IN THE COURT OF APPEALS OF TENNESSEE

AT KNOXVILLE

DON HARDEN,	) C/A NO. 03A01-9801-CV-00020
	)
Plaintiff-Appellant,	) KNOX CIRCUIT
	)
v.	) HON. WHEELER ROSENBALM,
	) JUDGE
DANEK MEDICAL, INC.,	)
	) AFFIRMED AND
Defendant-Appellee.	) REMANDED

CLINT J. WOODFIN, RALPH BROWN & ASSOCIATES, Knoxville, for Plaintiff-Appellant.

ROBERT R. CAMPBELL, HODGES, DOUGHTY & CARSON, and STEPHEN S. PHILLIPS AND JAMES M. BECK, PEPPER HAMILTON, LLP, Philadelphia, PA, for Defendant-Appellee.

O P I N I O N

Franks, J.

In this action for allegedly manufacturing a defective product which harmed plaintiff, the Trial Judge granted defendant summary judgment, and plaintiff has appealed.

The principal issue on appeal stated in plaintiff's brief is:

> Did the Trial Court commit reversible error by holding that no genuine issues of material fact existed in the record on August 19, 1997, and granting summary judgment to the defendant on that basis.

Appellant in his brief argues that the Trial Judge committed several errors which were not specified as issues in the statement of issues. The issue as stated is simply not reviewable. We said in *Leeson v. Chernau*, 737 S.W.2d 634 (Tenn. App. 1987) p.637:

> T.R.A.P. does not contemplate that an appellant may submit one blanket issue as to the correctness of the judgment and thereby open the door to argument upon various issues which might affect the correctness of the judgment.

Since the appellee effectively cured this defect by filing a "counter-statement of the issues presented", we will consider the issues presented.

This case arises from an operation that was performed by Dr. Glenn Jeffries in 1992 on the plaintiff who had been suffering back pain. Dr. Jeffries determined that plaintiff would benefit from back surgery stabilized by spinal instrumentation. In March of 1992, Dr. Jeffries performed the surgery and implanted a construct built from components made by Defendant Danek Medical , Inc. ("Danek"). In the operative procedure, Dr. Jeffries used bone screws to attach the construct through the pedicles of plaintiff's vertebrae.[1] Plaintiff's condition improved after surgery, but in July of 1993 his pain returned. On August 8, 1995, plaintiff underwent surgery to have the hardware removed from his back.

This action then followed in October 1995, wherein plaintiff alleged injuries from the implantation of a Danek device that was defective and/or unreasonably dangerous. In June 1996, Danek filed a Motion for Judgment on the Pleadings, arguing that the complaint failed to state a cause of action. Plaintiff moved to amend his complaint on July 17, 1996. On July 30, 1996, the Trial Court granted Danek's motion and dismissed the amended complaint. However, on August 8, 1996, plaintiff moved to file a second amended complaint and for reconsideration of the July 30 order. The Trial Court allowed the second amended complaint, but denied reconsideration of its dismissal of the claims in the first amended complaint. On June 4, 1997, Danek moved for summary judgment on the allegations in the second amended compliant, and as a part of that motion, Danek included Dr. Jeffries'

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[1]Each vertebra has left and right pedicles which face out and are more readily accessible to a surgeon than other parts of the vertebra.

deposition. On June 30, 1997 plaintiff gave notice to depose Dr. Jeffries. On August 15, 1997, plaintiff filed a Notice of Deposition. On August 19, 1997, the Trial Court quashed the Notice and denied plaintiff's Motion to Amend and granted Danek's Motion for Summary Judgment.

Plaintiff contends that the Trial Court erred in granting summary judgment on his failure to warn claim. He argues that defendant owed a duty to warn him that the safety of its system had been determined only for certain types of conditions and that implanting a pedicle screw system was a potentially dangerous procedure that only experienced surgeons performed.

As the moving party for summary judgment, the defendant had the burden of demonstrating that no genuine issue of material fact existed. *Shadrick v. Coker,* 963 S.W.2d 726 (Tenn. 1998). On appeal "we are required to view the evidence in the light most favorable to the non-moving party, draw all reasonable inferences in his favor, and discard all countervailing evidence." *Id.* Summary judgment is only proper "[i]f both the facts and conclusions to be drawn from the facts permit a reasonable person to reach only one conclusion . . ." *Id.*

Summary judgment was proper on this issue because the treating physician was aware of the risks and limitations of the surgery he performed with the hardware he installed. The defendant relied on the defense of learned intermediary. Under this doctrine, manufacturers of certain medical products "may reasonably rely on intermediaries to transmit their warnings and instructions." *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994). This defense is based upon the pivotal role that physicians play in the distribution of prescription products. *Id.* Physicians can be learned intermediaries only when they receive adequate warnings. *Id.* Thus, manufacturers are not shielded from liability if they provide inadequate warnings to physicians. *Id.*

In order to recover for failure to warn under the learned intermediary doctrine, a plaintiff must show : (1) that the defendant failed to warn the physician of a risk associated with the use of the product not otherwise known to the physician; and (2) that the failure to warn the physician was both a cause in fact and proximate cause of the plaintiff's injury. 63A Am.Jur.2d *Products Liability* §1200 (1984).

Generally, "a manufacturer will be absolved of liability for failure to warn for lack of causation where the consumer was already aware of the danger, because the failure to warn cannot be the proximate cause of the user's injury if the user had actual knowledge of the hazards in question." *Id.* at §1162. Under this doctrine, physicians are the "consumers" who must be warned. Thus, it is generally held that the learned intermediary doctrine may shield a manufacturer from liability when the physician was independently aware of the risks involved. *Id.* at §1162. *See Odom v. G.D. Searle & Co.*, 979 F.2d 1001 (4th Cir. 1992) (applying South Carolina law); *Stanback v. Parke, Davis & Co.*, 657 F.2d 642 (4th Cir. 1981)(applying Virginia law); *Spychala v. G.D. Searle & Co.*, 705 F.Supp. 1024 (D.N.J. 1988) (applying New Jersey law); *Ashman v. SK & F Lab Co.*, 702 F.Supp 1401 (N.D. Ill. 1988)(applying Illinois law); *Zanzuri v. G.D. Searle & Co.*, 748 F.Supp. 1511 (S.D. Fla. 1990)(applying Florida law); *Andre v. Mecta Corp.*, 587 N.Y.S.2d 334, (NY. App. Div. 1992) *appeal denied*, 648 N.E.2d 791.

In Dr. Jeffries' affidavit submitted by defendant, he stated that he was fully aware of the risks involved in using the hardware in this type of surgery. Moreover, he stated that he was familiar with the FDA regulatory status of the product. Finally, he stated that he did not rely upon certain literature distributed or sponsored by the defendant in making his determinations. Thus, the defendant's alleged failure to warn plaintiff is not considered to be the proximate cause of plaintiff's injury under this doctrine. While the "independent knowledge" defense is

not universally accepted, *see Seley v. G.D. Searle & Co.*, 423 N.E.2d 831 Ohio 1981), we follow the majority view among the courts that have decided this issue, which is consistent with Tennessee case law. *See Ball v. Mallinkrodt Chem. Works*, 381 S.W.2d 563, 568 (Tenn. App. 1964). (Trial Court did not err in refusing to submit improper warning claims to jury when "there was no evidence that [the treating physician] relied upon the brochure and all of the evidence shows that he was fully aware of the toxicity. . . ").

Plaintiff also argues that the Trial Court erred in granting judgment on the issue of his negligence per se claim. The complaint alleges that defendant violated 21 U.S.C. § 360 of the Food, Drug and Cosmetic Act ("FDCA").

Plaintiff contends that common law negligence suits are not preempted by the FDCA. *See Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996). Although *Medtronic* establishes that state common law negligence claims are generally not preempted, it does not resolve the precise issue in this case. The defendant does not argue that the negligence per se claim is preempted. Rather, it argues that since the FDCA does not provide for a private right of action, allowing negligence per se claims based on violations of the statute would be contrary to Congressional intent.

21 U.S.C. §337 provides:

> Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

Thus, it is necessary to determine if it would be proper to use the FDCA provision as a basis for a negligence per se claim.

In order to recover under the theory of negligence per se, a party must establish three elements. First, the defendant must have violated a statute or ordinance that imposes a duty or prohibition for the benefit of a person or the public. *Memphis Street Railway v. Haynes*, 81 S.W.374 (Tenn. 1904). Second, the injured party must

be within the class of persons intended to benefit from or be protected by the statute. *Traylor v. Coburn*, 597 S.W.2d 319 (Tenn.App. 1980). Finally, the injured party must show that the negligence was the proximate cause of the injury. *Long v. Brookside Manor*, 885 S.W.2d 70 (Tenn. App. 1994).

The FDCA was designed to protect the public as a whole. "*Toole v. Richardson-Merrell*, 60 Cal.Rptr. 398, 409 (Cal.Ct.App. 1967) (citing *United States v. Sullivan*, 332 U.S. 689 (1948)). Since the statute was designed at least in part to protect the public from unsafe medical products, the plaintiff has met the first two required elements. The issue thus becomes whether the FDCA's lack of a private cause of action precludes using it as a basis for negligence per se claims.

We have been cited no Tennessee authority which has determined whether a violation of the FDCA can support a negligence per se claim. Defendant cites *Rogers v. Memphis City Schools*, 1997 WL 675194 (Tenn. App.) for its contention that FDCA violations cannot support negligence claims. In *Rogers*, the plaintiff sought to bring a negligence action under the Tennessee Tort Liability Act. This claim was based in part on the defendant's alleged violation of the federal Individuals With Disabilities Act (IDEA). The plaintiff sought to recover damages for pain and suffering, which were not available under the remedial provisions of the IDEA. The court determined that the plaintiff could not circumvent or supplement the IDEA's provisions merely by bringing a state law claim. Since the IDEA constituted "the exclusive remedy for a child with disabilities asserting the right to a free appropriate public education," the plaintiff "failed to state a claim under the TGTLA." *Id.* at *4.

While *Rogers* is an instructive and well-reasoned opinion, it is not precisely on point. First, *Rogers* obviously dealt with a different statute, with different provisions from the one at issue in this case. Moreover, the IDEA provided an

independent remedial scheme whereby injured parties could seek relief. There is no similar provision in the FDCA. Thus, while *Rogers* provides guidance, it is not dispositive.

Other jurisdictions have reached differing results on this issue. Some jurisdictions have allowed plaintiffs to bring negligence claims per se on FDCA violations. In *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960), the Fourth Circuit determined that although the FDCA does not expressly provide a civil remedy for injured consumers, manufacturers who violated their statutory duties could be subject to negligence per se claims. *Accord: Stanton v. Astra Pharmaceutical Prods., Inc.*, 718 F.2d 553 (3rd Cir. 1983); *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398 (Cal.Ct.App. 1967).

Assuming *arguendo* that FDCA violations could be the basis for a negligence per se action, we believe summary judgment was still appropriate in this case. The plaintiff alleges that the defendant "marketed, promoted and distributed" its product for the purposes which the FDA had not approved, in violation of § 360 of the FDCA. Section 360 primarily deals with the duty of producers of drugs or devices to register with the Secretary of State for the state in which certain establishments are located.

It is not clear from plaintiff's complaint which portion of §360 the defendant is alleged to have violated. Plaintiff may have intended to allege violations of the Medical Device Amendments to the FDCA and not the general reporting requirements of § 360. If so, this allegation is not stated in the complaint. *See* T.R.C.P. 8.05 (addressing the pleading of statutory violations). It is not clear how the defendant failed to comply with its statutory duties. The complaint recites several examples of alleged misconduct by defendant. Assuming that these instances were breaches of § 360, summary judgment, nevertheless, was proper.

Assuming defendant did breach § 360, such breach was not the proximate cause of plaintiff's injuries. Assuming that the Appellant marketed, promoted and distributed its product for non-FDA approved purposes, Dr. Jeffries' affidavit states that he was fully aware of the FDA regulatory status of this product. The doctor chose to make an "off-label" use of the product. He relied entirely upon his own expertise and experience in deciding whether and how to use the defendant's product. According to his affidavit "[m]y professional decision concerning whether, how, or where to use instrumentation is not determined by whether a particular use of a particular drug or device has or has not been evaluated by the FDA."

To the extent that the plaintiff's complaint alleges improper marketing through the use of certain literature and promotional campaigns, Dr. Jeffries' affidavit establishes that he was not familiar with, and did not rely upon, any of these marketing techniques. Thus, assuming *arguendo*, that defendant violated § 360 of the FDCA, such violation was not, as a matter of law, the proximate cause of plaintiff's injury.

Plaintiff filed a notice of deposition before summary judgment was granted. The Trial Court quashed the notice and granted summary judgment. Plaintiff then filed a motion to alter or amend the final judgment and as a part of that motion, the plaintiff again attached an affidavit stating his need to depose Dr. Jeffries. The Trial Judge also denied this motion.

Rule 56.07 of the Tennessee Rules of Civil Procedure provides:

> Should it appear from the affidavits of a party opposing the motion that such party cannot for reasons stated present by affidavit facts essential to justify the opposition, the court may refuse the application for judgment or may order a continuance to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make such other order as is just.

In this case, the Trial Court did not abuse its discretion in refusing to allow further discovery. Defendant raised the learned intermediary defense in its answer. Over

seventeen months passed before the defendant, relying on Dr. Jeffries' affidavit, moved for summary judgment. The plaintiff waited until the day argument was to be heard on the motion before giving formal notice that he wished to take Dr. Jeffries' deposition. This was some seventy days after the summary judgment motion had been filed. Under these circumstances, we conclude the Trial Judge did not abuse his discretion in denying this motion.

Finally, plaintiff contends that the Trial Court erred in denying his third proposed amendment to his complaint. Plaintiff moved to amend for a third time on June 30, 1997.

Rule 15.01 of the Tennessee Rules of Civil Procedure provides: "A party may amend his pleadings once as a matter of course at any time before a responsive pleading is served . . . [o]therwise a party may amend his pleadings only by written consent of the adverse party or by leave of court . . ." Although permission to amend should be liberally granted, the decision is " within the sound discretion of the trial court, and will not be reversed unless abuse of discretion has been shown." *Welch v. Thuan*, 882 S.W.2d 792, 793 (Tenn.App. 1994). Factors the trial court should consider when deciding whether to allow amendments include "undue delay in filing; lack of notice to the opposing party; bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendment." *Merriman v. Smith*, 599 S.W.2d 548, 559 (Tenn.App. 1979).

In this case, plaintiff sought to amend his complaint to include allegations that one of the nuts holding the screws in his back was loose and that all four of the screws became loose within his spine. The report upon which this amendment was based is dated August 8, 1995, yet the appellant did not attempt to utilize it before, even when the defendant moved for judgment on the pleadings. The

plaintiff attempted to use the operative report as evidence that "[t]he TSRH spinal system and the pedical screws in particular were unreasonably dangerous and defective . . . " The alleged looseness in the screws, however, was observed only after the product was being dismantled, not while it was implanted. The screws were observed to be loose only after the rods and connectors were removed. There is nothing in the operative report to establish that any of the screws became loose while in the plaintiff's back, only that one of the nuts was loose.

For the foregoing reasons, we conclude the Trial Court did not abuse its discretion in denying this amendment.

We affirm the judgment of the Trial Court and remand with cost of the appeal assessed to the appellant.

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Herschel P. Franks, J.

CONCUR:

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Houston M. Goddard, P.J.

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Don T. McMurray, J.