IN THE COURT OF APPEALS OF TENNESSEE
WESTERN SECTION AT JACKSON

FILED

March 28, 2000

Cecil Crowson, Jr.
Appellate Court Clerk

ANN KING, TAMARA LITTLE, and BRIAN LITTLE,	)	
Plaintiffs/Appellants,	)	**No. W1999-02651-COA-R3-CV**
vs.	)	**Shelby Circuit No. 73049 T.D.**
DANEK MEDICAL, INC. and WARSAW ORTHOPEDIC, INC.,	)	
Defendants/Appellees.	)	

APPEAL FROM THE CIRCUIT COURT OF SHELBY COUNTY
AT MEMPHIS, TENNESSEE
THE HONORABLE JOHN R. McCARROLL, JR., JUDGE

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OPINION FILED:

AFFIRMED

ALAN E. GLENN, SPECIAL JUDGE

W. FRANK CRAWFORD, P.J., W.S. (Concurs)
DAVID R. FARMER, J. (Concurs)

O P I N I O N

The plaintiffs, Tamara Little, her husband, Brian Little, and Ann King brought this action against the defendants, Danek Medical, Inc. and Warsaw Orthopedic, Inc., alleging liability for the spinal system devices utilizing pedicle screws manufactured by the defendants. The Shelby County Circuit Court granted summary judgment as to the product liability claims and motions to dismiss as to the negligence *per se* claims. The plaintiffs timely appealed, raising three issues on appeal:

I. The trial court erred in finding that the Learned Intermediary Doctrine applied to the plaintiffs' claims pursuant to the Tennessee Products Liability Act.

II. The trial court erred in dismissing the plaintiffs' negligence *per se* claims.

III. The Federal Drug Administration-related testimony and documents concerning the TSRH device are admissible evidence in view of the plaintiffs' claims pursuant to the Tennessee Products Liability Act.

The defendants presented four additional issues:

I. Does Plaintiffs' failure to prove a defect or unreasonably dangerous condition in the TSRH medical device preclude their claims?

II. Does Plaintiffs' failure to prove cause in fact and proximate cause to a reasonable degree of medical certainty preclude their claims?

III. Does Plaintiffs' failure to prove that their alleged injuries were caused by a defect in the TSRH system preclude Plaintiffs' claims?

IV. Is cross-jurisdictional class action tolling permitted in mass tort settings, thereby precluding the running of the Tennessee personal injury statute of limitations during the pendency of any meritless class action in any court in the United States?

Based upon our review, we affirm the orders of the trial court granting the defendants' motions to dismiss the claims of negligence *per se* and motions for summary judgment as to the product liability claims.

I. FACTUAL BACKGROUND

The claims of these plaintiffs are among the several thousand that were filed nationwide against the manufacturers of internal fixation devices. The Danek system, which is the subject of the lawsuit, is described as follows:

> Danek's Texas Scottish Rite Hospital (TSRH) Spinal System device consists of screws, hooks, rods, transverse traction devices, connectors and other components which may be customized, for spinal fusion surgery purposes, on a patient-by-patient basis. The TSRH construct, once surgically inserted, is intended to immobilize the diseased portion of the patient's spine by connecting adjacent spinal vertebrae with steel rods or plates. The rods or plates are anchored to the patient's spine by metal screws which are themselves inserted into the spinal pedicles.

Minisan v. Danek Medical, Inc., 79 F. Supp. 2d 970, 972 (N.D. Ind. 1999) (footnote omitted). In utilizing the TSRH device with pedicle screws, the physicians who implanted them into the plaintiffs were making an "off-label" use of the product, as explained in Bell v. Danek Medical, Inc., No. CIV.A.96-1393, 1999 WL 335612, at *4 n.9 (E.D. La. May 24, 1999):

> "Off-label" is a term used to indicate that a particular medical device being used was not cleared by the FDA for marketing for that use. In the instance of pedicle screws, they have subsequently been approved for marketing for use in certain circumstances. As noted by Judge Lemelle, "[T]he FDA is the agency that clears labels not uses. It is unrefuted [with regard to pedicle screws] that "off-label" use of this product is not illegal and is in fact common place." *McCarthy v. Danek Medical, Inc.*, 1999 WL 262097, *4 (E.D. La. Jan. 5, 1999).

These consolidated cases present claims regarding the design and manufacture by the defendants of spinal system devices utilizing pedicle screws, which were implanted in the plaintiffs, Ann King and Tamara Little. We will consider each claim separately for the purpose of setting out the relevant facts.

A. Ann King

In September, 1992, plaintiff Ann King was diagnosed as having degenerative disc disease and instability of the spine by Dr. Orderia F. Mitchell. He is a graduate of the United States Air Force Academy and of Tulane University Medical School in 1977. Dr. Mitchell's internship was at Wright-Patterson Medical Center, and his orthopedic residency was at Tulane University Medical Center where he was chief resident during his final year. He has been board certified in orthopedic surgery since 1983 and, at the time of his deposition, was chief of orthopedic surgery and chief of orthotics at the United States Air Force Academy Hospital.

When Dr. Mitchell first saw King in 1992, she was having difficulty walking and was complaining of severe pain in her back, buttocks, thighs, and legs. As the result of his examination, Dr. Mitchell determined that she also was suffering from "nerve root compression, [a] slight bulging disk, and osteophyte formations," as well as instability of the spine. Accordingly, in September,

1993, Dr. Mitchell performed surgery on King during which he installed a TSRH spinal system that utilized pedicle screws. As the result of this surgery, King achieved a "solid fusion." Following the surgery, she did well and apparently did not report neck pain again until December, 1994. She went through several physical therapy sessions as a result and, as of January, 1995, was on a walking program. Dr. Mitchell testified that part of King's problems following the surgery resulted from the fact that she was "deconditioned," meaning that her activity level was limited to the "basic things" which she had to do for her daily lifestyle. Dr. Mitchell believed that her surgery was successful and that he had achieved a good result for her.

King testified in her deposition that she was sixty-three years old and had degenerative disc disease, which she did not relate to the allegation of the lawsuit. She said that she had back surgery in 1979 on discs C-4 and C-5 and on disc C-7 in 1987. She had that surgery because she had "spurs which caused tingling in [her] arms," as well as numbness, and had pain in her back or neck. The 1979 surgery resulted in fusion of discs C-5 and C-6, according to King. In 1989, she fell while at Jitney Jungle grocery store, resulting in a "mild concussion," as well as back and neck pain.

She further testified that one of her legs was shorter since the Danek spinal implementation was installed, and she attributes the difference in leg length to that device. She was overweight at the time of the surgery and had gained some weight following the surgery. She had been told by a doctor that her extra weight would put a strain on her back.

The device was removed from King by Dr. Darrel S. Brodke in June, 1997. She had first consulted with him in May, 1996, complaining of low back pain radiating into her left buttock and leg. Dr. Brodke thought that "much of her pain was not pedicle screw – was not originating from the screw." Following the removal of the device, King reported to Dr. Brodke that she was "significantly better." He testified that "[t]here was no evidence in the operating room that the hardware was causing any problems with [King's] nerves." As to whether the internal fixation device had caused certain of King's complaints, Dr. Brodke stated:

> I can't see how the internal fixation, specifically the screws and rods, are directly related to the leg pain or the improvement after their removal. I certainly believe Ms. King that she does have less pain both in her leg and her back. I don't think she's making it up, but I don't have an explanation for it.

In response to whether the device had failed, Dr. Brodke testified:

> There was very slight loosening of one screw in a sacral pedicle, but

> that wasn't significant enough to report it as a hardware failure because she had a solid fusion across that, and certainly none of the screws were loose or broken and the rod was not broken. None of the screws were loose – let me rephrase that. None of the screws were loose at their connection to the rod and the rod was not broken, and there wasn't a screw that was broken.
>
> If a pedicle screw was loose enough to cause a nonunion, I sort of consider that a hardware failure although it's not in the classic sense a hardware failure because it's not the fault of the hardware, more the biology of the patient.

B. Tamara Little

An internal fixation device manufactured by Danek was implanted in plaintiff Tamara Little in August, 1993, utilizing pedicle screws, by Dr. William Capicotto, a board certified orthopedic surgeon since 1988. He was a graduate of the medical school of the State University of New York at Buffalo, where he had also done his residency in orthopedic surgery. From 1986 until 1996, he was an assistant clinical professor in the department of orthopedic surgery at State University of New York Medical School. He was a past president of the Western New York Orthopaedic Society.

He testified that he had first seen Little on April 21, 1993, when she was complaining of severe pain in "her back and her right leg," as well as "mild weakness of the toe and ankle extensors on the right side." She had injured her back lifting a "cart of dishes from a bus tray." He stated that her leg was reddish blue and cold, and that he initially was concerned she had a clot in the leg or a "lymphatic obstruction." After a discogram, myelogram, and a CAT scan had been performed on her, Dr. Capicotto determined that she had a "degenerative and painful disc" at L4-5. According to Dr. Capicotto, Little had been in "severe pain" since October, 1992. He discussed with her the possibility of an operation, and both he and a nurse talked with her about the risks to a successful operation if she continued to smoke. In his testimony, Dr. Capicotto described the surgery that was performed on Little on August 26, 1993:

> Well, I removed the – the painful discs at L4-5 and L5-S1, and then she underwent a spinal fusion from L4 through the sacrum. Took bone graft from the right side of her pelvis, and I put the internal fixation device in, the TSRH internal fixation device from L4 through the sacrum.

He installed the TSRH device because he believed it to be the "best product on the market."

Dr. Capicotto saw Little in his office on October 5, 1993, at which time she told him that her back felt better than it had "in years." Although she had some aggravation in her right leg, straight leg raising did not bother her. She walked with a reciprocal gait and a minimal limp. She was

continuing to do well when seen by Dr. Capicotto on July 13, 1994. However, on October 10, 1994, she complained of "left-sided leg pain," and her husband demanded that she receive narcotic analgesics, to which Dr. Capicotto acquiesced. Dr. Capicotto was concerned that she might be suffering from a "recurrent disc herniation and/or pseudoarthrosis of the lumbar spine." He believed that she had achieved a solid fusion. He testified that on January 3, 1995, Little went to Buffalo General Hospital, where a second myelogram, a discogram, and a CAT scan of her lumbar spine were performed. These showed that she had achieved fusion and there was no postoperative scarring, disc herniations, spinal stenosis, cancer, or infection. The screws and rods were in the right positions, and there was no evidence of pseudoarthrosis.

Dr. Capicotto told Little that he could remove the hardware, because there was a possibility it was causing irritation "even though everything looked okay." That was the last time he saw Little. According to the plaintiffs' brief, the device was removed from Little by a Dr. Menkowitz, who allegedly discovered that "the pedicle screws were loose throughout and most prominently loose on the caudal portions bilaterally." This testimony is referred to as "Exhibit S2," but the document to which it is an exhibit is not identified in the brief. We have been unable to locate an "Exhibit S2" in the voluminous record in this case. In the abridgement prepared by the parties containing deposition excerpts upon which they rely, there is no excerpt from a Dr. Menkowitz, nor does a deposition from him appear to be in the record. Accordingly, we will disregard this representation in the plaintiffs' brief as to the alleged observations of Dr. Menkowitz. Each party must submit a brief which contains "appropriate references to the record." Tenn. R. App. P. 27(a)(6). It is not the responsibility of this court to "search a voluminous record" in an attempt to locate documents and testimony incorrectly cited in a brief. McReynolds v. Cherokee Ins. Co., 815 S.W.2d 208, 211 (Tenn. App.), perm. app. denied (Tenn. 1991).

Tamara Little testified that she was in constant pain from the time of her injury in October, 1992, until the spinal system device was explanted in 1996. She had previously injured her back while working as a waitress, as the result of bending and picking up a tray of dishes. She felt pain in her back and felt like her right leg was going to sleep. She began smoking a pack to a pack and a half of cigarettes in 1979 and had done so continuously since then, except for the period from August, 1993, until November or December, 1993. At the time of her deposition, she was smoking about one pack per day. During the August 1993 – November/December 1993 period, she smoked

about two cigarettes per day.

Little testified that she talked with Dr. Capicotto about spinal fusion surgery and was told that she had a better chance of achieving fusion if she quit smoking. She stated that during the period following her surgery, she had pains in her back from her spine to the hip area. She had pain in both her right and left legs. Just before the explant surgery, she was experiencing a throbbing pain along the right side of her spine. According to Little, the pain lessened after the explant. She testified that she had gone to Louisiana to be examined by Dr. Christopher Cenac and Dr. Richard Levy, and that she spent about a half hour with Dr. Cenac.

II. PROCEEDINGS IN THE TRIAL COURT

The trial court granted the defendants' motion to dismiss the plaintiffs' negligence *per se* claims on November 12, 1997. On October14 (King) and December 18 (Little), 1998, the trial court granted the defendants' motion for summary judgment on the claims alleging violations of the Tennessee Products Liability Act ("TPLA").

King filed a motion to reconsider the court's granting of summary judgment as to her claims, together with a supporting memorandum, to which was attached, or at least referred to, a number of documents that had apparently been produced in discovery by the defendants.[1]

III. ANALYSIS AND DISCUSSION OF LAW

This appeal presents a very unusual procedural situation. As to the plaintiffs' claims of a violation of the TPLA, the trial court determined that there were no genuine issues as to material fact and granted the defendants' motions for summary judgment. However, as to the plaintiffs' claims of negligence *per se* based upon alleged violation of the FDCA, the trial court granted the defendants' motions to dismiss for failure to state a claim upon which relief could be granted. Thus, as to the plaintiffs' TPLA claims, we consider the entire and voluminous record, including depositions and documents, but as to the negligence *per se* claims, we consider only the plaintiffs' pleadings setting out those claims.

A. Tennessee Products Liability Act

In Guiliano v. Cleo, Inc., 995 S.W.2d 88, 94 (Tenn. 1999), our supreme court set out the

[1]We cannot tell with certainty whether these documents were filed with King's memorandum, which was dated November 12, 1998, because the documents themselves bear a stamp of "March 22, 1999," as being the date they were received by the clerk.

standard of appellate review of a trial court's grant of summary judgment on the product liability claims as follows:

> The standards governing an appellate court's review of a motion for summary judgment are well settled. Summary judgment is appropriate only where the moving party demonstrates that there are no genuine issues of material fact and that he or she is entitled to judgment as a matter of law. *Byrd v. Hall*, 847 S.W.2d 208, 210 (Tenn. 1993); Tenn. R. Civ. P. 56.03. We review the summary judgment motion as a question of law in which our inquiry is *de novo* without a presumption of correctness. *Finister v. Humboldt Gen. Hosp., Inc.*, 970 S.W.2d 435, 437 (Tenn. 1998); *Robinson v. Omer*, 952 S.W.2d 423, 426 (Tenn. 1997). We must view the evidence and all reasonable inferences in the light most favorable to the nonmoving party. *Byrd*, 847 S.W.2d at 210-11. If both the facts and conclusions to be drawn therefrom permit a reasonable person to reach only one conclusion, then summary judgment is appropriate. *Robinson*, 952 S.W.2d at 426; *Bain v. Wells*, 936 S.W.2d 618, 622 (Tenn. 1997).

The plaintiffs argue that the trial court should not have granted the motions for summary judgment as to their TPLA claims, because there are genuine issues as to whether the pedicle screw devices implanted into the plaintiffs were in a "defective condition" or "unreasonably dangerous." Tennessee Code Annotated § 29-28-102 defines these two terms as:

> (2) "Defective condition" means a condition of a product that renders it unsafe for normal or anticipatable handling and consumption.
>
> (8) "Unreasonably dangerous" means that a product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller assuming that he knew of its dangerous condition.

Unless the product was in a defective condition or unreasonably dangerous when it left the control of Danek, there is no liability pursuant to Tenn. Code Ann. § 29-28-105(a):

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

In a product liability claim, the fact that a plaintiff is injured is not proof of a defect in the product. Whaley v. Rheem Mfg. Co., 900 S.W.2d 296, 299 (Tenn. App.), perm. app. denied (Tenn. 1995). Likewise, the failure or malfunction of the device, without more, will not make the defendant liable. Harwell v. American Medical Sys., Inc., 803 F. Supp. 1287, 1298 (M.D. Tenn. 1992). A plaintiff must show that there was something wrong with the product, Whaley, 900 S.W.2d at 300,

and trace the plaintiff's injury to the specific defect. Fulton v. Pfizer Hospital Products Group, Inc., 872 S.W.2d 908, 912 (Tenn. App. 1993), perm. app. denied (Tenn. 1994).

As to an internal fixation device utilizing pedicle screws, it does not *ipso facto* mean that a device is defective because a screw becomes loose, Savage v. Danek Medical, Inc., 31 F. Supp. 2d 980, 984 (M.D. Fla. 1999) (pedicle screw which was loose two weeks after being implanted "may have . . . been placed improperly . . . or loosened of its own accord"), or because a screw breaks, Minisan, 79 F. Supp. 2d at 977 ("It is a known fact in the medical community that bone screws may break due to a number of factors unrelated to any defect.").

Additionally, unless there is a showing that the particular defect or dangerous condition proximately caused the plaintiff's injury, the manufacturer is not liable. The inability of plaintiffs in numerous other pedicle screw claims to satisfy the requirement of proximate cause has resulted in summary judgments being granted on behalf of defendants. See Minisan, 79 F. Supp. 2d at 975-76; Danford v. Danek Medical, Inc., Nos. 95-2690, 95-2542, 1999 WL 613409 (W.D. Tenn. Mar. 22, 1999); Harden v. Danek Medical, Inc., 985 S.W.2d 449 (Tenn. App. 1998), perm. app. denied (Tenn. 1999); Jastrebski v. Smith & Nephew Richards, Inc., No. 02A01-9803-CV-00068, 1999 WL 144935 (Tenn. App. Mar. 18, 1999); Jordan v. Sofamor Danek Group, Inc., No. 02A01-9803-CV-00067, 1999 WL 74214 (Tenn. App. Feb. 16, 1999).

In determining whether a product is "unreasonably dangerous," the statute provides for a "consumer expectation" test and a "prudent manufacturer" test. Ray by Holman v. Bic Corp., 925 S.W.2d 527 (Tenn. 1996). The court explained the consumer expectation test:

> By definition, it could be applied only to those products in which "*everyday experience* of the product's users permits a conclusion. . . ." *Soule v. General Motors Corp.*, 8 Cal.4th 548, 34 Ca.Rptr.2d 607, 617, 882 P.2d 298, 308 (1994) (emphasis in original). For example, ordinary consumers would have a basis for expectations about the safety of a can opener or coffee pot, but, perhaps, not about the safety of a fuel-injection engine or an air bag.

925 S.W.2d at 531.

As to the prudent manufacturer test, the court stated:

> In contrast to the consumer expectation test, the prudent manufacturer test is more applicable to those circumstances in which an ordinary consumer would have no reasonable basis for expectations. Accordingly, expert testimony about the prudence of the decision to market would be essential.

Id. The prudent manufacturer test utilizes a "risk-utility balancing of factors" but still requires that

the plaintiff prove that damages were proximately caused by the unreasonably dangerous condition. The Ray court explained:

> Stated more precisely, we hold that the prudent manufacturer test set forth in the Tennessee Products Liability Act requires a risk-utility balancing of factors, including those factors identified as part of the Wade-Keeton prudent manufacturer test. The test under our statute does not include a shifting of the burden of proof to defendant. Rather, the burden remains on plaintiff in a products liability action to establish injury as a result of an unreasonably dangerous product.

Id. at 533 (footnote omitted).

B. Discussion

1. Testimony of Dr. Harold Alexander

To establish that a spinal system utilizing a pedicle screw device was "unsafe for its normal use," the plaintiffs rely upon the testimony of Harold Alexander, Ph.D., who has testified in a number of pedicle screw lawsuits on behalf of plaintiffs. His background was detailed in In Re: Orthopedic Bone Screw Products Liability Litigation, No. MDL 1014, 1997 WL 39583, at *1 (E.D. Penn. Jan. 23, 1997):

> Dr. Alexander holds a bachelor of science degree in aeronautics and astronautics and both a master's degree and Ph.D. in applied mechanics. From October 1986 to April 1996 Dr. Alexander was the Director of the Department of Bioengineering at the Hospital for Joint Diseases Orthopaedic Institute. He currently is a Professor of Orthopaedic Surgery at the New York University School of Medicine, a Grant Professor of Biomedical Engineering at the Department of Mechanical Engineering of the City College of New York, and a Adjunct Professor of Biomedical Engineering at the New Jersey Institute of Technology. Dr. Alexander has written or co-written scores of publications on bioengineering and has received numerous grants on the same.
>
> Dr. Alexander has served as an expert in hundreds of cases on matters involving seat belts, water slides, and breast implants, to name a few, during a period spanning nearly twenty years. In this litigation, Dr. Alexander offers expert testimony on the risks he believes are associated with pedicle screw devices – devices with which he has had very little experience, if any, until this litigation. Dr. Alexander relies primarily on the literature regarding pedicle screw fixation to either formulate or confirm his opinions.

The defendants argue that the plaintiffs cannot oppose the granting of summary judgment by relying on the opinion testimony of Dr. Alexander for purposes of "complication, causation, and FDA testimony," since the trial court had stricken portions of his testimony.

The trial court, in fact, did adopt the order and memorandum of the United States District Court for the Eastern District of Pennsylvania in Orthopedic Bone. Specifically, in this matter, the

trial court adopted the holdings in Orthopedic Bone which allowed the opinion testimony of Dr. Alexander to the extent that it was "within the strict limits of the elements that comprise the field of orthopedic bioengineering (biomechanics, biomaterials, biomedical engineering, and design and analysis of device research)," but excluded any of his opinions which "are governed by or require expertise" other than those previously set out by the court. 1997 WL 39583, at *6.

Dr. Alexander has been offered as a generic expert on behalf of plaintiffs in a number of pedicle screw implant cases. Courts assessing his opinions have found them overbroad, both because they ventured into areas in which he did not have expertise and because they were "generic" opinions rather than specific to the matter being considered by that court. As to the opinions of Dr. Alexander, the court, in Collins v. Danek Medical, Inc., Nos. 95-2829, 95-2542, 1999 WL 644813, at *7 (W.D. Tenn. Mar. 23, 1999) (footnotes omitted), a case with issues identical to those of the instant cases, stated:

> Collins alleges that the Luque device is defective under the theories of defective design, manufacturing defect, and a failure to warn. As proof that the Luque device was in a defective condition or unreasonably dangerous, Collins offers the testimony of Dr. Harold Alexander, Ph.D., an expert in the field of orthopedic bioengineering, and Dr. Andrew J. Kucharchuk, M.D., a board-certified orthopedic surgeon. As to Dr. Alexander, Collins quotes the following language from Dr. Alexander's report as evidence of unreasonably dangerous design or defect: "Unless and until a solid bony fusion is achieved, there will continue to be segmental motion between the vertebrae sought to be fused . . . such mechanical failures threaten injury to the spinal cord, cuada equina and nerve roots which lie in close proximity to the internal fixation device elements." Neither this portion of the report nor any other part of it provides sufficient evidence from which a trier of fact could find a defect or unreasonably dangerous design of the Luque device. Dr. Alexander's report is not fact specific to Collins' case. Dr. Alexander's report generally discusses the risks and benefits associated with pedicle screw fixation instrumentation in spinal fusion surgery compared to non-instrumentation spinal fusion. The report does not discuss Collins' medical condition or history or the Luque device used by Dr. Wood.

In the cases of King and Little, Dr. Alexander has again acted as a "generic expert," his opinions being unspecific as to the devices implanted into these plaintiffs or their precise claims for damages. The record does not reflect that he ever inspected the specific devices implanted into the plaintiffs. His report does not discuss their medical conditions or histories. Thus, we have the same concerns with Dr. Alexander's opinions, as did the court in Collins.

Throughout their brief, the plaintiffs have quoted extensively from the declaration of Dr. Alexander, as well as from his depositions. In view of the trial court's limits on the scope of Dr.

Alexander's opinions and the objections of the defendants to any of his testimony, we must consider to what extent Dr. Alexander's education and experience allow him to assert expert opinions in the areas in which he attempts to do so.

In his memorandum and order in Orthopedic Bone, 1997 WL 39583, at *2, Judge Bechtle observed that, as to a written "declaration" of Dr. Alexander which appears to differ somewhat from the one submitted in this case, "some of the opinions he offers in his report touch upon subjects in respect to which he is not qualified," one example being "clinical complications of pedicle fixation." Additionally, Judge Bechtle concluded:

> Dr. Alexander's background and experience qualify him to testify on matters concerning orthopedic bioengineering and its related disciplines, which in this case generally means how pedicle screws function in the human body and how the human body functionally, but not medically, responds to pedicle screws.

Orthopedic Bone, 1997 WL 39583, at *3.

As examples of statements which "venture outside the realm of his bioengineering expertise," Judge Bechtle cites opinions of Dr. Alexander, *inter alia*, that:

> 1. [T]hese forms of spinal fixation are not proven safe and effective and may pose a substantial risk. . . .
>
> 2. [D]evice manufacturers openly provided their products for pedicle fixation and encouraged orthopaedic surgeons to use them in that way.
>
> 3. [P]edicle screw devices may not be marketed legally in the United States.
>
> 4. Until [internal fixation] devices are adequately tested for pedicular fixation, it must be assumed that they are unreasonably dangerous and should not be in general use outside of controlled, clinical trials.
>
> 5. [P]edicle screw instrumentation remains experimental. . . .
>
> 6. [T]here is no sound scientific basis for the utilization of pedicle screw fixation in spinal fusion.

Id. at *3-4.

In limiting the scope of Dr. Alexander's testimony, Judge Bechtle concluded that "[p]laintiffs cannot 'piggyback' Dr. Alexander's exposure to other non-bioengineering subject areas onto his qualifications as an expert on orthopedic bioengineering and create a 'one-size-fits-all' mass of qualifications warranting his elevation to expert rank in those other areas." Id. at *4.

In this cause, the plaintiffs contend that, in arriving at his conclusions, Dr. Alexander applied

"basic principles of biomechanics, biomaterial and biomechanical engineering." However, the plaintiffs do not address the fact that other courts, when presented with similar opinions, have concluded that they require competency in areas where Dr. Alexander has no expertise. We have similar concerns, for many of his opinions offered in this case seem to be only a rewording of those rejected by other courts. In Edgar v. Danek Medical, Inc., No. 96-2451-CIV-T-24A, 1999 WL 1054864, at *2 (M.D. Fla. Mar. 31, 1999), the court, assessed the evidence, including testimony of Dr. Alexander, that Danek TSRH hardware was defective in either manufacture or design, and concluded that "[p]laintiffs' evidence on this point is indeed threadbare." For similar holdings by other courts, see Menges v. Depuy Motech, Inc., 61 F. Supp. 2d 817 (N.D. Ind. 1999), and Uribe v. Sofamor, S.N.C., No. 8:95CV464, 1999 WL 1129703, at *9-10 (D. Neb. Aug. 16, 1999). We note, as have other courts, that Dr. Alexander's recitation of defects in a generic pedicle screw device fails to show that the same defects existed in the Danek internal fixation devices implanted into King and Little.

2. Plaintiffs' Documents

Further, we find unhelpful to our consideration many of the documents upon which the plaintiffs place substantial reliance. The plaintiffs put these documents in the record without first having them authenticated or explained by a knowledgeable person or by utilizing a request for admissions.[2] However, in their briefs, the plaintiffs make arguments based upon their own interpretation of the meaning and significance of these documents, which, with the plaintiffs' exhibit numbers from the trial court, consist of the following:[3]

9. May 2, 1990, letter from the FDA to James Ritter of Warsaw Orthopedic, Inc. (sent by certified mail – returned receipt requested).

10. August 11, 1993, "Warning Letter" from the FDA to Danek.

11. December 21, 1993, FDA report styled "Update on Pedicle Screws."

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[2]This court reviewed a similar practice in Warmath v. Payne, 3 S.W.3d 487, 489 (Tenn. App.), perm. app. denied (Tenn. 1999), where the *pro se* defendants had inserted into the record certain documents attached as "exhibits" to their motion for summary judgment. Since those documents were "neither self-authenticating nor supported by any evidence, by affidavit or otherwise, purporting to identify or establish the authenticity of the document," they "were improper for consideration as submitted." Id. That analysis and conclusion applies to documents which the plaintiffs inserted into this record by a similar process.

[3]The exhibit numbers missing from this sequence refer to documents such as deposition excerpts which appear to be appropriate for our consideration.

12. June 22, 1993, letter from the FDA to the Buckman Company, regarding the Compact Cotrel-Debousset Spine System.

14. May 1993 report of Michael C. Sherman, Director of Product Development, styled "Top Tightening TSRH Engineering Issues."

15. April 13, 1993, meeting minutes of the Orthopedic Surgical Manufacturers Association.

16. March 12, 1993, draft of Proposed Guidelines for Lumbar Fusion of the Washington State Medical Association Industrial Insurance Advisory Committee.

18. December 7, 1987, letter from the FDA to Norex USA, Inc. regarding the Cotrel-Dubousset Universal Instrumentation for Spinal Surgery.

19. May 6, 1986, letter from the FDA to Warsaw Orthopedic regarding Intrapeduncular Segmental Fixation – The Luque System.

20. August 11, 1993, "Warning Letter" from the FDA to Danek regarding pedicle screws.

22. Advertisements for the DHS Hip Screw System manufactured by Synthes.

23. July 11, 1988, letter from Danek to Dr. John Herring.

25. February 12, 1993, letter from the Department of Neurosurgery at Lackland Air Force Base to Danek.

26. November 12-15, 1993, program brochure for a "State of the Spine from A to Z" seminar in Puerto Rico, sponsored by the Spinal Science Advancement Foundation and the University of Wisconsin at Madison.

27. January 24, 1994, letter from the Practical Anatomy and Surgical Technique Workshop of St. Louis to Danek.

29. March 6, 1991, letter from Danek to the CHMC Office of Medical Education.

30. November 30, 1988, Danek memorandum with attachments regarding the visit to Memphis by Dr. David Bradford.

32, 35, and 36. Personal Services Contracts between Danek and Dr. Eduardo Luque (3 Agreements).

33. March 26, 1991, Listing of holders of Danek stock options.

34. January 15, 1991, Danek Stock Option Agreement.

37. Listing of stock issued to Marina and Eduardo Luque.

38. January 29, 1991, letter from Danek to Dr. Luque.

39. Page 3 of an undated letter, apparently from the FDA to a Dr. Richard Treharne.

40. August 14, 1987, Patent Assignment from Dr. Eduardo Luque to Bio Technology, Inc.

41. April 1, 1992, letter from Danek to the FDA regarding the TSRH Lateral Offset Plate.

42. April 27, 1991, brochure for "Instrumentation in Spine Surgery" program in Louisville, Kentucky.

43. November 16, 1991, brochure for TSRH Spinal Implant Workshop and Course in Orlando, Florida.

44. May 10-14, 1992, brochure for Instrumentation Course at undisclosed location.

46. July 25 (year unknown) outline styled "Application of Dynalok Plate-Screw System to the Degenerative Spine."

47. April 2, 1992, Memorandum with attachments of Smith and Nephew Richards regarding a Simmons Clinicians' meeting.

48. May 13-15, 1993, Post Meeting Summary regarding "Pedicle Fixation of the Lumbar Spine and Other Advanced Techniques" seminar in Orlando, Florida.

51. July 25-26, 1992, brochure for "Specialized Spinal Instrumentation Seminar Applications: Degenerative Lumbar Instability" seminar in Orlando, Florida.

52. Danek vendor detail history report (date unreadable).

53. September 19, 1991, letter with attachment from TBI Press to Danek regarding the TSRH book.

54. January 30, 1992, Memorandum from the Texas Scottish Rite Hospital for Children to a Gary Lowery.

55. 1993 Memorandum, apparently with attachments, from Danek styled "Marketing MBO's for 1993."

56. September 2, 1988, letter with attachments and diagrams from Warsaw Orthopedic to the FDA.

57. April 6, 1989, letter from the FDA to Warsaw Orthopedic.

58. September 12, 1990, letter from Danek to the FDA regarding the TSRH Variable Angle Sacral Screw.

59. January 22, 1992, letter from the FDA to Danek regarding the TSRH Variable Angle Screw.

Because of the substantial reliance of the plaintiffs on these documents, we will set out the

arguments made in the trial court pleadings regarding them, illustrating the procedure whereby they became part of the appellate record.

These documents were referred to and apparently attached as exhibits to King's motion to reconsider the grant of summary judgment to the defendants. The defendants argued in their response to King's motion for reconsideration that the documents should be removed from the record because:

> The documents attached to the Motion to Reconsider were available to Plaintiff for a long time. Plaintiff simply chose not to file them or present them to the Court. Not only are they not timely, these documents should not be presented to the Court of Appeals when they were not presented to or considered by this Court. Plaintiff's attachment included documents regarding Synthes' hip screw, Luque, CD and top tightening TSRH, which are medical devices that were NOT implanted in this Plaintiff. Yet, these documents are attached to Plaintiff's motion. Washington State Board documents are attached, but this Plaintiff's surgery took place in Colorado. Thus, none of these documents are relevant to this Plaintiff's product liability claim.

However, King responded that the records were properly before the trial court and that:

> Danek incorrectly argues that the documents attached to Plaintiff's motion [for reconsideration] were not timely filed and not considered by the Court in this matter. These documents were previously and properly filed into the record in connection with Ann King's response to the first summary judgment motion filed against her in this matter. In response [to] the second summary judgment motion, Plaintiff incorporated by reference the Reply Memoranda to the original Summary Judgment Motions filed and all exhibits attached thereto. (See Plaintiff's Response to Summary Judgment Motion as Exhibit "A"). The documents attached to the motion at bar in the Appendix were complied [sic] into the Appendix for the Court's reference.

In response to the defendants' claims that the documents were hearsay and inadmissible, King replied:

> Plaintiff submits that Defendants seek to have the documents supporting her position stricken from the record not because the documents are hearsay with no testimony to provide any means of evidentiary admission before the Court, but because these documents create genuine issues of material fact which must be presented to a jury to resolve. For the Defendants to object to the admissibility is disingenuous. First, these documents were produced by the Defendants themselves through the course of discovery as evidenced by their own bates stamped numbers labeling the documents. These documents are not coming from a third party or an unknown source. They are the Defendants['] own corporate documents. Moreover, they are not being introduced at trial where some evidentiary connection needs to be established. Finally, Defendants never objected to the admissibility of these documents when the documents were initially filed into the record and Plaintiff submits that any objection they could have made has been waived.

King was correct in arguing to the trial court that documents which are not properly authenticated can become part of the record if the party objecting to the documents fails to make a timely objection to such records simply being attached to a pleading, or referred to in it, as seems to be the case here. Although the general rule is that, in a ruling on a summary judgment motion, the court should refuse to consider unauthenticated documents, 10B Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2738, at n.13 (3d ed. 1998), a failure to timely object to the use of such documents can constitute a waiver of the objection. Ahwinona v. State, 922 P.2d 884, 886 n.1 (Alaska 1996). However, since the defendants did not present as an issue on appeal whether the documents should be stricken, we will not attempt to determine whether such a waiver occurred.

The fact-finding process is thwarted when a litigant intentionally bypasses the appropriate procedures for authenticating and testing documents. Simply because King was successful in inserting these documents into the record in a fashion that left them untested by the adversary process does not mean that we must accept the arguments of her counsel as to their meaning and significance. King presents no explanation or authorities as to why this court should accept her counsel's interpretation of these documents, all of which appear to be technical and of debatable meaning and relevance. For example, Exhibit 14 consists of a memorandum regarding a TSRH top tightening screw device, which the plaintiffs insist demonstrates the screw breakage problem of the devices implanted into the plaintiffs. However, the defendants contend that top tightening devices described in the memorandum were not those implanted into the plaintiffs. Because of the method by which this document reached the court, we cannot determine which party is correct. Counsel cannot insert documents of this type into the record in such a fashion and then supply their own interpretations to the documents to create a genuine issue as to a material fact.

These documents, which the plaintiffs cite as "bullet points" throughout their briefs, taken even at face value, in no way identify a specific defect or dangerous condition in the devices implanted into King or Little, nor do they establish that the injuries alleged by the plaintiffs were proximately caused by a defect or dangerous condition in the implanted devices.

C. Defective Condition

We will first consider the plaintiffs' claims that the TSRH devices were defective.

Dr. William Capicotto, who implanted the device into Little, testified that he had implanted

over one thousand internal fixation devices. He doubted that he had looked at the package inserts for the TSRH spinal system: "I highly doubt I ever read that. It's a pedicle screw system. It's very straightforward. Very simple. There is [sic] bony landmarks that you use to put the instrumentation in." Dr. Capicotto believed that he had adequate knowledge regarding the TSRH system, which he had obtained "between going to courses and going to – being in fellowship and residency, and taking time from my practice to learn about using these instruments." He described internal fixation devices as being used "globally" and as "one of the standard accepted methods of internally fixing a spine to attain a solid spine fusion and help your patients." He said that he had training "[w]ithout fixation and with fixation." He uses internal fixation devices because:

> There's no comparison. The patients are out of bed quicker, they get home quicker, their pain relief is better, their rehabilitation is shorter. So I think that the risks and benefits, the risks – the risks and benefits of using an internal fixation device far outweigh not using an internal fixation device. Most operative bracing is much – similarly, the reoperation rate is lower. I – as I said, I don't – I don't think there's a question of whether or not it should be used. I think I – my bias is that it works.

He did not specifically recall when he learned that the FDA had not approved the use of pedicle screws. He testified that if a patient continued to smoke cigarettes after the surgery, it had a negative impact on fusion rates and that Little continued to smoke, even though he advised her not to.

As to Ann King, Dr. Orderia Mitchell testified that the internal fixation devices were the standard of care nationally and had been for a long time. He had used such devices since 1986 and believed them to be safe and effective. He testified that he used internal fixation devices from three manufacturers, one of which was Danek. He stated that his use of pedicle screw internal fixation devices was "off-label" as far as the FDA was concerned, but the FDA did not regulate the practice of medicine. He did not know until early 1994 that pedicle screws were not FDA approved. Regarding patients continuing to have pain after implantation, he stated:

> There are a lot of reasons a person can still have pain. Probably the first thing you tell a patient when you see them is that the procedures you do probably won't take away the majority of their pain. If they have multiple level problems, then there's a good chance that they will still have some pain. How much, a lot of the times, you can't tell them.
>
> And you also inform them that it's possible, either they have a fusion, the levels above that fusion may fail and be a source of potential problem or pain in the future.

Dr. Mitchell said that King had degenerative disc disease, degenerative joint disease, arthritis and spondylosis. In view of King's medical history and his diagnosis, Dr. Mitchell decided to install an internal fixation device, which achieved a solid fusion. He testified that he had recommended that she participate in physical therapy programs, but she had not done so on several occasions. As to King's continuing problems following the surgery, Dr. Mitchell held the opinion that:

> Yes. Yes, sir. I think that part of her problem is due to the fact that she has deconditioned muscles. And then part of the problem is the fact that she has an underlying disease process of the – arthritis and degeneration of her spine, which has occurred over time.

To demonstrate that a genuine issue exists as to whether the devices were defective, the plaintiffs set out testimony of Dr. Alexander which, according to the plaintiffs, "clearly establishes that the spinal implant device is **unsafe** for its normal use" (emphasis in original).[4] He stated that:

> [1] There is no scientifically valid evidence that pedicle screw internal spinal fixation instrumentation is either effective or safe as an adjunct to spinal fusion.
>
> [2] In my opinion pedicle screw internal fixation instrumentation has not been demonstrated or proven to be effective or safe, and it poses a significant and substantial risk of harm to patients.
>
> [3] In consideration of the fact that pedicle screw internal spinal fixation instrumentation has never been adequately tested and the patient risk vs. medical benefit ratio has never been properly evaluated, much less established, the uncontrolled marketing, promotion, and sale by the spinal implant manufacturers and the unrestrained clinical use by spine surgeons of such instrumentation has been reckless and irresponsible.
>
> [4] The complication rate of spinal fusion procedures employing pedicle screw instrumentation is significantly higher than the rate in procedures that do not utilize instrumentation, as well as procedures that use other, less invasive methods of internal spinal fixation such as laminar hooks and wires.
>
> [5] Pedicle screw internal spinal fixation instrumentation present a number of unique risks which make them potentially dangerous.
>
> [6] It is my further opinion that any theoretical medical advantage or benefit of pedicle screw internal spinal

[4]These excerpts are from the "Declaration of Harold Alexander, Ph.D., Regarding Pedicle Screw Internal Spinal Fixation Instrumentation," dated May 30, 1997.

> instrumentation is outweighed by the known and or recognizable hazards, risks, and dangers associated with it.

In their brief, the plaintiffs then summarize these excerpts from the testimony of Dr. Alexander by concluding:

> Appellants' expert states that the spinal implant device is unsafe for the foreseeable and anticipatable use of the product, i.e. insertion into the vertebral pedicles. Accordingly, Appellants' has [sic] demonstrated that there is a question of fact as to whether the TSRH spinal implant manufactured by Danek was defective under the TPLA.

The plaintiffs present Dr. Alexander's opinions without consideration as to what extent they venture outside the area of his expertise. In fact, it appears that of these six opinions of Dr. Alexander, which the plaintiffs cite as "bullet points" in support of their contention that "the spinal implant device is unsafe for normal use," all either venture substantially outside of biomechanics or require at least certain medical expertise. For instance, Dr. Alexander's opinion set out as the first "bullet point" of the plaintiffs is that "[t]here is no scientifically valid evidence that pedicle screw internal spinal fixation instrumentation is either effective or safe as an adjunct to spinal fusion." This appears to be even a broader statement than that disallowed by Judge Bechtle in Orthopedic Bone that "these forms of spinal fixation are not proven safe and effective and may pose a substantial risk." Certainly a substantial degree of medical expertise is required before such an opinion can be admissible. The other five opinions cited also require medical expertise which Dr. Alexander does not possess. However, the plaintiffs did not attempt to explain why we should accept a repackaging of Dr. Alexander's opinions which other courts have concluded were overbroad or inadmissible.

Thus, the plaintiffs, having failed to demonstrate why Dr. Alexander is qualified to give expert opinions which clearly require medical expertise that he does not possess, we conclude that his opinions, set out as bullet points, are not admissible pursuant to Tennessee Rules of Evidence 702. Even if we did accept the opinions of Dr. Alexander, they would be inadequate as a matter of law to demonstrate that there exist any genuine issues as to material facts as to whether the Danek systems implanted into King and Little were defective. Generalized testimony regarding theoretical defects in a generic pedicle screw device cannot compensate for the plaintiffs' inability to identify specific defects in the systems actually implanted into them. We agree with the conclusions in Menges v. Depuy Motech, Inc., 61 F. Supp. 2d 817 (N.D. Ind. 1999), wherein the court determined

that opinions of Dr. Alexander, nearly identical to those in this case, were insufficient to establish any genuine issues of fact as to whether a pedicle screw device manufactured by Depuy Motech was defective.

Thus, there being no genuine issue that the spinal system devices, manufactured by the defendants and implanted into the plaintiffs, were defective, summary judgment was properly granted as to this claim.

D. Unreasonably Dangerous

Additionally, the plaintiffs argue that a factual dispute exists as to whether the defendants' spinal system devices were "unreasonably dangerous," pursuant to Tenn. Code Ann. § 29-28-102(8), and urge that under both the "consumer expectation" test and the "prudent manufacturer" test, there exist material factual issues which preclude the granting of the defendants' motions for summary judgment. Citing the decision in Ray by Holman v. Bic Corp., 925 S.W.2d 527 (Tenn. 1996), the plaintiffs claim apparently that pursuant to either the consumer expectation or prudent manufacturer test, the defendants' devices were unreasonably dangerous. They argue that the plaintiffs themselves, rather than the implanting physicians, were the "consumers." Further, the plaintiffs contend that if the court had engaged in a risk-utility balancing of factors, it would have determined that genuine issues of fact exist as to whether the defendants were "prudent" manufacturers.

In support of their claim that the Danek devices implanted into them were unreasonably dangerous, the plaintiffs again cite the opinions of Dr. Alexander, as set out in his declaration and depositions. Once again, his opinions criticize generic devices rather than those implanted into the plaintiffs.

In making their arguments as to this point, the plaintiffs have not presented proof of a dangerous condition other than the generic opinions. Without any proof as to dangerous conditions of the specific devices implanted into King and Little, neither the consumer expectation nor the prudent manufacturer test can be applied.

The testimony of Dr. Alexander is unlike that of a plaintiff's expert witness in cases which they cite. In Rutherford v. Polar Tank Trailer, Inc., 978 S.W.2d 102, 104 (Tenn. App.), perm. app. denied (Tenn. 1998), the court concluded that material factual issues precluding summary judgment were raised by the affidavit of the plaintiff's expert, stating "that the flow valve on the tanker was

unreasonably dangerous and did not contain bleed vents downstream of the ball cock." In contrast to the generic testimony of Dr. Alexander, the plaintiff in Rutherford presented sufficient proof to raise a factual issue as to an unreasonably dangerous condition. In Ross v. Sofamor, S.N.C., No. 95-2542, 1999 WL 613357, at *8 n.14 (W.D. Tenn. March 10, 1999), the plaintiff also argued that the spinal systems utilizing pedicle screws were unreasonably dangerous under either the consumer expectation or prudent manufacturer test. However, the plaintiff in Ross, as have these plaintiffs, failed to present sufficient evidence allowing either test to be applied:

> Ross did not offer any further evidence to establish that the CD system was unreasonably dangerous under either the consumer expectation test or the prudent manufacturer test. See *Ray by Holman v. Bic Corp.*, 925 S.W.2d 527, 531 (Tenn. 1996) (noting that a plaintiff may use either test). Although the consumer expectation test may not apply to the instant case because an ordinary purchaser would not have the medical knowledge or a basis of expectations about the safety of the CD system, even if Dr. Pinto [the implanting physician] is considered to be the consumer of the CD system, Ross offered no evidence that the CD system did not meet his reasonable expectations. Under the alternative prudent manufacturer test, the court balances a number of risk-utility factors, including those identified under the Wade-Keeton prudent manufacturer test. See *Id.* at 533. Ross, however, did not provide any evidence of a dangerous condition or other factors under the test.

1. Testimony of Dr. Alexander

Dr. Alexander opines as to the five main risks in which, according to him, a spinal fixation device utilizing pedicle screws is unreasonably dangerous:

a. Screw Placement Problems

In response to counsel's question as to Dr. Alexander's concerns with placing a screw into the pedicle, Dr. Alexander responded:

> Well, because there are other issues involving in placing – placing screws so close to nervous tissue even if it isn't in contact. There is inflammatory response that is ongoing and then there is also the concern about eventual cut-out at a future date and impingement upon nervous tissue. In general I don't consider a priori that a screw in the pedicle is ever safe. It may be but it hasn't been proven to be safe.

Here, Dr. Alexander is testifying only as to a generic spinal fixation device, and not as to either of the specific devices installed into these plaintiffs or complications which they allegedly had as a result. Assuming, arguendo, that Dr. Alexander is competent to testify that placing a screw into the pedicle is never safe, his equivocal testimony does not advance the plaintiffs' claims for he admits that such procedures "may be [safe]." Apparently, Dr. Alexander believes that placing a

screw in the pedicle is unsafe because it has not been proven to him to be safe. However, summary judgment cannot be defeated by such reasoning. In Theriot v. Danek Medical, Inc., 168 F.3d 253 (5th Cir. 1999), the plaintiff also argued that Danek could not have informed the implanting surgeon of the risks because it had not properly tested the device:

> Theriot argues that because Danek did not adequately test the product, Danek could not properly inform Dr. Billings of the risks and, since Dr. Billings cannot have been properly informed, his belief that he was is irrelevant.
>
> In essence, Theriot is arguing that he should be permitted to proceed to trial if Danek cannot demonstrate that it adequately tested its product. There is no basis in the LPLA [Louisiana Products Liability Act] or case law for such a rule and we therefore conclude that the district court did not err in granting summary judgment.

168 F.3d at 256.

The theoretical possibility of injuries being caused by screw placement problems with a generic device attached by pedicle screws does not establish a genuine issue of material fact sufficient to defeat summary judgment.

b. Mechanical Device Failures

Dr. Alexander states that a second risk of pedicle screw devices is that there can be mechanical failure, such as screw pullout. However, there is no evidence of such failure in either King or Little. Assuming that Dr. Alexander is qualified to testify whether such devices in general are subject to mechanical failure, the possibility of such a failure does not create a genuine issue so as to preclude summary judgment.

c. Inflammatory Response

In their brief, the plaintiffs set out a portion of Dr. Alexander's testimony regarding material "sloughing" from an implanted generic pedicle screw device, which, he says, can cause inflammation and mechanical damage, acting "almost like a knife" to the tissue. The plaintiffs argue that this excerpt supports their claim that pedicle screw devices are "unreasonably dangerous." However, they have presented no evidence that "sloughing" occurred following the devices' being installed in either King or Little. Further weakening the plaintiffs' argument in this regard, Dr. Alexander also testified in his deposition, following the portion quoted by the plaintiffs:

> Q. Can you cite to any study which documents the damage as a result of sloughing and correlates it with any clinical problems?

A. No.

Q. So you can't cite to any study in the literature which correlates sloughing with inflammation. Is that correct?

A. Not sitting here today. I could search the literature and maybe find a reference to that but sloughing is a – you know, a term that you brought up, not a term that I brought up, and I'm not sure that that term would be used necessarily in the context of looking at the effect of inflammation.

Since "sloughing" appears to be a theoretical rather than an actual complication of at least some pedicle screw devices, and there is no proof that it occurred as to King or Little, the possibility of a "sloughing off" from a generic pedicle screw device cannot create a genuine issue as to a material fact.

d. Osteoporosis

According to the plaintiffs, Dr. Alexander's testimony showed that "pedicle fixation could also cause osteoporosis, a diminution in bone density which occurs through the well-known biomechanical process known as stress shielding." However, what Dr. Alexander appeared to state in this regard was that he had not "had the opportunity to [document osteoporic changes] but it is reported in the literature." Additionally, he did not attempt to testify that either King or Little developed osteoporosis as the result of their implants. In fact, as to the products of these defendants, Dr. Alexander stated:

Q. And you're not here to render an opinion that any of the systems manufactured by Smith and Nephew or Sofamor Danek have caused osteoporosis. Is that correct?

A. That's correct.

The theoretical possibility that some pedicle screw devices of other manufacturers can cause various bone problems, without proof that it occurred to these plaintiffs because of the products of these defendants, cannot defeat summary judgment.

e. Increased Risks

Citing several published articles, Dr. Alexander stated in his declaration that "[t]he complication rate of spinal fusion procedures employing pedicle screw instrumentation is significantly higher than the rate in procedures that do not utilize instrumentation, as well as procedures that use other, less invasive methods of internal spinal fixation such as laminar hooks and wires." Additionally, according to his declaration, "application of pedicle screw instrumentation

prolongs the operative procedure and increases the amount of total blood loss and the overall infection rate." Dr. Alexander was asked in his deposition about these statements:

> Q. Have you ever talked to a doctor about the opinions contained in that sentence, the prolonged operative procedure, increased amount of total blood loss and overall infection rate?
>
> A. Specifically debating those issues? No, I don't think so but I've seen evidence of the length of operative procedures and the amount of blood loss in some of the cases I saw presented at Joint Diseases that gave me some of those numbers.
>
> Q. But you can't cite any of them today. Is that correct?
>
> A. No.
>
> . . . .
>
> Q. Doctor, wouldn't you agree that issues with respect to how long the operative procedure takes, the amount of blood loss and the overall infection rate are really issues best addressed by a physician?
>
> A. Yes. I wouldn't – I wouldn't argue with that. I would think that a surgeon who has significant experience in those issues would be in a better position to address that than I might.
>
> Q. This really isn't your field, operative procedures, blood loss and infection rate, correct?
>
> A. That's correct.

Regarding his direct knowledge of pedicle screw fixation surgery, Dr. Alexander testified:

> Q. All right. Well, let's just stay with your general experience for a moment. Let's take the first sentence [from the declaration]. "The natural tamponade effect of the posterior paraspinal muscles against the decorticated posterior elements and bone graft is lost by interposing a large bulky pedicle screw device between the paraspinal musculature and the fusion site."
>
> What experience have you had where you've had opportunities to observe this take place?
>
> A. Well, I haven't – I haven't directly observed pedicle screw fixation surgery. I have observed videos of pedicle screw fixation surgery, I have observed spinal surgery involving Harrington rod fixation devices and I've participated in spinal surgery done on animals so I'm familiar with this anatomy and familiar with the interposing of a device in that anatomy.
>
> Q. What animals have you participated in spinal surgery on or observed spinal surgery – did you say you participated?

I didn't–

A. Participated. Dogs.

Q. Dogs. And is the anatomy of dogs similar to the anatomy of humans?

A. Well, it's not identical but it's similar, yes. Similar in the placement of the muscles and the placement – position of the muscles versus the vertebrae. The vertebrae are not necessarily similar.

Q. And there are significant differences between a dog's spine and a human's. Is that correct?

A. The spine itself, the vertebrae? Yes.

Q. Have you ever discussed the concepts that you've laid out in the paragraph we're discussing which is the first full paragraph on Page 10 with any physicians?

A. You mean surgeons rather than physicians I assume –

Q. I'll take any physicians.

A. Anyone with an M.D. Degree. I don't think specifically, no, no. I mean, I don't think these issues again – I don't think I've debated these issues with an individual physician.

Q. So let me understand what you're relying on to substantiate these opinions. It's your participation in implanting spinal systems into the spines of dogs –

A. Yes.

The plaintiffs assert that Dr. Alexander testified "regarding various papers on pedicle fixation systems that report on infection rates associated with pedicle fixation devices and notes that infections have been reported with the use of almost every device." However, Dr. Alexander further testified that not all devices have a higher infection rate. When asked to describe the medical literature on infection rates, Dr. Alexander answered:

Q. And describe that literature [regarding infection rates] for us.

A. As I indicated to you there are papers on virtually every single system that report infection rates. Some of those infection rates reported are not increased above those that one might expect from other methods of spinal fixation, for example and other papers do report an increased infection rate.

During one of his depositions, Dr. Alexander was asked specifically about infection rates of Danek devices:

> Q. Can you recall any articles that discuss increased rates of infection with respect to any Sofamor Danek system?
>
> A. No, I cannot.
>
> Q. Infection associated with pedicle screw instrumentation is really outside of your area. Isn't that correct, Dr. Alexander?
>
> A. Well, any – any response to an orthopedic device is not really outside of my area but – but I'm – but I'm not an expert in infection.

The fact that spinal systems of other manufacturers may have infection rates is irrelevant to the claims of these plaintiffs and cannot be utilized to defeat summary judgment.

Further, the plaintiffs assert that Dr. Alexander "testified that there already exists an alternative, safer design for spinal fixation devices that do not use pedicle screws." However, this appears to be an inaccurate characterization of Dr. Alexander's testimony, which follows:

> Q. My question is, can you identify an alternative design for a pedicle screw system? Any kind: Sofamor Danek, Smith and Nephew, Willsi, any kind?
>
> A. There are alternative design fixation devices that don't use pedicle screws. They predate the pedicle screws. They were used before the pedicle screw systems.
>
> In certain indications, they were not found to be effective or usable. But these pedicle screw devices have certain potential advantages and have risks associated with them, and they have not been appropriately tested to determine whether the benefits outweigh the risks, is the essence of what I have determined through this multiple-year odyssey that you pointed out that I've been on here. But yes, I have not proposed an alternative pedicle screw device, to answer your question.

Dr. Alexander did not propose an alternative design for a spinal fixation device utilizing pedicle screws. Instead, he recognized the existence of alternative spinal fixation devices which do not utilize pedicle screws but acknowledged that such devices were not always "effective or usable." In cases involving claims similar to those of King and Little, such dissimilar devices described by Dr. Alexander have been determined not to be alternative designs:

> Theriot claims that the product at issue here is a product whose purpose is to provide biomechanical stability. Theriot therefore argues that other products that do not use pedicle screws should be considered as alternative designs, such as external neck braces or internal systems that use hooks or wires. Underlying this argument is the assumption that all pedicle screws are defective and there can be no system using pedicle screws that would be an acceptable product. The problem with this argument is that it really takes issue

> with the choice of treatment made by Theriot's physician, not with a specific fault of the pedicle screw sold by Danek.

Theriot, 168 F.3d at 255.

The testimony of Dr. Alexander does not establish the existence of any genuine issues of material fact as to whether the defendants' devices were unreasonably dangerous.

2. Testimony of Drs. Cenac and Levy

Additionally, the plaintiffs presented testimony from two medical causation experts, Dr. Christopher Cenac and Dr. Richard Levy. Dr. Levy testified that he had incomplete records as to King. None of his records addressed her neurological state prior to the implantation surgery on September 17, 1993. In his examination of King, he found that she had a depression of the left ankle reflex. However, since he did not have complete records, he could not say that this condition predated the implant. He also determined that she had a "reduction in feeling in the left L-5 dermatome" that he felt was caused in part by the implant. However, Dr. Levy could not state "more probably than not that it [was] a direct result of the metallic implant," although he considered the implant among the causes. He did not have an opinion about the origin of her "tingling" sensation and doubted that she had arachnoiditis. He observed that her legs were of different length but did not state that the implant caused this. Thus, he did not testify as to a defect or dangerous condition in the device implanted into King.

Also, in opposition to the granting of summary judgment, the plaintiffs rely upon the testimony of their expert, Dr. Christopher Cenac, a board certified orthopedic surgeon of Houma, Louisiana, who reviewed the medical records of King and met with her for approximately thirty minutes, according to her testimony. The deposition of Dr. Cenac tells little of his qualifications. However, as to Dr. Cenac, this court determined in a previous case involving spinal implant litigation:

> Dr. Cenac's previous testimony in a pretrial deposition established that he is not an expert with respect to implants, including spinal implants, nor is he an expert in the area of design and manufacture of implants of any kind.

Jordan v. Sofamor Danek Group, Inc., No. 02A01-9803-CV-00067, 1999 WL 74214, at *3 (Tenn. App. Feb. 16, 1999).

The plaintiffs do not cite any testimony from Dr. Cenac showing any of the potential complications from the use of pedicle screw devices, discussed by Dr. Alexander, occurred as to

either of these plaintiffs. Dr. Cenac does not attempt to testify that the Danek devices implanted into the plaintiffs were dangerous or in a defective condition or that either plaintiff sustained damages as the result of the device. As to King, he testified that "she may or may not have arachnoiditis associated with the September '93 procedure;" that "she has acceleration of the degenerative process above the level of the instrumentation"; and that "there is some mention . . . in the medical records of loosening of the sacral screws, which I could not myself observe, but it is possible, and this movement may be the cause of her pain; and her bone graft appears to be minimal if any, and that may be due to the rigidity of the device relative to resorption." Additionally, he testified that King had "degenerative changes above the fusion," but it was "not a bad thing."

As to Little, Dr. Cenac wrote in a letter dated May 7, 1997, (referred to in the record as the "Cenac Report") to Thom E. Smith, a lawyer in Metairie, Louisiana:

> This patient exhibits residual from the use of pedicle fixation devices. The patient had loosening of the device and failure. Delayed union was observed at the time of the second operative procedure. The lumbar muscle mass is fibrotic. Neurological deficits are recorded in both lower extremities. All of the above can be associated with the use of the pedicle fixation device and failure of such device.

Neither this opinion nor the excerpts referred to by the plaintiffs from Dr. Cenac's depositions identify a specific defect or dangerous condition in the device implanted into Little so as to create a legitimate issue under the TPLA.

Even assuming that Dr. Cenac's statement that the conditions he observed in Little were "associated with the use of the pedicle fixation device and failure of such device," this conclusory opinion is insufficient to establish a defect or dangerous condition. Valente v. Sofamor, S.N.C., 48 F. Supp. 2d 862, 869 (E.D. Wis. 1999). Also, Dr. Cenac's testimony is deficient because it fails to rule out other causes of Little's pain. Driggers v. Sofamor, S.N.C., 44 F. Supp. 2d 760, 765 (M.D. N.C. 1998).

Thus, the testimony of Drs. Levy and Cenac failed to establish a genuine issue as to a defective condition of the Danek instrumentation implanted into the plaintiffs or causation between their injuries and the defendants' products.

3. Plaintiffs' Additional Proof as to Dangerous Condition

In the plaintiffs' brief, certain statements are attributed to Dr. Mitchell, who implanted the device into the plaintiff, Ann King. However, the attributed statements are the plaintiffs'

interpretations, rather than the actual deposition testimony of Dr. Mitchell. Based upon our review of the deposition excerpts from Dr. Mitchell, it is clear that the plaintiffs did not accurately summarize his testimony. For instance, without quoting the actual testimony, the plaintiffs characterize the following questions and answers as showing that "Dr. Mitchell admitted that he had no idea whether pedicle screw devices provide a better fusion rate versus noninstrumented surgeries." Actually, in this regard, Dr. Mitchell testified:

> Q. All right. In the cases where you believe internal fixation devices are warranted, do you think you get a better result percentage-wise using the internal fixation devices and obtaining a fusion versus noninstrumented surgery?
>
> A. Yes, sir.
>
> Q. All right. Have you made any study, or could you have any -- do you have any percentage numbers to tell the ladies and gentlemen of the jury, or is that just based on your opinion and your clinical practice?
>
> A. That's based on my observation.

It is not accurate for this exchange to be described as Dr. Mitchell's admitting he has no idea about the respective fusion rates. In fact, he knew that he achieved a better fusion rate with internal fixation devices.

Additionally, the plaintiffs assert in their brief, without setting out the actual testimony, that Dr. Mitchell "testified that he was only aware of clinical trials ongoing at the time of his deposition in late 1997 and not at the time of Appellant's surgery." Again, the plaintiffs have not accurately summarized the testimony of Dr. Mitchell. Actually, he testified that, considering both the past and future studies, he could not state which ones were dispositive:

> Q. Okay. Now, are you aware of any clinical studies or trials done to determine whether pedicle screw systems are reasonably effective for general clinical use?
>
> A. Well, they're -- I guess there are ongoing studies right now, because of the discussion we're having right now, that several of the universities, the training universities are doing, to determine that now.
>
> So compiling both retro -- prospective and retro studies. So, so, so, so do I know any -- which the definitive studies are? No, I can't give you what they are. But I know there are several of the major universities that are doing this, and Tulane University is one of those that is involved in the studies.

In their brief, the plaintiffs assert that "Dr. Mitchell also testified that he didn't recall whether

Danek provided information on the percentage of hardware failure for Danek's devices." That statement does not accurately describe the testimony of Dr. Mitchell in this regard. Although Danek may not have advised Dr. Mitchell of the percentage of failure, he testified that he thought he was told by Danek that failures occurred:

> Q. Well, in that information [booklets and literature from Danek] that you have, does it -- does it list any information concerning hardware failure in TSRH systems or other Danek-produced pedicle screw systems?
>
> A. Right now, I can't recall, but I think there was information on the fact that the screws can break and that the hard -- that the metal rods, also, can break.

There are instances in which the plaintiffs cite documents which cannot be used to support their claims. For instance, in their reply brief, the plaintiffs make the statement that "Danek knew that screw breakage was the most common form of failure in the TSRH system after conducting biomechanical testing of fatigue analysis, yet failed to adequately warn of the frequency of this risk occurrence." In support of this claim, the plaintiffs do not cite any testimony, but refer to an approximately twenty-page document (Exhibit 14 to King's motion to reconsider), "Top Tightening TSRH Engineering Issues," which bears the date May, 1993, and is authored by a Michael C. Sherman, "Director of Product Development." This document was Exhibit 14 to King's motion to reconsider, filed after the trial court had already granted the defendants' motion for summary judgment as to her product liability claim. The document does not show whether Sherman had any relationship with the defendants. The "Overview" section of this document refers to a "current TSRH system" and a new "Top Tightening T-Bolt TSRH system." One of the observations of the report is that "screw breakage was the primary mode of failure." It is unclear how this document relates, if at all, to the claims of these plaintiffs or whether either the "current TSRH" or "Top Tightening T-Bolt TSRH System" is that which was installed into either plaintiff. The plaintiffs' use of this report illustrates the problems caused by their inserting unauthenticated and unexplained documents into the record. This report may be a Danek document referring to the precise systems installed into the plaintiffs, as they argue, or, as the defendants claim, the systems referred to in the document may be different from those implanted into the plaintiffs. This document is unexplained by an appropriate witness or pleading, and the plaintiffs simply cannot provide their own interpretation of its meaning and relevance.

The plaintiffs have referred to similar unauthenticated and unexplained documents which they inserted into the record, arguing that these records show, in one way or another, that Danek failed to adequately warn physicians of "FDA admonishments" that the devices were not "FDA approved for posterior lumbar fixation" and that Danek nullified attempts to warn by their "overpromotion." These documents fail to demonstrate any relationship between the activities alleged and the decisions of the implanting physicians to install the Danek instrumentation into the plaintiffs.

Having carefully reviewed the authorities and evidence cited by the plaintiffs to demonstrate that there exist genuine issues of material fact as to whether the Danek devices were unreasonably dangerous, we conclude that they have failed to demonstrate that there exists any genuine issue of material fact in this regard. Accordingly, the defendants were entitled to summary judgment as to the plaintiffs' claims that the defendants' spinal systems were unreasonably dangerous.

E. Learned Intermediary Doctrine

In granting the defendants' motion for summary judgment, as to plaintiffs' TPLA claims, the trial court applied the learned intermediary doctrine, which is explained in Harden, 985 S.W.2d at 451:

> Under this doctrine, manufacturers of certain medical products "may reasonably rely on intermediaries to transmit their warnings and instructions." Pittman v. Upjohn Co., 890 S.W.2d 425, 429 (Tenn. 1994). This defense is based upon the pivotal role that physicians play in the distribution of prescription products. Id. Physicians can be learned intermediaries only when they receive adequate warnings. Id. Thus, manufacturers are not shielded from liability if they provide inadequate warnings to physicians. Id.
>
> In order to recover for failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) that the defendant failed to warn the physician of a risk associated with the use of the product not otherwise known to the physician; and (2) that the failure to warn the physician was both a cause in fact and proximate cause of the plaintiff's injury. 63A Am.Jur.2d *Products Liability* § 1200 (1984).

The treating physician in Harden had submitted an affidavit setting out his familiarity with the Danek product:

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

> plaintiff's injury under this doctrine. While the "independent knowledge" defense is not universally accepted, we follow the majority view among the courts that have decided this issue, which is consistent with Tennessee case law.

Id. at 452 (citations omitted).

However, the plaintiffs argue that Harden should be distinguished because of three main factual disputes, which, they contend, preclude the granting of summary judgment:

A. Whether the pedicle screw devices were in a defective condition;

B. Whether the pedicle screw devices were unreasonably dangerous;

C. Whether Danek failed to warn of the risks associated with the use of the devices, thereby rendering them "unreasonably dangerous."

As to the application of the learned intermediary defense to the plaintiffs' claims pursuant to the TPLA, they argue that it can be applied only as to their claim that the defendants failed to warn the implant physicians of the alleged unreasonably dangerous condition of the Danek instrumentation. However, the adequacy of the manufacturer's warning language has been determined to be a consideration both as to whether a product is defective or unreasonably dangerous. Cansler v. Grove Mfg. Co., 826 F.2d 1507, 1510-11 (6th Cir. 1987) (citing Young v. Reliance Elec. Co., 584 S.W.2d 663, 668-69 (Tenn. App. 1979). The court in Harden v. Danek Medical, Inc. applied the learned intermediary doctrine and noted what the plaintiff must demonstrate to establish a claim of failure to warn:

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

985 S.W.2d at 451.

King and Little, as did the plaintiff in Harden, have failed to establish that the defendants' alleged failure to warn was the proximate cause of their injuries. Both of the plaintiffs' implanting physicians were well experienced in the use of internal fixation devices utilizing pedicle screws. Both testified that they relied upon their own knowledge and judgment in deciding to implant the devices into the plaintiffs. The plaintiffs have not shown that these decisions were influenced by any representation which the defendants made or failed to make. Thus, the plaintiffs' claims in this regard fail because they have failed to establish that, had additional warnings been given, the

plaintiffs would not have sustained their injuries. Collins v. Danek Medical, Inc., Nos. 95-2829, 95-2542, 1999 WL 644813, at *9 (W.D. Tenn. Mar. 23, 1999) (citing Whitehead v. Dycho Co., Inc., 775 S.W.2d 593, 599-600 (Tenn. 1989) and Cansler, 826 F.2d at 1511). Accordingly, the learned intermediary doctrine applied to the plaintiffs' allegation of failure to warn, and summary judgment was properly granted as to this claim.

IV. NEGLIGENCE *PER SE*[5]

The trial court granted the defendants' motion to dismiss the allegations of negligence *per se*, concluding, pursuant to Tenn. R. Civ. P. 12.02(6), that they failed to state a claim upon which relief could be granted. The plaintiffs appealed that dismissal, which was consolidated, for purposes of appeal, with the grant of summary judgment as to the plaintiffs' claims pursuant to the TPLA.

As to the plaintiffs' claims of negligence *per se*, the trial court granted the defendants' motion to dismiss. Our standard of review as to the granting of a motion to dismiss is set out in Stein v. Davidson Hotel Co., 945 S.W.2d 715, 716 (Tenn. 1997). The court explained:

> A Rule 12.02(6), Tenn. R. Civ. P., motion to dismiss for failure to state a claim upon which relief can be granted tests only the legal sufficiency of the complaint, not the strength of a plaintiff's proof. Such a motion admits the truth of all relevant and material averments contained in the complaint, but asserts that such facts do not constitute a cause of action. In considering a motion to dismiss, courts should construe the complaint liberally in favor of the plaintiff, taking all allegations of fact as true, and deny the motion unless it appears that the plaintiff can prove no set of facts in support of her claim that would entitle her to relief. Cook v. Spinnaker's of Rivergate, Inc., 878 S.W.2d 934, 938 (Tenn. 1994). In considering this appeal from the trial court's grant of the defendant's motion to dismiss, we take all allegations of fact in the plaintiff's complaint as true, and review the lower courts' legal conclusions *de novo* with no presumption of correctness. Tenn. R. App. P. 13(d); Owens v. Truckstops of America, 915 S.W.2d 420, 424 (Tenn. 1996); Cook, supra.

In their briefs, the plaintiffs do not set out their specific pleadings from their trial court pleadings as to negligence *per se*. They simply present arguments as to why the trial court erred in dismissing their negligence *per se* claim.

The plaintiffs' negligence *per se* allegations are set out in their second amended complaint:

> IV.
> Count Three: Negligence Per Se - Manufacturer
>
> Plaintiffs re-allege and re-aver each and every allegation set forth in

[5]On this issue, Smith and Nephew, Inc. furnished the court with an amicus curiae brief which we have carefully reviewed. We appreciate the assistance which it provided.

> paragraphs I through V and further allege and aver that the Defendant's actions herein by failing to comply with the applicable provisions of the Medical Device Amendments ("MDA's") to the Food Drug and Cosmetic Act ("FDCA") constitutes a violation of said statute and constitutes negligence per se, rendering defendant liable for all damages herein pled.
>
> As a direct and proximate result of Danek's violations of the FDCA and MDA's , Plaintiffs have had Danek's pedicle screw devices surgically implanted, which caused Plaintiffs to suffer physical and mental harm. As a consequence, Plaintiffs have suffered and will continue to suffer losses such as past and future earnings and earning capacity, physical pain, mental anguish, permanent disabilities, medical and rehabilitation expenses and other losses, injuries and damages.

The plaintiffs were allowed to amend these allegations to set out the specific statutes which they claimed the defendants had violated. This amendment, set out in the trial court's order of September 11, 1997, alleged as follows:

> Count Three: Negligence Per Se - Manufacturer
>
> "Spinal fixation devices utilizing pedicle screws are subject to regulation by the Food and Drug Administration pursuant to the Food Drug and Cosmetic Act, 21 U.S.C. §301, et seq., and the Medical Device Amendment to that Act 21 U.S.C. §360, et seq. Defendants were in violation of sections 321, 331, 351, 352 and 360c of the aforementioned Act and Amended Act as follows:
>
> 21 U.S.C. §321 defines an adulterated medical device.
>
> 21 U.S.C. §331(a) prohibits the introduction or delivery into interstate commerce of a device that is adulterated or misbranded.
>
> 21 U.S.C. §352(f) sets forth the circumstances whereby a device will be deemed to be misbranded.
>
> 21 U.S.C. §351 sets forth the circumstances whereby a device will be deemed to be adulterated. More specifically, if the device is a class III device which has not received pre-market approval or 510(k) clearance with respect to each intended medical use for which is offered, it shall be deemed adulterated. See 21 U.S.C. §351 (f).
>
> In addition, a device shall be deemed to be adulterated "if it is a device for which [an investigational device] exemption has been granted . . . and the person who has been granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by [the FDA]." See 21 U.S.C. §351 (i).
>
> Class III medical devices are those which "present a potential unreasonable risk of illness or injury." See 21 U.S.C. §360c (a) (1) (C) (ii) (II). A pedicle screw device is a Class III device, and as such, the manufacturer of said device is subject to the aforementioned regulation and the defendants were in violation of said regulations.
>
> Prior to the Defendants' placement of the subject pedicle screw devices into interstate commerce, Defendants did not obtain pre-market approval or 510 (k) clearance for these devices, and these actions and inactions were in violation of 21 U.S.C. §351(f). The subject devices

> were, at all times relevant herein, misbranded and placed into interstate commerce in violation of 21 U.S.C. §351(f)[.]"

In their brief, the plaintiffs explained the negligence *per se* claim as follows:

> Despite these [FDA] regulatory restraints, the Appellees "commercialized" their pedicle screw fixation devices. On a massive and perhaps unprecedented basis, Appellees promoted these devices for use in the spinal pedicles outside the IDE clinical trials. In doing so, they violated numerous provisions of federal medical device law. Specifically, in commercializing an investigational use of a device, Danek violated the express prohibition against such conduct which is set forth in 21 *C.F.R.* §812.7. In promoting a medical device for such a use which has not received premarket approval of 510(k) clearance from the FDA, Danek violated the express statutory prohibition against the sale of unapproved or non-cleared devices as well as adulterating and misbranding the devices in violation of the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 *U.S.C.* §301, *et seq.*, and the Medical Device Amendments to that Act (MDAs), 21 *U.S.C.* §360, *et seq*. *See* 21 *U.S.C.* §§351(f)(1)(B), 360(c)(a)(1)(C), 360 (c)(c), 360 (c)(f)(1), 360(e), 352(o). . . .

We note that the plaintiffs have alleged in their brief violations of additional statutes which were not specified in the trial court pleadings as the basis for their claims.

Summarizing their claims of negligence *per se*, in their brief, the plaintiffs argue:

> The core issue of this case is whether or not Danek violated public duties and was a prudent manufacturer in making the decision to place the TSRH and Luque device into the stream of commerce knowing that human safety was at stake. The most important inquiry is thus the knowledge, activities, and conduct of defendant prior to and during the relevant time periods and their conscious indifference to the consequences of their activities. Medical devices, because human safety is at stake, are highly and strictly regulated by the FDA and an essential aspect of the Appellees' activities during the relevant time period is their knowledge of and actions regarding compliance, circumvention of, and negligent or knowing violation of FDA safety requirements and mandates. The FDA regulations and Appellees' prior actual and/or constructive knowledge of those regulations and their requirements, and their activities in response to those FDA regulations, is the essential element of the negligence per se cause of action. Thus, the negligence per se cause of action is an inseparable and necessary aspect of the entire case.

Citing Medtronic v. Lohr, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), the plaintiffs contend that the FDCA and MDA do not preempt state law claims that a manufacturer "negligently failed to comply with duties equal to, or substantially identical to, requirements imposed under federal law." Plaintiffs further contend that "[f]ederal law imposes a duty to use federal regulations and standards to underscore and enforce state products liability actions" and that the trial court erred in dismissing their negligence *per se* claims.

Subsequent to the Medtronic holding, the court in In Re: Orthopedic Bone Screw Products

Liability Litigation, 193 F.3d 781, 791 (3rd Cir. 1999), made clear the scope of that decision by explaining:

> Medtronic and Bone Screw I are crucially different from this case, however. Both raised the issue whether state common law claims were preempted by the FDCA and Medical Device Amendments. After Medtronic, it is clear that such claims survive, and Bone Screw I so held. Consequently, state law claims such as negligence, breach of implied warranty, and fraudulent misrepresentation are viable, even to the extent they seek recovery for conduct that may also have violated the FDCA. But neither Medtronic nor Bone Screw I purports to allow private plaintiffs to sue directly for violations of a federal statute in the absence of a separate underlying cause of action. They merely hold that such causes of action as previously existed under state law were not preempted by the FDCA and Medical Device Amendments.

Thus, Medtronic's effect is to recognize that a plaintiff can bring state law negligence claims "for conduct that may have also violated the FDCA," but, a plaintiff must have a "separate underlying cause of action" based upon state law. We must decide whether, given the nature of this case, such a state law cause of action is available to the plaintiffs.

Other courts, where plaintiffs have brought pedicle screw claims apparently identical to those in the instant cases, have not allowed FDCA based negligence *per se* claims. Talley v. Danek Medical, Inc., 179 F.3d 154 (4th Cir. 1999), involving a pedicle screw claim, explains the holding in Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960), upon which King and the Littles rely as to their negligence *per se* claim:

> Talley relies on our decision in Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960), to advance her claim that any violation of the FDCA constitutes negligence per se in Virginia. In that case we held that the misbranding of a bone nail, by wrongfully imprinting a dimension on the nail indicating that it would fit into a 9mm hole, violated a standard of care that would support a negligence per se claim under Virginia law. In that case, the plaintiff had undergone surgery in which the bone nail was to be inserted into the plaintiff's femur (thigh bone). When the surgeon sought to insert the nail into a 9mm hole, it would not fit properly because the misbranded nail was too large. The attempted insertion caused the plaintiff to lose the use of his leg. We held that the statutory requirement to label a surgical nail with the correct size on it established a standard of care because the mislabeling created an unreasonable risk for patients. Id. at 461. The alleged violation in Eutsler, however, is distinguishable from the alleged violation in Talley's case.

179 F.3d at 161.

The plaintiff in Talley had also alleged an FDCA based negligence *per se* claim like that of King and the Littles:

> Talley alleges that Danek marketed a surgical device for a use that

> had not been approved by the FDA and that that violated the FDCA and therefore established negligence per se. See 21 U.S.C. §360e(a) (requiring premarket approval for Class III medical devices); see also 21 U.S.C. §331(a) (prohibiting the introduction of adulterated or misbranded devices into interstate commerce), 351(f)(1) (defining adulterated devices to include unapproved Class III devices).

Id. at 160.

The plaintiffs' trial court pleadings regarding their negligence *per se* claims make it clear that they do not have a claim like the plaintiff in Eutsler, but instead are claiming, as did the plaintiffs in Talley, that the defendants marketed their device for a use not approved by the FDA.

However, the court in Talley concluded that an FDCA violation could not support the plaintiff's negligence *per se* claim. The court stated:

> Breach of the requirement not to misbrand a surgical nail is similar to a breach of a speed limit; each violates a specific and substantive standard of care that is intended to protect others. The holding in Eutsler, however, does not establish the principle that the simple failure to obtain approval of advice from the FDA, standing alone, can support a negligence per se claim. The administrative requirement that a given device be approved by the FDA before being marketed – as opposed to a specific substantive requirement that a device be safe and effective – is only a tool to facilitate administration of the underlying regulatory scheme. Because it lacks any independent substantive content, it does not impose a standard of care, the breach of which could form the basis of a negligence per se claim. Its breach is analogous to the failure to have a driver[']s license.

Id. at 161. We agree with this reasoning. The plaintiffs have not even attempted to show that the statutes upon which they base their negligence *per se* claim set out other than administrative requirements.

Additionally, in Uribe v. Sofamor, S.N.C., No. 8:95CV464, 1999 WL 1129703, at *16 (D. Neb. Aug. 16, 1999), another pedicle screw fixation case, the court agreed with the Talley holding that a negligence *per se* claim could not be based upon violations of the FDCA alleged by the plaintiff. The court agreed that the FDCA imposed administrative requirements rather than standards of care. Additionally, the court noted that the plaintiff in Uribe had failed to present a prima facie case that his continuing pain was caused by the defendant's internal fixation system. Further, the court considered the fact that the implanting physician had utilized the device for the off-label purpose of pedicle fixation, and no evidence had been presented showing a proximate relationship between the physician's decision to utilize the device and the absence of FDA approval for such a use. Thus, the court granted summary judgment to the defendant as to the claim of negligence *per se*.

Likewise, in Johnson v. Smith & Nephew Richards, Inc., No. 97-CV-363-K, 1999 WL 1117105, at *2 (N.D. Okla. Sept. 30, 1999), the court, citing Talley, held that the FDA requirement that a device be approved before being marketed was an "administrative requirement" and "without independent substantive content," which could not support a claim of negligence *per se* because it did not impose a standard of care.

The cases relied upon by the plaintiffs as the basis for their arguments that Tennessee recognizes FDCA and MDA based negligence *per se* claims are so different procedurally and substantively from the instant situation that they are not persuasive. The plaintiffs cite Bellamy v. Federal Express Corp., 749 S.W.2d 31, 33 (Tenn. 1988), as an example that federal statutes and their state counterparts "create a basis of liability for negligence per se, which gives the maximum effect to those statutes intended by the legislative bodies who enacted the statutes." However, the claims in that case were quite different from those brought by King and Little. Bellamy had alleged that as he was inspecting the conveyers and walkways for his employer, who was one of the contractors working on the construction of the Federal Express hub, he fell through a gap not marked by any barricades or warning signs in the grating of a walkway. Bellamy claimed that the defendants had violated one or more of the Federal Occupational Safety and Health Standards, which the Tennessee Commissioner of Labor was authorized to adopt, pursuant to Tenn. Code Ann. § 50-3-201 (1983). One issue in Bellamy was whether the trial court properly granted summary judgment to the defendants. It was not an issue in Bellamy, as it is in the instant case, whether the statutes relied upon by the plaintiffs established a standard of care, or merely set out administrative requirements. Thus, the Bellamy holding is not helpful in our consideration.

A claim of negligence *per se* based upon a penal statute was examined in Cook v. Spinnaker's of Rivergate, Inc., 878 S.W.2d 934 (Tenn. 1994). Cook, who was a minor, had been involved in a single car accident. Shortly before the accident, she allegedly had been served alcoholic beverages, in violation of Tenn. Code Ann. § 57-4-203(b)(1) (making it a misdemeanor to sell or furnish alcoholic beverages to persons under age 21), and § 57-4-203(c)(1) (making it a misdemeanor to sell or furnish alcoholic beverages to a "visibly intoxicated" person). The court noted that "standard of conduct" could be "prescribed in a statute," so that the "violation of the statute may be deemed to be negligence per se." Cook, 878 S.W.2d at 937. Before negligence *per se* could be established in this manner, however, "it must be shown that the statute violated was designed to impose a duty or

prohibit an act for the benefit of a person or the public." Id. Additionally, the court noted the requirement set out in Smith v. Owen, 841 S.W.2d 828, 831 (Tenn. App.), perm. app. denied (Tenn. 1992), that the injured party be within the class of persons to be protected. Cook, 878 S.W.2d at 973. In Smith, a child had been injured as the result of improper wiring in a rental house, and the court found that negligence *per se* could be based upon the defendant's violation of the Cookeville Building Code:

> SECTION 303.4 – ELECTRIC LIGHTS AND OUTLETS REQUIRED . . . In addition to the electric light fixture in every bathroom and laundry room, there shall be provided at least one (1) convenience outlet. Every such outlet and fixture shall be properly installed shall be maintained in good and safe working condition, and shall be connected to the source of electric power in a safe manner.

841 S.W.2d at 830.

This ordinance has precise and readily understandable requirements not paralleled by the FDCA and MDA statutes upon which the plaintiffs base their allegations.

Thus, the Tennessee decisions relied upon by the plaintiffs as supporting their negligence *per se* claim can be distinguished because those decisions apply statutes with substantive context, rather than the FDCA statutes which set out only administrative requirements, as are relied upon in the instant case. The plaintiffs failed to analyze these FDCA statutes and demonstrate that they impose a standard of care, which was shown to be necessary in the previous decisions of the Tennessee courts allowing statute or ordinance based claims of negligence *per se*. Additionally, the plaintiffs, in arguing for the viability of their negligence *per se* claims have not dealt with the procedural and factual element setting their claims apart from those cases, namely the presence of implanting physician between the defendants and the plaintiffs. The existence of an independent actor between a plaintiff and a defendant is a factor not present in the negligence *per se* Tennessee decisions upon which the plaintiffs rely. Additionally, in asserting that they are within the class of persons to be protected by the particular FDCA statutes upon which they rely, the plaintiffs do not discuss the facts that physicians, in implanting internal fixation devices utilizing pedicle screws, are engaging in "off-label" usages which are not prohibited and that such usages have been recognized by the FDA as being the nationwide standard of care.

The plaintiffs contend that Ponthieux v. Danek Medical, Inc., No. 96-3141 (consolidated under Ross, No. 95-2542) (W.D. Tenn. May 28, 1999), held that Tennessee law recognizes a claim

for negligence *per se* based upon an FDCA violation. The trial court granted summary judgment to the defendants on the plaintiffs' negligence *per se* claim because the plaintiffs could not demonstrate proximate cause between the claimed FDCA violation and the injury. In a footnote, the Ponthieux court cited In Re: Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3rd Cir. 1998), for the proposition that "the FDCA's lack of a private right of action does not bar Ponthieux from asserting this claim." We do not interpret this language in the footnote to be a finding, as the plaintiffs claim, that Tennessee allows a negligence *per se* claim based solely upon the FDCA. Rather, it simply recognizes that such a claim would not be preempted.

Additionally, the plaintiffs cite several cases from other states as authority for their arguments as to an FDCA based negligence *per se* claim. However, those cases differ so substantially from the instant cases that we do not find them to be persuasive. The decedent in Milkiewicz v. Baxter Healthcare Corp., 963 F. Supp. 1150 (M.D. Fla. 1996), had undergone a mitral valve replacement, with a valve which had been designed, constructed, and sold by the defendant. Claims of negligence were made against the defendant after the deceased allegedly died because of a leak in the valve. Milkiewicz simply construes Lohr to hold that state law negligence claims were not preempted by the FDCA.

McNeil Pharmaceutical v. Hawkins, 686 A.2d 567 (D.C. 1996), also cited in the plaintiffs' brief, involved an action that had been brought on behalf of a decedent who had died from severe liver failure three months after ingesting a drug manufactured by the defendant and prescribed for muscle stiffness. Contrary to the plaintiffs' assertion that the court in McNeil held that "the FDCA and the FDA regulations . . . were proper for use in a negligence per se cause of action," the Court of Appeals reversed the trial court for allowing evidence of statutes and regulations without first making the proper determination as to their applicability. The court explained:

> Our review of the statutes and regulations admitted here raises questions on whether they can be used to establish a standard of care for negligence per se purposes in the absence of adequate examination by the trial court to determine whether they were applicable and whether they could be understood by the jury without guidance from the court or expert testimony concerning their meaning. The court admitted dozens of statutes and regulations, some possibly applicable in the determination of a standard of care and at least one clearly not.

McNeil, 686 A.2d at 580.

McNeil also explained the relationship between a statute or regulation and a claim of

negligence *per se*:

> To prevail on a negligence per se theory, the plaintiff may, in certain circumstances and under specified conditions as discussed in Part B, rely on a statute or regulation as proof of the applicable standard of care. Proof of "[an] unexplained violation of that standard renders the defendant negligent as a matter of law," so long as the violation was the proximate cause of the injuries, and the alleged injuries were of the type which the statute was designed to prevent.

Id. at 578 (citations omitted).

The court in McNeil examined many of the same cases relied upon by King and the Littles to determine the extent to which statutes and regulations were admissible to show negligence *per se* and determined that they did not support such a claim:

> In support of that argument, Hawkins cites several cases in which FDA regulations were admitted to establish the standard of care. We think that Hawkins's reliance on those cases is misplaced because in each case cited, unlike the circumstances presented here, the violation at issue was clear and uncomplicated, and involved only a small number of readily understandable statutes. See Stanton by Brooks v. Astra Pharm. Prod., Inc., 718 F.2d 553, 560 (3d Cir. 1983) (pharmaceutical company failed altogether to submit NDA for a new drug and failed to forward any of more than 200 adverse reactions to the FDA); Hoffman v. Sterling Drug, Inc., 485 F.2d 132 (3d Cir. 1973) (company advertised a change in the market use of drug but failed altogether to submit NDA for the new purpose as required by the FDA); Orthopedic Equip. Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960) (incorrect diameter stated on surgical nail label could be negligence per se under FDA statute prohibiting "misbranding," where nail became stuck in plaintiff's leg); Toole v. Richardson-Merrell, Inc., 251 Cal.App.2d 689, 60 Cal.Rptr. 398 (1967) (company filed NDA, reporting 50% death rates in animal testing when 100% had died, and included wholly fictitious data).

Id. at 580. In these cases, as reviewed by McNeil and also relied upon by these plaintiffs, the factual claims and procedural postures are so unlike those presented in this appeal that we do not find them to be applicable. The claims of these plaintiffs, unlike those examined by McNeil, do not involve allegedly "clear and uncomplicated" violations based upon a "small number of readily understandable statutes." Id. at 580.

When alleging a statute or regulation based negligence *per se* claim, it is not sufficient for a plaintiff to assume, as these plaintiffs have, that the alleged violation of a statute automatically supports a claim of negligence *per se*. Even if the plaintiffs are within the class to be protected by the statute, see Harden, 985 S.W.2d at 452, a statutory negligence *per se* claim cannot stand unless the statute establishes a standard of care. Talley explains the reason for this rule:

> Where a statutory provision does not define a standard of care but merely imposes an administrative requirement, such as the requirement

> to obtain a license or to file a report to support a regulatory scheme, violation of such requirement will not support a negligence per se claim. Even if the regulatory scheme as a whole is designed to protect the public or to promote safety, the licensing duty itself is not a standard of care, but an administrative requirement. See Ridge v. Cessna Aircraft Co., 117 F.3d 126, 131 (4th Cir. 1997) (holding that federal regulations making a pilot responsible for operation of his aircraft and requiring him, upon request, to submit a written report to the government whenever he deviates from an aviation rule in an emergency provide for "general standards of conduct," but do "not impose a particular duty," and thus their violation was not negligence per se in Virginia)[.]
>
> . . . .
>
> In concluding that the FDCA requirement for prior approval of a medical device does not itself support a claim for negligence per se, we do not intend to trivialize the alleged violation of administrative statutory provisions. They are essential to the underlying federal regulatory scheme that serves important societal interests. But because such specific approval rules are administrative, they do not amount to a legislative judgment as to the standard of care, and accordingly, breach of these provisions in themselves cannot underlie a negligence per se claim.

179 F.3d at 159.

We have examined the statutes cited by the plaintiffs as the basis for their negligence *per se* claim and agree that they lack sufficient substantive content to support such a claim. Accordingly, based upon all of these considerations, we conclude that the plaintiffs cannot bring an FDCA based negligence *per se* claim.

Thus, as to the plaintiffs' claims of negligence *per se*, we conclude that they can prove no set of facts which would entitle them to relief. Accordingly, the trial court was correct in granting the defendants' motion to dismiss as to this claim.

V. STATUTE OF LIMITATIONS

The defendants have presented as an additional issue, whether Tennessee recognizes cross-jurisdictional class action tolling. Acknowledging the ruling in this regard in Maestas v. Sofamor Danek Group, Inc., No.02A01-9804-CV-00099, 1999 WL 74212 (Tenn. App. Feb. 16, 1999), limited perm. app. granted (Tenn. 1999), the defendants state that they are presenting the issue to preserve it, should this matter reach our supreme court. Since the issue was not briefed by the defendants, we decline to rule that they were entitled to summary judgment based upon the expiration of the statute of limitations.

VI. ADMISSIBILITY OF FDA RELATED TESTIMONY AND DOCUMENTS

As to this issue, the plaintiffs appear to be contending that if this court affirms the trial court's

order granting summary judgment as to the negligence per se claims, we should rule that "FDA related testimony and documents" are admissible in a trial on causes of action which may remain. Explaining this argument, the plaintiffs state in their brief:

> It is impossible to understand why Appellees did certain things with regard to design, manufacture, and promotions without including their knowledge of and active response to FDA regulations, inquiries, warnings, and strictures. Since the excluded negligence per se cause of action and excluded FDA evidence has a reasonable connection to the central issue of whether or not Appellees were liable under the Tennessee Products Liability Act, and since such exclusion would not be harmless error, a reversal of any verdict not in plaintiff's favor would be mandated. A needless and expensive new trial involving the negligence per se issues could be prevented by allowing a full and complete introduction of the contested FDA regulatory evidence and related FDA matters which would prove or disprove the negligence per se allegations.

In making this argument, the plaintiffs apparently anticipate that the trial court may make an evidentiary ruling excluding certain FDA evidence as it did in another spinal fixation case which apparently did not involve these plaintiffs:

> As previously stated, the only case in which the Trial Court in Tennessee dismissed evidence relating to the FDA regulatory status occurred in Burton v. Smith & Nephew, Case No. 72995. The Defendant in that matter brought a Motion in Limine, just prior to trial, to exclude evidence relating to FDA regulatory status of the device at the time of the Plaintiff's surgery. The Trial Court granted the Defendant's Motion in Limine and that ruling was appealed interlocutorily and is pending before this Court. In fact, Appellees have never filed a motion in Shelby County which has been granted by the Trial Court, dismissing the FDA evidence in these cases or in any others included in In Re: Spinal Screw Litigation, Case No. 00103D.

It appears that the plaintiffs are asking us to give a blanket ruling on an evidentiary matter not presented to the trial court.

We agree with the defendants that we are being asked to give an advisory opinion on a matter which is not properly before this court. Accordingly, we decline to rule on this evidentiary matter.

CONCLUSION

Based upon the foregoing authorities and reasoning, we affirm the orders of the trial court granting the defendants' motion for summary judgment as to the plaintiffs' product liability claims and motion to dismiss as to the negligence *per se* claims.

Costs of the appeal are assessed against the plaintiffs, for which let execution issue if necessary.

_____
ALAN E. GLENN, SPECIAL JUDGE

CONCUR:

_____
W. FRANK CRAWFORD, P.J., W.S.

_____
DAVID R. FARMER, J.