UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

CIVIL ACTION NO. 3:94CV-634-H

JAMES CLARK and BONNIE E. CLARK — PLAINTIFFS

V.

DANEK MEDICAL, INC. — DEFENDANT

MEMORANDUM OPINION

This case arises from the implantation of a spinal fixation device manufactured by Danek Medical. Over the years enough people have complained about such devices that many of the cases were grouped in one district court as multi-district litigation. Plaintiffs' case was one of those, though it is not clear that it is typical of the others. Clark and his wife filed suit asserting a variety of claims under negligence and strict liability, alleging that Danek failed to provide adequate warnings and that the company produced a device defective in both its design and manufacture.[1]

The Court and the parties agreed to a period of discovery followed by preliminary dispositive motions. The Court now considers those motions. The parties agree that all discovery as to substantive issues is now complete. The Court has discussed the pending

[1] The Clarks argue that Danek failed to notify the Food and Drug Administration ("FDA") of the intended use of certain components of the implant and thus committed negligence and fraud. Because Plaintiffs never actually asserted such a claim in this case and because no prior order from the Multi-District Litigation court made such claims part of this case, the Court will not consider them now. Instead, the Court has allowed Plaintiff additional time to file a Motion for Leave to File an Amended Complaint. The Court has no preconception about whether such a motion should be sustained.

motions at length in a conference with the parties and has considered their responses to oral questions in resolving these issues.

I.

Clark opted for the spinal fusion operation after a long history of lower back trouble which rose to a disabling level after an on-the-job mishap in February of 1991. Clark's orthopedic surgeon, Dr. Stephen Glassman, recommended an operation to fuse the two lower lumbar vertebrae with the upper sacral vertebra -- an L4-S1 spinal fusion. He further recommended the use of Danek's TSRH implant, a prescription device named after the Texas Scottish Rite Hospital that pioneered its development. The TSRH implant consists of many components which physicians may use in a variety of ways to promote fusion. As used in Mr. Clark's case, the TSRH implant included bone screws attached to both the sacral vertebra and to the pedicles of the lumbar vertebrae. These screws provided the connection points for a construct of rods designed to stabilize the vertebrae.

Danek sought approval from the Food and Drug Administration ("FDA") to market the bone screw components of the TSRH system for use in the sacral vertebrae, rather than for attachment to the pedicles of the lumbar vertebrae. While the FDA did approve limited marketing of the TSRH implant as an experimental pedicle fixation system, the agency apparently declined to clear the way for routine marketing of the pedicle screw components because of concerns about their safety and effectiveness. Nevertheless, according to the Clarks, Danek began to actively promote the TSRH implant as a pedicle fixation system and to train surgeons in its use. The company allegedly provided royalties, stock options, and other remuneration to physicians (known as "product champions") who promoted the implant at

seminars and training courses organized and/or funded by Danek. Other physicians became familiar with the device and prescribed its use.[2] This situation was possible because federal law regulates only the marketing of medical devices and not their use by physicians. In other words, regardless of how Danek marketed the implant, physicians could prescribe its use off-label (i.e., in a manner not approved by the FDA).

Before proceeding with the operation, Dr. Glassman explained the risks of spinal fusion: the bones might not fuse, the components of the implant might break because of movement, and the operation might not result in any pain relief. Dr. Glassman explained that Clark's three-pack-a-day smoking habit might reduce the chances of fusion. Dr. Glassman did not inform Clark that the FDA had not approved the marketing of the bone screws for use in the pedicles nor did Dr. Glassman inform Clark of the FDA's concerns about pedicle screws.

In June of 1991, Dr. Glassman performed the surgery. Clark seemed to improve afterwards, although over the next year and a half his spine did not fuse fully. His pain returned to its previous level, or worse. An x-ray in February of 1993 showed the TSRH implant intact. A year later another x-ray showed that the rods in the implant had fractured. Sometime during this period, Clark began to feel a "cutting" sensation. Dr. Glassman diagnosed pseudarthrosis (a.k.a. failed fusion, or "non-union") and concluded that the broken rods might be causing some of Clark's pain. He recommended the removal of the broken TSRH implant. In June of 1994, Dr. Glassman performed the explant surgery during which he also supplemented the fusion process. The operation revealed that Clark achieved a L4 and L5 fusion, but no fusion between L5 and

[2] The only evidence in the record as to Dr. Glassman is that he became familiar with the TSRH device during his training, used the device many times and, using his own medical judgment and experience, chose it as best suited for Mr. Clark in these circumstances.

S1. Furthermore, the surgery showed that the other components of the TSRH system suffered no failure or loosening. While Clark experienced some improvement after the 1994 operation, including the disappearance of the cutting pain, his overall discomfort returned to presurgical levels by September of 1995.

In October of 1994, Clark and his wife filed this suit in Kentucky state court. Mr. Clark sought compensation for his medical problems; Mrs. Clark sought recovery for her loss of companionship. Their claims are (1) design defect, manufacturing defect, and failure to warn, all under strict liability; (2) the same defect and warning theories under negligence; (3) negligence in the sale of the implant; and (4) breach of warranties, both express and implied.[3] After Danek removed to federal court, the case was transferred to the Eastern District of Pennsylvania for the multi-district litigation proceedings styled *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014. A significant amount of discovery proceeded under the supervision of the multi-district litigation court. In early 1998, the multi-district court remanded the case to this Court.

II.

Initially, the Clarks advance a theory that they refer to as "negligence per se." Under this rubric, the Clarks contend that Danek's violations of federal regulatory statutes caused harm.

If the Clarks mean that Danek owes them some duty under federal law, then the Clarks would seem to be attempting to argue a private right of action clearly barred by *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 487 (1996). If, on the other hand, the Clarks mean that Danek distributed

[3] Among its other rulings, the multi-district court has dismissed all express warranty claims. Plaintiffs do not argue that their claim somehow survived that dismissal. Nor do Plaintiffs argue for the continued validity of the implied warranty claim in their motion opposing summary judgment. The Court, therefore, will treat the implied warranty claim as abandoned and dismiss it accordingly.

a defective and dangerous device because the company violated federal law, then Plaintiffs need to describe the alleged defect under some established theory. The mere violation of law does not amount to a defect absent evidence of an actual flaw in manufacturing, design, warning, or some other aspect of the product itself. To the extent that the Clarks mean to argue that Danek failed to warn of the lack of FDA approval for pedicle screw components of the implant, then this claim is subsumed by the couple's products liability claims discussed below. Similarly, to the extent the Clarks mean to argue that Danek negligently misrepresented information to the FDA, then the claim is swallowed by the fraud on the FDA theory, which is not yet a part of this case. *See supra* note 1.

In sum, the Court sees no independent basis for a negligence per se claim separate from the other theories advanced elsewhere in this case.

III.

Plaintiffs' claims in negligence and strict liability may be summarized as follows: (1) the TSRH implant is defective and unreasonably dangerous because its design either does not promote or actually inhibits bone fusion; and (2) the TSRH implant is defective and unreasonably dangerous as sold because Defendant failed to warn physicians, who in turn failed to warn the Clarks, that the TSRH was not FDA approved as a pedicle screw device. Each of these events, Plaintiffs say, caused or contributed to their injuries.

Defendant broadly attacks each of these theories as unsupported by any valid evidence that the TSRH implant is defective. Moreover, Defendant argues strenuously that none of these actions can be shown to have caused any of Plaintiffs' injuries.

A.

Overlaying Plaintiffs' entire argument is their claim that a design defect caused the TSRH implant to inhibit fusion or actually caused non-union in this case.[4] In essence, the design defect is that the TSRH implant does not work and even an adequate warning or appropriate informed consent would fail to make the device reasonably safe for use in the treatment of back problems.

Simply because non-union occurs in this case does not tend to suggest that the device is defective.[5] *See Perkins v. Trailco Mfg. and Sales Co.,* 613 S.W.2d 855, 857 (Ky. 1981) (explaining the amount of circumstantial evidence necessary to establish causation). The TSRH implant is supposed to improve the chances of a union, not guarantee it. Everyone agrees that a union does not occur with every use. To prevail at the summary judgment stage, the Clarks must have evidence that the TSRH implant does not work or that it actually inhibits fusion. The Clarks rely on the generic expert testimony of Dr. Harold Alexander and that of Dr. Robert Pennell.

Dr. Alexander asserts that without proper testing, the TSRH must be presumed defective and unreasonably dangerous. Dr. Alexander did not identify any actual defect or unsafe condition. Thus, his testimony constitutes nothing more than, possibly, an opinion about the duty to test medical products fully. This testimony falls well short of that necessary.

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[4] At various points in their motion opposing summary judgment, the Clarks appear to raise a claim under either strict liability and/or negligence based on Danek's inadequate testing of the TSRH device. To the extent that the Clarks mean that Danek failed to discover and warn of risks associated with the implant, the Court will treat the claim as subsumed by the failure to warn argument. Similarly, to the extent that the Clarks suggest that Danek failed to conduct proper testing as part of its attempted compliance with federal regulations, the Court will consider the claim encompassed by the misrepresentation to the FDA theory not yet part of the case. *See supra* note 1. If, however, the Clarks mean that the inadequate testing constituted a design defect, the claim fails because it does not rest on any identified flaw in the design of the implant.

[5] Dr. Robert Pennell's expert testimony seems to confirm this legal principle. He said that if fusion does not occur the rod will eventually break.

Usually, in implant cases, the claim is that the device failed because the pedicle screws did not securely hold the rod. Because the rod is insecure it does not assist and may even inhibit fusion. If indeed that is a defect of the TSRH implant (or if the Clarks intend to claim some other design flaw), then the difficulty in this case appears to be the absence of any evidence showing that such a problem existed here or that a loosening of the screws or a breaking of the rod contributed to the non-fusion. The Court has reviewed the evidence and has repeatedly questioned counsel about evidence that either the screws or the broken rod caused non-union. There is evidence of neither. Plaintiff relies upon Dr. Robert Pennell, whose report provides only superficial support. However, his conclusion seems absolutely without foundation. Dr. Pennell's opinion is one without any supporting facts. Moreover, the facts tend to show, if anything, that non-union existed prior to the rod breaking.

Plaintiffs' argument is essentially that even an appropriate warning cannot make this device safe for use by physicians. However, Plaintiffs present no evidence to support such a broad indictment of the TSRH implant. What the evidence does clearly suggest is that the TSRH implant is the sort of desirable but unavoidably unsafe product described by the Restatement (Second) of Torts, §402A, comment k. The evidence suggests that Plaintiffs' claims are most appropriately considered in that context.

B.

Under comment k, the crucial question raised by any unavoidably unsafe product is whether the manufacturer provided an adequate warning. If accompanied by an adequate warning, a desirable but unsafe product is not unreasonably dangerous.

Kentucky cases allow failure to warn claims under either negligence or strict liability.

See Tobin v. Astra Pharmaceutical Prods., Inc., 993 F.2d 528, 535-36 (6th Cir. 1993); *Hutt v. Gibson Fiber Glass Prods., Inc.*, 914 F.2d 790, 793 (6th Cir. 1990). The Court believes that for all practical purposes the claims are identical. *See Snawder v. Cohen*, 749 F. Supp. 1473, 1476 (W.D. Ky. 1990) ("theories of negligence and strict liability in failure to warn cases have been deemed to be functional equivalents" (internal quotation marks omitted)). At this stage, the critical issue is whether the Clarks offer evidence showing that Danek failed to provide an adequate warning along with the TSRH device.

The Clarks contend that Danek failed to convey two important kinds of information. First, the Clarks allege that Danek did not explain the risks of using the TSRH implant (or more specifically, the risks associated with using bone screws in the pedicles) as identified by the FDA. Second, the Clarks allege that Danek did not explain that, because of those risks, the FDA did not approve the marketing of the bone screws for use in the pedicles. In more generic terms, the Clarks complain of Danek's failure to warn fully of the dangers and FDA status of the TSRH implant.

Danek did supply an FDA-approved package insert with the TSRH implant. However, this action does not necessarily defeat a failure to warn claim. *See Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1112 (4th Cir. 1988); *Etcheverry v. Tri-Ag Serv., Inc.*, 76 Cal. Rptr. 2d 466, 469 (Cal. Ct. App. 1998). The insert described the risks and possible consequences of breakage following non-union and it referred in more general terms to the risks associated with non-union. But, according to the Clarks, the insert did not mention the FDA's concerns about the risks created by the pedicle screw components of the implant, nor did the insert mention the lack of FDA approval for the marketing of bone screws for use in the pedicles.

Although Danek did warn about many of the risks identified by the Clarks, it does not claim to have warned of the FDA's decision not to approve bone screws for their intended component use in the pedicles as part of the TSRH implant. As to the generic risks of the operation and the TSRH device, it is difficult to imagine that a further description of the risks would have changed Mr. Clark's decision. However, the Court will discuss caution in a later section.

C.

Arguing in the alternative, Danek explains that even if the package insert provided an inadequate warning, Dr. Glassman should have informed Mr. Clark of all the important risks and considerations relevant to the use of the TSRH implant. In other words, Danek asserts the so-called "learned intermediary defense."

For a variety of reasons, the Court concludes that Danek is not entitled to summary judgment based upon the learned intermediary defense. Several neighboring states have adopted the defense either as statutory or common law. *See*, *e.g.*, Ohio Rev. Stat. § 2307.76(C); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548 (Ind. Ct. App. 1979); *Laws v. Johnson*, 799 S.W.2d 249, 252-53 (Tenn. Ct. App. 1990). While Kentucky courts have not yet applied the rule, the Court concludes that they might do so in these circumstances. Kentucky cases reveal a pronounced concern with issues of superseding cause in products liability cases. *See Montgomery Elevator Co. v. McCullogh*, 676 S.W.2d 776, 779-80 (Ky. 1984). When a manufacturer provides medical equipment to a physician, it should be able to rely upon that physician to give the proper warnings and obtain appropriate informed consent. The failure of a physician to obtain informed consent would seem to constitute a superseding cause.

Nevertheless, even if the Court decided this unsettled question of state law it would not resolve the motion in Danek's favor. *See Snawder*, 749 F. Supp. at 1480 (declining to adopt the learned intermediary defense but refusing to grant summary judgment because a material dispute over whether a drug manufacturer provided an adequate warning to the physician and whether the physician in turn provided an adequate warning to the patient).

A dispute of material fact exists as to whether Danek provided an adequate warning to Dr. Glassman. The learned intermediary defense would apply only if Dr. Glassman possessed independent knowledge of crucial information but failed to convey that information to Mr. Clark. Dr. Glassman did not warn Mr. Clark about the FDA status of pedicle screws or about the FDA non-approval for this use. However, no evidence suggests that the surgeon knew these facts at the time of Mr. Clark's operation.

D.

The record raises serious questions about whether the Clarks offer insufficient proof of causation as to their remaining strict failure to warn claim. Even if the Clarks have offered evidence of medical causation, Danek faces liability only if the company's failure to warn caused the Clarks' injuries.

The Court sees at least two possible ways in which Danek's allegedly insufficient warning could have led to the Clarks' injuries. First, with more information, Dr. Glassman might have chosen not to use the TSRH implant. *See*, *e.g.*, *Windham v. Wyeth Labs., Inc.*, 786 F. Supp. 607, 612 (S.D. Miss. 1992) (focusing on physician's decision-making). Second, after hearing of the risks associated with pedicle screws, Mr. Clark might have decided against the

operation or he might have requested a different implant.[6] *See Snawder*, 749 F. Supp. at 1479-80 (describing the standards for causation in a failure to warn case involving prescription drugs and noting the need for an inference that the patient would have made a different decision after hearing the proper warning).

In essence, the Clarks need to show some evidence from which a jury might conclude that an adequate warning would have altered the conduct that led to the injury. *See id.* Considering Mr. Clark's desperation at the time he opted for surgery, Dr. Glassman's familiarity with and enthusiasm for the TSRH implant, and the warning which Dr. Glassman did provide about the operation and the use of implants generally, this seems like a difficult burden. After examining the record, the Court finds no evidence to support the assertion that either Mr. Clark or Dr. Glassman would have made a different decision had either known that the TSRH was not FDA approved for this specific operation.

In fact, the only evidence in the record supports the opposite conclusion. Dr. Glassman's deposition testimony contains extensive evidence of his experience and training with the TSRH system. At no point did the surgeon suggest that additional information from Danek might have caused him to use a different implant or no implant at all. Similarly, Mr. Clark's deposition testimony suggests that he would have chosen to undergo the operation regardless of additional information about the riskiness of the implant. For instance, Mr. Clark stated: "They give me an 80 percent chance of me being better. I thought that was better than no chance at all." Plaintiff's

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[6] The focus of Plaintiffs' argument seems to be that neither Danek nor Dr. Glassman warned Mr. Clark of the dangers associated with pedicle screw devices. Those dangers are similar to those associated with the operation generally: the possibility of non-union. This makes it very unlikely that knowing of these specific dangers would make much difference to a patient who was already informed of the same risks. Moreover, the supposed risk of which Mr. Clark is alleged not to have been informed, in fact, never materialized. The pedicle screws did not become loose and malfunction. This fact adds to the impression that Plaintiffs cannot show causation.

Deposition, at 81. Even more directly, he admitted: "I was going to do anything to get better." *Id.* at 83. Therefore, based on the record, the Court concludes that the Clarks have failed to introduce sufficient evidence to allow a reasonable jury to conclude that either Dr. Glassman or Mr. Clark might have acted differently. Without such evidence, the Clarks cannot establish the causation necessary to support a failure to warn claim. Accordingly, the Court grants summary judgment for Danek on this point.

IV.

With the Clarks' claims of negligence per se, product liability (under both negligence and strict liability), and breach of warranty dismissed, no claims now remain in this suit. Because the Court has allowed Plaintiffs time to file a motion to amend, the Court will suspend dismissing this suit pending resolution of that issue.

The Court shall enter an Order consistent with this Memorandum Opinion.

JOHN G. HEYBURN II
JUDGE, U.S. DISTRICT COURT

cc: Counsel of Record

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

CIVIL ACTION NO. 3:94CV-634-H

JAMES CLARK and
BONNIE E. CLARK — PLAINTIFF

V.

DANEK MEDICAL, INC. — DEFENDANT

ORDER

Defendant has moved for summary judgment on all the Clarks' claims. Being otherwise sufficiently advised,

IT IS HEREBY ORDERED that Defendant's Motion for Summary Judgment is SUSTAINED. Plaintiffs' claims under warranty and product liability defect are DISMISSED WITH PREJUDICE.

The Court has previously allowed Plaintiff additional time in which to file a Motion for Leave to File an Amended Complaint. Therefore, this order is not final, because potential pending motions may add other causes of action.

This ___ day of March, 1999.

JOHN G. HEYBURN II
JUDGE, U.S. DISTRICT COURT

cc: Counsel of Record

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