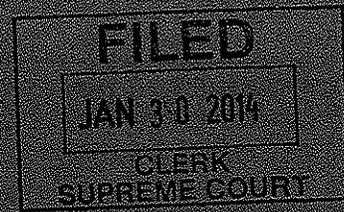


SUPREME COURT OF KENTUCKY
NO. 2013-SC-000111-D



LORETTA SARGENT

APPELLANT

APPEAL FROM THE
COURT OF APPEALS OF KENTUCKY
FILE NO. 2011-CA-001696
AND FAYETTE CIRCUIT COURT
NO. 10-CI-680

WILLIAM SHAFFER, M.D.

APPELLEE

BRIEF FOR APPELLANT

Submitted by

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CERTIFICATE REQUIRED BY 76.12 (6)

It is hereby certified that a true and correct copy of the Brief for Appellant was served by mail on the 30 day of January, 2014 on the following: Hon. Pamela R. Goodwine, Fayette Circuit Court, 120 N. Limestone Street, Room 534, Lexington, KY 40507, Clerk of the Court of Appeals, 360 Democrat Drive, Frankfort, KY 40601 and Bradley A. Case, Esq. and Stephen Matingly, Esq., Dinsmore and Shohl, LLP, 101 S. Fifth Street, Suite 2500, Louisville, KY 40202, counsel for the Appellee.

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INTRODUCTION

This is a medical malpractice case involving informed consent. The trial court instructed the jury only on the doctor's duty to exercise ordinary care in obtaining informed consent but refused to also instruct the jury on the additional duty of the doctor to give the patient sufficient information so as to generally understand the substantial risks as required by KRS 304.40-320 (2). Thus the trial court erroneously refused to instruct on a specific statutory duty, resulting in a defense verdict and judgment, which was erroneously affirmed by the Court of Appeals. This Court granted discretionary review.

STATEMENT CONCERNING ORAL ARGUMENT

Oral argument will be beneficial. This case involves the question of whether a specific statutory duty must be included in an instruction based on common law. The case therefore rises above a decision affecting just this case to a decision affecting all future cases where there is both a statutory and a common law duty.

Moreover, the trial court and the Court of Appeals confused the law on informed consent with the law on malpractice. Though similar, the law is different. Oral argument will resolve this confusion.

STANDARD FOR REVIEW

The propriety of a trial court's jury instruction must be considered by this Court under a *de novo* standard of review. Hamilton v. CSX Transportation, Inc., 208 S.W.3d 272 (Ky. App. 2006). The "[i]nstructions must be based upon the evidence and they must properly and intelligibly state the law." Howard v. Commonwealth, 618 S.W.2d 177, 178 (Ky. 1981).

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STATEMENT OF THE CASE

PROCEDURAL FACTS

Appellant ("Mrs. Sargent") presented two theories of liability against the Appellee ("Dr. Shaffer") at trial: malpractice and lack of informed consent.

Malpractice occurs when in treating a patient the doctor fails to observe the duty to exercise that degree of care expected of a reasonably prudent doctor under the same or similar circumstances. This duty has long been recognized in Kentucky. See Blair v. Eblen, 461 S.W. 2d 370 (Ky. 1970)

Lack of informed consent occurs when in telling the patient the substantial risks the doctor fails to observe the duty to exercise that degree of care expected of a reasonably prudent doctor under the same or similar circumstances AND the doctor fails to observe the duty to give the patient sufficient information so that a reasonable individual would have a general understanding of the substantial risks. The first duty has long been recognized in Kentucky since Holton v. Pfingst, 534 S.W.2d 786 (Ky. 1975), which was codified by KRS 304.40 – 320 (1) in 1976. The second duty has also been long recognized in Kentucky in KRS 304.40 – 320 (2), also enacted in 1976.

There is a substantial difference between the first and second duties. The first duty is doctor based, *i.e.*, what a reasonably prudent doctor would tell a patient. The second is patient based, *i.e.*, what a reasonably prudent patient would understand. The first duty involves doctor testimony usually from experts as to what the standard of care requires a doctor to tell. Often this results in an expert debate. The second duty involves

testimony as to what the patient understood and whether this understanding was reasonable.

At the conclusion of all evidence the trial court gave an instruction on malpractice and an instruction on informed consent. The informed consent instruction was erroneous. The trial court instructed that in obtaining informed consent the doctor had a duty to exercise that degree of care expected of a reasonably competent doctor under the same or similar circumstances but the trial court refused to instruct on the statutory requirement that the doctor also had a duty to give the patient sufficient information so that a reasonable individual would have a general understanding of the substantial risks.

Because KRS 304.40-320 lies at the heart of this appeal, it is set forth in its entirety:

304.40-320 Informed consent; when deemed given

In any action brought for treating, examining, or operating on a claimant wherein the claimant's informed consent is an element, the claimant's informed consent shall be deemed to have been given where:

- (1) The action of the health care provider in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with the accepted standard of medical or dental practice among members of the profession with similar training and experience, and
- (2) A reasonable individual, from the information provided by the health care provider under the circumstances, would have a general understanding of the procedure and medically or dentally acceptable alternative procedures or treatments and substantial risks and hazards inherent in the proposed treatment or procedures which are recognized among other health care providers who perform similar treatments or procedures;
- (3) In an emergency situation where consent of the patient cannot reasonably be obtained before providing health care services, there is no requirement that a health care provider obtain a previous consent.

There being no emergency in this case, only paragraphs (1) and (2) were applicable. The trial court refused to instruct on paragraph (2). The jury returned a verdict for Dr. Shaffer on both the malpractice instruction and on the erroneous informed consent instruction. The trial court entered a judgment based on the verdict. The Court of Appeals affirmed. This Court granted discretionary review.

MATERIAL FACTS

On February 18, 2009, Dr. Shaffer performed back surgery on Mrs. Sargent at the University of Kentucky Samaritan Hospital in Lexington. The surgery was primarily done for the pain of a herniated disc at the T12-L1 level. This is the level where the thoracic vertebrae end and the lumbar vertebrae begin. After surgery Loretta was paralyzed from the level of the surgery down, with no feeling, no movement and no bowel or bladder control. These injuries are permanent.

All physicians testifying at trial stated this disc surgery at T12-L1 carried a risk of paralysis and loss of bowel and bladder control. Some physicians placed the risk higher than others, but all agreed that paralysis was a risk. Dr. Shaffer used a posterior approach coming in from the back. He therefore had to pass to one side of the dura with its enclosed spinal cord in order to reach the portion of the herniated disc lying on the opposite side. The spinal cord itself ends just below this level, at a place known as the conus, which is the part of the cord tapering down like a cone to the cauda equina, or nerve roots, coming off the bottom of the cord itself. These nerve roots enervate below this level, giving function to the lower extremities and to the bowel and bladder.

Surgery in this area carries a risk of manipulation of the spinal cord and/or loss of blood supply to the spinal cord, causing injury to the spinal cord, with resultant loss of

function below. Dr. Shaffer, in a post-operative note, after he found neurological injury, noted “likely secondary to spinal manipulation” (R 0099-0100; VR: 08/30/11, 09:21:00).

The informed consent testimony at trial on behalf of Mrs. Sargent came from her and her two experts. It focused on the fact that Dr. Shaffer never told her that she could be paralyzed from the level of the surgery down, with no bladder or bowel control, for the rest of her life. Her experts testified this failure to so inform her was below the standard of care.

The informed consent testimony at trial on behalf of Dr. Shaffer came from him and his two experts. All admitted Dr. Shaffer never told Mrs. Sargent she could be paralyzed with no bladder and bowel control. Dr. Shaffer did tell her she could have a “nerve injury”, so the testimony focused on the opinions of Dr. Shaffer and his experts that “nerve injury” met the standard of care.

The trial testimony will be quoted at some length in this Brief for Appellant because it precisely demonstrates why the statutory duty imposed by KRS 304.40-320 (2) must be in the informed consent instruction. The testimony comes from Mrs. Sargent and her two physician experts and Dr. Shaffer and his two physician experts.

1. Mrs. Sargent’s Tesimony

Mrs. Sargent testified she was not told and did not understand she had a risk of paralysis and loss of bowel and bladder function.

VR: 8/31/11, 12:10:02

Q: What was your understanding of the risks of the procedure?

A: Well, I just thought he could take the pain away and be back working at the bank again.

VR: 8/31/11, 12:39:21

Q: What do you remember Dr. Shaffer telling you about the risks of the surgery?

A: Well, he told me that he was going to try to relieve my pain and it was never mentioned to be paralyzed.

Q: You're positive about that?

A: I'm positive about that.

Q: Would you have had the surgery knowing you could be paralyzed?

A: No, because....

Q: You're sure about that?

A: Yes I'm sure about that.

Q: What did you think the risks were?

A: Well, to me it sounded like that he could help me and you know, relieve the pain and that's really what I was, you know, wanting and he didn't talk to me like it would be that long of an operation. And that he'd go in there and do what he thought was wrong and see if that's what it all was and he would take that away and I'd be able to maybe walk better.

Q: Do you remember an office visit, I know the date is February the 12th, but this is the last time you were there and you were there in that office and you knew the surgery was coming up in just six days. Were you told, if you remember, that there was a risk of a nerve injury?

A: Well, yes, I guess so.

Q: Did you think that meant paralysis from the level of the surgery down?

A: Oh, no, I never did think it meant that. I just thought, you know, well it's a nerve thing, when he got in there to do what he was gonna do, he'd you know, that it may not help the nerve that was something wrong with, that's all I thought about.

VR: 8/31/11, 12:43:15

Q: Did not say you could be paralyzed?

A: No, I don't...

Q: Did he say you could have a loss of the ability to control your bladder or your bowels?

A: No, uh uh, that wasn't in the...

Q: That you'd be permanently in a wheelchair?

A: No, no, no.

Q: Did he mention anything like that?

A: No, sir.

2. The Expert Testimony for Mrs. Sargent

Mrs. Sargent presented two experts at trial, Dr. DeLong, a neurosurgeon and Dr. Banco, an orthopedic surgeon. Both testified that Dr. Shaffer's failure to tell Mrs.

Sargent she could be paralyzed with no bowel and bladder control was below the standard of care.

Dr. DeLong testified at trial as follows:

VR: 8/30/11, 10:56:53

- Q: I'm going to ask if you have an opinion based on everything you have seen and read about this case, do 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. Do you have an opinion?
- A: Yes, I do have an opinion.
- Q: And what is it?
- A: That he did not.
- Q: Tell us real quickly the reason why?
- A: I don't think he gave her a proper informed consent. He didn't inform her adequately of the risks of the surgery. He was overly optimistic in the benefits and he didn't present the alternatives to her. He used a very dangerous approach to try to take out a calcified, inherent, herniated disc in the thoracic region, the T12-L1. And it was simply not a standard accepted approach it was dangerous approach.
- Q: Was a written consent form or an office visit telling Loretta Sargent that she could have a "nerve injury" or an "injury to nerves", was that adequate in your opinion to explain the risk of paralysis?
- A: No, it was not.
- Q: Tell us why.
- A: Because nerve injury does not imply the paralysis. It implies a rather minor injury to a nerve 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 deficit in the sensation supplied by that nerve but it doesn't imply complete, total paralysis from the waist down with a deficit, complete absence of bladder and bowel function. A nerve injury simply does not have that connotation to the average person.
- Q: In the surgeries that you have performed on the spine where there is any appreciable risk at all of paralysis, is that the word you use to tell your patients?
- A: That is the word I used, I used the word paralysis.
- Q: That's not too strong a word to use?
- A: It's a scary word but the spine surgery is scary. And the purpose of informed consent is to inform the patient adequately what the risks he or she is facing when they accept the surgeon's recommendation so if you try to whitewash the informed consent and try to whitewash the risks, the patient isn't hearing the truth, the whole truth and nothing but the truth.

Dr. Banco testified at trial as follows:

VR: 8/31/11, 9:08:54

Q: 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: In my opinion, no.

Q: Did he adequately explain the risks of the procedure?

A: In my opinion, no.

VR: 8/31/11, 9:10:39

Q: Was a written consent form telling Loretta she could have "nerve injury" adequate to tell her of the risks of paralysis?

A: No, in my opinion, no.

VR: 8/31/11, 9:27:47

Q: What was wrong with the consent process here?

A: Well, I think Dr. Shaffer did, uh, give the consent form in his office, and it's documented in his chart, um, however, the risks were reasonably good, but were not accurate enough. They're not, in my opinion they weren't extensive enough. This patient had some very high risk factors for having a neurological complication during this surgical procedure. My opinion is that, these risks should've been more clearly outlined on his pre-operative consultation in his office and on the written consent from that Loretta Sargent signed. He talked about bleeding and nerve damage and other general issues, but you know, her chances of having a significant neurological deficit in this particular situation was higher than the standard, was higher than the normal and that should've been articulated, if it was not articulated, it's not in the record. And it's not on a written consent. And the word "paralysis" should've been used in my opinion.

VR: 8/31/11, 9:32:59

Q: You don't think the word "paralysis" is too strong to use with a patient?

A: No, because I think the risks of paralysis were greater than normal, much greater than normal.

VR: 8/31/11, 9:52:56

Q: Does it deliver a false sense of security if 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 think there's a big difference in nerve injury and paralysis. It's a huge difference.

Q: What is the difference?

A: 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 it depends upon the extent of the paralysis, right? Is it complete, is it incomplete and how dense is the paralysis? They're two different words. Myocardial muscle damage or cardiac failure, nerve damage, heart failure, nerve damage, paralysis, I mean that's a good analogy I think.

3. Dr. Shaffer's Testimony

Dr. Shaffer testified he saw Mrs. Sargent for 6 to 8 months before her surgery, that he discussed the option of surgery vs. no surgery, and that he told her surgery should be done only as a last resort. In his office note, Dr. Shaffer wrote that the risks were infection, bleeding, nerve damage, dural leak, injury to the nerve, and destabilization of scoliosis requiring fusion. The consent form prepared under the control of Dr. Shaffer stated a risk of "nerve injury" and "injury to surrounding structures". (R 0102-0104). The consent form is attached as **EXHIBIT 5** in the Appendix.

It is absolutely clear that Dr. Shaffer never told Mrs. Sargent that she could be paralyzed from the level of surgery down, with no bowel and bladder function.

VR: 8/30/11, 9:30:27

Q: Did you at any time tell Loretta that she could be paralyzed with this surgery?

A: I never used the term paralyzed.

Q: You never used the term paralyzed?

A: No, I did not.

Q: Did you ever use the term paraplegic?

A: No, I did not.

VR: 8/30/11, 9:35:50

- Q: Now I invite you to look at your notes and tell me, if you ever in your notes, from the time you first saw her until the operation, ever talked about paralysis or paraplegia, in those terms.
- A: I did not use those terms at any time, no.
- Q: Did you ever in those notes from day one until the surgery, including this counseling session that we just talked about where you specifically said what the risks were, is it ever in any of those notes that she could have a bowel incontinence problem or a bladder incontinence problem?
- A: No.
- Q: That is to say she can lose control of her bowels or bladder?
- A: No.
- Q: That she could be wheelchair-bound?
- A: No.
- Q: That she'll have to be lifted from bed to wheelchair and wheelchair to bed?
- A: No.
- Q: That she's going to be basically without any motor function from the level of your surgery down?
- A: No.
- Q: That basically she'll have no sensory function or ability to feel anything from the level of your surgery down?
- A: Not in those terms.

VR: 8/30/11, 9:38:18

- Q: Did you find that Loretta was an intelligent lady?
- A: Oh yes.
- Q: Did you find that she was a very sweet lady, she was very charming?
- A: She's, you know, she's like my grandmother, she's...
- Q: Do you think she would come in this courtroom and lie to this jury?
- A: Of course not.
- Q: She will come in here and she will say, "I had no earthly idea that I could be paralyzed, that I wouldn't be able to move from that level of surgery down, that I wouldn't be able to feel anything, that I'd have to use a Heuer lift, that I'd be in a wheelchair, that I couldn't drive, that I couldn't do all these other things, I had no earthly idea." So why didn't you tell her? Real simple, why didn't you tell her, "you can be paralyzed, do you know what that means, Loretta? That means from here down, you won't have anything." Why didn't you tell her that?
- A: I don't usually use terms like that in discussing this type of surgery with my patients.

VR: 8/30/11, 10:03:18

- Q: So just to close, you would agree with me, that either in your notes or in your memory, you cannot recall a single incident of time, all the way up to

the surgery, where you said, she could be paralyzed, or could be a paraplegic, have total loss of function below the level of your surgery – no ability to move, no ability to have sensation, no bowel control, no bladder control, do you agree with that, correct?

A: Yes.

4. The Expert Testimony for Dr. Shaffer

Dr. Shaffer presented two experts, Dr. Shaffrey, a neurosurgeon and Dr. Boden, an orthopedic surgeon. Both testified that in what he told Mrs. Sargent Dr. Shaffer complied with the standard of care.

Dr. Shaffrey testified at trial as follows:

VR: 8/31/11, 3:17:57

Q: Did any standard of care that you know of in the spine surgery community require Dr. Shaffer to use the specific term “paralysis” when advising Mrs. Sargent of the risks of this procedure?

A: Well the word “nerve injury” encompasses for many people the entire spectrum of things from the slightest numbness to devastating injury. One of the issues is, what you write on a consent form or what the time you spend seeing someone aren’t directly related. From what I could glean from the records is that Dr. Shaffer at least 8 times, I think nine, he came and spoke as well at the pain management doctor’s office, that there’s nine times where there seems to be a substantial amount of time spent with the patient, and what’s happening is I think there, that’s really where the work of what your informed consent is, is that you sit down there and you tell somebody...

VR: 8/31/11, 3:19:48

Q: If Dr. Shaffer informed her of the risk of nerve injury, damage to the nerves, said things like this surgery could make you worse, said things like, you shouldn’t consider this surgery unless you’re really miserable and had her try non-operative therapy and things like that, would that have been an appropriate informed consent process for this particular surgery?

A: Yes.

VR: 8/31/11, 3:25:03

Q: Have you seen the consent form?
A: I have.
Q: Your memory is good, I'm sure, and that is, it says "nerve injury", it doesn't say anything about paralysis, or paraplegia or any of the other things that happened to this poor woman?
A: That is correct but it's my belief that that's within the spectrum of nerve injury.
Q: A nerve injury can be major or minor?
A: Correct.

VR: 8/31/11, 3:30:02

Q: Would you agree that nerve injury could mean anything as simple as a slight loss of nerve to a finger?
A: Yes.
Q: Could it mean that you had a limited nerve injury to a leg, not even a foot drop?
A: Yes.
Q: Can a patient with a nerve injury lead a normal life?
A: Yes.
Q: Not have to be on a walker, not have to be in a wheelchair, not have bowel problems, not have bladder problems?
A: Yes.
Q: There are patients with nerve injuries who drive cars and go to work?
A: There are indeed, yes.
Q: There are patients with nerve injuries who do not have to suffer from somebody bathing them for example, or bowel changes or diaper changes or whatever?
A: There are, yes.
Q: There are nerves from the head to the toe and run the gamut between major and minor, correct?
A: That's true, yes.
Q: So the word nerve injury could mean any of that, correct?
A: Correct.

Dr. Boden testified at trial as follows:

VR: 9/1/11, 9:38:46

Q: Can you just give us an overview of your opinion of two issues in this case – the first on whether Dr. Shaffer acted reasonably in obtaining informed consent from Mrs. Sargent prior to the operation?
A: Yes, I think he did.

VR: 9/1/11, 10:12:14

Q: In your opinion did the standard of care require Dr. Shaffer to advise Mrs. Sargent of the risk of paralysis using the specific term "paralysis" in obtaining informed consent?

A: I don't believe so. In my 21 years of doing this, I have never used the word paralysis during informed consent for an operation with patients, even in situations where I think the risk of paralysis is greater than it was in Mrs. Sargent's case.

At the conclusion of the evidence, Mrs. Sargent's counsel offered a specific instruction on informed consent based on KRS 304.40-320 (2). The tendered instruction is attached as **EXHIBIT 4** in the Appendix. As previously mentioned, KRS 304.40-320, enacted in 1976, provides in paragraph (1) that in obtaining informed consent a doctor must act "in accordance with the accepted standard" and in paragraph (2) that in addition to complying with paragraph (1), a doctor must also give the patient sufficient information so that a "reasonable individual" would have a "general understanding" of the "substantial risks and hazards "

Paragraph (2) clearly and unequivocally places on a doctor the additional duty, separate and apart from exercising ordinary care, to give sufficient information so that a reasonable patient will generally understand the substantial risks. If a doctor complies with the duty in paragraph (1), a doctor may still not comply with the duty in paragraph (2). Paragraph (1) speaks to what reasonably prudent doctors do. Paragraph (2) speaks to what reasonably prudent patients will generally understand. The duties are different.

The trial court refused to give the proposed instruction and over Mrs. Sargent's objection gave only a general informed consent instruction that told the jury only that Dr. Shaffer, in disclosing the "risks and benefits", must exercise the degree of care and skill expected of a reasonably competent physician specializing in orthopedic spine

surgery....” A copy of the trial court’s given instruction is attached as **EXHIBIT 3** in the Appendix. Thus, under the instruction given by the trial court, the jury knew that Dr. Shaffer had a duty to exercise ordinary care to disclose the “risks and benefits”. The jury did NOT know that Dr. Shaffer had the additional duty to disclose such information as would give a “reasonable” patient a “general understanding” of the “substantial risks and benefits.”

Following a verdict for Dr. Shaffer, the trial court entered its Judgment, a copy of which is attached as **EXHIBIT 2** in the Appendix. Mrs. Sargent appealed to the Court of Appeals and raised, inter alia, this issue on the informed consent instruction. The Court of Appeals affirmed the trial court. Its Opinion affirming is attached as **EXHIBIT 1** in the Appendix.

ARGUMENT

1. THE TRIAL COURT ERRONEOUSLY REFUSED TO INSTRUCT ON A STATUTORY DUTY

The trial court refused to instruct on KRS 304.40-320(2), enacted in 1976, which provides that in obtaining informed consent the doctor has a duty to give sufficient information so that a reasonable patient will understand the substantial risks. This is a specific statute creating a specific duty in a larger statute titled “Informed consent; when deemed given”. There is no doubt it is applicable to all cases involving the issue of informed consent.

The history of duties of doctors and hospitals in Kentucky is not complex. The history demonstrates the importance of KRS 304.40-320(2) and why it must be included in the instructions.

In 1970, the Kentucky Supreme Court (then Court of Appeals) decided Blair v. Eblen, 461 S.W.2d 370 (Ky. 1970), a malpractice case. That case held that Kentucky would no longer follow a community standard in malpractice cases and specifically instructed that the duty on a doctor in a malpractice case was the duty to use that degree of care and skill expected of a reasonably competent physician in that specialty acting in the same or similar circumstances.

In 1975, the Kentucky Supreme Court (then Court of Appeals) decided Holton v. Pfingst, 534 S.W.2d 786 (Ky. 1975), an informed consent case. That case held that in a case involving whether the doctor properly advised the patient of the risks, the duty was the same as in a malpractice case, *i.e.*, to use that degree of care and skill expected of a reasonably competent physician in that specialty acting in the same or similar circumstances.

In 1976, the General Assembly enacted KRS 304.40-320. In paragraph (1) it codified Holton v. Pfingst. In paragraph (2) it created an additional duty that whatever the doctor told the patient, a reasonable patient had to have a general understanding of the substantial risks.

In 1981, the Supreme Court of Kentucky decided Rogers v. Kasden, 612 S.W.2d 133 (Ky. 1981), a malpractice case. That case held that the duty on a hospital was to exercise that degree of care and skill ordinarily expected of reasonable and prudent hospitals under similar circumstances.

Blair, Holton, KRS 304.40-320 and Rogers have been the foundation upon which all medical malpractice and informed consent cases have been based. Any discussion of duty in malpractice and informed consent cases traces to this established law.

It is easy to confuse malpractice cases with informed consent cases, a mistake made by the trial court and the Court of Appeals. While there have been numerous malpractice cases since Blair, Holton, KRS 304.40-320 and Rogers, there have been few informed consent cases and even fewer informed consent cases discussing KRS 304.40-320. NO CASE HAS DISCUSSED WHETHER KRS 304.40-320 (2) SHOULD BE IN THE INSTRUCTIONS.

In 1992, the Supreme Court of Kentucky decided Keel v. St. Elizabeth Medical Center, 842 S.W.2d 860 (Ky. 1992), an informed consent case. That case held that under its facts, expert testimony was not required in order to prove lack of informed consent. The Supreme Court quoted KRS 304.40-320 and held that that statute did not always require expert testimony.

In 1999, the Court of Appeals decided Hawkins v. Rosenbloom, 17 S.W.3d 116 (Ky. 1999), an informed consent case. That case held that under its facts expert testimony was required to prove lack of informed consent. The Court of Appeals quoted KRS 304.40-320 and specifically stated:

Part (2) deals specifically with what a reasonable person should be told before deemed to have given informed consent.
(Emphasis added)

In 2000, the Supreme Court of Kentucky decided Vitale v. Henchey, 24 S.W.3d 651 (Ky. 2000), a no consent case. That case held that where there is no consent whatsoever, the case is one of assault and battery and not lack of informed consent. KRS 304.40-320 therefore does not apply.

Similarly, in 2000, the Supreme Court of Kentucky decided Coulter v. Thomas, 33 S.W.3d 522 (Ky. 2000), a no consent case. That case held that where there is no consent whatsoever, KRS 304.30-320 does not apply.

There being no Kentucky case even discussing whether KRS 304.40-320(2) should be in the instructions, the statute clearly stands. There is only one way that a statute like this may have effect, and that is in the instructions. If it is not, the statute is null and void and the General Assembly wasted its time in passing it.

2. THE COURT OF APPEALS OPINION IS ERRONEOUS WITH RESPECT TO ITS INTERPRETATION OF CASES UNDER A MALPRACTICE INSTRUCTION.

The Court of Appeals confused the law on an informed consent instruction with the law on a malpractice instruction. That Court discussed three cases where the issue was what specific duties, if any, should be in a malpractice instruction. These cases did not involve an informed consent instruction. They didn't even mention KRS 304.40-320.

In Rogers v. Kasden, 612 S.W.2d 133 (Ky. 1981), a malpractice case, the Kentucky Supreme Court detailed the proper instruction to be given in a malpractice case against a hospital. It held a plaintiff's wish list of hospital duties does not belong in such an instruction. None of the plaintiff's wish list in that case was based upon a Kentucky statute.

In Humana of Kentucky, Inc. v. McKee, 834 S.W.2d 711 (Ky.App. 1992), a malpractice case, the Court of Appeals held that a statutory duty must be in the malpractice instruction. Humana involved a claim that the hospital negligently failed to diagnose a newborn with PKU because it did not test for PKU in violation of KRS 214.155, requiring hospitals to perform the test within twenty-four hours of a child's

birth. The Court of Appeals held that the trial court did not err by instructing the jury on the hospital's specific statutory duty to administer the test. The Court of Appeals distinguished Rogers and held:

In Rogers, the court found error in the instructions because they were too detailed and because they imposed more duties upon the defendant hospital than the law required. However, the court did not hold, as Humana suggests, that the duty instructions in a hospital liability case must be limited to a single instruction on ordinary care. On the contrary, hospitals are required to comply with many statutory duties in addition to that of exercising ordinary care. 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 duty, standing alone, may be sufficient to support a claim of negligence.

Id. at 722.

In Hamby v. U.K. Med. Ctr., 844 S.W.2d 431 (Ky. App. 1993), a malpractice case, the Court of Appeals held that certain enumerated duties the plaintiff wanted in the malpractice instruction were properly excluded. The primary rationale for the holding in Hamby, however, was tied to the fact that the duties were not set out specifically by statute. The duties were found by the plaintiff in the hospital's policies and procedures.

In Hamby, the Court stated that in medical negligence cases specific duties traditionally have been excluded, even though statutory duties have been used in other types of cases, such as automobile accident litigation. *Id.* at 433. It is important to note, however, that the Court in Hamby recognized a critical exception, acknowledging that:

[a]n exception to the general rule was carved out by this Court when it affirmed the [trial court's] instruction which specified a hospital's duty to administer a PKU test to newborn infants as required by KRS 214.155. Because the statute was so specific, the expert testimony supported the duty, and failure to perform the required test was a clear

substantial factor in causing [plaintiff's] problems, we can distinguish that from the case at bar. Here, the experts varied significantly as to the actual necessity for using interstitial probes, especially under the facts of this case. [In this case] [w]e do not have such a specific statute...

Id. (Internal citations omitted.)

In its Opinion, the Court of Appeals did not cite its own recent case of Slone v. Central Baptist Hospital, 2003-CA-001576-MR (copy of Opinion is attached as **EXHIBIT 6** in the Appendix), a malpractice case. In that case, the Court of Appeals held that plaintiff's wish list of duties should not be in the instruction, but noted:

The exception created in Humana is applicable when a duty is specifically created by statute or regulation and the breach of that duty would result in liability.

In the case at bar, the Court of Appeals took three cases involving malpractice instructions and interpreted them to mean that KRS 304.40-320 (2) should not be in an informed consent instruction. The Court of Appeals is wrong for two reasons.

First, the case law as it presently stands on malpractice instructions is that a specific statute creating a specific duty, the breach of which creates liability, should be in a malpractice instruction. This is the only conclusion that may be reached by a careful reading of the facts and holdings of Humana (1992), Hamby (1993) and Slone (2003). Only Humana involved a specific statute creating a duty and the Court of Appeals properly held the duty should be in the malpractice instruction. Hamby and Slone involved plaintiffs' wish lists, none of which were based on a statute.

Second, it is improper to draw an analogy from cases involving malpractice instructions to a case involving an informed consent instruction because KRS 304.40-320's creation of a duty cannot be ignored.

To be sure, the trial court relied on *Palmore and Cetrulo, Kentucky Instructions to Juries, Civil, § 23.10 (2010)*. That section gives the usual ordinary care instruction for an informed consent case, and cites *Holton v. Pfingst, supra*. That section does not mention KRS 304.40-320 at all.

In § 23.01 on malpractice, *Palmore and Cetrulo*, in a comment, state that duties found in hospital regulations or policies should not be included in the instructions on malpractice, citing *Hamby* and *Rogers*. More importantly however, *Palmore and Cetrulo* include an entire section on the statutory duty of a hospital in a PKU test and mandate that the KRS statute should be in the instructions. See § 23.14.

In its Opinion in this case the Court of Appeals cited *Office, Inc. v. Wilkey*, 173 S.W.3d 226 (Ky. 2005). That case was neither a malpractice case nor an informed consent case. Rather, it was a slip and fall case at a health club. The plaintiff wanted a wish list of duties in his tendered instruction, which the trial court refused to give. The trial court gave the usual ordinary care instruction, which the Supreme Court ruled was sufficient. The Supreme Court emphasized the "bare bones" approach. The case has no relevance here because no statute was involved.

3. THE ERRONEOUS INFORMED CONSENT INSTRUCTION WAS HIGHLY PREJUDICIAL AND REQUIRES REVERSAL.

Erroneous jury instructions are presumed to be prejudicial. The party defending the erroneous instruction bears the burden of showing that no prejudice resulted. *McKinney*

v. Heisel, 947 S.W.2d 32, 35 (Ky.1997). Actually, the failure to place in the informed consent instruction the language of KRS 304.40-320 (2) was highly prejudicial to Mrs. Sargent.

The jury knew Dr. Shaffer had a duty to exercise ordinary care to tell Mrs. Sargent the risks of the proposed surgery. The jury did NOT know that Dr. Shaffer had a further duty, even exercising ordinary care, to explain these risks so that a reasonable individual would have a general understanding of them.

Dr. Shaffer told Mrs. Sargent that the surgery carried risks and she should have the surgery as a last resort. The consent form told Loretta she had a risk of "nerve injury" or "injury to surrounding structures." Believing the defense experts, the jury concluded that this was enough to satisfy Dr. Shaffer's duty to exercise ordinary care to tell the risks. Properly instructed, however, the jury could and probably would have concluded that this was not enough information to give Mrs. Sargent a general understanding that she could be paralyzed with no bowel or bladder function.

A jury under an instruction that a doctor must tell the risks and benefits may find differently than a jury under an instruction that a doctor must give sufficient information so that the patient will have a general understanding of the substantial risks and benefits. For example, a doctor tells a patient he may injure a nerve during elbow surgery, but doesn't tell the patient his nerve injury may result in loss of use of his hand. Before a heart catheterization procedure, a doctor tells the patient the catheter might dislodge some plaque, but does not tell the patient the dislodged plaque may go to the brain causing a debilitating stroke. Before an operation to straighten a crooked arm a doctor tells the patient there might be an infection, but does not tell the patient if a bone is infected the

patient can lose the arm. The doctors may obtain defense experts that testify this meets the standard of care of what reasonably prudent doctors would tell, without giving the patients a general understanding of the substantial risks.

In this case, Dr. Shaffer told Mrs. Sargent he may injure a nerve doing spinal surgery, but didn't tell Mrs. Sargent her nerve injury may result in paralysis and loss of control of bowel and bladder. His experts testified the giving of this information was within the standard of care. Dr. Shaffer admitted he did not tell Mrs. Sargent she could be paralyzed and Mrs. Sargent testified she had no idea she could be paralyzed. Under the instruction given by the trial court, a jury could easily find Dr. Shaffer had complied with his duty when it was obvious Mrs. Sargent did not have a general understanding of what that injury meant.

4. THE ERRONEOUS INFORMED CONSENT INSTRUCTION WILL RESULT IN SUBSTANTIAL INJUSTICE IN FUTURE CASES INVOLVING INFORMED CONSENT AND WILL RESULT IN FURTHER JUDICIAL REJECTION OF STATUTORY DUTIES.

If the Court of Appeals Opinion is allowed to stand, even if "not to be published," numerous future malpractice cases involving informed consent will be erroneously tried. Doctors will obtain informed consent by using language they understand but not language their patients understand. The General Assembly placed this legal duty on doctors and its statute should not be ignored. As it now stands, paragraph (2) has been rendered null and void. Juries should be properly instructed as to both the common law and the statutory law.

The trial court and the Court of Appeals frequently cited to Kentucky's philosophy of bare bones instructions. They emphasized that such instructions may be

fleshed out by counsel in closing arguments. But the pronouncements of a trial judge in the instructions carries irrefutable and supreme authority. What a lawyer says as an advocate in closing argument is easily disputed or ignored.

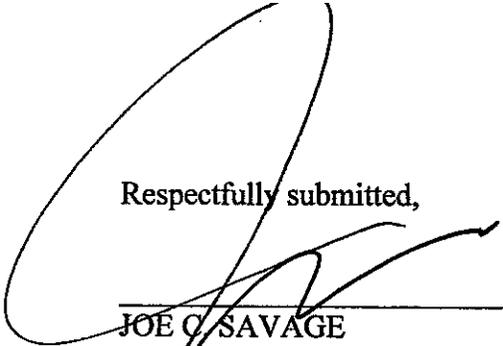
Instructions are vitally important. Jurors are told they represent the law and must be followed even if some jurors disagree with them. They are read to the jury before closing arguments. Copies are given to the jurors. Usually counsel refer to them in closing arguments. It is beyond dispute that they should correctly state the applicable law, bare bones or not.

The Kentucky Supreme Court should not allow a Court of Appeals Opinion to stand that approves the complete abrogation of a statutory duty. What statutory duty may next be ignored and in what type of case? The General Assembly has the power to make law in this context and its powers should be respected by our courts.

CONCLUSION

The trial court refused to include in its informed consent instruction the statutory duty in KRS 304.40-320(2). This was a highly prejudicial error which resulted in a defense verdict and judgment, which was erroneously affirmed by the Court of Appeals. The Court of Appeals Opinion should be reversed and this case sent back for a new trial with a proper instruction.

Respectfully submitted,



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APPENDIX

1. OPINION OF THE COURT OF APPEALS
2. JUDGMENT OF THE TRIAL COURT
3. INSTRUCTION GIVEN BY THE TRIAL COURT ON INFORMED CONSENT
4. INSTRUCTION TENDERED BY THE APPELLANT ON INFORMED CONSENT
5. CONSENT TO SURGERY FORM SIGNED BY APPELLANT
6. OPINION OF THE COURT OF APPEALS IN SLONE V. CENTRAL BAPTIST HOSPITAL, 2003-CA-001576-CR