IN THE COURT OF APPEALS OF TENNESSEE
AT NASHVILLE
January 5, 2010 Session

SANDRA YEVETTE TURNER AS NEXT FRIEND, NEXT OF KIN, NATURAL MOTHER & PERSONAL REPRESENTATIVE OF JESSICA JOVAN TURNER, DECEASED v. STERILTEK, INC. ET AL.

Appeal from the Circuit Court for Davidson County
No. 03C-1977 Barbara N. Haynes, Judge

No. M2009-00325-COA-R3-CV - Filed March 3, 2010

Mother of deceased patient brought suit for ordinary negligence and medical malpractice against hospital and company that sterilized its surgical instruments and equipment. In this second appeal, the issue is whether the trial court erred in granting summary judgment in favor of both defendants. We conclude that the trial court properly granted summary judgment as to the sterilization company, but we reverse the grant of summary judgment as to the hospital because the hospital failed to negate an element of the plaintiff's negligence claim.

Tenn. R. App. P. 3 Appeal as of Right; Judgment of the Circuit Court Affirmed in Part, Reversed in Part

ANDY D. BENNETT, J., delivered the opinion of the Court, in which HERSCHEL P. FRANKS, P.J., and PATRICIA J. COTTRELL, P.J., M.S., joined.

W.H. Stephenson, II and Michael D. Noel, Nashville, Tennessee, for the appellant, Sandra Yevette Turner.

J. Cole Dowsley, Jr., Thomas I. Carlton, Jr., and Jay N. Chamness, Nashville, Tennessee, for the appellee, Steriltek, Inc.

Erin Palmer Polly, Nashville, Tennessee, for the appellee, Vanderbilt University d/b/a Vanderbilt University Medical Center.

OPINION

FACTUAL AND PROCEDURAL BACKGROUND

Facts

As this is the second appeal in this case, we will adopt the factual summary included in the previous opinion of this court:

> After complaining of pain and loss of function in her left knee, in February 2002, Jessica Turner ("Jessica") underwent arthroscopic knee surgery. She had continuing post-operative difficulities and was re-examined with a CT scan. Ultimately, Jessica was diagnosed with osteosarcoma–a type of bone cancer–of the left distal femur.
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> Left untreated, osteosarcoma can result in amputation of the affected limb. To avoid amputation, Jessica's physicians scheduled her for a surgical procedure in which she would undergo a tumor resection, a total knee arthroplasty, and receive a prosthetic femur. The procedure was to be performed by . . . Herbert Schwartz, M.D. ("Dr. Schwartz"), with . . . Ed Glenn, M.D. ("Dr. Glenn") assisting. The surgery was to be performed at . . . Vanderbilt University Medical Center ("Vanderbilt"), and was scheduled for July 12, 2002 . . . .
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> Vanderbilt had contracted with . . . Steriltek, Inc. ("Steriltek") to provide surgical instruments, which were sterilized off-site, to Vanderbilt. The instrument sterilization process at Steriltek is complex and involves several steps. The process begins when the instruments and batteries are brought to Steriltek's facility and unloaded in a decontamination area. They are decontaminated and sent through a washing machine. They are then reassembled and packaged in preparation for sterilization.
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> The packaged instruments are first wrapped in a polypropylene wrap and sealed with a chemical indicator tape. Inside each wrap is a chemical indicator strip. Both the tape and the strip change colors to indicate exposure to the sterilant, which in this case was hydrogen peroxide gas. Immediately after the sterilization process, the chemical indicator tape that seals the wrap is observed for a change in color. In contrast, the chemical indicator strip is not observed until the wrap is opened at the point of use.

The wrapped instruments go through several sterilization cycles. During this process, the sterilization machine tracks the parameters of each cycle, indicating pressure readings and the duration of each cycle. These parameters are printed out on mechanical tape at the completion of the process.

As additional confirmation that the instruments and batteries are sterilized, Steriltek performs a biological test on each load. The biological test is performed by placing a biological test pack inside the sterilizer with the instruments. The test then determines whether the sterilant killed certain microorganisms present in the biological test pack. For a period of forty-eight hours after the sterilization process, the biological test pack is monitored to confirm that the sterilization process was effective.

Steriltek provided the sterilization services on the instruments and batteries for Jessica's surgery. These batteries and instruments were delivered to Vanderbilt well before expiration of the 48-hour period required to confirm effective sterilization.

On the date of the surgery, July 12, 2002, Kevin Allen ("Allen"), a registered nurse and site director for Steriltek's sterilization facility, received a report that a July 10, 2002 biological test on some surgical instruments and batteries resulted in bacterial growth, indicating that the instruments and batteries in that load might not be sterile. Some of these were to go to Vanderbilt, so Allen went to Vanderbilt to retrieve the potentially-contaminated instruments. He learned that some of the instruments and batteries being used in Jessica's surgery were part of the potentially contaminated load.

Allen then advised Dr. Schwartz of the problem. At that time, Jessica's tumor resection was complete, but the other procedures had not been performed. After receiving this information, Dr. Schwartz decided to abort the surgery at that point and wait to insert the arthroplasty and prosthetic femur. In order to stabilize Jessica's knee during the interim, Dr. Schwartz had to create a cement spacer, which was impregnated with antibiotics, that he inserted to replace the part of the femur that he had already removed.

On September 20, 2002, Jessica returned to Vanderbilt for the remainder of the surgery. At that time, Dr. Schwartz successfully completed the surgical procedures originally planned. Unfortunately, at some point later, Jessica died.

Turner v. Steriltek, Inc., No. M2006-01816-COA-R3-CV, 2007 WL 4523157, at *1-2 (Tenn. Ct. App. Dec. 20, 2007).

In July 2003, Jessica's mother and personal representative, Sandra Yevette Turner, filed suit against Steriltek, Vanderbilt, Dr. Schwartz, and Dr. Glenn. The complaint includes multiple claims of ordinary negligence and medical malpractice. Ms. Turner alleged that Steriltek was negligent in failing to provide sterilized instruments and in "failing to warn, prior to the surgical procedure, that the equipment and/or instrumentation was contaminated, unsterile, and unsafe to use." She further alleged that Steriltek breached its contract with Vanderbilt and thereby breached its obligations to her as a third-party beneficiary of the contract. As to Vanderbilt, Ms. Turner alleged that the hospital "negligently failed to have in place a system of proper surgical protocols, procedures, and measures to assure that surgical instrumentation was clean, sterile, and in a safe condition suitable prior to its actual use during the course of surgery."

Vanderbilt and the individual physicians filed a motion for summary judgment in December 2004. The motion was accompanied by an expert affidavit from Dr. Schwartz, who opined that he, Dr. Glenn, and Vanderbilt "complied with the recognized standard of acceptable medical practice in Nashville, Tennessee at the time the care and treatment was rendered," that they "acted with ordinary and reasonable care" in providing care to Jessica, and that their actions were not the proximate cause of any injuries to Jessica. The plaintiff responded but did not submit expert proof. In a September 2005 order, the court granted the motion for summary judgment in favor of the Vanderbilt defendants but allowed plaintiff's counsel time to depose the scrub nurse and the circulating nurse to gain evidence in support of a motion to reconsider. The court denied the plaintiff's motion to reconsider in July 2006.

Steriltek filed its own motion for summary judgment in March 2006 with an affidavit of Allen as an expert on Steriltek's sterilization processes. Allen opined that the instruments used in Jessica's surgery were, in fact, properly sterilized and that the biological test results were a false positive. The plaintiff opposed Steriltek's motion for summary judgment but submitted no expert proof. In June 2006, the court granted Steriltek's motion for summary judgment.

Prior Appellate Decision

On appeal, this court discussed the distinction between ordinary negligence and medical malpractice and examined the claims made against each of the defendants to determine whether expert proof was required. *Turner v. Steriltek, Inc.*, 2007 WL 4523157, at *4-5. We affirmed the summary judgments in favor of Dr. Schwartz and Dr. Glenn and against the hospital on the basis of vicarious liability for the actions of the physicians. *Id.* at

*5-6. We determined that summary judgment was improper as to the claim that Vanderbilt was negligent in failing to use appropriate protocols and procedures to assure the proper sterilization of instruments, stating that, "Because Vanderbilt provided no evidence on the issue of the adequacy of its procedures for providing sterilized instruments, Vanderbilt failed to establish the absence of a genuine dispute on this material fact." *Id.* at *8.

With respect to Steriltek, we determined that summary judgment was appropriate on the claim for failure to provide instruments and batteries that were properly sterilized. *Id.* at *9. We likewise found summary judgment proper on the plaintiff's claim as a third-party beneficiary of the contract between Steriltek and Vanderbilt. *Id.* at *10. As to the allegations that Steriltek failed to warn Vanderbilt that the instruments would not be safe to use until the 48-hour biological test had been completed, however, summary judgment was not proper. *Id*. Steriltek's supporting affidavit did not address the failure to warn. *Id.*

Remand

On remand, Vanderbilt filed a motion for summary judgment supported by an affidavit of Michael J. Hughes, RN, BSN, MA, CNOR, its assistant administrative director of surgical support services. After a hearing in late October 2008, the trial court ruled that Vanderbilt's motion for summary judgment was well taken and granted the motion, but the court also stated that its order would not become final immediately. The plaintiff was given 30 days within which to depose Hughes and to submit an expert affidavit to support her claim. The plaintiff deposed Hughes and filed a motion to reconsider. In a January 2009 order, the trial court noted that "Plaintiff failed to submit to the Court an expert affidavit to support her claim against Vanderbilt." The court granted Vanderbilt's motion for summary judgment and denied the plaintiff's motion to reconsider.

Steriltek filed a motion for summary judgment in February 2009 along with a supplemental affidavit from Allen. The court granted Steriltek's motion for summary judgment.

In this appeal, we must determine whether the trial court properly granted summary judgment in favor of Vanderbilt and Steriltek.

STANDARD OF REVIEW

In reviewing a summary judgment, this court must make a fresh determination that the requirements of Tenn. R. Civ. P. 56 have been satisfied. *Hunter v. Brown*, 955 S.W.2d 49, 50 (Tenn. 1997). The party seeking summary judgment bears the burden of demonstrating that no genuine disputes of material fact exist and that the party is entitled to judgment as a

matter of law. *Godfrey v. Ruiz*, 90 S.W.3d 692, 695 (Tenn. 2002). We must take the strongest legitimate view of the evidence in favor of the nonmoving party, allow all reasonable inferences in favor of that party, and discard all countervailing evidence. *Id.*; *Byrd v. Hall*, 847 S.W.2d 208, 210-11 (Tenn. 1993). If there is a dispute as to any material fact or if there is any doubt as to the existence of a material fact, summary judgment cannot be granted. *Byrd*, 847 S.W.2d at 211; *EVCO Corp. v. Ross*, 528 S.W.2d 20, 25 (Tenn. 1975). To shift the burden of production to the nonmoving party who bears the burden of proof at trial, a moving party must negate an element of the opposing party's claim or "show that the monmoving party cannot prove an essential element of the claim at trial." *Hannan v. Alltel Publ'g Co.*, 270 S.W.3d 1, 9 (Tenn. 2008).

ANALYSIS

In this second appeal, we must determine whether the trial court properly granted summary judgment in favor of Vanderbilt regarding the plaintiff's remaining claim that the hospital should have implemented a policy or procedure to quarantine equipment and instruments for 48 hours after sterilization. As to Steriltek, we must determine whether the trial court properly granted summary judgment regarding the plaintiff's claim that Steriltek should have warned Vanderbilt that there was a risk that the instruments and batteries were not safe if used prior to the expiration of the 48-hour period following sterilization. As was discussed in the previous appeal, both of these claims are for ordinary negligence, not medical malpractice. *Turner v. Steriltek, Inc.*, 2007 WL 4523157, at *8-9.

Vanderbilt

In a cause of action for negligence, a plaintiff must establish five elements: "a duty of care owed by the defendant to the plaintiff," "conduct falling below the applicable standard of care amounting to a breach of that duty," injury or loss, cause in fact, and proximate cause. *McClenahan v. Cooley*, 806 S.W.2d 767, 774 (Tenn. 1991). In this case, we believe the disputed element to be breach of the duty of care. Vanderbilt does not appear to dispute that it has a duty to use reasonable care to insure the proper sterilization of its instruments and equipment.

The question of whether there has been a breach of the duty of care is an issue to be determined by a jury. *See West v. E. Tenn. Pioneer Oil Co.*, 172 S.W.3d 545, 552 (Tenn. 2005). Summary judgment is appropriate only when "the facts and conclusions to be drawn therefrom permit a reasonable person to reach only one conclusion." *Id.* at 550 (quoting *Seavers v. Methodist Med. Ctr. of Oak Ridge*, 9 S.W.3d 86, 91 (Tenn. 1999)). We must determine whether Vanderbilt shifted the burden of production to the plaintiff by presenting

evidence sufficient to negate the element of a breach of the standard of care with respect to its sterilization protocols and procedures.

Vanderbilt asserts that it presented expert testimony from Hughes sufficient to establish that its sterilization policies and procedures complied with the appropriate standard of care. Hughes served as Vanderbilt's Assistant Administrative Director, Surgical Support Services, and was responsible for the sterilization systems used at the hospital. Hughes's affidavit contains the following pertinent statements:

> I am familiar with appropriate policies and procedures governing the sterile processing of surgical instruments. I make this Affidavit based on a review of the applicable sterile processing policies in effect at Vanderbilt on the date of Jessica Turner's July 12, 2002 surgery, along with my personal knowledge, education, experience, and training.
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> . . . .
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> On July 12, 2002, Vanderbilt had in effect a Sterrad Sterilizer Policy and a Sterilizers: Quality Control of Loads Policy. Neither Policy required Vanderbilt to quarantine for any amount of time medical instruments or equipment sterilized via Sterrad. Rather, medical personnel could utilize medical equipment and instruments immediately upon completion of sterilization via Sterrad.
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> On July 12, 2002, standard procedure did not require medical personnel to quarantine for any amount of time medical equipment or instruments sterilized via Sterrad. Rather, standard procedure held that medical personnel could utilize medical equipment and instruments immediately upon completion of sterilization via Sterrad.
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> Despite my contact with several other medical facilities, I know of no other medical facility that upholds a policy or procedure requiring medical personnel to quarantine for any amount of time medical equipment or instruments sterilized via Sterrad. Rather, these medical facilities permit medical personnel to utilize medical equipment and instruments immediately upon completion of sterilization via Sterrad.

Hughes's expert credentials were not challenged by the plaintiff, and Vanderbilt takes the position that Hughes's testimony effectively establishes that the hospital's actions complied with the appropriate standard of care.

Were this a case of medical malpractice, Vanderbilt's position would likely have merit because in medical malpractice cases expert testimony from a qualified medical professional can establish the applicable standard of care and the absence of any breach of that standard of care. *See* Tenn. Code Ann. § 29-26-115. As we previously stated, however, the claims at issue here are not for medical malpractice. *Turner v. Steriltek, Inc.*, 2007 WL 4523157, at *8-9. The plaintiff's remaining claim against Vanderbilt is for ordinary negligence, and evidence concerning "standard practice" does not conclusively establish that the hospital acted in accordance with the standard of reasonable care. The relevant question is whether Vanderbilt's policy--putting medical instruments and equipment back into use immediately upon receiving them from Steriltek--constituted reasonable care under the circumstances. *See Ferguson v. Nationwide Prop. & Cas. Ins. Co.*, 218 S.W.3d 42, 58 (Tenn. Ct. App. 2006).

We cannot say that the evidence presented by Vanderbilt effectively negated the existence of a breach of the duty of care, thereby shifting the burden of production to the plaintiff. The affidavit of Hughes does not bolster the reasonableness of Vanderbilt's policy of using sterilized instruments before the 48-hour biological tests were complete. Rather, Hughes merely states that other hospitals use the same type of protocol. There is no proof concerning statistical probabilities of infection using the current protocol or the relative costs and benefits of quarantining instruments for 48 hours after the first two steps of the sterilization process. As the plaintiff points out, Hughes testified in his deposition that all three parts of the Sterrad process were important to insuring proper sterilization, that surgery should not be performed if there is a question as to the sterility of instruments, and that proceeding to surgery before receiving the 48-hour test results meant there was a risk that contaminated instruments would be used. In short, there remain factual questions as to the reasonableness of the protocol used by Vanderbilt to insure the sterilization of its instruments.

In the previous decision of this court, we reversed the grant of summary judgment in favor of Vanderbilt as to its alleged failure to have a system to assure adequate sterilization of instruments and equipment based upon the following reasoning: "Because Vanderbilt provided no evidence on the issue of the adequacy of its procedures for providing sterilized instruments, Vanderbilt failed to establish the absence of a genuine dispute on this material fact." *Turner v. Steriltek, Inc.*, 2007 WL 4523157, at *8. In this appeal, we have concluded that the trial court erred in granting Vanderbilt's motion for summary judgment because the hospital has again failed to produce any evidence concerning the adequacy of its sterilization procedures.

Steriltek

The plaintiff's remaining claim against Steriltek is that the company was negligent in failing to warn Vanderbilt that there was a risk of contamination when using instruments or equipment before the expiration of the 48-hour test period.[1]

Based upon the undisputed facts in the record, we conclude that the trial court properly granted summary judgment in favor of Steriltek. Under the contract between Steriltek and Vanderbilt, Steriltek was obligated to return all sterilized items to the hospital facility within eight hours of their pick-up from the hospital facility. Moreover, there is no dispute that Vanderbilt itself used the same three-step Sterrad process for sterilizing some of its instruments itself at the hospital. We know of no authority or reasoning that would require someone to warn another of a risk about which the other was already aware.

Costs of appeal are assessed against Vanderbilt, for which execution may issue if necessary.

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ANDY D. BENNETT, JUDGE

[1] Although the plaintiff's brief mentions a duty to warn the patient, nothing in the brief or elsewhere in the record provides any legal basis or argument for the existence of such a duty on the part of Steriltek to Jessica. At oral argument, Steriltek stated its understanding that the remaining claim was based on a duty to warn the hospital, a statement not refuted by the plaintiff on rebuttal. We conclude that any such claim by the plaintiff has been waived on appeal.