

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SCOTT ZEMAITATIS AND : CIVIL ACTION
STEPHEN ZEMAITATIS :
 :
v. :
 :
 :
INNOVASIVE DEVICES, INC. : NO. 98-1221

MEMORANDUM AND ORDER

Norma L. Shapiro, S.J.

March 17, 2000

A jury found by a preponderance of the evidence that a defectively designed product of defendant Innovasive Devices, Inc. ("Innovasive") was a substantial factor in causing harm suffered by plaintiff, Scott Zemaitatis. The verdict awarded Zemaitatis was \$47,000 in medical expenses and \$250,000 for pain and suffering. Innovasive, moving for judgment as a matter of law, a new trial, and/or remittitur of the pain and suffering award, argues that: 1) it was error to allow plaintiff's expert witness to testify; 2) it was error to preclude defendant's expert witness from testifying about FDA approval data; 3) the verdict was against the weight of the evidence; and 4) a remittitur of damages should be granted. Zemaitatis moved to mold the verdict and for delay damages under Pennsylvania Rule of Civil Procedure 238.

BACKGROUND

Plaintiff Scott Zemaitatis ("Zemaitatis") was a varsity swimmer and soccer player at Eastern Regional High School in Voorhees, New Jersey, when his left shoulder became dislocated in May, 1995; there was a spontaneous reduction. This happened again four or five times in the following months. In August, 1995, Zemaitatis consulted Dr. Joseph P. Iannotti ("Dr. Iannotti") about his shoulder; at Zemaitatis's request, Dr. Iannotti did not operate on plaintiff to correct the condition until March 7, 1996.

The operative procedure involved placing suture anchors in plaintiff's shoulder. The suture anchors, designed and manufactured by Innovasive, consisted of a collar and a pin inserted into the collar to expand outward against the bone surface. Suture material was pre-loaded into an eye at the top of the pin. Defendant's delivery system also included a drill with a pre-fixed depth, drill guide, and gun trigger. Dr. Iannotti drilled holes, inserted three collars, pushed in the pins, and tied sutures to the eyes of the pins. The ligaments around the shoulder were then tied in place.

Zemaitatis followed a rehabilitation program after the operation, but noticed a clicking noise and felt some discomfort in his shoulder. Dr. Iannotti recommended corrective surgery; at the second operation two months later, Dr. Iannotti found the

pins in all three anchors protruding above the level of the bone; he corrected this by filing each pin to bone level.

After the second surgery, Zemaitatis claimed to suffer increasing shoulder pain affecting his ability to play soccer and swim. He insisted on a third surgery in June, 1997; it revealed degenerative changes in the articular cartilage around his shoulder bone.

DISCUSSION

I. Plaintiff's expert witness

In order to establish defectiveness of the suture anchor and causation, plaintiff offered the expert testimony of Dr. Steven Batterman. The court held two hearings in accordance with Daubert v. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), to consider Dr. Batterman's proposed testimony and arguments of counsel.¹ Under Daubert, the trial court makes a determination whether: 1) the proposed witness is qualified as an expert, 2) the expert employs a reliable reasoning or methodology; and 3) the reasoning or methodology is relevant. See Daubert, 509 U.S. at 592-93. The test is flexible and should focus on reasoning and methods not conclusions. See Daubert, 509 U.S. at 594-95. It was ordered that Dr. Batterman could testify that: 1) defendant's suture anchor system was defectively

¹ Defendant made the same arguments at the Daubert hearings that he makes in his post-trial motion.

designed because it was loaded from the front rather than the rear; and 2) the engineering of defendant's product caused plaintiff's injury. Dr. Batterman was precluded from testifying that defendant's system was defective for any other reason, or giving medical opinions.

Innovasive argues it was error to allow Dr. Batterman to testify at all because his testimony lacked a scientific basis. Innovasive also argues that Dr. Batterman lacked specific qualifications as to education, training or experience necessary for him to render an opinion regarding the design of the suture anchors. It is true that Dr. Batterman is a jack-of-all-trades expert, but the court was satisfied he possessed sufficient qualifications to testify in the limited areas permitted. The court determined that Dr. Batterman's opinion regarding loading of the suture anchors was admissible because it had sufficient scientific basis to aid the jury in reaching an accurate result. See In re: Paoli Railroad Yard PCB Litigation, 35 F.3d 717, 746 (3d Cir. 1994). These findings satisfied the Daubert requirements; no new evidence or argument has been presented post-trial.

II. Innovasive's expert witness

Innovasive argues that its expert, Steven Kurz, should have been allowed to testify to Food and Drug Administration data ("FDA data") he reviewed to assess the safety of Innovasive's

suture anchor.² The court denied Innovasive's motion in limine to allow testimony regarding the FDA data because it was irrelevant and unduly prejudicial. See Fed. R. Evid. 402, 403.

Innovasive obtained FDA approval of the suture anchor by asserting it was "substantially equivalent" to other devices already on the market. See 21 U.S.C. § 360e(b)(1)(B). Devices on the market have not all been rigorously tested by the FDA; most devices currently on the market have not received detailed FDA review. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 477-78 (1996). The suture anchor at issue was never subjected to FDA de novo review. Cf. Medtronic, Inc. v. Lohr, 518 U.S. at 479 ("in contrast to the 1,200 hours necessary to complete a [de novo FDA review], the ["substantial equivalence" review] is completed in an average of only 20 hours."); Orthopedic Bone Screw Prods. Liab. Litig., 193 F.3d 781, 786 (3d Cir. 1999) (if a device obtains FDA approval because of its substantial equivalence, it may be introduced into commerce without pre-market approval based on safety and efficacy data from independent investigation). Testimony of FDA approval was likely to lead the jury to believe the FDA conducted substantial testing of the suture anchors; it would give the product an unearned stamp of approval. The court

² Innovasive cited no legal authority in its post-trial memorandum supporting its assertion that the FDA data should have been admitted, or that the failure to admit the FDA data was reversible error.

determined the evidence, if admitted, would unduly prejudice the jury.

Non-constitutional error in a civil suit is harmless if "it is highly probable that the error did not affect the outcome of the case." West v. Philadelphia Elec. Co., 45 F.3d 744, 752 (3d Cir. 1995). Even if Dr. Kurz were allowed to testify to the FDA data he reviewed in assessing the safety of Innovasive's suture anchor, it is highly probable that the jury would have found for Zemaitatis because of the testimony of Dr. Batterman and Dr. Iannotti.

III. The weight of the evidence

A verdict will be stricken as against the weight of the evidence only where "a miscarriage of justice would result if the verdict were to stand . . . this limit upon the district court's power to grant a new trial seeks to ensure that a district court does not substitute its judgment of the facts and the credibility of the witnesses for that of the jury." Delli Santi v. CNA Insurance Cos., 88 F.3d 192, 201 (3d Cir. 1996) (internal quotes omitted). To allow a district court to override a jury decision more freely would denigrate the American judicial system.

Innovasive argues that, in addition to basing his case on inadmissible expert testimony, Zemaitatis relied on equivocal testimony by his surgeon, Dr. Iannotti, on whether the suture anchors were defective. It would have been quite reasonable for

the jury to have found that Zemaitatis's adverse result was caused by Doctor Iannotti's negligence in inserting the device or not checking to be sure the device was seated properly. There was reason to question the credibility of the doctor's testimony. But credibility determinations are for the jury. The jury verdict should not be set aside because the court would have reached a different result. The court cannot conclude that the jury verdict was a miscarriage of justice.

IV. Remittitur

The verdict awarded Zemaitatis was \$47,000 in medical expenses and \$250,000 for pain and suffering. In reviewing a jury's award of damages, a court must ensure that the verdict is clearly supported by the evidence, and that it is not excessive as a matter of law. See Starceski v. Westinghouse Electric Corp., 54 F.3d 1089, 1100 (3d Cir. 1995); Gumbs v. Pueblo International, Inc., 823 F.2d 768, 773 (3d Cir. 1987). The objective is to ensure that the jury has come to a rationally based conclusion. Starceski, 54 F.3d at 1100. A district court must ensure "that jury awards do not extend beyond all reasonable bounds." Walters v. Mintec, 758 F.2d 73, 82 (3d Cir. 1985). A district court has broad discretion in granting or denying remittitur. See Delli Santi v. CNA Insurance Cos., 88 F.3d 192, 206 (3d Cir. 1996).

Zemaitatis, a young man interested in sports, postponed his

first operation until the conclusion of the 1996 soccer season. His second operation followed two months later, and his third operation was performed year thereafter; the third operation was performed at Zemaitatis's insistence because of purported pain, not because Dr. Iannotti thought it necessary. Zemaitatis testified he experienced pain on a daily basis since his first operation in March, 1996 and has been forced to curtail his athletic pursuits because of this shoulder pain; there was evidence his arthritis may grow worse as he ages. For this past and future pain and suffering, Zemaitatis received an award of \$250,000.

In Gumbs v. Pueblo International, Inc., plaintiff slipped and fell on oil in defendant's supermarket. Plaintiff suffered a sprained coccyx, a back spasm, resultant osteoarthritic changes, and some herniation of an intervertebral disk. 823 F.2d 768, 774 (3d Cir. 1987). At the time of the accident, plaintiff "had preexisting scoliosis, an osteoarthritic condition of the spine, and weighed about 240 pounds which even she considered 'very heavy' . . ." Id. at 775. Plaintiff claimed that as a result of the pain from her fall, she could no longer enjoy jogging, swimming, tumbling, and tennis, and that the pain she suffered interfered with her marital relationship. Id. Plaintiff also claimed that her accounting practice and secretarial school work suffered as a result of her pain. Id.

At trial, a jury awarded plaintiff \$900,000 for past and future pain and suffering, mental anguish, and loss of enjoyment of life. Gumbs, 823 F.2d at 769. The district court ordered a remittitur to \$575,000. Id. at 770. The Court of Appeals, after reviewing jury verdicts in tort cases involving similar injuries, ordered a further remittitur to \$235,000 as the maximum recovery that a jury reasonably could have awarded the plaintiff for pain and suffering, mental anguish, and loss of enjoyment of life.

The jury evidently believed Zemaitatis suffered significant, life-altering pain as a result of Innovasive's defectively designed product and that he has been and will continue to be restricted from engaging in physical activities he formerly enjoyed. The award for pain and suffering was approximately five times the medical damages. It was only \$15,000 more than the award permitted in Gumbs. The injuries here are less than those claimed by the plaintiff in Gumbs, but Gumbs was decided nearly 15 years ago. The jury award for pain and suffering here is not so unreasonable that remittitur is mandated. In the absence of adverse comparisons to other jury verdicts in similar product liability cases, the court declines to grant a remittitur for pain and suffering.

The \$47,000 award for medical expenses is comprised of \$40,000 for a future joint replacement operation, and \$6,791 for prior medical expenses, presumably rounded to \$7,000 by the jury.

The award is based on Dr. Iannotti's testimony that a future joint replacement operation would cost "probably close to about thirty thousand, maybe forty thousand dollars." The jury award for medical expenses is not so unreasonable that remittitur is mandated.

V. Delay Damages

Pennsylvania Rule of Civil Procedure 238 provides delay damages to a prevailing plaintiff in a civil action seeking monetary relief for bodily injury. See Pa. R. Civ. Proc. 238(a)(1). Damages are calculated at the rate of one percent plus the prime rate published in the first edition of the Wall Street Journal for the calendar year(s) for which damages are awarded. See Pa. R. Civ. Proc. 238(a)(3). Delay damages are awarded from one year after the date original process was served to the date of the award. See Pa. R. Civ. Proc. 238(a)(2)(ii).

Innovasive's post-trial motions will be denied, so Zemaitatis's motion for delay damages will be granted. The parties agree that the relevant time period is 122 days (March 16, 1999 until July 16, 1999), and the applicable interest rate is 8.75%. The total amount of delay damages is \$8,686.23.

CONCLUSION

The jury verdict in favor of Zemaitatis was based on findings that Innovasive designed and manufactured a defective product causing Zemaitatis injuries; it was supported by sufficient evidence to permit a reasonable jury to find in his favor by a preponderance of the evidence. There are no legal grounds for setting aside the jury's verdict, granting a new trial, entering a judgment as a matter of law, or granting a remittitur. Zemaitatis's motion for delay damages will be granted.

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ORDER

AND NOW this 17th day of March, 2000, upon consideration of defendant's post trial motions and supplemental post trial motion, plaintiff's responses thereto, plaintiff's motion to mold the verdict and for delay damages pursuant to Federal Rule of Civil Procedure 238, and defendant's answer thereto, and in consideration of the attached memorandum,

it is **ORDERED** that:

1. The post trial motions of defendant Innovative Devices for judgment as a matter of law, for a new trial, or for a remittitur, are **DENIED**.

2. The supplemental post trial motion of defendant Innovative Devices for a new trial is **DENIED**.

3. Plaintiff's Motion to Mold the Verdict and for Delay Damages Pursuant to Federal Rule of Civil Procedure 238 is **GRANTED**. The verdict rendered by the jury in the amount of \$297,000.00 is molded to add \$8,686.23 in delay damages, for a total verdict in the amount of \$305,686.23 against defendant, Innovative Devices, Inc.

Norma L. Shapiro, S.J.