RENDERED: MARCH 24, 2022
TO BE PUBLISHED

Supreme Court of Kentucky

2020-SC-0587-DG

CHARMIN WATSON AND STEPHEN WATSON — APPELLANTS

V.

ON REVIEW FROM COURT OF APPEALS
NO. 2019-CA-1271
SCOTT CIRCUIT COURT NO. 14-CI-00771

LANDMARK UROLOGY, P.S.C. AND AMBERLY KAY WINDISCH, M.D. — APPELLEES

OPINION OF THE COURT BY JUSTICE VANMETER

AFFIRMING

Prior to performing a medical procedure, a health care provider is generally required to obtain the patient's informed consent. In Kentucky, the requirements for informed consent are established by statute. KRS[1] 304.40-320. The issue we resolve in this case is whether the Scott Circuit Court erred, as subsequently affirmed by the Court of Appeals, in dismissing Charmin Watson's action alleging Dr. Amberly Kay Windisch failed to obtain Watson's informed consent prior to surgical placement of a mid-urethral sling to address complaints of stress urinary incontinence. Based on the record, we hold that

[1] Kentucky Revised Statutes.

the trial court did not err and therefore affirm its judgment and the Court of Appeals' opinion.

I. FACTS AND PROCEDURAL BACKGROUND.

In September 2012, Ms. Watson consulted with Dr. Windisch[2] complaining of urinary incontinence. After an evaluation over three visits, Dr. Windisch recommended the placement of a mid-urethral mesh sling. Dr. Windisch's medical charting reflects that she discussed possible complications of the sling surgery with Ms. Watson, although it does not specify which complications were explained. In her November 5, 2012, office note, Dr. Windisch documented the following interaction:

> Educational materials concerning the proposed surgical procedure were supplied to the patient. I explained the options concerning the surgery versus other more conservative treatment. I did tell the patient about various alternatives and why the Sling Procedure was indicated in her particular circumstance. I advised the patient about the possible outcome and the possibility of infection post operatively [sic]. The patient expressed an understanding with regard to possible complications and outcome.

Neither Ms. Watson nor Dr. Windisch was able to recall the specifics of their 2012 conversation. During her deposition, Ms. Watson testified that she could not remember what complications Dr. Windisch discussed with her, if any:

> Q. Okay. Tell me what you remember about the surgery that – that Dr. Windisch recommended to you?
>
> A. What I can remember – what she recommended?

[2] Landmark Urology, P.S.C. was the professional entity within which Dr. Windisch practiced. Landmark and Dr. Windisch will be referred to throughout this opinion collectively as "Dr. Windisch."

Q. Uh-huh.

A. Is just that we would go in as an outpatient, and she would insert the mesh sling.

Q. Did she explain to you how that would help alleviate your problems or –

A. Yes.

Q. Okay. Did she explain to you the complications of the surgery?

A. No.

Q. She didn't give you any materials about the surgery at all?

A. She might have gave me some pamphlets or something like that, yes.

Q. Did you read those pamphlets?

A. Well, I – probably, yeah.

Q. Probably. Okay.

A. Yes.

Q. Did those pamphlets discuss any of the complications with the surgery?

A. Not that I can recall, no.

Q. All right. In terms of the conversation you had with Dr. Windisch about that surgery, do you have any specific recollection of it?

A. No, sir.

Q. Okay. So Dr. Windisch may have talked with you about the complications. You just don't remember?

A. She may have, yes.

Q. Okay. All right. Did you get a second opinion on that surgery, or did you feel comfortable with Dr. Windisch?

A. I didn't get no second opinion – opinion, no.

Q. Did you feel comfortable with Dr. Windisch at that time?

A. At that time, yes.

Q. Okay. Did you do any additional research other than looking at the pamphlets Dr. Windisch gave you? Did you get on the internet and research mesh procedures or talk with anyone that had the procedure done before, anything?

A. No.

While Dr. Windisch was unable to recall the specifics of her conversation with Ms. Watson, she described her customary routine for obtaining a patient's informed consent for a mid-urethral sling surgery:

> Q. It says you advised the patient about possible outcome and possibility of infection postoperatively. Sitting here today, I'm sure you don't recall the exact discussion that you would have had with Mrs. Watson, do you?
>
> A. No.
>
> Q. What do you think you would have – seeing that note, what do you believe you would have told her at that time when you were discussing this procedure?
>
> A. What I always discuss with my patients is kind of what I had stated earlier about there is always a risk of recurrence of the incontinence though the idea is that it should last for a good duration of time. There's always the risk that there may be difficulty with emptying the bladder or voiding or – or voiding after the procedure, particularly in individuals with a mixed incontinence, which she had.
>
> There's always the risk of damage to the urethra or the bladder. There's always a risk in this situation, discussing using mesh, of migration or erosion or extrusion of that material. More than likely I did discuss with her a pubovaginal sling using either her own autologous fascia or cadaveric fascia, and that can also have those risks. Usually, there's not so much a risk of erosion, but there's still a risk of migration or recurrence or incomplete emptying, all that sort of thing.

Prior to surgery, Ms. Watson signed an Exposure and Informed Consent Form ("Consent Form"). The Consent Form disclosed that Dr. Windisch would be performing a transvaginal urethral sling procedure to treat stress incontinence and that Ms. Watson acknowledged the following particular risks: "1) Bleeding[;] 2) Infection[;] 3) **Damage to the urethra/bladder**[;] 4) Incomplete emptying[.]" (Emphasis added).

On November 14, 2012, Dr. Windisch performed surgery as planned to install the transvaginal retropubic urethral sling. Following the placement of the sling, Dr. Windisch performed an intraoperative cystoscopy to ensure that the integrity of Watson's bladder and urethra had not been compromised. At the time, she observed no evidence of injury to either organ. Several days later, Ms. Watson experienced an episode of urinary retention, a common complication of sling surgery, but reported that she was doing well afterward.

Two months later, in January 2013, Ms. Watson advised Dr. Windisch that she was experiencing no change to her incontinence. On January 29, 2013, Dr. Windisch performed a follow-up cystoscopy, which showed Ms. Watson's bladder and urethra to be normal. Ms. Watson subsequently reported some improvement in her symptoms. In March 2013, Dr. Windisch stopped treating Ms. Watson and referred her to another urologist as Dr. Windisch was relocating her practice to North Carolina.

In November 2013, Dr. Ballert, another urologist, evaluated Ms. Watson as she had complaints of pain and incontinence, although the symptoms had improved and were not bothersome. Three months later, Dr. Ballert performed a cystoscopy and discovered that an area of the mesh sling installed by Dr. Windisch had eroded into Ms. Watson's urethra and bladder, requiring reconstructive surgery. In March 2014, Ms. Watson underwent a surgical procedure to remove the mesh but thereafter continued to experience problems she claims originated from Dr. Windisch's sling surgery.

In November 2014, the Watsons filed suit alleging that Dr. Windisch "failed to exercise the degree of care and skill that would be expected of an ordinarily prudent person or reasonably competent physician or healthcare provider under like or similar circumstances." The Watsons' complaint did not explicitly refer to informed consent, inadequate consent, or the statute outlining informed consent, KRS 304.40-320. Mr. Watson also filed a loss of consortium claim following the results of his wife's surgery.

The Watsons' expert witness, urologist Dr. Tracey Wilson, opined that Dr. Windisch violated the standard of care by failing to diagnose the erosion of the sling in January 2013. Dr. Wilson's CR[3] 26 expert disclosure did not include any opinions related to informed consent. In her deposition, Dr. Wilson testified that she did not intend to offer an opinion at trial regarding informed consent because she had not seen any information regarding Dr. Windisch's consent process. However, she did testify that she believed Dr. Windisch's written consent form should have contained warnings regarding mesh-specific erosion and extrusion.

The trial court scheduled a jury trial for February 2019. At the final pretrial conference, Dr. Windisch moved in limine to exclude reference to inadequate informed consent, arguing that the Watsons had not adequately pled or advanced an informed consent claim during litigation. Dr. Windisch maintained that the Watsons should be precluded from presenting an informed

[3] Kentucky Rules of Civil Procedure.

consent claim at trial because it was not explicitly alleged in their complaint, was not raised in discovery, and was not a part of their CR 26 expert disclosures. Dr. Windisch also argued that the Watsons could not meet their burden of proof because the executed informed consent expressly detailed ureteral and bladder injury as a known risk, and the Watsons' only expert witness had already testified that she did not intend to offer an opinion at trial regarding informed consent. The trial court denied the motion in limine, since informed consent was adequately pled as a claim based in negligence.

The trial court, however, converted Dr. Windisch's motion in limine regarding informed consent into a motion for partial summary judgment, hearing arguments on the merits of the informed consent claim. The Watsons argued that Dr. Windisch had failed to obtain informed consent by failing to explain to Ms. Watson the specific risk of injury due to erosion or migration of the mesh sling, necessitating reconstructive surgery.

The trial court granted summary judgment in favor of Dr. Windisch on the Watsons' informed consent claim. The trial court concluded that the Watsons' claim failed as a matter of law, stating:

> In the case at hand, the consent form warned the Watson[s] generally of blood clots in veins and lungs, hemorrhage, allergic reactions, cardiac arrest, and death as commonly associated with surgical procedures. The consent form then specifically, through handwritten annotation, warned of bleeding, infection, damage to urethra bladder, and incomplete emptying. Watson has alleged the injuries of pain, incontinence, and pain during intercourse. In comparing Watson's injuries with the risks enumerated in the consent form, this court finds that no reasonable jury could find that Watson was not adequately informed of the risks associated with the procedure for purposes of informed consent.

> Unlike [*Sargent v.*] *Shaffer*[, 467 S.W.3d 198 (Ky. 2015)] and [*Argotte v.*] *Harrington*[, 521 S.W.3d 550 (Ky. 2017)], there was no range of possibilities left by the consent form for Watson to judge. No party or expert disputes that the consent form conveys its intended instruction. The expert physician retained by Watson has admitted on record that what is written on the consent form are all complications associated with any type of sling. Watson admits to being provided with pamphlets concerning mesh surgery which she does not remember if she read, nor does she remember the conversation she had with Windisch about the surgery or if they talked about the associated complications. The burden is on Watson to show that Windisch failed to obtain her informed consent and there is an issue of material fact that must be reserved for the jury.
>
> In the absence of any expert opinion specifically critical of Dr. Windisch regarding informed consent, and with no real testimony regarding the substance of the conversation, we are left to rely on the signed consent form. Without more evidence to rebut the form, this court does not find any issue of material fact concerning informed consent. The court finds that the signed consent form on its face conveys the risks associated with the surgery.

Although Watsons' claim for Dr. Windisch's alleged breach of the standard of care in performing the surgery and failing to diagnose the erosion was still pending, the Watsons immediately appealed the summary judgment to the Court of Appeals. That Court dismissed that appeal since it was from an interlocutory order. *Watson v. Georgetown Cmty. Hosp.*, 2019-CA-000264-MR (Ky. App. May 8, 2019). Upon remand, the Watsons then voluntarily moved to dismiss all theories of liability, other than the informed consent claim. The trial court entered an order granting that motion and making its summary judgment as to informed consent final and appealable. CR 54.02.

The Court of Appeals affirmed the trial court. On the Watsons' motion, we granted discretionary review.

II. STANDARD OF REVIEW.

The standard for the issuance of summary judgment is whether the record demonstrates "no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." CR 56.03. In *Steelvest, Inc. v. Scansteel Service Center, Inc.*, 807 S.W.2d 476, 483 (Ky. 1991), we reaffirmed that summary judgment "should only be used to terminate litigation when, as a matter of law, it appears that it would be impossible for the respondent to produce evidence at the trial warranting a judgment in his favor and against the movant." (Internal quotation and citation omitted). To survive a properly supported summary judgment motion, the opposing party must have presented at least some affirmative evidence showing that there is a genuine issue of material fact for trial. *Id.* at 482.

In determining whether the trial court erred in granting summary judgment,

> [W]e must consider whether the trial court correctly found that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Kentucky Rule of Civil Procedure ("CR") 56.03; *see also Pearson ex rel. Trent v. Nat'l Feeding Sys., Inc.*, 90 S.W.3d 46, 49 (Ky. 2002). We review *de novo* the trial court's grant or denial of a motion for summary judgment. *Caniff v. CSX Transp., Inc.*, 438 S.W.3d 368, 372 (Ky. 2014) (citation omitted).

Cmty. Fin. Servs. Bank v. Stamper, 586 S.W.3d 737, 741 (Ky. 2019). We review the record "in a light most favorable to the party opposing the motion for summary judgment and all doubts are to be resolved in [her] favor." *Steelvest,* 807 S.W.2d at 480.

III. ANALYSIS.

The Watsons argue before us, as they did in the Court of Appeals, that the trial court erred in granting summary judgment because genuine issues of material fact existed as to whether Dr. Windisch complied with KRS 304.40-320. This statute sets forth the requirements of a valid informed consent:

> In any action brought for treating, examining, or operating on a claimant wherein the claimant's informed consent is an element, the claimant's informed consent shall be deemed to have been given where:
>
> (1) The action of the health care provider in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with the accepted standard of medical . . . practice among members of the profession with similar training and experience; and
>
> (2) A reasonable individual, from the information provided by the health care provider under the circumstances, would have a general understanding of the procedure and medically . . . acceptable alternative procedures or treatments and substantial risks and hazards inherent in the proposed treatment or procedures which are recognized among other health care providers who perform similar treatments or procedures[.]

A physician, or any health care provider, satisfies the duty to obtain the patient's consent only if both provisions are met. *Sargent v. Shaffer*, 467 S.W.3d 198, 207 (Ky. 2015). And, as in any medical malpractice claim, the plaintiff bears the burden of proof. *See Vitale v. Henchey*, 24 S.W.3d 651, 656 (Ky. 2000) (stating that "as a result of *Holton* and the Kentucky Informed Consent Statute, an action for a physician's failure to disclose a *risk or hazard of a proposed treatment or procedure* is now undisputedly one of negligence and brings into question professional standards of care[]").

A. KRS 304.40-320(1).

To show that a physician failed to comply with the first subsection of the statute, a plaintiff must demonstrate that the physician in question failed to meet the accepted standard of "the applicable medical specialty" when obtaining informed consent. *Argotte v. Harrington*, 521 S.W.3d 550, 555 (Ky. 2017), *overruled on other grounds by Univ. Med. Ctr. v. Shwab*, 628 S.W.3d 112 (Ky. 2021); *Sargent*, 467 S.W.3d at 209. In *Shwab*, we reaffirmed that informed consent is a process, not a document. 628 S.W.3d at 121 (quoting *Kovacs v. Freeman*, 957 S.W.2d 251, 254 (Ky. 1997)). We also noted in *Shwab* that the "crucial component" under KRS 304.40-320(1) is evidence that a medical care provider's actions did not comply "with the accepted standard of medical . . . practice among members of the profession with similar training and experience." 628 S.W.3d at 125.

In this case, as in *Shwab*, the Watsons' medical expert, Dr. Wilson, provided testimony that Dr. Windisch breached the standard of care in her post-operative care of Ms. Watson. Admittedly, Dr. Wilson was critical of what she knew of Dr. Windisch's informed consent procedure, specifically that Dr. Wilson should have provided more specificity in her written detail. The entirety of Dr. Wilson's testimony concerning informed consent, is the following:

> Q: Okay. With the understanding that — and we'll talk about this in a minute — that you have concerns about discussions with the patient about a reduced efficacy for situations where there's not urethral hypermobility, I don't see anything in your disclosure here you're making an opinion that Dr. Windisch deviated by not adequately

informing the patient of the risks of the procedure. Is that fair?

A. You said that you don't see anything in my disclosure where she discussed the reduced risk of efficacy with that? I don't know the details of her consent process.

Q. And maybe we can sort of eliminate a line of questioning here. You're not going to offer any opinions at trial that Dr. Windisch did not adequately inform the patient about the risks of the procedure.

A. No, because I have not seen any information about her informed consent process.

Q. Okay. You reviewed Dr. Windisch's office notes, correct?

A. Correct.

Q. You reviewed the hospital record, correct?

A. Correct.

Q. You saw the signed informed consent form?

A. I'm sure that it was included.

Q. Okay. I just don't want there to be any loose ends, Doctor.

(Exhibit Number 9 was marked for identification)

Q. Exhibit 9, I'll show you this. And we can get to Dr. Windisch's notes in a minute, but in terms of this consent form, clearly Ms. Watson was informed that bleeding, infection, damage to the urethra and/or bladder and incomplete emptying were potential complications of the transvaginal urethral sling being performed by Dr. Windisch, correct?

A. Correct.

Q. All right. And so in terms of Dr. Wilson's perception of the case, is this an adequate — is this adequate to satisfy informed consent of this patient?

A. Not for mesh.

Q. Okay. Let's look at — On November 5th of 2012, Dr. Windisch reported that, “Educational materials concerning the proposed surgical procedure were supplied to the patient: I explained the options concerning surgery versus more conservative treatment. I did tell the patient about various alternatives and why the sling procedure was indicated in her particular circumstance.” I'm sorry.

[Opposing counsel]. I'm just giving her the records so that she can —

Q. We're on page . . .

A. I see it.

Q. Okay. Based upon this charting by Dr. Windisch in conjunction with the signed consent form, that's adequate to inform the patient of the risk complication of the procedure correct?

A. No. I mean, she — "I did tell the patient about various alternatives." They're not specified, but in my deposition — or in my disclosures thing there, you know, I commented about the lack of urethral hypermobility. So what those various alternatives are, she's not detailed. They could be observation. It could be pessary insertion. It could be different types of slings. And when someone doesn't have urethral hypermobility and, you know, there's a known decreased efficacy with a midurethral sling for those patients, another option is an autologous sling or an allograft sling. So when she says "various alternatives," it's kind of vague.

Q. So what I'm hearing you say is you don't have enough information as you sit here today to assess whether – to formulate an opinion on whether or not Dr. Windisch complied with the standard of care in terms of informed consent.

A. Correct.

Q. Okay.

A. And — Well, I'll just leave it at that.

Q. Okay.

A. I mean, in regards to what she wrote on the consent regarding complications, those are all potential complications associated with any type of sling. I think that, though, especially in this era that we're in, especially in light of all of the mesh complications that we have, it's important to write the complications that are specific to mesh like erosion and extrusion and possible need for revision, dyspareunia, fistula formation.

Q. Do you write each of those on your informed consent?

A. I do.

Q. Okay.

A. Well, I write them in my discussion with the patient detailed, so like my notes here would have all of that spelled out.

Q. All right. And do you maintain — There are a lot of different kits obviously, right, TBTO, TBT, various manufacturers?

A. Uh-huh.

Q. Those manufacturers have materials that are provided to urologists who then can send those on to the patient, correct?

A. Sure.

Q. And those materials typically cover those complications and untoward events that you just discussed, correct?

A. I don't know because I don't use those materials. I discuss them. I make sure as the operating physician that I'm giving that information to my patient, not relying on some company to do it for me.

Q. Sure. But my question was, do those materials contain that —

A. I don't know because I don't use them.

Q. You've never looked at them?

A. No.

By contrast, as the Watsons concede, Dr. Windisch's two experts, Dr. Mickey Karram and Dr. Howard B. Goldman, both testified that Dr. Windisch's actions and disclosures complied with the applicable standard of care in obtaining Ms. Watson's informed consent. The Watsons, however, argue that Dr. Wilson's testimony created a disagreement about the standard of care that is appropriately decided by a jury.[4] We disagree.

[4] The Watsons additionally point to a 2008 FDA Public Health Notification titled, "Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ prolapse and Stress Urinary Incontinence." Although the Watsons' Appellants' Brief fails to detail where in the record this document was produced to the trial court, their Reply Brief supplies more information and states that Dr. Windisch's experts were questioned about this document. Significantly, no doctor opined that the FDA Notice established an applicable standard of care.

Dr. Wilson expressly did not render an opinion of the standard of care concerning informed consent. She opined as to her, Dr. Wilson's, practice. She discounted the use of manufacturer's literature. We held in *Shwab* that "KRS 304.40-320(1) requires more than one physician's personal opinion regarding how [she] believes informed consent should work." 628 S.W.3d at 125. Thus, Dr. Wilson's testimony simply does not constitute evidence that Dr. Windisch's actions for obtaining consent fell outside the accepted standard of medical practice. *See id.* at 125-26 (internal quotations and citations omitted).

B. KRS 304.40-320(2).

The second subsection of the statute focuses on the patient's general understanding and is couched in terms of a reasonable individual. Specifically, the focus is on that individual's general understanding of the procedure, medically acceptable alternative procedures or treatments, and substantial risks and hazards inherent in the proposed treatment or procedures which "are recognized among other health care providers who perform similar treatments or procedures[.]" KRS 304.40-320(2). As we held in *Sargent*, this subsection established the objective standard concerning the information that a reasonable individual must be provided. 467 S.W.3d at 209. In *Shwab*, we held that this information must be evaluated from the perspective of "a reasonable individual," and not from the subjective understanding or memory of the particular plaintiff. 628 S.W.3d at 127.

Our opinion in *Shwab* is further important because we explicitly held that KRS 304.40-320(2) required disclosure of "substantial risks and hazards"

as testified to by expert witnesses, *i.e.*, providers who perform similar treatments or procedures. *Id.* at 129. In doing so, we overruled *Sargent* and *Argotte* to the extent those opinions suggested "that the substantiality of a risk is a jury question that does not depend on medical evidence." *Id.*

The record discloses that Dr. Windisch employed recognized methods of informing her patient of the procedure, alternatives and substantial risks. Dr. Windisch discussed the proposed sling surgery with Ms. Watson during a clinic visit on November 5, 2012. Ms. Watson verified that the two had a discussion. Dr. Windisch provided educational pamphlets to Ms. Watson. Again, Ms. Watson conceded she was given materials to review and that she "probably read" them. Dr. Windisch's discussion was memorialized in a contemporaneous medical chart:

> I explained the options concerning the surgery versus other more conservative treatment. I did tell the patient about various alternatives and why the Sling Procedure was indicated in her particular circumstance. I advised the patient about the possible outcome and the possibility of infection post operatively [sic]. The patient expressed an understanding with regard to possible complications and outcome.

Dr. Windisch utilized a printed informed consent document. The preprinted portion of the document identified the general risks and hazards associated with surgery including "infection, blood clots in veins and lungs, hemorrhage, allergic reactions, cardiac arrest, and even death." The informed consent document allowed for surgery specific information to be handwritten. Here, the form expressly and unambiguously set out that "Dr Windisch was performing a "transvaginal urethral sling" to treat "stress incontinence" and that the

following were risks and hazards of the particular procedure: l) Bleeding[;] 2) Infection[;] 3) Damage to urethra bladder[;] 4) Incomplete emptying[.]" Ms. Watson signed the form on November 14, 2012. The signature was witnessed. Finally, Dr. Windisch gave Ms. Watson the opportunity to ask questions. The informed consent document also included a certification by Dr. Windisch that she had fully explained the risks and benefits of the procedure and "answered fully all of the patient's questions." Dr. Windisch signed the certification. As previously noted, Dr. Wilson was critical of Dr. Windisch's failure to document in writing mesh-specific complications, such as migration/erosion/extrusion. On the other hand, Dr. Windisch's testimony was that she, as matter of habit and routine, discusses the possibility of erosion and migration with her sling patients, and that the educational materials she provided addressed mesh-specific complications. Again, informed consent is a process, not a document. *Schwab,* 628 S.W.3d at 121. Dr. Wilson did not opine as to the applicable standard of care, only as to her practice. Further, Dr. Wilson was ill-suited to advise on the content of any educational materials since, as she testified, she does not use and has never looked at them. By contrast, Dr. Windisch's experts, Drs. Karram and Goldman, testified that Dr. Windisch had appropriately advised Ms. Watson.

Based on the foregoing, the trial court did not err in granting Dr. Windisch's motion for summary judgment on the issue of informed consent.

C. Adequacy of Notice Pleading—Informed Consent.

While the foregoing resolves this matter, we address briefly Dr. Windisch's argument that Ms. Watson failed to adequately plead failure of informed consent. Her argument is that following the November 2012 surgery and the filing of the complaint in 2014, the first notice that lack of informed consent was an issue arose in the deposition of Dr. Wilson, in October 2018. In other words, almost six years following the events at issue. The practical effect of this lapse was that both Ms. Watson and Dr. Windisch were unable to testify as to the precise conversations they had in November 2012. In addition, Dr. Windisch was unable to produce the educational materials she provided to Ms. Watson.

"Kentucky is a notice pleading jurisdiction, where the central purpose of pleadings remains notice of claims and defenses." *Russell v. Johnson & Johnson, Inc.*, 610 S.W.3d 233, 240 (Ky. 2020) (internal quotation and citation omitted); CR 8.01 ("[a] pleading which sets forth a claim for relief, whether an original claim, counterclaim, cross-claim, or third-party claim, shall contain (a) a short and plain statement of the claim showing that the pleader is entitled to relief"). In other words, a complaint is merely required to give a defendant fair notice and identify the claim. *Id.* at 241 (citing *Grand Aerie Fraternal Ord. of Eagles v. Carneyhan*, 169 S.W. 3d 840, 844 (Ky. 2005) and *Cincinnati, Newport, & Covington Transp. Co. v. Fischer*, 357 S.W.2d 870, 872 (Ky. 1962)). And as held in *Holton v. Pfingst*, 534 S.W.2d 786, 788 (Ky. 1975), a medical malpractice claim based on lack of informed consent is a negligence claim.

Significantly, however, the legislature has effectively codified the elements of informed consent by enacting KRS 304.40-320.

Here, the facts demonstrate the issue of informed consent was not specifically pled or mentioned in discovery until six years after institution of the suit. When informed consent was raised, it occurred during the deposition of Dr. Wilson, who twice stated she would not be opining on Dr. Windisch's conduct as to informed consent. Consequently, Dr. Windisch reasonably believed the medical negligence alleged only regarded the surgical implanting of the urethral sling. As the standard for establishing malpractice in a particular kind of surgery differs from proving informed consent for that surgery, this case shows that a general claim of medical malpractice without specific mention of informed consent fails to give adequate notice of the essential nature of the claim. Because identifying which professional standard the doctor is alleged to have violated is essential to a medical malpractice claim, we now hold a medical malpractice claim based upon lack of informed consent must be specifically pled since a generalized claim of medical malpractice fails to give fair notice to the defendant that informed consent will be at issue.

We know as well that although plaintiffs must specifically plead the lack of informed consent, necessary information regarding that claim may not always be available immediately. Therefore, trial courts are encouraged to allow plaintiffs to freely amend their complaints in appropriate situations.

IV. CONCLUSION.

Based on the foregoing, the Scott Circuit Court correctly entered its judgment dismissing the Watsons' action. We therefore affirm it and the Court of Appeals.

All sitting. All concur.

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