IN THE COURT OF APPEALS OF TENNESSEE
AT JACKSON
April 2000 Session

GRETCHEN BISH, ET AL. v. SMITH & NEPHEW RICHARDS, INC., ET AL.
EUGENE HAFFEY, ET AL. **v. SOFAMOR DANEK GROUP, INC.,** ET AL.
GRETCHEN BISH, ET AL, Relating to Donald Burton **v. SMITH & NEPHEW,** ET AL.

An Interlocutory Appeal from the Circuit Court for Shelby County
Nos. 72995-1, 73049-1 The Honorable John R. McCarroll, Jr., Judge

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No. W1998-00373-COA-R9-CV - Filed August 23, 2000

These are consolidated interlocutory appeals of products liability suits against the manufacturers of spinal fixation devices. The trial court dismissed plaintiffs' negligence *per se* claims based on the alleged violation of the Food, Drug and Cosmetics Act (FDCA) and the Medical Device Amendments (MDA). In one of the cases, the trial court also granted defendants' motion *in limine* to exclude all Federal Drug Administration (FDA) regulatory evidence information and documents concerning the fixation devices. Plaintiffs appeal the rulings of the trial court.

Tenn.R.App.P. 9; Interlocutory Appeal; Judgment of the Circuit Court Affirmed and Remanded.

W. FRANK CRAWFORD, P.J., W.S., delivered the opinion of the court, in which ALAN E. HIGHERS, J. and DAVID G. HAYES, J., joined.

Roy F. Amedee, Jr., LaPlace, LA; Lisa June Cox, Jackson, TN, for Appellants, Haffey, Bish and Burton

Glen Reid, Jr., Memphis, TN; James B. Irwin, Nathan T. Gisclair, Jr., Sally I. Gaden, New Orleans, LA, for Appellees, Smith & Nephew, Inc.

Murray Levin, Philadelphia, PA; George Lehner, Washington, D.C., Sam B. Blair, Jr., Memphis, TN, for Appellees Danek Medical, Inc., Warsaw Orthopaedic, Inc. and Sofamor Danek Group, Inc.

OPINION

The three cases before the court on interlocutory appeal were consolidated because they involve common questions of law and fact. In September and October, 1995, complaints were filed in Shelby County, Tennessee on behalf of numerous plaintiffs who allegedly suffered injuries and damages as a result of the implantation of internal spinal fixation devices utilizing pedicle screws against numerous manufacturers of these devices, including Sofamor Danek Group, Inc., Warsaw Orthopaedic, Inc., Danek Medical, Inc.(hereinafter collectively referred to as Danek), and Smith & NEPHEW Richards, Inc. The complaints assert multiple causes of action against the defendants, including strict liability, negligence, negligence *per se*, breach of express warranty, breach of implied warrant, failure to warn, unlawful promotion, negligent misrepresentation, civil conspiracy, concert of action, and negligent infliction of emotional distress. The complaints also allege that the devices involved had not received the required FDA clearance and/or approval and allege fraud, fraudulent marketing and unlawful promotion against the named defendants.[1]

Due to the number of plaintiffs, a Case Management Order was entered by the trial court. This Order designated fourteen plaintiffs for trial, and the plaintiffs in this appeal are some of those designated.

Of the three appeals now before this Court, one appeal is in the Haffey suit, originally filed in the Circuit Court of Shelby County on October 3, 1995 against Danek. The second appeal is a separate, similar complaint, represented by plaintiff, Gretchen Bish, filed against manufacturer, Smith & Nephew Richards, Inc.[2] The third appeal is in a case represented by plaintiff Donald Burton, and presents the issue of the admissibility of Federal Drug Administration ("FDA") related evidence during the trial of the case involving only Smith & Nephew Richards, Inc.

On November 12, 1997, the trial court granted appellees' motion to dismiss the plaintiffs' negligence *per se* claims, holding:

> 1. No private right of action exists under the federal Food, Drug & Cosmetic Act (FDCA), and to allow a negligence *per se* claim based upon alleged violations of it would be inconsistent with the FDCA;
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> 2. The federal and Tennessee Statutes, federal FDA Regulations, and FDCA sections referred to by Plaintiffs in their Complaints and Memoranda are not suitable as negligence *per se* standards in these pending cases;

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[1] The non-product liability claims were dismissed by the trial court and are not part of this appeal.

[2] Sofamor Danek Group, Inc. (now Medtronic Sofamor Danek, Inc.), Danek Medical, Inc., and Warsaw Orthopaedic, Inc. were party defendants in the Bish lawsuit but have been voluntarily dismissed with prejudice and now are parties only to the appeal from the Haffey suit.

> 3. Even if the federal and Tennessee Statutes, and federal FDA Regulations and FDCA sections referred to by Plaintiffs in the Complaints and Memoranda were suitable as negligence *per se* standards, the causal connection between the alleged violations of the federal and Tennessee Statues, federal FDA Regulations and FDCA and Plaintiffs' alleged injuries is too tenuous to constitute proximate cause.
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> 4. Plaintiffs have failed to state a negligence *per se* claim upon which relief can be granted.
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> IT IS ORDERED, ADJUDGED AND DECREED that Defendants' Motions to Dismiss Plaintiffs' Negligence *per se* claims are granted, and Plaintiffs' negligence *per se* claims are dismissed with prejudice.

On January 21, 1998, the trial judge ruled in open court that the FDA regulatory information would not be proper evidence and would only serve to confuse the jury. On April 3, 1998, the trial court entered its order granting defendants' motion *in limine* regarding the admissibility of all regulatory (FDA) evidence as it previously ruled. The Haffey and Bish appellants were granted interlocutory appeals. Subsequently, after a mistrial, the Burton appellant was granted an interlocutory appeal. The three appeals were consolidated.

The appellants present four issues for review as stated in their brief:

> 1. Whether the use of FDA regulatory information or regulations as evidence is proper?
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> 2. Whether use of FDA regulatory information or regulations is relevant to issues to be determined at trial?
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> 3. Whether admission of evidence of FDA regulatory information or regulations would be precluded under Section 403 of the Tennessee Rules of Evidence in that such evidence would be prejudicial, confusing to a jury or a waste of time?
>
> 4. Whether the trial court erred in granting Appellees' Motion to Dismiss Appellants' Negligence *per se* Claims?

We will consider the fourth issue first.

This issue is controlled by our Opinion in ***King v. Danek Medical, Inc.***, No. W1999-02651-COA-R3-CV, 2000 WL 311143 (March 28, 2000, Tenn.Ct.App.). In ***King***, the trial court dismissed precisely the same negligence *per se* claims made by the plaintiffs in the instant case. In affirming the trial court, the ***King*** Court stated:

When alleging a statute or regulation based on a 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)[.]
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> ....
>
> 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.
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> 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.
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> 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.

King, at *34.

In light of the ruling in ***King***, we find this issue without merit.

Appellants' Issues 1 through 3 address the question of admissibility into evidence of FDA regulatory information and regulations. The initial briefs filed in the case for the most part referred to the ruling of the court that generally denied the introduction of FDA regulatory evidence in response to a motion *in limine* in the Burton case. At oral argument, reference was made to plaintiff Burton's offer of proof, and the court requested supplemental briefs from the parties concerning a more precise description of the evidence that was not allowed. Burton's supplemental brief highlights the offers of proof of Leslie Sprinkle, Jeff Cobb, and Dr. Carl Larson. The offers of proof were quite extensive and detailed, and we will attempt to briefly summarize the key elements of each witness's testimony.

Leslie Marvin Sprinkle testified that he is vice-president of regulatory and clinical affairs and quality of Smith & Nephew. His testimony primarily focused on clinical studies of orthopaedic implants in humans. In connection with FDA regulations, Sprinkle defined a 510 (k) submission as documents that are provided to the FDA to determine whether a product is essentially equivalent to a product that was in interstate commerce prior to May 28, 1976. He also explained that Pre-Market Approval (PMA) was an application to the FDA which involves clinical trials as an Investigation of Device Exemption (IDE). He testified that between 1991 and 1993, Smith & Nephew had no 510 (k) clearing the Simmons spinal rating system for the posterior or pedicular application. His testimony detailed his understanding of FDA regulations which was related to his company and the Simmons rating system. He also discussed the company's actions in response to FDA communication and explained Smith & Nephew's decision-making process related to the Simmons pedicle screw device.

Jeff Cobb testified that he is the director of regulatory affairs for Smith & Nephew. He was questioned concerning the 510 (k) submission of a clearance letter for the pedicle screw device for only the intended use of anterior lateral fixation. He testified that this was the only clearance they had until 1995, but that Smith & Nephew made their own independent determination that the 510 (k) submission was unnecessary for other uses. He was also questioned concerning communications from the FDA concerning IDE and proposed deficiencies in the IDE application. He testified

concerning the company's decision to terminate the IDE. He was also questioned concerning various communications from the FDA and identified exhibits dealing with FDA communications concerning the fixation device. He was further questioned concerning his trip report for a seminar discussing advertising, labeling, and consumer education, and testified concerning a recall of a reported defective locking nut.

Dr. Carl Larson testified that he was a former director of the General Restorative Devices Division of the FDA. Dr. Larson testified in depth about FDA regulations as they relate to medical devices and his perception of a manufacturer's duties pursuant to the law. He testified that the FDA identified certain risks with regard to posterior pedicle screw fixation. He testified that anterior lateral fixation was not subject to the same risks as the pedicle screw fixations and that neither Smith & Nephew nor other manufacturers successfully completed IDE and generated scientifically reliable data to establish the safety of any pedicle screw device. Dr. Larson's testimony extensively discussed the regulations and the duties of the manufacturer with regard to the law.

The evidentiary rules pertinent to our inquiry are Tenn.R.Evid. 401, 402, and 403. They provide:

> **Rule 401. Definition of "relevant evidence."** - "Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.
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> **Rule 402. Relevant evidence generally admissible; irrelevant evidence inadmissible.** - All relevant evidence is admissible except as provided by the Constitution of the United States, the Constitution of Tennessee, these rules, or other rules or laws of general applicable in the courts of Tennessee. Evidence which is not relevant is not admissible.
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> **Rule 403. Exclusion of relevant evidence on grounds of prejudice, confusion, or waste of time.** - Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

All of plaintiffs' asserted causes of action comprise a product liability action as defined in T.C.A. § 29-28-102 (5)(1980). In order to recover in such an action against a manufacturer or seller of a product, the plaintiff must prove that the product was "in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer of seller." T.C.A. § 29-28-105 (1980).

Relevant evidence means evidence having any tendency to make existence of any fact that is of consequence to determination of the action more probable or less probable than it would be

without the evidence. ***Given v. Low***, 661 S.W.2d 687 (Tenn. Ct. App. 1983). In ***Otis v. Cambridge Mut. Fire Ins. Co.***, 850 S.W.2d 439 (Tenn. 1992), the Court said:

> In Tennessee admissibility of evidence is within the sound discretion of the trial judge. When arriving at a determination to admit or exclude even that evidence which is considered relevant trial courts are generally accorded a wide degree of latitude and will only be overturned on appeal where there is a showing of abuse of discretion. ***Strickland v. City of Lawrenceburg***, 611 S.W.2d 832 (Tenn. Ct. App. 1980); Tennessee Rules of Evidence 401; ***Austin v. City Memphis***, 684 S.W.2d 624 (Tenn. Ct. App. 1984); ***Inman v. Aluminum Co. of America***, 697 S.W.2d 350 (Tenn. Ct. App. 1985).
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> We consider the rule in ***McCormack v. Riley,*** 576 S.W.2d 358, 360 (Tenn. Ct. App. 1978) to be applicable here:
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> > Not all logically relevant evidence is admissible. Thus evidence which would advance the inquiry but would also inflame or unduly distract the jury or require an undeserved expenditure of judicial time or unfairly surprise the opponent may not be admissible. ***See McCormick on Evidence*** § 185 (2d ed. 1972). The probative weight of evidence must be balanced against those attendant costs in determining that evidence should be admitted.
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> ***Id.*** at 360.

850 S.W.2d at 442-443.

Evidence upon a fact not in issue is irrelevant and not admissible unless collaterally admissible. ***Bridges v. CSX Transp., Inc.,*** 845 S.W.2d 760 (Tenn. Ct. App. 1992). In ***Bridges***, the Court noted: "[T]here must be some relevance between evidence offered and the issues for trial. Simply because evidence may bolster a plaintiff's case does not make it irrelevant." ***Id.*** at 764.

In the instant cases, the plaintiffs are required to prove that the fixation devices were defective or unreasonably dangerous at the time they left the manufacturer's control. It appears from our review of the record that the evidence excluded by the trial court and offered in proof does not tend to prove the determinative issues in the case nor lead to evidence that would prove such issues. The FDA's approval or nonapproval of the devices without more does not tend to prove that the devices were defective or unreasonably dangerous. Moreover, a review of the testimony of the three witnesses offered by plaintiff Burton aptly illustrates the reason for Tenn.R.Evid. 403. The introduction of the proof concerning the FDA activity in regulation would result in a confusion of the issues, could mislead the jury, and without question would result in undue delay and a waste of

time. Under the state of this record, if there is any probative value to the testimony, it is substantially outweighed by the dangers outlined in Rule 403. The trial court did not abuse its discretion in excluding the proffered evidence.

Accordingly, the orders of the trial court are affirmed. These cases are remanded to the trial court for such further proceedings as are necessary. Costs of the appeal are assessed against the appellants, Eugene Haffey, Gretchen Bish, and Donald Burton.

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W. FRANK CRAWFORD, PRESIDING JUDGE, W.S.