United States Court of Appeals
For the Eighth Circuit

No. 21-2964

Mary Bayes; Philip Bayes

Plaintiffs - Appellees

v.

Biomet, Inc.; Biomet Orthopedics, LLC; Biomet U.S. Reconstruction, LLC; Biomet Manufacturing LLC, formerly known as Biomet Manufacturing Corp.

Defendants - Appellants

Appeal from United States District Court
for the Eastern District of Missouri - St. Louis

Submitted: September 21, 2022
Filed: December 14, 2022

Before SMITH, Chief Judge, KELLY and GRASZ, Circuit Judges.

SMITH, Chief Judge.

Mary and Philip Bayes sued Biomet, Inc. and associated entities (Biomet) after Mary Bayes's M2a Magnum hip implant failed. The M2a Magnum is a large diameter metal-on-metal hip implant produced by Biomet. Mary argued that the implant caused irreparable damage to her hip joint and surrounding tissues. A jury awarded Mary $20

million in damages. The jury awarded an additional $1 million in damages to her husband Philip for his loss of consortium. Biomet appeals, arguing that (1) the jury's verdict was inconsistent, (2) the Bayes failed to establish the required standard of care, (3) the Bayes failed to show a breach by Biomet, and (4) the damages award was excessive. We disagree and affirm the judgment of the district court.[1]

I. *Background*

Mary Bayes has long suffered from arthritis. A surgeon using the Biomet M2a Magnum replaced her right hip joint in January 2008 and her left hip joint in April 2008. The M2a Magnum completely replaces the hip joint using an alloy of metals, including cobalt and chromium for both the ball and the cup of the implant.

In 2010, Mary began experiencing increasing pain in her left hip. X-rays showed significant bone degeneration in her left hip. Consequently, she underwent corrective surgery by a new surgeon that replaced the M2a Magnum with a ceramic-on-plastic hip implant in March 2011. The new surgeon, upon opening the hip joint, observed severe damage to the joint and surrounding tissue. Metal ions had permeated the nearby soft tissues, causing severe necrosis. Since this revision surgery, Mary has suffered 12 dislocations of her left hip. Doctors have performed seven hip revision surgeries on her. Mary now uses a fully constrained hip replacement, preventing normal hip function such as sitting in a typical posture. Mary's doctors state that continued hip dislocations are highly likely. As a result, she must markedly limit her life activities to avoid dislocations.

Mary sued Biomet in May 2013. Mary alleged that Biomet negligently designed the M2a Magnum and was strictly liable for its design, manufacture, and distribution. The jury trial began October 5, 2020, and lasted 13 days. The court gave

[1]The Honorable Stephen R. Clark, United States District Judge for the Eastern District of Missouri.

two instructions regarding liability. Jury Instruction No. 10 detailed the proof requirements for "strict liability—product defect." R. Doc. 362, at 11. These requirements included that "[t]he M2a Magnum was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use" and that "the M2a Magnum was used in a manner reasonably anticipated." *Id.* Jury Instruction No. 11 stated the negligence requirements, including that "the M2a Magnum was in a defective condition unreasonably dangerous" and "Biomet failed to use ordinary care to design the M2a Magnum to be reasonably safe." *Id.* at 12. At the conclusion of the evidence, Biomet requested a judgment as a matter of law. The district court denied this motion, concluding that sufficient evidence of causation had been adduced. The jury found for Biomet on the strict liability claim but for Mary on the negligence claim, awarding her $20 million.

Biomet then renewed its motion for judgment as a matter of law. Biomet requested a verdict in its favor, arguing that the jury's negligence verdict for Mary was logically inconsistent with and thus irreconcilable with its strict liability verdict in Biomet's favor. In the alternative, Biomet requested a new trial or remittitur on damages. The court denied its motions. The court stated that the verdicts were not contradictory and that Mary put forward sufficient evidence of breach, causation, and damages. Biomet timely filed notice of this appeal.

II. *Discussion*

On appeal, Biomet argues that (1) the verdicts were inconsistent and require a new trial or directed judgment for Biomet, (2) the plaintiffs failed to establish the required standard of care for Biomet, (3) the plaintiffs failed to establish a breach by Biomet, and (4) the damages were excessive and require remittitur or a new trial.

A. *Inconsistent Verdicts*

Mary presented strict liability product-defect and negligent design claims to the jury. Before submitting the case to the jury, the court instructed it on each claim in Jury Instructions No. 10 and No. 11 respectively.

INSTRUCTION NO. 10.

On Plaintiffs' claim for strict liability-product defect, your verdict must be for Mrs. Bayes if you believe:

1. Biomet sold the M2a Magnum in the course of its business, and

2. the M2a Magnum was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use, and

3. the M2a Magnum was used in a manner reasonably anticipated, and

4. Such defective condition, as existed when the M2a Magnum was sold, directly caused or directly contributed to cause damage to Mrs. Bayes.

INSTRUCTION NO. 11

On Plaintiffs' claim for negligence, your verdict must be for Mrs. Bayes if you believe:

1. Biomet designed the M2a Magnum, and

2. the M2a Magnum was in a defective condition unreasonably dangerous, and

3. Biomet failed to use ordinary care to design the M2a Magnum to be reasonably safe, and

4. such failure directly caused or directly contributed to cause Mrs. Bayes to sustain damage.

The phrase "ordinary care" as used in this instruction means that degree of care that an ordinarily careful person would use under the same or similar circumstances.

R. Doc. 362, at 11–12.

Following its deliberations, the jury returned a verdict for Biomet on the strict liability product-defect claim and for Mary on the negligent design claim. Following the return of the verdict, Biomet argued that the verdict was inconsistent and moved for a new trial or altered judgment. The district court denied the motion, and Biomet appeals the district court's denial of its requested post-trial relief.

Whether a jury verdict is irreconcilably inconsistent is a question of law that we review de novo. *SEC v. Quan*, 817 F.3d 583, 589 (8th Cir. 2016). We will conclude that the district court should have granted a new trial "only if there was 'no principled basis upon which to reconcile the jury's inconsistent findings.'" *Top of Iowa Co-op. v. Schewe*, 324 F.3d 627, 633 (8th Cir. 2003) (quoting *Bird v. John Chezik Homerun, Inc.*, 152 F.3d 1014, 1017 (8th Cir. 1998)).

The jury's verdict was not contradictory on its face. The strict-liability claim was defined in Jury Instruction No. 10. The instruction told the jury that two of the elements of strict liability require proof of reasonably anticipated use. Paragraph two required that the M2a Magnum be defective when "put to a reasonably anticipated use." R. Doc. 362, at 11. Paragraph three required that the M2a Magnum be "used in a manner reasonably anticipated." *Id.* Jury Instruction No. 11, which addressed negligence, differed. It contained no requirement that the jury find proof of a reasonably anticipated use.

Biomet does not dispute the differing proof elements in the two instructions. Rather, it urges the court to conclude that the element of strict liability requiring proof of reasonably anticipated use was undisputed and thus functionally stipulated. Biomet points to the closing arguments. In closing, Mary's counsel argued, "The M2a Magnum was used in a manner reasonably anticipated. Well, this is an easy one." R. Doc. 357, at 112:9–11. In its closing, Biomet omitted discussion of the element of reasonably anticipated use. The absence of contrary argument by Biomet did not create a constructive stipulation obviating the necessity of a jury finding of an element of Mary's claim. An assertion of a disputed stipulation requires record evidence of the stipulation. *See Gander v. Livoti*, 250 F.3d 606, 610 (8th Cir. 2001) ("There might have been some tacit agreement at the status conference, but there is no record of what the parties stipulated to in terms of the facts of this case. Consequently, we find that there exists no stipulation that would be binding . . . .").

Without a stipulation, the presence of an essential element of a claim remained for the fact finder. At trial, Biomet's strategy focused on potential medical misuse of the device. It adduced evidence that the surgeon installed Mary's M2a Magnum implant outside of the angle recommended by accepted guidelines. Dr. Steven Kurtz, an expert witness for Biomet, testified that the implantation angle of Mary's left hip implant was not in a "biomechanically optimal position." R. Doc. 345, at 60: 17–20. Dr. Thomas Fleeter, another Biomet expert witness, testified that the angle of Mary's left hip implant was "beyond what was recommended, and that lead to metal-on-metal wear and metallosis and many of the problems that she has experienced." R. Doc. 353, at 116: 2–4.

Biomet attempted to persuade the jury that the implant was used beyond what was reasonably anticipated. A reasonable jury could have agreed. The jury may have made a principled decision to find negligence but not strict liability after viewing the evidence. The district court found that the verdicts were not contradictory. We agree.

B. *Standard of Care*

Biomet argues that Mary needed to establish the highly technical standard of care used in the medical device industry. Mary, in turn, responds that she only needed to establish the standard of care of a reasonably ordinary person, as reflected in Jury Instruction No. 10. We do not reach the question of which standard of care is required. Mary supplied sufficient evidence under either standard.

When reviewing a post-verdict motion for judgment as a matter of law, our analysis reflects our "hesitancy to interfere with a jury verdict." *Bavlsik v. Gen. Motors, LLC*, 870 F.3d 800, 805 (8th Cir. 2017).

> [T]he district court must (1) consider the evidence in the light most favorable to the prevailing party, (2) assume that all conflicts in the evidence were resolved in favor of the prevailing party, (3) assume as proved all facts that the prevailing party's evidence tended to prove, and (4) give the prevailing party the benefit of all favorable inferences that may reasonably be drawn from the facts proved.

Ryan Data Exch., Ltd. v. Graco, Inc., 913 F.3d 726, 732–33 (8th Cir. 2019) (alterations in original) (quoting *Washington v. Denney*, 900 F.3d 549, 558 (8th Cir. 2018)).

After this, "the court must then deny the motion if reasonable persons could differ as to the conclusions to be drawn from the evidence." *Id.* at 733 (quoting *Denney*, 900 F.3d at 558–59). We therefore look to the evidence put forward by Mary.

Mari Truman, a biomedical engineer with a history of designing orthopedic devices, testified as an expert witness for Mary. Truman testified that the M2a Magnum was unreasonably dangerous. She highlighted the increased friction and wear of metal-on-metal implants like the M2a Magnum. She gave a history of metal-

on-metal implants and their associated problems. This history included, among other things, references to a consensus document produced by a substantial number of biomedical engineers on the standards needed for a new generation of metal-on-metal hip implants. This consensus discussed the dangers of ion and particle toxicity. Truman testified that Biomet did not follow the steps recommended by the consensus. Truman also discussed a letter written to Biomet from an orthopedic surgeon, Dr. William Hozack. This letter stated Dr. Hozack's concern that Biomet's metal-on-metal hip implants would cause deleterious systemic effects by releasing metal ions. Further evidence showed that Biomet did not test the M2a Magnum in humans before bringing it to mass market. *See* R. Doc. 345, at 133:17–134:7. Biomet's machine testing used a standard that was not designed for metal-on-metal implants. *See* R. Doc. 348, at 127:16–131:25. Mary's experts testified that Biomet's testing did not replicate the practical conditions of the human body in motion. *See* R. Doc. 322-1, at 27.

Based on the record before it, the jury could have, in its discretion, believed or discounted Truman's testimony in its entirety. Further, the jury could have determined whether Biomet's testing procedures met industry standards. If credited by the jury, this testimony was a sufficient evidentiary basis to conclude that Biomet failed to meet a reasonable standard of care. When reviewing a renewed motion for a judgment as a matter of law, "we must resolve credibility issues in favor of the verdict." *United States v. Spears*, 454 F.3d 830, 832 (8th Cir. 2006). Therefore, we credit this testimony. The district court's ruling that Mary established a sufficient standard of care is affirmed.

C. *Insufficient Evidence of Breach*

Biomet also argues that Mary failed to establish that the M2a Magnum was defectively designed. In order to recover under Missouri negligent design law, the plaintiff must show the defendant breached its duty of care in designing the product. *Blevins v. Cushman Motors*, 551 S.W.2d 602, 608 (Mo. 1977) (en banc). Biomet

raises an over-generalized characterization that Mary only put forward evidence that all metal-on-metal hip implants are defectively designed. It then attempts to defeat that strawman by arguing that such class-wide criticism does not establish that the M2a Magnum specifically was defectively designed. Because Mary put forward evidence that actual choices Biomet made in the specific design of the M2a Magnum were negligent, this argument fails.

Mary presented the jury with evidence of at least two possible negligent design choices by Biomet. First, Mary argued that Biomet's metal-on-metal choice, in conjunction with the limited testing it received, was negligent. Mari Truman testified that metal-on-metal implants create harmful metal ions. Biomet contends that this cannot be a design defect, as it is common to the class of metal-on-metal hip implants. However, the correct class of comparison is all hip implants, as metal-on-metal is a specific design choice used in the creation of a hip implant system. Dr. Paul Lux agreed that this is a problematic choice because "when metal rubs against metal, it creates particles, ions . . . . And these ions are toxic." R. Doc. 334, at 55:13–14. The design choices Biomet made parallel the design choices challenged in *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748 (Mo. Ct. App. 2008). In that case, specific design choices in the creation of Kool cigarettes, using menthol and increasing nicotine levels, increased the probability of harm from the cigarettes. *Id.* at 795. Similarly, Mary produced evidence that the design choice to use metal-on-metal surfaces instead of ceramic or plastic in the M2a Magnum increased the probability of harm from the implant's use. The choice of using metal surfaces in the articulating hip joint is a design that the jury could have fairly judged as reasonable or negligent.

Second, Mary presented evidence that the choice of the larger implant cup was negligent. When Mari Truman was asked if the head size of the cup was part of what made the M2a Magnum defective, she responded, "Yes, it was, . . . those things with a bigger head just give you more area to have wear . . . and more ions." R. Doc 330,

at 104:7–14. Biomet countered that the large head size reduced, not increased, the levels of ions released, citing a scientific article. *See* R. Doc 330, at 150:14–20. The jury was given this competing evidence about the reasonableness of the large femoral head diameter on the M2a Magnum, and it was within its discretion to weigh this evidence.

Because the jury had a sufficient evidentiary basis to find a design defect, we do not overturn its determination. We review the jury's finding "in the light most favorable" to its verdict. *Borchardt v. State Farm Fire & Cas. Co.*, 931 F.3d 781, 784 (8th Cir. 2019). Therefore, the decision of the district court is affirmed.

D. *Excessive Verdict*

Lastly, Biomet argues that the jury verdict of $20 million for Mary was excessive and that the district court should have granted remittitur. We give great deference to the judgment of the district court, as "the district court has the benefit of hearing the testimony and observing the demeanor of the witnesses throughout the trial." *Bonner v. ISP Techs., Inc*., 259 F.3d 924, 932 (8th Cir. 2001). Our standard of review is for a manifest abuse of discretion. *Tedder v. Am. Railcar Indus., Inc.*, 739 F.3d 1104, 1111 (8th Cir. 2014). Missouri state law governs the adequacy of damages. *Sanford v. Crittenden Mem'l Hosp.*, 141 F.3d 882, 884 (8th Cir. 1998). "Although the appropriateness of a new trial is a federal procedural question decided by reference to federal law, in determining whether a state law claim damage award is excessive, state case law guides our inquiry." *Id.* (citation omitted). Under Mo. Ann. Stat. § 537.068, a jury verdict is excessive when "the amount of the verdict exceeds fair and reasonable compensation for plaintiff's injuries and damages." The Missouri Supreme Court instructs courts to look to

> (1) loss of income, both present and future; (2) medical expenses; (3) plaintiff's age; (4) the nature and extent of plaintiff's injuries; (5) economic considerations; (6) awards given and approved in comparable

> cases; and (7) the superior opportunity for the jury and the trial court to evaluate plaintiff's injuries and other damages.

Emery v. Wal-Mart Stores, Inc., 976 S.W.2d 439, 448 (Mo. 1998) (en banc) (per curiam).

Mary received only non-economic damages. The injuries behind the pain and suffering damages were undisputedly severe. Mary has undergone seven hip revision surgeries. None have been able to provide her complete relief. The severe necrosis of tissue around her left hip joint will permanently prevent proper hip function. Mary had suffered at least 12 hip dislocations since the installation of the M2a Magnum. She is highly likely to suffer further dislocations. Routine aspects of daily living, such as sitting, walking, and sleeping have become sources of fear and discomfort. A verdict of $20 million is undoubtedly large, but it is not clearly disproportionate to the severe and irreparable injury Mary has experienced. "Awards for pain and suffering are often 'highly subjective and should be committed to the sound discretion of the jury, especially when the jury is being asked to determine injuries not easily calculated in economic terms.'" *Hudson v. United Sys. of Ark., Inc.*, 709 F.3d 700, 705 (8th Cir. 2013) (quoting *Frazier v. Iowa Beef Processors, Inc.*, 200 F.3d 1190, 1193 (8th Cir. 2000)).

Awards from similar cases are not out of proportion to the $20 million damages award. While other awards for metal-on-metal hip implant failures have often been smaller, other plaintiffs' injuries have been materially less severe. In *Kirschner v. DePuy Orthopaedics*, the plaintiff underwent a single revision surgery and was awarded $17.5 million in pain and suffering damages. 3:16-cv-01526, 2017 WL 10087150, at *2 (N.D. Tex. Nov. 14, 2017). This award was exclusive of another $28 million of punitive damages awarded. *Id.* at *3. In *Kransky v. Depuy Orthopaedics, Inc.*, the jury awarded $8 million to a plaintiff who had undergone a single revision surgery. No. B249576, 2016 WL 3960033, at *1 (Cal. Ct. App. July 21, 2016). It is

not incommensurate to award Mary $20 million when she has undergone seven revision surgeries and has regained only very limited mobility.

Whether $20 million is the correct compensation for a lifetime of hip dislocations and seven revision surgeries is a difficult question. We defer to the jury's judgment in this inquiry and do not usurp the supervision of the district court lightly. Mary's damages award was not "plain injustice or a monstrous or shocking result." *Eich v. Bd. of Regents for Cent. Mo. State Univ.*, 350 F.3d 752, 763 (8th Cir. 2003) (internal quotation marks omitted). We affirm the district court's denial of remittitur or a new trial.

III. *Conclusion*

We hold that the district court did not err in denying Biomet's motions for a judgment as a matter of law, a new trial, or remittitur. Accordingly, we affirm the judgment of the district court.