

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Louis Gareis and Lillian Gareis,

Plaintiffs,

v.

Civil No. 16-4187 (JNE/DTS)
ORDER

3M Company and Arizant
Healthcare, Inc.,

Defendants.

Plaintiffs Louis Gareis and Lillian Gareis (“Plaintiffs”) initiated this action against Defendants 3M Company and Arizant Healthcare, Inc. (“Defendants”) for injuries Mr. Gareis alleged that he suffered through use of the Bair Hugger patient warming system during his surgery. Plaintiffs’ case is the first bellwether of the Bair Hugger MDL (15-md-2666).

The Court granted Defendants’ motion for summary judgment on Plaintiffs’ claims for negligence, failure to warn, unfair and deceptive trade practices, misrepresentation, and unjust enrichment. ECF No. 113. On May 30, 2018, a jury returned a verdict in favor of Defendants on the remaining strict liability claim for design defect. Specifically, the jury concluded that Plaintiffs failed to prove by a preponderance of the evidence that (1) the Bair Hugger was unreasonably dangerous for its intended use, (2) a reasonable safer alternative design existed, and (3) Mr. Gareis’ injury would not have occurred but for the use of the Bair Hugger. ECF No. 466.

Plaintiffs now move for a new trial. ECF No. 482. Defendants oppose the motion. ECF No. 492. Plaintiffs chose to file no reply to Defendants' opposition. ECF No. 505; *see also* D. Minn. LR 7.1. For the reasons below, the Court denies the motion.

LEGAL STANDARD

The Court may grant a new trial “for any reason for which a new trial has heretofore been granted in an action at law in federal court.” Fed. R. Civ. P. 59. “A new trial is appropriate when the first trial, through . . . legal errors at trial, resulted in a miscarriage of justice.” *Gray v. Bicknell*, 86 F.3d 1472, 1480 (8th Cir. 1996). To prevail, Plaintiffs must demonstrate that the alleged errors in the trial caused them prejudice. *See Acuity v. Johnson*, 776 F.3d 588, 596 (8th Cir. 2015) (requiring a showing of prejudice to prevail on a motion for a new trial).

DISCUSSION

Plaintiffs cite four main reasons for requesting a new trial. First, they argue that the Court erred in applying South Carolina substantive law to their claims. ECF Nos. 482, 483. Second, they argue that the Court incorrectly applied South Carolina law in its pretrial ruling dismissing claims for negligence, failure to warn, unfair and deceptive trade practices, misrepresentation, and unjust enrichment. Third, they argue that the Court erred in excluding some of their evidence. Fourth, they argue that the Court erred in admitting certain expert testimony.¹ *Id.*

¹ Plaintiffs' motion also states that the Court erred in its “instructions to the jury [and] the formulation of the special verdict.” ECF No. 482 at 1. But neither the motion nor its supporting memorandum make clear the alleged errors. For that reason, the Court cannot rule on these alleged errors.

Plaintiffs fail to establish that the Court erred in its pretrial decision to (1) apply South Carolina substantive law and (2) dismiss Plaintiffs' claims for negligence, failure to warn, unfair and deceptive trade practices, misrepresentation, and unjust enrichment. *See* ECF No. 113 (applying South Carolina law when granting in part Defendants' motion for summary judgment on these claims). The Court therefore denies the motion as to the first and second reasons for a new trial. For the reasons below, the Court also denies the motion as to the third and fourth reasons for a new trial.

I. The Exclusion of Evidence

Plaintiffs asserting a claim for design defect “must show that the design of the product caused it to be unreasonably dangerous.” *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 14 (S.C. 2010) (citation omitted). South Carolina follows the risk-utility test in making this determination. *Id.* The “focus of [the] risk-utility test centers upon the alleged defectively designed product.” *Id.* at 15. It requires Plaintiffs to (1) “point to a design flaw in the product,” (2) “present evidence of a reasonable alternative design,” and (3) “show how [their] alternative design would have prevented the product from being unreasonably dangerous.”² *Id.* at 16. “The presentation of the alternative design must include consideration of the costs, safety and functionality associated with the alternative design.” *Id.* Factors to consider include “the usefulness and desirability of the product,

² Plaintiffs seem to argue that South Carolina law does not here require evidence of an alternative design. As support, Plaintiffs cite the Restatement (Third) of Torts. ECF No. 483 at 24-25. But in *Branham*, the Supreme Court of South Carolina stated clearly: “in a product liability design defect action, the plaintiff *must* present evidence of a reasonable alternative design.” 701 S.E.2d at 16 (emphasis added).

the cost involved for added safety, the likelihood and potential seriousness of injury, and the obviousness of danger.” *Id.* at 13 (citation omitted).

Plaintiffs challenge the Court’s exclusion of three types of evidence that, they insist, would have helped to prove the above elements of a design defect claim. Plaintiffs maintain that the Court improperly excluded (1) evidence of Defendants’ knowledge of the risks and utility of the Bair Hugger, (2) “evidence of multiple alternative designs,” and (3) evidence of the function of the Bair Hugger’s “filtration system and of heater-cooler recalls.” ECF No. 483 at 23-30; ECF No. 482 at 2. Plaintiffs conclude that the exclusion of this evidence justifies a new trial.

Plaintiffs identify no prejudice resulting from the allegedly improper exclusion of the above evidence. This was their burden. *Gray*, 86 F.3d at 1480; *Acuity*, 776 F.3d at 596. What is more, “[a]n allegedly erroneous evidentiary ruling does not warrant a new trial ‘unless the evidence [or its exclusion] was so prejudicial that a new trial would likely produce a different result.’” *Harrison v. Purdy Bros. Trucking Co.*, 312 F.3d 346, 351 (8th Cir. 2002) (citation omitted). Plaintiffs do not discuss how the result of a trial would vary with the admission of the above evidence. So a new trial is unwarranted.

At any rate, the Court denies the motion for a new trial for the additional reason that the Court properly excluded the three types of evidence.

1. Defendants’ Knowledge of the Risks and Utility

Plaintiffs argue that the “Court erred in excluding evidence of 3M’s knowledge of risk-utility.” ECF No. 483 at 23. Yet Plaintiffs’ memorandum in support of their motion does not specifically discuss the excluded evidence. Plaintiffs’ motion, however, cites

without discussion the following evidence of “Defendants’ conduct and knowledge regarding the risks and utility of the product”: “[Tr. 82.1-10 & P1025] (email from Van Duren to Hansen), [Tr. 1001.24-1002.3] (testimony regarding change of design based on utility of changes), [Tr. 1065.15-20] (inadequate warnings bearing on risk-utility analysis), [and] [Tr. 1126, 1131] (safer alternative of other designs including VitaHEAT and Hot Dog).” ECF No. 482 at 2.

The Court properly excluded the above evidence. The risk-utility test “centers upon the allegedly defectively designed product.” *Branham*, 701 S.E.2d at 15. The manufacturer’s mental state is not an element of a strict liability claim for design defect. *See, e.g., Bragg v. Hi-Ranger, Inc.*, 462 S.E.2d 321, 539-40 (S.C. Ct. App. 1995) (“[I]n a product liability action based on strict liability where a design defect is alleged, . . . [t]he focus . . . is on the condition of the product, without regard to the action of the seller or manufacturer.”); *Branham*, 701 S.E.2d at 9 (citing *Bragg* to explain that a negligence claim, “unlike [a claim for] strict liability, . . . focus[es] on the conduct of the seller or manufacturer, and liability is determined according to fault”). Evidence of Defendants’ mental state therefore addresses no element of Plaintiffs’ claim. Moreover, Defendants’ mental state as to the utility and risks of the Bair Hugger does not here “make it more or less probable” that the Bair Hugger was unreasonably dangerous. *See Fed. R. Evid. 401* (deeming evidence relevant only if it “has any tendency to make a fact more or less probable than it would be without the evidence”). The evidence of Defendants’ knowledge is thus irrelevant and inadmissible. *See Fed. R. Evid. 402* (“Irrelevant evidence is not admissible.”)

2. Multiple Alternative Designs

Plaintiffs state that they “sought to present evidence at trial of several reasonable alternatives, but were improperly limited to a single choice.” ECF No. 483 at 29. They claim that “South Carolina law does not limit alternative designs to those that achieve the same function by the same mechanism.” *Id.* They offer no additional arguments and discuss none of the excluded alternative designs.

Plaintiffs cite no South Carolina authority requiring the admission of additional alternative designs here. Nor is the Court aware of any. The Court therefore declines to find error in its rulings on alternative designs. *See generally* MDL ECF Nos. 249, 304.

3. The Filtration System and Heater-Cooler Recalls

Plaintiffs state that they “made [a] formal offer of proof on the function of the Bair Hugger filtration system and its internal contamination [DOC 343], and evidence of heater-cooler recalls [DOC 420].” ECF No. 483 at 30. Plaintiffs then summarily conclude: “These were further evidence of Defendants’ knowledge of the risk-utility of its design and it was error to exclude them.” *Id.*

Plaintiffs give no reason to reverse the Court’s ruling on this evidence, nor is the Court aware of any. *See* ECF No. 306. The Court therefore declines to find any error in the exclusion of this evidence.

II. The Admission of Evidence

Federal Rule of Civil Procedure 26 obligates a party to disclose a report of the opinions of a testifying expert. This report must include “a complete statement of all opinions the witness will express and the basis and reasons for them,” “the facts or data

considered,” and “any exhibits that will be used to summarize or support” the opinions. Fed. R. Civ. P. 26(a)(2)(B). Rule 26(e) also obligates a party to supplement previously disclosed expert reports “if the party learns that in some material respect the” report “is incomplete or incorrect, and if the” supplemental information “has not otherwise been made known to the other parties during the discovery process or in writing.”

A district court may exclude the evidence of a party who fails to follow the disclosure requirements of Rule 26, unless nondisclosure was “substantially justified or harmless.” *Wegener v. Johnson*, 527 F.3d 687, 692 (8th Cir. 2008) (quoting Rule 37). When considering whether nondisclosure is “substantially justified and harmless,” courts balance “the reason for noncompliance, the surprise and prejudice to the opposing party, the extent to which allowing the information or testimony would disrupt the order and efficiency of the trial, and the importance of the information or testimony.” *Id.*

Plaintiffs argue that the Court improperly allowed Defendants’ expert witnesses to offer previously undisclosed opinions or exhibits. They claim that this evidence “took Plaintiffs by surprise and deprived Plaintiffs of the opportunity to prepare a full cross-examination of Defendants’ experts.” ECF No. 483 at 33-34. They conclude that this unfair surprise warrants a new trial. *See, e.g., Sanford v. Crittenden Mem’l Hosp.*, 141 F.3d 883, 886 (8th Cir. 1998) (“Surprise during trial, by major variance in theory of recovery or defense, undisclosed until after the trial is underway, is a long-established ground for granting a new trial motion.”); *see also Harrison*, 312 F.3d at 351 (“An allegedly erroneous evidentiary ruling does not warrant a new trial ‘unless the evidence was so prejudicial that a new trial would likely produce a different result.’”)

Plaintiffs allege six instances of improperly admitted expert testimony.³ None supports a new trial.

1. The Airflow Visualization Study

Plaintiffs state that, “[d]uring their direct examination of Dr. Abraham, Defendants published to the jury DX 945, a videotape that purported to be an airflow visualization study using fog to ‘validate’ the results of Dr. Abraham’s CFD experiment.” ECF No. 483 at 34. Plaintiffs objected to the admission of the video, arguing that Dr. Abraham had not disclosed his intention to use the video. *Id.* The Court allowed the video, and Plaintiffs contend that the “inability to see the video during discovery prevented Plaintiffs from effectively cross-examining Dr. Abraham at deposition or trial regarding the details of how [Dr.] Abraham conducted the experiment.” *Id.* at 35.

But Plaintiffs knew about the video. They saw it on the Bair Hugger MDL Science Day, ECF No. 492 at 29, they referenced it in their motion to exclude the opinions of Dr. Abraham, MDL ECF No. 822 at 19, they explained that it was available on “3M websites,” *id.*, and they asked Dr. Abraham about it in a deposition, ECF No. 456-4 at 144, 327-33. Moreover, Defendants referenced the video and provided the online link to it in their opposition to Plaintiffs’ motion to exclude the opinions of Dr. Abraham. MDL ECF No. 933 at 17. Plaintiffs received yet more notice in

³ In their motion, Plaintiffs cite more than six instances. ECF No. 483 at 2-3. Yet Plaintiffs only discuss six instances in the memorandum supporting their motion. With regard to those instances cited in the motion but not discussed in the memorandum, Plaintiffs have offered no argument about why the evidence was improperly admitted and why the admission justifies a new trial. The Court perceives no reason to find that it improperly admitted the undiscussed evidence or that a new trial is justified. The Court thus declines to order a new trial for admitting the undiscussed evidence.

Dr. Abraham's 2017 expert report, in which he described the "air flow visualization experiment carried out in an actual operating room." MDL ECF No. 934-1 at 3.

Rule 26 requires supplementation unless the information has "otherwise been made known to the other parties during the discovery process or in writing." The video was made known. There was thus no violation of disclosure requirements. Nevertheless, even had there been a violation, the admission of the video was harmless. *See Smith v. Tenet HealthSystem SL, Inc.*, 436 F.3d 879, 889 (8th Cir. 2006) (finding nondisclosure in expert report and the subsequent admission of the undisclosed evidence harmless where objecting party received notice of the undisclosed evidence in a deposition). In other words, Plaintiffs fail to prove any Rule 26 violation or surprise justifying a new trial.

2. Dr. Abraham's Testimony About the Saarinen Study

Plaintiffs state that, over objection, "Defendants solicited testimony from Dr. Abraham about the Saarinen study" and showed a video of the study. ECF No. 483 at 36. Plaintiffs explain that "[Dr.] Abraham never cited the Saarinen study or discussed it in his Rule 26 report; as a result, Plaintiffs did not have the ability to ask [Dr.] Abraham any questions about his opinions of the study at his deposition." *Id.* They insist that this requires a new trial.

Plaintiffs' expert, Dr. Elghobashi, cited the Saarinen study in his 2017 expert report. He described the study as focused on "the escape of air into an isolation room during opening and closing of a door and passage of a human figure." MDL ECF No. 932-2 at 8. Dr. Abraham did not cite the Saarinen study in his rebuttal report. But Dr. Abraham's report did opine on the phenomenon behind the Saarinen study: "In terms

of upsetting the room air motion, focus should be given to movement of people or equipment, or opening of doors and other motion. These motions have the potential to cause much more significant flow alteration than the Bair Hugger.” MDL ECF No. 934-1 at 30.

The Court ultimately permitted evidence and testimony on the Saarinen study from Dr. Abraham because (1) Plaintiffs’ expert, Dr. Elghobashi, cited to it, (2) Dr. Abraham was in the courtroom for Dr. Elghobashi’s testimony, and (3) Dr. Abraham’s expert report expressed an opinion regarding the substance of the Saarinen study. ECF No. 478 at 1719-27. The Court also noted that admission of the evidence was not prejudicial to Plaintiffs because the meaning of the Saarinen study was “painfully clear to everybody”—“that if you open a door and you can feel the wind, it’s going to have an impact on the airflow.” ECF No. 478 at 1727; *see also id.* at 1725 (Plaintiffs’ counsel explaining that “[e]veryone knows that opening doors may have an effect on airflow”). The admission of the Saarinen evidence and testimony was therefore harmless and did not otherwise violate Rule 26. Even had the Court erred in admitting the evidence, the error “was [not] so prejudicial that a new trial would likely produce a different result.” *Harrison*, 312 F.3d at 351. And so the Court declines to order a new trial on this basis.

3. Michael Keen’s Testimony on Electrocautery Machines

Plaintiffs argue that the Court improperly overruled without argument their objection to Defendants asking HVAC expert, Michael Keen, “to opine on whether electrocautery machines blow air into the operating room.” ECF No. 483 at 37 (citing ECF No. 478 at 1611).

Yet Plaintiffs did not object to Defendants asking Mr. Keen “to opine on whether electrocautery machines blow air into the operating room.” ECF No. 483 at 37. Rather, Plaintiffs objected to the following question: “what’s your understanding as to whether [the electrocautery machine] . . . would typically be used during hip replacement surgery?” ECF No. 478 at 1611. And Plaintiffs point to no questions to or testimony from Mr. Keen about whether electrocautery machines blow air. Accordingly, Plaintiffs’ argument fails.

4. Michael Keen’s Testimony on Dr. Elghobashi’s CFD Study

When Defendants asked Mr. Keen about Dr. Elghobashi’s CFD study, “plaintiffs’ counsel objected, pointing out that these opinions were not disclosed in [Mr.] Keen’s report, and that [Mr.] Keen admitted he was not a CFD expert and would not be offering any opinions about Dr. Elghobashi or his model at trial—a fact stipulated by Defense counsel at [Mr.] Keen’s deposition.” ECF No. 483 at 37-38.

For their part, Defendants explain that “Dr. Elghobashi’s final report was not available when Mr. Keen prepared his expert report or at the time of his deposition.” ECF No. 492 at 33. Defendants also note that, contrary to Plaintiffs’ assertion, they never stipulated that Mr. Keen would offer no opinions related to Dr. Elghobashi’s study. *Id.* (citing statement from defense counsel during deposition of Mr. Keen specifically reserving right to offer Mr. Keen’s opinions on Dr. Elghobashi’s study).

The Court overruled Plaintiffs’ objection but limited Mr. Keen’s testimony to the ways the operating room modeled in Dr. Elghobashi’s study differed from Mr. Gareis’ actual operating room, which Mr. Keen observed firsthand. ECF No. 478 at 1616. It was

not error to allow Mr. Keen to testify to his personal observations of the Bair Hugger and Mr. Gareis' operating room. Further, Plaintiffs fail to establish how inclusion of this testimony prejudiced them. The motion for a new trial is denied as to this ground.

5. Dr. Hannenberg's Testimony on ASA Scores

Plaintiffs explain that the "Court allowed Dr. Hannenberg to opine on the significance of ASA scores over Plaintiffs' objections. ECF No. 483 at 39. This was error, they insist, because neither Dr. Hannenberg's expert report nor his deposition discussed ASA scores.

According to Dr. Hannenberg's testimony, ASA scores are a "physical status system" for "ranking that's meant to describe the patient's condition coming into surgery." ECF No. 476 at 1251. Dr. Hannenberg indicated that there are five different ASA scores and that a score of 3 "is meant to describe a patient with a moderate degree of compensated illnesses." *Id.* at 1255.

Defendants maintain that this discussion of ASA scores falls "within the scope of Dr. Hannenberg's" expert report. As such, no Rule 26 violation occurred. They reason that "ASA scores describe (and assign a numerical value to) 'co-existing conditions' that may impact a patient's susceptibility to infection." ECF No. 492 at 34. Dr. Hannenberg's expert report states that a patient's "co-existing conditions are known to impair" defenses against infections. MDL ECF No. 729-1 at 4. From this, Defendants conclude that the expert report covered the concept of ASA scores. But even if the Court erred in allowing discussion of the ASA scores, Defendants insist that Plaintiffs "do not

even attempt to show any prejudice resulting from Dr. Hannenberg’s testimony.” ECF No. 492 at 35. A new trial is therefore unwarranted. The Court agrees.

6. Reference to the Food and Drug Administration

Before trial, the Court granted Plaintiffs’ motion to exclude references to (1) the Food and Drug Administration’s (“FDA”) clearance of the Bair Hugger and (2) an FDA letter stating that the FDA found no association between infections and use of devices like the Bair Hugger. ECF No. 306.

Plaintiffs claim that Defendants’ counsel improperly “solicited testimony about the August 2017 FDA letter in violation of the Court’s Order” by starting to ask a witness about the FDA’s examination of a potential association between infections and devices like the Bair Hugger. ECF No. 483 at 40. Plaintiffs objected to this question, the witness never answered, the parties discussed the matter at sidebar, and the Court restricted further questioning. *See* ECF No. 473 at 687-88. Plaintiffs then requested that “the testimony be stricken from the record.” ECF No. 483 at 40. The Court denied the request. *Id.* For this reason, Plaintiffs move for a new trial.

But Plaintiffs cite no prejudice. Further, there is no testimony to strike. No witness offered testimony concerning either FDA clearance or the FDA letter. *See* ECF No. 473 at 687-88. And striking counsel’s question was unnecessary. The Court twice warned the jury that questions from counsel are not evidence. *See* ECF Nos. 469 at 131; 480 at 2169. These warnings cured any potential prejudice to Plaintiffs from Defendants’ question. *See, e.g., United States v. Buchannon*, 878 F.2d 1065, 1067 n.2 (8th Cir. 1989) (“The [district c]ourt gave a cautionary instruction that lawyer’s questions are not

evidence. That was a sufficient curative precaution, even if the question was improper”); *United States v. Weaver*, 554 F.3d 718, 724 (8th Cir. 2009) (same). As a result, the Court did not err in refusing to strike the question from the record.

CONCLUSION

Based on the files, records, and proceedings herein, IT IS ORDERED THAT:

1. Plaintiffs’ Motion for a New Trial (ECF No. 482) is DENIED.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: October 26, 2018

s/ Joan N. Ericksen

JOAN N. ERICKSEN
United States District Judge