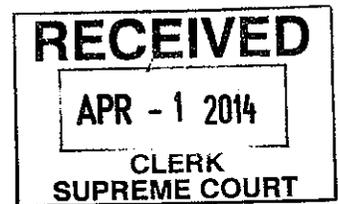


COMMONWEALTH OF KENTUCKY
SUPREME COURT
NO. 2013-SC-000111-D



LORETTA SARGENT

APPELLANT

v.

Court of Appeals No. 2011-CA-001696-MR
Fayette Circuit Court No. 10-CI-680

WILLIAM SHAFFER, M.D.

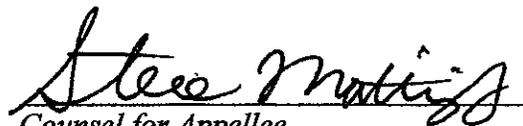
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It is hereby certified that a true and accurate copy of the foregoing was mailed on March 31, 2014, by Federal Express to Susan Stokley Clary, Clerk of the Kentucky Supreme Court, State Capitol Building, Room 209, 700 Capitol Avenue, Frankfort, KY 40601, and by first class U.S. mail to Samuel P. Givens, Jr., Clerk of the Kentucky Court of Appeals, 360 Democrat Drive, Frankfort, Kentucky, 40601, Joe C. Savage Law Firm, Security Trust Building, 271 W. Short Street, Suite 300, Lexington, Kentucky 40507; and the Hon. Pamela R. Goodwine, Fayette Circuit Court, Division 4, 382 Robert F. Stephens Courthouse, 120 North Limestone Street, Lexington, KY 40507.


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STATEMENT CONCERNING ORAL ARGUMENT

The Appellee, Dr. William Shaffer, believes that oral argument is not necessary. This appeal involves only one issue: whether the trial court correctly instructed the jury on Dr. Shaffer's duty in obtaining the informed consent of the Appellant, Loretta Sargent, for a surgical procedure. The trial court's instruction, which has been the standard duty instruction used in informed consent claims for nearly 40 years, is based on well-reasoned precedent from this Court and the Court of Appeals. Dr. Shaffer welcomes oral argument, however, if the Court believes that it would be of assistance in clarifying the trial record or the issue on appeal.

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COUNTERSTATEMENT OF THE CASE

This case arose from an elective spine surgery that the Appellee, Dr. William Shaffer, performed on the Appellant, Loretta Sargent, on February 18, 2009, when Sargent was 71. At the time, Dr. Shaffer was an orthopaedic spine surgeon at the University of Kentucky.¹ After surgery, Sargent experienced weakness and numbness in her lower extremities, which progressed into near-complete paraplegia. She contended at trial that Dr. Shaffer was negligent in obtaining her informed consent to surgery and in performing one part of the procedure, the removal of a herniated disc at the T12-L1 level. The jury found for Dr. Shaffer on both questions of alleged negligence, and the trial court entered a judgment reflecting the verdict.

Sargent appealed, raising one issue applicable to each of her theories of negligence. As to the informed consent claim, Sargent argued that the trial court should have given a different jury instruction that contained the language in Kentucky's informed consent statute, KRS 304.40-320. Concerning the surgical negligence claim, she argued that the trial court should not have permitted Dr. Shaffer to use a particular spine model to demonstrate how he performed the surgery. The Court of Appeals rejected these arguments and affirmed the judgment.

Sargent moved for discretionary review on only one of these two issues: the correct instruction on a physician's duty in obtaining a patient's informed consent for a medical procedure. Sargent did not ask this Court to review the part of the Court of Appeals' opinion affirming the trial court's ruling on the spine model issue impacting the surgical negligence claim. Thus, only the portion of the judgment concerning the informed consent claim is at issue in this appeal.

¹ Dr. Shaffer subsequently moved to Iowa for family reasons. (VR: 9/1/11; 1:29:00 – 1:29:26.)

Sargent's medical history was an important part of the proof at trial, especially with respect to the informed consent claim. Sargent's back problems started long before she first saw Dr. Shaffer in 2008. In 2001, Sargent underwent surgery for severe lower back and leg pain. A Lexington neurosurgeon, Dr. James Bean, performed a procedure to "decompress" the L2-3 and L3-4 levels of Sargent's spine by removing bone spurs that were putting pressure on nerves.² Sargent experienced serious post-surgical complications, including transient lower extremity paralysis, numbness, and the loss of motor control in her left foot.³ These complications necessitated a second "rescue" operation eight days after the first surgery. (*Id.*) This time, Dr. Bean performed a laminectomy at the T12-L1 level and removed part of a herniated disc in that area. (*Id.*)⁴

After these procedures, Sargent never recovered motor control in her left foot, and this condition (known as a "foot drop") eventually required amputation of her left big toe.⁵ Sargent also continued to have severe back and leg pain that was not relieved with medication. (*Id.*) She inquired to Dr. Bean about whether another surgery could help her problems, but Dr. Bean recommended conservative pain-management treatment.⁶

Although she tried conservative treatments over the next several years – including medication, physical therapy, and epidural steroid injections – Sargent experienced little, if any, relief.⁷ Sargent's condition severely limited her daily life activities. (*Id.*) By 2008, she had to use a motorized cart when shopping because she could not tolerate

² Def. Ex. 9.

³ R. 67.

⁴ A laminectomy involves removal of part of the lamina, a bone in the spinal column, to relieve pressure on the spinal elements or the nerve roots exiting the spinal canal.

⁵ Def. Ex. 26; Plf. Ex. 6, 6-9-08.

⁶ R. 70.

⁷ Plf. Ex. 6, 6-9-08.

walking through a store. (*Id.*) Sargent saw several other surgeons, but none was willing to offer surgery to help her problem.⁸

In May 2008, Sargent saw another spine surgeon, Dr. Harry Lockstadt with Bluegrass Orthopaedics in Lexington.⁹ Dr. Lockstadt ordered an MRI of the lumbar spine, which showed a large disc herniation at T12-L1 and stenosis and disc degeneration at multiple lower levels of the spine.¹⁰ Dr. Lockstadt thought Sargent could be helped by a surgical procedure involving a T12-L1 discectomy and decompression of several lower levels of her lumbar spine.¹¹ Believing that Sargent needed to see a surgeon in the university setting, Dr. Lockstadt referred her to Dr. Shaffer.¹²

Dr. Shaffer first saw Sargent on June 9, 2008.¹³ Although Sargent was interested in having surgery from the outset, Dr. Shaffer did not initially recommend or offer it. Instead, he attempted conservative treatments, including medications and a back brace.¹⁴ He also referred Sargent to a UK pain management specialist, Dr. Jay Grider, who performed an epidural steroid injection.¹⁵ Dr. Grider offered Sargent other non-surgical options, including an implanted narcotics pump or a dorsal column stimulator, but Sargent declined them.¹⁶ Sargent was determined to have surgery, which she felt was the only way to gain relief.¹⁷

⁸ VR: 8/31/11; 1:45:46-1:46:16.

⁹ *Id.* at 7:21:16.

¹⁰ *Id.* at 7:21:16, 7:39:33; Def. Ex. 31.

¹¹ VR: 8/31/11; 7:42:06.

¹² *Id.* at 7:41:00.

¹³ Plf. Ex. 6.

¹⁴ VR: 8/31/11; 1:57:00-1:57:55; Plf. Ex. 6.

¹⁵ Def. Ex. 11.

¹⁶ *Id.*; VR: 8/30/11; 3:24:50.

¹⁷ VR: 8/31/11; 1:56:00-1:57:09.

Before offering surgery, Dr. Shaffer saw Sargent in the University of Kentucky spine clinic eight times over a seven-month period.¹⁸ During each visit, he sought to impress on her that another surgery would be complicated and would include serious risks.¹⁹ Dr. Shaffer explained at trial, “I... spent many counseling sessions, not just the one I documented at the end, but many visits, you know, formal and informal, where I said ‘Loretta, you’ve got to really think about this. This is a big deal. Okay?’”²⁰ He told Sargent that surgery could make her worse, damage her nerves, and injure the neural structures. (*Id.*) He explained that the surgery he would perform would be a “salvage procedure” that would entail “trying to make something better that has been badly damaged previously.”²¹ Dr. Shaffer informed Sargent that decompressing her spinal nerve roots would be difficult – “like chipping a worm out of a concrete block without hurting the worm.”²²

Dr. Shaffer did not offer surgery until an office visit on January 23, 2009, seven months after he first saw Sargent.²³ He agreed to perform a lumbar laminectomy and decompression procedure, which would involve removal of bone and scar from multiple levels of Sargent’s lumbar spine.²⁴ Based on what he saw after this initial removal of bone and scar tissue, Dr. Shaffer would also consider removing what remained of the T12-L1 level herniated disc that had been partially removed by Dr. Bean in 2001. (*Id.*)

¹⁸ Plf. Ex. 6; VR: 9/1/11; 1:36:00-1:39:11.

¹⁹ VR: 9/1/11; 1:38:55-1:39:54; 8/30/11; 9:27:30, 9:32:20-9:34:34.

²⁰ VR: 8/30/11; 9:39:47-9:41:28.

²¹ *Id.* at 9:33:26-9:33:44.

²² *Id.* at 9:40:30-9:40:45.

²³ Plf. Ex. 6.

²⁴ Plf. Ex. 7, 8.

Dr. Shaffer required Sargent to obtain medical clearance before surgery.²⁵ After a Lexington cardiologist, Dr. Pamela Combs, cleared Sargent, Dr. Shaffer scheduled a pre-surgery counseling session with Sargent and her family.²⁶ During this visit, he discussed the risks of the surgery, including the risk of infection, bleeding, nerve damage, dural leak, injury to the nerve, and destabilization of the scoliosis requiring fusion. (*Id.*) On the morning of the procedure, Sargent signed a consent form that listed these risks.²⁷

The surgery took place on February 18, 2009, at UK Good Samaritan Hospital. Dr. Shaffer decompressed levels L5 to L1 of the spine.²⁸ He then proceeded to remove the remaining herniated disc at the T12-L1 level. (*Id.*) Dr. Shaffer testified that with all the lower-level bone removed, he had more room to operate when removing the disc.²⁹ He successfully removed most of the remaining herniated disc using a “posterolateral approach” from the right side.³⁰ Sargent was transported to the recovery room in stable condition. (*Id.*)

Sargent initially had trace motor function and some sensation in both legs.³¹ But over the next few days, she experienced increasing weakness and loss of sensation in her lower extremities. (*Id.*) Nine days after surgery, Sargent was transferred to Cardinal Hill

²⁵ Plf. Ex. 6.

²⁶ Plf. Ex. 6; Def. Ex. 27; VR: 9/1/11; 1:43:54-1:46:09.

²⁷ The consent form says, “my doctor has told me that some problems (risks and complications) may happen if I have this procedure. These possible problems include: bleeding, infection, nerve injury, injury to sensitive structures, dural tear, and anesthesia. No one has guaranteed me that this procedure will have certain results.” (Plf. Ex. 7.)

²⁸ Plf. Ex. 8.

²⁹ VR: 9/1/11; 2:06:30-2:07:47.

³⁰ *Id.* at 2:09:23-2:10:29; Plf. Ex. 8. In 2001, Dr. Bean used a similar “posterolateral” approach from the opposite (left) side in removing part of the same herniated disc. (R. 67.)

³¹ VR: 9/1/11; 2:16:51-2:18:10.

Hospital, where she underwent six weeks of rehabilitation.³² Before he relocated to Iowa, Dr. Shaffer saw Sargent in his office four times after her discharge from Cardinal Hill.³³

Sargent commenced this action in February 2010. (R. 1.) The language of her complaint is very important for purposes of the issue on appeal. Sargent alleged simply that Dr. Shaffer was “negligent in [his] care and treatment of Loretta Sargent.” (R. 1 at ¶9.) Sargent did not make any specific allegations of negligence against Dr. Shaffer. Most important, she did not assert a specific claim for lack of informed consent, allege a violation of KRS 304.40-320 (the informed consent statute), or even mention the term “informed consent.” (*Id.*)

During discovery and at trial, both parties had ample opportunity to develop and present their positions on Dr. Shaffer’s surgical care and the cause of Sargent’s outcome. Sargent called two well-qualified spine surgery experts: Dr. Bradford DeLong, a retired neurosurgeon from Idaho; and Dr. Robert Banco, an orthopedic spine surgeon from Boston. Sargent’s experts maintained that Dr. Shaffer was negligent in two respects: (1) his informed consent process was unreasonable because he did not use the specific words “paralysis” or “paraplegia”; and (2) his use of a posterolateral approach to remove the remaining T12-L1 herniated disc was improper and caused Sargent’s paralysis.³⁴

Dr. Shaffer also called two well-qualified experts: Dr. Scott Boden, an orthopedic spine surgeon at Emory University; and Dr. Christopher Shaffrey, a neurosurgeon of the University of Virginia. They supported Dr. Shaffer’s care in every respect. Dr. Boden and Dr. Shaffrey testified that Dr. Shaffer’s approach to the T12-L1 disc was appropriate,

³² R. 109, 112-117.

³³ VR: 9/1/11; 2:22:39-2:22:51.

³⁴ See DeLong testimony, VR: 8/30/11; 10:56:00; Banco testimony, VR: 8/31/11; 9:08:00.

commonly used, and well within the standard of care.³⁵ Moreover, both defense experts testified that Dr. Shaffer's approach was not the likely cause of Sargent's paraplegia. They explained that her condition likely resulted from an unforeseeable vascular event, not manipulation of the area around the spinal cord during removal of the herniated disc.³⁶

Dr. Shaffer's experts also established that Dr. Shaffer's informed consent process complied with accepted standards of care in the spine surgery field. Dr. Boden testified that he was not aware of any standard or guideline in the field that requires a surgeon to use the word "paralysis" when obtaining consent for a procedure like the one performed on Sargent.³⁷ Dr. Shaffrey testified that Dr. Shaffer did not need to use the words "paralysis" or "paraplegia" because the near-total paraplegia of the sort experienced by Sargent was "a distinctly unusual event"; he estimated that the risk of such an outcome from this procedure was 1/3000 to 1/5000.³⁸ Dr. Shaffer also offered evidence at trial demonstrating that, during the years before she saw Dr. Shaffer, Sargent underwent multiple medical procedures after signing consent forms disclosing a risk of paralysis or death.³⁹ This evidence, combined with Sargent's unrelenting desire to have another spine surgery, justified an inference that Sargent would have proceeded with spine surgery in 2009 even if the particular word "paralysis" had been used in the consent form or during her discussions with Dr. Shaffer.

³⁵ See Boden testimony, VR: 9/1/11; 9:39:04-9:39:26; Shaffrey testimony, VR: 8/31/11; 2:42:24-2:42:57.

³⁶ VR: 8/31/11; 3:10:00-3:12:54; 9/1/11, 9:57:00-9:59:54.

³⁷ VR: 9/1/11; 10:19:48-10:20:42.

³⁸ VR: 8/31/11; 3:12:57-3:15:01.

³⁹ Def. Ex. 22, 23; VR: 8/31/11; 1:54:00.

At the conclusion of the evidence, the trial court, over Dr. Shaffer's objection, decided to give separate jury instructions on the two allegations of medical negligence.⁴⁰ The jury found for Dr. Shaffer on both questions of alleged liability.⁴¹ Sargent appealed, raising two claims of error: (1) that the trial court erred by allowing Dr. Shaffer to use a spine model to demonstrate how he performed the procedure at issue; and (2) that the trial court erred by declining to give Sargent's tendered instruction on Dr. Shaffer's duty in obtaining Sargent's informed consent. The Court of Appeals rejected both arguments and affirmed the judgment.⁴² Sargent moved for discretionary review, challenging only the Court of Appeals' ruling on the informed consent jury instruction issue. There is no issue before this Court regarding the separate jury verdict on the surgical negligence claim.

ARGUMENT

I. The trial court gave the correct instruction on a physician's duty in obtaining a patient's informed consent.

The trial court gave the following correct instruction on Dr. Shaffer's duty in obtaining Sargent's informed consent:

With respect to disclosing to Plaintiff, Loretta Sargent, the risks and benefits of the surgical operation he proposed to perform upon her it was the duty of the Defendant, William Shaffer, M.D., to exercise the degree of care and skill expected of a reasonably competent physician specializing in orthopaedic spine surgery acting under similar circumstances.

(Judgment, App. 1.)

⁴⁰ See Judgment, Appendix 1, and VR: 9/1/11; 12:08:38. As detailed in Section II.B below, the trial court was not required to give a separate instruction on informed consent, because Sargent's complaint did not contain an informed consent claim; it only recited a general allegation of medical negligence against Dr. Shaffer.

⁴¹ Judgment, App. 1.

⁴² Sargent's brief at App. 1.

Sargent does not dispute that this instruction has been given by trial courts throughout the Commonwealth for nearly 40 years in cases involving claims that a physician was negligent in obtaining a patient's informed consent for a medical procedure. The trial court's instruction was patterned on Palmore & Cetrulo's model instruction for informed consent claims. See Palmore & Cetrulo, *Kentucky Instructions to Juries*, § 23.10.⁴³

Palmore's model instruction is based on this Court's longstanding precedent. It has been clear since *Holton v. Pfingst* was decided in 1975 that an informed consent claim alleging failure to adequately explain the risks of a procedure is a claim for negligence in failing to conform to the professional standards of the medical profession. *Holton v. Pfingst*, 534 S.W.2d 786, 788 (Ky. 1975); see also *Keel v. St. Elizabeth Med. Ctr.*, 842 S.W.2d 860, 861 (Ky. 1992); *Vitale v. Henchey*, 24 S.W.3d 651, 656 (Ky. 2000); *Hawkins v. Rosenbloom*, 17 S.W.3d 116, 119 (Ky. App. 2000).

The informed consent statute, KRS 304.40-320, which was enacted in 1975, did not change the law on a physician's duty in obtaining informed consent. Rather, as this Court explained in *Lewis v. Kenady* and *Vitale*, the statute simply codifies this Court's holding that an informed consent claim, like any other medical malpractice claim, is a negligence claim implicating professional standards of care. In *Lewis*, this Court wrote that KRS 304.40-320 "attempts to codify the common law as to when informed consent has been given and obtained...." 894 S.W.2d 619, 623 n.1 (Ky. 1994). In *Vitale*, the Court stated that KRS 304.40-320 codified *Holton's* holding that "an action for a physician's failure to disclose a risk or hazard of a proposed treatment or procedure is

⁴³ This model instruction and the other model instructions from Palmore's *Kentucky Instructions to Juries* discussed herein are enclosed at Appendix 2.

now undisputedly one of negligence and brings into question professional standards of care.” 24 S.W.2d at 656 (emphasis removed). *Vitale* and *Lewis* demonstrate that the enactment of KRS 304.40-320 did not alter a physician’s duty in obtaining a patient’s informed consent for a medical procedure. That duty is to act as a reasonably competent physician in his or her specialty of medicine acting under the same or similar circumstances. *Id.* The instruction given by the trial court correctly stated this duty. (Judgment, App. 1.)⁴⁴ Neither *Vitale* nor *Lewis* suggests that the language of KRS 304.40-320 should be incorporated into a jury instruction.

The trial court’s instruction is the standard duty instruction that has been given by trial courts throughout the Commonwealth ever since *Holton* was decided in 1975. The instruction was not erroneous. As this Court explained in *Olifice v. Wilkey*, 173 S.W.3d 226, 230 (Ky. 2005), the question on appeal is not whether the trial court’s instructions “best stated the law, but rather whether the delivered instructions misstated the law.” There is no credible argument that the trial court’s instruction “misstated the law” regarding Dr. Shaffer’s duty in obtaining Sargent’s informed consent. The trial court did not err in instructing the jury on Sargent’s informed consent claim.

II. The trial court did not abuse its discretion by declining to give Sargent’s proposed instruction on Dr. Shaffer’s duty in obtaining informed consent.

Sargent argues that the trial court erred by declining to give her proposed instruction on Dr. Shaffer’s duty in obtaining informed consent. The standard of review for this claim of error is abuse of discretion. “It is within a trial court’s discretion to deny

⁴⁴ In conducting the direct examination of Sargent’s expert witnesses, Sargent’s own counsel suggested that the language used in the trial court’s instruction correctly states a physician’s duty in obtaining informed consent. (See DeLong testimony, VR: 8/30/11, 10:56:53, “[D]o you have an opinion that in obtaining the consent of Loretta Sargent to perform surgery, whether Dr. Shaffer did or did not exercise that degree of care expected of a reasonably prudent and competent spine surgeon?”; Banco testimony, VR: 8/31/11, 9:08:54, “In obtaining the consent of Loretta Sargent to perform surgery, did Dr. Shaffer exercise that degree of care expected of a reasonably competent spine surgeon?”).

a requested instruction, and its decision will not be reversed absent an abuse of that discretion.” *Office*, 173 S.W.3d at 229.⁴⁵

Sargent’s proposed instruction stated,

It was the duty of William Shaffer, M.D. to obtain Loretta Sargent’s informed consent before the surgery. Informed consent shall be deemed to have been given where (1) the action of Dr. Shaffer in obtaining the consent of 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 William Shaffer, MD, 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.

(Sargent’s brief at App. 4.) This proposed instruction tracks the language of KRS 304.40-320, which provides in relevant part,

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

⁴⁵ In recent cases, this Court has reiterated that trial courts have the authority to deny requested instructions, “and their decision to do so will only be reversed for an abuse of discretion.” *Savage v. Three Rivers Med. Ctr.*, 390 S.W.3d 104, 118 (Ky. 2012); *Nazar v. Branham*, 291 S.W.3d 599 (Ky. 2009). The Court recently observed that there is some inconsistency in the case law concerning the proper standard of review for alleged errors in jury instructions. *Goncalves v. Commonwealth*, 404 S.W.3d 180, 193 n.6 (Ky. 2013). The standard of review makes no difference in this case, because the trial court’s instruction correctly stated Dr. Shaffer’s duty in obtaining Sargent’s informed consent, and the trial court correctly rejected Sargent’s proposed informed consent instruction.

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.

The trial court did not err or abuse its discretion by declining to give Sargent's proposed instruction for the following five reasons: (1) there is no precedent requiring the trial court to give the instruction proposed by Sargent; (2) because Sargent did not assert a separate cause of action for failure to obtain informed consent, the trial court was not even obligated to give a separate instruction on informed consent; (3) Sargent's proposed instruction would deviate from and violate this Court's longstanding commitment to the "bare bones" method of instructing juries; (4) in medical negligence cases against physicians, specific duties required by the standard of care are set forth through expert testimony, as they were in this case, not through jury instructions; and (5) the rationale for including certain statutory duties in jury instructions – the doctrine of negligence *per se* – does not apply under the procedural facts of this case or to KRS 304.40-320 in general.

A. No appellate decision sanctions, let alone mandates, the use of Sargent's proposed instruction.

Neither this Court nor the Court of Appeals has ever held that the language of KRS 304.40-320 should be included in the jury instruction on a physician's duty in obtaining a patient's informed consent. This Court has discussed KRS 304.40-320 in several different cases.⁴⁶ In none of those cases has the Court suggested that the language of this statute should be included in the jury instruction on an informed consent claim.

⁴⁶ *Keel*, 842 S.W.2d 860, *Lewis*, 894 S.W.2d at 623 n.1; *Kovacs v. Freeman*, 957 S.W.2d 251, 255-56 (Ky. 1997); *Vitale*, 24 S.W.3d at 655-656.

Instead, as mentioned above, the Court has stated that the statute simply codifies the common-law principle confirmed in *Holton* – that a claim alleging negligence in the informed consent process is just like any other medical negligence claim and implicates professional standards of care. *Vitale*, 24 S.W.3d at 656; *see also Lewis v. Kenady*, 894 S.W.2d 619, 623 n.1 (Ky. 1994).

The decisions of this Court and the Court of Appeals do not provide any indication that a trial court is required to instruct a jury using the language of KRS 304.40-320. There is no appellate decision reversing a trial court for declining to give an instruction containing the language of KRS 304.40-320. Nor is there any appellate decision upholding a trial court instruction employing the language of KRS 304.40-320. The trial court followed well-established Kentucky law when it instructed the jury on Dr. Shaffer’s duty in obtaining Sargent’s informed consent. It therefore cannot be said that the trial court’s decision not to give Sargent’s proposed instruction was “arbitrary, unreasonable, unfair, or unsupported by sound legal principles.” *See Love v. Walker*, ___ S.W.3d ___, 2014 Ky. LEXIS 84, *16 (Ky. 2014). The Court need not engage in any further analysis to affirm the judgment below.

B. The evidence and law did not support a separate jury instruction on the informed consent claim, much less one including the language of KRS 304.40-320.

The trial court was not even obligated to provide a separate instruction on Dr. Shaffer’s duty in obtaining Sargent’s informed consent. Sargent’s complaint did not contain an informed consent claim; it asserted only a general allegation of medical negligence against Dr. Shaffer. (Complaint, R. 1.) The complaint alleged simply that Dr. Shaffer “was negligent in [his] care and treatment of Loretta Sargent.” (*Id.* at ¶ 9.)

Sargent did not assert a separate count for alleged lack of informed consent or for an alleged violation of KRS 304.40-320. (*Id.*)

In *Campanell v. Figert*, the Court of Appeals held that when the complaint does not include a separate count for lack of informed consent, the trial court is not required to provide a separate instruction on informed consent. No. 2008-CA-621-MR, 2009 Ky. App. Unpub. LEXIS 145, *6-7 (Ky. App. 2009).⁴⁷ Like Sargent, the plaintiff in *Campanell* contended at trial that a surgeon was negligent in performing a surgical procedure and in obtaining the plaintiff's informed consent. The trial court declined to give a separate informed consent instruction requested by the plaintiff. Instead, the trial court gave the following single instruction on the defendant-physician's duty: "It was the duty of the Defendant Patricia L. Figert, M.D., ***in advising and/or treating Plaintiff***, Terry L. Campanell, to exercise the degree of care and skill expected of a reasonably competent physician specializing in general surgery and acting under similar circumstances." *Campanell*, 2009 Ky. App. Unpub. LEXIS 145 at *6 (emphasis supplied).

The Court of Appeals affirmed and held that the trial court properly instructed the jury. The appellate court held that because the plaintiff had not asserted a separate claim for lack of informed consent, the trial court was not required to give a separate instruction on informed consent. As the Court of Appeals explained, "In his complaint against Dr. Figert and Surgical Care Associates, Campanell only alleged negligence as result of the

⁴⁷ Dr. Shaffer argued at trial that under *Campanell*, only one interrogatory was needed on Dr. Shaffer's alleged negligence. (VR: 9/1/11; 12:08:38.) A copy of the *Campanell* case is attached at Appendix 3 as required by CR 76.28(4)(c). Dr. Shaffer's counsel is not aware of any published decision from this Court or the Court of Appeals addressing the issue of whether the trial court must provide a separate jury instruction on informed consent when the plaintiff has not included a claim in the complaint for failure to obtain informed consent.

care and treatment he received. He did not allege a lack of informed consent...*Informed consent was at issue in the case only insofar it related to the standard of care, but was not alleged as a separate cause of action.*” *Id.* at *6-7 (emphasis supplied).

The same is true here. Sargent got more than the law required when the trial court decided to give a separate instruction on the informed consent claim. Sargent made only a general allegation of medical negligence in her complaint. The complaint does not include a distinct cause of action for failure to obtain informed consent and does not mention KRS 304.40-320. Thus, as Dr. Shaffer argued at trial, the court would have been justified in declining to give a separate instruction on Dr. Shaffer’s duty in obtaining Sargent’s informed consent. It follows that the trial court did not err or abuse its discretion by declining to give Sargent’s proposed informed consent instruction incorporating language from KRS 304.40-320.

C. Sargent’s proposed informed consent instruction would violate the bare bones principle that has become an accepted, unquestioned and relied upon foundation of Kentucky law on jury instructions.

The trial court’s instruction was consistent with the “bare bones” principle of jury instructions, which has long been recognized in this Commonwealth as the best way to facilitate the jury’s resolution of disputed *factual* issues. Sargent’s proposed instruction, in contrast, contains the type of abstract legal phrases that this Court has maintained should not be included in instructions. The trial court was correct to reject the instruction tendered by Sargent in favor of the bare bones instruction that has traditionally been given for this type of claim.

Sargent argues that by declining to give her proposed instruction, the trial court did not fully inform the jury about Kentucky law on a physician’s duty in obtaining informed consent. Sargent concedes that subsection (1) of KRS 304.40-320 simply

codifies *Holton* and confirms that in obtaining a patient's informed consent, a physician is required to act in accordance with accepted professional standards. Sargent argues, however, that subsection (2) of the statute imposes a separate, additional duty on physicians to provide patients with enough information that "[a] reasonable individual...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."⁴⁸ Sargent contends that unless this alleged additional duty is included in the jury instruction, the "General Assembly wasted its time" in enacting KRS 304.320 because the jury would not know that the statute sets forth the law on informed consent. (*Id.* at 16, 19-21.)

Sargent's argument is premised on a misunderstanding of the function of jury instructions as well as the legislative intent behind the statute. As this Court has explained, the function of jury instructions in Kentucky is **not** "to advise the jury on the law of the case."⁴⁹ Juries decide disputed *factual* questions, not questions of law. "In Anglo-American jurisprudence the function of the jury is to decide contested issues of fact. In order to perform this function there is no need for jurors to know the legal effect of their resolution of contested issues of fact." *Robinson v. Murlin Phillips & MFA Ins. Co.*, 557 S.W.2d 202, 204 (Ky. 1977).

Thus, when it comes to instructions, the *less* the jury knows about the law, the better: "[T]he less the jurors know about the law of the case[,] the easier it is for them to

⁴⁸ Sargent's brief at 2, 14 (quoting KRS 304.40-320(2)).

⁴⁹ *Office*, 173 S.W.3d at 229 (quoting 2-13 Palmore & Cetrulo, *Kentucky Instructions to Juries*, § 13.01, App. 2).

remain strictly within the province of fact-finding.”⁵⁰ As this Court explained in *Olifice*, the function of jury instructions in Kentucky is to provide the jury with just enough information to allow it to determine what it must believe from the evidence to resolve each disputed *factual issue* in favor of the party with the burden of proof. *Olifice*, 173 S.W.3d at 229.⁵¹ Jury instructions in negligence cases set forth a party’s rights or duties not because jury instructions are supposed to state the law of the case, but “only as a convenient means of presenting the *factual question* of whether such rights or duties were violated.” *Id.* (emphasis supplied).

This Court has explained that “bare bones” instructions like the ones given in this case best allow the jury to perform its function of deciding contested questions of fact. Accordingly, Kentucky law “mandates the use of ‘bare bones’ jury instructions in all civil cases.” *Id.* at 229; *see also Harp v. Commonwealth*, 266 S.W.3d 813, 819 (Ky. 2008) (“Our precedent of longstanding leaves no doubt that we have adhered to the ‘bare bones’ principle of jury instructions.”).

On several occasions, this Court has explained that jury instructions should set forth only the “skeleton” – i.e., the minimum law necessary for the jury to understand what factual questions it must decide to find for the party with the burden of proof – and it is up to counsel in closing argument to elaborate on, or “flesh out,” the parties’ respective duties. In *Collins v. Galbraith*, this Court’s predecessor explained,

⁵⁰ 2-13 Palmore & Cetrulo, *Kentucky Jury Instructions*, § 13.01 “Function of Jury Instructions.” (App. 2.)

⁵¹ In *Olifice*, this Court noted that Kentucky legal commentators uniformly agree on this point. *Id.* at 228-229, quoting the following passage from Kurt A. Phillips, Jr., 7 *Kentucky Practice: Rules of Civil Procedure Annotated*, § 51 (5th Ed. 1995): “The function of instructions is only to state what the jury must believe from the evidence in order to return a verdict in favor of the party who bears the burden of proof. In Kentucky, the content of jury instructions on negligence should be couched in terms of duty. They should not contain an abundance of detail, but should provide only the ‘bare bones’ of the question for jury determination.”

Contrary to the practice in some jurisdictions, where the trial judge comments at length to the jury on the law of the case, the traditional objective of our form of instructions is to confine the judge's function to the bare essentials and let counsel see to it that the jury clearly understands what the instructions mean and what they do not mean.

494 S.W.2d 527, 531 (Ky. 1973). One year later, in *Cox v. Cooper*, Justice Palmore wrote "Our approach to instructions is that they should provide only the bare bones, which can be fleshed out by counsel in their closing arguments if they so desire." 510 S.W.2d 530 (Ky. 1974). More recently, in *Olfice*, this Court explained that under the bare bones approach, the trial court's jury instructions set forth the "skeleton," and "[t]his skeleton may then be fleshed out by counsel on closing argument." *Olfice*, 173 S.W.3d at 136.

As the Court has observed, bare bones instructions "serve the courts and juries well because they pare down unfamiliar and often complicated issues in a manner that jurors, who are often not familiar with legal principles, can understand." *Id.* at 229. The bare bones approach ensures that abstract and general statements of legal principle, which could be confusing to jurors, are not included in instructions.⁵² Justice Palmore's treatise instructs, "An abstract or general statement of legal principle, no matter how correct or pertinent to the case, has no place in the instructions...." *Id.* More than 60 years ago, the former Court of Appeals articulated the rationale behind this rule: "Broad legal concepts have very little meaning to the lay juror who is confronted with an immediate and exact factual problem. General instructions are subject to the criticism that they often create false issues, and tend to mislead rather than inform. Concrete instructions are to be encouraged." *Id.* (quoting *Reed v. Craig*, 244 S.W.2d 733, 735 (Ky. 1951)).

⁵² See 2-13 Palmore & Cetrulo, *Kentucky Jury Instructions*, § 13.11 "Common Pitfalls in Preparing Instructions" (App. 2).

As the above authorities make clear, jury instructions need not – and, in fact, should not – include every valid legal proposition related to a defendant’s duty.⁵³ Sargent is thus incorrect to argue that the trial court’s instruction was deficient because it allegedly did not fully set forth all legal propositions related to Dr. Shaffer’s duty in obtaining Sargent’s informed consent.

The *Olifice* case provides an excellent example of how jury instructions on duty do not need to include all valid legal propositions related to the party’s duty. *Olifice* was a premises liability case involving an alleged slip and fall on the deck of a health club pool. The plaintiff argued that the trial court erred by declining to use his proposed instructions on the defendant’s duty, which stated that in addition to the general duty to exercise ordinary care to maintain its premises in a reasonably safe condition, the defendant had several specific duties, including: to undertake a reasonable inspection of the pool; to take reasonable precautions to protect its invitees from foreseeable danger; and to warn business invitees if the defendant had actual knowledge of the danger. *Olifice*, 173 S.W.3d at 227. Trial resulted in a defense verdict. Agreeing with the plaintiff’s argument that the trial court erred by declining to give his proposed instructions, the Court of Appeals vacated the judgment and remanded for a new trial.

This Court reversed. The Court held that even though the additional duties listed in the plaintiff’s proposed instructions were accurate statements of the law, it was proper for the trial court not to include them in the jury instructions. *Id.* at 229-231. This Court wrote, “Although [plaintiff’s] proposed instructions certainly contained valid legal propositions, they exceeded the requirements of the ‘bare bones’ approach because the

⁵³ As the Court of Appeals has explained, “It is apparent that Kentucky is not a jurisdiction which favors instructing the jury at length regarding every subtle nuance of the law which may be relevant to a particular case.” *King v. Grecco*, 111 S.W.3d 877, 882 (Ky. App. 2002).

dispositive issue in this case--Club Olympic's duty of care--could be resolved" through the instructions given by the trial court. *Id.* at 230. As the Court explained, "***the duty to keep the premises in a reasonably safe condition encompasses the additional specific duties***" set forth in the plaintiff's proposed instruction. *Id.* (emphasis supplied). Reiterating an oft-repeated maxim, this Court emphasized that it is the role of counsel to "flesh out during closing argument the legal nuances that are not included within the language of the instruction." *Id.*

In this case, the bare bones framework functioned precisely as contemplated in *Olfi*. The trial court's instruction on Dr. Shaffer's duty – which stated that Dr. Shaffer had a duty "to exercise the degree of care and skill expected of a reasonably competent physician specializing in orthopaedic spine surgery acting under similar circumstances" when disclosing the risks and benefits of the procedure to Sargent – encompassed the alleged additional "specific duties" that Sargent argues are embodied in subsection (2) of KRS 304.40-320.

The trial court's standard duty instruction provided the skeleton, and Sargent's experienced counsel was able to "flesh out" during closing argument any "legal nuances" not included in the instruction. After reading the instruction on Dr. Shaffer's duty in obtaining Sargent's informed consent, Sargent's counsel told the jury,

There is a duty on Dr. Shaffer – and everybody in this courtroom agreed with me – and there's an AMA Code of Ethics...and it says that you have to tell a person of the substantial risks and you've got to be correct with them, and you've got to be fair with them, and you've got to tell them the truth. And then there's that one section that I kept emphasizing – the last one at the bottom – that says, in essence, you can't whitewash this thing because you think that the patient will not do the surgery. You can't be paternalistic, and I know you all know what that word

means. I do, I think... There's no question he has a duty to give her the benefits and the risks. Did he fail in that duty? Dr. Banco says yes, he did. And Dr. DeLong said yes, he did.

(See VR: 9/1/11; 5:32:44–5:34:08.) Sargent's counsel "fleshed out" Dr. Shaffer's duty using the very terms that Sargent argues must be included in the jury instruction. He explained to the jury that Dr. Shaffer had a duty to discuss the "substantial risks" of the procedure. He argued that paralysis was one of those substantial risks: "He [Dr. Shaffer] is required... by his own group, the American Academy of Orthopaedic Surgeons, to tell the substantial risks, which would include one of the catastrophic things that can happen. That's his own group that talks about that. And the catastrophic thing that can happen here is paralysis. Not a dural injury. Paralysis." (*Id.* at 5:34:58-5:35:31.)

In addition, Sargent's counsel argued that Dr. Shaffer needed to use the word "paralysis" to sufficiently explain the risks of the procedure to an individual in Sargent's circumstances. He contended that Sargent's history of suffering a nerve injury in Dr. Bean's 2001 procedure made it particularly important for Dr. Shaffer to explain that his proposed procedure carried a risk of "paralysis," as opposed to merely nerve injury. He maintained that because Sargent had experienced foot drop as a result of Dr. Bean's 2001 procedure, she did not think that "nerve damage" would include paralysis or bowel and bladder dysfunction. (*Id.* at 5:26:00-5:28:46.) Sargent's counsel argued that based on the information provided by Dr. Shaffer, Sargent had no idea that she could be paraplegic as a result of surgical complications. (*Id.*) He claimed that as a result of her prior experience, it was reasonable for a patient in Sargent's position to believe that "nerve injury" might include foot drop or sciatica but to not have the "slightest idea" that she could be paralyzed. (*Id.* at 5:49:00-5:49:21.)

Thus, Sargent's attorney told the jury that he believed, "[p]aralysis' was the only way to explain what has happened to her. And that risk was at least enough of a risk so that she should have been warned about it. And she was not." (*Id.* at 5:36:00-5:36:55.) Sargent's closing argument clearly "fleshed out" Dr. Shaffer's duty in obtaining informed consent. The instruction given by the trial court functioned exactly as contemplated by this Court's multiple decisions confirming that jury instructions on duty should adhere to the bare bones principle. It was appropriately left to the jury to determine which party's medical evidence was more credible and persuasive.⁵⁴

Moreover, a simple comparison of the trial court's instruction and Sargent's proposed instruction highlights the value of concrete, bare bones instructions and the risk of jury confusion presented by instructions like the one proposed by Sargent. The trial court's instruction on Dr. Shaffer's duty informed the jury that in discussing the risks and benefits of the surgery, Dr. Shaffer had a duty "to exercise the degree of care and skill expected of a reasonably competent physician specializing in orthopaedic spine surgery acting under similar circumstances." (Judgment, App. 1.) This is a simple enough instruction for jurors, who are often not familiar with legal concepts, to understand.

Sargent's proposed instruction, on the other hand, unnecessarily ran the risk of confusing the jury by injecting abstract legal terminology into the instruction on Dr. Shaffer's duty in obtaining informed consent. It is replete with abstract legal phrases that would have "very little meaning to the lay juror who is confronted with an immediate and

⁵⁴ As this Court recently stated, "Kentucky jurisprudence is clear that the role of the jury is held in high esteem and should not be limited except in clear circumstances. The role of the jury in interpreting the evidence and finding the ultimate facts is an American tradition so fundamental as to merit constitutional recognition. . . . The conscience of the community speaks through the verdict of the jury, not the judge's view of the evidence." *Shelton v. Ky. Easter Seals Soc'y, Inc.*, 413 S.W.3d 901, 917 n.60 (Ky. 2013).

exact factual problem.” *Reed*, 244 S.W.2d at 735. Sargent’s instruction would have required the jury to interpret and evaluate the meaning of several abstract legal phrases: whether Dr. Shaffer’s “action” in the informed consent process was “in accordance with the accepted standard of medical practice among members of the profession with similar training and experience”; and whether, based on the information provided by Dr. Shaffer, a “reasonable individual” would have a “general understanding” of the procedure, of “medically acceptable alternative procedures,” and of “substantial risks and hazards inherent in the proposed treatment or procedure” (but only if those if those “substantial risks and hazards” are ones that are “recognized among other health care providers who perform similar treatments or procedures”). (Sargent’s brief at App. 4.)

It was not an abuse of discretion for the trial court to give the standard bare bones instruction on Dr. Shaffer’s duty and to decline to give Sargent’s proposed instruction, which was inconsistent with the bare bones framework.

D. Specific duties are not included in the instructions in medical negligence cases, because the specific duties are set forth by expert testimony, as they were in this case.

This Court and the Court of Appeals have held that bare bones instructions are particularly useful in medical negligence cases, in which the specific duties imposed by the standard of care under the circumstances are set forth by expert testimony. *Rogers v. Kasden*, 612 S.W.2d 133 (Ky. 1981); *Hamby v. University of Kentucky Medical Ctr.*, 844 S.W.2d 431, 433 (Ky. App. 1992). This case provides a perfect illustration of why the basic framework established in *Rogers v. Kasden* has served courts, juries, and litigants well.

In *Rogers*, this Court confirmed that jury instructions in medical negligence cases should not include a list of specific duties beyond the general duty of ordinary care. 612

S.W.2d 133, 135. The Court held that the trial court erred by instructing the jury that the defendant-hospital, in addition to the general duty of ordinary care, had several specific duties, including, for example, a duty “[t]o provide nurses knowledgeable of the requirements for adequately providing patient care necessary under circumstances like or similar to those in this case.” *Id.* The Court found that this list of specific duties violated the bare bones principle. As the Court explained, jury instructions on negligence “should not contain an abundance of detail, but should provide only the bare bones of the question for jury determination. This skeleton may then be fleshed out by counsel on closing argument.” *Id.* at 136 (citing *Cox*, 510 S.W.2d at 535).

In *Hamby*, the Court of Appeals elaborated on *Rogers* and held that this principle applies even when the specific duties are imposed by a statute or regulation. 844 S.W.2d at 433. The plaintiff in *Hamby* argued that the trial court erred by declining to include in the jury instruction federal regulations imposing certain duties on providers using the hyperthermia treatment that had allegedly injured the plaintiff. *Id.* at 433.⁵⁵ The instruction given in *Hamby*, like the one in this case, provided that the physician was required “to exercise that degree of care and skill expected of an ordinary, prudent, and competent physician specializing in radiation oncology and trained in the use and administration of hyperthermia.” *Id.* Like Sargent, Hamby argued that this instruction was insufficient “because, where statutory duties exist in a negligence case, the trial court must issue instructions which advise a jury of those specific duties.” *Id.*

⁵⁵ These duties included a duty to obtain informed consent to the treatment, a duty to use the equipment in accordance with certain FDA conditions, and a duty to notify the FDA before deviating from its prescribed protocol. *Id.*

The Court of Appeals rejected Hamby's argument: "Although statutory duties have been used to enumerate specific duties in certain types of automobile accident cases, we have traditionally excluded them in medical malpractice cases." *Id.*

The Court of Appeals drew this distinction for two reasons. First, the court found that Hamby's proposed instructions were inconsistent with Kentucky's strong policy favoring bare-bones jury instructions. Citing *Rogers v. Kasden*, the court emphasized that "jury instructions on negligence...should not contain an abundance of detail, but should provide only the bare bones of the question for jury determination. This skeleton may then be fleshed out by counsel on closing argument." *Id.* Hamby clarified that *Rogers* extends equally to duties imposed by statute or regulation.

Even more important, the court observed that "in medical malpractice cases, expert testimony is always used to show the standard of care for a particular type of practice and procedure. The standard of care for physicians and surgeons is established by the medical profession itself." *Id.* As the court noted, Palmore's model instructions "make[] it clear that more specific instructions are given in automobile cases than in medical malpractice cases." *Id.* (citing 2 J. Palmore & R. Eades, *Kentucky Instructions to Juries* §§ 16, 23 (1989)). The court explained that there are good reasons for this distinction. In automobile cases, ordinary care consists of "following statutory duties of obeying stop signs, yielding a right-of-way, and observing speed laws, etc., whereas in the practice of medicine, there are numerous variables which must be taken into account in each specific case." *Id.* Automobile accident cases typically do not involve expert testimony about what the standard of care requires of a driver under the circumstances. It

sometimes makes sense to include statutory duties in automobile cases because the jury would not otherwise know of the “undisclosed duties” imposed by statutes. *Id.*

The same is not true in medical malpractice cases because the specific duties required by the standard of care are *always* established through expert testimony. *Id.* The court noted that the specific duties that Hamby wanted in the instruction “were presented at great length through the expert testimony, exhibits, and arguments of counsel to be part of the ‘care and skill expected of an ordinary, prudent and competent physician specializing in radiation oncology and trained in the use and administration of hyperthermia.’” *Id.*

As this case illustrates, the framework established in *Rogers* and *Hamby* continues to work well in practice. The trial court’s bare bones instruction on Dr. Shaffer’s duty set forth the basic legal framework necessary for the jury to resolve the disputed factual questions concerning the informed consent process. The jury heard detailed testimony from all four retained experts and Dr. Shaffer about the duties of a spine surgeon in obtaining a patient’s informed consent for the type of procedure performed by Dr. Shaffer. Every one of these spine surgeons testified that a physician has the duty to discuss with a patient the risks and benefits of, as well as alternatives to, a proposed treatment.⁵⁶ In addition, while cross-examining Dr. Shaffer and his experts, Sargent used a section from the American Medical Association Code of Medical Ethics discussing a

⁵⁶ VR: 8/30/11; 9:26:00-9:26:37 (Dr. Shaffer); *Id.* at 11:20:58-11:21:52 (Dr. DeLong); VR: 8/31/11; 9:25:19-59 (Dr. Banco); *Id.* at 3:21:00-3:23:12 (Dr. Shaffrey); and VR: 9/1/11; 10:12:24, 10:25:00 (Dr. Boden).

patient's right to informed consent and the physician's duty to present the medical facts accurately to a patient.⁵⁷

All five spine surgeons who took the stand at trial testified at length about the specific duties required of Dr. Shaffer under the circumstances and whether Dr. Shaffer complied with those duties in obtaining Sargent's informed consent. Sargent's neurosurgery expert, Dr. DeLong, offered an opinion that Dr. Shaffer did not adequately inform Sargent of the risks of the surgery, that he was overly optimistic about the possible benefits, and that he did not provide her with sufficient information about possible alternative treatments.⁵⁸ Dr. DeLong testified that he did not believe that a phrase used by Dr. Shaffer – "nerve injury" and "injury to nerves" – adequately explained the risk of paralysis to a reasonable individual in Sargent's position:

nerve injury does not imply paralysis. It implies a rather minor injury to a nerve or -- or at least a limited injury. If a single nerve is injured, then the patient might end up with weakness in a muscle or even paralysis of a muscle or a -- or a deficit in the sensation supplied by that nerve, but it doesn't imply complete, total paralysis from the waist down with a -- a -- a deficit -- complete absence of bladder and bowel function. A nerve injury simply does not have that connotation to the average person.

...

Because nerve injury does not connote paralysis. I think -
- I think the average person, when they hear a nerve injury,
would -- would not think of total paraplegia from the waist
down with bladder and bowel out.⁵⁹

Dr. DeLong stated that in his practice, he would have instead used the word "paralysis," because he felt this was necessary to fully inform the patient and provide "the truth, the

⁵⁷ VR: 8/30/11; 9:26:00-9:26:37 (Dr. Shaffer); VR: 8/31/11; 3:21:00-3:23:12 (Dr. Shaffrey); and VR: 9/1/11; 10:12:24, 10:25:00 (Dr. Boden).

⁵⁸ VR: 8/30/11; 10:56:55-10:59:23.

⁵⁹ *Id.* at 10:58:30-10:59:23, 11:20:48-11:21:52, and 11:24:25-11:25:21.

whole truth, and nothing but the truth.”⁶⁰ Dr. DeLong testified that in obtaining informed consent, a physician has a duty to tell a patient about “the worst things that can happen, not totally remote things, but things that have some chance of happening.”⁶¹ He testified that the informed consent document should include the “substantial risks” of the procedure.⁶² In Dr. DeLong’s opinion, paralysis was a “substantial risk” of the procedure – he believed that there was a “10 to 20 percent chance of paralysis under the best of circumstances.”⁶³ Dr. DeLong further testified that he did not believe Dr. Shaffer adequately discussed with Sargent the possible alternative treatments.⁶⁴

Sargent’s other expert, Dr. Banco, also offered his opinion about a spine surgeon’s general duty in obtaining informed consent for a procedure:

[W]hat the physician needs to do when they’re [sic] speaking about a particular surgical procedure with the patient is to tell them the most common risks of the surgical procedure and to include, in my opinion, some of the catastrophic complications that could occur, and to tell them what the likelihood, if possible, of those complications, what the likelihood is for those complications.⁶⁵

Dr. Banco testified that in his opinion, Dr. Shaffer did not adequately disclose the risks of the procedure.⁶⁶ Dr. Banco believed that Dr. Shaffer was required to use the word “paralysis” because the risk that she would be paralyzed from the procedure was as high as 25%.⁶⁷ Like Dr. DeLong, Dr. Banco testified that he did not believe that the term

⁶⁰ *Id.* at 10:59:26-11:00:02.

⁶¹ *Id.* at 11:21:10-11:21:52.

⁶² *Id.* at 11:22:38-11:22:42.

⁶³ *Id.* at 11:23:05-11:23:48.

⁶⁴ *Id.* at 11:27:39-11:38:48. Dr. DeLong offered this testimony despite acknowledging that before offering surgery, Dr. Shaffer attempted numerous alternative conservative treatments, including a back brace, a referral to a pain-management physician, and epidural injections. (*Id.* at 11:27:41-11:28:08.)

⁶⁵ VR: 8/31/11; 9:25:39-9:26:11.

⁶⁶ *Id.* at 9:25:21-9:54:00.

⁶⁷ *Id.* at 9:27:52-9:29:11, 9:32:15-9:33:09, and 9:48:58-9:54:39.

“nerve injury” would have allowed a reasonable person in Sargent’s position to understand that paralysis was a risk of the procedure:

Q. Does it deliver a false sense of security when you do not say paralyzed but you only say nerve injury?

A. Well, to me it does, yes. To me it does. As a physician, I -- I think there's a big difference in nerve injury and paralysis; it's a huge difference.

Q. What is the difference?

A. Well, paralysis means you have no function of an extremity or two extremities or four extremities. Nerve injury means you have a foot drop, and you're functioning very normally, you have a brace on your foot, and you're walking around and everything is fine. Paralysis means that you can't walk, you're wheelchair bound, maybe, or, you know, depends upon the extent of the paralysis.⁶⁸

Dr. Shaffer responded with an abundant amount of his own medical evidence from which a jury could have concluded that he acted reasonably in the informed consent process. Dr. Shaffer was asked by Sargent’s counsel to explain what he believed his duty was in obtaining Sargent’s informed consent to the procedure. Dr. Shaffer explained:

My duty as a physician is to explain to the patient the alternatives of medical care, their risks, their benefits, try to weigh one, you know, type of care against another type of care, and to, in concert with the patient, what we call shared decision making where the patient is educated over a period of time well enough that we come to a conclusion that is in the patient's best interest. The patient makes the final decision. At no time would anybody say -- I would never say that you have to have an operation. You never have to have an operation. There is no circumstance where you would have to have an operation short of a catastrophic, traumatic event. And even then patients, you know, do elect to treat, you know, a fractured spine non-operatively and I'm more than happy to do that if that's what they decide to do. So in the six to eight months before this procedure, every time I saw Loretta Sargent, there was more discussion about her condition, what were the options available to her, what she and I needed to come to -- I had to convince myself that she was one, could be helped and

⁶⁸ *Id.* at 9:52:57-9:53:39.

two, had a realistic understanding of the comp -- you know, the complicated procedure that we were going to undertake. And during that time, I also satisfied to myself, not from the medical records and what she's done over the previous seven years, all of the non-operative options that I could think of that might help her, that might, you know, give her a modicum of relief and -- and help her with her life. And that's what I think informed consent is.⁶⁹

Dr. Shaffer testified that over the course of many counseling sessions, he explained to Sargent that the surgery could damage her nerves, that it could make her worse, and that the procedure was a difficult surgery that was akin to trying to chip a worm out of a concrete block.⁷⁰

Dr. Shaffer's experts also testified extensively about a physician's duty in obtaining informed consent and about whether a reasonable individual provided with the information given to Sargent would have understood the substantial risks of the procedure.

Dr. Shaffer's neurosurgery expert, Dr. Shaffrey, testified that Dr. Shaffer's use of the term "nerve injury" was appropriate because the term "is commonly used to cover the spectrum of different injuries from mild to severe."⁷¹ He explained that "the word nerve injury encompasses for many people the entire spectrum of -- of things from the slightest numbness to devastating injury."⁷²

More important, Dr. Shaffrey strongly disagreed with Sargent's experts about the risk that Sargent would experience the complication of near-total paralysis of the lower extremities. He explained that that it was appropriate for Dr. Shaffer not to use the words "paralysis" or "paraplegia" because the risk that Sargent would suffer near-complete loss

⁶⁹ VR: 8/30/11; 9:26:23-9:28:26.

⁷⁰ *Id.* at 9:32:23-9:42:57.

⁷¹ VR: 8/31/11; 2:43:08-2:43:34.

⁷² *Id.* at 3:18:11-3:18:24.

of function in her lower extremities, bowel, and bladder was very remote – between a 1/3000 and 1/5000 chance, by Dr. Shaffrey’s estimate.⁷³ In other words, paralysis of the sort experienced by Sargent was not a “substantial risk” of the procedure. Dr. Shaffrey explained that the type of injury suffered by Sargent was “a distinctly unusual event.”⁷⁴

Like all of the other experts who testified in the case, Dr. Shaffrey agreed that a physician has a duty to discuss with a patient “the benefits, risks, possible appropriate treatment alternatives” of a proposed procedure.⁷⁵ During cross-examination by plaintiff’s counsel, Dr. Shaffrey discussed at length what he believed a patient in Sargent’s circumstances would understand when hearing the term “nerve injury.”⁷⁶ He explained that his discussion of the risk of nerve injury and paralysis with each patient varies depending on the nature of the procedure being performed and the patient’s prior experiences.⁷⁷ He explained that with this procedure, “the risk of nerve injury was...way higher than what the risk was of paralysis...a thousand times higher or some level.”⁷⁸

Dr. Shaffer’s orthopaedic surgery expert, Dr. Boden, also testified that he believed Dr. Shaffer acted appropriately in obtaining Sargent’s informed consent.⁷⁹ Dr. Boden indicated that he never uses the word “paralysis” because it means different things to different patients.⁸⁰ Like Dr. Shaffrey, Dr. Boden testified that the standard of care did not require Dr. Shaffer to use the terms “paralysis” or “paraplegia” under these circumstances because the type of global paralysis that Sargent experienced was an

⁷³ *Id.* at 3:12:57-3:15:01.

⁷⁴ *Id.* at 3:12:18-3:15:01.

⁷⁵ *Id.* at 3:22:14-3:22:24.

⁷⁶ *Id.* at 3:25:25-3:31:01.

⁷⁷ *Id.* at 3:28:41-3:32:54.

⁷⁸ *Id.* at 3:37:54-3:38:54.

⁷⁹ VR: 9/1/11; 3:37:54-3:38:54.

⁸⁰ *Id.* at 10:14:50.

“exceptionally unlikely outcome” (i.e., not a substantial risk).⁸¹ Dr. Boden testified that he is not aware of any standard or guideline in the field that requires a surgeon to use the word “paralysis” when obtaining consent for a procedure like the one performed by Dr. Shaffer.⁸²

In short, the bare bones framework functioned in this case just as contemplated by the decisions of this Court and the Court of Appeals in *Rogers* and *Hamby*. The trial court’s instruction set forth Dr. Shaffer’s basic duty in obtaining Sargent’s informed consent to surgery, and the expert testimony presented to the jury delineated the specific requirements of the standard of care under the circumstances of this case.⁸³ Counsel then had a sufficient opportunity to “flesh out” these issues during closing argument. It was for the jury to decide, based on the conflicting expert testimony, which party had the more credible and convincing case.

E. The doctrine of negligence *per se* – which is the basis for including statutory duties in instructions – does not apply to KRS 304.40-320.

Sargent argues that subsection (2) of the statute establishes a “specific statutory duty” for healthcare providers and that any specific statutory duty must be included in the jury instruction on a defendant’s duty.

To understand why Sargent’s argument is incorrect, it is important to first understand why certain statutory duties *are* properly included in jury instructions setting forth the defendant’s duties. Statutes imposing specific legal duties are included in jury instructions if a violation of the statute, standing alone, could constitute negligence *per se*. See *Humana of Kentucky, Inc. v. McKee*, 834 S.W.2d 711, 722 (Ky. App. 1992). As

⁸¹ *Id.* at 10:09:50.

⁸² *Id.* at 10:19:48.

⁸³ Sargent had a full and fair opportunity to present her case through expert testimony. She has not complained on appeal about any ruling of the trial court excluding or limiting expert testimony.

the court explained in *McKee*, “the court obviously is required to instruct the jury regarding that duty because the violation of such a duty, standing alone, may be sufficient to support a claim of negligence.” *Id.*

KRS 446.070 was enacted in 1942 to codify the common law doctrine of negligence *per se*. *St. Luke Hosp., Inc. v. Straub*, 354 S.W.3d 529, 534 (Ky. 2011). Both at common law and under KRS 446.070, there is an important limitation on the doctrine of negligence *per se*: the doctrine “applies only if the alleged offender has violated a statute **and** the plaintiff was in the class of persons which that statute was intended to protect.” *Davidson v. American Freightways, Inc.*, 25 S.W.3d 94, 99-100 (Ky. 2000) (emphasis supplied). In *Straub*, the Court reiterated, “In accord with traditional legal principles related to the common law concept of negligence *per se*, the statute [KRS 446.070] applies when the alleged offender violates a statute **and** the plaintiff comes within the class of persons intended to be protected by the statute.” *Straub*, 354 S.W.3d at 534 (emphasis supplied).

The doctrine of negligence *per se* applies most commonly in highly regulated areas like the operation of automobiles on public roads. KRS Chapter 189 sets forth numerous statutory duties that must be followed by anyone operating a motor vehicle. For example, KRS 189.040 imposes requirements related to the use of headlights on motor vehicles. One subsection of the statute states,

Whenever a motor vehicle is being operated on a roadway or shoulder adjacent thereto during the times specified in KRS 189.030, **the driver shall use** a distribution of light or composite beam directed high enough and of sufficient intensity to reveal persons and vehicles at a safe distance in advance of the vehicle, subject to the requirements and limitations hereinafter set forth.

KRS 189.040(4) (emphasis supplied).

This statute – which creates a specific duty for drivers to use headlights at certain times – is properly included in the jury instruction when there is evidence to support its applicability to the case.⁸⁴ The statute clearly imposes a duty, stating that “*the driver shall use*” headlights at appropriate times. In an automobile accident case, the plaintiff is typically within the class of persons the statutes in KRS Chapter 189 were designed to protect. Thus, a violation of any of the specific statutory duties imposed by KRS Chapter 189 constitutes negligence *per se*.⁸⁵

When there is evidence to support the applicability of a statutory duty (and the plaintiff is within the class of persons protected by the statute), the jury is instructed in a particular way. In *Henson*, a case involving a personal-watercraft collision, this Court explained,

The “general duty,” breach of which gives rise to liability, is the duty to exercise ordinary care, and properly drafted instructions utilize “specific duties” as imposed by statutes only as amplification of the “general duty,” and not as the source of such duty. Where there is a statutory duty, the usual instruction, after explaining the general duty, will then specify that such general duty “includes” certain enumerated specific duties. See illustrative instructions in *Palmore*, *Kentucky Instructions to Juries*, Vol. 2, Chapter 16, Automobiles.

Henson, 319 S.W.3d at 425-426 (quoting *Wemyss v. Coleman*, 729 S.W.2d 174, 180 (Ky. 1987)). *Palmore*’s model instruction for a nighttime automobile collision provides a good example of what this type of instruction should look like:

It was the duty of D in driving his automobile to exercise ordinary care for the safety of other persons using the

⁸⁴ See 2-16 *Palmore & Cetrulo*, *Kentucky Jury Instructions* § 16.05 (model instruction for nighttime automobile collision cases) (App. 2).

⁸⁵ Chapter 16 of *Palmore*’s *Kentucky Jury Instructions* provides examples of how these specific statutory duties are included in the jury instructions. See *Henson v. Klein*, 319 S.W.3d 413, 425-26 (Ky. 2010); see also 2-16 *Palmore & Cetrulo*, *Kentucky Jury Instructions* §§ 16.05, 16.09, 16.11, 16.16 (App. 2).

highway, and this general duty included the following specific duties:...

(e) to have his automobile equipped with headlights so aimed and of sufficient intensity to reveal persons at a distance of at least 350 feet ahead under ordinary atmospheric conditions [on bright beam or 100 feet on low beam, to which he was to dim when approaching within 500 feet of an oncoming vehicle]

2-16 Palmore & Cetrulo, *Kentucky Jury Instructions* § 16.05 (App. 2).

The primary case relied on by Sargent, *Humana of Kentucky, Inc. v. McKee*, 834 S.W.2d 711 (Ky. App. 1992), does not apply in this case. *McKee* merely represents an application of the doctrine of negligence *per se* in the context of an alleged statutory violation by a **hospital**, not a physician. In the 22 years since *McKee* was decided, it has not been extended beyond its specific facts. The *McKee* case involved KRS 214.155, a statute that requires hospitals to test all newborns for a congenital metabolic disorder, phenylketonuria (PKU). This statute, like the statutes and regulations governing automobiles, imposes a discrete, concrete obligation – that hospitals “shall...cause to have administered to every such infant or child in its or his care tests for heritable disorders, including but not limited to phenylketonuria (PKU).” KRS 214.155. The plaintiff alleged that the hospital failed to test for PKU in violation of KRS 214.155 and that he was injured as a result. *Id.* at 713. The trial court instructed the jury that the hospital had a statutory duty to test for PKU, and the jury found for the plaintiff.

The Court of Appeals held that the trial court did not err by instructing the jury on the hospital’s duty to administer a PKU test as required by KRS 214.155. *Id.* The appellate court sanctioned the inclusion of the statutory duty in the instruction only because a violation of the PKU-testing statute, standing alone, could constitute negligence *per se*: “If a plaintiff, as here, in part bases his or her claim upon proof as to a

hospital's negligent failure to comply with a statutory duty, the court obviously is required to instruct the jury regarding that duty because the violation of such a duty, standing alone, may be sufficient to support a claim of negligence." *Id.* at 722. The Court of Appeals explained, "hospitals are required to comply with many statutory duties in addition to that of exercising ordinary care." *Id.*

As the court noted, the PKU-testing statute is similar to the automobile statutes that are typically included in the jury instructions: "[W]e find that the issue in this case is indistinguishable from that present in other cases, such as actions arising out of simple automobile accidents, in which trial courts routinely instruct upon both statutory and common law duties." *Id.* Indeed, *Palmore* has created a specific instruction for cases involving the PKU-testing statute.⁸⁶ This statute is patterned after the jury instructions involving automobile statutes: it states the general duty of the hospital to exercise ordinary care and goes on to provide that this general duty "included the specific duty to cause a PKU test to be administered" to the plaintiff. (*Id.*)

McKee does not apply in this case for several reasons. First, Sargent did not assert a negligence *per se* claim in this case. She made only a general allegation of medical negligence in her complaint. Second, the doctrine of negligence *per se* – which was the basis for including the statutory language in the instruction in *McKee* – does not apply to KRS 304.40-320, because patients are not within the class of persons that KRS 304.40-320 was intended to protect. *See Straub*, 354 S.W.3d at 534; *Davidson*, 25 S.W.3d at 99-100.

⁸⁶ *See* 2-23 *Palmore & Cetrulo, Kentucky Jury Instructions* § 23.14, "Liability of Hospital to Patient; Statutory Duty; Standard of Care" (App 2).

The legislative history of KRS 304.40-320 demonstrates that the statute was part of a tort-reform effort and was designed to protect health care providers, not patients. The statute is located within the Insurance Code in a subtitle labeled “Health Care Malpractice Insurance” and a section called “Claims.” See KRS Chapter 304.40. The stated purpose of the section that includes KRS 304.40-320 was “to promote the health and general welfare of the inhabitants of the Commonwealth *through the adoption of reforms in health care malpractice claims.*” KRS 304.40-250 (emphasis supplied). Two of the nine statutes within this section (KRS 304.40-270 and 304.40-330) have since been repealed.

KRS 304.40-320 was intended to protect *physicians* by requiring an objective standard to be applied when “determining whether the information provided by the physician would likely have resulted in any different decision by the plaintiff.”⁸⁷ As the statute’s drafters wrote in their report to the governor, “The purpose of [subsection 2] is to eliminate the possibility of...a plaintiff’s testifying that had he known of an unforeseeable [sic] or unlikely injury he would not have consented to the recommended health care.” *Id.*

This uncontroverted legislative history demonstrates that patient-plaintiffs like Sargent are not within the class of persons that the General Assembly sought to protect when it enacted the statute. Therefore, the doctrine of negligence *per se* does not apply

⁸⁷ *Report of Governor’s Hospital and Physicians Professional Liability Insurance Advisory Cmte., Majority Report, Explanatory Comments*, p. 5 (Nov. 26, 1975) (Appendix 4). As detailed in Section IV below, KRS 304.40-320 would arguably be unconstitutional if this Court were to interpret it as imposing a duty that must be set forth in the jury instruction on a claim alleging negligence in the informed consent process. This Court construes statutes to avoid constitutional issues as long as there is a reasonable alternative interpretation that does not present constitutional concerns. In this case, the Court should simply find, as it has suggested before, that KRS 304.40-320 does nothing more than memorialize this Court’s holdings that a claim for lack of informed consent in discussing the risks of a procedure is merely a claim for negligence implicating professional standards of care. This reasonable interpretation avoids the constitutional concerns discussed in Section IV below.

when a plaintiff alleges that a physician violated KRS 304.40-320. Because of the absence of a legal basis for a negligence *per se* claim, the statutory language should *not* be included in the jury instruction on a physician's duty in cases involving alleged medical negligence in the informed consent process.

In addition, *McKee* is distinguishable because the PKU-testing statute, like a traffic statute, imposes a specific requirement on hospitals – to perform a PKU test on all newborns – that would be unknown to the jury if it were not included in the instructions. Hospitals, like the operators of automobiles, are subject to various statutes and regulations, the violation of which could constitute negligence *per se* if the plaintiff is in the class of persons intended to be protected by the statute or regulation at issue. For example, hospitals are required to test newborns for numerous other genetic conditions in addition to PKU (KRS 214.155 and 902 KAR 4:030), to screen infants for potential hearing loss (KRS 216.2970), and to report positive screenings for HIV or AIDS to public authorities (KRS 214.645 and 902 KAR 2:020).

In contrast, Dr. Shaffer's specific duties *as a physician* in obtaining informed consent, which are established by the medical profession itself, were set forth through expert testimony by Dr. Shaffer's peers as contemplated by *Holton*, *Keel*, and *Hamby*. There was no risk that the jury would be unaware of Dr. Shaffer's professional duties under the circumstances of the case, because those professional duties were set forth in detail through expert testimony by spine surgeons. When it enacted KRS 304.40-320, the General Assembly did not purport to establish the standard of care for physicians in obtaining informed consent. The requirements of the standard of care are set forth

through expert testimony, which allows the standard of care in each particular case to evolve to reflect developments in the medical profession.

Last, *McKee* does not apply because KRS 304.40-320 gives rise to a presumption, rather than a statutory duty. The language of KRS 304.40-320 differs significantly from statutes giving rise to specific legal duties (e.g., the PKU testing statute and the automobile statutes in KRS Chapter 189). KRS 304.40-320 does not state, for example, that a healthcare provider “shall obtain a patient’s informed consent.” Nor does it state that in obtaining a patient’s informed consent, a healthcare provider “shall provide the patient with a general understanding of the procedure” and “the substantial risks and hazards” of the procedure.

Instead, the statute appears to create a *presumption* that informed consent “shall be deemed to have been given” under certain circumstances. This is the most sensible reading of the statute’s plain language. The statute’s title, “Informed consent – When deemed given,” suggests that it creates a presumption. Likewise, the first sentence of the statute strongly implies that it gives rise to a presumption that informed consent was obtained if certain conditions are satisfied: “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....*” KRS 304.40-320 (emphasis supplied).

Because KRS 304.40-320 sets forth a presumption, rather than a statutory duty, it should not be included in the jury instructions. This Court has consistently held that presumptions should generally not be included in jury instructions.⁸⁸ In *Mason v.*

⁸⁸ See *Meyers v. Chapman Printing Co.*, 840 S.W.2d 814, 824 (Ky. 1992) (“In instructing juries, Kentucky uses the ‘bare bones’ method. This does not include explaining evidentiary matters or

Commonwealth, this Court explained that “[p]resumptions are in the nature of guides to be followed by the trial judge in determining whether there is sufficient evidence to warrant the submission of an issue to the jury, and should not be included in the instruction.” 565 S.W.2d 140, 141 (Ky. 1978). The plain language of KRS 304.40-320 appears to create a presumption to be utilized by a trial judge in deciding whether there is evidence sufficient to submit to the jury a question concerning alleged negligence in obtaining informed consent. If the trial court, after applying the presumption in light of the evidence presented to the jury, decides that a jury question exists, the presumption itself should not be included in the jury instruction. *Id.*

III. The trial court’s decision not to give Sargent’s proposed instruction did not prejudice Sargent.

Sargent was not prejudiced by the trial court’s instruction on Dr. Shaffer’s duty in obtaining Sargent’s informed consent. As Sargent admits, reversal for an allegedly erroneous jury instruction is not required unless “there is a substantial likelihood the jury was confused or misled by the instructions....” *McKinney v. Heisel*, 947 S.W.2d 32, 35 (Ky. 1997). Unless there is a reasonable possibility that the allegedly erroneous instruction affected the jury’s verdict, the verdict should not be set aside. *Emerson v. Commonwealth*, 230 S.W.3d 563, 570 (Ky. 2007).

There is no reasonable possibility that the jury was confused or misled by the instruction in this case, which correctly stated that when “disclosing...the risks and benefits of the surgical operation,” Dr. Shaffer had a duty to exercise the degree of care and skill expected of a reasonably competent physician specializing in orthopaedic spine surgery acting under similar circumstances.” (Judgment, App. 1.) Sargent argues that

evidentiary presumptions within the instructions.”); *Brooks v. Lexington-Fayette Urban County Hous. Auth.*, 132 S.W.3d 790, 809 (Ky. 2004).

she was prejudiced by the failure to give her proposed instruction because the jury did not know that Dr. Shaffer had a duty to explain the procedure in such a way that a “reasonable individual” in Sargent’s position would have a general understanding of the procedure, the “substantial risks” of the procedure, and “medically acceptable alternative procedures.”

Sargent’s argument ignores the substantial testimony on the informed consent process offered by her own expert witnesses and by Dr. Shaffer and his expert witnesses. There was consensus among the experts that in obtaining Sargent’s informed consent, Dr. Shaffer was required to inform her of the substantial risks of the procedure, provide her with a general understanding of the procedure, and make her aware of any medically acceptable alternative procedures. Neither Dr. Shaffer nor his experts disputed this. *See* Section II.D, *supra*. Likewise, each physician who testified agreed that a surgeon must explain risks in a way that a patient can understand them (i.e., provide enough information that a “reasonable individual” understand the procedure, the risks of the procedure, and any alternative procedures). *Id.* The comprehensive physician testimony about Dr. Shaffer’s duty in obtaining informed consent was consistent with the language of Sargent’s proposed instruction. Thus, there could have been no question in the jury’s mind that in order to act as a “reasonably competent physician specializing in orthopaedic spine surgery,” Dr. Shaffer was required to provide Sargent with enough information that a “reasonable individual” in Sargent’s position would have a general understanding of the procedure, the “substantial risks” of the procedure, and “medically acceptable alternative procedures.”

Sargent resorts to speculation when she argues that the jury must have been misled by the instruction given, or else it would not have found that Dr. Shaffer complied with his duty when obtaining Sargent's informed consent. It is far more likely that the jury simply found that in obtaining Sargent's consent to the procedure, Dr. Shaffer had complied with all of the specific duties discussed by the five spine surgeons who testified at trial about the informed consent process. Dr. Shaffer's experts presented evidence that "paralysis," "paraplegia," and complete bowel and bladder dysfunction were *not* "substantial risks" of Dr. Shaffer's procedure, because the odds of Sargent experiencing her unfortunate outcome as a result of a surgery performed at no higher than the T12-L1 level were extremely remote. In addition, Dr. Shaffer and his experts explained that, in their many years of experience with patients, terms like "nerve damage" and "nerve injury" are broad enough to encompass the full range of possible neurologic injury, including paralysis. Dr. Shaffer also presented evidence that he had reasonably discussed the benefits of the procedure. His experts explained that they would have agreed to operate on Sargent and that the procedure had a likelihood of improving Sargent's condition. Dr. Shaffer explained that he told Sargent the procedure could make her worse and that it was a "salvage operation." Last, Dr. Shaffer presented overwhelming evidence that he had not only discussed "medically acceptable alternatives" to the procedure with Sargent, but also had attempted several different medically acceptable alternatives, none of which succeeded at alleviating Sargent's life-altering pain. Thus, there is no basis in the record to support Sargent's argument that she was prejudiced by the trial court's decision not to give her proposed informed consent instruction.

IV. The principle of constitutional avoidance supports a finding that the language of KRS 304.40-320 should not be included in jury instructions.

This Court has consistently recognized that it has a duty to construe statutes in a way that avoids constitutional issues if at all possible. In *In re Beverly Hills Fire Litigation*, this Court stated, “In considering the proper construction appropriate to KRS 413.135 we are motivated in part by our duty to render the acts of the legislature viable by interpreting such acts consistent with constitutional mandates, and to avoid construction that ‘threatens unconstitutionality,’ whenever reasonably possible.” 672 S.W.2d 922, 925-926 (Ky. 1984). More recently, this Court “reiterate[d] the long-observed principle that constitutional adjudication should be avoided unless it is strictly necessary for a decision in the case.” *Stephenson v Woodward*, 182 S.W.3d 162, 168 (Ky. 2005). Accordingly, the Court should adopt any reasonable interpretation of a legislative enactment that would avoid raising concerns about the constitutionality of the statute. *Id.*; see also *Elery v. Commonwealth*, 368 S.W.3d 78, 94-95 (Ky. 2012) (“By limiting that statute to such cases...we avoid any concern about the constitutionality of the statute. That alone would require us to read the statute in such limited fashion, so long as the reading is a reasonable one.”) (internal citations omitted). If a statute can reasonably be construed in a way that would avoid constitutional concerns posed by an alternative construction, the Court should adopt the construction that avoids constitutional issues. *Id.*

This “constitutional avoidance” principle requires the Court to reject Sargent’s construction of KRS 304.40-320. Sargent construes the statute as giving rise to a statutory duty that must be included in the jury instruction in cases alleging negligence in the informed consent process. This construction of KRS 304.40-320, however, would

raise serious issues about whether the statute violates the Kentucky Constitution. *See Keel*, 842 S.W.2d at 862-863 (Leibson, J., concurring). In his concurrence in *Keel*, Justice Leibson confirmed that a case alleging negligence in discussing the risks of a procedure is simply “a negligence case subject to the usual rules pertaining to medical negligence cases....” *Id.* at 863. Justice Leibson took issue with the fact that the Court’s opinion even referenced KRS 304.40-320. His concurring opinion explains,

KRS 304.40-320 should have no bearing whatever on this case because it is a plainly unconstitutional legislative intrusion into liability for common law wrongs (negligence and assault and battery) protected from such intrusion by our *Kentucky Constitution, Secs. 14, 54 and 241. Constitutionally, the statute cannot define the duty.*

Id. (emphasis supplied). As Justice Leibson no doubt recognized, KRS 304.40-320 was enacted as part of a tort reform effort – it was designed to protect physicians and health care insurers by making it more difficult for patients to assert informed consent claims. *See* Section II.E, *supra*. As detailed above, legislative history reflects that KRS 304.40-230 was intended to “to eliminate the possibility of ...a plaintiff’s testifying that had he known of an unforeseeable [sic] or unlikely injury he would not have consented to the recommended health care.”⁸⁹ Construing the statute as Sargent requests would implicate the constitutional concerns raised by Justice Leibson in *Keel*.

Fortunately, there is a reasonable alternative construction, and it is the same construction this Court has adopted when discussing the statute in prior cases: that KRS 304.40-320 does nothing more than codify *Holton*’s holding that a claim for negligence in discussing the risks of the procedure is a claim of medical negligence that implicates professional standards of care. That is the interpretation set forth by this Court in both

⁸⁹ *Report of Governor’s Hospital and Physicians Professional Liability Insurance Advisory Cmte., Majority Report, Explanatory Comments*, p. 5 (Nov. 26, 1975) (App. 4).

Lewis and *Vitale* and that is supported that statute's legislative history.⁹⁰ It is not only a "reasonable" construction of KRS 304.40-320 – it is the best construction. Consistent with the principle of constitutional avoidance, this Court should confirm its prior statements that KRS 304.40-320 merely codifies the common law on informed consent and does not need to be included in the jury instruction on a physician's duty in obtaining informed consent.

V. If the Court changes the law to require an instruction based on the language of KRS 304.40-320, its change should apply prospectively only.

If this Court finds that the language of KRS 304.40-320 must be included in jury instructions, it should make this ruling prospective only and should not reverse the judgment in this case. The trial court properly applied existing law when it provided the model informed consent instruction proposed by *Palmore* and utilized by trial courts throughout the Commonwealth ever since *Holton* was decided in 1975. It would be manifestly unfair to Dr. Shaffer and the trial court to reverse the judgment and remand the case for a new trial on the informed consent claim.

This Court has the discretion to make application of its holding prospective only. "It is within the inherent power of a Court to give a decision prospective or retrospective application. It is further permissible to have a decision apply prospectively in order to avoid injustice or hardship." *Hagan v. Farris*, 807 S.W.2d 488, 490 (Ky. 1991). This Court recently stated that making a ruling prospective only may be appropriate when the Court is "overruling old precedent upon which the losing party has relied." *Branham v.*

⁹⁰ See *Lewis*, 894 S.W.2d at 623 n.1 (KRS 304.40-320 "attempts to codify the common law as to when informed consent has been given and obtained..."); *Vitale*, 24 S.W.2d at 656 (stating that KRS 304.40-320 simply codified *Holton*'s holding that "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").

Stewart, 307 S.W.3d 94, 102 (Ky. 2010). It is proper for the Court to hold that a ruling is prospective only when “parties have acted in reliance on the law as it existed, and a contrary result would be unconscionable.” *Id.* (quoting *Hagan*, 807 S.W.2d at 490).

If the Court changes the jury instruction in informed consent cases, it should make this ruling prospective only. For nearly 40 years, litigants, practitioners, and trial courts have relied on this Court’s holding in *Holton* and *Palmore*’s model instruction when instructing the jury on a physician’s duty in obtaining informed consent. No case from this Court or the Court of Appeals has even hinted that *Palmore*’s model instruction is insufficient or that the language of KRS 304.40-320 should be included in a jury instruction. The “bare bones” method of instructing juries – which courts and practitioners have also come to rely in both criminal and civil matters – would be violated and placed in jeopardy if the Court adopts *Sargent*’s position. Dr. Shaffer and the trial court in this case are not the only ones who have relied on this established law on informed consent and bare bones instructions. Unless this Court makes its ruling prospective only, numerous judgments currently on appeal, or being considered for appeal, could be imperiled by such a drastic change in the law. If it elects to change the law, which it should not do, this Court should avoid injustice and hardship by holding that its opinion applies in future cases only.

CONCLUSION

For the above reasons, this Court should affirm the trial court’s judgment and the Court of Appeals’ opinion affirming that judgment. If the Court elects to require an instruction of the sort proposed by *Sargent*, it should make any such ruling prospective-only and should not reverse the judgment in this case. And if the Court reverses the

judgment in this case, it should remand the case with instructions for a new trial only on Sargent's claim of negligence in the informed consent process.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Stephen J. Mattingly".

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APPENDIX

1	Judgment entered September 12, 2011
2	Palmore & Cetrulo, <i>Kentucky Instructions to Juries</i> , §§ 13.11, 16.05, 16.09, 16.11, 16.16, 23.10, 23.14
3	<i>Campanell v. Figert</i> , No. 2008-CA-621-MR, 2009 Ky. App. Unpub. LEXIS 145, *6-7 (Ky. App. 2009)
4	<i>Report of Governor's Hospital and Physicians Professional Liability Insurance Advisory Cmte.</i> (Nov. 26, 1975)

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