United States Court of Appeals
For the Eighth Circuit

No. 21-2263

Lori Nicholson

Plaintiff - Appellee

Willis William Nicholson

Plaintiff

v.

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

Defendants - Appellants

Appeal from United States District Court
for the Northern District of Iowa

Submitted: April 13, 2022
Filed: August 24, 2022

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

GRASZ, Circuit Judge.

This products liability case arises out of the multidistrict litigation[1] ("MDL") proceedings regarding Biomet's M2a Magnum hip-replacement device. After experiencing complications from a hip replacement surgery using the M2a Magnum, Lori Nicholson sued Biomet, Inc., Biomet Orthopedics, LLC, Biomet Manufacturing LLC, and Biomet U.S. Reconstruction, LLC (collectively, "Biomet"), alleging multiple claims, including defective design. A jury ultimately found in Nicholson's favor, concluding the M2a Magnum was defectively designed. The jury also awarded Nicholson punitive damages. Biomet moved for a new trial and renewed its motion for judgment as a matter of law, but the district court[2] denied these motions. For the reasons set forth below, we affirm.

I. Background

Nicholson's left hip was replaced in 2007 with Biomet's M2a Magnum—a large metal-on-metal articulation total hip replacement device. About four years later, Nicholson returned to her surgeon, Dr. Emile Li, with hip pain and a cyst at the crease of her left hip. Dr. Li determined Nicholson's symptoms were caused by the M2a Magnum's loosening and migration. Dr. Li attributed the cyst and migration to metal-on-metal wear and the release of metal ions. Dr. Li tested Nicholson's chromium and cobalt levels through a blood draw and discovered Nicholson's chromium level was six times the normal rate. Dr. Li diagnosed Nicholson with metallosis—deposition of metal debris into bodily fluids and tissue—and concluded the M2a Magnum had failed. Dr. Li recommended Nicholson have a revision surgery to replace the metal-on-metal M2a Magnum with

[1]The Judicial Panel on Multidistrict Litigation transferred products liability cases concerning Biomet's M2a Magnum to the United States District Court for the Northern District of Indiana. *In re Biomet M2a Magnum Hip Implant Prod. Liab. Litig.*, 896 F. Supp. 2d 1339, 1340–41 (J.P.M.L. 2012). The United States District Court for the Northern District of Indiana then transferred Nicholson's case to the Northern District of Iowa.

[2]The Honorable C.J. Williams, United States District Judge for the Northern District of Iowa.

a metal-on-polyethylene ("metal-on-poly") device. Dr. Li performed Nicholson's revision surgery months later without complication, and Nicholson's condition improved.

Nicholson later sued Biomet, asserting multiple claims—including one for defective design.[3] Nicholson also sought punitive damages, alleging Biomet knew the M2a Magnum's metal-on-metal design was defective yet continued to design, manufacture, and market the device with a conscious and deliberate disregard for the rights and safety of consumers. Biomet moved for summary judgment on all claims. The district court granted summary judgment in favor of Biomet on all claims except for Nicholson's defective design and punitive damages claims. Among the claims on which the district court awarded summary judgment to Biomet was a product liability claim based on a failure to warn. The district court held the warnings and instructions for the device were adequate as a matter of law.

The case proceeded to a jury trial on the defective design claim and punitive damages. The jury found for Nicholson, finding the alleged design defect of the M2a Magnum caused Nicholson's injuries, and awarded $1,050,000 in compensatory damages. The jury further found Biomet's conduct constituted a willful and wanton reckless disregard for the rights and safety of consumers and awarded Nicholson $2,500,000 in punitive damages.

Biomet then filed two post-trial motions. First, Biomet moved for a new trial claiming the district court erred in admitting evidence and refusing to give appropriate jury instructions. Second, Biomet moved for judgment as a matter of law on Nicholson's defective design claim and on Nicholson's request for punitive

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[3]Nicholson's defective design claim is governed by Iowa law. *Adams v. Toyota Motor Corp.*, 867 F.3d 903, 916 (8th Cir. 2017) ("State law governs the substance of . . . diversity-based products liability actions.") (alteration in original) (quoting *Pritchett v. Cottrell, Inc.*, 512 F.3d 1057, 1063 (8th Cir. 2008)); *see also* Complaint, ECF No. 1 at 2, *Nicholson v. Biomet, Inc*, No. 3:18-cv-03057 (N.D. Iowa 2021) (claiming federal jurisdiction under 28 U.S.C. § 1332).

damages. The district court denied both motions. Biomet now appeals the district court's denial of these post-trial motions.

II. Analysis

A. Biomet Was Not Denied a Fair Trial

Biomet claims the district court erred in denying its motion for a new trial. Specifically, Biomet argues it is entitled to a new trial because the district court erroneously: (1) admitted testimony relying on post-2007 data regarding the performance of metal-on-metal devices while refusing to allow Biomet to introduce evidence of the M2a Magnum's performance in 2007; (2) failed to instruct the jury on its previous ruling that the M2a Magnum's warnings were adequate as a matter of law; and (3) admitted certain testimony from Nicholson's experts.

We review the district court's denial of a new trial for abuse of discretion. *Bank of Am., N.A. v. JB Hanna, LLC*, 766 F.3d 841, 851 (8th Cir. 2014). When a motion for new trial is based on evidentiary rulings or jury instructions, "we will not reverse the district court in the absence of 'a clear and prejudicial abuse of discretion.'" *SEC v. Cap. Sols. Monthly Income Fund, LP*, 818 F.3d 346, 353 (8th Cir. 2016) (quoting *White v. McKinley*, 605 F.3d 525, 533 (8th Cir. 2010)); *accord Vaidyanathan v. Seagate US LLC*, 691 F.3d 972, 976 (8th Cir. 2012). In other words, "[a] new trial is necessary only when the errors misled the jury or had a probable effect on a jury's verdict." *Vaidyanathan*, 691 F.3d at 978 (quoting *Slidell, Inc. v. Millennium Inorganic Chems., Inc.*, 460 F.3d 1047, 1054 (8th Cir. 2006)).

1. Post-2007 Evidence and the M2a Magnum's Performance

Biomet first argues a new trial is needed because the district court erroneously permitted Nicholson to introduce evidence regarding post-2007 data on the performance of metal-on-metal devices while it forbade evidence of the M2a Magnum's performance. Biomet sought to introduce evidence that, on the week of

Nicholson's surgery in 2007, the MAUDE database[4]—a government database housing medical device reports—showed only one complaint of the M2a Magnum's loosening out of approximately 25,000 devices sold. The district court excluded Biomet's evidence, along with any evidence of gross data from either side on failure rates, because the data's probative value did not outweigh the danger of misleading the jury. The district court, however, allowed post-2007 evidence relating to causation issues.

At trial, Nicholson's experts Mari Truman and Dr. John Cuckler testified that metal-on-metal devices had higher rates of revision surgery than metal-on-poly devices because metal-on-metal devices have a higher risk of causing damage.[5] These experts used post-2007 data and academic research to reach their conclusions. In response, Biomet sought to elicit testimony from Dr. Li explaining that, out of the 200 M2a Magnums he had used in surgery, Nicholson's was the only revision he performed. Biomet also sought to introduce evidence of post-market surveillance data up to 2016 showing the M2a Magnum performed almost identically to metal-on-poly devices and performed substantially better than other metal-on-metal

[4]The MAUDE database houses medical device reports submitted to the United States Food and Drug Administration ("FDA") by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as health care professionals, patients, and consumers. FDA, Medical Device Reporting (MDR): *How to Report Medical Device Problems*, https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems (last visited Aug. 8, 2022); *see also* 21 C.F.R. § 803.1(a) (establishing requirements for medical device reporting).

[5]The district court also allowed Dr. George Kantor to testify about the number of revision surgeries he has performed on patients with second generation metal-on-metal hips. Biomet did not object to this testimony at trial but now argues the district court erroneously admitted this testimony. Accordingly, we review the district court's admission of Dr. Kantor's number of revision surgeries for plain error. *See Dixon v. Crete Med. Clinic, P.C.*, 498 F.3d 837, 849–50 (8th Cir. 2007). Assuming for the sake of argument the admission of this testimony was plain error, the testimony did not prejudice Biomet's substantial rights. We therefore reject Biomet's argument.

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