations, the punitive damages in this case were only meant to address profits made in Indiana, as opposed to nationwide. Importantly, the manufacturers' Indiana profits from the vaginal mesh product were just slightly over $150,000. Because the amount of punitive damages should be determined from the perspective of the manufacturer, this award was excessive when compared to the defendants' relatively small profit. The court noted that here the jury's $10 million compensatory award was larger than many other vaginal mesh verdicts. When compensatory damages are substantial, the U.S. Supreme Court has indicated that due process may permit punitive damages to be no more than equal to the amount of

compensatory damages. Given this authority, the court reduced the jury's original $25 million punitive damages award to $10 million.

The court's grant of remittitur was conditional based on the patient's acceptance of the reduced award. The court provided that either the patient can accept the reduced punitive damages award, and, thus, be awarded $20 million in total as opposed to the original $35 million originally awarded by the jury, or she can reject the reduced award and then the court would order a new trial on the issue of punitive damages.

The case is No. 2:17-cv-00114-PPS-JEM.

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Companies: Johnson & Johnson; Ethicon Inc.

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