[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 01-16209

D.C. Docket No. 99-01250-CV-FAM

CHARLES MCCORVEY,

Plaintiff-Appellant,

SCHENELL MCCORVEY,

Plaintiff,

versus

BAXTER HEALTHCARE CORP.,

Defendant-Cross-
Claimant-Appellee,

C.R. BARD, INC.,

Defendant-Cross-
Claimant-Appellee.

Appeals from the United States District Court
for the Southern District of Florida

(July 24, 2002)

Before CARNES, HILL and KRAVITCH, Circuit Judges.

KRAVITCH, Circuit Judge:

Charles McCorvey appeals the grant of summary judgment to defendants C.R. Bard, Inc. ("Bard") and Baxter Healthcare Corp. ("Baxter"), respectively the manufacturer and distributor of a catheter that erupted inside of him, on his strict product liability action. Additionally, McCorvey challenges the district court's exclusion of an affidavit he offered by an engineering expert, on the ground that it did not have the necessary indicia of reliability.

I. Background

In February 1995, McCorvey underwent a transurethral resection of his prostate, a surgical procedure, after which a 30 cc-capacity Bard-manufactured catheter was inserted in his bladder. Written instructions accompanied 30 cc Bard catheters advising that the device should be filled with no more than 36 cc's of sterile water, but McCorvey's doctor inserted 50 cc's of saline solution into the balloon portion of the catheter before insertion to test the device, then deflated the balloon. The catheter was placed inside McCorvey uninflated, and once inside him the balloon portion was again inflated with 50 cc's of saline solution. Deposition testimony by McCorvey's medical experts indicated that it was general medical

practice to fill catheters to such volumes.

Six hours after insertion, the balloon portion of McCorvey's catheter spontaneously erupted and fragmented inside of him. Doctors extracted the catheter, which hospital employees discarded. McCorvey alleges that he experienced persistent symptoms of frequent urinary outflows, urgency with urination, and pain due to the catheter's eruption, even after its removal. Approximately a year and a half after McCorvey's initial operation, a doctor found an additional fragment of the balloon portion of the catheter lodged inside McCorvey's prostate. McCorvey underwent yet another procedure to remove the additional fragment, after which the hospital employees photographed and then discarded it.

McCorvey filed a Florida law product defect suit against Bard and Baxter under a theory of strict liability.[1] Bard filed a motion for summary judgment, adopted by Baxter. In an effort to defeat summary judgment, McCorvey responded by offering three expert affidavits, two medical and one engineering, all of which maintained that the subject catheter was defectively designed or manufactured, and/or was not safe for its intended purpose. Bard then moved to exclude the

[1]In one of McCorvey's amended complaints, his wife joined the suit, claiming loss of services, enjoyment, and companionship of her husband. She does not, however, appeal the dismissal of her claims.

proffered expert engineering affidavit. The district court struck the engineer's opinions for not meeting the criterion of reliability necessitated by Federal Rule of Evidence 702 and detailed by Daubert v. Merrell Dow Pharm., 509 U.S. 579 (1993). It also entered summary judgment for the defendants, finding that McCorvey was not entitled to a legal inference of product defect, referred to as a Cassisi inference under Florida law. McCorvey appeals both rulings.

II. Discussion

We first turn to the decision by the district court to exclude the affidavit offered by McCorvey's engineering expert. This court reviews rulings on the admissibility of expert testimony for abuse of discretion. See Allison v. McGhan Med. Corp., 184 F.3d 1300, 1306 (11th Cir. 1999); see also Gen. Elec. Co. v. Joiner, 522 U.S. 136, 138-39 (1997). In addition, we note that "[t]he burden of laying the proper foundation for the admission of expert testimony is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence." Allison, 184 F.3d at 1306 (citing Daubert, 509 U.S. at 592, n.10).

Daubert requires that trial courts act as "gatekeepers" to ensure that speculative, unreliable expert testimony does not reach the jury. Federal Rule of Evidence 702, governing the admissibility of expert evidence, provides that if

"specialized knowledge will assist the trier of fact, ... a witness qualified as an expert..., may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles, and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702. In deciding whether these requirements of Rule 702 are met, Daubert instructs courts to consider the following factors: (1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community. Daubert, 509 U.S. at 593-94.

In concluding that the methodology of McCorvey's engineering expert was not scientifically reliable and that his causation opinion was based wholly on speculation, the district court noted that the expert: did not test alternative designs for the catheter; did not talk to medical personnel; was unable to cite scientific literature in support of his theories; and did not consider or test possibilities for failure that could have come from sources outside the product, such as the effect of improper storage conditions, contaminants, or human error.

McCorvey argues that his engineering expert's affidavit was erroneously

excluded because the district court weighed the credibility of the expert's testimony, a function that is uniquely within the province of the jury and thus inappropriate for a court ruling on a motion for summary judgment. See Abel v. Dubberly, 210 F.3d 1334 (11th Cir. 2000). McCorvey further contends that any critique of the expert's methodology should have been brought out in cross-examination, rather than used as a basis to exclude under Daubert. McCorvey's contentions, rather than amounting to an argument that the district court abused its discretion in applying Daubert and the requirements of Federal Rule of Evidence 702, instead seem to implicitly reject the gatekeeper function of the trial courts specifically prescribed by the Supreme Court. Rulings on admissibility under Daubert inherently require the trial court to conduct an exacting analysis of the proffered expert's methodology.

McCorvey had the burden to show that his expert was "qualified to testify competently regarding the matters he intend[ed] to address; [] the methodology by which the expert reache[ed] his conclusions is sufficiently reliable; and [] the testimony assists the trier of fact." Maiz v. Virani, 253 F.3d 641, 664 (11th Cir. 2001). Recognizing that our review of evidentiary rulings by trial courts on the admission of expert testimony is "very limited," id. at 662, we do not find reversible error in the district court's conclusion that McCorvey did not meet this

burden, and that his proffered engineering expert's was not sufficiently reliable under Daubert and Federal Rule of Evidence 702.

Even with the exclusion of the engineering expert's affidavit, however, McCorvey's two medical expert affidavits remained in evidence. Considering all the record evidence, the district court awarded summary judgment in favor of the defendants, reasoning that McCorvey had failed to set forth admissible evidence necessary to establish his prima facie case of product liability. We review de novo a district court's grant of summary judgment, applying the same legal standards as the district court. See Johnson v. Bd. of Regents of Univ. of Ga., 263 F.3d 1234, 1242 (11th Cir. 2001). A grant of summary judgment is appropriate only where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). We construe the facts and draw all reasonable inferences in the light most favorable to the non-moving party. Wideman v. Wal-Mart Stores, Inc., 141 F.3d 1453, 1454 (11th Cir. 1998).

Under Florida law, a strict product liability action requires the plaintiff to prove that (1) a product (2) produced by a manufacturer (3) was defective or created an unreasonably dangerous condition (4) that proximately caused (5)

injury. See Edward M. Chadbourne, Inc. v. Vaughn, 491 So.2d 551, 553 (Fla. 1986). In the instant case, the district court based its grant of summary judgment on its finding that McCorvey had not offered any admissible evidence of either the third element, a product defect, or the fourth element, a causal link between the alleged defect and his injuries. McCorvey counters that his expert affidavits, even excluding the one offered by the engineer, were sufficient to establish these elements; additionally, McCorvey claims that the court erred in not affording him an inference of product defect, which also would have allowed him to take his case to a jury. In Florida strict product liability actions, a legal inference is created that the subject product was defective at both the time of injury and the time of sale when that product "malfunctions during normal operation." Cassisi v. Maytag Co., 396 So.2d 1140 (Fla. 1st Dist. Ct. App. 1981). This inference is generally referred to in Florida case law as a Cassisi inference.

We hold that McCorvey is entitled to the benefit of a Cassisi inference of product defect, and that the district court erred in not affording him this inference. First, the medical expert affidavits here establish that filling a 30 cc-capacity catheter to 50 cc's, despite Bard's recommendations to the contrary, is normal use,

and constitutes standard urological practice.[2] Although an industry-wide practice might not defeat a warning, the instant action is not a failure to warn case, but rather a manufacturing defect suit; the common "misuse" involved here is sufficient to establish that the occurrence in question, i.e. the fragmentation and spontaneous eruption of the catheter inside of McCorvey, "differs either from the manufacturer's intended result or from other units of the same product line," which

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[2]Indeed, one of these affidavits was offered by a doctor who had personally handled and inserted hundreds of catheters, almost all manufactured by Bard, and who averred that "[w]hile C.R. Bard, Inc. apparently recommends that the inflation capacity of a 30 cc balloon used in Charles McCorvey to be 35 cc's of sterile water, the customary and standard practice for Urologists is to inflate these 30 cc balloons to at least 50 cc's when traction of the catheter is required; venous bleeding is halted with traction and cannot be stopped in any other fashion." He continued, "[t]he catheter which fragmented inside Charles McCorvey was inflated to approximately 50 cc's which fits squarely within the standard of medical practice for urologists in and outside of Florida. I customarily fill these same catheters to 50 cc's with saline or water and this has been my practice over at least the past 21 years." This doctor offered that the inflation of the subject catheter to 50 cc's before insertion was "appropriate" and usual." He also conducted his own experiment with a catheter of identical dimension as the one placed in McCorvey. He filled the device to 60 cc's of sterile water and placed twenty pounds on the inflated balloon for seventy-two hours, "which is far greater pressure than found in a bladder of a human being." The catheter which was the subject of this experiment did not deflate or fragment, as did McCorvey's.

The second doctor offering an affidavit, the performing doctor, has performed hundreds of transurethral resection of the prostate operations, as well as hundreds of other transurethral surgeries. He has also, like the author of the first affidavit, inserted hundreds of catheters, mostly manufactured by Bard. This doctor offered that he "always" inflates the Bard 30 cc catheters to at least 50 cc's to test them. Additionally, he averred that "[f]rom [his] experience as a urologist in South Florida, all other urologists that I know do the same as I did in relation to inserting the catheter into Mr. McCorvey, inflating the 30 cc catheter to 50 cc's, and testing the device by inflating it to 50 cc's before insertion into the patient." It is "customary and standard practice for Urologists [ ] to inflate these 30 cc balloons to at least 50 cc's to 60 cc's of sterile water or saline for insertion purposes into patients." This doctor submitted that he "customarily fill[s] these same catheters to 50 cc's to 60 cc's of saline or water and this has been [his] practice over at least the past 21 years."

according to expert testimony, were regularly inflated to similar levels.[3] Id. at 1146. We consider these facts sufficient to show that the catheter here erupted during the course of normal operation. Second, it is apparent that the subject catheter malfunctioned. Fragments of the catheter were found in McCorvey's bladder and prostate after its eruption and up to almost a year and a half subsequently. This constitutes proof of malfunction, and this, along with the malfunction having occurred during normal operation, establishes both prerequisites for application of a Cassisi inference.

The district court here seemed to find significance in the fact that the catheter was not destroyed, but rather discarded by hospital employees. However, Cassisi allows, but does not require, that the product be destroyed in the accident which gives rise to the suit.[4] See Cassisi, 396 So.2d at 1151. Although the district

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[3]The dissent finds it irrelevant to the determination of whether a Cassisi inference applies that McCorvey's catheter was subject to treatment and handling no different than hundreds, if not thousands, of the same catheters, which did not spontaneously fragment. We cannot agree. We find it extremely significant that, based upon McCorvey's expert medical affidavits, the inflation of Bard catheters beyond their recommended levels did not normally result in eruption. Clearly something was different between these non-erupting catheters and McCorvey's catheter; taking all inferences in favor of McCorvey, we must assume that this difference was not a variation in the inflation levels of the catheters. We therefore can infer, under Cassisi, that the difference was that McCorvey's catheter suffered from a manufacturing defect, while the other Bard catheters which were filled with the same amounts of water or solution did not. We stress, however, that the defendants remain free to rebut this inference at trial and point to the over-inflation of McCorvey's catheter as a possible reason for eruption and fragmentation here.

[4]The authority on this point in Florida case law is unanimous. See e.g., Cassisi, 396 So.2d at 1551; see also Miller v. Allstate Ins., 650 So.2d 671, 675 n.4 (Fla. 3d Dist. Ct. App. 1995). Florida's Fifth District Court of Appeals, however, has stated that it is "unwilling to

court emphasized that McCorvey's admissible expert affidavits did not pinpoint a specific defect in the catheter, Cassisi and its progeny also do not require such specificity for a plaintiff to be afforded a legal inference of product defect. See id. at 1153 (holding that it is "immaterial that the plaintiffs failed to identify the specific cause of the malfunction since it is inferred that the malfunction itself, under such circumstances, is evidence of the product's defective condition at both the time of the injury and at the time of sale"); see also Parke v. Scotty's, 584 So.2d 621, 623 (Fla. 1st Dist. Ct. App. 1991). Similarly, the district court erred in finding that McCorvey's failure to negate alternative grounds of causation, besides a manufacturing defect, was fatal to his strict liability claim. McCorvey did not have any such obligation once he met the two requirements of Cassisi discussed above. See Cassisi 396 So. 2d at 1149, 1150; Jones v. Heil Co., 566 So.2d 565, 567 (Fla. 1st Dist. Ct. App. 1990).

Because the Cassisi inference may be applied to cases in which the subject product is lost or destroyed, making even the requirement of proving malfunction

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extend [the Cassisi inference] to spoliation cases." Torres v. Matsushita Elec. Corp., 762 So.2d 1014, 1017 (Fla. 5th Dist. Ct. App. 2000). Contra Miller, 650 So.2d 671. The holding of Torres, though, is limited to the facts of that case, which involved the loss of the subject product by an agent of the plaintiff, namely her attorney. Here, the subject catheter was discarded by hospital employees, third parties in no way acting as agents of McCorvey. Moreover, in the instant case spoliation was never pleaded as an affirmative defense by the defendants, and therefore it is not considered a spoliation case.

difficult, in such cases "absolute positive proof of product malfunction is not necessary... ." Wortham v. A.H. Robins Co., 734 F.2d 676, 683 (11th Cir. 1984). It is in these cases that negating other potential causes of the accident becomes important to the plaintiff's ability to establish his entitlement to an inference of product defect. See id. In the instant case, however, as we noted, there is "absolute positive proof" that the catheter malfunctioned, and therefore McCorvey may proceed to trial without either pointing to the specific defect involved or negating other possible causes of the catheter's malfunction.

Furthermore, despite indications to the contrary by the district court, it is not necessary that the subject product require only passive participation for the Cassisi inference to apply. "The type of product is immaterial to the question whether the [] inference applies, provided it is one subject to Section 402A's standard for defectiveness." Cassisi, 396 So. 2d at 1552, n. 25. See also Miller v. Allstate Ins., 650 So.2d 671, 674 (Fla. 3d Dist. Ct. App. 1995) (holding the Cassisi inference available where a new car crashed into a wall and the plaintiff testified that the accelerator stuck); Parke, 584 So. 2d at 623. Whether or not a product survives the malfunction, "the facts essential for the inference's application are simply proof of the malfunction during normal operation." Cassisi, 396 So.2d at 1151.

In conclusion, we note that although any alternatives to a manufacturing

defect as possible causes of the catheter's eruption, including McCorvey's doctor having over-inflated the catheter beyond manufacturer recommendations, are not enough to override the Cassisi inference, they may be highly relevant at trial. Strict product liability and a Cassisi inference of product defect were "designed to assist the plaintiff in his quest for the jury's consideration of the issues alleged." Cassisi 396 So. 2d at 1147. It is for this reason that summary judgment for the defendants would be inappropriate here. They remain free, however, to offer argument and evidence at trial that might negate McCorvey's inference of product defect and rebut his prima facie case.

III. Conclusion

Based on the foregoing, we AFFIRM with respect to the exclusion of the engineering expert's affidavit, and REVERSE with respect to the grant of summary judgment to the defendants.

AFFIRMED in part, REVERSED in part.

HILL, Circuit Judge, dissenting:

As I read the record, the following facts are clear:

1. A catheter such as the one in this case contains a balloon-like element.
2. The catheter must be inflated with sterile solution to remain properly positioned in the patient's body.
3. The written instructions of the manufacturer state that the 30 cc catheter is designed to be inflated by the introduction of no more than 36 cc's of solution.
4. It is my experience from childhood that balloons will inherently burst if overinflated.
5. Here all agree that the doctor ignored the manufacturer's instructions. He inserted 50 cc's of solution into the 30 cc catheter, observing that folks did that all the time.
6. The balloon-like element of the catheter, thus overinflated, burst.

The majority interprets Florida products liability tort law to hold that this set of facts creates an inference that the catheter, with its 30 cc balloon, was defective because it fractured when overinflated by 66% of its stated capacity. The inference created by this interpretation is that, if the balloon burst when 166% of the amount of liquid it was capable of receiving was forced into it, then it also would have

burst had the doctor inserted 100%, or the correct amount!

I am not willing to conclude that this inference, which, to me, appears illogical, is correct under Florida law unless the Supreme Court of the State of Florida tells me that it is. I would certify this question.