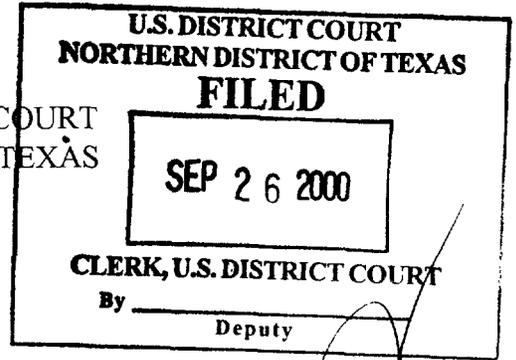


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ORIGINAL

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION



DEBRA L. DYER and  
MICHAEL DYER,

Plaintiffs,

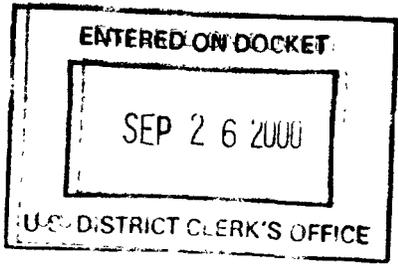
v.

DANEK MEDICAL, INC. and  
RICHARDSON MEDICAL CENTER,

Defendants.

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Civil Action No. 3:95-CV-0928-L



**MEMORANDUM OPINION AND ORDER**

Before the court are Defendant Danek Medical, Inc.'s ("Danek") Motion for Summary Judgment, filed May 15, 1998<sup>1</sup>; Defendant Richardson Hospital Authority d/b/a Baylor/Richardson Medical Center's ("RHA") Motion for Summary Judgment, filed May 15, 1998; and Danek's Motion to Strike or Preclude Testimony of Andrew Kucharchuk and Harold Alexander, filed July 8, 1998. After careful consideration of the motions, briefs, evidence submitted by the parties and applicable law, the court finds that no genuine issue of material fact exists regarding Plaintiffs' claims. Accordingly, the court **grants** summary judgment for both Defendants.

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<sup>1</sup>Defendant Richardson Hospital Authority ("RHA") previously filed a Motion for Deemed Summary Judgment on May 15, 1998. That motion sought to adopt by reference Danek's Motion for Summary Judgment, asserting that Defendants were identically situated as to all items in Danek's motion. This court granted RHA's motion on September 30, 1999. Therefore, the resolution of the issues raised by Danek will be applicable to both Defendants.

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## **I. Factual and Procedural Background<sup>2</sup>**

Debra Dyer originally injured her back in July 1990. Her physician, Dr. Abbass Sekhavat, performed spinal surgery in November 1990. After Ms. Dyer injured herself again in a fall, Dr. Sekhavat discovered a ruptured disk and performed a second surgery in May 1991, attempting to achieve spinal fusion. She again injured her back in November 1991. Despite this third injury, the spinal fusion performed in May 1991 was apparently initially successful, although Ms. Dyer experienced severe episodes of back pain. In September 1992, however, an examination revealed that the spinal fusion had failed. Dr. Sekhavat recommended instrumented spinal fusion surgery, which he performed in April 1993 at RHA. This involved the surgical implantation of a spinal fusion fixation device, designed to immobilize the patient's spine and allow the vertebrae to fuse. The device was attached to Ms. Dyer's spine by means of screws inserted into the pedicles, bony structures that extend posteriorly from each vertebra. In the process of inserting the screws, Dr. Sekhavat fractured the inferomedial wall of one pedicle on the right side of Ms. Dyer's spine, and eventually was able to attach the device only to the left side of her spine. Four to six months after the surgery, Ms. Dyer began experiencing debilitating pain, much worse than she had experienced in the preceding three years. She also experienced medical problems that were not present before the surgery.

The device used by Dr. Sekhavat for the 1993 surgery, called the Texas Scottish Rite Hospital ("TSRH") Spinal System, was manufactured by Danek. Such devices are subject to regulation by the Food and Drug Administration ("FDA") in accordance with the Medical Device

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<sup>2</sup>The facts contained herein are either undisputed or, where they are disputed, presented in the light most favorable to Plaintiffs as the nonmovants.

Amendments (“MDAs”) to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (“FDCA”). Under the MDAs, the FDA categorizes medical devices as either Class I (no unreasonable risk of illness or injury, and therefore subject only to general controls applicable to all medical devices), Class II (more likely to cause harm if defective or misused, and therefore subject to additional controls), or Class III (not approved for marketing until the manufacturer provides the FDA with adequate assurance that the device is safe and effective). Class III devices are approved for marketing through one of three different procedures: a rigorous review by the FDA referred to as “premarket approval” (“PMA” process); a “grandfathering” provision for devices already on the market when the MDAs were enacted, pending completion of the PMA process; or a limited FDA review to establish that the device is “substantially equivalent” to a grandfathered device (“§ 510(k)” process) The PMA process often involves stringently controlled clinical trials under the Investigational Device Exemption (“IDE”) provisions of the FDCA. An IDE allows a device to be used only in supervised clinical trials, not for commercial marketing and distribution.<sup>3</sup>

The TSRH system received marketing approval as substantially equivalent to a grandfathered device, through the § 510(k) process. This FDA clearance, however, only covered attachment of the device through “sacral screws” or “anterior screws.”<sup>4</sup> The FDA clearance had specifically excluded marketing the TSRH as a pedicular screw fixation device, as noted in the letter sent to Danek. At the time of Ms. Dyer’s surgery, the FDA had explicitly warned that the TSRH system could not be

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<sup>3</sup> For a lengthy discussion of the classification process for medical devices, see *Medtronic, Inc v. Lohr*, 518 U.S. 470, 475–80 (1996).

<sup>4</sup> Danek also received approval to conduct IDE clinical trials of pedicular fixation with the system, but the trials did not provide data sufficient to support premarket approval. The TSRH system later cleared the PMA system and received FDA approval, but not until well after Ms. Dyer’s surgery and the commencement of this action.

legally marketed for pedicular fixation, which is the method Dr. Sekhavat used; nevertheless, Danek intended the TSRH system to be used in that way and took extensive actions to promote such use, despite the FDA warning. These actions included agreements with selected spine surgeons to promote the system, organizing and funding courses and seminars, and agreements with manufacturers of similar devices to promote pedicular fixation devices as the standard of care for spinal fusion surgery. Danek and its agents promoted the TSRH system as safe and effective for use by pedicular fixation, but did not disclose that such use had not been cleared by the FDA. Similarly, there was no disclosure of financial relationships between Danek and the surgeons and hospitals who promoted the device. In essence, Plaintiffs contend that these actions created a “black market for pedicle screw fixation devices.”<sup>5</sup>

Dr. Sekhavat is a board certified orthopedic surgeon. He has performed numerous spinal surgeries using instrumentation, and predominately uses the TSRH system when he decides to use instrumentation with pedicular fixation. He has attended lectures and courses regarding pedicular fixation devices, although none specifically about the TSRH system, and could not remember whether he had received any promotional material concerning the TSRH system. At the time of Ms. Dyer’s surgery, Dr. Sekhavat was aware of the possible complications arising from such fusion surgery and was aware that the surgery could fail and that the screws and rods could break. He considered that the device was FDA-approved; he was not aware that the FDA had not approved the system for use in this particular manner, or even that FDA would have to approve such specific use.

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<sup>5</sup> Plaintiffs’ Table of Contents and Table of Authorities for Response to Defendants Danek Medical, Inc.’s Motion for Summary Judgment and Recharadson Medical Center’s Motion for Deemed Summary Judgment (“Response”), at 11.

Ms. Dyer and her husband filed suit against Danek and RHA in April 1995 in state court for damages resulting from use of the TSRH system. The suit alleged five different bases for recovery: 1) strict liability based on design defect; 2) strict liability based on marketing defect; 3) breach of express warranty; 4) breach of implied warranty; and 5) violation of various provisions of the Texas Deceptive Trade Practices Act (“DTPA”), Tex. Bus. & Com. Code Ann. §§ 17.41 et seq. (West 1999). Defendants removed the case to federal court in May 1995. In October 1995, the case (along with more than two thousand other cases) was transferred to the United States District Court for the Eastern District of Pennsylvania for multidistrict litigation. *In re: Orthopedic Bone Screw Products Liability Litigation*, MDL Docket No. 1014. After the completion of MDL pretrial proceedings, the case was remanded to this court in December 1997.

## **II. Summary Judgment Standard**

Summary judgment shall be rendered when 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 that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986); *Ragas v. Tennessee Gas Pipeline Company*, 136 F.3d 455, 458 (5<sup>th</sup> Cir. 1998). A dispute regarding a material fact is “genuine” if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When ruling on a motion for summary judgment, the court is required to view all inferences drawn from the factual record in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986); *Ragas*, 136 F.3d at 458.

Once the moving party has made an initial showing that there is no evidence to support the nonmoving party's case, the party opposing the motion must come forward with competent summary judgment evidence of the existence of a genuine fact issue. *Matsushita*, 475 U.S. at 586. Mere conclusory allegations are not competent summary judgment evidence, and thus are insufficient to defeat a motion for summary judgment. *Eason v. Thaler*, 73 F.3d 1322, 1325 (5<sup>th</sup> Cir. 1996). Unsubstantiated assertions, improbable inferences, and unsupported speculation are not competent summary judgment evidence. *See Forsyth v. Barr*, 19 F.3d 1527, 1533 (5<sup>th</sup> Cir.), *cert. denied*, 513 U.S. 871 (1994). The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports his claim. *Ragas*, 136 F.3d at 458. Rule 56 does not impose a duty on the court to "sift through the record in search of evidence" to support the nonmovant's opposition to the motion for summary judgment. *Id.*, *see also Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 915-16 & n.7 (5<sup>th</sup> Cir.), *cert. denied*, 506 U.S. 832 (1992). "Only disputes over facts that might affect the outcome of the suit under the governing laws will properly preclude the entry of summary judgment." *Anderson*, 477 U.S. at 248. Disputed fact issues which are "irrelevant and unnecessary" will not be considered by a court in ruling on a summary judgment motion. *Id.* If the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to its case and on which it will bear the burden of proof at trial, summary judgment must be granted. *Celotex*, 477 U.S. at 322-23.

### **III. Analysis**

Danek's motion for summary judgment asserts that Plaintiffs provided no evidence of the following aspects of Plaintiffs' claims: 1) that the product was defectively designed or manufactured; 2) that alleged inadequate warnings caused Dr. Sekhavat's choice of medical treatment and Ms.

Dyer's injuries, as required by the "learned intermediary" doctrine; 3) that Danek made, and Ms. Dyer relied on, any express warranty; 4) that the product was not fit for Ms. Dyer's particular purpose, or that she relied on any implied warranty; 5) that there was any misrepresentation or breach of warranty supporting recovery under DTPA; and 6) that the product caused Ms. Dyer's injuries.<sup>6</sup> RHA adopted these same arguments and advances two additional arguments: 1) that Plaintiffs failed to provide notice to RHA (a governmental subunit) of the injuries within six months, as required by the Texas Civil Practice and Remedies Code; and 2) that strict product liability is not applicable when, as here, a hospital delivers the product as part of the furnishing of medical services rather than as an independent sale of goods.

#### **A. Strict Liability for Design Defect**

Defendants contend that Plaintiffs has produced no evidence of a design defect and no evidence that such a defect caused Ms. Dyer's injuries. The court need not address the question of causation, because it is clear that Plaintiffs have not satisfied their burden of identifying a specific design defect of the TSRH system. Strict liability for design defect requires a showing that the product is "unreasonably dangerous as designed, taking into consideration the utility of the product and the risk involved in its use." *American Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 432 (Tex. 1997). The Texas Supreme court has identified five factors relevant to this determination: "(1) the utility of the product to the user and to the public as a whole weighed against the gravity and likelihood of injury from its use; (2) the availability of a substitute product which would meet the

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<sup>6</sup> Plaintiffs offer, as evidence of causation, statements by Dr. Andrew T. Kucharchuk and Dr. Harold Alexander. Danek has moved to strike or exclude testimony by these two experts. The court need not address this motion or evaluate the evidence, because as noted below the court does not reach the issue of causation.

same need and not be unsafe or unreasonably expensive; (3) the manufacturer's ability to eliminate the unsafe character of the product without seriously impairing its usefulness or significantly increasing its costs; (4) the user's anticipated awareness of the dangers inherent in the product and their avoidability because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and (5) the expectations of the ordinary consumer." *Id.*

The Texas Supreme Court has also recently confirmed the "common-law jurisprudence [that identifies] the availability of a safer alternative design [as not only] a factor to be considered in the risk-utility analysis [but also] a requisite element of a cause of action for defective design." *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999). Plaintiffs must offer evidence, at the summary judgment phase, of a safer design for the same specific purpose that would be equally effective and not unreasonably expensive. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255–56 (5th Cir. 1999) (applying similar Louisiana law); *American Tobacco Co.*, 951 S.W.2d at 433. An alternative design that did not use pedicle screws would not suffice for a showing of design defect. *Theriot*, 168 F.3d at 255.

In their response to the motion for summary judgment, Plaintiffs identify only three pieces of evidence to support their claim of a design defect:

- 1) a report by Dr. Harold Alexander ("[P]edicle screw based spinal fixation devices are not proved safe and effective and pose a substantial risk to treated patients. Until these devices are adequately tested for pedicular fixation, it must be assumed they are

unreasonably dangerous and should not be in general use outside of controlled, clinical trials.”);<sup>7</sup>

2) a “declaration” by Dr. Gary Franklin (“It is my opinion to a reasonable degree of medical certainty . . . that the indications, efficacy, and outcome of lumbar fusion procedures have not been adequately studied, and that the outcomes of such procedures are worse than those results which are reported.”);<sup>8</sup> and

3) an affidavit by Dr. Stephen Kimmel (“[B]ased on my review of the literature, I cannot determine with any degree of certainty how safe or efficacious pedicle screws are in comparison to other available, approved procedures. . . . In my opinion, the best available evidence . . . suggested that there might be increased risks associated with the use of pedicle screws.”).<sup>9</sup>

All three of the items advanced by Plaintiffs are suspect as being merely conclusory allegations and unsupported assertions, and thus insufficient to support the nonmovant’s burden; however, even when viewing this evidence in the light most favorable to Plaintiffs, a more fundamental problem exists. Plaintiffs have failed to clearly identify a safer design alternative, which is a prerequisite for a finding of design defect. *See Hernandez*, 2 S.W.3d at 256. The failure

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<sup>7</sup> Response, Exhibit 2, at 7. Plaintiffs’ decision to submit this as evidence of a design defect is questionable at best. In MDL pretrial proceedings, the quoted material from Dr. Alexander’s report has already been determined to be outside the scope of his expertise. *See In re: Orthopedic Bone Screw Products Liability Litigation*, 1997 WL 39583, at \*3 (E.D. Pa. Jan. 23, 1997). Danek has moved to strike or preclude testimony by Dr. Alexander. The court need not address this motion, because even in considering this evidence the court reaches the same result.

<sup>8</sup> Response, Exhibit 4, at 2.

<sup>9</sup> Response, Exhibit 3, at ¶ 41.

to address this requirement is fatal to Plaintiffs' claim.<sup>10</sup> The court concludes that Defendants are entitled to judgment as a matter of law as to the strict liability for design defect claim.

## **B. Breach of Warranty**

Plaintiffs claim breaches of both express and implied warranties. Claims of express warranties were addressed in MDL pretrial proceedings, and dismissed with prejudice with respect to any plaintiff who failed to show good cause by December 18, 1996 that the claims should be maintained. *In re Orthopedic Bone Screw Products Liability Litigation*, 1996 WL 900339 (E.D. Pa. Dec. 3, 1996). Defendants contend, and Plaintiffs did not dispute, that Plaintiffs have failed to show good cause and therefore their claims of express warranty have been dismissed. In addition, Defendants challenge the implied warranty claim, asserting an absence of evidence both that the TSRH was not fit for the particular purpose and that it caused Ms. Dyer's injury. Plaintiffs also chose not to dispute this challenge. The court therefore concludes that Defendants are entitled to judgment as a matter of law on the claims of breach of express and implied warranties.

## **C. DTPA and Strict Liability for Marketing Defect**

### **1. Representation Claims**

The complaint alleges violations of several provisions of DTPA involving affirmative representations or warranties, including Tex. Bus. & Com. Code Ann. § 17.46(b)(2) (West 1999) ("causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services"); *id.* § 17.46(b)(5) ("representing that goods or services have sponsorship,

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<sup>10</sup> Plaintiffs' failure to address this requirement is puzzling, particularly since it is discussed in two of the cases that Plaintiffs cite. See *American Tobacco Co.*, 951 S.W.2d at 433 ("if there is no safer alternative to [the product], then [it is] not unreasonably dangerous as a matter of law"); *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995) (because plaintiff "offered no evidence of a safer design . . . , we hold that this product is not defectively designed as a matter of law").

approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he does not”; *id.* § 17.46(b)(7) (“representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another”); and *id.* § 17.50(a)(2) (“breach of an express or implied warranty”). The elements of such DTPA actions are that the plaintiff is a consumer; the defendant engaged in acts that were false, misleading, or deceptive; and those acts were a producing cause of the plaintiff’s injuries. *Id.* § 17.50(a)(1).

Plaintiffs apparently abandon any DTPA claims based on affirmative representations or warranties. In their response to the motion for summary judgment, they offer no evidence of any representations or warranties made to Plaintiffs or Dr. Sekhavat, or any causal relationship between such representations or warranties and Dr. Sekhavat’s decision to use the TSRH system. The response only alleges a failure to disclose material information as support for their DTPA claims. The court therefore concludes that Defendants are entitled to judgment as a matter of law on the DTPA claims involving affirmative misrepresentations or breach of express and implied warranties.

## **2. Failure to Disclose**

Plaintiffs also allege a violation of the DTPA based on failure to disclose. *See id.* § 17.46(b)(23) (“the failure to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed”). The complaint and the response to Danek’s motion for summary judgment make clear that Plaintiffs’ claim of strict liability for marketing defect also rests on an alleged failure to warn users of potential dangers. For a marketing defect claim, plaintiffs must show an inherent risk,

known to or foreseeable by the plaintiff, for which adequate warning or instructions were not disclosed to the plaintiff, rendering the product unreasonably dangerous, and causing the plaintiff's injury. *Jaimes v. Fiesta Mart, Inc.*, 21 S.W.3d 301, 305–06 (Tex. App.—Houston [1st Dist.] 1999, pet. denied).

The difficulty with Plaintiffs' claims based on a failure to disclose is that in this case Dr. Sekhavat stands between Plaintiffs and Defendants. Texas recognizes the learned intermediary doctrine, under which manufacturers need only warn the ultimate user's physician. *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 662 (Tex. App.—Houston [14th Dist.] 1998, no pet.). The learned intermediary doctrine applies to all causes of action, including strict liability and DTPA violations, based on a failure to warn. *In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700, 709 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999); *Wyeth-Ayerst Lab. Co. v. Medrano*, 2000 WL 1093090 (Tex. App.—Texarkana Aug. 7, 2000, n.p.h.).

The learned intermediary doctrine was originally applied to prescription drugs, but Texas courts have extended the doctrine to medical devices. *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999); *Bean*, 965 S.W.2d at 663; *but see Kinzer v. Landon*, 1996 WL 354880, at \*5 (Tex. App.—Houston [14th Dist.] June 27, 1996, writ denied) (limiting the doctrine to prescription drugs). Texas courts have not yet specifically addressed the question of whether the doctrine applies to spinal fixation devices. Such an interpretation, however, would be completely consistent with the factors justifying the learned intermediary doctrine: the existence of a physician-patient relationship; the physician's integral involvement in selecting the product; and the physician's superior understanding of the interplay between the product's dangers and the patient's conditions. *See Bean*, 965 S.W.2d at 663. In addition, the court notes that several other states have addressed this specific

question and applied the learned intermediary doctrine to spinal fixation devices, including the TSRH system. *See, e.g., Talley v. Danek Med., Inc.*, 179 F.3d 154, 162–63 (4th Cir. 1999) (applying Virginia law); *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp.2d 1310, 1321 (N.D. Okla. 2000); *Baraukas v. Danek Med., Inc.*, 2000 WL 223508, at \*4 (M.D.N.C. Jan. 13, 2000); *Jones v. Danek Med., Inc.*, 1999 WL 1133272, at \*7 (D.S.C. Oct. 12, 1999); *Samarah v. Danek Med., Inc.*, 70 F. Supp.2d 1196, 1204 (D. Kan. 1999); *Hornbeck v. Danek Med., Inc.*, 1999 WL 1117107, at \*3 (W.D. La. Aug. 5, 1999), *aff'd*, \_\_\_ F.3d \_\_\_ (5th Cir. 2000); *Lawrence v. Sofamor, S.N.C.*, 1999 WL 592689, at \*4 (N.D.N.Y. Aug. 2, 1999); *Parks v. Danek Med., Inc.*, 1999 WL 1129706 (N.D. Ind. June 17, 1999); *Wheat v. Sofamor, S.N.C.*, 46 F. Supp.2d 1351, 1363 (N.D. Ga. 1999); *Coleman v. Danek Med., Inc.*, 43 F. Supp.2d 637, 646 (S.D. Miss. 1999); *Alexander v. Danek Med., Inc.*, 37 F. Supp.2d 1346, 1350 (M.D. Fla. 1999); *Huntman v. Danek Med., Inc.*, 1998 WL 663362, at \*5 (S.D. Cal. July 24, 1998). The court therefore concludes that, if presented with the issue, Texas courts would interpret the learned intermediary doctrine as applicable to the specific device at issue here.

In a failure to warn case involving a learned intermediary, the plaintiff must demonstrate that the product supplier's failure to warn the intermediary is a producing cause of injury. *Boswell v. Burroughs Wellcome Co.*, 1997 WL 198746, at \*2 (Tex. App.—Dallas Apr. 24, 1997, writ denied); *Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 912 (Tex. App.—El Paso 1989, writ denied). “If the prescribing physician is aware of the risks associated with the use of a [product], the manufacturer's failure to warn the physician of those risks is not a producing cause of a patient's injury.” *Boswell*, 1997 WL 198746, at \*2. Even if the physician is not aware of a risk, “the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would not have used or prescribed the

product.” *Willett v. Baxter Int’l, Inc.*, 929 F.2d 1094, 1099 (5th Cir. 1991) (applying similar Louisiana law); *see also In re Norplant*, 955 F. Supp. at 710 (applying the *Willett* standard to Texas law).

Plaintiffs identify several risks which they assert were not adequately disclosed by Danek, including neurologic deficit, pseudoarthrosis, pedicle fracture, soft tissue damage, and inadequate fusion. Their response to the motion for summary judgment, however, overwhelmingly focuses on the failure to warn about the FDA regulatory status of the pedicular fixation devices. Based on a review of the evidence offered, the court concludes that, of the risks identified by Plaintiffs, the regulatory status of the device was the only relevant information of which Dr. Sekhavat was not aware at the time of the surgery.<sup>11</sup> Those risks of which Dr. Sekhavat was independently aware cannot satisfy a failure to warn claim. *See Boswell*, 1997 WL 198746, at \*2. Thus, Plaintiffs remaining claims depend on whether Dr. Sekhavat would have decided against use of the TSRH system if advised that the FDA had not approved the device for pedicular fixation.

Neither party offered evidence that directly addressed this question. In the motion for summary judgment, however, Danek offered evidence from Dr. Sekhavat’s deposition that is at least suggestive in this regard. Dr. Sekhavat stated that he has attended lectures and courses and reviewed studies concerning pedicular fixation devices, and considers them to be reasonably safe and effective based on his medical judgment and experience.<sup>12</sup> In 1996, which was after the FDA warning had

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<sup>11</sup> Compare Deposition of Abbass Sekhavat on July 25, 1996 (“Deposition”), at 57 (discussing awareness of normal risks of the surgery) with Deposition at 71, 109, 125 (discussing Dr. Sekhavat’s lack of knowledge about the FDA regulatory status). This deposition is included as Exhibit B in Danek’s motion for summary judgment.

<sup>12</sup> *Id.* at 92–100, 122–23.

been brought to his attention,<sup>13</sup> Dr. Sekhavat was still performing fusion surgeries employing pedicular fixation devices, using primarily the TSRH system.<sup>14</sup> Certainly the trier of fact would reasonably infer from this evidence that Dr. Sekhavat's decision would have been unchanged even if warned of the FDA regulatory status of the TSRH system before Ms. Dyer's surgery.

Although this evidence is not dispositive on the issue of causation for the failure to warn, Defendants have clearly met their burden under *Celotex*. They need not negate the existence of a material fact; pointing out the absence of evidence is sufficient to shift the burden to nonmovants to provide competent summary judgment evidence. Plaintiffs have not met their burden of identifying specific evidence in the record and articulating the precise manner in which that evidence demonstrates the existence of a material fact dispute. Instead, Plaintiffs raise two arguments concerning the application of the learned intermediary doctrine.

First, Plaintiffs contend that Dr. Sekhavat cannot be considered a learned intermediary if he were not adequately warned. Although the learned intermediary doctrine does not eliminate the need for an adequate warning, this argument ignores the requirement of causation. The cases cited by Plaintiffs either did not address the issue of causation, *see Williams v. Upjohn Co.*, 153 F.R.D. 110, 114 (S.D. Tex. 1994), or included testimony indicating that the physician would have decided against treatment if supplied an adequate warning, *see Proctor v. Davis*, 682 N.E.2d 1203, 1212 (Ill. App. Ct. 1997); *Incollingo v. Ewing*, 282 A.2d 206, 218 (Pa. 1971). Disqualifying a physician as

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<sup>13</sup> *Id.* at 96.

<sup>14</sup> *Id.* at 99–100.

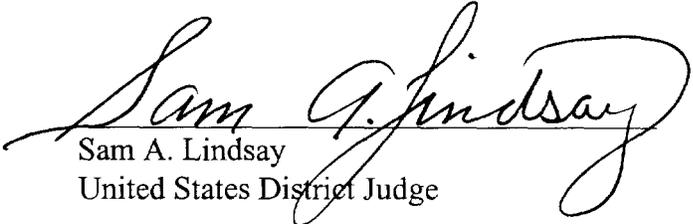
a learned intermediary simply based on the absence of a warning by the manufacturer is inconsistent with the causation requirement. The court therefore rejects this argument.

Second, Plaintiffs contend that under the Texas prudent patient standard for informed consent, the appropriate test is objective rather than subjective—whether a reasonable person, rather than the particular patient, would have refused the procedure if informed of the risks. See *McKinley v. Stripling*, 763 S.W.2d 407, 410 (Tex. 1989); *Wise v. Watson*, 2000 WL 567082, at \*3 (Tex. App.—Dallas May 9, 2000, no pet.). If applicable, this would eliminate the need for any evidence as to Ms. Dyer’s or Dr. Sekhavat’s probable reaction to a warning about the regulatory status of the TSRH system. The informed consent standard, however, applies to negligence actions against physicians, rather than failure to warn actions against product manufacturers and supplies. *Nevauex v. Park Place Hospital, Inc.*, 656 S.W.2d 923, 925 (Tex. App.—Beaumont 1983, writ ref’d n.r.e.). The court further notes that the FDA regulatory status of spinal fixation devices was identified, in MDL pretrial proceedings, as a factor that need not be disclosed to the patient as a “risk” of medical procedures. *In re Orthopedic Bone Screw Products Liability Litigation*, 1996 WL 107556, at \*3 (E.D. Pa. Mar. 8, 1996) (“The FDA labels given to a medical device do not speak directly to the medical issues surrounding a particular surgery. They are not, therefore, required to be disclosed pursuant to the law of informed consent.”) (applying Pennsylvania law). Plaintiffs’ second argument therefore also fails. Because neither of Plaintiffs’ challenges to application of the learned intermediary doctrine stands, and they have pointed to no specific evidence that would satisfy the causation requirement, the court concludes that Defendants are entitled to judgment as a matter of law on the marketing defect and DTPA failure to disclose claims.

#### IV. Conclusion

Danek also argues that Plaintiffs presented no evidence that the TSRH system caused Ms. Dyer's injuries. Additionally, RHA moves for summary judgment on the grounds that Plaintiffs did not timely provide the required notice to RHA and that strict liability does not apply to products provided as an integral part of the furnishing of medical services. Based on its rulings, the court need not address these additional grounds for summary judgment. For the above-stated reasons, there is no genuine issue of material fact present in the record with respect to any of Plaintiffs' claims, and Defendants are entitled to judgment as a matter of law. Defendant Danek Medical, Inc.'s Motion for Summary Judgment is **granted** with respect to both Defendants, and Plaintiffs' claims are hereby **dismissed** with prejudice. Defendant Richardson Hospital Authority d/b/a Baylor/Richardson Medical Center's Motion for Summary Judgment and Danek Medical, Inc.'s Motion to Strike or Preclude Testimony of Andrew Kucharchuk and Harold Alexander are **denied as moot**.

It is so ordered this 26<sup>th</sup> day of September, 2000.

  
Sam A. Lindsay  
United States District Judge