IADC COMMITTEE NEWSLETTER

MEDICAL DEFENSE AND HEALTH LAW

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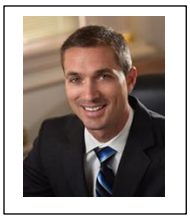
IN THIS ISSUE

Erik W. Legg and Samantha Thomas-Bush review a new decision of the Supreme Court of Kentucky addressing the degree to which expert testimony is necessary to create a fact issue on an informed consent claim.

Informed Consent, Experts and Openings

ABOUT THE AUTHORS



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The law in Kentucky continues to evolve with respect to informed consent claims in medical negligence cases, with the Kentucky Supreme Court rendering a not-yet-published opinion on June 15, 2017 that potentially allows the informed consent claim at issue to make its way to a jury without an expert witness. *See, Argotte v. Harrington*, __ S.W.3d __, 2017 WL 2591803 (Ky. June 15, 2017)[1].

The claim at issue arose after the defendant, Dr. Argotte, performed two surgical procedures on the plaintiff, Jacqulyn Harrington, consisting of placement of an inferior vena cava (IVC) filter, and a gastric bypass. Only the IVC placement procedure was pertinent to the Court's decision. Prior to surgery, Dr. Argotte obtained the patient's signature on an informed consent form. Among the risks which the form stated that the plaintiff had been informed of, was the term "migration of filter." The form went on to state that the patient had been informed by the doctor and his staff "of the procedure to be performed" and that the patient was "now aware of the risks involved." *Id*. at *2-3. The plaintiff testified at deposition that she had been rushed by the doctor's office to sign the form and that it was not explained to her. The plaintiff further testified that Dr. Argotte told her that it was necessary for him to place the IVC filter prior to performing the gastric bypass surgery in order to protect against the risk of development of a pulmonary embolism, and that he was unwilling to perform the gastric bypass without the IVC filter. *Id*.

Ms. Harrington testified that despite the inclusion of the words "migration of filter" – which term she said the doctor never explained to her – within the informed consent form, 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." *Id*. at *3. In short, she claimed to have remained uninformed about the risk of fragmentation or fracturing of the filter.

The injury giving rise to the lawsuit was discovered approximately two years after Dr. Argotte performed the gastric bypass / IVC placement, when the plaintiff began experiencing severe chest pain. Evaluation demonstrated that the IVC filter had fractured, and pieces of the filter had migrated and lodged in Ms. Harrington's lungs. She was told that the filter fragments in her lungs could not be removed. *Id*. Ms. Harrington filed a medical negligence claim in the Circuit Court of McCracken County, Kentucky, and the case proceeded to trial.

During the plaintiff's opening statement, Ms. Harrington's counsel told the jury that Dr. Argotte had failed to inform the patient of the risk of fracturing/fragmentation, and had also failed to inform her of the possibility that the filter could have been removed in order to abate this risk. Plaintiff's counsel also told the jury that Ms. Harrington did not have an expert to testify as to what Dr. Argotte had been required to tell the patient in order to

[1] It should be noted that this opinion is not yet final and citation to it may be premature.

meet the standard of care, submitting instead that the jurors could apply their own "common sense" in deciding what Ms. Harrington should have been told. *Id*. at *4.

Agreeing with the defendant that the plaintiff could not prevail without an expert witness, the trial court granted Dr. Argotte's motion for directed verdict following plaintiff counsel's opening statement. The intermediate Court of Appeals reversed and remanded, finding that the plaintiff should have been afforded an opportunity at trial to demonstrate that an exception was applicable in this case to the general rule requiring expert testimony in medical negligence cases. The Kentucky Supreme Court then granted discretionary review and considered two issues on appeal: Whether a trial judge may, as a matter of procedure, direct a verdict after opening statements; and whether the two informed consent claims brought by Plaintiff could survive without an expert witness.

On the procedural issue, the Supreme Court noted that "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." *Id*. at *6 (citing *Lambert v. Franklin Real Estate Co.*, 37 S.W.3d 770, 774 (Ky. App. 2000)).

Having confirmed that it may be permissible in some circumstances for a trial court to grant a directed verdict based upon admissions made in opening statements, the Court moved on to the substantive question specific to this case, which it framed as follows: "[W]hether 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', *Bierman [v. Klapheke]*, 967 S.W.2d [16 (Ky. 1983)] at 18, and thus fatal to her case, *Baker [v. Case Plumbing Manufacturing Co.]*, 423 S.W.2d [258 (Ky. 1968)] at 259." *Id*. at *7.

In answering that question, the Court first reviewed the requirements of Kentucky's informed consent statute, KRS § 304.40-320. Pivotal to the majority's determination of the case was its observation that the statute requires a physician to satisfy two separate standards in order to provide adequate informed consent. First, the physician's actions in obtaining informed consent must be in accordance with the applicable medical standard of care. *Id*. at *8. Second, the risk information conveyed by the doctor must be sufficient to provide "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." *Id*. This latter element provides an objective standard, based not upon what information is conveyed to the individual patient but to the theoretical reasonable person. *Id*.

The Court found that the trial court's directed verdict was in error because the plaintiff's admitted lack of expert testimony automatically defeated only the first element, but not the second, and the statutory construction of the statute at issue required compliance with both elements of the informed consent statute by healthcare provider. *Id*. at *9-10. The Court further found that the only necessary expert opinion with respect to the informed consent statute was whether the "risks and hazards" at issue had been "recognized among other health care providers who perform similar treatments or procedures." *Id*. at *10 (quoting *Sargent v. Shaffer*, 467 S.W.3d 198, 209 (Ky. 2015)). To that point, the Court concluded that "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", during his discovery deposition, in which he acknowledged that the IVC filter could "fracture and migrate." *Id*. at *10. Whether Dr. Argotte's disclosure of that risk, using that language, provided a reasonable person with the requisite general understanding of the risk of filter fragmentation, was determined by the Court to be a fact question. *Id*. at *10-12.

Essentially, the Court determined that the defendant health care provider himself may provide credible testimony in an informed consent claim as to the standard of what risks should reasonably be explained, and therefore, a non-party health care provider expert may not always be needed by the Plaintiff to prevail on that issue. *See Id*. at *10-11.

As noted above, a second informed consent claim was advanced by plaintiff in that she claimed not to have been informed that the IVC filter *could be removed*. *Id*. at *12. The Kentucky Supreme Court affirmed the trial court's dismissal as to that second claim, on the basis that it did not involve a "substantial risk," pursuant to KRS § 304.40-320. *Id*. The dissenting justices seized upon this holding as evidence of inconsistency within the majority opinion. Three of the seven justices sitting dissented on the issue of whether the directed verdict was proper in this particular matter. The dissent reasoned that, in an informed consent claim, there should be evidence provided by an expert witness to determine whether the migration and fracturing of the filter posed a "substantial" risk, which is required in KRS § 304.40-320(2). *Id*. at *22-23. Deposition testimony by Dr. Argotte's expert witness indicated that there was no known increased risk of the fracture and/or migration of this particular IVC filter at the time it was implanted (although only later science revealed that up to twenty-five percent (25%) of such filters can fracture). *Id.* at *16. A jury would need context from an expert, the Court reasoned, to determine what was "substantial." *Id*. at *22-23. This was the same test used by the majority to affirm the dismissal of the plaintiff's second informed consent claim regarding the retrieval/removal of the IVC filter. *Id*. at *12. The dissenting justices argued that the majority failed to exercise consistency of approach, when the majority did not analyze whether the fracture and migration of the filter was a "substantial" risk. *Id*. at *22.

While this case may be limited in applicability because it arose in an unusual procedural posture, *i.e.*, a directed verdict following opening statements, the dissenting Justices' concern is understandable. *Argotte*'s holding has the potential to muddy the water as to what standard of proof is required to establish whether a risk is "substantial" under the statute. Once the decision becomes final, plaintiffs in jurisdictions with similar informed consent standards are likely to cite to it when attempting to lower the bar for establishing a jury issue in informed consent cases where plaintiff's expert testimony is weak or absent.

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