IN THE SUPREME COURT OF TENNESSEE
AT KNOXVILLE
November 3, 2014 Session

IKE J. WHITE III v. DAVID A. BEEKS, M.D.

Appeal by Permission from the Court of Appeals, Eastern Section
Circuit Court for Bradley County
No. V07554 J. Michael Sharp, Judge

No. E2012-02443-SC-R11-CV – Filed May 18, 2015

The issue in this health care informed consent case is whether the trial court erred by limiting the testimony of plaintiff patient's expert witness regarding the risks that the defendant doctor was required to disclose to obtain the patient's informed consent for surgery. The doctor performed a spinal fusion on the patient. His back pain initially improved, but subsequently worsened. The patient sued the doctor, claiming his back pain was caused by nerve compression due to ectopic bone growth at the site of the fusion. The patient alleged that the doctor failed to give him adequate information to enable him to give an informed consent to the surgery. In a pretrial deposition, the patient's expert testified that to obtain informed consent, the doctor was required to advise the patient that he would use a bone-grafting protein and inform the patient about all the potential risks arising from its use, including risks that allegedly caused harm and risks that did not cause harm. The trial court granted the doctor's motion to limit the patient's expert witness testimony to only those risks that allegedly materialized and injured the patient. The jury returned a verdict in favor of the doctor. In a divided opinion, the Court of Appeals affirmed the trial court's exclusion of the expert medical testimony. We hold that the trial court erred by excluding expert testimony regarding undisclosed medical risks that had not materialized. Because this error, more probably than not, influenced the jury's verdict, the patient is awarded a new trial.

Tenn. R. App. P. 11 Appeal by Permission; Judgment of the Court of Appeals Reversed

SHARON G. LEE, C.J., delivered the opinion of the Court, in which CORNELIA A. CLARK, GARY R. WADE, JEFFREY S. BIVINS, and HOLLY KIRBY, JJ., joined.

H. Franklin Chancey, Cleveland, Tennessee, for the appellant, Ike J. White III.

Richard A. Smith and Stacy Lynn Archer, Chattanooga, Tennessee, for the appellee, David A. Beeks, M.D.

OPINION

I.

Ike J. White III, aged nineteen, had suffered from back pain for over a year. His pain affected his mobility and sleep, and he was unable to work or continue his education. In January 2006, Mr. White sought treatment from Dr. David A. Beeks, an orthopedic surgeon then practicing in Cleveland, Tennessee. In May 2006, after conservative treatment was unsuccessful, Dr. Beeks operated on Mr. White's lower back, fusing select discs and joints to stabilize the spine by using the bone-grafting product, InFuse.[1] Mr. White's back pain initially improved. Approximately six weeks after surgery, however, Mr. White again reported significant lower back pain. Subsequent tests indicated that ectopic or abnormally placed bone had formed at the site of the surgery.

On July 13, 2007, Mr. White filed a health care liability suit against Dr. Beeks in the Bradley County Circuit Court.[2] In an amended complaint, Mr. White alleged that Dr. Beeks had failed to obtain Mr. White's informed consent to the surgery by not advising Mr. White of his intention to use InFuse, the manner in which it would be used, or the risks associated with its use. Mr. White's informed consent claim was centered on the theory that Dr. Beeks' use of InFuse caused the ectopic bone growth, which, in turn, caused pressure to be placed on a nerve in Mr. White's back. This pressure on the nerve was alleged to be causing Mr. White's continued back pain.

In a pretrial deposition, Mr. White's expert medical witness, Dr. Melvin Law, testified that based on his personal experience treating patients, the use of InFuse had caused ectopic bone growth in one case; a cystic lesion, which is an inflammatory reaction, in probably ten cases; and postoperative radiculitis or fluid collection in fifteen to twenty percent of patients. Dr. Beeks moved to limit Dr. Law's trial testimony regarding the risks of surgery that should have been disclosed to only those risks that materialized and allegedly caused harm, and to exclude testimony about the potential

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[1] InFuse is a human-engineered "bone morphogenic protein, which is designed to stimulate bone growth and promote fusion." *White v. Beeks*, No. E2012-02443-COA-R3-CV, 2013 WL 6451764, at *1 (Tenn. Ct. App. Dec. 9, 2013).

[2] The complaint alleged that Dr. Beeks breached the recognized standard of acceptable medical practice by failing to exhaust more cautious remedies before performing surgery, by performing a risky surgical procedure, by failing to perform proper follow-up care, and by failing to diagnose Mr. White's postsurgical condition in a timely manner. The jury found in favor of Dr. Beeks, and this ruling is not an issue on appeal.

risks that did not occur. Dr. Beeks contended those risks were not relevant under Tennessee Rule of Evidence 401 and would potentially be prejudicial to him under Tennessee Rule of Evidence 403. In response, Mr. White argued that the jury should hear all of the risks. The trial court granted the motion and limited Dr. Law's testimony to only those risks associated with InFuse that allegedly occurred and caused an injury to Mr. White.

A jury trial was conducted over four days in August 2012. Mr. White testified that he had suffered back pain stemming from three separate incidents.[3] Mr. White testified that he had trouble walking, touching his toes, and sleeping more than four hours a night because of his pain. In addition, Mr. White was unable to work or continue his education. Mr. White took over-the-counter pain medications and used heating pads and ice packs to reduce his pain. After the pain became too much to bear, Mr. White went to the emergency room in January 2006. That same month, he sought treatment from Dr. Beeks, who examined Mr. White, reviewed his x-rays, and recommended physical therapy.

Mr. White testified that physical therapy did nothing to ease his pain, which included a sensation like a "lightning bolt shooting down [his] leg." When he visited Dr. Beeks for a follow-up appointment on February 3, 2006, Mr. White ranked his pain a 10 out of 10,[4] and he told Dr. Beeks that physical therapy was not helping his ongoing pain. As a result, Dr. Beeks ordered an MRI of the lumbar spine, which showed a degenerative disc with herniation. Dr. Beeks reviewed the results with Mr. White and told him he had a herniated disc pushing on one of his nerve roots. Dr. Beeks recommended that Mr. White undergo a surgical fusion because surgery was the only viable option at that point.[5]

Surgery was scheduled, but Mr. White cancelled it to get a second opinion. Dr. Beeks referred Mr. White to Dr. Stephen Dreskin for pain management and to discuss nonsurgical treatment. Mr. White testified that he had rated his pain level "an 8 or a 9 out of 10" when he met with Dr. Dreskin, who subsequently gave him an epidural steroid injection in his back. Because this injection made him feel worse, Mr. White did not

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[3] Before seeking any medical treatment, Mr. White had fallen down a flight of stairs at his mother's house, hurt himself lifting a 200-pound car transmission, and had an accident on a three-wheeler. Mr. White testified that his back hurt worse after the three-wheeler accident than it had hurt between the two prior accidents.

[4] According to Mr. White's testimony, 10 out of 10 meant "the worst pain" on the scale used.

[5] Mr. White testified that he did not believe that he took notes during this meeting, but was "pretty sure" he could recall everything Dr. Beeks had told him that day.

schedule a second epidural steroid injection. Dr. Dreskin recommended surgery to address Mr. White's ongoing pain.

Mr. White returned to Dr. Beeks' office, and they again discussed surgery. As Mr. White recalled, Dr. Beeks "said he was going to put a rod and two screws in it and some kind of fake bone mass." Mr. White stated, however, that Dr. Beeks never told him what that meant, never used the word "InFuse," and never talked to him about any of the risks involved. Mr. White also testified that Dr. Beeks did not discuss with him whether it was necessary to use the artificial bone mass or the prospects for a successful surgery if the artificial bone mass was not used. Dr. Beeks spoke to him about the basic risks of surgery, "like . . . not wak[ing] up." However, Mr. White denied ever being told that Dr. Beeks intended to "use a product to help [his spinal] fusion grow." Dr. Beeks told him that there was a seventy percent chance the surgery would help him and a thirty percent chance it would not. Dr. Beeks gave Mr. White an opportunity to ask questions, and Mr. White inquired about his recovery, how long he would be in the hospital, and how much pain he would have. On May 2, 2006, Dr. Beeks operated on Mr. White's lower back, fusing his spine.

According to Mr. White, his back pain improved after surgery, but soon the pain returned, including "a real sharp drilling kind of pain every time [he] put any pressure on [his] right leg, [and a] fuzzy lightning bolt kind of feeling . . . down [his] right leg." Subsequent tests indicated that ectopic bone had formed at the site of the surgery. Mr. White elected not to undergo additional surgery to remove the bone growth.

Dr. Law testified that Dr. Beeks failed to provide the information required by the standard of care in order to obtain Mr. White's informed consent to the surgery. He explained that Dr. Beeks was obliged to discuss the rationale for the surgery and the alternative treatments or alternative types of surgery, which included simple decompression without fusion or other types of fusion procedures. Dr. Law opined that Dr. Beeks should have explained to Mr. White that he had the option of deciding whether to use InFuse during surgery. In addition, Dr. Law said that Dr. Beeks should have described the relative advantages of InFuse, the complications associated with its use, the potential to increase the chance for a successful fusion when using InFuse versus not, and the manner in which InFuse would be used. Further, Dr. Law stated that Dr. Beeks should have explained the risks of performing a fusion, as opposed to a simpler type of decompression procedure. Notably, Dr. Law testified that Dr. Beeks should have disclosed to Mr. White that the main risks of using InFuse were nerve pain, irritation, and ectopic bone growth. Consistent with the trial court's pretrial order, Dr. Law did not testify as to any other risks, including fluid collection or cystic lesions. Dr. Law admitted that he does not discuss every possible "theoretical complication with a patient" in order to obtain informed consent. In Dr. Law's opinion, the use of InFuse caused ectopic bone

growth at the site of the fusion, and the bone growth precipitated Mr. White's compressive radiculopathy, which caused pain.

Dr. Beeks testified that he discusses with his patients the risks associated with medical procedures because he could not expect the typical patient to know of such risks and "the patients need to make an informed decision of whether they want to have a procedure." Dr. Beeks stated that he had given Mr. White enough information so that he could make an informed decision. Dr. Beeks covered with Mr. White the risk of death, the possibility of an infection, and the potential for paralysis or increased weakness. The surgical consent form, signed by Dr. Beeks and Mr. White, stated that Dr. Beeks had "fully explained the nature and purpose of the operation/procedure, possible alternative methods of treatment, the risks involved[,] and the possibility of complications."

Though he never specifically mentioned InFuse to Mr. White, Dr. Beeks testified that he "would have mentioned that [he was] going to use alternative bone-graft products to supplement so that [he] didn't have to go to [Mr. White's] iliac crest." Dr. Beeks indicated that he decided not to get into technical specifics because he "wanted to keep . . . th[e] discussion as straightforward as possible; and, mostly . . . wanted [Mr. White] to know what his potential outcomes were." Dr. Beeks did not believe Mr. White needed "to know the specifics of the metallurgy of the screws or the difference in the hundreds of different types of bone-grafting options . . . available." As a result, Dr. Beeks focused his discussion with Mr. White on the general risks that could result from the surgery, such as the risk of nonunion, the potential for hardware issues, the possibility of not healing, and the chance of neurological injury. At the time of the surgery, Dr. Beeks was aware InFuse could cause ectopic bone growth but that it did not result in any neurological injury.

Dr. Beeks' expert medical witness, Dr. Christopher Kauffman, testified that Dr. Beeks had complied with the standard of care for a surgeon in obtaining Mr. White's informed consent for the surgery. According to Dr. Kauffman, informed consent requires telling patients "the things that . . . could [a]ffect their ability to get better and get back to work or their overall health status." Dr. Kauffman indicated that Dr. Beeks had to review the options available to Mr. White and recommend the procedure that would be most successful in alleviating Mr. White's pain without significant complications. Dr. Beeks had to tell Mr. White about the relevant risks, such as the possibility of an infection or death, and the risks associated with the recommended type of posterior lumbar interbody fusion procedure.

In Dr. Kauffman's opinion, based upon the leading study on InFuse in 2006—the year the surgery was performed—there were more benefits to using InFuse than risks, as compared to using a regular bone graft procedure. InFuse was associated with an increased incidence of ectopic bone growth; however, the ectopic bone growth had not been shown to cause neurological problems and, thus, could not be properly labeled a

"risk" of the procedure. Thus, Dr. Kauffman stated that it was not clear whether the ectopic bone growth actually caused harm to Mr. White, especially because his presurgical pain mirrored his postsurgical pain. In addition, Dr. Kauffman testified that Mr. White was a cigarette smoker[6] and that smoking hindered the healing process after a spinal fusion. Dr. Kauffman concluded that he could not say with certainty whether the ectopic bone growth was causing neurological problems, or if prior nerve aggravation and the bone's failure to fuse correctly because of continued smoking were the real sources of Mr. White's ongoing pain.

The jury returned a verdict in favor of Dr. Beeks, and Mr. White appealed, arguing that he was entitled to a new trial because the trial court had erred by excluding Dr. Law's testimony concerning the undisclosed risks that did not occur. A divided panel of the Court of Appeals affirmed the trial court's judgment. *White*, 2013 WL 6451764, at *9. The majority opinion held that the trial court did not abuse its discretion in limiting Dr. Law's testimony, reasoning that any risks that did not ripen into an injury are without legal consequence. *Id*. at *8. The dissent opined that the trial court had committed reversible error by limiting Dr. Law's testimony because the relevant consideration in an informed consent case is "whether or not the health care provider informed the patient of *all* significant risks as required to be disclosed to the patient to satisfy the acceptable standard of care." *Id.* at *10-12 (Swiney, J., dissenting).

We granted Mr. White's application for permission to appeal to decide whether the exclusion of expert testimony regarding undisclosed risks that had not materialized constituted an abuse of discretion, and if so, whether the error more probably than not influenced the jury's verdict.

II.

The doctrine of informed consent attempts to reconcile the tension between a physician's desire to do what he or she feels is best for a patient and the patient's right to personal autonomy and self-determination over his or her own body. *See generally* W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* § 32 (5th ed. 1984); Ben A. Rich, *Medical Paternalism v. Respect for Patient Autonomy: The More Things Change the More They Remain the Same*, 10 Mich. St. U. J. Med. & L. 87 (2006). Implicit in this notion of self-determination is the importance of receiving a patient's consent for any procedure and the preservation of the patient's right to make decisions about his or her medical care. Keeton, *supra*, at 190. Informed consent developed from the theory of

[6] At trial, Mr. White testified that he had been a smoker for several years, sometimes smoking as much as a pack of cigarettes a week. In addition, Mr. White stated, "The only time I stopped [smoking] was for about . . . a week when I had my surgery."

battery, which created a cause of action for a "nonconsensual, intentional, and offensive touching of another without lawful justification." *Black's Law Dictionary* 182 (10th ed. 2014); *see Schloendorff v. Society of N.Y. Hosp*., 105 N.E. 92, 93 (N.Y. 1914) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.").

Courts established the basic principles of informed consent in the early 1900s, recognizing that a patient could bring a cause of action against a medical practitioner for performing an unauthorized medical procedure. *See, e.g.*, *Pratt v. Davis*, 79 N.E. 562, 565 (Ill. 1906); *Mohr v. Williams*, 104 N.W. 12, 16 (Minn. 1905). Soon after, this principle was extended to necessitate consent for medical procedures, requiring that a physician's treatment not exceed the patient's wishes, regardless of what the physician, in his or her professional judgment, felt was best. *See Rolater v. Strain*, 137 P. 96, 99 (Okla. 1913).

In *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, the doctrine of informed consent, as it is known today, was first articulated. 317 P.2d 170, 181 (Cal. Ct. App. 1957). In *Salgo*, the California Court of Appeals examined not only the patient's consent, or lack thereof, but also the underlying medical information upon which the patient's decision was based. The court held that a physician should make a "full disclosure" of any facts necessary for a patient's "intelligent" consent to a proposed treatment, but a physician should also take into account the patient's mental and emotional state to decide how much and what information constituted full disclosure for informed consent. *Id.* Thus, *Salgo* planted the seed of informed consent and signaled the beginning of a slow shift away from a strict battery theory to a more context-sensitive informed consent theory.

Over the years, courts have attempted to fill out the contours of the informed consent doctrine. They have grappled with the required standard of disclosure, *see, e.g.*, *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972); defined instances when informed consent is not possible or not required, *see e.g.*, *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 360 (Iowa 1987); and explained the standard for causation, *see, e.g.*, *Adamski v. Moss*, 638 A.2d 1360 (N.J. Super. Ct. App. Div. 1994); *Mello v. Cohen*, 724 A.2d 471 (Vt. 1998). Thus, the doctrine, once rooted in the concept of pure battery, evolved to become more nuanced and better reflect the realities of medical practice.

In Tennessee, the doctrine of informed consent has evolved in much the same manner. This Court first recognized the medical battery cause of action in *Butler v. Molinski*. 277 S.W.2d 448, 451-52 (Tenn. 1955) (distinguishing between actions for negligent malpractice and those premised upon the unauthorized performance of an operation). Fourteen years later, the Court explained in *Ray v. Scheibert* that a medical battery action would result when a "plaintiff did not effectively consent—*therefore, did*

not consent at all—to the operation which the defendant performed." 450 S.W.2d 578, 581 (Tenn. 1969) (emphasis added). On remand in *Ray*, the Court of Appeals stated that when no "informed or knowledgeable" consent for a procedure was obtained (and no exception was applicable), a physician would be liable to a patient for injuries resulting from the procedure, "regardless of whether such injuries resulted from negligence or otherwise." *Ray v. Scheibert*, 484 S.W.2d 63, 71 (Tenn. Ct. App. 1972).

In 1974, the Court of Appeals first stated the legal standard for an informed consent action. *Longmire v. Hoey*, 512 S.W.2d 307, 309 (Tenn. Ct. App. 1974). In *Longmire*, the intermediate appellate court held that in an informed consent claim, the plaintiff had the burden to show that either the surgical procedure was not actually authorized or the physician withheld material information regarding the risks involved, thus preventing the patient from making an intelligent choice when giving consent. *Id*. at 310. The *Longmire* court further clarified that in cases where the physician withheld material information, "the withheld information must be of such nature as to vitiate any verbal or written consent given." *Id*. Nevertheless, the court acknowledged that it would be humanly impossible to disclose every aspect and risk of a surgery and that such disclosure would likely prevent a layperson from forming a rational decision. *Id*. Thirteen years later, this Court again considered informed consent and, in a narrow holding, determined that a physician's deviation from the standard of care would constitute a battery, because "the doctrine of battery [is] applicable to cases involving [treatment] performed without informed or knowledgeable consent." *Cardwell v. Bechtol*, 724 S.W.2d 739, 750 (Tenn. 1987) (quoting *Ray*, 484 S.W.2d at 71) (emphasis and internal quotation marks omitted).

In 1998, the Court reaffirmed the *Cardwell* framework in *Shadrick v. Coker*, reiterating, "the doctrine of lack of informed consent is based upon the tort of battery." 963 S.W.2d 726, 732 (Tenn. 1998). The Court held that a health care provider would be liable for injuries resulting from a procedure performed without informed consent, regardless of whether those injuries resulted from negligence. *Id.* Later the same year, however, the Court, for the first time, severed the theories of medical battery and informed consent. *Blanchard v. Kellum*, 975 S.W.2d 522, 524 (Tenn. 1998). The Court stated, "[T]here is a distinction between: (1) cases in which a doctor performs an unauthorized procedure; and (2) cases in which the procedure is authorized but the patient claims that the doctor failed to inform the patient of any or all the risks inherent in the procedure." *Id.* A cause of action alleging an unauthorized procedure sounds in battery, while one alleging a lack of disclosure for an authorized procedure rests on an informed consent theory. *Id.* In cases where the patient has given consent, the inquiry shifts to examining the information underlying the consent and asks "whether the doctor provided *any* or *adequate* information to allow a patient to formulate an intelligent and informed decision when authorizing or consenting to a procedure." *Id*. (citing *Shadrick*, 963 S.W.2d at 726). Two years later, the Court of Appeals applied *Blanchard* and stated

that an action for informed consent "does not relate to the manner in which the procedure was performed, but rather to the manner in which the physician obtained the patient's consent to perform the procedure." *Church v. Perales*, 39 S.W.3d 149, 159 (Tenn. Ct. App. 2000) (citing *German v. Nichopoulos*, 577 S.W.2d 197, 202 (Tenn. Ct. App. 1978)).

Under the *Blanchard* analysis, Mr. White's action is not a case of medical battery because he authorized Dr. Beeks to perform the spinal fusion. Mr. White, however, claims that Dr. Beeks did not give him the "full story" as to all the risks involved with the use of InFuse. Dr. Beeks claims that he adequately informed Mr. White of the risks and, in any case, the harm he suffered was not caused by the procedure. Accordingly, this claim falls squarely in the realm of informed consent.

Because this is an informed consent case, Tennessee Code Annotated section 29-26-118, requires that Mr. White prove:

> by evidence as required by § 29-26-115(b)[7] that the defendant did not supply appropriate information to the patient in obtaining 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 specialty, if any, that the defendant practices in the community in which the defendant practices and in similar communities.

Tenn. Code Ann. § 29-26-118 (2000 & Supp. 2012). Thus, in this case, Mr. White was required to prove by expert testimony 1) the information that Dr. Beeks should have disclosed to Mr. White to obtain his informed consent for the surgery, as established by the recognized standard of acceptable professional practice in the specialty of orthopedic surgery in Cleveland, Tennessee or similar community; 2) whether Dr. Beeks disclosed appropriate information to Mr. White to comply with the recognized standard of acceptable professional practice in the same or similar community; and 3) whether a reasonable person in Mr. White's position would have consented to the surgery if he had been provided with the information required by the recognized acceptable professional practice. *See Ashe v. Radiation Oncology Assocs.*, 9 S.W.3d 119, 121 (Tenn. 1999). This last requirement is an objective standard for assessing causation in informed consent cases and asks the factfinder to decide "what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance." *Id.* at 122 (quoting *Canterbury*, 464 F.2d at 791 (internal quotation mark omitted)); *see* Tenn. Code Ann. §§ 29-26-115, -118; *see also Blanchard*, 975 S.W.2d at 524; *Hawk v. Chattanooga*

[7] Tennessee Code Annotated section 29-26-115(b), which discusses who may testify as an expert witness in a medical malpractice claim, is not at issue in this case.

Orthopaedic Grp., P.C., 45 S.W.3d 24, 32 (Tenn. Ct. App. 2000) (quoting *Shadrick*, 963 S.W.2d at 732).[8] The decision a particular patient, such as Mr. White, would have made had he known all of the risks is relevant, but not controlling. *Ashe*, 9 S.W.3d at 122 (citing *Canterbury*, 464 F.2d at 791). The plaintiff must prove each element, and the actual existence of each element is a question of fact for the factfinder.

III.

A.

Decisions regarding the admission or exclusion of evidence are generally entrusted to the sound discretion of the trial court. *Mercer v. Vanderbilt Univ., Inc.*, 134 S.W.3d 121, 131 (Tenn. 2004) (citing *Otis v. Cambridge Mut. Fire Ins. Co.*, 850 S.W.2d 439, 442 (Tenn. 1992)); *see also Smartt v. NHC Healthcare/McMinnville, LLC*, No. M2007-02026-COA-R3-CV, 2009 WL 482475, at *13 (Tenn. Ct. App. Feb. 24, 2009) (holding that the trial court did not abuse its discretion in admitting evidence to prove an element of the medical malpractice claim after applying the balancing test of Tennessee Rule of Evidence 403).

We review a trial court's decision to admit or exclude evidence under an abuse of discretion standard. *Otis*, 850 S.W.2d at 442. A trial court abuses its discretion by applying an incorrect legal standard or reaching an illogical or unreasonable decision that causes an injustice to the complaining party. *Gonsewski v. Gonsewski*, 350 S.W.3d 99, 105 (Tenn. 2011); *Brown v. Crown Equip. Corp.*, 181 S.W.3d 268, 273 (Tenn. 2005); *State v. Gilliland*, 22 S.W.3d 266, 270 (Tenn. 2000); *State v. Shirley*, 6 S.W.3d 243, 247 (Tenn. 1999). In reviewing the trial court's exercise of discretion, we presume that the trial court's decision is correct and review the evidence in a light most favorable to upholding the decision. *Lovlace v. Copley*, 418 S.W.3d 1, 16-17 (Tenn. 2013) (quoting *Gonsewski*, 350 S.W.3d at 105). Discretionary decisions, however, require a conscientious judgment, consistent with the facts, that takes into account the applicable law. *Lee Med. Inc. v. Beecher*, 312 S.W.3d 515, 524 (Tenn. 2010).

Tennessee Rule of Evidence 401 defines relevant evidence as "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." Tenn. R. Evid. 401. "[E]vidence is relevant if it helps the trier of fact resolve an issue of fact." *State v. James*, 81 S.W.3d 751, 757 (Tenn. 2002) (quoting Neil P. Cohen, et al., *Tennessee Law of Evidence* § 4.01[4], at 4-8 (4th ed. 2000)). Tennessee

[8] The Court does not find it necessary to nor does it in this case address the issue of whether a party must prove proximate cause to prevail in an informed consent cause of action.

Rule of Evidence 402 states, "All relevant evidence is admissible except as [otherwise provided for by law]." Tenn. R. Evid. 402.

Relevant evidence, however, 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." Tenn. R. Evid. 403; *see also Mayo v. Shine*, 392 S.W.3d 61, 66-67 (Tenn. Ct. App. 2012) (finding that the probative value of the evidence, that a patient returned to the same doctor after allegedly suffering harm as a result of the doctor's negligence, was outweighed by the potential for prejudice). The plain language of the rules of evidence "strongly suggests that when the balance between the evidence's probative value and any prejudicial effect is close, the evidence should be admitted." *Goodale v. Langenberg*, 243 S.W.3d 575, 587 (Tenn. Ct. App. 2007) (citing *Richardson v. Miller*, 44 S.W.3d 1, 21 (Tenn. Ct. App. 2000)) (internal quotation marks omitted). Moreover, "[e]xcluding otherwise relevant evidence under Tenn. R. Evid. 403 is an extraordinary step that should be used sparingly." *Levine v. March*, 266 S.W.3d 426, 439 (Tenn. Ct. App. 2007); *see also Wicks v. Vanderbilt Univ.*, No. M2006-00613-COA-R3-CV, 2007 WL 858780, at *10 (Tenn. Ct. App. Mar. 21, 2007).

In his pretrial deposition, Dr. Law testified that the patient should be told of the following risks associated with InFuse: ectopic bone growth and different types of possible responses in the patient, specifically cystic lesions behind the spine, radiculitis, and fluid collection. According to Dr. Law, both cystic lesions and fluid collection would have necessitated additional procedures and/or surgery. Based on the pretrial order, Dr. Law testified at trial only to the risks of ectopic bone growth and "inflammatory reactions, that can cause continued nerve pain." He was not allowed to testify about any other risks, including details of the specific inflammatory reactions, or additional procedures that these risks might have required.

A prudent person needs to be informed of all "perils bearing significance" in order to give informed consent. *See Ashe*, 9 S.W.3d at 122 (quoting *Canterbury*, 464 F.2d at 791) (internal quotation mark omitted). "Perils bearing significance" necessarily include those perils that caused harm and those that did not. The fact that a risk did not materialize does not make it less of a risk. At the time a patient is making a decision whether to undergo a medical procedure, he needs to know prospectively the risks he is facing—not just those risks that in hindsight materialized and caused him harm. The fact that a risk did not materialize during or after surgery is not a determining factor in whether it should have been disclosed to a patient before surgery. Accordingly, the jury should have been allowed to hear Dr. Law's complete testimony about the risks of InFuse, as this evidence would have been relevant under Tennessee Rule of Evidence 401 in the jury's assessment of what a prudent person would have decided if properly informed of all the significant risks.

Even though the evidence is relevant under Rule 401, it could still be inadmissible under Rule 403, 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." We hold that the excluded evidence was highly probative on the issue of whether a prudent person in Mr. White's position would have consented to the procedure despite the risks. These risks were neither remote nor highly speculative. We do not conclude that there was danger of unfair prejudice, confusion of issues, or that the introduction of Dr. Law's testimony as to the additional risks would have been cumulative or caused undue delay. Accordingly, Dr. Law's complete testimony about the risks of InFuse was relevant, under Tennessee Rule of Evidence 401, to the jury's assessment of what a prudent person would have decided if properly informed of all the significant risks, and the trial court erred by conditioning inclusion of the evidence on whether the undisclosed risks actually occurred.

B.

Having concluded the trial court erred in excluding the evidence, we must now determine whether the error was harmful and warrants reversal. An erroneous exclusion of evidence is harmful "when considering the whole record, error involving a substantial right more probably than not affected the judgment or would result in prejudice to the judicial process." *See In re Estate of Smallman*, 398 S.W.3d 134, 152 (Tenn. 2013) (quoting *State v. Gomez*, 367 S.W.3d 237, 249 (Tenn. 2012)) (internal quotation marks omitted); *see also* Tenn. R. App. P. 36(b). In a jury case, we must carefully examine the entire record to determine "whether [exclusion] of the evidence, more probably than not, influenced the jury's verdict." *See Smallman*, 398 S.W.3d at 152 ("[W]hether [the evidentiary error] is sufficiently prejudicial to require reversal depends on the substance of the evidence, its relation to the other evidence, and the peculiar facts and circumstances of the case."). We do not act as a second jury by combining our harmlessness inquiry with our own assessment of liability. *State v. Rodriguez*, 254 S.W.3d 361, 373-74 (Tenn. 2008). Rather, the goal is to identify the actual basis for the jury's decision, *State v. Mallard*, 40 S.W.3d 473, 489 (Tenn. 2001) (quoting *Momon v. State*, 18 S.W.3d 152, 168 (Tenn. 1999)), and to determine whether the exclusion of evidence, more probably than not, affected the verdict. *Smallman*, 398 S.W.3d at 152.

The jury was required to determine what information Dr. Beeks was obligated to disclose to Mr. White in accordance with the recognized standard of care, whether Dr. Beeks deviated from the standard of care by not disclosing adequate information to Mr. White, and whether a reasonable person in Mr. White's position, adequately informed of the risks inherent in the use of InFuse, would have consented to its use. *See Ashe*, 9 S.W.3d at 123. In making this determination, the jury could have considered "the

plaintiff's idiosyncrasies, fears, age, medical condition, and religious beliefs." *Id.* at 124 (citing *Fain v. Smith*, 479 So. 2d 1150, 1155 (Ala. 1985); *Bernard v. Char*, 903 P.2d 667, 674 (Haw. 1995); *Backlund v. Univ. of Wash.*, 975 P.2d 950 (Wash. 1999)). The jury was also instructed to consider the presence or absence of alternative procedures/treatments, the potential risks and benefits of those procedures, and the impact on Mr. White's health if InFuse had not been used.[9]

On these issues, the jury heard from a number of witnesses including Dr. Beeks and his expert witness, Dr. Kauffman, and Mr. White and his expert witness, Dr. Law. In his pretrial deposition, when asked what risks were associated with the use of InFuse, Dr. Law stated,

> I've had one case of ectopic bone growth. I've had, oh, probably [ten] cases of a cystic lesion that forms behind the, in the patient's spinal canal. It's an inflammatory response. I've had probably a [fifteen] percent, [fifteen] to [twenty] percent inciden[ces] of patients developing inflammation postoperative – I would say, I would lump them all into [fifteen] to a [twenty] percent complication rate where patients either developed postoperative radiculitis or they developed a postoperative fluid

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[9] Dr. Beeks requested the following special jury instruction, which was agreed upon by the parties and provided to the jury:

> A physician has a duty to give a patient certain information before treating the patient; the information the physician must disclose is that information about the treatment involved and its attendant risks to enable the patient to make an intelligent decision about whether to undergo the treatment. The information that must be provided to the patient is that information that would be provided by physicians in the specialty in the community in which the physician practices or in similar communities.
>
> In this case, plaintiff has the burden of proving:
>
> > (1) What a reasonable medical practitioner in the same or similar community would have disclosed to the patient about InFuse and the risks of it;
> > (2) That the defendant departed from the standard; and
> > (3) That a reasonable patient in plaintiff's position would have refused the treatment with InFuse if properly advised of the risks.
>
> In determining how a reasonable patient would have acted under the circumstances, you should consider the testimony of the plaintiff, the plaintiff's idiosyncrasies, fears, age, medical condition, and religious beliefs, the presence or absence of alternative procedures/treatments and the potential risks and benefits thereof, and the impact of not using InFuse on plaintiff's health.

> collection where I had to take them back to surgery to draw the fluid off, or they have developed a cystic situation which I've actually had to take them back to surgery for.

At trial, however, Dr. Law was precluded from testifying about the risks of InFuse that had not materialized. Consequently, he was not allowed to tell the jury about the risks of cystic lesions, fluid collection, or any other risks associated with InFuse that did not materialize. Thus, when asked at trial what risks were associated with InFuse, Dr. Law stated only the following: "[T]he main risk is inflammatory reactions, that can cause continued nerve pain. It can cause nerve irritation[,] and also the ectopic bone growth certainly is a complication that should be explained to the patient."

After a careful review of the record, we hold that Mr. White was deprived of key evidence that was critical to his ability to prove his informed consent claim. This was a close case. The expert witnesses on behalf of Mr. White and Dr. Beeks offered differing opinions as to whether Dr. Beeks disclosed to Mr. White adequate information about the risks associated with spinal fusion surgery and the use of InFuse. Unlike Dr. Law, however, Dr. Beeks and his expert, Dr. Kauffman, were not precluded from offering substantial testimony against Mr. White's informed consent claim. Had Dr. Law's testimony not been limited, the jury would have heard expert proof demonstrating that Dr. Beeks failed to disclose to Mr. White that the use of InFuse was associated with a number of risks, in addition to ectopic bone growth and inflammation, that not only might have caused Mr. White continued back pain, but might have necessitated further invasive procedures. Given the issues in dispute, this would have had a significant effect on the jury's determination of whether Dr. Beeks obtained Mr. White's informed consent before using InFuse and whether a prudent person in Mr. White's position, adequately informed, would have consented to its use. The effect of the trial court's ruling was that the jury did not have the opportunity to hear relevant, admissible evidence supporting Mr. White's informed consent claim. *Cf. White v. Vanderbilt*, 21 S.W.3d 215, 229-30 (Tenn. Ct. App. 1999) (finding that the erroneous exclusion of an expert's deposition was not harmless, as it prevented the plaintiffs, in a close case, from introducing relevant evidence to support their medical malpractice claim); *Brown v. Daly*, 968 S.W.2d 814, 817-18 (Tenn. Ct. App. 1997) (finding that the erroneous exclusion of a party's proffered statement on the basis that it was hearsay was not harmless, as exclusion of this testimony prejudiced that party's ability to refute the opposing party's defense); *Pankow v. Mitchell*, 737 S.W.2d 293, 298 (Tenn. Ct. App. 1987) (finding that the erroneous exclusion of a prior complaint filed by the plaintiff containing statements contradicting the plaintiff's trial testimony was not harmless, as the contradicting information contained in the complaint was relevant to a contested, material issue at trial).

We hold that the erroneous exclusion of Dr. Law's testimony, more probably than not, affected the outcome of the trial. *See Smallman*, 398 S.W.3d at 152. Accordingly,

the error was not harmless, and Mr. White is entitled to a new trial on his informed consent claim.

Conclusion

We hold that the trial court erred by excluding expert testimony regarding undisclosed medical risks that had not materialized. This error, more probably than not, affected the jury's verdict. Therefore, the judgments of the trial court and the Court of Appeals are reversed, and the case is remanded to the trial court for a new trial on the issue of informed consent consistent with the holdings in this opinion. Costs of this appeal are assessed to David A. Beeks, M.D., for which execution may issue if necessary.

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SHARON G. LEE, CHIEF JUSTICE