RENDERED: JUNE 15, 2017
TO BE PUBLISHED

Supreme Court of Kentucky

FINAL
DATE 7/6/17 Kim Redmon, DC

2015-SC-000465-DG

ALEX ARGOTTE, M.D. — APPELLANT

V.

ON REVIEW FROM COURT OF APPEALS
CASE NO. 2014-CA-001050-MR
MCCRACKEN CIRCUIT COURT NO. 08-CI-01512

JACQULYN G. HARRINGTON — APPELLEE

OPINION OF THE COURT BY JUSTICE VENTERS

AFFIRMING

This appeal arises out of a medical malpractice claim brought in the McCracken Circuit Court by Appellee, Jacqulyn G. Harrington, alleging that Appellant, Dr. Alex Argotte, failed to obtain her informed consent before undertaking a surgical procedure on her. In Harrington's opening statement at trial, her attorney informed the court and the jury that she would not present an expert witness because "you can use your own common sense" to determine if Harrington had been informed of the risks associated with the procedure. After concluding that Harrington could not prevail without the opinion of a testifying expert, the trial court dismissed Harrington's claim before the first witness was called.

The primary issue before us is whether Harrington's concession that she would not present an expert's testimony justified the trial court's entry of a directed verdict. The Court of Appeals reversed, concluding that the trial court too hastily dismissed the case since the evidence to be presented at trial may have established an exception to the general rule requiring expert testimony to establish a professional standard of care. The Court of Appeals rendered its opinion one month before the publication of our opinion in *Sargent v. Shaffer*, 467 S.W.3d 198 (Ky. 2015), which plumbed the depths of Kentucky's statutory standard for informed consent, KRS 304.40-320. On discretionary review, we affirm the judgment of the Court of Appeals, although we do so on different grounds based upon our decision in *Sargent*. Consequently, we remand the matter to the trial court for further proceedings.

I. FACTUAL AND PROCEDURAL BACKGROUND

Dr. Argotte performed two surgical procedures for Harrington: the placement of an inferior vena cava filter (IVC filter) and a subsequent gastric bypass surgery. Harrington's claim pertains only to the placement of the IVC filter which was done as a necessary antecedent to the gastric bypass surgery.

Before implanting the IVC filter, Dr. Argotte obtained a written consent form signed by Harrington. Pertinent provisions of the form are as follows:

> I have been informed of the nature, risk, consequences, and alternatives of the operation or procedure to be performed. The hospital is requesting that I sign this request form stating that I fully understand the operation or procedure, which was explained by my doctor.
>
> Physician Statement Risk:

Migration of filter[1]

> I have been made fully aware by Dr. Argotte and/or his staff of the procedure to be performed and I am now aware of the risks involved.

Harrington testified in a pre-trial deposition that neither Dr. Argotte nor his staff explained the consent form to her and that she felt rushed by Dr. Argotte's office staff to sign the papers they handed to her. Harrington also testified that Dr. Argotte advised her that the IVC filter was necessary to protect her from the risks associated with a pulmonary embolism (a blood clot) that might form as a result of the bypass surgery. He told Harrington he would not perform the gastric bypass procedure without having the IVC filter in place. Harrington testified that Dr. Argotte never personally advised her of any risks associated with the IVC filter or the process of implanting it. She was, of course, ostensibly aware from the written form that "migration of filter" was a risk, but she was not told that the filter could fracture and that fragments of the filter could break loose and travel through her veins to affect vital organs.

About two and one-half years after these procedures were performed, Harrington suffered severe chest pain. Prompt medical treatment disclosed that the IVC filter had fractured, allowing fragments of the device to migrate to her lungs and lodge there. Doctors surgically removed the main component of the IVC filter but the fragments in her lungs could not be removed. She

[1] The form also identified 19 other "risks" but none of them are pertinent to this appeal.

complains of continuing pain and discomfort and fear that fragments may migrate further resulting in serious harm or death.

In his opening statement at the start of the trial, Harrington's attorney explained to the court and the jury that the evidence would show that Dr. Argotte obtained Harrington's consent to the procedure without adequately informing her of the risks associated with the implanting of an IVC filter. He displayed an enlarged photocopy of the signed consent form identifying "migration of filter" as a risk but revealing nothing about the risk of "fracturing" or "fragmentation" of the filter. Counsel informed the jury that the evidence would show that Dr. Argotte never informed Harrington of the risk that the filter could fracture and break into fragments which could then lodge in her lungs, despite his knowledge of that possibility, and that future health problems or death could result from such fragmentation. Counsel also told the jury that the evidence would show that Dr. Argotte never informed Harrington that the IVC filter could eventually be removed to eliminate the risk of harm from fragmentation. Counsel also acknowledged that Harrington would not have a doctor testifying "about what a doctor should have told her," stating that the jurors could use their common sense to decide what a person in Harrington's shoes should have been told.

At the close of Harrington's opening statement, Dr. Argotte moved for a directed verdict, arguing that without an expert witness, Harrington was unable to prove a breach of the standard of care regarding informed consent. After considering arguments, the trial court agreed that Harrington could not

prevail at trial. Accordingly, the trial court directed a verdict in favor of Dr. Argotte and dismissed Harrington's claim.

The Court of Appeals reversed the dismissal and remanded the matter to the trial court. The Court of Appeals concluded that the trial court failed to consider that evidence adduced at trial could establish an exception to the general rule requiring expert testimony in medical cases. We granted discretionary review to address the granting of a directed verdict at the conclusion of the opening statement and to further examine whether Harrington's lack of informed consent claim could survive without an expert witness.

II. ANALYSIS

A. Directed verdicts on opening statements

Before addressing the substantive issue relating to informed consent, we must first address the unusual procedural posture of this case: the granting of a directed verdict dismissing the plaintiff's claim immediately after the plaintiff's opening statement. The general standard for granting a directed verdict is applicable here as it is in any directed verdict situation. "[A] trial judge cannot enter a directed verdict unless there is a complete absence of proof on a material issue or if no disputed issues of fact exist upon which reasonable minds could differ." *Biermann v. Klapheke*, 967 S.W.2d 16, 18-19 (Ky. 1998). "The trial court must draw all fair and reasonable inferences from the evidence in favor of the party opposing the motion." *Commonwealth v. Sawhill*, 660 S.W.2d 3, 5 (Ky. 1983). On appellate review of an order granting a

directed verdict, the test is whether "under the evidence as a whole it would not be clearly unreasonable for a jury to find [for the plaintiff]." *Id.*

Both parties in this action recognize, and we agree, that a directed verdict may be granted immediately after an opening statement. However, that summary disposition of a case is proper "only when counsel has made admissions that are fatal to his client's case." *Baker v. Case Plumbing Manufacturing Co.*, 423 S.W.2d 258, 259 (Ky. 1968) (citing *Riley v. Hornbuckle*, 366 S.W.2d 304, 305 (Ky. 1963)).

> [T]he court may take a case from a jury or enter judgment where it is clear from an opening statement either that the plaintiff cannot recover or that the defendant has no defense, as the case may be. This regards the statement as a judicial admission of the nonexistence of or inability to prove a cause of action or a defense, but even in such a case the action of the court should be exercised cautiously and only where the admission is clear.

Co-De Coal Co. v. Combs, 325 S.W.2d 78, 79 (Ky. 1959).

> In general, a directed verdict should not be granted until the conclusion of the plaintiff's case. . . . Nevertheless, Kentucky cases recognize the power of a trial court to decide a case upon the opening statements of counsel where they clearly and definitely disclose no cause of action or no defense, or admit facts the existence of which precludes a recovery by their clients. However, the cases admonish that the practice is a dangerous one and the power should be exercised with caution.

Lambert v. Franklin Real Estate Co., 37 S.W.3d 770, 774 (Ky. App. 2000).

Because fatal judicial admissions in opening statements are rare and the consequences of a directed verdict before hearing the evidence are severe, prudent trial judges are cautious and normally reluctant to grant such relief.

Although we disagree with the trial judge's decision to grant a directed verdict in this case, we commend the caution and careful deliberation he applied to the issue.

With this affirmation that a directed verdict *may* be properly granted at opening statements before the presentation of any evidence, we next consider whether *this* directed verdict was properly granted. The dispositive question is whether the acknowledgement in Harrington's opening statement that she would not present an expert witness to prove her claim that Dr. Argotte failed to obtain her informed consent was a judicial admission of a "complete absence of proof on a material issue," *Biermann*, 967 S.W.2d at 18, and thus fatal to her case, *Baker*, 423 S.W.2d at 259.

B. Lack of informed consent and the need for expert testimony

To determine whether Harrington's admission that she would not present expert testimony was fatal to her claim, we must examine the nature of her claim that Dr. Argotte failed to obtain her informed consent to implant the IVC filter. We begin with a review of what Kentucky law requires a physician to do in order to obtain the patient's informed consent.

KRS 304.40-320 establishes the legal standard for the informed consent that a physician must have before exposing a patient to the risks associated with a particular medical procedure. As we explained in *Sargent*, 467 S.W.3d at 206-207, a physician obtains the patient's informed consent to perform a medical procedure when the two elements of the statutory standard are met. First, pursuant to subsection (1) of KRS 304.40-320:

> 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.

Second, pursuant to subsection (2) of KRS 304.40-320:

> 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.

The first element of informed consent requires that the actions of the defendant physician in obtaining the patient's consent to be within the acceptable standard of practice of the applicable medical specialty. The second element of informed consent is an objective standard, requiring that the risk information conveyed to the patient by the health care provider must be such that it provides, not the specific patient, but "a reasonable individual," with "a general understanding of the . . . 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." As explained in *Sargent*:

> Subsection (1) covers the means employed by the health care provider to obtain the patient's consent. The 'action of the health care provider' in obtaining consent must be 'in accordance with the accepted standards of [the relevant] medical or dental practice[.]' KRS 304.40–320(1). Quite differently, Subsection (2) covers the content of 'the information provided,' and it sets forth the objective standard that 'a reasonable individual' must gain from that information a 'general understanding' of the risks 'recognized among health care providers who perform similar treatments[.]' KRS 304.40–320(2). The two subsections perform very different

functions and address two different aspects of 'informed consent.' 467 S.W.3d at 209.

Significant to our review is our conclusion in *Sargent*, based upon the conjunctive use of the word "and" in the statute between the two subsections of KRS 304.40-320, that to satisfy the statutory standard for obtaining the patient's informed consent, the physician must comply with *both* subsections. *Id.* 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."). Consequently, a breach of the statutory standard may be established by proving that the medical provider failed to meet either one of the two subsections of KRS 304.40-320.

To show that a physician failed to comply with subsection (1) of the statute, a plaintiff must show the physician's actions for obtaining consent fell outside "the accepted standard of medical or dental practice." Ordinarily, the failure to comply with a medical profession standard can only be proven by expert testimony. We agree that under the circumstances before us that without expert testimony, Harrington could not show that "the actions of [Dr. Argotte] in obtaining the consent of the patient [were not] in accordance with the accepted standard of medical . . . practice." KRS 304.40-320(1). But the viability of Harrington's claim does not depend upon showing a violation of KRS 304.40-320(1). Even if Harrington conceded that element to Dr. Argotte, she could nevertheless prevail on her claim by showing that the information he

provided regarding the risk failed to satisfy the second element, KRS 304.40-320(2). To comply with the statute, the healthcare provider must satisfy both elements of informed consent.

Proving the failure to comply with subsection (2) of KRS 304.40-320 requires an expert opinion only as needed to establish "whether the 'risks and hazards' involved [in the 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. *Id.*

Dr. Argotte himself provided the expertise required to show what risks associated with the IVC filter should be included in the notice to the patient. In a pre-trial deposition which would be available as evidence at trial, Dr. Argotte testified that the risks associated with an IVC filter included the risk that it could "fracture and migrate." Therefore, the only issue remaining was the factual question of whether the information he 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. That factual question is one that

could readily be resolved by reasonable jurors without the assistance of expert testimony.

Perhaps a physician would understand "migration of filter" to be synonymous with "fracturing and fragmenting" and, therefore, within the professional standard of care. But the obvious function of KRS 304.40-320(2) is to require physicians to inform patients of the risks associated with their treatment using terms generally understandable to a "reasonable individual." Harrington's admission that she would not call an expert witness may have foreclosed her ability to prove that Dr. Argotte failed to comply with subsection (1) of KRS 304.40-320, but it was not a judicial admission that would defeat her ability to prove the physician's failure to comply with KRS 304.40-320(2).

To summarize, Harrington's admission that she would not call an expert to testify was not fatal to her claim and thus was not a proper basis for entry of a directed verdict. Even if Dr. Argotte's actions, with respect to informing Harrington of the risks she faced, satisfied the professional standard under subsection (1) of KRS 304.40-320, or Harrington's lack of expert testimony made it impossible for her to prove otherwise, reasonable minds could still differ on whether Dr. Argotte complied with the KRS 304.40-320(2). Since providing informed consent requires compliance with both statutory elements, Harrington could make out a prima facie case by negating only one aspect of the statutory informed consent standard.

Because all parties acknowledged that fracturing and fragmenting of the filter, and the subsequent migration of filter fragments, to other parts of the

body, were risks associated with the procedure, the question of fact remaining was whether the phrase "migration of filter" would provide a reasonable individual with a general understanding of that risk. No expert is required for that determination. Consequently, Harrington's admission that she would not be presenting an expert witness cannot be regarded as an admission negating Harrington's cause of action. The trial court erred in granting the directed verdict.

C. Harrington's claim that Dr. Argotte failed to inform her that the IVC filter could be removed

Harrington also asserted at trial that Dr. Argotte breached his duty to obtain her informed consent because he failed to inform her that the IVC filter could be removed. This facet of her claim was also dismissed with the directed verdict. We find no fault with the dismissal of that claim. The fact that the IVC filter could be removed after her bypass surgery is not "a substantial risk" of the IVC filter placement and thus is not subject to the duty of giving informed consent. KRS 304.40-320 is not implicated in that issue.

Perhaps proper medical care dictates that Harrington should have been advised that the filter could be removed; perhaps not. The issue required medical expertise that Harrington apparently did not have. We conclude that the dismissal of that claim by the trial court was proper.

III. CONCLUSION

For the foregoing reasons, we affirm the Court of Appeals' decision to reverse the judgment of the McCracken Circuit Court dismissing Appellee's

claim. This matter is hereby remanded to the McCracken Circuit Court for further proceedings consistent with this opinion.

All sitting. Cunningham, VanMeter, and Wright, JJ., concur. Keller, J. concurs in part and dissents in part by separate opinion in which Minton, C.J. and Hughes, J. join.

KELLER, J. CONCURRING IN PART AND DISSENTING IN PART: I respectfully concur in part and dissent in part. I concur with the majority's well-reasoned conclusion that a directed verdict may be properly granted following opening. Furthermore, I agree with the majority that the trial court properly granted a directed verdict on Harrington's claim that Dr. Argotte failed to inform her that the IVC filter could be removed. However, I dissent as to that part of the majority's opinion which concludes that a directed verdict was not proper in this case.

The majority states that Harrington did not need an expert to establish the standard of care required in this informed consent case. According to the majority, "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." (Citing *Sargent*, 467 S.W.3d at 209). While that analysis may apply in some cases, I do not believe it applies in this case. Because I believe the standard the

majority developed in *Sargent* and applied herein is fact-intensive, I briefly summarize the pertinent parts of the record below.

As the majority notes, Dr. Argotte performed two surgical procedures on Harrington; however, the issue on appeal involves only the IVC filter surgery. Therefore, like the majority, my focus is only on that surgery and the informed consent, or lack thereof, that Dr. Argotte obtained from Harrington.

In early May 2005, Dr. Argotte surgically placed an IVC filter prior to performing gastric bypass surgery. Harrington had no apparent problems with that filter until December 2007, when she began to experience severe chest pain and sought treatment in the emergency room. X-rays indicated that the IVC filter had fractured; two pieces of the filter had lodged in Harrington's lungs; and one piece had lodged in her "left pulmonary artery take off." In order to prevent any further migration, a surgeon removed the remainder of the filter. However, surgery to remove the pieces that had migrated was deemed too risky and those pieces remain in place.

Harrington filed suit against Dr. Argotte and the IVC filter manufacturer. The parties eventually dismissed the manufacturer by agreed order, and Harrington proceeded against Dr. Argotte. Harrington asserted that Dr. Argotte violated the standard of care by failing to obtain adequate informed consent to perform the surgery and in how he subsequently performed that surgery. As to consent, it appears from the record that Harrington believes that Dr. Argotte should have advised her that: he was using a retrievable IVC filter; the IVC filter could be removed sometime after surgery, although he was not authorized

to do so; there was a risk the IVC filter could fracture; and if the filter fractured, pieces of the filter could migrate. As to the surgery itself, it appears that Harrington's primary complaint was that Dr. Argotte did not remove the IVC filter after he performed the gastric bypass surgery. Although Harrington ultimately dropped her claim related to the surgery, that claim is intertwined with her informed consent claim. Therefore, I summarize the testimony regarding both informed consent and the surgery below.

Dr. Argotte testified in his deposition that he advised Harrington regarding deep vein thrombosis (DVT) and the filter's role in helping reduce the risks associated with DVT. He also testified that he advised Harrington of the risks associated with implantation of the filter, including the risks of fracture and migration. I note that, at the time of the surgery, the medical community was not aware that this particular retrievable IVC filter had a greater than average propensity to fracture and migrate, and Dr. Argotte testified that he advised Harrington that all filters carried those risks. It is not clear from Dr. Argotte's deposition whether he advised Harrington that the filter was retrievable; however, it is clear that Dr. Argotte only intended to retrieve the filter "if indicated," and Dr. Argotte apparently saw no such indication.

Dr. Gaar, Dr. Argotte's expert witness, testified that the retrievable IVC filter used by Dr. Argotte in 2005 had been approved for use by the FDA, and those filters were marketed for both temporary and permanent use. According to Dr. Gaar, at the time of Harrington's surgery, retrievable filter fragmentation was rare and the risk was thought to be no greater than the risk associated

with permanent filters.[2] Despite the rarity of fracturing, Dr. Gaar stated that he would have advised Harrington of that risk as part of "global informed consent."

Regarding the surgery, Dr. Gaar stated that he does not personally implant IVC filters, leaving that task to interventional radiologists. However, he does require implantation of permanent filters with "super obese" patients in part because he believes the risk of DVT essentially never completely subsides post-surgery. Dr. Gaar has never recommended that an IVC filter be removed and, he noted that, in 2005, most interventional radiologists in his area would not have attempted to remove a functioning retrievable IVC filter that had been in place for more than six weeks. Finally, Dr. Gaar testified that he believes a surgeon who implants a retrievable IVC filter with the idea of removing it should discuss that option with the patient.

Dr. Silverman, Harrington's expert witness, testified that a surgeon should not use a retrievable IVC filter unless the plan is to retrieve it. According to Dr. Silverman, Dr. Argotte should have retrieved the filter no later than six months after he performed the gastric bypass surgery. As to whether a surgeon should advise a patient of the risk of fracture and migration, Dr. Silverman was somewhat inconsistent.

> Q: In [Dr. Argotte's] care for this patient do you have any criticisms that would relate to his informed consent process?

---

[2] Dr. Gaar testified that data available at the time of his deposition showed the IVC filter used by Dr. Argotte fractures approximately 25% of the time. However, at the time of Harrington's surgery, the fracture rate for that IVC filter was believed to be the same as for other retrievable and permanent filters.

A: I didn't see informed consent for the inferior vena cava filter in relation to personally discussing the incidence of fracture and migration.

Q: Do you believe that a reasonably competent physician should discuss the specific risks of fracture and migration with a patient before placing an inferior vena cava filter?

A: We just said that it's a known complication, fracture and migration. If the surgeon himself or herself is placing the filter, then it's incumbent upon them to actually discuss the risks of that procedure, which would include fracture and migration, which are really the main risks of that procedure.

Q: I'm going to show you what I understand to be the consent to surgery signed by Ms. . . . Harrington for the vena cava filter and ask if the list of risks is an appropriate list of risks in this case.

A: Everything is on here except for the fracture of the filter.

Q: In May of 2005, was fracture of the filter a known risk?

A: Yes.

Q: Is it your opinion that a physician should tell a patient that fracture of the filter is a potential risk of this surgery?

A: I think migration is good enough. I don't think it's negligence or a lack of patient responsibility or patient duties to list fracture. I think migration takes care of that.

Q: And am I correct that migration of the filter is listed on this form?

A: Yes.

Harrington testified that Dr. Argotte told her that he would not perform the gastric bypass surgery if she did not have an IVC filter. However, she stated that he did not tell her that the filter was retrievable or whether he intended to retrieve it. Harrington also testified that Dr. Argotte did not tell her about the risks of fracture or migration. And, although she admitted to signing

the consent form, Harrington testified that the form was presented to her along with a number of other forms she had to sign and that no one explained the form's contents to her.

Approximately three weeks before trial, Harrington's counsel advised Argotte's counsel that Harrington would not be calling any expert witnesses to testify at trial and that Harrington was only pursuing the informed consent claim. At a pre-trial conference two and a half weeks before trial and again the morning of trial, counsel for Harrington confirmed the preceding. The morning of trial, counsel for Dr. Argotte noted that Harrington was not going to call any physicians to testify at trial. Based on that lack of medical evidence, counsel argued that, without some medical testimony, Harrington would not be able to prove that the IVC filter fractured or that pieces of the filter migrated, thus, she would not be able to prove her case. Counsel for Harrington noted that Dr. Argotte had never contested the fact that the filter fractured and that pieces migrated. Furthermore, counsel noted that he could establish those facts through Dr. Argotte. The court was somewhat skeptical that Harrington could prove her case; however, the court indicated that it would address the issue when, and if, it arose during trial, and the parties proceeded with *voir dire*.

During his opening statement counsel for Harrington stated that Dr. Argotte did not tell Harrington that: she had a choice as to whether to have a filter implanted and to choose the type of filter; he was implanting a retrievable filter which could be removed; there were different risks and benefits for retrievable and permanent filters; he was not authorized to remove the filter;

and the filter could fracture. According to counsel, if Harrington had known the preceding she would have made different decisions. Finally, counsel stated that Harrington would not be calling an expert witness to testify regarding informed consent because "[y]ou can use your own common sense and decide for yourself what a person in [Harrington's] shoes should have been told, and you can decide whether she was told or not."

Following this opening statement, Dr. Argotte moved for a directed verdict. In support of his motion, Dr. Argotte argued that Harrington needed an expert witness to define what the standard of care is. Harrington argued that she did not need an expert relying on language from *Keel v. St. Elizabeth Med. Ctr.*, 842 S.W.2d 860, 862 (Ky. 1992), "that expert evidence is not required in all instances where the claim is lack of informed consent." The court recognized the holding in *Keel*; however, the court noted that the hospital in *Keel* "offered Keel *no information whatsoever* concerning any possible hazards of this particular procedure[.]" *Id.* (emphasis in original.) Unlike the plaintiff in *Keel*, Harrington admitted that she had been given some information, and she signed a consent form. Therefore, the court found that Harrington's reading and application of *Keel* was incorrect. The court then granted Dr. Argotte's motion because the court believed expert witness testimony was necessary and Harrington had admitted she was not going to present any such testimony.

Harrington filed a motion to alter, amend, or vacate, which the trial court denied, and this appeal followed. The Court of Appeals reversed, holding that

whether an expert witness is required is fact-specific and the court could not have made that determination following opening statement because no facts had been presented to the jury.

ANALYSIS.

As the majority states, in analyzing a trial court's directed verdict on appeal, the "test is whether 'under the evidence as a whole it would not be clearly unreasonable for a jury to find [for the plaintiff].'" Citing *Sawmill,* 660 S.W.2d at 5. In making that analysis, the Court should view the evidence in the light most favorable to the party opposing the motion. *Biermann,* 967 S.W.2d at 18-19.

Initially, I note that Harrington did not argue at trial that she failed to understand Dr. Argotte's explanation of the IVC filter surgery and its risks. She argued that Dr. Argotte gave no explanation whatsoever regarding the surgery. The majority holds that the issue is not whether Harrington was informed of the risks but whether a reasonable person would have understood the risk information that was provided. I fail to see how a reasonable person could have understood, or misunderstood for that matter, an explanation that she never received. If we take Harrington's argument at face value, then her reliance on *Keel* was appropriate because expert testimony is unnecessary when a patient receives no information regarding the risks of a procedure. 842 S.W.2d at 862.

However, as the trial court noted, we cannot take Harrington's argument at face value because she did receive information regarding the risks of the IVC

filter surgery. In fact, Harrington signed a consent form acknowledging that the risks on the form had been discussed with her. Therefore, I believe the trial court correctly determined that *Keel* was distinguishable and, pursuant to *Sargent,* this Court must determine if the explanation Harrington received met the requirements of KRS 304.40-420.

In making that determination, the majority relies on *Sargent* and undertakes a two-step analysis. I dissented in *Sargent,* however, I recognize that it is currently the law and therefore should be applied to this set of facts. I believe that the majority's application of *Sargent* is too simplistic. According to the majority, the first step in the *Sargent* analysis is to determine if Dr. Argotte obtained Harrington's consent "in accordance with the accepted standard of medical or dental practice among members of the profession with similar training and experience." I agree with the majority that Harrington would not have been able to prove a violation of this standard without the testimony of an expert witness.

However, I disagree with the majority that Harrington could have met the requirements of the second step without an expert witness. As the majority states, the primary issue is whether a reasonable person would have understood that the risk of the filter migrating included the risk that the filter might "break into fragments which could then migrate to other bodily organs." The majority believes that issue "could readily be resolved by reasonable jurors without the assistance of expert testimony." If that were the only facet of this

issue, I might agree with the majority's analysis. However, I do not believe that the step-two *Sargent* analysis is that simple generally or as applied to this case.

KRS 304.40-320(2) provides that informed consent shall be deemed to have been given if:

> 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[.]

I agree that, under *Sargent*, the jury could have decided without expert guidance whether a reasonable person could have understood that "migration" encompassed fracture and migration. However, that is not all KRS 340.40-320(2) requires. It also requires that the risk must have been a "substantial" risk that was "inherent in the proposed treatment" and that was "recognized among other health care providers who perform similar treatments or procedures." *Id.* The majority skirts this requirement by stating that "all parties acknowledged that fracturing and fragmenting of the filter, and the subsequent migration of filter fragments, were risks associated with the procedure."

It is true that all of the physicians agreed that there is a risk that IVC filters, either permanent or retrievable, can fracture. However, whether the risk exists is not the only issue. The risk must also be "substantial." I do not believe that a jury of laypersons, without guidance from providers who perform similar treatments or procedures, *i.e.*, expert witnesses, can independently

determine whether a risk is substantial.[3] Thus, Harrington was required to present expert testimony to at least establish the substantiality of the risk, and I cannot fault the circuit court for directing a verdict when Harrington admitted she had no such expert.

I note that the majority opinion does not address Harrington's complaint that Dr. Argotte failed to advise her that he was using a retrievable IVC filter. I would hold that resolution of this issue required expert witness testimony for the same reasons the majority held that expert witness testimony was needed regarding Dr. Argotte's alleged failure to advise Harrington that the filter could be removed.

Finally, although I disagree with the majority and believe the trial court correctly granted a directed verdict, I would instruct the trial court on remand to limit the parties to the evidence and witnesses that they identified in their pre-trial disclosures. Minton, C.J. and Hughes, J. join.

[3] Obviously, once there has been an appropriate determination regarding the adequacy of the informed consent, a plaintiff will have to prove causation and the other elements of the tort.

COUNSEL FOR APPELLANT:

Jonathan Rodgers Oliver
James Allen Sigler
Whitlow, Roberts, Houston & Straub, PLLC

COUNSEL FOR APPELLEE:

Clifton Aaron Boswell
Clifton A. Boswell, PLC

Charles S. Wible
Charles S. Wible Law Offices, PSC