IN THE COURT OF APPEALS OF TENNESSEE
WESTERN SECTION AT JACKSON

BARBARA JORDAN,

Plaintiff-Appellant,

Vs.

SOFAMOR DANEK GROUP, INC., ET AL,

Defendants-Appellees.

Shelby Circuit No. 73049
C.A. No. 02A01-9803-CV-00067

FROM THE SHELBY COUNTY CIRCUIT COURT
THE HONORABLE JOHN R. MCCARROLL, JR., JUDGE

Sam B. Blair, Jr.; Baker, Donelson, Bearman & Caldwell of Memphis
Steve Phillips and Murray Levin; Pepper Hamilton of Philadelphia, PA
George Lehner; Pepper Hamilton of Washington, D.C.
For Appellees

Roy F. Amedee,Jr. of LaPlace, LA
Lisa June Cox of Jackson
For Appellant

AFFIRMED AND REMANDED

Opinion filed:

W. FRANK CRAWFORD,
PRESIDING JUDGE, W.S.

CONCUR:

DAVID R. FARMER, JUDGE

HEWITT P. TOMLIN, JR., SPECIAL JUDGE

This is a products liability case. Plaintiff-Appellant, Barbara Jordan, appeals the order of the trial court granting summary judgment to Defendants-Appellees, Sofamor Danek Group, Inc., Danek Medical, Inc., and Warsaw Orthopaedic, Inc. (collectively referred to as Sofamor

Danek).

After suffering from back problems since an automobile accident in 1975, Ms. Jordan underwent spinal surgery on November 5, 1992, during which a laminectomy and foraminoctomy was performed, disc material and scar tissue was removed, and a spinal fixation system utilizing pedicle screws was implanted in her spine to aid in bone fusion.[1] Sofamor Danek was the manufacturer of the device implanted during the 1992 surgery.[2] Several weeks after the surgery, Ms. Jordan's back problems reoccurred. After two years of conservative treatment, Ms. Jordan underwent back surgery again on May 30, 1995, during which, among other things, the spinal fixation system was removed. It was noted during this surgery that bone fusion was solid on the right side of her vertebrae, not solid at all levels on the left side, and that further fusion was not necessary. There is no evidence that the implanted device broke, bent, loosened or malfunctioned in any way.

After removal of the device, Ms. Jordan continued to experience back problems. After an examination by another physician, it was revealed through x-rays that Ms. Jordan's spine had collapsed. On July 15, 1996, Ms. Jordan underwent further spinal surgery in which, among other things, another spinal fixation system utilizing pedicle screws was implanted. The manufacturer of this device is unknown, but it is conceded that Sofamor Danek was not the manufacturer.

On October 3, 1995, a complaint was filed in Shelby County, Tennessee on behalf of numerous plaintiffs who allegedly suffered injuries and damages as a result of the implantation of internal spinal fixation devices utilizing pedicle screws against numerous manufacturers of these devices including Sofamor Danek Group, Inc. On October 12, 1995, a First Amended Complaint was filed naming additional plaintiffs including Ms. Jordan. The case was subsequently removed to federal court but was later remanded. After remand, a Second Amended Complaint was filed naming Danek Medical, Inc. and Warsaw Orthopaedic, Inc. as manufacturers of the devices. The complaints asserted numerous causes of action against the

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[1] Ms. Jordan underwent surgery on the discs in her back in 1985. This surgery did not involve any internal fixation device.

[2] In its brief, Sofamor Danek states that the device implanted in Ms. Jordan was not manufactured by any of them. Rather, they assert that the device has always been manufactured by Sofamor, S.N.C., a French company that in November 1992 was not related to any of them. However, Sofamor Danek states in its brief that the technical arguments concerning Sofamor Danek Group, Inc.'s current position as a holding company were not presented to the trial court and are not an issue on appeal.

defendants including strict liability, negligence, negligence per se, breach of express warranty, breach of implied warranty, failure to warn, unlawful promotion, negligent misrepresentation, civil conspiracy, concert of action, and negligent infliction of emotional distress.[3]

Due to the number of plaintiffs, a Case Management Order was entered by the trial court. This order designated fourteen plaintiffs for trial, and Ms. Jordan is one of those designated.

On August 6, 1997, Sofamor Danek filed a motion for summary judgment which the trial court granted by order entered November 4, 1997.

Ms. Jordan has appealed, and the only issue on appeal is whether the trial court erred in granting summary judgment to Sofamor Danek.

A motion for summary judgment should be granted when the movant demonstrates that there are no genuine issues of material fact and that the moving party is entitled to a judgment as a matter of law. Tenn. R. Civ. P. 56.04. The party moving for summary judgment bears the burden of demonstrating that no genuine issue of material fact exists. ***Bain v. Wells***, 936 S.W.2d 618, 622 (Tenn. 1997). On a motion for summary judgment, the court must take the strongest legitimate view of the evidence in favor of the nonmoving party, allow all reasonable inferences in favor of that party, and discard all countervailing evidence. ***Id.*** In ***Byrd v. Hall***, 847 S.W.2d 208 (Tenn. 1993), our Supreme Court stated:

> Once it is shown by the moving party that there is no genuine issue of material fact, the nonmoving party must then demonstrate, by affidavits or discovery materials, that there is a genuine, material fact dispute to warrant a trial. In this regard, Rule 56.05 provides that the nonmoving party cannot simply rely upon his pleadings but must set forth *specific facts* showing that there is a genuine issue of material fact for trial.

Id. at 211 (citations omitted) (emphasis in original).

Summary judgment is only appropriate when the facts and the legal conclusions drawn from the facts reasonably permit only one conclusion. ***Carvell v. Bottoms***, 900 S.W.2d 23, 26 (Tenn. 1995). Since only questions of law are involved, there is no presumption of correctness regarding a trial court's grant of summary judgment. ***Bain***, 936 S.W.2d at 622. Therefore, our review of the trial court's grant of summary judgment is ***de novo*** on the record before this Court. ***Warren v. Estate of Kirk***, 954 S.W.2d 722, 723 (Tenn. 1997).

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[3] The non-product liability claims were dismissed by the trial court for all designated plaintiffs and are not part of this appeal.

Ms. Jordan asserts that the trial court erred in granting summary judgment in that there is a genuine dispute of material facts as to whether the implantation of the pedicle screws manufactured by Sofamor Danek was the proximate cause of her injuries. She relies primarily on the affidavit of her orthopedic expert, Dr. Christopher E. Cenac, which states:

> 1.) [Dr. Cenac] has been requested . . . to give an opinion as to what damages, if any, were suffered by Barbara Jordan as a result of her first operation in 1992 wherein she was implanted with a spinal fixation device utilizing pedicle screws manufactured by Sofamor Danek.
>
> 2.) He is of the opinion that she did in fact incur injuries as a result of the implantation of the Sofamor Danek device;
>
> 3.) Specifically, as a result of the extensive dissection and decompression of the bony structures that occurred during the implantation of the Sofamor Danek spinal fixation device, her back was more susceptible to spinal collapse, which in fact occurred after the hardware was removed in 1995;
>
> 4.) His review of the medical records indicates that as a result of the collapsing of the spine which was first noted in April of 1995 at L-3 and L-4, which resulted from the decompression, she was required to undergo additional surgery in 1996;
>
> 5.) Therefore, it is more likely than not, that the Sofamor Danek pedicle screw device utilized in the 1992 implant was a substantial contributing cause to the necessity of Barbara Jordan's second surgery.

Dr. Cenac's previous testimony in a pretrial deposition established that he is not an expert with respect to implants, including spinal implants, nor is he an expert in the area of design and manufacture of implants of any kind. He also testified regarding Ms. Jordan's condition in relation to the spinal fixation device as follows:

> Q. You indicated that she had a rather complicated medical history, is that correct?
> A. She certainly did.
> Q. What do you mean by that?
> A. Well, she started having a laminectomy diskectomy and instrumentation, and that failed, and as a result of that she developed a rather severe collapse of the spine, scoliosis, deformity.
> Q. That was an uninstrumented procedure; is that correct?
> A. That was an instrumented procedure.
> Q. Excuse me. That's what I meant. The '92 procedure was an instrumented procedure, is that correct?
> A. She had an instrumented procedure in '92.
> Q. Right.
> A. And it failed. As a result of that she developed a rather severe scoliosis deformity and forward tilting of the spine. . . .
>
> The problems that I associated with the instrumentation device was the muscle fibrosis from the inflammatory response, the radiculitis from the inflammatory response, and the severe spinal disability because of the initial failed instrumentation

fusion because of resorption of the graft and the rigidity of the device.

Q. Given her rather complicated history, is it possible to attribute any of the residuals that you've identified to any particular device?

A. I don't think so. It would be very hard to objectively quantify that for you.

Q. Or to any particular component of any one of the devices that was used?

A. No, that's correct. Or the answer remains the same for that question.

Q. I will mark as I guess this would be 16-D a report prepared by Dr. Levy on Barbara Jordan, dated June 7th. And certainly feel free to review the whole report, but I'm going to direct your attention to Page 10, particularly the last paragraph beginning on Page 10.

A. The same conclusion.

Q. The same conclusion?

A. Yes.

Q. You don't disagree with his conclusion there that -- and I'm looking on page 10, "It is virtually impossible to determine what specific neurological deficit Miss Jordan had prior to the operation on November 5, 1992, as compared with the neurological abnormalities in the lower extremities following that operation because of the varied postoperative findings."

A. Yes. We came to the same conclusion in that she had severe atrophy of the right lower extremity, reflex and sensory deficits. There has been a significant change in the examination neurologically following the July '96 two-stage operation.

Q. But Dr. Levy does not attribute that to the instrumentation because that was a very complicated -- multiple stage operation, is that correct?

A. Two stages.

Q. Right.

A. Well, he says that it's an inescapable conclusion that Mr. Jordan has had -- that Mrs. Jordan has had both objective and subjective evidence of deterioration in her postoperative neurological state which must be considered a complication of the July '96 surgery, and I said the same thing.

Q. But it would be impossible to really attribute it to the instrumentation at that point given the nature of the multiple entries made at that surgery; is that correct?

A. Well, we got different devices. We got one in the front and we got one in the back, et cetera, so I can't tell you thirty percent is from this and forty percent is from that. I got to tell you --

Q. It's the whole package?

A. The whole package, that's a good word.

Dr. Cenac's deposition was filed by Sofamor Danek in support of its motion for summary judgment. Sofamor Danek also filed a deposition of Ms. Jordan's other expert, Dr. Richard W. Levy, a neurosurgeon. Dr. Levy evaluated Ms. Jordan concerning her injuries and damages and testified that he was not presenting himself as an expert of epidemiology, manufacturing standards, design standards, or any FDA regulatory standards. He further testified in pertinent

part as follows:

> Q. Do you have an opinion, to a reasonable degree of medical certainty, that the first procedure dated 11/5/92 -- strike that -- do you have an opinion to a reasonable degree of medical certainty that the surgical stainless steel internal fixation device used in the November 5th, 1992 surgery caused any neurological deficit that you have found in your exam?
> A. No. . . .
> * * *
> Q. Did Ms. Jordan suffer from retroscoliosis?
> A. Yes.
> Q. How long did she suffer from that?
> A. I don't know.
> Q. But is that a situation that develops, or is that a congenital type development?
> A. Well, I think it probably is not congenital or developmental in this lady; but I can't answer how long she's had it.
> Q. She also had degenerative disc disease?
> A. Yes, sir.
> Q. And she had kyphosis?
> A. Yes.
> Q. And she had spondylosis?
> A. Yes.
> Q. Osteoporosis?
> A. Yes.
> Q. Stenosis?
> A. Yes.
> Q. Those, would you call those diseases or conditions?
> A. No. Those are manifestations of age, I would think.
> Q. But those are certainly not caused by surgical stainless steel?
> A. No.
> Q. And certainly those conditions, in some part, play into her current condition?
> A. Yes.
> * * *
> Q. And I know you may say [the device] may impinge on the nerve, but I'm trying to determine whether you have opinions beyond the neurological deficit.
> A. Yes. If the pedicle in which the screw is placed was, for whatever reason, malformed developmentally or fractured as a result of the screw being placed in it, I will have a comment about that.
>
> I will not have a comment about the screw, per se, other than for its length and the appropriateness of using a particular length screw in a given case.

Sofamor Danek asserts that the trial court properly granted summary judgment because Ms. Jordan has no proof to establish the necessary elements of her claim.

As part of the Tennessee Products Liability Act, T.C.A. § 29-28-105(a) (1980) provides:

> A manufacturer or seller of a product ***shall not be liable*** for any injury to person or property caused by the product ***unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the***

manufacturer or seller.

(emphasis added). Thus, a plaintiff must prove that the product was either defective or unreasonably dangerous at the time it left the control of the manufacturer or seller, regardless of the legal theory relied upon. ***Fulton v. Pfizer Hosp. Products Group, Inc.***, 872 S.W.2d 908, 911 (Tenn. App. 1993).

T.C.A. § 29-28-102(2) (1980) defines defective condition as "a condition of a product that renders it unsafe for normal or anticipatable handling and consumption." A product is unreasonably dangerous if it, as defined in T.C.A. § 29-28-102(8) (1980), is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer . . . assuming that he knew of its dangerous condition."

Moreover, T.C.A. § 29-28-105(b) (1980) provides that in determining whether a product is defective "the state of scientific and technological knowledge available to the manufacturer . . . at the time the product was placed on the market . . . is applicable." Consideration should also be given "to the customary design, methods, standards and techniques of manufacturing, inspecting and testing by other manufacturers or sellers of similar products." T.C.A. § 29-28-105(b) (1980).

As a general rule, an injury in and of itself is not proof of a defect and thereby does not raise any presumption of defectiveness. ***Fulton***, 872 S.W.2d at 911 (citing ***Gates v. Ford Motor Co.***, 494 F.2d 458, 459 (10th Cir. 1974); ***Mullins v. Seaboard Coastline Ry. Co.***, 517 S.W.2d 198, 201 (Tenn. App. 1974)). Thus, it is not enough to show that the product caused the plaintiff's injury or was involved in it. ***Whaley v. Rheem Mfg. Co.***, 900 S.W.2d 296, 300 (Tenn. App. 1995). Rather, "[t]he burden is upon the plaintiff to 'show that there is something wrong with the product.'" ***Fulton***, 872 S.W.2d at 911 (quoting ***Tatum v. Cordis Corp.***, 758 F. Supp. 457, 461 (M.D. Tenn. 1991)).

From a review of the record, we find no proof that the product was defective or unreasonably dangerous. Ms. Jordan offered no proof that Sofamor Danek failed to employ or follow proper manufacturing procedures or that the design of the product was deficient. No proof was offered that the medical device was designed or manufactured improperly or that

Sofamor Danek violated some standard of care in the design or manufacture of the medical device. She offered no proof that the product should have been made a different way or by using a different material. Furthermore, there is no evidence in the record that Sofamor Danek deviated from acceptable standards of quality or conduct.

Although the trial court's order does not specify the basis for granting summary judgment, it appears that summary judgment was granted because there are no genuine issues of material fact in that Ms. Jordan failed to provide any proof that a defect in the implanted device caused her injuries and damages. "Summary judgment is required if . . . the non-moving party fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." ***Tatum***, 758 F. Supp. at 461 (citing ***Celotex Corp. v. Catrett***, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552, 91 L. Ed. 2d 265 (1986)). ***See also Blair v. Allied Maintenance Corp.***, 756 S.W.2d 267, 270 (Tenn. App. 1988).

In opposition to the summary judgment motion, Ms. Jordan relies solely on the affidavit and deposition of Dr. Cenac. Sofamor Danek first argues that the affidavit testimony contradicts the deposition testimony and thus results in cancelling out both testimonies. ***Tibbals Flooring Co. v. Stanfill***, 219 Tenn. 498, 410 S.W.2d 892 (1967); ***Ayers v. Rutherford Hosp., Inc.***, 689 S.W.2d 155 (Tenn. App. 1984). Dr. Cenac testified in his deposition that it is impossible to attribute any of Ms. Jordan's residuals to a particular device, and yet in the affidavit he opines that the Sofamor Danek device was a contributing cause of Ms. Jordan's second surgery. This appears to be a direct contradiction and thus, under the authority cited, the testimony is rendered a nullity.

However, even if we assume that the affidavit testimony is admissible, Ms. Jordan has still failed to prove an essential element of her case. Dr. Cenac's affidavit states that the premise for his above-stated opinion is that "as a result of the extensive dissection and decompression of the bony structures that occurred during the implantation of the Sofamor Danek spinal fixation device, her back was more susceptible to spinal collapse, which in fact occurred after the hardware was removed in 1995." Dr. Cenac's premise does not lead to the conclusion he states in his opinion. In effect, what he is stating is that the actions of the surgeon caused the subsequent spinal collapse. There is nothing in Dr. Cenac's affidavit or his deposition that can

serve as proof that a defective or unreasonably dangerous device manufactured by Sofamor Danek caused Ms. Jordan's problems. In the absence of such proof, which is essential for plaintiff to proceed, summary judgment was properly granted.

Accordingly, the order of the trial court is affirmed, and the case is remanded to the trial court for such other proceedings as may be necessary. Costs of the appeal are assessed against the appellant.

W. FRANK CRAWFORD,
PRESIDING JUDGE, W.S.

CONCUR:

DAVID R. FARMER, JUDGE

HEWITT P. TOMLIN, JR.
SPECIAL JUDGE