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

[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.

devices. The district court excluded this evidence and upheld its rulings in denying Biomet's motion for a new trial.

a. The MAUDE Data

Biomet argues the district court abused its discretion by excluding its MAUDE data. Biomet argues this evidence was relevant because it "powerfully supported the reasonableness of Biomet's conduct in designing and selling the M2a Magnum in 2007." Biomet also argues the district court erred in excluding the evidence based on relevancy because critiques concerning the data's meaning and value "are more appropriately directed to the weight, rather than the admissibility of this evidence." *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1332 (M.D. Fla. 2015).

Even if we assume the district court erred in excluding the MAUDE data, it is unlikely the data would have substantially swayed the jury. *See Russell v. Anderson*, 966 F.3d 711, 729 (8th Cir. 2020) (holding this court will not disturb the verdict unless "it is likely that the jury would have been substantially swayed by the wrongly excluded testimony if it had been admitted") (quoting *Hall v. Arthur*, 141 F.3d 844, 849 (8th Cir. 1998)). The jury was tasked with determining whether Biomet's M2a Magnum design was defective. Nicholson presented evidence that Biomet knew of the foreseeable risks of using metal-on-metal devices and that reasonable alternative designs (metal-on-poly) would have reduced those foreseeable risks. *See* Restatement (Third) of Torts: Prods. Liab. § 2(b) (defining defective design); *see also Wright v. Brooke Grp. Ltd.*, 652 N.W.2d 159, 169 (Iowa 2002) (adopting sections 1 and 2 of the Restatement (Third) of Torts: Products Liability for product defect cases). The MAUDE data suggesting the M2a Magnum's success in 2007 does not refute any of Nicholson's evidence. Success of the M2a Magnum does not mean the design did not have foreseeable risks and that those risks could not have been prevented with an alternative design. We thus hold that any alleged error in excluding the MAUDE data was harmless. *See White*, 605 F.3d at 533 (holding reversal is necessary only if "there is no reasonable assurance the jury would have

reached the same" verdict had the excluded evidence been admitted) (quoting *Wilson v. City of Des Moines*, 442 F.3d 637, 641 (8th Cir. 2006)).

b. Testimony Relying on Post-2007 Data

Next, Biomet argues the district court erred in admitting testimony relying on post-2007 data on metal-on-metal devices. Biomet argues Nicholson should not "have been allowed to present evidence showing how the M2a Magnum performed and compared with products *after* 2007, since Biomet could not reasonably have known about or acted on that information" at the time of Nicholson's surgery. Biomet is correct in that post-2007 data was inadmissible to show the M2a Magnum product was defectively designed. Biomet cannot be held liable for not acting on the post-2007 revision-rate data on the M2a Magnum at the time of Nicholson's surgery in 2007. *See* Restatement (Third) of Torts: Prods. Liab. § 2(b) cmt. d ("If such a design could have been practically adopted *at the time of sale* and if the omission of such a design rendered the product not reasonably safe, the plaintiff establishes [design] defect[.]" (emphasis added)).

But the post-2007 revision-rate data was admissible to prove causation—that is, the M2a Magnum's metal-on-metal design *caused* Nicholson's injury. Under Iowa law,

> [A] plaintiff seeking to recover damages on the basis of a design defect must prove "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe."

Wright, 652 N.W.2d at 169 (quoting and adopting Restatement (Third) of Torts: Prods. Liab. § 2(b)). The plaintiff must also show the defective design caused the plaintiff's injury. *Huber v. Watson*, 568 N.W.2d 787, 790 (Iowa 1997) ("In products

liability, the plaintiff must prove his or her injuries were proximately caused by an item manufactured or supplied by the defendant.").

Here, Truman's and Dr. Cuckler's testimonies—relying on post-2007 data—suggesting metal-on-metal devices had higher revision rates went toward proving causation. Their testimony was limited to data concerning revision rates based on patients' adverse biologic reactions to the metal-on-metal device. Thus, the evidence was probative of whether the M2a Magnum caused Nicholson's complained-of injuries—hip implant failure based on loosening of the device, a pseudo cyst consistent with metal-on-metal wear, and increased chromium levels.

Further, the danger of prejudice did not substantially outweigh the evidence's probative value given the district court's limiting instructions explaining that post-2007 evidence could only be used for purposes of causation. *See* Fed. R. Evid. 403*; United States v. Howard*, 977 F.3d 671, 676 (8th Cir. 2020), *cert. denied*, 142 S. Ct. 123 (2021) (holding a limiting instruction "diminished the prejudicial effect of the evidence"). The district court explicitly warned the jury it "can't use [post-2007] evidence to try to determine whether [Biomet] should have known about the results of [studies] that clearly occurred before—or after the implant." Given the evidence's probative value establishing causation and the district court's limiting instructions, we will not disturb the jury's verdict because of the admission of this evidence.

c. Dr. Li's Revisions and M2a Magnum's Post-Market Data

Biomet also argues the district court erred by precluding Biomet from offering fair rebuttal. Biomet argues that Dr. Li's revision testimony and the M2a Magnum's post-market data should have been admitted—even if the evidence was not originally admissible—because Nicholson's expert testimony "opened the door." We disagree.

"The doctrine of opening the door allows a party to explore otherwise inadmissible evidence on cross-examination when the opposing party has made

unfair prejudicial use of related evidence on direct examination." *Valadez v. Watkins Motor Lines, Inc.*, 758 F.3d 975, 981 (8th Cir. 2014) (quoting *United States v. Midkiff*, 614 F.3d 431, 442 (8th Cir. 2010)). "But the door is not opened to all similar, inadmissible evidence." *Id.* The evidence introduced must be in response to something elicited during the opposing party's evidence. *Id.* In other words, it must actually rebut the initial testimony. *See Hamilton v. Nix*, 809 F.2d 463, 469 (8th Cir. 1987).

The evidence Biomet sought to introduce was not related to Nicholson's expert testimony relying on post-2007 data. Nicholson's expert testimony relying on post-2007 data established that metal-on-metal devices are known to cause the type of injuries suffered by Nicholson. As the district court made abundantly clear in its limiting instructions, the evidence was only admissible for the purpose of causation. Biomet's proffered evidence did not speak to causation. Dr. Li's history of revision surgery on patients with the M2a Magnum device and post-market data of the M2a Magnum do not rebut Nicholson's claim that metal-on-metal devices cause the injuries at issue here. Thus, because Biomet's proffered evidence does not speak to causation, the district court did not abuse its discretion in excluding this evidence.

2. Expert Testimony

Biomet also argues the district court abused its discretion in allowing Nicholson's experts—specifically, Truman and Dr. Kantor—to testify on issues they were not qualified to address. Biomet argues the testimony given by the experts was outside their scope of expertise and unfairly prejudicial, warranting a new trial. For the following reasons, we disagree.

a. Truman's Testimony

Biomet argues the district court erroneously allowed Truman, a biomedical engineer, to testify as to the causal relationship between metal ions produced by the

M2a Magnum device and adverse biologic reactions in patients. Before trial, the MDL court held that Truman "can't testify as an expert on the clinical effects of metal ions" because she was not qualified to do so. But at trial, Truman testified that medical reports and literature reported adverse reactions caused by metal ions produced from metal-on-metal devices. This included testimony about the medical impact of metal ions in the body.

Biomet argues Truman's testimony was inadmissible under Federal Rule of Evidence 703 because it went beyond the scope of her expertise. Indeed, under Rule 703, "[a] scientist, however well credentialed [she] may be, is not permitted to be the mouthpiece of a scientist in a different specialty." *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002). Rule 703 does, however, allow experts to offer "an opinion on facts or data in the case that the expert has been made aware of or personally observed . . . [i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject[.]" Fed. R. Evid. 703.

The district court did not err in admitting Truman's testimony because her testimony was limited to her opinion on the design of the M2a Magnum. Truman did not testify as to whether metal ions caused certain clinical effects. Instead, she relied on medical experts' opinions about the clinical effects of metal ions to draw her conclusion as to whether the M2a Magnum was defective in its design. Biomedical engineers, such as Truman herself, unquestionably rely on such data from medical experts when designing medical devices compatible with the human body. Thus, Truman correctly used medical reports and literature as contemplated by Rule 703 to support her opinion as a biomedical engineer on the design of the M2a Magnum.

If any of Truman's testimony inadvertently touched on the causation of adverse medical reactions, any danger of prejudice was mitigated by the district court's limiting instructions. The district court gave several limiting instructions explaining Truman did not have personal knowledge of metal ions and how metal

ions affect the body. The district court also explained that Truman was using expert reports to form her opinion on the M2a Magnum's design. Given that these instructions effectively addressed Biomet's concerns about Truman's testimony being mistaken for that of a medical expert, it is hard to imagine that any alleged error in admitting the testimony prejudicially influenced the outcome of the trial. *See United States v. Bassett*, 762 F.3d 681, 688 (8th Cir. 2014) ("[A] proper limiting instruction serves as a protection against unfair prejudice.") (alteration in original) (quoting *United States v. Cockerham*, 417 F.3d 919, 921 (8th Cir.2005)). For this reason, we hold the district court did not abuse its discretion in admitting Truman's testimony.

b. Dr. Kantor's Testimony

Biomet next argues the district court abused its discretion in allowing Dr. Kantor, an orthopedic surgeon, to testify on the ethics or criminality of introducing the M2a Magnum without first conducting clinical testing. Biomet also takes issue with Nicholson's attorney's comments regarding Dr. Kantor's testimony during closing arguments.

At trial, the district court permitted Dr. Kantor to give his opinion on the dangerousness of marketing a product without clinical testing—despite Biomet's objections. The MDL court had precluded testimony from Dr. Kantor on the sufficiency of Biomet's testing and clinical studies. The MDL court concluded Dr. Kantor's opinion was not reliable on this topic based on Dr. Kantor's admitting he had only looked at *some* of Biomet's testing. Yet at trial, the district court admitted the following testimony:

> [Nicholson]: What is your opinion with respect to the dangerousness of marketing a product without doing clinical testing?
>
> [Dr. Kantor]: I think it's unethical. I think it borders on criminal behavior, if you know that that—if you know that

> that material can be deleterious and harmful to patients, including—including the life of patients, because of the complications related to the introduction—reintroduction of a failed material.

Then, during closing argument, Nicholson's counsel reiterated Dr. Kantor's testimony, but directed it toward Biomet's testing specifically:

> [Nicholson]: Dr. Kantor said that what was done was unethical and borderline criminal. Those are very strong—
>
> [Biomet]: I'm going to object to that, Your Honor. I think that was stricken.
>
> [The Court]: Yeah, it was not. My recollection is that came in.
>
> [Nicholson]: Yeah. Those are very strong words, very strong words from a doctor, talking about a medical device company. And, obviously, he has very strong feelings, and that came through in spades.

Even if the district court erroneously admitted Dr. Kantor's testimony and Nicholson's counsel's statement during closing arguments, Biomet fails to show the errors "prejudicially influenced the outcome of the trial." *Coterel v. Dorel Juv. Grp., Inc.*, 827 F.3d 804, 807 (8th Cir. 2016) (quoting *Regions Bank v. BMW North Am., Inc.*, 406 F.3d 978, 980 (8th Cir. 2005)). "To determine whether the evidentiary errors . . . prejudicially influenced the outcome of the case, we look to the jury's verdict." *Id.* at 808 (quoting *Qualley v. Clo–Tex Int'l, Inc.*, 212 F.3d 1123, 1131 (8th Cir. 2000)). Here, the jury was asked to determine whether Biomet's M2a Magnum product was defective in design. While the ethical or criminal nature of Biomet's conduct is irrelevant to Nicholson's defective design claim under Iowa law, *see Wright*, 652 N.W.2d at 169, the jury was clearly instructed on the proper elements of defective design, *see Interstate Fin. Corp. v. Iowa City*, 149 N.W.2d 308, 313 (Iowa 1967) (holding proper instructions cured trial court's erroneous admission of testimony), and Biomet can only offer speculation that the jury improperly

considered Dr. Kantor's testimony as to the ethical or criminal nature of Biomet's conduct. "Speculation, however, is not a sufficient basis for finding [the appellants'] substantial rights were affected, and we will not set aside the jury's verdict in this case." *Coterel*, 827 F.3d at 808 (alteration in original) (quoting *Regions Bank*, 406 F.3d at 981).

To the extent Biomet claims the alleged errors prejudicially influenced the jury's award of punitive damages, we also find this unpersuasive. Given the evidence of Biomet's willful and wanton disregard for safety detailed below, we cannot say the evidence complained of was so prejudicial a new trial would likely produce a different result. *See Parkhurst v. Belt*, 567 F.3d 995, 1003 (8th Cir. 2009) (holding evidentiary error would have been harmless because overwhelming evidence supported verdict).

3. Jury Instructions

Biomet next argues that the district court erroneously refused to instruct the jury that the district court had previously found the M2a Magnum's warnings and instructions were adequate as a matter of law. Biomet proposed two jury instructions on this point. The district court initially agreed to give these instructions but ultimately excluded them, finding the adequacy of the M2a Magnum's warnings and instructions were irrelevant.

a. The District Court Did Not Abuse Its Discretion

Biomet argues the district court abused its discretion in failing to instruct the jury that the M2a Magnum's instructions and warnings were adequate as a matter of law. Biomet argues the omission of this instruction was erroneous because the "instructions and warnings accompanying the product" are expressly listed in Iowa Civil Jury Instruction 1000.4 as a factor to consider in assessing "whether a product was reasonably safe." Nicholson admits warnings and instructions are listed as a

factor on which the court could have instructed the jury.[6] But Nicholson maintains the district court was not required to include this factor because the evidence and issues presented to the jury did not involve the adequacy of the M2a Magnum's warnings and instructions. We agree.

Biomet simply failed to produce evidence at trial that its warnings or instructions for the M2a Magnum created a defense to Nicholson's design defect claim. The district court possesses a broad discretion in instructing the jury. While the district court's jury instructions "must fairly and adequately represent the law of the forum state," it is "not required to instruct on issues that do not find support in the record." *McCoy v. Augusta Fiberglass Coatings, Inc.*, 593 F.3d 737, 744 (8th Cir. 2010) (quoting *Brown v. Sandals Resorts Int'l.*, 284 F.3d 949, 953 (8th Cir. 2002)). Here, the trial record is void of any attempt by Biomet to suggest the M2a Magnum's warnings and instructions negated Nicholson's claim that a reasonable alternative design existed.

Biomet argues it cannot be faulted for not introducing evidence of M2a Magnum's warnings or instructions at trial because the district court had already

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[6]Iowa Civil Jury Instruction 1000.2 lays out what is required to prove a defective design claim. Relevant here, a plaintiff must prove that the product was defective at the time it left defendant's control by showing "[a] reasonable alternative safer design could have been practically adopted at the time of sale or distribution," "[t]he alternative design would have reduced or avoided the foreseeable risks of harm posed by the product," and "[t]he omission of the alternative design renders the product not reasonably safe." Iowa Civ. Jury Instr. 1000.2 (propositions 4–6) (formatting altered). Instruction 1000.4 then provides instructions for determining whether an alternative design is reasonable and whether the omission of the alternative design renders the product not reasonably safe. Iowa Civ. Jury Instr. 1000.4 ("Concerning propositions 4, 5, and 6 of Instruction No. [1000.2], you may consider the following factors . . . ."). The instructions provide a non-exhaustive list of factors to consider. *See* Iowa Civ. Jury Instr. 1000.4 (providing at the end of the factor list: "Any other factor shown by the evidence bearing on this question"). One factor listed is "[t]he instructions and warnings accompanying the product." *Id.* (formatting altered).

concluded they were legally sufficient. But the district court's summary judgment ruling concluded the M2a Magnum's warnings and instructions were legally sufficient in the context of Nicholson's failure to warn claim.[7] This ruling has no bearing on whether the M2a Magnum's warnings and instructions prove an alternative design was unreasonable or would not have prevented the foreseeable risks it posed. Minding the district court's broad discretion in formulating its jury instructions, we affirm the district court's decision to not instruct the jury on the sufficiency of the M2a Magnum's warnings and instructions.

B. Punitive Damages

Lastly, Biomet argues the district court erred in denying its motion for judgment as a matter of law on the issue of punitive damages. We review the district court's denial of a motion for judgment as a matter of law de novo and consider the evidence in the light most favorable to the jury's verdict. *Procknow v. Curry*, 826 F.3d 1009, 1013 (8th Cir. 2016). "Judgment as a matter of law is only appropriate when no reasonable jury could have found for the nonmoving party." *Monohon v. BNSF Ry. Co.*, 17 F.4th 773, 780 (8th Cir. 2021) (quoting *Southern Wine & Spirits of Nev. v. Mountain Valley Spring Co.*, 646 F.3d 526, 533 (8th Cir. 2011)). Accordingly, we give high deference to the jury's verdict, drawing all reasonable

[7]Nicholson's failure to warn claim was a separate and distinct cause of action from its design defect claim. Under Iowa law, a plaintiff can claim a product is defective based on a manufacturing defect, a defective design, or that the product is defective because of inadequate instructions or warnings. *See* Restatement (Third) of Torts: Prods. Liab. § 2. These are treated as separate claims with separate standards of liability. *See Wright*, 652 N.W.2d at 168. To establish a failure to warn claim, a plaintiff must show that a product "is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings." Restatement (Third) of Torts: Prods. Liab. § 2(c). Here, the district court granted summary judgment on Nicholson's failure to warn claim because it found the M2a Magnum's warnings and instructions warned consumers of the foreseeable risks that materialized with Nicholson here.

inferences in favor of the verdict. *Gruttemeyer v. Transit Auth.*, 31 F.4th 638, 646 (8th Cir. 2022).

Under Iowa Code § 668A.1(1)(a), punitive damages are appropriate when a plaintiff proves by a "preponderance of clear, convincing, and satisfactory evidence, the conduct of the defendant from which the claim arose constituted willful and wanton disregard for the rights or safety of another." Iowa law defines "willful and wanton" conduct as "an act of an unreasonable character in disregard of a known or obvious risk that was so great as to make it highly probable that harm will follow, and which thus is usually accompanied by a conscious indifference to the consequences." *Mercer v. Pittway Corp.*, 616 N.W.2d 602, 617 (Iowa 2000) (quoting *Fell v. Kewanee Farm Equip. Co.*, 457 N.W.2d 911, 919 (Iowa 1990)). Thus, Nicholson bore the burden of proving, by a preponderance of clear, convincing, and satisfactory evidence, that Biomet acted with a willful and wanton disregard of safety in designing the M2a Magnum.

Viewing the evidence in the light most favorable to the verdict, the district court did not err in denying Biomet's motion for judgment as a matter of law on punitive damages. At trial, Nicholson introduced evidence suggesting Biomet should have tested the M2a Magnum device before introducing it to the market but failed to do so. For example, Truman testified that a consensus document from a metal-on-metal conference suggested conducting clinical trials monitoring the metal-on-metal wear and ion measurements in the body. Truman also testified that Dr. Hozack, an orthopedic surgeon who Biomet used as a consultant, wrote a letter to Biomet detailing the concerns of "potential long-term systematic effects of metal ion release" in metal-on-metal devices. Further, Dr. Kantor testified that first-generation metal-on-metal devices were considered a "failed system" and that introducing a second-generation metal-on-metal design without clinical testing was "dangerous." Dr. Kantor testified he urged Biomet to conduct testing on the second-generation design to determine whether the performance of the metal-on-metal design had improved.

Nicholson also introduced email evidence. One email from a Biomet administrator instructed Biomet employees to "push [projects] to completion as soon as possible" and to "not accept delays" on projects that will impact Biomet's bottom line. Another email sent from a consulting doctor designing the M2a Magnum to Biomet officials suggested further testing of ion release. A reply to that email from a Biomet official expressed concern that metal ion release data "could be [sic] sales to a halt." A memo from the same consulting doctor expressed concern over data showing adverse responses to metal-on-metal hip devices and the potential medical malpractice implications.

Viewing all reasonable inferences in favor of the jury's verdict awarding punitive damages, it is reasonable to conclude that, despite known dangers of past metal-on-metal designs and advisement to conduct testing before releasing the M2a Magnum device, Biomet willfully and wantonly disregarded other peoples' safety by not conducting long-term clinical trials to monitor the level of metal ions released with the metal-on-metal device's wear. A reasonable jury could conclude that Biomet designed the M2a Magnum with a willful or wanton disregard for the safety of others.

Biomet argues punitive damages are inappropriate here as a matter of law because Biomet issued legally sufficient warnings and instructions with the M2a Magnum. But allowing Biomet to evade liability for known defects of the M2a Magnum before marketing the product simply by issuing safety warnings would defy the purpose of design defect claims. *See* Restatement (Third) Torts: Prods. Liab. § 2 cmt. a (stating liability for products that are defectively designed or sold without adequate warnings or instructions "creat[es] incentives for manufacturers to achieve optimal levels of safety in designing and marketing products"). And Biomet fails to provide controlling authority supporting its argument that legally sufficient warnings and instructions prohibit the award of punitive damages. The Iowa cases Biomet cites do not support this proposition. *See Kinseth v. Weil-McLain*, 913 N.W.2d 55, 78–79 (Iowa 2018) (clarifying that Iowa law does not permit punitive damages where a defendant who had no specific knowledge of a product's harmful

defect failed to act, even if industry peers had such knowledge); *Fell*, 457 N.W.2d at 919–20 (holding punitive damages were inappropriate where the risk of injury from defect was not so great as to make it highly probable that an injury would occur); *see also* Restatement (Third) of Torts: Prods. Liab. § 2 cmt. *l* ("In general, when a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks."). Moreover, the cases Biomet provided from our court[8] are distinguishable in that, in those cases, the refusal to award punitive damages did not frustrate the safety purposes and incentives of design defect liability. *See Drabik v. Stanley-Bostitch, Inc.*, 997 F.2d 496, 510–11 (8th Cir. 1993) (affirming denial of punitive damages where the danger posed by product was dependent on customer's conduct, warnings against the conduct could negate the danger posed by the product, and there was a significant undertaking to remedy the previous defect by defendant); *Hofer v. Mack Trucks, Inc.*, 981 F.2d 377, 383 (8th Cir. 1992) (affirming district court's refusal to submit punitive damages to the jury because there was ample evidence defendant adequately tested product and a complete absence of evidence the defendant had knowledge of any unreasonable risk); *Lockley v. Deere & Co.*, 933 F.2d 1378, 1389–90 (8th Cir. 1991) (holding punitive damages were improper because defendant did take steps to remedy the problem and no reasonable jury could have inferred the defendant acted with conscious indifference to the safety of others).

In sum, the district court did not err in denying Biomet's motion for judgment as a matter of law on punitive damages. Viewing the evidence in the light most favorable to the verdict, a reasonable jury could have found in favor of Nicholson on the issue of punitive damages. We thus affirm the district court's denial.

[8]None of the Eighth Circuit cases provided by Biomet applied Iowa law. *See Drabik v. Stanley-Bostitch, Inc.*, 997 F.2d 496, 505 (8th Cir. 1993) (applying Missouri law); *Hofer v. Mack Trucks, Inc.*, 981 F.2d 377, 382 (8th Cir. 1992) (applying South Dakota law); *Lockley v. Deere & Co.*, 933 F.2d 1378, 1389 (8th Cir. 1991) (applying Arkansas law).

III. Conclusion

For the reasons set forth above, we affirm the district court's denial of Biomet's motion for a new trial and motion for judgment as a matter of law.
