RENDERED: NOVEMBER 13, 2020; 10:00 A.M. NOT TO BE PUBLISHED

## Commonwealth of Kentucky

# Court of Appeals

NO. 2019-CA-1271-MR

#### CHARMIN WATSON AND STEPHEN WATSON

APPELLANTS

## APPEAL FROM SCOTT CIRCUIT COURT HONORABLE JEREMY M. MATTOX, JUDGE ACTION NO. 14-CI-00771

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

v.

**APPELLEES** 

#### OPINION AFFIRMING

\*\* \*\* \*\* \*\* \*\*

BEFORE: CALDWELL, JONES, AND KRAMER, JUDGES.

JONES, JUDGE: Appellants Charmin and Stephen Watson (hereinafter collectively referred to as "the Watsons") appeal the Scott Circuit Court's decision to grant summary judgment in favor of the Appellees Landmark Urology, P.S.C., and Dr. Amberly Kay Windisch, M.D. (hereinafter collectively referred to as "Dr. Windisch"). The Watsons argue that the circuit court erred in deciding their negligence-based claim for lack of informed consent as a matter of law; they maintain that the circuit court should have allowed the claim to be decided by a jury. Having reviewed the record in conjunction with all applicable legal authority, we affirm the circuit court's summary judgment.

#### I. BACKGROUND

In 2012, fifty-two-year-old Mrs. Watson was treated by urologist Dr. Amberly Kay Windisch at Dr. Windisch's Landmark Urology practice. Over the course of three visits, Dr. Windisch evaluated Mrs. Watson's complaints of urinary incontinence and diagnosed Mrs. Watson with moderate mixed incontinence, with stress incontinence being her primary problem.

There are several forms of incontinence – urge incontinence, stress incontinence, and mixed incontinence. Stress urinary incontinence occurs when there is urinary leakage caused by activities such as sneezing, laughing, coughing, or lifting. Mixed incontinence, from which Mrs. Watson suffered, manifests as a combination of both stress and urge incontinence symptoms. Stress urinary incontinence symptoms may be resolved surgically through the installation of a mid-urethral sling. Sling surgery involves the implantation of a thin strip of synthetic mesh under the urethra, which acts as a hammock to provide support during times of physical stress to prevent or reduce urine leakage. While generally considered to be safe and efficacious, sling surgery does come with known

- 2 -

complications, including bleeding, infection, damage to the urethra or bladder, and incomplete emptying. Even with the possibility of such complications, urethral slings are considered as a group to be the "gold standard" for treating urinary incontinence.

After her evaluation, Dr. Windisch recommended the placement of a mid-urethral mesh sling to treat Mrs. Watson's mixed incontinence. Dr. Windisch's medical charting reflects that she discussed possible complications of the sling surgery with Mrs. 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.

Record ("R.") at 577.

Neither Mrs. Watson nor Dr. Windisch could recall the specifics of their 2012 conversation. During her deposition, Mrs. 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?

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.

R. at 572.

Although Dr. Windisch also could not remember the specifics of her

conversation with Mrs. Watson, she described her usual routine for obtaining

informed consent from a patient prior to performing 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.

R. at 583.

Prior to surgery, Mrs. 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 Mrs. Watson was acknowledging the following risks:

1) Bleeding

- 2) Infection
- 3) Damage to the urethra/bladder
- 4) Incomplete emptying

R. at 580.

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, there was no evidence of injury to either organ.

Several days later, Mrs. Watson experienced an episode of urinary retention, a common complication of sling surgery, but reported that she was doing well afterward. In January of 2013, Mrs. Watson informed Dr. Windisch that there had been no change to her incontinence. On January 29, 2013, Dr. Windisch performed a follow-up cystoscopy, which showed Mrs. Watson's bladder and urethra to be normal. Subsequently, Watson reported some improvement in her symptoms. In March 2013, Dr. Windisch stopped treating Mrs. Watson and referred her to another urologist as Dr. Windisch was relocating her practice to North Carolina.

In November 2013, Mrs. Watson sought the evaluation of another urologist, Dr. Ballert. Mrs. Watson complained of pain and incontinence but noted that her symptoms had improved and were not bothersome. Three months later,

- 7 -

Dr. Ballert performed a cystoscopy and discovered that an area of the mesh sling installed by Dr. Windisch had eroded into Mrs. Watson's urethra and bladder, requiring reconstructive surgery. On March 14, 2014, Mrs. Watson underwent a surgical procedure to remove the mesh but continues to experience problems she claims originate from Dr. Windisch's sling surgery.

On November 7, 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." R. at 4. The Watsons' complaint did not explicitly reference informed consent, inadequate consent, or the statute outlining informed consent, KRS<sup>1</sup> 304.40-320. Mr. Watson also filed a loss of consortium claim following the results of his wife's surgery.

Plaintiffs identified one expert witness, urologist Dr. Tracey Wilson, who offered criticism that she believed Dr. Windisch violated the standard of care by failing to diagnose the erosion of the sling on January 29, 2013. Dr. Wilson's CR<sup>2</sup> 26 expert disclosure did not include any opinions related to informed consent. Dr. Wilson testified in her deposition that she did not intend to offer an opinion at trial regarding informed consent because she had not seen any information

<sup>&</sup>lt;sup>1</sup> Kentucky Revised Statutes.

<sup>&</sup>lt;sup>2</sup> Kentucky Rules of Civil Procedure.

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.

Trial was scheduled for February 19, 2019. On February 7, 2019, the circuit court held a final pretrial conference. There, 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 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 acknowledged that her motion was moot if the Watsons did not intend to present an informed consent claim at trial. 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.

At the conference, the circuit court denied Dr. Windisch's motion *in limine* in part, concluding that informed consent was adequately pled as a claim based in negligence. However, the circuit court then exercised its discretion and converted Dr. Windisch's motion *in limine* regarding informed consent into a

- 9 -

motion for partial summary judgment. The circuit court entertained arguments on the merits of the informed consent claim and took the motion for partial summary judgment under advisement.

On February 8, 2019, the Watsons filed a response to the newly converted motion for summary judgment. The Watsons argued that Dr. Windisch had failed to obtain informed consent by not fully explaining to Mrs. Watson that there was a risk of injury due to erosion or migration of the mesh sling,

necessitating reconstructive surgery.

On February 12, 2019, the circuit court entered an order granting

summary judgment on the Watsons' informed consent claim. The circuit court

concluded that the Watsons' claim failed as a matter of law, explaining:

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.

## R. at 603-04.

The Watsons still had a claim against Dr. Windisch for breaching the standard of care in performing the surgery and failing to diagnose the erosion. However, they immediately appealed the summary judgment to our Court. Dr. Windisch moved to dismiss the appeal on the ground that it was from an interlocutory order. We agreed and dismissed the appeal for lack of jurisdiction. The Watsons then voluntarily moved to dismiss all other theories of liability. After the circuit court granted the Watsons' motion to dismiss, only the informed consent claim was left, meaning the prior summary judgment order was no longer interlocutory.

This appeal followed.

#### II. STANDARD OF REVIEW

"[S]ummary judgment is to be cautiously applied and should not be used as a substitute for trial" unless "there is no legitimate claim under the law and it would be impossible to assert one given the facts." *Steelvest, Inc. v. Scansteel Serv. Ctr., Inc.*, 807 S.W.2d 476, 483 (Ky. 1991); *Shelton v. Kentucky Easter Seals Soc'y, Inc.*, 413 S.W.3d 901, 916 (Ky. 2013), *as corrected* (Nov. 25, 2013). A motion for summary judgment should only be granted "when it appears impossible for the nonmoving party to produce evidence at trial warranting a judgment in his favor" even when the evidence is viewed in the light most favorable to him. *Steelvest*, 807 S.W.2d at 482; *Shelton*, 413 S.W.3d at 905. 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. *Steelvest*, 807 S.W.2d at 482.

The standard of review on appeal from summary judgment is "whether the trial court correctly found that there were no genuine issues as to any material fact and that the moving party was entitled to judgment as a matter of law." *Lewis v. B & R Corp.*, 56 S.W.3d 432, 436 (Ky. App. 2001) (quoting *Scifres* 

- 12 -

v. Kraft, 916 S.W.2d 779, 781 (Ky. App. 1996); citing CR 56.03; Palmer v.

*International Ass'n of Machinists & Aerospace Workers*, 882 S.W.2d 117, 120 (Ky. 1994)). Because there are no factual findings at issue, the appellate court may review that trial court's decision *de novo*. *Shelton*, 413 S.W.3d at 905; *Barnette v*. *Hosp. of Louisa*, *Inc.*, 64 S.W.3d 828, 829 (Ky. App. 2002). On appeal, the record must be viewed in a light most favorable to the party who opposed the motion for summary judgment, and all doubts are to be resolved in his favor. *Malone v*. *Kentucky Farm Bureau Mut. Ins. Co.*, 287 S.W.3d 656, 658 (Ky. 2009).

#### III. ANALYSIS

The Watsons' sole issue on appeal is whether the circuit court erred granting summary judgment in favor of Dr. Windisch on their lack of informed consent claim. More specifically, the Watsons argue that material issues of fact exist as to (1) whether Dr. Windisch's communications with Mrs. Watson complied with the standard of care; and (2) whether Dr. Windisch failed to convey a general understanding of the risks and hazards of the surgery such that a reasonable individual would understand those risks. According to the Watsons, Dr. Windisch failed to comply with the standard of care by failing to disclose that the mesh sling could migrate and erode, causing damage that would require subsequent remedial surgery. As a preliminary matter, we address whether the Watsons' complaint was inadequately pled with regard to their informed consent claim, as this would render the substantive issue before us moot. Dr. Windisch contends that the Watsons' complaint failed to provide adequate notice of their claim for lack of informed consent because their complaint alleged only general negligence. We disagree.

Kentucky is a notice-pleading state. "All that is necessary is that a claim for relief be stated with brevity, conciseness and clarity." *Nat. Res. & Envtl. Prot. Cabinet v. Williams*, 768 S.W.2d 47, 51 (Ky. 1989) (citation omitted). A pleading that sets forth a claim for relief must contain a short and plain statement of the claim showing why the pleader is entitled to relief. CR 8.01(1)(a). According to our Supreme Court, "[d]espite the informality with which pleadings are nowadays treated, and despite the freedom with which pleadings may be amended, the central purpose of pleadings remains notice of claims and defenses." *Hoke v. Cullinan*, 914 S.W.2d 335, 339 (Ky. 1995) (citations omitted). For example, Kentucky courts have held that citing or referring to a statute provides adequate notice of a statutory claim. *Williams*, 768 S.W.2d at 51.

It is true that using generalized legal terms does not encompass all possible associated theories for the purpose of providing notice. Dr. Windisch points out that, as our Supreme Court held in *Hoke v. Cullinan*, a complaint

pleading only general negligence does not put a defendant on adequate notice that the plaintiff is also pursuing a claim of recklessness. *Hoke*, 914 S.W.2d at 340. In that case, the Court's determination was based upon the "qualitative differences between negligence and recklessness, the former consisting of a failure to exercise ordinary care and the latter consisting of conscious indifference . . . ." *Id.* at 339 (citation omitted).

However, it is also clear under Kentucky law that, "regardless of its form," an informed consent action is at its core an action for "negligence in failing to conform to a proper professional standard .... " Holton v. Pfingst, 534 S.W.2d 786, 788 (Ky. 1975), superseded by statute as stated in Sargent, 467 S.W.3d 198. Rather than imposing a qualitatively different standard, KRS 304.40-260 "amplifies" the general duty of ordinary professional care. Sargent, 467 S.W.3d at 206 (quoting Wemyss v. Coleman, 729 S.W.2d 174, 180 (Ky. 1987)) ("It is equally well-established that the legislature may 'as amplification of the "general duty",' impose specific, or special, duties."). KRS 304.40-320 does not create a separate claim, nor is there a requirement that the statute be specifically pled. Instead, the amplified duties set out therein are incorporated into the jury instructions. Sargent, 467 S.W.3d at 206; Henson v. Klein, 319 S.W.3d 413, 425-26 (Ky. 2010); Humana of Kentucky, Inc. v. McKee, 834 S.W.2d 711, 722 (Ky. App. 1992) ("[T]he court obviously is required to instruct the jury regarding that duty because the violation

of such a [statutory] duty, standing alone, may be sufficient to support a claim of negligence.").

In this case, the Watsons filed suit alleging that Dr. Windisch was negligent in her care and treatment of Mrs. Watson's medical problems. In pretrial discovery, the Watsons' evidence focused on establishing that Dr. Windisch was negligent in her failure to diagnose the intrusion of the mesh sling onto Mrs. Watson's urethra and in her failure to adequately inform Mrs. Watson of the possible risks associated with the surgery. Furthermore, both parties pursued lines of inquiry, albeit brief ones, regarding informed consent during the depositions of Dr. Wilson, Dr. Windisch, and Mrs. Watson. Therefore, it cannot be said that Dr. Windisch was taken unawares of the Watsons' intent to pursue an informed consent claim.<sup>3</sup> We find the circuit court correctly determined that the claim had

467 S.W.3d at 202 (emphasis in original).

<sup>&</sup>lt;sup>3</sup> Moreover, our Supreme Court made note of an identical pleading situation in *Sargent v. Shaffer*:

Sargent filed suit in the Fayette Circuit Court alleging that Dr. Shaffer was negligent in his care and treatment of her medical problems. In pre-trial discovery and at trial, Sargent's evidence focused on establishing that Dr. Shaffer was negligent in his performance of the surgical procedure *and* negligent in his failure to adequately inform her of the possible risks associated with the surgery. Both sides presented expert testimony on both theories of negligence. After overruling defense motions for directed verdicts, the trial court gave a separate jury instruction on each theory of liability.

been sufficiently pled, as lack of informed consent falls under the broad umbrella of negligence.

Having established the sufficiency of the Watsons' complaint, we now turn to the crux of this appeal. "[I]t is a well-established principle of [Kentucky] law that, as an aspect of proper medical practice, physicians have a general duty to disclose to their patients in accordance with accepted medical standards the risks and benefits of the treatment to be performed." *Sargent*, 467 S.W.3d at 206. The General Assembly, in exercising its "prerogative to amplify, or expound upon, the general duty of a medical provider," enacted the Kentucky Informed Consent Statute, which provides:

> 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 or dental 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 or dentally 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. "[A]s 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." *Vitale v. Henchey*, 24 S.W.3d 651, 656 (Ky. 2000).

A physician successfully obtains informed consent to perform a medical procedure only when *both* elements of the statutory standard are met. *Sargent*, 467 S.W.3d at 207 ("Construed in accordance with its plain terms and obvious meaning, it is readily apparent that . . . a medical treatment provider has satisfied the duty to obtain the patient's consent only if both provisions are met."). Accordingly, a physician's failure to satisfy just one of those elements results in liability.

To show that a physician failed to comply with KRS 304.40-320(1), 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*, 521 S.W.3d at 555; *Sargent*, 467 S.W.3d at 209. Ordinarily, the failure to comply with a medical profession standard can only be proven by expert testimony. *Argotte*, 521 S.W.3d at 556.

Dr. Wilson readily testified that she would not offer her expert opinion regarding the issue of informed consent. During her deposition, Dr.

Wilson clearly opined that she did not have sufficient information to determine

whether Dr. Windisch complied with the standard of care and would not be

offering her expert opinion on the matter:

Q. [W]e can get to Dr. Windisch's notes in a minute, but in terms of this informed 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. Alright. And so in terms of Dr. Wilson's perspective of the case, is this an adequate - is this adequate to satisfy informed consent of this patient?

A. Not for mesh.

• • • •

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 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.

R. at 587-88.

Although Dr. Wilson differentiated between what she personally would have done to obtain informed consent and what the sparse record shows Dr. Windisch did, she did not testify that Dr. Windisch deviated from the standard of care. Without any expert testimony and with such a limited record on the matter, the Watsons cannot show that the actions of Dr. Windisch were not in accordance with the accepted standard of medical practice as required by KRS 304.40-320(1). However, even though the Watsons cannot succeed under subsection 1 of the Informed Consent Statute, they could nevertheless prevail on their claim by showing that Dr. Windisch failed to satisfy KRS 304.40-320(2). The second component of the statutory duty imposed by KRS 304.40-320 addresses the content of the information provided by the physician when obtaining consent. Expert opinion is necessary only to establish "whether the 'risks and hazards' involved [in a plaintiff's claim] are among those 'recognized among other health care providers who perform similar treatments or procedures."" *Sargent*, 467 S.W.3d at 209. "Otherwise, whether the physician's notice to the patient would provide 'a reasonable individual' with a 'general understanding of the procedure and . . . [the] substantial risks and hazards inherent in the proposed treatment' is a question 'perfectly suited for application by jurors of ordinary competence, education, and intellect' without the need for expert testimony." *Argotte*, 521 S.W.3d at 556 (citation omitted).

The Watsons argue on appeal that "there is an issue of material fact regarding whether or not 'damage to urethra bladder' would provide a 'reasonable individual' with a 'general understanding' of the risk that the mesh sling could migrate, extrude, or erode into the urethra and bladder, which would require a subsequent revision surgery to reconstruct the bladder." Appellants' Br. at 16-17. Essentially, they maintain that KRS 304.40-320(2) requires a physician to disclose not only the recognized risks and hazards of a procedure, but also the mechanisms by which those injuries may occur.

In its flagship informed consent case, Sargent v. Shaffer, our Supreme Court explained: "Subsection (2) covers the content of 'the information provided,' and it sets forth the objective standard that 'a reasonable individual' must have from that information a 'general understanding' of the risks 'recognized among health care providers who perform similar treatments[.]" Sargent, 467 S.W.3d at 209 (citation omitted). In that case, the Kentucky Supreme Court addressed the question of whether the risks disclosed to the plaintiff encompassed the complications that actually arose, thereby providing notice for purposes of informed consent. Id. at 202. When discussing the risks of a lumbar laminectomy and decompression procedure, the plaintiff's physician warned of "infection, bleeding, nerve damage, dural leak, injury to the nerve, and destabilization of the scoliosis requiring fusion" and provided a written consent form additionally listing "injury to the surrounding structures" and "anesthesia." Id. at 205. The patient contended, however, that in order to obtain informed consent, the physician needed to use terms such as "paralysis," "incontinence," "loss of bowel and bladder control," and other such variations to provide proper notice of the potential risks. Id.

Ultimately, our Supreme Court determined that there was an issue of fact as to whether "nerve damage," "injury to nerve," and "injury to surrounding structures" would have adequately informed a patient that the surgery carried a risk

- 22 -

of more specific symptoms such as "paralysis," "incontinence," and "loss of bowel and bladder control[.]" *Id*. As such, the plaintiff patient was entitled to a specific jury instruction spelling out the "reasonable individual" and "general understanding" standards codified in KRS 304.40-320(2). *Id*. at 209.

Two years later, in Argotte v. Harrington, our Supreme Court revisited the issue of informed consent. In that case, a plaintiff alleged that her physician inadequately obtained informed consent for the placement of an IVC filter when the physician failed to inform her that the filter could fracture and migrate to other bodily organs. Argotte, 521 S.W.3d at 556. Instead, the physician informed the plaintiff of the risk of "migration of filter[.]" Id. The question before the Court was whether "the information [the physician] provided about those risks, 'migration of filter,' would provide 'a reasonable individual' with 'a general understanding' of the risk that the filter could break into fragments which could then migrate to other bodily organs." Id. The Court determined that while "a physician would understand 'migration of filter' to be synonymous with 'fracturing and fragmenting," a question of fact remained as to whether such terminology would provide a reasonable layperson with a general understanding of what bodily results that risk would entail. Id. at 556-57.

The Watsons contend that the present case is analogous to *Argotte v*. *Harrington*, arguing that Dr. Windisch violated her duty of care by failing to

- 23 -

inform Mrs. Watson that the mesh sling could migrate, erode, or extrude. Dr. Windisch's consent form warned Mrs. Watson generally of blood clots in the veins and lungs, hemorrhage, allergic reactions, cardiac arrest, and death as risks commonly associated with surgical procedures. Dr. Windisch made an additional handwritten notation warning of bleeding, infection, damage to the urethra/bladder, and incomplete emptying. Mrs. Watson has alleged injuries of pain, incontinence, and pain during intercourse, which the circuit court determined to be encompassed by "damage to the urethra/bladder." Dr. Windisch's consent form did not, however, disclose the mechanism through which such injuries could be sustained.

Contrary to the Watsons' assertion, the *Argotte* court was concerned that the term "migration" was too benign a description to necessarily encompass specific possible bodily injuries; in other words, the physician disclosed the mechanism of the complication rather than the risks that could occur. *Id.* In contrast to the facts of *Argotte*, Dr. Windisch's informed consent form addressed the injury – damage to the urethra and bladder – rather than the possible mechanisms by which that specific injury might occur. As established by *Sargent* and *Argotte*, such a disclosure is not required under KRS 304.40-320(2). Informed consent requires only the disclosure of potential risks, not the mechanism by which those potential injuries may occur. As Dr. Windisch points out, "[t]he use of amorphous terms of migration or erosion in an informed consent document is unnecessary when the essence of the risk is injury or damage to a particular organ or structure." Appellee's Br. at 16.

The Watsons also contend that Dr. Windisch should have informed Mrs. Watson that a subsequent surgery could be necessary to remove the sling if any of those processes occurred. We note that the Informed Consent Statute does not require a physician to detail the exact consequences of possible risks associated with a procedure. A subsequent remedial surgery like the one Mrs. Watson underwent is a potential risk associated with surgical procedure complications but not an injury itself.

Dr. Windisch's informed consent document warned of the exact injury Mrs. Watson unfortunately sustained as a result of the sling procedure. Based on the limited evidence before us, we cannot find an issue of material fact to submit to a jury and, therefore, affirm the circuit court's judgment.

#### **IV.** CONCLUSION

In light of the foregoing, we AFFIRM the judgment of the Scott Circuit Court.

## ALL CONCUR.

## BRIEF FOR APPELLANTS:

B. Clark Batten, IID. Seth CoomerStephen M. O'Brien, IIILexington, Kentucky

## BRIEF FOR APPELLEE AMBERLY KAY WINDISCH, M.D.:

Clayton L. Robinson Jonathan D. Weber Lexington, Kentucky