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Cecil Crowson, Jr.
Appellate Court Clerk

IN THE SUPREME COURT OF TENNESSEE
AT NASHVILLE

FOR PUBLICATION

Filed: March 13, 2000

RHONDA S. BRYANT, and husband, NATHAN G. BRYANT,	)	
PLAINTIFFS/APPELLANTS,	)	DAVIDSON CIRCUIT NO. 96C-1013
v.	)	Hon. Walter C. Kurtz, Judge
HCA HEALTH SERVICES OF TENNESSEE, INC., d/b/a CENTENNIAL MEDICAL CENTER,	)	NO. M1998-00770-SC-R11-CV
DEFENDANT/APPELLEE.	)	

FOR APPELLANTS:

CHARLES J. WILLIAMS
JOHN B. CARLSON
Nashville

G. THOMAS NEBEL
Nashville

FOR APPELLEE:

C. J. GIDEON, JR.
MARGARET MOORE
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O P I N I O N

COURT OF APPEALS AFFIRMED

HOLDER, J.

OPINION

We granted this appeal to address whether a hospital has a legal duty to obtain the informed consent of a patient undergoing a surgical procedure ordered and performed by a non-employee doctor. We hold that Tenn. Code Ann. § 29-26-118 does not require a hospital to obtain the informed consent of a patient. A hospital, however, may assume an independent legal duty to obtain informed consent under certain circumstances not present in this case. The trial court's grant of the defendant's motion for summary judgment is affirmed, and the case is remanded.

FACTS

The plaintiff, Rhonda Bryant, sustained a back injury as the result of an automobile accident in 1979. She was diagnosed as having four fractured vertebrae. She returned to her normal activities without restrictions approximately nine months after the accident. She later developed kyphosis, or curvature of her spine. Doctors informed her that she might eventually need a surgical procedure during the 1980s to correct the curvature.

Ms. Bryant was involved in another automobile accident in 1992. The 1992 accident aggravated her previous spinal injury. She suffered persistent back pain and was referred to Dr. Stephen McLaughlin, an orthopedic surgeon. Dr. McLaughlin diagnosed Ms. Bryant as having kyphosis. He then referred her to Dr. David McCord.

Dr. McCord met with Ms. Bryant at his office and ordered studies on her back. Both an MRI and a CT scan revealed a moderate compression fracture, mild stenosis, and exaggerated kyphosis. Dr. McCord recommended to Ms.

Bryant that she undergo surgery to correct her kyphosis. He proposed the implantation of rods, screws, and plates.

The procedure proposed by Dr. McCord was apparently less invasive than the surgical procedures discussed with Ms. Bryant during the 1980s. Dr. McCord did not guarantee the results of the surgery. He informed Ms. Bryant that the curvature could worsen should she elect not to have the surgery. He conveyed to Ms. Bryant a high likelihood that the surgery would be successful and that she would be able to return to work six months after the surgery. Dr. McCord also informed Ms. Bryant that if the procedure were unsuccessful, she would have to undergo a second, more invasive procedure.

Ms. Bryant elected to undergo surgery. Dr. McCord's office provided her a consent form entitled "What to Expect from Back Surgery." The form outlined numerous complications that could result from having back surgery. Ms. Bryant signed and returned the form to Dr. McCord.

Dr. McCord admitted Ms. Bryant to the defendant hospital, Centennial Medical Center, on May 2, 1993. Dr. McCord was not an employee of the defendant. On May 3, he performed back surgery on Ms. Bryant. During this surgery he implanted pedicle screws. Neither a Brantigan Cage nor a custom carbon fiber cage was implanted in 1993.

Ms. Bryant's condition worsened following the implantation of the pedicle screws. Dr. McCord recommended a second, more invasive surgery to Ms. Bryant. This procedure involved entering Ms. Bryant's chest cavity, removing rods, replacing screws, and implanting a bone cage. Ms. Bryant signed a consent form which provided that she agreed to participate in a research study involving the implantation of a Brantigan I/F cage.

Dr. McCord admitted Ms. Bryant to the defendant hospital in February of 1994. On February 21, he installed both a carbon fiber cage and pedicle screws into her spine. Ms. Bryant continued experiencing severe pain following the second surgery. She eventually had to have a morphine pump installed into her body, and she underwent additional surgery.

The plaintiffs, Rhonda S. Bryant and Nathan G. Bryant, filed an action against a variety of defendants including the defendant hospital, Centennial Medical Center. Pertinent to the issue now before us, the plaintiffs have alleged: that the defendant hospital failed to "warn plaintiffs that the FDA had specifically rejected the pedicle or back screws and/or plates (and other hardware) for implantation in the spine;" that the defendant hospital failed to "warn plaintiff that the pedicle screw devices, cages and hardware implanted in her spine . . . were experimental . . . ;" that the defendant hospital failed to "supply the appropriate information to the plaintiff in obtaining his [sic] informed consent;" and that the defendant hospital failed "to insure that the doctor obtained the appropriate informed consent from the plaintiff . . . ." The trial court granted the defendant summary judgment on the issue of informed consent. The Court of Appeals held that the hospital did not have a duty to obtain Ms. Bryant's informed consent and affirmed the grant of summary judgment with respect to the issue of informed consent.

ANALYSIS

We granted review to address whether a hospital owes a general duty to obtain the informed consent of a patient undergoing a surgical procedure ordered and performed by a non-employee doctor. The issue is one of first impression in Tennessee.[1]

[1]The vast majority of jurisdictions having previously addressed this issue have declined to impose upon a hospital the general duty to obtain informed consent. Krane v. Saint Anthony Hosp. Sys., 738 P.2d 75 (Colo. App. 1987); Petriello v. Kalman, 576 A.2d 474 (Conn. 1990); Parr (continued...)

The plaintiffs' informed consent claim is predicated upon a theory of battery. Blanchard v. Kellum, 975 S.W.2d 522, 524 (Tenn. 1998); see also Cardwell v. Bechtol, 724 S.W.2d 739, 750 (Tenn. 1987) (holding that failure to comply with standard of care when obtaining informed consent constitutes battery). The existence of a legal basis upon which an actionable battery may be predicated in the case now before us is both a question of law and a matter of statutory interpretation. The plaintiffs have urged this Court to consider expert testimony when defining the legal basis for their claim. The proffered expert testimony opines that:

> the recognized standard of care of acceptable professional practice in Nashville for hospitals required [the defendant] to provide appropriate information on material risks concerning spinal surgery involving the use of pedicle screws.

This testimony, however, pertains only to an element of an informed consent battery claim, the standard of care. While expert testimony may define the standard of care, expert testimony neither defines nor creates a legal right to pursue a remedy.

The plaintiffs first must allege a cognizable legal claim to which relief may be granted. If a legal basis for the suit exists, the proffered expert testimony may then be introduced to establish the elements of the claim. Our initial focus in this appeal is whether the plaintiffs are entitled to legal protection if the defendant had acted in a manner consistent with the plaintiffs' allegations.

The claim against the defendant hospital involves matters of medical science and requires specialized skills not ordinarily possessed by lay persons.

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[1](...continued)
v. Palmyra Park Hosp., 228 S.E.2d 596 (Ga. App. 1976); Pickle v. Curns, 435 N.E.2d 877 (Ill. App. 1982); Pauscher v. Iowa Methodist Med. Ctr., 408 N.W.2d 355 (Iowa 1987); Ackerman v. Lerwick, 676 S.W.2d 318 (Mo. App. 1984); Bing v. Thunig, 143 N.E.2d 3 (N.Y. 1957); Kershaw v. Reichert, 445 N.W.2d 16 (N.D. 1989); Goss v. Oklahoma Blood Inst., 856 P.2d 998 (Ok. App. 1990); Ritter v. Delaney, 790 S.W.2d 29 (Tex. App. 1990); Cross v. Trapp, 294 S.E.2d 446 (W. Va. 1982).

See generally Peete v. Shelby County Health Care Corp., 938 S.W.2d 693 (Tenn. Ct. App. 1996). Accordingly, the defendant is within the purview of the Medical Malpractice Act ("Act"), and the plaintiffs' claims are governed by that Act. See Tenn. Code Ann. §§ 29-26-115 –120 (1980 & 1997 Supp.). The Act provides for a medical malpractice cause of action based on the inadequacy of a patient's consent to a medical procedure. See Tenn. Code Ann. § 29-26-118. The "informed consent" statute is codified at Tenn. Code Ann. § 29-26-118 and provides:

> In a malpractice action, the plaintiff shall prove by evidence as required by § 29-26-115(b) that the defendant did not supply appropriate information to the patient in obtaining his informed consent (to the procedure out of which plaintiff's claim allegedly arose) in accordance with the recognized standard of acceptable professional practice in the profession and in the speciality, if any, that the defendant practices in the community in which he practices and in similar communities.

We must now address whether § 29-26-118 may be applicable to a hospital when a non-employee physician performs a surgical procedure.

The construction of a statute is a question of law that appellate courts review de novo and without a presumption of correctness. Myint v. Allstate Ins. Co., 970 S.W.2d 920, 924 (Tenn. 1998). The cardinal rule of statutory construction is to effectuate legislative intent. Id.; Locust v. State, 912 S.W.2d 716, 718 (Tenn. Ct. App. 1995). Courts shall assume that the legislature purposely inserted each word into a statute and that each word conveys intent, has meaning, and has purpose. Id. Where words of the statute are clear and fully express the legislature's intent, there is no room to resort to auxiliary rules of construction. Roberson v. University of Tennessee, 912 S.W.2d 746, 747 (Tenn. Ct. App. 1995). Accordingly, the interpretation of an unambiguous statute shall be restricted to the natural and ordinary meaning of the language employed by the legislature. Austin v. Memphis Pub. Co., 655 S.W.2d 146, 148 (Tenn. 1983). If, however, a statute is ambiguous, we must consider the language employed in

context of the entire statute without any forced or subtle construction which would extend or limit its meaning. Wilson v. Johnson County, 879 S.W.2d 807, 809 (Tenn. 1994). A statute is ambiguous if the statute is capable of conveying more than one meaning. In re Conservatorship of Clayton, 914 S.W.2d 84, 90 (Tenn. Ct. App. 1995).

The informed consent statute does not clearly delineate whether hospitals have a duty to procure informed consent to surgical procedures performed by non-employee doctors. The statute employs the term "defendant" when defining the elements of an informed consent cause of action. See Tenn. Code Ann. § 29-26-118 ("the defendant did not supply appropriate information to the patient . . . ."). The term "defendant" would, at first blush, seemingly include a hospital. The term "defendant" would also seem to include: pharmacists, registered nurses, physician's assistants, nurse anesthetists, anesthetists, emergency medical technicians, or any other person or entity that may commit an act of medical negligence.

The statute requires that the "defendant" provide "information" in "accordance with the . . . specialty, if any, that the defendant practices . . . ." Tenn. Code Ann. § 29- 26-118. A hospital does not *practice* the specialties of non-employee physicians. Moreover, a hospital "shall not restrict or interfere with medically appropriate diagnostic or treatment decisions." Tenn. Code Ann. § 63-6-204(d)(1)(A). Accordingly, the language of the statute suggests that the legal duty to obtain consent is imposed only on the physician who orders or directs the surgical procedure. An interpretation requiring the hospital to provide "information" in "accordance with the . . . specialty, if any, that the [surgeon] practices . . . ." potentially renders absurd results. Such a broad interpretation would seemingly impose a similar duty upon registered nurses, medical technicians, or other health-care providers involved in the patient's care to

procure a patient's consent prior to a surgical procedure. An overly broad interpretation, therefore, could interfere with the physician-patient relationship.

Informed consent is predicated on a theory of battery. See generally Cardwell v. Bechtol, 724 S.W.2d 739, 750-51 (Tenn. 1987). The statute protects a patient from a physician who commits a battery when performing a procedure without legally sufficient consent. See generally id. A hospital usually provides a staffed facility in which a non-employee physician may perform a procedure. A hospital, however, does not perform the surgical procedure merely as a by-product of the non-employee physician's use of the hospital facilities. Accordingly, it is the non-employee physician and not the hospital who commits the battery when a surgical procedure is performed without legally effective consent.

We believe that Tenn. Code Ann. § 29-26-118 focuses on the physician ordering the surgical procedure. Mere status as one involved in a patient's care is insufficient to trigger a statutory duty under the informed consent statute. We hold that Tenn. Code Ann. § 29-26-118 generally does not require a hospital to procure a patient's informed consent to surgical procedures ordered and performed by non-employee doctors.

In the case now before us, Dr. McCord was neither an agent nor an employee of the defendant hospital during the time frame in question. He was an independent medical practitioner utilizing the defendant's facilities to perform a surgical procedure on Ms. Bryant. Dr. McCord ordered and performed the surgical procedure in question. Pursuant to Tenn. Code Ann. § 29-26-118, Dr. McCord and not the defendant was required to obtain Ms. Bryant's informed consent for the surgical procedure.

INDEPENDENT LEGAL DUTY

The plaintiff argues that the defendant assumed an independent duty to procure her informed consent by participating in a monitored investigational study involving implantation of pedicle screws. We disagree.

A hospital may assume "an independent duty which it would not ordinarily bear" with regard to informed consent by participating in a clinical study monitored by the Federal Drug Administration ("FDA"). Watkins v. Hospital of the University of Penn., 737 A.2d 263, 268 (Pa. Super. Ct. 1999). In Friter v. Iolab Corp., 607 A.2d 1111 (Pa. Super. Ct. 1992), the hospital was participating in an investigational clinical study monitored by the FDA. As a participant in the study, the hospital was required by federal regulations to obtain informed consent from any patient undergoing the experimental treatment. The court in Friter "found an exception to the general rule that there is no independent duty for a non-physician to obtain a patient's informed consent." Watkins, 737 A.2d at 268.

Similarly, in Kus v. Sherman Hosp., 644 N.E.2d 1214 (Ill. App. 1995), the hospital was involved in a monitored clinical study for the implantation of intraocular lens. The implantation of intraocular lens into human subjects was permitted only under the Medical Device Amendments ("MDA") of 1976 exemption for experimental devices. See generally 21 U.S.C. § 301, et seq. (1988). Pursuant to federal regulations, the internal review board of the defendant hospital was charged with the responsibility of assuring that "legally effective informed consent [was] obtained." Kus, 644 N.E.2d at 1216. Moreover, the federal regulations mandated that certain disclosures be provided to patients involved in the study. In Kus, the court held that the hospital had an independent duty to obtain the informed consent of patients receiving implantation of

intraocular lens permitted under the federal investigational exemption. Id. at 1219-1222.

In the case now before us, Dr. McCord was involved in a clinical study involving the use of pedicle screws in conjunction with an I/F Brantigan Cage. This study was monitored by the defendant hospital's Institutional Review Board. Ms. Bryant, however, concedes that she was "never the subject to [*sic*] a research study that was monitored and reviewed by [the defendant's Institutional Review Board] and a Brantigan I/F Cage was not utilized in her surgery."

Unlike the implantation of the introcular lens in both Friter and Kus, the pedicle screws were not implanted into Ms. Bryant under the MDA exemption for experimental devices. Pedicle screws were approved for off-label uses prior to Ms. Bryant's surgery. See Femrite v. Abbott Northwestern Hosp., 568 N.W.2d 535, 541 (Minn. Ct. App. 1997) (noting pedicle screws approved for off-label use in 1986). The plaintiff has not demonstrated that this off-label use was subject to the federal study or mandatory monitoring. The defendant, therefore, was not required by federal regulations to obtain Ms. Bryant's informed consent.

CONCLUSION

We hold that a hospital generally is not required to procure a patient's informed consent to surgical procedures ordered and performed by non-employee doctors. The hospital, however, may assume an independent legal duty to obtain the informed consent of a patient undergoing a procedure that is a part of an investigational study monitored by the FDA. The requisite circumstances necessary to impose this independent legal duty upon the hospital have not been met by the facts presented in this appeal. The trial court's grant of summary judgment for the defendant on this issue of informed consent is affirmed. The case is remanded for further proceedings consistent

with this opinion. The costs of this appeal shall be taxed against the plaintiffs for which execution may issue if necessary.

JANICE M. HOLDER, JUSTICE

Concurring:

Anderson, C.J.
Birch, and Barker, J.J.

Drowota, J., Not Participating