NO. COA98-840

NORTH CAROLINA COURT OF APPEALS

Filed: 19 October 1999

GREGORY OSBURN and JOY C. OSBURN,
Plaintiff-Appellants,

v.

DANEK MEDICAL, INC., SOFAMOR-DANEK GROUP, INC., WARSAW ORTHOPAEDIC, INC., KEITH M. MAXWELL, M.D., KEITH M. MAXWELL, M.D., P.A., and ST. JOSEPH'S HOSPITAL,
Defendant-Appellees.

Appeal by plaintiffs from orders and judgments entered in Buncombe County Superior Court, including order entered 12 December 1997 and judgment entered 29 August 1997 by Judge Ronald K. Payne; and order entered 10 July 1997 and order and judgment entered 22 May 1997 by Judge Forrest A. Ferrell. Heard in the Court of Appeals 25 February 1999.

Donald B. Hunt for plaintiff-appellants.

Smith, Helms, Mulliss & Moore, L.L.P., by J. Donald Cowan, Jr. and Lisa Frye Garrison, for Danek Medical, Inc., Sofamor-Danek Group, Inc., and Warsaw Orthopaedic, Inc., defendant-appellees.

Young, Moore and Henderson P.A., by Joseph W. Williford and Brian O. Beverly, for Keith M. Maxwell, M.D., and Keith M. Maxwell, M.D., P.A., defendant-appellees.

Roberts & Stevens, P.A., by Isaac N. Northup, Jr. and Jacqueline D. Grant, for St. Joseph's Hospital, defendant-appellee.

JOHN, Judge.

Plaintiffs Gregory Osburn (Osburn) and wife Joy C. Osburn appeal certain orders and judgments entered in the trial court.

We conclude plaintiffs' assignments of error are unfounded.

Pertinent factual and procedural background includes the following: Osburn fell and suffered injury in 1989 and subsequently sought treatment from defendant Dr. Keith M. Maxwell, M.D. (Dr. Maxwell). Dr. Maxwell performed back surgery on Osburn in October 1990, implanting an ISF Luque II plate and screw spinal fixation device (ISF Luque II device). In February 1992, Dr. Maxwell removed the ISF Luque II device, replacing it with a TSRH spinal fixation device (TSRH device). A third spinal surgery was performed on Osburn by Dr. Maxwell in 1993, and in 1994 Dr. Maxwell removed the TSRH device.

Both the ISF Luque II and the TSRH devices implanted in Osburn were manufactured by defendants Danek Medical, Inc. (Danek) and Warsaw Orthopaedic, Inc. (Warsaw), which corporations were purchased by defendant Sofamor-Danek Group (Sofamor) in 1993. Osburn's four operations were each performed at the premises of defendant St. Joseph's Hospital (St. Joseph's). Notwithstanding his extensive surgical history, Osburn continued to experience pain.

The instant suit was initiated in 1995 and an amended complaint filed in 1996. Plaintiffs asserted the following claims: (1) fraud against Danek, based upon alleged violation of Food and Drug Administration (FDA) regulations; (2) fraudulent marketing and promotion against Danek; (3) civil conspiracy, concert of action and negligence *per se* against all defendants; (4) medical malpractice and constructive fraud against defendants Dr. Maxwell and St. Joseph's; (5) fraud against Dr. Maxwell and

St. Joseph's based upon their alleged assertions that the ISF Luque II and the TSRH devices used in Osburn's back were "safe and effective"; (6) loss of consortium against all defendants; and (7) punitive damages against all defendants.

The trial court entered summary judgment in favor of Danek, Warsaw, Sofamor, and St. Joseph's on 22 May 1997. On 10 July 1997, the trial court entered partial summary judgment in favor of defendants Dr. Maxwell and Keith M. Maxwell, M.D., P.A. (Dr. Maxwell, P.A.), Dr. Maxwell's medical practice corporation, on all plaintiffs' claims against those defendants save that of negligence. At trial, the jury returned a verdict of no negligence. The trial court thereupon entered judgment 29 August 1997 dismissing plaintiffs' claims as to Dr. Maxwell and Dr. Maxwell, P.A. Plaintiffs moved for a new trial, which motion was denied in an order entered 12 December 1997.

Plaintiffs appeal the foregoing judgment and order as well as the grant of summary judgment in favor of Danek, Warsaw, Sofamor and St. Joseph's and of partial summary judgment to Dr. Maxwell and Dr. Maxwell, P.A.

Plaintiffs first assign error to the trial court's jury instructions on the issue of informed consent. Plaintiffs argue Dr. Maxwell had a duty to inform them of the experimental nature of the ISF Lusque II and TSRH devices used by Dr. Maxwell in Osburn's back surgery, and that the trial court erred in refusing to instruct the jury as to this duty. We hold the jury was properly instructed under present applicable law.

The pertinent statute, N.C.G.S. § 90-21.13 (1993), provides

as follows:

(a) No recovery shall be allowed against any health care provider upon the grounds that the health care treatment was rendered without the informed consent of the patient . . . where

(1) The action of the health care provider in obtaining the consent of the patient . . . was in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities; and

(2) A reasonable person from the information provided by the health care provider under the circumstances, would have a general understanding of the procedures or treatments and of the usual and most frequent risks and hazards inherent in the proposed procedures or treatments which are recognized and followed by other health care providers engaged in the same field of practice in the same or similar communities . . . .

To meet the statutory standard,

the health care provider must provide the patient with sufficient information about the proposed treatment and its attendant risks to conform to the customary practice of members of the same profession with similar training and experience situated in the same or similar communities. In addition, the health care provider must impart enough information to permit a reasonable person to gain a "general understanding" of both the treatment or procedure and the "usual and most frequent risks and hazards" associated with the treatment.

Foard v. Jarman, 326 N.C. 24, 26-27, 387 S.E.2d 162, 164 (1990)

(quoting G.S. § 90-21.13(a)(2)).

Plaintiffs filed a written request for jury instructions on

25 August 1997, requesting that the jury be instructed that

the health care provider has a duty, in exercising reasonable care under the circumstances, to inform the patient of the experimental nature of the proposed procedure.

Plaintiffs renewed their request during the charge conference

conducted 28 August 1997.

The trial court declined plaintiffs' tendered instructions,

stating that the duty of a physician to inform patients that a

device is experimental was not the standard of care under G.S. §

90-21.13. The court charged the jury that plaintiffs were required to prove Dr. Maxwell did not obtain Osburn's informed consent either

> by failing to provide information to [Osburn] which would, under the same or similar circumstances, have given a reasonable person a general understanding of the procedures and treatments to be used, and the usual and most frequent risks and hazards inherent in them as recognized by other orthopedic surgeons in the same or similar communities[; or] by not obtaining [consent] in accordance with the standard of practice among other orthopedic surgeons with the same or similar training and experience and who were situated in the same or similar communities at the time in question.

The trial court further related to the jury the contentions of each party pertaining to the alleged investigative and experimental nature of the proposed procedures and thereafter charged, *inter alia*, that if it found:

> [Dr. Maxwell] was negligent in that he did not inform the plaintiff that the [ISF Luque II or TSRH devices were] investigational or experimental, and that such was not in accordance with the standard of practice [for] obtaining consent among other orthopedic surgeons, which standard would require him to so inform [Osburn] . . . ,

it should answer in favor of plaintiffs.

We believe the court's comprehensive instructions were in full accordance with G.S. § 90-21.13(a) and alerted the jury that evidence of the investigational or experimental status of the devices was properly considered in its resolution of the issue of Dr. Maxwell's negligence. Rather than requiring physicians to inform patients in every instance that a procedure is experimental in nature, G.S. § 90-21.13 directs a physician to indicate the status of a procedure and risks involved therein

> in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities,

G.S. § 90-21.13(a)(1), and in such a manner that a reasonable person would under the circumstances derive from the information

> a general understanding of the procedures or treatments and of the usual and most frequent risks and hazards inherent in the proposed procedures or treatments which are recognized and followed by other health care providers engaged in the same field of practice in the same or similar communities,

G.S. § 90-21.13(a)(2).

Plaintiffs rely heavily upon *Estrada v. Jaques*, 70 N.C. App. 627, 321 S.E.2d 240 (1984); however, after careful review, we conclude *Estrada* is inapposite. In *Estrada*, a physician-defendant moved for summary judgment and was thereby required to show his compliance with G.S. § 90-21.13. *Estrada*, 70 N.C. App. at 645, 321 S.E.2d at 251. This Court observed the physician-defendant had admitted in his pleadings that the procedure in question was experimental, and concluded such admission established "the usual and most frequent risks and hazards inherent in [the procedure or treatment]" as recognized by other orthopedic surgeons in the same or similar community. *Id.* at 648, 321 S.E.2d at 253-54 (quoting G.S. § 90-21.13(a)(2)). Accordingly, we continued, the physician was required to show, as a matter of law for purposes of summary judgment, that his patient had "a general understanding," G.S. § 90-21.13(a)(2), of the associated risks as recognized by other health care providers, including the experimental nature of the procedure. *Id.* at 648, 321 S.E.2d at 254.

Plaintiffs perceive *Estrada* as establishing a *per se* rule requiring the jury to be instructed that a health care provider in every instance has a duty to inform a patient of the

experimental nature of a proposed treatment procedure. To the contrary, *Estrada* is a limited holding founded upon the particular circumstances therein. Should the statute governing informed consent be deemed to require amendment to provide as plaintiff contends, that is the province of our General Assembly. *See Elliott v. Elliott*, 235 N.C. 153, 158, 69 S.E.2d 224, 227 (1952) (appellate court "does not make the law[; t]his is the province of the General Assembly"). Based on the foregoing, we hold the trial court did not err in declining plaintiffs' proposed jury instructions on the issue of informed consent.

Plaintiffs' second major assignment of error is directed at the trial court's entry of summary judgment in favor of Danek, Warsaw, Sofamor, St. Joseph's and Dr. Maxwell on plaintiffs' claims of violation of FDA regulatory requirements. Plaintiffs' argument is unfounded.

The Federal Food, Drug, and Cosmetics Act (FDCA) provides that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a) (1994). "Courts have generally interpreted this provision to mean that no private right of action exists to redress alleged violations of the FDCA." *Summit Technology v. High-Line Medical Instruments*, 922 F.Supp. 299, 305 (C.D. Cal. 1996); *see also Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3rd Cir.), *cert. denied*, 513 U.S. 965, 130 L. Ed. 2d 342 (1994) ("violations of the FDCA do not create private rights of action"), and *Bailey v. Johnson*, 48

F.3d 965, 968 (6th Cir. 1995) ("Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA").

Notwithstanding, plaintiffs insist that the United States Supreme Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 135 L. Ed. 2d 700 (1996), held that state causes of action may be maintained for violation of FDA regulations. Plaintiffs misread *Lohr*.

Lohr involved a question of whether § 360k of the FDCA, 21 U.S.C. § 360k (1994), pre-empted plaintiffs from bringing a *common-law* state claim. *Id.* at 474, 135 L.Ed.2d at 709. The Court held "[n]othing in § 360k denies . . . the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495, 135 L. Ed. 2d at 721. Contrary to plaintiffs' assertion, therefore, the Court's holding does not give rise to an implied private state cause of action for violation of FDA regulations or requirements. Plaintiffs also assert in passing that they "may seek damages based on state claims for violation of FDA regulations and requirements." Again, no recognized state claim, either statutory or common law, is precluded by the "by and in the name of the United States" language of 21 U.S.C. § 337(a). The Third Circuit Court of Appeals held that

> [r]efusing to entertain [a fraud on the FDA claim] solely because the statutory scheme does not contain a private cause of action would be the equivalent of finding preemption of state law claims contrary to the clear holding of *Lohr.*

In Re Orthopedic Bone Screw Liability Litigation, 159 F.3d 817, 825 (3d Cir. 1998). Further, plaintiffs may produce evidence of

alleged FDA violations to substantiate state law claims. *See Loewy v. Stuart Drug & Surgical Supply, Inc.*, No. 91 CIV. 7148, 1999 WL 216656, at *3 (S.D.N.Y. Apr. 14, 1999) (FDA violations may be offered as proof on state common law claim). However, plaintiffs are precluded by 21 U.S.C. § 337(a) from bringing a state claim "to redress alleged violations of the FCDA." *Summit Technology*, 922 F. Supp. at 305.

Plaintiffs also contend the trial court erred in granting summary judgment in favor of Danek, Warsaw, and Sofamor on plaintiffs' fraud claim.

> A defendant may show as a matter of law that [it] is entitled to summary judgment in [its] favor by showing that there is no genuine issue of material fact concerning an essential element of the plaintiff's claim for relief and that the plaintiff cannot prove the existence of that element.

Blue Ridge Sportcycle Co., v. Schroader, 60 N.C. App. 578, 580, 299 S.E.2d 303, 304 (1983) (citation omitted). "When a trial court considers a motion for summary judgment, 'the evidence is viewed in the light most favorable to the non-moving party.'" *Yates v. Haley*, 103 N.C. App. 604, 606, 406 S.E.2d 659, 660 (1991) (quoting *Hinson v. Hinson*, 80 N.C. App. 561, 563, 343 S.E.2d 266, 268 (1986)).

Plaintiffs alleged in Count I of their amended complaint that:

> 92. The FDA was ignorant of the fact that these devices and device components were intended by Danek for use as pedicle screw fixation devices.
>
> 93. Were it not for these fraudulent acts and statements, the FDA would not have issued 510(k) clearances for Danek's pedicle screw fixation devices and device components . . ., the devices would not have been introduced into interstate commerce, and the

Plaintiff would not have been exposed to the dangerous device . . . .

The elements of fraud are:

> "(1) [f]alse representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with the intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party."

Helms v. Holland, 124 N.C. App. 629, 634, 478 S.E.2d 513, 516 (1996) (quoting *Carver v. Roberts*, 78 N.C. App. 511, 513, 337 S.E.2d 126, 128 (1985)).

Careful review of the record reflects failure of the evidence upon an essential element of plaintiffs' claim, *i.e.*, that the FDA was in fact deceived. Plaintiffs assert that Danek misrepresented to the FDA the intended use of its plate and screw device and perpetrated this fraud, upon denial of its application for FDA approval of the ISF Luque II device for use in pedicles, by resubmitting identical components to the FDA for approved use in long or flat bones such as in pelvic, femoral condyle, and tibia plateau fractures. Plaintiffs conclude that as a result of

> the misrepresentations . . . regarding the intended use of the plates and screws, the FDA cleared these components as substantially equivalent to pre-amendment devices.

Even considered in the light most favorable to plaintiffs, the evidence, as opposed to plaintiffs' conclusory assertion, *see Morrison-Tiffin v. Hampton*, 117 N.C. App. 494, 505, 451 S.E.2d 650, 658, *disc. review denied*, 339 N.C. 739, 454 S.E.2d 654 (1995) (to defeat properly supported summary judgment motion, "facts, as distinguished from allegations," must be produced, and non-movant may not "rely on mere conjecture"), fails to raise a genuine issue of material fact as to whether the FDA was in fact deceived.

No evidence or testimony from FDA representatives indicated the agency was deceived by Danek's actions. Rather, it appears from the record that the FDA was aware Danek eventually intended the plate and screw system for use in pedicles. Indeed, the FDA in 1986 approved Danek's request to conduct clinical trials to "develop data on the safety and effectiveness of the Luque II device for pedicular fixation." No evidence was presented raising a genuine issue of material fact as to the deception element of plaintiffs' fraud claims, and summary judgment was therefore properly granted as to said claims.

Plaintiffs next assign error to the trial court's grant of summary judgment to Danek, Warsaw, Sofamor, St. Joseph's and Dr. Maxwell on the issue of negligence *per se*. Plaintiffs assert the foregoing defendants violated the FDCA and FDA regulations, which violations led to damages suffered by plaintiffs, thereby establishing a cause of action for negligence *per se*.

> A safety statute or a safety regulation having the force and effect of a statute creates a specific duty for the protection of others. . . . A member of the class intended to be protected by a statute or regulation who suffers harm proximately caused by its violation has a claim against the violator. . . .

Baldwin v. GTE South, Inc., 335 N.C. 544, 546, 439 S.E.2d 108, 109 (1994) (citations omitted).

In addressing plaintiffs' contention of negligence *per se*, we need look no further than the requirement for a causal relationship between the alleged regulatory violation by defendants and the injury alleged by plaintiffs. The record before us fails to reflect evidence raising a material fact as to the existence of such a relationship.

Plaintiffs' expert medical witness, Dr. Alois Gibson (Dr. Gibson), testified that the two devices used in Osburn's back appeared to have functioned properly. Dr. Gibson related that he knew of no failure of the devices and found "no indication that there was any misplacement." Dr. Gibson further stated that use of the devices did not cause Osburn's pain, and that the pain continued after removal of the devices.

During his testimony, Dr. Gibson offered the opinion that surgery probably should not have been performed upon Osburn. Specifically, he asserted, "I did not find any indications for the surgery." He observed that Osburn had "failed back syndrome" and explained that

> [a] person with a failed back syndrome is a person who has had multiple operations, continues to complain of pain, is disabled and may or may not have physical findings abnormal.

However, the issue of whether surgery was medically justified is not before us. The question is whether evidence presented to the trial court raised an issue of material fact as to whether the alleged violation of the FDCA and FDA regulations constituted the proximate cause of damages suffered by plaintiffs. At no time during his testimony did Dr. Gibson link the devices used in Osburn's back to the latter's ongoing problems which commenced with his work-related injury. The trial court did not err in its grant of summary judgment on the issue of negligence *per se*.

Plaintiffs further challenge the trial court’s entry of summary judgment in favor of Danek, Warsaw, and Sofamor on plaintiffs' claim of fraudulent marketing and promotion. Plaintiffs alleged in their amended complaint that

misrepresentations of the "safety and efficacy" of the devices were made to induce physicians to perform and patients to undergo pedicle screw fixation surgery involving the use of Danek's devices.

The foundation of plaintiffs' claim for fraudulent marketing and promotion was reliance by Dr. Maxwell and by plaintiffs upon alleged misrepresentations by Danek. Again, no record evidence raises an issue of material fact regarding such reliance either by Dr. Maxwell or by plaintiffs. Dr. Maxwell testified he contracted to "manufacture the ISF Luque system and the TSRH system" and that he "lectured with regard to the use of the ISF Luque system and TSRH system." Further, Dr. Maxwell submitted information to Danek as part of an investigational study on the ISF Luque II device to "prove its good points and expose any bad points."

Thus, rather than showing reliance by Dr. Maxwell on representations by Danek in his decision to use the ISF Luque II or TSRH devices in surgery, the record indicates Dr. Maxwell was an active participant in development of the device. No evidence shows plaintiffs relied on representations by Danek. The trial court did not err in granting summary judgment on plaintiffs' claim of fraudulent marketing and promotion.

In view of the foregoing disposition of plaintiffs' appeal of rejection of their claims either by the trial court on summary judgment or by the jury, it is unnecessary to address plaintiffs' claims of loss of consortium and punitive damages. Likewise, we do not discuss defendants' cross-assignments of error. As to plaintiffs' remaining assignments of error, we have carefully reviewed each and find them unfounded.

No error.

Judge WALKER concurs.

Judge MCGEE concurring in part and dissenting in part.

==========

Judge McGEE concurring in part and dissenting in part.

I respectfully dissent from the majority opinion's determination that the jury instructions on the issue of informed consent were proper.

Plaintiffs argued that Dr. Maxwell had a duty to inform them of the experimental nature of the devices used by Dr. Maxwell in Gregory Osburn's back surgery, and that the trial court erred in refusing to instruct the jury as to this duty.

As the majority states, the pertinent statute is N.C. Gen. Stat. § 90-21.13(a)(1) and (2). "Subsection (a)(2) establishes an objective standard to determine whether the patient would have obtained a general understanding of the procedures or treatments contemplated and of the usual and most frequent risks and hazards inherent in them." *Nelson v. Patrick*, 58 N.C. App. 546, 550, 293 S.E.2d 829, 832 (1982). In order to meet this standard, "the health care provider must impart enough information to permit a reasonable person to gain a 'general understanding' of both the treatment or procedure and the 'usual and most frequent risks and hazards' associated with the treatment." *Foard v. Jarman*, 326 N.C. 24, 27, 387 S.E.2d 162, 164 (1990).

However, in cases where the treatment or procedure is experimental, a health care provider's lack of knowledge of the ordinary risks may prevent the health care provider from fully

informing the patient. In *Estrada v. Jaques*, 70 N.C. App. 627, 649, 321 S.E.2d 240, 254 (1984), our Court held

> that where the health care provider offers an experimental procedure or treatment to a patient, the health care provider has a duty, in exercising reasonable care under the circumstances, to inform the patient of the experimental nature of the proposed procedure. With experimental procedures the "most frequent risks and hazards" will remain unknown until the procedure becomes established. If the health care provider has a duty to inform of *known* risks for *established* procedures, common sense and the purposes of the statute [G.S. 90-21.13] equally require that the health care provider inform the patient of any *uncertainty* regarding the risks associated with *experimental* procedures. This includes the experimental nature of the procedure and the *known or projected most likely risks*.

As noted in *Estrada,* "[o]ne federal court has explicitly established such a rule, that the patient 'must always be fully informed of the *experimental nature* of the treatment *and* of the foreseeable consequences of that treatment.'" *Id.,* citing *Ahern v. Veterans Admin.,* 537 F. 2d 1098, 1102 (10th Cir. 1976).

Plaintiffs' attorney filed a written request for a jury instruction that "the health care provider has a duty, in exercising reasonable care under the circumstances, to inform the patient of the experimental nature of the proposed procedure." Plaintiffs' attorney again presented the request for special jury instructions during the charge conference. The trial court declined to apply the rule in *Estrada,* stating that the duty of a physician to inform patients that a device is experimental is not the standard of care under N.C. Gen. Stat. § 90-21.13.

"It is well established that when a party aptly tenders a written request for a specific instruction which is correct in itself and supported by the evidence, the failure of the court to give the instruction, at least in substance, is reversible error."

Indiana Lumbermen's Mutual Ins. Co. v. Champion, 80 N.C. App. 370, 379, 343 S.E.2d 15, 20-21 (1986) (citations omitted). The instruction requested by plaintiffs was a correct statement of the law as set forth in *Estrada*. *Estrada* establishes that a health care provider has a duty to inform patients of the experimental nature of a procedure. Further, there is substantial evidence in the record to support such an instruction, including: testimony that during 1991-1993 pedicle screw implants were investigational and had not received approval by the FDA; evidence that Dr. Maxwell contributed to an investigation by Sofamor Danek which was being submitted to the FDA; statements from the FDA to Danek requiring that patients be informed of the experimental nature of the ISF Luque and TSRH devices; and testimony that the concept of the pedicle screw and plate is new in its application to the spine.

I am not saying that a health care provider must inform the patient of the FDA classification or status of a device, an issue discussed by defendants Keith M. Maxwell, M.D. and Keith M. Maxwell, M.D., P.A. As stated by a Pennsylvania court, "the FDA does not regulate the practice of medicine" and "a physician . . . is generally free to use a medical device in a manner different from that for which the FDA has approved the device for commercial sale, *i.e.*, an 'off-label' use." *Southard v. Temple University Hospital*, 731 A.2d 603 (Pa. Super. 1999). However, the FDA classification or status is evidence in determining whether a device is experimental. After reviewing all of the evidence, and after proper instruction by the trial court as to a physician's

duty to inform a patient of the experimental nature of the device, it was for the jury to decide whether this device was experimental and whether defendants Keith M. Maxwell, M.D. and Keith M. Maxwell, M.D., P.A. breached their duty to plaintiffs.

Since plaintiffs' request for jury instruction was correct in the law and supported by the evidence, it was reversible error for the trial court to refuse to give the requested instruction. Plaintiff is entitled to a new trial against Keith M. Maxwell, M.D. and Keith M. Maxwell, M.D., P.A. on the question of informed consent. This determination also reopens the questions of loss of consortium and punitive damages as to these defendants, and these issues should be remanded for trial.