IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SANDRA TAYLOR, ET AL.	**:**	**CIVIL ACTION**
	:	
v.	**:**	**95-7232**
	:	
DANEK MEDICAL, INC., ET AL.	**:**	

MEMORANDUM

Broderick, J **December 29, 1998**

This is a bone screw case. Plaintiff Sandra Taylor and her husband claim damages arising out of the implantation of the Cotrel-Dubousset ("CD") system in Mrs. Taylor's spine during surgery on April 10, 1992. Defendants Danek Medical, Inc., Sofamor S.N.C., Sofamor-Danek and Sofamor Inc. (collectively "Sofamor") are the manufacturers of the CD device. Defendant Youngwood Medical Specialties, Inc. f/k/a National Medical Speciality, Inc., f/k/a Stuart Medical Speciality, Inc. ("Youngwood") is the distributor. Presently before the court are Defendant Sofamor and Defendant Youngwood's motions for summary judgment. For the reasons which follow, the Court will grant in part and deny in part Defendants' motions for Summary Judgment.

The material facts concerning which there are no genuine issues are summarized as follows:

Mrs. Taylor, a nurse, injured her back while moving a patient in 1985 and injured it again while turning a patient in November 1991. An MRI performed by Dr. John Manning on January 25, 1992 revealed disk degeneration, bulging, and a small disk herniation, all at the L5-S1 level. Mrs. Taylor worked with Dr. Richard A. Balderston, M.D., an orthopedic surgeon, and on

February 19, 1992, she came under his care. By March 3, 1992, her lower back pain, which radiated into her buttocks and posterior lateral thighs, had become so severe that she stopped working. Dr. Balderston diagnosed Plaintiff Taylor with instability at L5-S1 and she was scheduled for lumbar decompression and fusion surgery, with instrumentation.

On April 10, 1992, Dr. Balderston performed surgery on Mrs. Taylor at Pennsylvania Hospital and implanted a Cotrel Dubosset ("CD") device in Mrs. Taylor's spine. The device consists of screws, hooks, rods, transverse traction devices and connection components that allow surgeons to fashion a customized construct for each surgical case. The purpose of the construct is to align and immobilize the spine while the bone graft material grows together to form a solid, bony fusion. Dr. Balderston used a surgical technique, "pedicle fixation," placing two screws in the sacrum and two screws in the pedicles of L5 to attach CD rods to Mrs. Taylor's spine.

Following this procedure, Mrs. Taylor continued to suffer from a constant pain in her lower back without any relief. Mrs. Taylor also stated that after her surgery, her lower back pain was sharper and the pressure was higher. She further testified that the pain was worse than it was prior to surgery.

For several years after her April 1992 surgery, Mrs. Taylor continued to experience pain. Dr. Edward J. Vresilovic removed the device from Mrs. Taylor's spine on March 13, 1997. While the fusion was explored and found to be solid bilaterally, Dr. Vresilovic implanted titanium cages and iliac crest bone graft at L5-S1. Mrs. Taylor continues to experience pain.

On October 2, 1996, Plaintiffs Sandra and Raymond Taylor filed an Amended Complaint alleging fraud on the FDA (Count I); civil conspiracy (Count II); concert of action (Count III);

fraudulent marketing and promotion (Count IV); negligent misrepresentation (Count V); strict liability (Count VI); liability per se (Count VII); negligence (Count VIII); breach of implied warranty of merchantability (Count IX); and loss of consortium (Count X). Defendants Sofamor and Youngwood filed separate motions for summary judgment on Counts IV through X. Plaintiffs have opposed the motions.

The CD Device

The CD device is a prescription medical device which is only available to the general public through a prescribing physician. The United States Food and Drug Administration ("FDA"), through the Food Drug and Cosmetic Act ("FDCA") and Medical Device Amendments ("MDA"), regulates the marketing and labeling of medical devices, such as the CD device. See Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) (discussing history of the MDA). The MDA requires classification of medical devices into three categories based upon the risk that they pose to the public. Class I devices present no unreasonable risk of illness or injury and are subject only to general manufacturing controls. See 21 U.S.C. § 360c(a)(1)(A). Class II devices are potentially more harmful and are subject to federal performance regulations. Id § 360c(a)(1)(B). Class III devices present a potentially "unreasonable risk of illness or injury," and are subject to the strictest regulation. Id. § 360c(a)(1)(C).

Before a new Class III device may be introduced into the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. Id. § 360e(d)(2). Securing this "premarket approval" is an arduous and time-consuming task, because each submission requires an average of 1,200 hours of FDA review. See Lohr, 518 U.S.

at 477. The premarket approval process requires a manufacturer to submit, and the FDA to review: all available information concerning all investigations of the device's safety and effectiveness; detailed information regarding the device's design, components and principles of operation; a full description of manufacturing methods and controls; and a full statement of marketing plans. See 21 U.S.C. § 360e(c)(1).

There are three important exceptions to the requirement that Class III medical devices receive premarket approval before being placed on the market. First, a manufacturer can obtain an Investigational Device Exemption ("IDE"), which allows limited use of an experimental medical device to gather the type of data necessary to support a premarket approval application. See 21 U.S.C. § 360j(g). Though an IDE allows use of a class III device in clinical trials, it does not permit introduction to the general public.

Second, the MDA allows Class III devices that were in commerce prior to its enactment to remain on the market until the FDA initiates and completes a premarket approval analysis for those "predicate" devices. See id. § 360e(b)(1)(A). This "grandfathering" provision reflects Congress' recognition "that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices." Lohr, 518 U.S. at 477-78.

Third, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices wait for FDA approval, and to ensure that improvements to existing devices are introduced quickly, the MDA allows devices that are "substantially equivalent" to an existing predicate device to avoid the premarket approval process. See Lohr, 518 U.S. at 478; 21 U.S.C. § 360e(b)(1)(B). The procedure a manufacturer follows to take advantage of this exception is known as the "§ 510(k) process" after the number of the relevant section in the original Act.

Lohr, 518 U.S. at 478. A § 510(k) application must include information supporting the device's substantial equivalence to a predicate device and proposed labeling for the device. See 21 C.F.R. § 807.87. For a device to be approved under the § 510(k) process, the FDA must determine that the new device has the same intended use as the predicate device and that it possesses the same technological characteristics or is as safe and effective as the predicate device. See 21 U.S.C. § 360c(I)(1)(A). The advantage of the § 510(k) process is significant to manufacturers: review of a § 510(k) application by the FDA requires an average of only twenty hours of agency time, compared to the 1,200 hours required for full pre-market approval. See Lohr, 518 U.S. at 478-79.

In 1987, Sofamor, acting through Stuart Medical Specialty (now Youngwood), submitted a premarket notification to the FDA requesting § 510(k) clearance to market the CD device, which included a vertebral screw component. On December 7, 1987, the FDA rejected the vertebral screw component of Sofamor's application, determining that the CD device's vertebral screws represent "new device designs and methods of posterior spinal fixation which raise new questions of safety and effectiveness." FDA Letter attached as Defense Ex. D1. The FDA characterized the vertebral screws as Class III devices requiring premarket approvals before they could be marketed. Id. Several of the CD device components, however, including the CD rods and the sacral screws, were cleared for marketing by the FDA. Id.

Standard for Summary Judgment

The parties agree that the law of Pennsylvania is applicable to this diversity case. Pennsylvania is where Mrs. Taylor had her surgery, and where she currently lives and continues to experience back pain.

Federal Rule 56 dictates that a court shall grant summary judgment "if 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 a judgment as a matter of law." Fed.R.Civ.P. 56(c). A disputed factual matter is a genuine issue "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is material if it might affect the outcome of the lawsuit under the governing substantive law. Id.

When ruling on a motion for summary judgment, the Court must view the evidence in the light most favorable to the non-movant. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). The Court must accept the non-movant's version of the facts as true, and resolve conflicts in the non-movant's favor. Big Apple BMW, Inc. v. BMW of North American, Inc., 974 F.2d 1358, 1363 (3d Cir. 1992), cert. denied, 507 U.S. 912 (1993).

In response to a motion for summary judgment, the non-moving party has the burden to "do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita, 475 U.S. at 586. The non-moving party may not rely on bare assertions, conclusory allegations or suspicions. Fireman's Ins. Co. of Newark v. DuFresne, 676 F.2d 965, 969 (3d Cir. 1982). Rather, the non-movant must then "make a showing sufficient to establish the existence of every element essential to his case, based on the affidavits or by the depositions and admissions on file." Harter v. GAF Corp., 967 F.2d 846, 852 (3d Cir. 1992). In order to defeat a motion for summary judgment, the non-moving party must produce evidence which "set(s) forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e). The "mere

existence of a scintilla of evidence" to support the non-movant's position is not enough to defeat the summary judgment motion. Anderson, 477 U.S. at 252.

Plaintiffs' Claims

Count I

Count I, entitled "Fraud (on the FDA)" alleges a state fraud claim. Plaintiffs allege Defendants misrepresented to the FDA the intended use of the screws.

Count I was dismissed by the transferee court on two grounds. In re: Orthopedic Bone Screw Prod. Liab. Litig., MDL 1014, 1997 WL 305257 (E.D. Pa. March 1997). First, the transferee court determined that allowing a fraud on the FDA claim would essentially create a private right of action for violation of the FDCA and that "any grant of an implied private right of action would be contrary to the letter and spirit of the statute." Id. at *2. Second, the transferee court determined that dismissal of plaintiffs' fraud on the FDA claims was warranted under Fed. R. Civ. P. 12(b)(6) because "the alleged fraud cannot be said to have been a proximate cause of plaintiffs' alleged injuries." Id. at *4. Plaintiffs appealed.

On November 17, 1998, the Third Circuit reversed the transferee court. In re: Orthopedic Bone Screw Prod. Liab. Litig., 159 F.3d 817 (3d Cir. 1998). The Third Circuit analyzed the transferee court's decision in light of the Supreme Court case Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). In reversing the transferee court's first ground, the Third Circuit held that "refusing to entertain . . . fraudulent misrepresentation claims solely because the statutory scheme does not contain a private cause of action would be the equivalent of finding preemption of the state law claims contrary to the clear holding of Lohr." Id. at 825. With respect to the transferee court's

second ground, the Third Circuit concluded that the transferee court erred in determining that all of the MDL 1014 plaintiffs had failed to allege a legally sufficient causal nexus. The Third Circuit held that district courts must determine whether case specific plaintiffs have alleged a causal nexus only after the controlling law has been identified in each case. Id. at 827.

On December 1, 1998, Defendants filed a petition for rehearing en banc in the Third Circuit. Meanwhile, Plaintiffs Sandra and Raymond Taylor filed a motion in this Court to reinstate their fraud on the FDA claim.

Defendants' motions for summary judgment do not address any claims in Count I.

Count II

Count II alleges two conspiracies by the defendants. See In Re: Orthopedic Bone Screw Prod. Liab. Litig. 1997 WL 186325 *7 (E.D. Pa. April 1997). The first conspiracy alleges misrepresentations to the FDA in the documents submitted to obtain § 510(k) clearance for the medical device. Id. The second conspiracy alleges fraudulent and deceptive conduct which actively concealed material facts from surgeons who attended medical seminars. Id.

On November 10, 1998, this Court severed and stayed the first conspiracy claim pending a decision by the Third Circuit on similar claims which had been appealed and by that same Order this Court dismissed the second conspiracy claim with the approval of the parties.

Defendants' motions for summary judgment do not address any claims in Count II.

Count III

Count III, which is labeled "Concert of Action" alleges fraudulent and deceptive conduct and is apparently based on the Restatement (Second) of Torts § 876. Insofar as the count alleges fraudulent and deceptive conduct which actively concealed material facts from surgeons who attended medical seminars, it was dismissed by this Court's Order of November 10, 1998, without any objection from the parties. Insofar as the count alleges misrepresentations to the FDA in the documents submitted to obtain § 510(k) clearance for the medical devices, it has been severed and stayed by this Court's Order of November 10, 1998, pending a decision by the Third Circuit on the viability of such claims.

Defendants' motions for summary judgment do not address any claims in Count III.

Count IV

In Count IV, entitled "Fraudulent Marketing and Promotion," Plaintiffs appear to allege a state fraud claim. Plaintiffs allege that Sofamor and Youngwood failed to disclose to surgeons that the FDA had not cleared the CD device for commercial distribution as a pedicle screw fixation device; that the Investigational Device Exemption clinical trials failed to produce reliable and scientific evidence that the CD device was safe and effective; and "that the incidence of painful and disabling complications known to be associated with the use of the CD device for pedicle screw fixation was not established by valid and reliable scientific evidence." Amended Complaint ¶ 211. In sum, Plaintiffs allege the Defendants fraudulently failed to disclose the risks concerning the use of CD device for pedicle instrumentation. Defendants contend they are

entitled to summary judgment because Plaintiffs have provided no evidence of causation or justifiable reliance on any alleged misrepresentation.

Under Pennsylvania law, the elements of fraud are: (1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity; (4) with the intent of misleading another into relying on it; (5) justifiable reliance; and (6) resulting injury which was proximately caused by reliance. Gibbs v. Ernst, 647 A.2d 882, 889 (Pa. 1994). Plaintiffs' theory is that, without Defendants' fraudulent representations to a surgeon, a surgeon would not have implanted the CD device in Plaintiff.

The fact that the alleged misrepresentations were made to the surgeon and not directly to Mrs. Taylor is not a bar to her claim. Pennsylvania has adopted the Restatement (Second) of Torts. Section 310 of the Restatement (Second) makes it clear that "an actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by . . . a third person in reliance upon the truth of the representation . . . ." As the Restatement (Second) indicates, however, Plaintiff must prove reliance on the Defendants' alleged misrepresentations.

The Third Circuit has provided guidance on what constitutes sufficient evidence of reliance. See Stanton by Brooks v. Astra Pharmaceutical Prod. Inc., 718 F.2d 553 (3d Cir. 1983) (Becker, J.). In Stanton, the Third Circuit discussed the evidence which formed a legally sufficient causal connection between a drug manufacturing defendant's misleading conduct and the plaintiff's injury. While couched in terms of causation rather than reliance, the Stanton Court concluded that the testimony of four well qualified expert witnesses allowed the jury to infer that

physicians receiving the correct information would have considered such information in deciding how and whether to use the drug on their patients. Id. at 569.

Plaintiffs have not come forward with any evidence that surgeons receiving the correct information would have considered such information in deciding how and whether to use the device on their patients. While Plaintiffs have submitted several expert reports, these reports present no evidence of reliance. Therefore, this Court will grant summary judgment to the Defendants on Count IV on the ground that the non moving party (the Plaintiffs) may not rely on the allegations of the complaint, but must come forward with evidence which will establish the existence of every element essential to Plaintiffs' case. Plaintiffs have presented no evidence of "justifiable reliance" and have therefore failed to produce evidence of an essential element of their claim.

Count V

In Count V, entitled "Negligent Misrepresentation/402B of the Restatement of Torts (Second)," Plaintiffs allege that Defendants Sofamor and Youngwood failed to exercise reasonable care to assure that representations regarding the CD device were accurate, truthful, complete and not misleading.

Section 402B of the Restatement (Second) of Torts provides:

> One engaged in the business of selling chattels who, by advertising, labels or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer of the chattel caused by justifiable reliance upon the misrepresentation, even though: (a) it is not made fraudulently or negligently, and (b) the consumer has not bought the chattel from, or entered into any contractual relation with the seller.

Pennsylvania adopted this provision of the Restatement in Klages v. General Ordnance Equip. Corp., 367 A.2d 304 (Pa. 1977). An essential element of this claim is justifiable reliance. See Restatement (Second) of Torts § 402B. Comment j reads "The rule here stated applies only where there is justifiable reliance upon the misrepresentations of the seller, and physical harm results because of such reliance, and because of the fact which is misrepresented."

As this Court discussed with respect to Count IV, Plaintiffs have failed to come forward with any evidence of justifiable reliance on the alleged misrepresentations by the Defendants. As Plaintiffs have failed to produce evidence of an essential element of their claim, this Court will grant summary judgment for the Defendants on Count V, on the ground that the non-moving party may not rely on the allegations of the complaint, but must come forward with evidence which will establish the existence of every element essential to Plaintiffs' case. Plaintiffs have presented no evidence of "justifiable reliance" and have therefore failed to produce evidence of an essential element of their claim.

Count VI

In Count VI of the Amended Complaint, entitled "Strict Liability in Tort," Plaintiffs allege design defect (¶ 224), manufacturing defect (¶ 225), and failure to warn (¶¶ 226-230) claims.

Pennsylvania has adopted Section 402A of the Restatement (Second) of Torts. Under Pennsylvania law, the elements of strict liability are: (1) the product was defective; (2) the defect was the proximate cause of plaintiff's injuries; and (3) the defect causing the injury existed at the

time the product left the seller's hands. Pavlik v. Lane Limited/Tobacco Exporters International, 135 F.3d 876, 881 (3d Cir. 1998).

Design Defect

Defendants contend they are entitled to summary judgment on the design defect claim because Plaintiffs have failed to produce evidence of a design defect and that the defect was the proximate cause of Mrs. Taylor's pain. As this Court noted above, two essential elements of any products liability claim are proof of an actual defect in defendants' product and that the defect was the proximate cause of plaintiff's injuries. Davis v. Berwind Corp. 690 A.2d 186, 190 (Pa. 1997).

Under Pennsylvania law as it exists today, the Pennsylvania Supreme Court has interpreted the strict liability provisions of Section 402A of the Restatement (Second) of Torts as being inapplicable to prescription drugs. Hahn v. Richter, 673 A.2d 888, 891 (Pa. 1996). It is clear that the Supreme Court of Pennsylvania has ruled that the negligence standard that was used in Hahn is applicable to prescription drugs. Id. The Supreme Court of Pennsylvania recognizes that prescription drugs present a unique set of risks and benefits in that what may be harmful to one patient may be beneficial to another. The Court stated in Hahn: "Comment k, titled 'Unavoidably unsafe products,' denies application of strict liability to products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." Id. Therefore, this Court predicts that the Pennsylvania Supreme Court will determine, pursuant to its reasoning in Hahn, that prescription medical devices are likewise not covered by Section 402A of the Restatement (Second) of Torts. Summary judgment will therefore be granted to

Defendants on Plaintiffs' design defect claim under Section 402A of the Restatement (Second) of Torts.

Furthermore, it is of interest to note that the Restatement (Third) of Torts: Products Liability states:

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

Restatement (Third) of Torts: Products Liability § 6(c) (1998). This section incorporates the "learned intermediary rule" which has been recognized in Pennsylvania's negligence cases. See Incollingo v. Ewing, 282 A.2d 206 (Pa. 1971). It is also this Court's prediction that the Supreme Court of Pennsylvania will eventually adopt Section 6(c) of the Restatement (Third) of Torts: Products Liability. Under the standard set forth in the Restatement (Third) of Torts, Products Liability, Defendants are likewise entitled to summary judgment in that Plaintiffs have not come forward with any evidence which would support a claim that "the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients."

For the above reasons, summary judgment will be granted to Defendants on Plaintiffs' strict liability design defect claim.

Manufacturing Defect

In their opposition to Defendants' summary judgment motions, Plaintiffs neither contend, nor provide any evidence, in support of their manufacturing defect claim. As heretofore discussed, to defeat a summary judgment motion, the non-moving party cannot rest on the allegations in the complaint, but must make a showing sufficient to establish the existence of every element essential to her case. Since Plaintiffs have failed to come forward with evidence of essential elements of their claim, this Court will grant summary judgment for Defendants on the manufacturing defect claim. Furthermore, as heretofore pointed out, this Court predicts that the Supreme Court of Pennsylvania will determine, pursuant to its reasoning in Hahn, that prescription medical devices are not covered by § 402A of the Restatement (Second) of Torts.

Failure to Warn

Plaintiffs' Amended Complaint alleges a failure to warn claim under strict liability. (¶¶ 226-230). As the Pennsylvania Supreme Court stated, in Hahn v. Richter, 673 A.2d 888, 890 (Pa.1996):

> In Incollingo v. Ewing, where the manufacturer of a prescription drug was alleged to have caused injury by providing inadequate warnings to physicians about dangers associated with use of the drug, the manufacturer's duty to exercise reasonable care in providing adequate and proper warnings was recognized by this court. Negligence, not strict liability, was alleged as the basis for recovery. We noted that under comments j and k strict liability was not applicable to the case. We further stated: Since the strict liability rule of § 402A is not applicable, the standard of care required is that set forth in § 388 of the Restatement dealing with the lability of a supplier of chattel known to be dangerous for its intended use. Under this section, the supplier has a duty to exercise reasonable care to inform those for whose use the article is supplied of the

> facts which make it likely to be dangerous. (internal citations omitted) (emphasis in original).

It is clear, therefore, that where the adequacy of warnings associated with prescription drugs is at issue, negligence is the only recognized basis of recovery. Id. at 891. The Supreme Court of Pennsylvania recognizes that prescription drugs present a unique set of risks and benefits in that what may be harmful to one patient may be beneficial to another. Therefore, this Court predicts that the Pennsylvania Supreme Court will determine, pursuant to its reasoning in Hahn, that prescription medical devices are likewise not covered by Section 402A of the Restatement (Second) of Torts. Summary judgment will therefore be granted for Defendants on Plaintiffs' failure to warn claim under Section 402A of the Restatement (Second) of Torts.

Again, it is of interest to note that the Restatement (Third) of Torts: Products Liability states:

> A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacture knows or has reason to know that health-care provider will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Restatement (Third) of Torts: Products Liability, § 6(d) (1998). This section incorporates the "learned intermediary rule" which has been recognized in Pennsylvania's negligence cases. See Incollingo v. Ewing, 282 A.2d 206 (Pa. 1971). It is also this Court's prediction that the Supreme Court of Pennsylvania will eventually adopt Section 6(d) of the Restatement (Third) of Torts: Products Liability. Under the standard set forth in the Restatement (Third) of Torts, Products

Liability, Defendants are likewise entitled to summary judgment in that Plaintiffs have not come forward with any evidence which would support a claim under Section 6(d).

For the above reasons, summary judgment will be granted to Defendants on Plaintiffs' strict liability failure to warn claim.

Count VII

In Count VII, titled "Liability Per Se," Plaintiffs allege that Defendants violated provisions of the FDCA and MDA which caused harm to Plaintiff. Specifically, Plaintiffs allege Defendants violated 21 U.S.C. § 331 which reads:

> The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. (b) The adulteration or misbranding or any food, drug, device or cosmetic in interstate commerce. (c) The receipt in interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

Under the FDCA, "a . . . device shall be deemed to be adulterated" with respect to an intended use if it is a Class III device which has not received premarket approval or § 510(k) clearance with respect to that intended use. See 21 U.S.C. § 351(f). The FDCA provides that "a. . .device shall be deemed to be misbranded" unless its labeling bears "adequate directions" for the intended use of the device including indications, effects, relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purposes for which it is intended. See 21 U.S.C. § 352(f); 21 C.F.R. §§ 801.4, 801.109. In sum, Plaintiffs allege Defendants marketed and sold the CD screws

for pedicle fixation in the lumbar spine before the FDA cleared that intended use and in doing so violated the FDCA's provisions on adulteration and misbranding.

Negligence per se is a claim based on violation of a statute or regulation. See Cecile Indust. Inc., v. United States, 793 F.2d 97 (3d Cir. 1986). When a statute or regulation provides that under certain circumstances particular acts shall or shall not be done, it may be interpreted as fixing a standard for all members of a community, from which it is negligence to deviate. Under Pennsylvania law, negligence per se consists of four elements: (1) the purpose of the statute must be, at least in part, to protect the interest of a group of individuals, as opposed to the public generally; (2) the statute or regulation must clearly apply to the conduct of the defendant; (3) the defendant must violate the statute or regulation; and (4) the violation of the statute or regulation must be the proximate cause of the plaintiff's injuries. Id. at 99-100.

Regarding the first requirement, the Pennsylvania Supreme Court has stated that the purpose of the asserted statute or regulation must be: (a) to protect a class of persons which includes Plaintiff; (b) to protect the particular interest which is invaded; (c) to protect that interest against the kind of harm which has resulted and (d) to protect that interest against the particular hazard from which the harm results. Congini by Congini v. Portersville Valve Co., 470 A.2d 515, 517-18 (Pa. 1983), quoting Restatement (Second) of Torts, § 286 (1965).

In the instant case, the first two elements of negligence per se have been established. The FDCA and MDA were enacted "to provide for the safety and effectiveness of medical devices intended for human use." Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). Plaintiff, as the ultimate user of a regulated medical device, is among the class of persons intended to be protected by the FDCA and MDA. In addition, the FDCA and MDA were enacted to protect Plaintiff from the

particular hazard which resulted in Plaintiff's harm. As to the second element, the FDCA and MDA clearly apply to the alleged conduct of the Defendants. See, e.g., In Re: Orthopedic Bone Screw Prod. Liab. Litig., 159 F.3d 817 (3d Cir. 1998).

As the Third Circuit has recently pointed out, "a district court, having jurisdiction of the parties and the subject matter, cannot decline to enforce liability imposed by relevant state common law." In Re: Orthopedic Bone Screw Prod. Liab. Litig., 159 F.3d 817, 824 (3d Cir. 1998). The relevant state common law applicable to this count is negligence per se.

With respect to the third element, the Plaintiffs have submitted evidence that, as of the date of Mrs. Taylor's surgery, Sofamor and Youngwood had not received FDA clearances to market screws for use in the pedicles of the lumbar spine. Plaintiffs have attached deposition testimony from surgeons showing that screws were delivered into interstate commerce for use in the pedicles of the lumbar spine.

As to the fourth element, that the violation of the statute must be the proximate cause of Plaintiff's injury, Plaintiffs' expert Dr. Magdy Shady has concluded in his report that the screws used in the pedicles of the Mrs. Taylor's lumbar spine are the cause of her continued pain.

It appears, therefore, that Plaintiffs have come forward with evidence as to each element of a negligence per se claim under Pennsylvania law. Therefore, this Court will deny the defendants' motions for summary judgment in view of the fact that the Plaintiffs have raised genuine issues of material fact in connection with the negligence per se claim.

Count VIII

Count VIII of the Amended Complaint is entitled "Negligence." Negligence is the doing of some act which a reasonably prudent person would not do, or the failure to do something which a reasonably prudent person would do. It is the failure to use the ordinary care a reasonably prudent person would use under the same or similar circumstances. The plaintiff has the burden of proving not only that the defendant deviated from the standard of care, but that the defendant's negligence was the proximate cause of plaintiff's injuries.

Plaintiffs have alleged negligence by Sofamor and Youngwood as follows: producing a device that was poorly designed (¶ ¶246-7); failing to conduct adequate tests and studies (¶ 248); failing to provide appropriate warnings (¶ 249); and failing to obtain proper regulatory clearances (¶ 251).

The Court has determined that the first three allegations of negligence fall into two distinct categories and will discuss them under the headings "negligent design" and "negligent failure to warn." With respect to the last allegation of negligence, failure to obtain proper regulatory clearances, this Court has already determined that failing to obtain proper regulatory clearances is the basis of Plaintiffs' negligence per se claim. Therefore, the discussion in Count VII is applicable to this allegation and the Court will not repeat the discussion here. The Defendants' motions of summary judgment will be denied on the ground that Plaintiffs have raised genuine issues of material fact in connection with Plaintiffs claim of failure to obtain proper regulatory clearances.

Negligent Design

As heretofore pointed out, in response to Defendants' motions for summary judgment, the Plaintiffs must come forward with evidence that the Defendants engaged in conduct that deviated from the general standard of care expected under the circumstances, and that this deviation proximately caused Plaintiffs actual harm. As evidence of negligence, Plaintiffs have produced the report of Dr. Harold Alexander.

The transferee court has already ruled that Dr. Alexander is qualified to testify "on matters concerning orthopedic bioengineering and its related disciplines" including "biomechanics, biomaterial, biomedical engineering, and design and analysis of device research." In Re Orthopedic Bone Screw Prod. Liab. Litig., 1997 WL 39583, *3 (E.D.Pa. Jan. 23, 1997).

In his report, Dr. Alexander states:

> Experts in the biomechanics of lumbar fusion, publishing in Spine in 1995 have . . . proposed that the following specific actions should have been initiated: 1) Perform FEM studies of a complete fusion construct, including adjacent levels in different kinds of fusions with or without spinal instrumentation. 2) Perform diagnosis-specific clinical trials. These should be prospective an multicenter in nature. 3) Study the mechanical environment, particularly the strain magnitude and direction, to maximize fusion potential. 4) Resorbable devices should be studied because this alleviates potential long term problems associated with spinal implants. 5) The mechanical characteristics of different regions of the spine should be studied to assess differences in the potential for graft failure. 6) Because mechanical factors may affect bone induction, they should be studied in the presence of growth factors.

Plffs Ex 2 at 1-2. Dr. Alexander concludes: "These activities should have been initiated before the widespread use of these devices." Id. Thus, Dr. Alexander states an opinion as an expert in orthopedic bioengineering that the CD device with pedicle screw fixation at the time of Plaintiff's surgery had been inadequately tested.

In addition to providing evidence of negligence, Plaintiff must come forward with evidence that the manufacturer's negligence was the proximate cause of Plaintiff's injury. As the Court discussed earlier, the report of Dr. Shady concludes, in pertinent part, that "Ms. Taylor's increased pain was caused by the CD pedicle screw instrumentation." Therefore, in response to Defendants' summary judgment motions, Plaintiffs have come forward with evidence of negligence and proximate cause, thereby raising a genuine issue of material fact as to whether Defendants' product was negligently designed and that this negligence caused Mrs. Taylor's injuries. Defendants' motions for summary judgment will be denied with respect to the negligent design claim on the ground that Plaintiffs have come forward with evidence which establishes the existence of each element of their claim.

Failure to Warn

The learned intermediary rule was first applied by the Pennsylvania Supreme Court in Incollingo v. Ewing, 282 A.2d 206, 220 (1971). In describing the duty of manufacturers with respect to prescription drugs, the Court stated "[s]ince the drug was available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor." Id. It is established under Pennsylvania law that a prescription drug manufacturer may meet its duty to warn by providing an adequate warning to a learned intermediary. Mazur v. Merck & Co. Inc. 964 F.2d 1348, 1355 (3d Cir. 1992). Prescription drug manufacturers provide information about the risks of medicines "to the person who most needs and can best evaluate it--the physician." Id. at 1357. As heretofore pointed out,

this Court predicts the Supreme Court of Pennsylvania would apply the same learned intermediary doctrine to medical devices which can only be acquired by a physician's prescription.

The Pennsylvania Supreme Court has formulated the prescription drug manufacturer's duty to warn under the Section 388 "reasonableness" standard of the Restatement (Second) of Torts. Mazur, 964 F.2d at 1354; see also Hahn v. Richter, 673 A.2d 888 (Pa. 1996). Section 388 states:

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those who the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied if the supplier . . . fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts, § 388.

The Plaintiffs must come forward with evidence that Defendants failed to exercise reasonable care in warning the learned intermediary, and that the failure to warn is the proximate cause of Mrs. Taylor's injury. Whether the warning was adequate depends on whether a learned intermediary, having considered the "the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient," would use his independent judgement to prescribe a medical device. Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383 (Pa. 1991). Generally, expert medical testimony is required to determine whether the drug manufacturer's warning to the medical community is adequate. See e.g., Demmler v. Smithkline Beecham Corp., 671 A.2d 1151, 1154 (Pa. Super 1996).

Plaintiffs in this case have not called our attention to any expert who will testify that the package insert provided inadequate warning to a surgeon implanting a medical device. Plaintiffs have failed to come forward with any evidence that the Defendants' warning in this case was inadequate to discharge their duty to warn. The Defendants' motions for summary judgement in connection with negligent failure to warn will be granted on the ground that Plaintiffs have failed to come forward with evidence of an essential element of their claim.

Count IX

In Count IX of the Amended Complaint, entitled "Breach of Implied Warranty of Merchantability," Plaintiffs allege that Defendants impliedly warranted to Plaintiff and Plaintiff's implanting surgeon that the CD device was merchantable.

To establish liability for breach of an implied warranty of merchantability, the Plaintiff must prove Defendants' product failed to meet the definition of merchantable. Merchantable products must: "(1) pass without objection in the trade under the contract description; (2) in the case of fungible goods, [be] of fair average quality with the description; (3) [be] fit for the ordinary purposes for which such goods are used; (4) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; (5) [be] adequately contained, packaged and labeled as the agreement may require; and (6) conform to the promises or affirmations of fact made on the container or label, if any." 13 Pa. Stat. § 2314(b).

This provision of the Code provides a remedy for the buyer of goods from a merchant. The implied warranty of merchantability serves to protect buyers when the goods purchased are below commercial standards.

As this Court noted earlier, the Pennsylvania Supreme Court has recently excluded prescription drugs from the applicability of Section 402A. Hahn v. Richter, 673 A.2d 888 (Pa. 1996). The Hahn court specifically discusses comment k of the Restatement (Second) of Torts, entitled "unavoidably unsafe products," and reasons that comment k denies application of strict liability to products such as prescription drugs, which have medical risks, but are not deemed defective and unreasonably dangerous when marketed with proper warnings. Id. at 890. The medical device at issue in this case is an "unavoidably unsafe product" within the meaning of comment k.

The very nature of prescription medical products which are considered "unavoidably unsafe products" precludes the imposition of a warranty of fitness for "ordinary purposes." See e.g., Makripodis v. Merrell-Dow Pharm. Inc., 523 A.2d 374 (Pa. Super. 1987). A patient's inability to assess and weigh the potential risks inherent in these products is precisely the reason that they are dispensed only by prescription, and that prescription medical product manufacturers have a duty to warn learned intermediaries, not the public or the patient. See Mazur v. Merck & Co., Inc., 964 F.2d 1348 (3d Cir. 1992); Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383 (Pa. 1991). Because Pennsylvania does not recognize strict liability claims for prescription medical products and applies the learned intermediary doctrine, this Court predicts that the Pennsylvania Supreme Court would exclude a cause of action based on the implied warranty of merchantability for prescription medical devices.

This Court will grant Defendants' motions for summary judgment on Count IX on the ground that Plaintiffs cannot recover under the implied warranty of merchantability for prescription medical devices under Pennsylvania law.

An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SANDRA TAYLOR, ET AL.	**:**	**CIVIL ACTION**
	:	
v.	**:**	**95-7232**
	:	
DANEK MEDICAL, INC., ET AL.	**:**	

ORDER

AND NOW, this 29th day of December, Defendant Danek Medical, Sofamor S.N.C., Sofamor-Danek and Sofamor Inc. (collectively "Sofamor") and Defendant Youngwood Medical Specialties, Inc. f/k/a National Medical Speciality, Inc., f/k/a Stuart Medical Speciality, Inc. ("Youngwood") having each filed motions for summary judgment and the Plaintiff having opposed; for the reasons stated in this Court's Memorandum of December 29, 1998;

IT IS ORDERED: Defendant Sofamor and Defendant Youngwood's Motions for Summary Judgment are **GRANTED** as to Plaintiffs' fraudulent marketing and promotion claim in count IV, negligent misrepresentation/Section 402B of the Restatement (Second) of Torts claim in count V, design defect, manufacturing defect, and failure to warn claims pursuant to Section 402A of the Restatement (Second) of Torts in count VI, negligent failure to warn claim in count VIII, and breach of implied warranty of merchantability claim in count IX, and judgment shall be entered in favor of Defendant Sofamor and Defendant Youngwood and against Plaintiffs with respect to said claims;

IT IS FURTHER ORDERED: Defendant Sofamor and Defendant Youngwood's motions for summary judgment are **DENIED** as to Plaintiffs' negligence per se claim in count VII and negligent failure to obtain proper regulatory clearances and negligent design claims in count VIII.

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RAYMOND J. BRODERICK, J