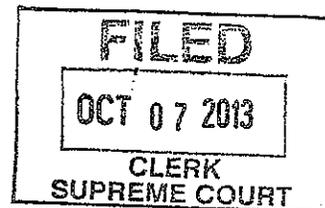


COMMONWEALTH OF KENTUCKY
SUPREME COURT
CASE NO. 2012-SC-000829



COURT OF APPEALS
CASE NOS. 2011-CA-000884 and 2011-CA-000905

WARREN CIRCUIT COURT
CIVIL ACTION NO. 08-CI-02176
HON. STEVE A. WILSON, JUDGE

AMBREEN FRASER, M.D.

APPELLANT

V.

MATTHEW MILLER

APPELLEE

BRIEF ON BEHALF OF APPELLANT, AMBREEN FRASER, M.D.

CERTIFICATE OF SERVICE

This will certify that ten copies of this brief were on this *3rd* day of October, 2013 forwarded by U.S. Mail to: Susan Stokley Clary, Clerk, Kentucky Supreme Court, 700 Capitol Avenue, Room 209, Frankfort, Kentucky 40601-3488; and that a true and correct copy of same was placed in the U.S. Mail on this date to the following: Samuel P. Givens, Jr., Clerk, Kentucky Court of Appeals, 360 Democrat Drive, Frankfort, Kentucky 40601; Hon. Steve A. Wilson, Judge, Warren Circuit Court, Division 1, Warren County Justice Center, 1001 Center Street, Suite 404, Bowling Green, Kentucky 42101; and Brian L. Schuette, 719A Dishman Lane, Bowling Green, Kentucky 42104. This will further certify that the Record on Appeal has been returned to the Clerk prior to the filing of this brief.

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A handwritten signature in black ink, appearing to read "Matthew P. Cook".

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INTRODUCTION

This is a medical malpractice lawsuit in which Matthew Miller asserts that Ambreen Fraser, M.D., negligently treated him by administering him a single dose of a therapeutic pain medication, Ketorolac, and that this drug subsequently caused him to suffer irreversible kidney failure. Dr. Fraser denies that she negligently treated Matthew by giving him one shot of Ketorolac for his pain. The case proceeded to a jury trial in the Warren Circuit Court and the jury found for Dr. Fraser, concluding that her treatment did not cause Matthew's injury. Matthew appealed the defense judgment and Dr. Fraser filed a cross-appeal, challenging the trial court's denial of her motions for summary judgment and directed verdict on the issue of foreseeability. A three-judge panel of the Court of Appeals reversed the defense trial judgment and ordered a new trial in an opinion which was designated for publication (See Exhibit A attached). This Court subsequently granted Dr. Fraser's motion for discretionary review.

STATEMENT CONCERNING ORAL ARGUMENT

Dr. Fraser requests that the Court hear oral arguments in this case. The issues presented in this appeal include one of first impression in the Commonwealth – whether or not a physician must obtain informed consent to administer therapeutic medication (as opposed to the requirement to do so for an invasive surgical procedure). In addition, oral argument would permit the parties to more fully enunciate their positions on the issues presented and allow the Court to question counsel for the parties on matters that need to be further addressed.

STATEMENT OF POINTS AND AUTHORITIES

INTRODUCTIONi

STATEMENT CONCERNING ORAL ARGUMENTii

STATEMENT OF POINTS AND AUTHORITIESiii

STATEMENT OF THE CASE1

 CR 76.121

INTRODUCTION1

FACTUAL BACKGROUND3

ARGUMENT16

PRESERVATION OF ISSUES FOR APPELLATE REVIEW16

NEITHER ISSUE RAIED BY MATTHEW ON APPEAL
 WAS PRESERVED FOR REVIEW17

Regional Jail Authority v. Tackett, 770 S.W.2d 225 (Ky. 1989)17

THE INFORMED CONSENT ISSUE WAS NOT
 PROPERLY PRESERVED17

 CR 5118

Kroger Co. v. Willgruber, 920 S.W.2d 61 (Ky. 1996)18

Bogie v. Royal Crown Bottling Co. of Danville, Inc.,
 343 S.W.2d 809 (Ky. 1961)18

 Kentucky Rule of Evidence 10318

Hart v. Commonwealth, 116 S.W.3d 481 (Ky. 2003)18, 19

Baze v. Commonwealth, 965 S.W.2d 817 (Ky. 1997)19

THE DR. GOLD REBUTTAL ISSUE WAS NOT
 PROPERLY PRESERVED19

THE TRIAL JUDGE RULED CORRECTLY ON BOTH ISSUES RAISED BY MATTHEW ON APPEAL21

THE TRIAL COURT’S RULING ON THE INFORMED CONSENT CLAIM WAS CORRECT21

Keel v. St. Elizabeth Medical Center, 842 S.W.2d 860 (Ky. 1992)Passim

Lewis v. Kenady, 894 S.W.2d 619 (Ky. 1994)21

KRS § 304.40-23021, 22

Snawder v. Cohen, 804 F.Supp. 910 (W.D. Ky. 1992)22, 23

Butts v. Watts, 290 S.W.2d 777 (Ky. 1956)23

Johnson v. Vaughn, 370 S.W.2d 591 (Ky. 1963)23, 24

Jarboe v. Halting, 397 S.W.2d 775 (Ky. 1965)24

Coulter v. Thomas, 33 S.W.3d 522 (Ky. 2000)24

Vitale v. Henchey, 24 S.W.3d 651 (Ky. 2000)24

Harris v. Commonwealth, 313 S.W.3d 40 (Ky. 2010)24, 25

Boyer v. Smith, 497 A.2d 646 (Pa. Super. Ct. 1985)25, 26

Gray v. Grunnagle, 223 A.2d 663 (Pa. 1966)25, 26

Cary v. Arrowsmith, 777 S.W.2d 8 (Tenn. Ct. App. 1989)26

THE TRIAL JUDGE’S RULING ON THE PROPOSED REBUTTAL WITNESS WAS CORRECT27

Commonwealth, Department of Highways v. Ochsner, 392 S.W.2d 446 (Ky. 1965)27

Sea v. Commonwealth of Kentucky, Department of Highways, 418 S.W.2d 766 (Ky. 1967)27

Shell v. Commonwealth, 245 Ky. 535; 53 S.W. 954 (1932)27, 28

CR 43.0228

| | |
|--|--------|
| <i>Goodyear Tire & Rubber Co. v. Thompson</i> , 11 S.W.3d 575 (Ky. 2000) | 28 |
| <i>Miller v. Eldridge</i> , 146 S.W.3d 909 (Ky. 2004) | 28 |
| <u>THE HARMLESS ERROR DOCTRINE APPLIES</u> | 29 |
| <i>CSX Transportation, Inc. v. Begley</i> , 313 S.W.3d 52 (Ky. 2010) | 29 |
| <u>MATTHEW'S IRREVERSIBLE KIDNEY FAILURE WAS NOT FORESEEABLE TO DR. FRASER AT THE TIME OF TREATMENT</u> | 30 |
| <i>Lee v. Farmer's Rural Electric Co-Op Corp.</i> , 245 S.W.3d 209 (Ky. App. 2007) | 32, 33 |
| <i>Mullins v. Commonwealth Life Ins. Co.</i> , 839 S.W.2d 245 (Ky. 1992) | 32 |
| <i>Sheehan v. United Services Auto. Ass'n</i> , 913 S.W.2d 4 (Ky. App. 1996) | 32 |
| David J. Leibson, <i>13 Kentucky Practice: Tort Law</i> , 2 nd Ed, § 10.3 (Thompson-West 2008) | 32 |
| <i>Gordon v. Procter Gamble Distrib. Co.</i> , 789 F.Supp. 1384 (W.D. Ky. 1992) | 33 |
| <i>Halfways, Inc. v. Hammonds</i> , 113 S.W.3d 85 (Ky. 2003) | 33 |
| <i>City of Jackson v. Estate of Stewart ex rel. Womack</i> , 908 So.2d 703 (Miss. 2005) | 33, 34 |
| <i>Mountain v. Procter Gamble Co.</i> , 312 F.Supp. 534 (E.D. Wis. 1970) | 34 |
| <i>Booker v. Revlon Realistic Prof'l Prods., Inc.</i> , 433 So.2d 407 (La. Ct. App. 1983) | 34 |
| <i>Adelman-Tremblay v. Jewel Cos., Inc.</i> , 859 F.2d 517 (7 th Cir. 1998) | 34 |
| <i>Jordan v. Geigy Pharmaceuticals</i> , 848 S.W.2d 176 (Tex. Ct. App. 1992) | 35 |
| <u>CONCLUSION</u> | 35 |
| <u>APPENDIX</u> | — |
| <u>APPENDIX INDEX</u> | — |

- Exhibit A – Kentucky Court of Appeals Panel Opinion, December 7, 2012
- Exhibit B – Consent Form
- Exhibit C – Plaintiff's Expert Disclosures, Rule 26 Discovery Responses and Pre-trial Compliance Filings
- Exhibit D – Plaintiff's Proposed Jury Instructions
- Exhibit E – Warren Circuit Court Trial Order and Judgment, May 13, 2011
- Exhibit F – Plaintiff's Supplemental Expert Disclosure of Dr. Craig Denham
- Exhibit G – Deposition Transcript of Dr. Craig Denham, April 7, 2011
- Exhibit H – Ketorolac Package Insert
- Exhibit I – E-mail from Dr. T.E. Hunley, February 26, 2008

STATEMENT OF THE CASE

Ambreen Fraser, M.D., by counsel, pursuant to CR 76.12(4)(c)(iv), offers the following statement of the case.

INTRODUCTION

This case involves a claim of medical negligence which was tried before a jury in the Warren Circuit Court and resulted in a defense verdict. On the day in question, Matthew Miller saw Dr. Fraser, complaining of abdominal pain and vomiting. After obtaining consent to treat and then examining Matthew, Dr. Fraser gave him one 60 mg dose of Ketorolac, a non-steroidal anti-inflammatory drug, for his pain. Several days later, Matthew was diagnosed with a rare and irreversible form of kidney failure known as renal cortical necrosis and he subsequently required a kidney transplant. Physicians at Vanderbilt University Medical Center who saw Matthew after Dr. Fraser did, also diagnosed him with a severe case of pancreatitis, a condition which can take several days after symptoms first appear to diagnose and which can cause renal cortical necrosis.

Matthew asserts that the single dose of Ketorolac given to him by Dr. Fraser caused his irreversible kidney failure. Dr. Fraser denies this and contends she treated Matthew within the accepted standard of care. After a multiple day trial where several expert witnesses testified for each party, the jury found for Dr. Fraser, concluding that her treatment of Matthew, including the decision to give him one shot of Ketorolac for his pain, did not cause his injury.

A three-judge panel of the Court of Appeals (Judges Michael Caperton (presiding), James Lambert and Shea Nickell) entered an opinion reversing the defense jury verdict and ordering a new trial, concluding that the trial court erred in not instructing the jury on a claim of lack of informed consent – separate and distinct from the general negligence instruction which was given and rejected by the jury – and not allowing Matthew to argue this claim. The panel

construed Kentucky law for the first time to require a physician to obtain specific informed consent before administering therapeutic medication to a patient. If left undisturbed, this groundbreaking decision – which will affect every Kentucky physician who treats patients – was reached despite the fact that Matthew did not preserve the lack of informed consent claim for appellate review.

Specifically, Matthew: (1) failed to raise the lack of informed consent issue during summary judgment briefing prior to trial; (2) did not disclose any expert testimony on the lack of informed consent claim as required by the pre-trial order; (3) his counsel informed the trial court at the final pre-trial conference that lack of informed consent was not a central theme of his case and did not mention the claim at all in his pre-trial compliance filings; (4) put on no expert proof on lack of informed consent by deposition, at trial or by avowal; (5) did not object to Dr. Fraser's motion for directed verdict on the informed consent claim which was granted; (6) failed to tender a proposed jury instruction on lack of informed consent; and (7) did not object to the trial court's jury instructions – which were those tendered by his counsel. The Court of Appeals panel ignored all of these points and reached the merits of the informed consent claim. The panel also ignored the jury's specific finding of no causation by Dr. Fraser under the negligence instruction – which meant that any failure to permit argument or to instruct on lack of informed consent was harmless.

In addition, the Court of Appeals panel failed to rule for Dr. Fraser on Matthew's other claim of error – whether or not it was reversible error for the trial court to deny his request to recall one of his expert witnesses (who had already testified at trial in his case-in-chief) on rebuttal to comment on a juror's question. This issue was not preserved for appellate review with avowal testimony and even ignoring this, the decision to deny the requested rebuttal witness

was not an abuse of discretion by the trial judge and is also subject to the harmless error doctrine given the jury's conclusion that Dr. Fraser did not cause Matthew's injury. Finally, the Court of Appeals panel erred in finding against Dr. Fraser on her cross-appeal on the unforeseeability of Matthew's injury.

FACTUAL BACKGROUND

Matthew presented for treatment at the Urgentcare Clinic in Bowling Green on January 8, 2008, with complaints including abdominal pain. On this date, Matthew was sixteen and a half years old. He vomited twice before arriving at Urgentcare and did so again for a third time while there. Matthew did not appear dehydrated or volume depleted when he presented to Dr. Fraser. He had a normal pulse, blood pressure and pH level of his urine. He also had normal respiration and moist mucous membranes. (See Trial CD 8-1-11-CD-70.4, May 10, 2011 at 09:27:40-09:49:06). Matthew had no previous history of kidney problems. Matthew's mother, Tammy Miller, signed a consent form for his treatment at Urgentcare. This document, which is attached as Exhibit B, states as follows:

CONSENT: I know or have been advised that I (or patient named above) am (is) suffering from a condition warranting medical care and therefore voluntarily consent to such medical care, including routine diagnostic procedures and medical treatment by the physicians of Park Street Partners, dba Urgentcare and Corpcare, their assistants and designees, and other employees of Park Street Partners as is necessary or advisable in their judgment.

Dr. Fraser examined Matthew and ordered the following drugs to be given to him: Ketorolac (the generic form of Toradol, a prescription strength, non-steroidal anti-inflammatory drug); Rocephin (an antibiotic); and Phenergan (anti-nausea medication). At issue in this case is the administration of the single 60 mg dose of the NSAID, Ketorolac. After being given the single dose of Ketorolac, Matthew's pain improved and he was sent home with the instruction to return to Urgentcare the next day (and to go immediately to the emergency room if his symptoms

worsened in the interval). Overnight, Matthew continued to have pain and vomiting episodes. He returned to Urgentcare the next day and was seen by another physician. He subsequently was sent to Greenview Regional Hospital in Bowling Green and after a CT scan was ordered and performed, Matthew was ultimately diagnosed with kidney failure. Specifically, he was diagnosed with a rare and irreversible form of kidney failure known as renal cortical necrosis. Subsequently, he was also noted by physicians at Vanderbilt University Medical Center to have a severe case of pancreatitis. (See Trial CD 8-1-11-CD-70.4, May 10, 2011 at 10:31:12-10:31:30). After undergoing dialysis and other treatment at Vanderbilt, Matthew received a kidney transplant several months later.

This lawsuit was filed on December 1, 2008 on behalf of Matthew. (Record on Appeal (“ROA”) pp. 1-5). After obtaining the age of majority, Matthew was allowed to amend his complaint against Dr. Fraser. (ROA, pp. 217-218). In his amended complaint, Matthew alleged negligent conduct against Dr. Fraser, stating as follows:

13. Dr. Fraser did not advise Mr. Miller, who was a minor at the time of treatment or his parents, of the risks associated with the administration of Ketorolac Tromethamine or otherwise take the steps necessary to obtain informed consent.

14. If Dr. Fraser had advised Mr. Miller and/or his parents of the risks of Ketorolac Tromethamine, he/they would have declined the proposed administration of this drug.

24. Dr. Fraser deviated from the standard of care by ordering the administration of Ketorolac Tromethamine for Mr. Miller while he was in a state of hypovolemia and at risk for become [sic] further hypovolemic and this deviation was the proximate cause of Mr. Miller’s irreversible renal failure and resulting legal damages.

25. Dr. Fraser deviated from the standard of care by failing to address Mr. Miller’s hydration status before administering Ketorolac Tromethamine and this

deviation was the proximate result of Mr. Miller's irreversible renal failure and resulting damages.

(ROA, pp. 220-221). Matthew seeks over twenty million dollars in alleged damages. (ROA, pp. 761-762).

Dr. Fraser denies any wrongdoing or negligent conduct in her treatment of Matthew. (ROA, pp. 11-13 and 224-232). Dr. Fraser denies that Matthew presented to her with clinical dehydration or hypovolemia or that Ketorolac was contraindicated for this patient. She denies that her administration of a single dose of Ketorolac caused Matthew's renal cortical necrosis and the need for him to have a kidney transplant.

Baxter Healthcare Corporation manufactures, packages and sells Ketorolac. The testimony in this case was that during the years 2006-2008, there were 6,791,073 Ketorolac units sold by Baxter and the only claimed allegation of permanent kidney failure following a single dose of the drug was the one made in this case. (Deposition of Andrew Owsiak, M.D., pp. 42-43).

One of Dr. Fraser's expert witnesses is Richard J. Johnson, M.D., F.A.C.P., a professor of medicine at the University of Colorado. Dr. Johnson is a leading expert worldwide in the field of nephrology – the study of kidney disease. He testified that the type of kidney failure experience by Matthew cannot be caused by non-steroidal medication such as Ketorolac. Rather, Dr. Johnson opined that Matthew's pancreatitis caused the irreversible kidney failure. (Deposition of Dr. Johnson, September 23, 2010, pp. 15-19). Specifically, Dr. Johnson stated: "NSAIDs can potentiate acute renal failure which is a – you know, the classic acute renal failure, which is a reversible form of kidney disease ... But this was acute cortical necrosis, where there was infarction of a large region of the kidney. Nonsteroidals do not cause that." (Deposition of Dr. Johnson, September 23, 2010, p. 16). In addition, Dr. Johnson stated: "... I do not think the

NSAIDs are the cause of the cortical necrosis. It's never been reported. Pancreatitis causes cortical necrosis." (Deposition of Dr. Johnson, September 23, 2010, p. 104).

In his expert disclosures (and Rule 26 discovery responses and pre-trial compliance filings), Matthew did not identify any expert witness who proposed to testify in favor of or even about a claim of lack of informed consent. (See ROA, pp. 18-20, 34-36, 51-52, 180-190, 235-243, 376-382 and 656-677; documents attached hereto as Exhibit C).

Dr. Fraser moved for a summary judgment (ROA, pp. 244-323) and argued that she was entitled to prevail based upon the consent form signed by Matthew's mother and the unforeseeability of his kidney condition, irreversible renal cortical necrosis. There was extensive briefing on this motion. Matthew's responses to the summary judgment motion are found in the Record on Appeal at pages 385-464 and 675-758. There is no reference in any of these 162 pages to a claim for lack of informed consent.

Ultimately, Warren Circuit Court Judge Steve Wilson overruled Dr. Fraser's motion for summary judgment on the foreseeability issue at the final pretrial conference on April 19, 2011, concluding that there were jury questions on the issues of breach of duty and causation. (ROA, p. 760). However, at the final pre-trial conference, Matthew's counsel stated that informed consent was not a central theme of his case. (See Warren Circuit Court Hearing Video, 8-1-11-CD-62; April 19, 2011 at 09:18:00-09:19:07).

During the pre-trial conference on April 19, 2011, Matthew's counsel indicated he would subsequently e-mail his proposed jury instructions to the trial judge (even though the pre-trial order made them due at this hearing (ROA, p. 212)). Matthew's counsel also stated that the viability of the informed consent claim, which he stated was not a central theme of his case, would depend on the proof at trial. Matthew's counsel erroneously believed he could argue lack

of informed consent at trial even without expert proof, wrongly contending this is a *res ipsa loquitor* case and that the claim could be dealt with in the jury instructions as needed. At this hearing, Judge Wilson granted Dr. Fraser's motion in limine (ROA, pp. 571-596) to preclude testimony from Matthew or his parents that they would have refused the dose of Ketorolac if they had been advised of all of its "risks." The trial court agreed that this was improperly speculative. This testimony from the parents was added by avowal – but there was never any expert testimony presented (even by avowal) in support of the informed consent claim.

Thereafter, Matthew's counsel did e-mail Judge Wilson his proposed jury instructions (attached hereto as Exhibit D) but he did not then or ever tender a proposed lack of informed consent instruction and accordingly, waived the claim. The case proceeded to a jury trial in the Warren Circuit Court beginning on May 3, 2011. At trial, Matthew expended considerable time trying to prove that he was dehydrated or volume depleted at the time he presented for treatment to Dr. Fraser in an attempt to show that it was inappropriate for her to administer a single dose of Ketorolac to him. In addition, Matthew went to great lengths to discount the defense theory of pancreatitis as the cause of his irreversible renal cortical necrosis.

Matthew's standard of care expert witness was Craig Denham, M.D., a family medicine physician from Maysville, Kentucky. Dr. Denham testified at trial on May 4, 2011. (*See* Trial CD 8-1-11-CD-70.1, May 4, 2011 at 10:23:25-02:14:30). Dr. Denham opined that Dr. Fraser deviated from the standard of care in administering Ketorolac; that Matthew was dehydrated at the time he presented for treatment with Dr. Fraser; and that pancreatitis was not the cause of the irreversible kidney failure. Dr. Denham did not offer any expert testimony on lack of informed consent in a deposition or at trial nor did Matthew present any avowal testimony from this

witness or any other expert witness on this topic. Likewise, his pre-trial expert disclosure was silent on this claim.

Matthew also called his treating nephrologist at Vanderbilt University, Tracy Hunley, M.D. and Kathy Jabs, M.D. (called at trial by deposition). Dr. Hunley testified at trial on May 4, 2011. (See Trial CD 8-1-11-CD-70.1, May 4, 2011 at 02:38:20-05:03:45). Dr. Hunley gave opinion testimony that Ketorolac caused Matthew's renal injury and his subsequent need for a kidney transplant and he attempted to discount the defense pancreatitis causation theory – although he conceded that Matthew had severe pancreatitis and that the medical literature did document cases of pancreatitis causing irreversible renal cortical necrosis, the condition experienced by Matthew. (See Trial CD 8-1-11-CD-70.1, May 4, 2011 at 04:46:30-04:56:55). He also confirmed that an instance of Ketorolac causing renal cortical necrosis had never been described.

Matthew also called Benjamin Gold, M.D. as an expert witness at trial. Dr. Gold is a pediatric gastroenterologist who practices in Atlanta, Georgia. Dr. Gold testified at trial on May 4, 2011. (See Trial CD 8-1-11-CD-70.1, May 4, 2011 at 05:04:45-05:52:19). Dr. Gold gave opinion testimony that Matthew was dehydrated when he presented for treatment to Dr. Fraser; that Ketorolac was contraindicated in his case; and he attempted to discount the defense causation theory that pancreatitis caused Matthew's irreversible kidney injury. Dr. Gold described Matthew's pancreatitis as mild to moderate and stated that it resolved on its own. He clearly articulated his opinion that pancreatitis had nothing to do with Matthew's renal failure.

Dr. Gold came to Bowling Green to testify live at trial on May 4, 2011. Matthew chose to put him on the stand at the end of this day of trial. An agreement was reached by counsel and the trial court where each side would have thirty minutes to question Dr. Gold because he was

called so late in the day (after 5:00 p.m. local time) and apparently could not stay over to testify the next day. Judge Wilson offered to tape the testimony of Dr. Gold outside of the presence of the jury and to show it to them later. Matthew's counsel declined this offer prior to Dr. Gold's testimony and stated his preference for the thirty minute per side approach. (*See* Trial CD 8-1-11-CD-70.1, May 4, 2011 at 05:04:00-05:04:45).

Matthew also played all or selected portions of the video depositions of several other physicians during his case-in-chief. This included the depositions of Dr. Fraser; defense expert Dr. Richard Johnson; Dr. Kevin Kelly, a treating pediatrician; and Dr. Kevin Burner, the radiologist who first detected Matthew's kidney failure.

Matthew announced the close of his case-in-chief on the afternoon of May 6, 2011. (*See* Trial CD 8-1-11-CD-70.3, May 6, 2011 at 02:40:25). At that time, Dr. Fraser filed a written motion for directed verdict (ROA, pp. 772-802). The Warren Circuit Court also heard an oral motion for directed verdict from Dr. Fraser at this time on all claims, including the one for lack of informed consent. (*See* Trial CD 8-1-11-CD-70.3, May 6, 2011 at 02:40:30-02:55:10). Matthew's counsel did not object to the motion on this claim, stating nothing in response. Judge Wilson granted the motion, stating that there needed to be and was not any expert testimony from Matthew to support the informed consent claim. (*See id.*; *see also* Trial CD 8-1-11-CD-70.3, May 6, 2011 at 09:09:10-09:15:20). This ruling was confirmed at the close of all proof when Matthew's counsel again did not object to a directed verdict on the informed consent claim (to the extent it had not been previously dismissed). (*See* Trial CD 8-1-11-CD-70.5, May 11, 2011 at 02:14:30-02:22:40).

In her case-in-chief, Dr. Fraser first called Dr. Robert Kuhn, a doctor of pharmacy at the University of Kentucky. Dr. Kuhn testified out of order by agreement of the parties on May 6,

2011. (See Trial CD 8-1-11-CD-70.3 at 10:03:40-11:56:40). Dr. Kuhn testified that the dosage of Ketorolac given by Dr. Fraser was appropriate and that Ketorolac had no role in Matthew's irreversible kidney failure. He further expressed the opinion that Matthew's kidney failure was not the kind which is caused by the administration of NSAIDs, such as Ketorolac.

Dr. Fraser next called Dr. Marcus Patton, an anesthesiologist, as an expert witness. Dr. Patton testified on May 6, 2011. (See Trial CD 8-1-11-CD-70.3 at 02:55:25-04:09:59). Dr. Patton testified that Dr. Fraser acted within the standard of care in treating Matthew; that Ketorolac was not improperly given in this setting; that the dosage of Ketorolac administered to Matthew was within the acceptable range for his age and weight; and that Matthew was not volume-depleted enough to make the use of this drug a problem as was evidenced by his physical exam and test results. Dr. Patton testified that he had never heard of a case where one shot of Ketorolac had caused irreversible kidney failure in his thirty-five years of practice.

Dr. Fraser testified on her own behalf on May 10, 2011. (See Trial CD 8-1-11-CD-70.4, May 10, 2011 at 09:15:10-12:11:40). During her testimony, Dr. Fraser emphasized that all three physicians who saw Matthew prior to the diagnosis of his kidney failure (herself, Dr. Grace from Urgentcare and hospital radiologist Dr. Burner) had concluded that he was not dehydrated or volume depleted. (See Trial CD 8-1-11-CD-70.4, May 10, 2011 at 10:00:45-10:02:06). Dr. Fraser was allowed, over Matthew's objection, to state that she did not believe that Ketorolac had caused Matthew's permanent kidney failure. In so ruling, the trial court acknowledged that this opinion had been disclosed prior to trial and that there had been no motion in limine from Matthew. Judge Wilson also ruled that Dr. Fraser could be cross-examined on her expertise (or lack thereof), in the field of nephrology. (See Trial CD 8-1-11-CD-70.4, May 10, 2011 at 10:11:05-10:15:05).

The trial court did sustain an objection from Matthew's counsel when Dr. Fraser was asked how soon renal failure could occur due to pancreatitis. Judge Wilson limited Dr. Fraser to testifying about her experience with pancreatitis and how quickly its symptoms occur. To this end, Dr. Fraser testified that it can take several days to diagnose pancreatitis if there is no history as here. (See Trial CD 8-1-11-CD-70.4, May 10, 2011 at 10:19:50-10:30:59). Of course, it was several days after Dr. Fraser saw Matthew (and several physicians later) that the Vanderbilt doctors finally diagnosed him with severe pancreatitis. (See Trial CD 8-1-11-CD-70.4, May 10, 2011 at 10:31:12-10:32:05).

Next, Dr. Fraser called Dr. Medhat Grace, the medical director at the Urgentcare Clinic in Bowling Green. Dr. Grace testified on May 10, 2011. (See Trial CD 8-1-11-CD-70.4, May 10, 2011 at 01:32:40-02:42:02). Dr. Grace testified that Dr. Fraser's treatment of Matthew was within the standard of care. He further testified that Matthew was not at risk for renal failure due to volume depletion. Dr. Grace also described his decision to order additional readings on the blood drawn from Matthew which ultimately led to the detection of the high levels of amylase and lipase that allowed his pancreatitis to be diagnosed.

Dr. Fraser then called Dr. Larry Jo Russell, a family practice physician from Hendersonville, North Carolina, as an expert witness on May 10, 2011.¹ (See Trial CD 8-1-11-CD-70.4, May 10, 2011 at 03:03:30-04:20:40). Prior to his testimony at trial, Judge Wilson heard a proffer and *voir dire* of Dr. Russell's expected testimony on the issue of causation. Therein, Dr. Russell stated pancreatitis caused Matthew's irreversible renal failure. Dr. Russell stated that his opinion was based on his medical education, reading and personal experience, not based upon the testimony of defense expert Dr. Johnson or anything he read in the other defense

¹ Matthew's counsel chose not to depose Dr. Russell prior to trial.

expert depositions. Dr. Russell testified that renal failure is a known complication of pancreatitis and that he treats pancreatitis on a regular basis and that he has seen renal effects from pancreatitis in his patients. Judge Wilson subsequently ruled that Dr. Russell could testify to both standard of care and causation and express the opinions that were disclosed prior to trial and which were never challenged by Matthew in a pre-trial motion in limine. (*See* Trial CD 8-1-11-CD-70.4, May 10, 2011 at 03:04:05-03:13:55).

During his trial testimony before the jury, Dr. Russell expressed the opinion that Dr. Fraser had complied with the standard of care in her treatment of Matthew. He further expressed the opinion that pancreatitis, not the administration of Ketorolac, was the likely cause of his irreversible renal failure. Finally, Dr. Russell testified that Matthew was not at risk for renal failure due to volume depletion at the time of his presentation for treatment to Dr. Fraser and that Ketorolac was not contraindicated for this patient.

The jury was then shown the trial video deposition of Dr. Richard Johnson, the nephrologist from the University of Colorado, previously discussed herein. The playing of this video deposition began on May 10, 2011 (*See* Trial CD 8-1-11-CD-70.4, May 10, 2011 at 04:34:15-04:58:00) and continued on the morning of May 11, 2011 (*See* Trial CD 8-1-11-CD-70.5, May 11, 2011 at 09:09:50-11:14:40). In his deposition, Dr. Johnson testified that the type of kidney failure experienced by Matthew cannot be caused by non-steroidal medication such as Ketorolac. Dr. Johnson gave the opinion that Matthew's pancreatitis caused his irreversible kidney failure. (*See* Deposition of Dr. Johnson, September 23, 2010, pp. 15-16, 103-105).

The final defense witness was Dr. Gary Howerton, an emergency room physician from Bowling Green. Dr. Howerton testified on May 11, 2011. (*See* Trial CD 8-1-11-CD-70.5, May 11, 2011 at 11:28:15-02:02:00). Prior to his trial testimony, Matthew attempted to exclude Dr.

Howerton as a cumulative witness under Kentucky Rule of Evidence 403. Judge Wilson heard argument from counsel on this issue beginning on May 10, 2011 (*See* Trial CD 8-1-11-CD70.4, May 10, 2011 at 04:24:40-04:32:36 and 05:01:35) and again on the morning of May 11, 2011 (*See* Trial CD 8-1-11-CD-70.5, May 11, 2011 at 08:47:20-08:58:20). In response to this motion to exclude, counsel for Dr. Fraser again reminded the Court that Dr. Howerton (and all defense experts) were timely disclosed prior to trial and that Matthew did not file any pre-trial motions in limine. Matthew's counsel acknowledged that the trial court had wide discretion on this issue and stated that under Rule 403: "you're right no matter what you decide here." (*See* Trial CD 8-1-11-CD-70.4, May 10, 2011 at 04:32:00-04:32:05). Ultimately, Dr. Howerton was allowed to testify.

At trial, Dr. Howerton expressed the opinion that Dr. Fraser had exercised the appropriate standard of care in her treatment of Matthew. He further stated his opinion that it was impossible that Matthew was dehydrated at the time of his presentation for treatment to Dr. Fraser at Urgentcare on January 8, 2008.

Dr. Fraser closed her case-in-chief on the afternoon of May 11, 2011. (*See* Trial CD 8-1-11-CD-70.5, May 11, 2011 at 02:02:10). After brief rebuttal testimony from Matthew and his mother, all proof was closed. The trial court declined Matthew's request to recall one of his expert witnesses, Dr. Benjamin Gold, on rebuttal to respond to a juror question from May 5, 2011 on how long pancreatitis has to be present for kidney failure to occur, concluding that he had already testified against the defense pancreatitis causation theory and holding that it was improper to allow him to return to testify again on the same subject. (*See* Trial CD 8-1-11-CD-70.3, May 6, 2011 at 09:15:41-09:20:41). The reader should remember that the trial judge also

granted Matthew's objection to Dr. Fraser answering the question about how soon renal failure could occur due to the onset of pancreatitis (*see* citation on pages 10-11 herein).

Thereafter, Dr. Fraser renewed her motion for directed verdict on the issues of unforeseeability of the injury (to the extent it had not been previously dismissed); on the issue of punitive damages; on the issue of the sufficiency of proof on damages; on the issue of informed consent; and on the issue of foreseeability of the damage expenses claimed by Matthew. (*See* Trial CD 8-1-11-CD-70.5, May 11, 2011 at 02:14:30-02:30:30). Judge Wilson granted the defense motions for directed verdict on the claim for punitive damages and the claim of lack of informed consent. All other motions for directed verdict were denied.

The trial court used the proposed jury instructions tendered by Matthew's counsel. On May 10, 2011 Judge Wilson indicated to counsel that he was going to use the Plaintiff's instructions to which Matthew's counsel responded: "I have no objection to my instructions." (*See* Trial CD 8-1-11-CD-70.4, May 10, 2011 at 12:24:00-12:24:45). Importantly, it should be noted that Matthew did not submit a proposed jury instruction on lack of informed consent nor did he ever specifically object to the trial court's instructions.

The jury returned a verdict for Dr. Fraser on the evening of May 11, 2011, concluding that it did not believe her treatment was a substantial factor in causing Matthew's injury. (ROA, pp. 768-769). On May 13, 2011, Judge Wilson entered a consistent Trial Order and Judgment. (ROA, pp. 803-806) (attached hereto as Exhibit E). Matthew filed a notice of appeal from the Trial Order and Judgment. (ROA, pp. 809-815). Dr. Fraser then filed a notice of cross-appeal from the rulings which denied her motions for directed verdict and summary judgment on the issue of foreseeability. (ROA, pp. 817-819).

On December 7, 2012, a three-judge panel of the Court of Appeals (Judges Michael Caperton (presiding), James Lambert and Shea Nickel) entered an opinion designated for publication which reversed and remanded the defense trial judgment and ordered a new trial. (See Exhibit A attached). The panel concluded that the trial judge somehow committed reversible error in not allowing Matthew to argue his lack of informed consent claim to the jury and for failing to instruct the jury on this claim. On page eight of the opinion it is stated: “[Matthew] Miller was prepared to offer evidence from Dr. Craig Denham of Maysville, Kentucky, that Dr. Fraser deviated from the standard of care by failing to obtain informed consent.” Respectfully, this statement is incorrect as there was never any such disclosure or proffer of evidence (even by avowal) on this claim from Dr. Denham or anyone else. (See Dr. Denham’s expert disclosure and deposition; attached respectively as Exhibits F and G).

The Court of Appeals panel did not rule on Matthew’s second issue raised on appeal, whether or not the trial judge abused his discretion in declining the request to recall Dr. Benjamin Gold for a second round of testimony on rebuttal. In addition, the panel also found for Matthew on Dr. Fraser’s cross-appeal on the foreseeability of the injury.

Dr. Fraser subsequently filed a motion for discretionary review with this Court. The Court granted Dr. Fraser’s motion in this regard on September 18, 2013.

ARGUMENT

PRESERVATION OF ISSUES FOR APPELLATE REVIEW

Dr. Fraser preserved the informed consent issue for appellate review through the following steps: (1) the filing of her answers to Matthew's complaint and amended complaint (ROA, pp. 11-13 and 224-232); (2) the filing of her motion for summary judgment (ROA, pp. 244-323); (3) the filing of her motions for directed verdict (ROA, pp. 772-802 and at Trial CD 8-1-11-CD-70.3, May 6, 2011 at 02:30:00-02:55:10 and Trial CD 8-1-11-CD-70.5, May 11, 2011 at 02:14:30-02:30:30); (4) the Trial Order and Judgment entered by the Warren Circuit Court (ROA, pp. 803-806); (5) her briefs filed with the Kentucky Court of Appeals herein and her arguments on this issue at oral argument before the Court of Appeals panel; and (6) through her motion for discretionary review filed with this Court.

Dr. Fraser preserved the issue of the trial court's ruling on Matthew's request to recall Dr. Benjamin Gold on rebuttal through the following steps: (1) her objection to Matthew's request to recall Dr. Gold on rebuttal and the trial court's ruling precluding the recall of Dr. Gold (Trial CD 8-1-11-CD-70.3, May 6, 2011 at 09:15:41-09:20:41); (2) the Trial Order and Judgment entered by the Warren Circuit Court (ROA, pp. 803-806); (3) the filing of her briefs with the Court of Appeals and her arguments on this issue at oral argument before the Court of Appeals panel; and (4) the filing of her motion for discretionary review with the Court herein.

Dr. Fraser preserved her cross-appeal on the issue of the unforeseeability of Matthew's injury through the following: (1) the filing of her motion for summary judgment (ROA, pp. 244-323); (2) the filing of her motions for directed verdict (ROA, pp. 772-802 and at Trial CD 8-1-11-CD-70.3, May 6, 2011 at 02:40:25-02:55:10 and at Trial CD 8-1-11-CD-70.5, May 11, 2011 at 02:14:30-02:30:30); (3) the filing of her notice of cross-appeal (ROA, pp. 817-819); (4) the

filing of her prehearing statement with the Court of Appeals on May 31, 2011; (5) the filing of her briefs with the Court of Appeals and her arguments on this issue at oral argument before the Court of Appeals panel; and (6) through the filing of her motion for discretionary review with the Court herein.

**NEITHER ISSUE RAISED BY MATTHEW ON APPEAL
WAS PRESERVED FOR REVIEW**

Matthew raised two issues before the Court of Appeals – (1) whether or not the trial court erred on the lack of informed consent claim and (2) whether or not the trial court erred by declining his request to recall a rebuttal witness who had already testified in his case-in-chief. Neither of these issues was properly preserved for appellate review and they were consequently waived. *See Regional Jail Authority v. Tackett*, 770 S.W.2d 225, 228 (Ky. 1989) (appellate court is without authority to review unpreserved issues).

THE INFORMED CONSENT ISSUE WAS NOT PROPERLY PRESERVED

As to the lack of informed consent claim, Matthew did not ever disclose an expert witness to testify on this issue. The statement by the Court of Appeals panel that Plaintiff expert witness, Dr. Craig Denham, was prepared to do so is incorrect and not supported by anything in the record. There was no testimony from any expert witness, including Dr. Denham, in a deposition or at trial (nor was there any avowal testimony) presented on this point. Matthew did not address the lack of informed consent claim in his written summary judgment responses and his counsel went as far as to state at the pre-trial conference that it was not a central theme of his case (and this is confirmed by the failure to mention this claim at all in his pre-trial compliance filings). Matthew did not object to directed verdict being entered on this claim nor did he tender a jury instruction on lack of informed consent or object to the jury instructions given by the trial court.

All of this was pointed out to the Court of Appeals by Dr. Fraser in her briefs and at oral argument and the panel chose to ignore that the issue was not preserved for appellate review. By doing so, the Court of Appeals panel cast aside long-settled Kentucky law that holds that appellate courts lack jurisdiction to review unpreserved issues and opens the flood gates for future appeals of unpreserved claims of error because the opinion is designated for publication.

CR 51(3) states as follows: “No party may assign as error the giving or the failure to give an instruction unless he has fairly and adequately preserved his position by an offered instruction or by motion, or unless he makes objection before the court instructs the jury, stating specifically the matter to which he objects and the ground or grounds of his objection.” By failing to submit a proposed instruction on this issue and by not objecting to the trial court’s instructions, Matthew waived any subsequent review on this issue. *See Kroger Co. v. Willgruber*, 920 S.W.2d 61, 64 (Ky. 1996) (by not raising instruction issue at trial, party was precluded from doing so on appeal); *Bogie v. Royal Crown Bottling Co. of Danville, Inc.*, 343 S.W.2d 809, 810 (Ky. 1961) (appellant who neither offered instruction of his own nor objected to those given by court was precluded from contending that instructions were erroneous).

Likewise, the failure to disclose any expert testimony on lack of informed consent or to offer any testimony on this issue either at trial or by avowal indicates that this issue was waived by Matthew. Appellate courts cannot guess what Dr. Denham or some other expert might have said about lack of informed consent. To preserve an allegation of error regarding the exclusion of this claim, it was incumbent upon Matthew to request the trial court to enter the excluded evidence into the record by avowal or through a proffer of evidence and he failed to do so. Kentucky Rule of Evidence 103(a)(2); *Hart v. Commonwealth*, 116 S.W.3d 481, 484 (Ky. 2003). In *Hart*, this Court noted that “[a]ppellate courts review records; they do not have crystal balls.”

Id. at 484. "Prejudice will not be presumed from a silent record." *Baze v. Commonwealth*, 965 S.W.2d 817, 824 (Ky. 1997). Without the required expert proof, the trial judge was correct to hold that Matthew was not entitled to a lack of informed consent instruction and that his counsel could not argue lack of informed consent to the jury.

THE DR. GOLD REBUTTAL ISSUE WAS NOT PROPERLY PRESERVED

In addition, Matthew failed to preserve the issue of whether or not the trial judge erred in declining his request to recall Dr. Benjamin Gold on rebuttal to answer a juror question about the defense pancreatitis theory. Specifically, the juror question was how long a patient would have to suffer from pancreatitis in order to experience kidney failure. Dr. Gold, the Plaintiff's gastroenterologist expert witness, had previously testified during Matthew's case-in-chief and expressed his opinion that pancreatitis had no causal role in Matthew's development of irreversible kidney failure. Once Judge Wilson declined the request to recall Dr. Gold on rebuttal, it was incumbent on Matthew to preserve this issue by placing what Dr. Gold would have stated on rebuttal into the record by avowal. This did not occur. Because it did not occur, there is no way to know what Dr. Gold would have said and whether or not it was improperly excluded. It can only be presumed that Dr. Gold would have repeated his prior opinion testimony that pancreatitis did not cause Matthew's irreversible kidney failure. Since this testimony had already been given from this witness there was no abuse of discretion in declining the request to recall the witness.

Matthew's argument that he was precluded from putting any avowal testimony in the record from Dr. Gold is simply incorrect. This issue was raised when Matthew's counsel approached the trial court and requested the opportunity to recall Dr. Gold to testify on rebuttal about the juror's question. Matthew's counsel proposed that Dr. Gold be deposed by telephone

during a trial recess and then to have that deposition testimony subsequently read to the jury on rebuttal. All of this was taking place while Dr. Fraser was putting on her case-in-chief at trial. Dr. Fraser's counsel objected to this request and the trial court ruled that Dr. Gold could not be recalled on rebuttal as he had already testified about the pancreatitis causation theory. (See Trial CD 8-1-11-CD 70.3, May 6, 2011 at 09:15:41-09:20:41).

Matthew's counsel never requested the opportunity to put on avowal proof from Dr. Gold on this issue. Likewise, he made no proffer as to what Dr. Gold would have testified to on rebuttal. Matthew's counsel was perfectly free to have Dr. Gold placed under oath before a court reporter and to testify as to what he would have said on rebuttal and then to tender it to the trial court for placement in the record by avowal. Defense counsel did not have to be present or participate for this to occur and the argument by Matthew's counsel that he would have been held in contempt for proceeding in this manner is not credible. Judge Wilson never stated or even implied that Matthew's counsel could not put in sworn testimony for avowal purposes. Alternatively, counsel could have had Dr. Gold author a letter outlining his proposed rebuttal testimony which could have been tendered to the trial court for placement in the record by avowal. For whatever reason, Matthew's counsel chose to do neither of these things and the record is silent on what Dr. Gold would have testified to on rebuttal.

It is plain that the Court of Appeals panel erred in ignoring Matthew's failure to preserve either issue he raised on appeal and the panel should not have reached the merits of either issue and certainly should not have reversed the trial verdict based on this record.

**THE TRIAL JUDGE RULED CORRECTLY ON BOTH ISSUES
RAISED BY MATTHEW ON APPEAL**

**THE TRIAL COURT'S RULING ON THE INFORMED
CONSENT CLAIM WAS CORRECT**

Trial Judge Wilson correctly ruled on both issues raised by Matthew on appeal – namely, the lack of informed consent ruling and the rebuttal ruling. It was correct to dismiss the lack of informed consent claim for failure of expert proof because the topic was outside the jury's experience and understanding – this is not a *res ipsa loquitur* case where the jury could infer a need to obtain an informed consent or negligent conduct for failing to do so. (See Trial CD 8-1-11-CD-70.3, May 6, 2011 at 09:09:10-09:15:20; see also *Keel v. St. Elizabeth Medical Center*, 842 S.W.2d 860, 863 (Ky. 1992) (Leibson, J., concurring) (“the claimant needs an expert to prove failure to exercise reasonable care, i.e., lack of a ‘proper disclosure,’ unless the risk is so substantial a lay jury could conclude from the circumstances presented that reasonable care required disclosure”)). In addition, there is no Kentucky authority requiring a physician to obtain specific informed consent for the administration of therapeutic medication and the panel's holding to the contrary is incorrect (contrasted with the need to do so for an invasive surgical procedure – see *Lewis v. Kenady*, 894 S.W.2d 619 (Ky. 1994)).

The Court of Appeals' reliance on the decision in *Keel* is misplaced. Neither it nor KRS § 304.40-320 impose a duty on a Kentucky physician to obtain informed consent prior to administering therapeutic medication to a patient. This statute states in pertinent part: “In any action brought for treating, examining or operating on a claimant wherein the claimant's informed consent is an element...” (Emphasis added). Matthew's claims sound in negligence and he has not and cannot show that informed consent is an element of his general negligence claim against Dr. Fraser especially without expert testimony to bolster that claim. In addition,

this statute, by its very wording, contemplates and requires expert proof on the issue when it states informed consent is deemed to be 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 ...”. (Emphasis added).

The issue in *Keel* was “whether expert testimony is necessary to support a patient’s claim that a medical procedure was done without his informed consent”. *Id.* at 860 (emphasis added). The procedure at issue was “a CT scan which was to include the injection of a contrast dye material.” *Id.* at 860-861. The plaintiff therein developed thrombophlebitis after an alleged allergic reaction to the contrast dye material used in the CT scan. The plaintiff had not been given any information about the hazards of the procedure; however, the hospital routinely questioned patients undergoing the procedure whether they ever had a reaction to contrast dye materials. *Id.*

The *Keel* Court recognized that “in most cases, expert medical evidence will likely be a necessary element of the plaintiff’s proof in negating informed consent.” *Id.* at 862. The Court made an exception to this rule based upon the specific facts presented in that case and did not require expert proof on lack of informed consent, stating the failure to adequately inform of risks was so apparent that even lay persons would easily recognize it from the evidence presented. It is apparent that the holding in *Keel* is the rare exception to the recognized rule that expert proof is needed by a plaintiff to present a jury issue on a claim of lack of informed consent.

An important Kentucky case which analyzed the holding in *Keel* is United States District Court Judge Charles Simpson’s opinion in *Snawder v. Cohen*, 804 F.Supp. 910 (W.D. Ky. 1992). Therein, the Court granted summary judgment to a physician who had not “warned” a mother

prior to administering a polio vaccine to her child. Judge Simpson applied Kentucky law and discussed the *Keel* decision at length in explaining his ruling for the physician. The Court stated: "the crucial factor in *Keel* was that the hospital routinely questioned patients about their reactions which plainly evidenced its own recognition of the substantial possibility of such reactions. The court concluded that this routine questioning without any accompanying warning of the substantial risk was an inconsistency evident to any layman, and, therefore, expert evidence was unnecessary. Unlike the plaintiff in *Keel*, the plaintiff here has not offered any non-technical evidence showing that Dr. Cohen's silence with respect to risks of the oral polio vaccine was inconsistent with his usual actions in administering polio vaccines." *Id.* at 913. Thus, the Court held the plaintiff's failure to present expert proof that Dr. Cohen breached the standard of care in not obtaining informed consent prior to administering the vaccine was fatal to the claim.

The same holding should follow in the instant matter. There is no proof that Dr. Fraser deviated from her standard actions in administering Ketorolac to Matthew. A lay jury cannot be said to understand complex renal issues and the impact that one shot of a commonly-used pain medication might, if we accept Matthew's causation theory, send a patient into an irreversible kidney failure. This case most assuredly would have to fall within the general rule announced in *Keel* that expert proof is required to make out an actionable lack of informed consent claim.

The instant case is not similar to the facts in *Keel* or other like cases where the exception to the expert proof rule was invoked due to patently obvious breaches of duty by doctors. *See Butts v. Watts*, 290 S.W.2d 777 (Ky. 1956) (dentist, in extracting a tooth, left tooth fragments in the socket which were easily discovered by another dentist); *Johnson v. Vaughn*, 370 S.W.2d 591 (Ky. 1963) (doctor who was treating patient suffering from gunshot wound in the throat, left the hospital while patient was still in danger and then refused to release patient to another doctor,

who was at the hospital, for approximately one hour); and *Jarboe v. Halting*, 397 S.W.2d 775 (Ky. 1965) (doctor misdiagnosed pregnant patient as having a uterine tumor and failed to perform pregnancy test before surgery). Clearly, the instant case does not fit in to this exception to the general rule category and expert testimony was required here on the lack of informed consent claim and failed as a matter of law for lack of it.

In addition, because *Keel* involved a medical procedure, not the administration of therapeutic pain medication as in the instant matter, it cannot be used to support an additional jury instruction for medical negligence for failure to obtain informed consent. In the instant case, the trial court correctly refused to give Matthew a second bite at the apple (in addition to the general negligence instruction which was given) because he failed to put on the required expert proof on informed consent as an element of an alleged breach of duty and this issue was not within the jury's common knowledge.

It is important to note that Matthew wanted another negligence instruction based upon the lack of informed consent theory. He did not ever assert a battery claim. This Court has held that the informed consent statute does not apply when a procedure is performed without the patient's consent; rather, the claim that should be brought is one for battery. *See Coulter v. Thomas*, 33 S.W.3d 522, 525 (Ky. 2000) (citing *Vitale v. Henchey*, 24 S.W.3d 651 (Ky. 2000)). An action brought on lack of informed consent grounds brings negligence principles into play, which requires expert testimony. However, an action for battery involves a question of fact, i.e., did the patient consent to the procedure? Expert testimony is therefore not required when pursuing a battery claim. Here the claim attempting to be asserted was for lack of informed consent; there was no battery claim. Thus, Judge Wilson did not abuse his discretion in not giving a separate informed consent negligence instruction based on lack of expert proof. *See Harris v.*

Commonwealth, 313 S.W.3d 40, 50 (Ky. 2010) (decision not to give an instruction is reviewed for abuse of discretion).

Imagine the consequences to Kentucky physicians and patients if there was an informed consent requirement before any therapeutic medication could be given. Would a doctor have to show every patient the package insert for all therapeutic medications (including Advil, Ibuprofen and other NSAIDs) before dispensing it? How much longer would routine doctor appointments be if this was the law in Kentucky? These questions are not raised to make light of Matthew's condition; both Dr. Fraser and the undersigned counsel have great hope for Matthew's continued good health. Rather, these issues are pointed out to call the Court's attention to the implications raised by the Court of Appeals panel's decision for both patients and physicians in Kentucky.

The Court of Appeals panel did not address the enormous practical challenges its published opinion, if left in place, will create for Kentucky physicians and their patients. The Court of Appeals panel should not be the final voice on this issue of first impression in Kentucky. This Court should decide what Kentucky's position on informed consent is and whether or not the trial judge erred in refusing to instruct on this claim or permit argument on it to the jury given the specific record he had before him.

Decisions from other jurisdictions are instructive on the difference between giving therapeutic medication and performing medical procedures and the need to obtain informed consent in the latter and not in the former. In *Boyer v. Smith*, 497 A.2d 646 (Pa. Super. Ct. 1985), it was held as follows:

We are of the opinion that the doctrine of informed consent should continue to be limited in its applicability to only those cases involving surgical or operative medical procedures. In *Gray, supra [v. Grunnagle*, 223 A.2d 663 (1966)], our supreme court expressly grounded its adoption of the informed consent doctrine upon the legal theory that the performance of a medical procedure with a patient's informed consent constitutes a technical assault or battery. To now

expand the doctrine's current applicability to cases involving the administration of therapeutic drugs would be to radically depart from, and indeed obliterate, the foundation upon which the *Gray* decision stands.

Id. at 659 (emphasis added).

Other cases are in accord. Specifically, in *Cary v. Arrowsmith*, 777 S.W.2d 8 (Tenn. Ct. App. 1989), the plaintiff sued the defendant physician for medical negligence regarding his prescription for a specific kind of eye drop medication over a fourth month period which the plaintiff claimed caused a detached retina. *Id.* at 13. The plaintiff's theory was that the administration of the eye drops, which included a risk of detached retina, without the patient's informed consent, constituted battery. The Court held that the legal remedy for allegations regarding improper therapeutic drug treatment was a medical malpractice action focusing on the propriety of the decision to administer the medication (a general negligence claim), not an action for battery or a separate negligence action based on the failure to obtain informed consent to a specific component part of that treatment. *Id.* at 21.

Dr. Fraser and Urgentcare obtained the consent of Matthew's mother to treat him (*see* Exhibit B attached). This consent included the right to treat Matthew with therapeutic medication based upon the physician's best medical judgment. Kentucky law does not require a physician to obtain separate consent for each component of treatment. Dr. Fraser's treatment of Matthew was not a surgical procedure which would have required additional informed consent to be obtained. In the absence of any such authority, there can be no claim against Dr. Fraser for failure to obtain informed consent to administer Ketorolac to him. To the extent that Matthew attempted to premise liability on such a theory, the trial court was correct to dismiss the claim. There was no expert proof on this purported claim and the trial judge was correct to refuse to allow Matthew to

argue this issue to the jury.² There was no requirement to instruct the jury separately on this issue because of the decision to give the instruction on the medical negligence claim.

**THE TRIAL JUDGE'S RULING ON THE PROPOSED
REBUTTAL WITNESS WAS CORRECT**

Matthew and his counsel knew prior to trial that Dr. Fraser was going to argue that pancreatitis was a possible cause of his irreversible kidney failure. Specifically, this was the opinion of Dr. Richard Johnson, Dr. Fraser's nephrology expert, which was stated in his pre-trial depositions. Dr. Johnson did not testify in person at trial; rather, his deposition testimony was played for the jury. Thus, there was no surprise testimony for the Plaintiff to rebut. Given this knowledge, Matthew had Dr. Gold and his other witnesses ready to testify about the pancreatitis theory during their in-chief testimony and they did so repeatedly. To the extent that he wanted Dr. Gold to do so again in rebuttal was improper and the trial court correctly excluded this. This is especially true since Judge Wilson also precluded Dr. Fraser herself from answering the same question during her trial testimony (*see* citation at pages 10-11 herein). The trial judge's rulings were fair to both parties on this issue.

It has been held in Kentucky that evidence which ought to have been offered in-chief is inadmissible when offered as rebuttal testimony. *See Commonwealth, Department of Highways v. Ochsner*, 392 S.W.2d 446, 448 (Ky. 1965); *Sea v. Commonwealth of Kentucky, Department of Highways*, 418 S.W.2d 766, 768 (Ky. 1967). The purpose of rebuttal evidence is not simply to reiterate or give cumulative evidence to that presented in the case-in-chief. *See Shell v.*

² Even if the Court were to hold that Kentucky physicians must obtain informed consent prior to dispensing or administering therapeutic medication, such a holding would not mandate a new trial here or the reversal of the defense verdict since expert proof would still be required to reach a jury on this claim and the failure of Matthew to identify or present any such expert proof (even by avowal). Thus, the defense judgment should be left undisturbed no matter how the Court rules on the scope of informed consent.

Commonwealth, 245 Ky. 535, 53 S.W. 954, 956 (1932). The trial judge always has discretion to allow or deny evidence in rebuttal which should have been offered in-chief under CR 43.02(d). Here, Matthew cannot show that Judge Wilson abused his discretion by declining the request to allow Dr. Gold to testify in rebuttal after he had addressed the pancreatitis defense theory in his prior testimony.

This Court has held that “abuse of discretion is the proper standard of review of a trial court’s evidentiary rulings.” *Goodyear Tire & Rubber Co. v. Thompson*, 11 S.W.3d 575, 577 (Ky. 2000). “The test for abuse of discretion is whether the trial judge’s decision was arbitrary, unreasonable, unfair, or unsupported by sound legal principles.” *Id.* at 581. The Court has also recognized the deferential role of appellate courts in applying this standard of review stating: “appellate courts must recognize the unfortunate but necessary corollaries of deference to the trial court: that it is possible for a trial court to rule contrary to what an appellate court would do without abusing its discretion or being clearly erroneous and that an appellate court is powerless to disturb such rulings.” *Miller v. Eldridge*, 146 S.W.3d 909, 917 (Ky. 2004).

Applying this standard to the instant matter reveals that Judge Wilson acted well within his discretion in determining that Dr. Gold could not testify again concerning his opinions on the defense pancreatitis causation theory. Indeed, Matthew’s counsel himself recognized the great deference given to the trial judge in deciding evidentiary matters at trial as noted on page 13 herein when he stated to Judge Wilson on his motion to exclude one of the defense experts as cumulative that: “you’re right no matter what you decide here.” (*See* Trial CD 8-1-11-CD-70.4, May 10, 2011 at 04:32:00-04:32:05). Counsel understood that the trial judge’s ruling would be upheld under the abuse of discretion standard. That same standard of review applies on the Dr. Gold rebuttal issue and there was no abuse of discretion in refusing to permit Dr. Gold to return

to the stand on rebuttal after he had previously opined on the pancreatitis causation theory in Matthew's case-in-chief.

THE HARMLESS ERROR DOCTRINE APPLIES

Even if there was an error made on the issues raised by Matthew which are addressed above, which is not conceded, the harmless error doctrine applies and the jury verdict should be left undisturbed. The jury made a specific finding that Dr. Fraser did not cause Matthew's injury which should be respected and upheld. (See ROA, p. 805).

In applying the harmless error doctrine to a jury instruction issue, this Court has stated that "the court determines whether the result probably would have been the same absent the error or whether the error was so prejudicial as to merit a new trial." See *CSX Transportation, Inc. v. Begley*, 313 S.W.3d 52, 69 (Ky. 2010). Given the jury's specific finding of no causation against Dr. Fraser under the general negligence instruction, it is probable to conclude that the same jury would have likewise found for her under a separate lack of informed consent instruction by finding no causation against her. Thus, the Court should conclude, just as it did in *Begley*, "that the error in refusing the instruction was not so prejudicial as to warrant a new trial."³ *Id.*

The same harmless error conclusion should be made on the rebuttal issue involving Dr. Gold. The jury found for Dr. Fraser and found no causation against her even after hearing Dr. Gold's testimony for Matthew in his case-in-chief. This included his opinion that pancreatitis did not contribute in any way to Matthew developing irreversible kidney failure. It is likewise

³ The reader will recall that Matthew and his counsel did not even tender a proposed jury instruction on lack of informed consent nor was there any expert proof (even by avowal) on lack of informed consent. This bolsters the contention that the harmless error doctrine should apply.

probable that the jury would have reached the same decision if Dr. Gold had been allowed to return to the stand on rebuttal and offer similar testimony to the juror question about pancreatitis.⁴

**MATTHEW'S IRREVERSIBLE KIDNEY FAILURE WAS NOT FORESEEABLE
TO DR. FRASER AT THE TIME OF TREATMENT**

Matthew has not and cannot point the Court to any other case in the history of recorded medicine where an otherwise healthy person, as he was on January 8, 2008, received a single shot of a pain medication, Ketorolac, and thereby was caused to experience irreversible renal cortical necrosis. He does not dispute the accuracy of the figures supplied by Baxter Healthcare on the number of units of Ketorolac sold in the years surrounding his single dose of this medication (nearly seven million units) nor does he question that the company has not received an accusation in any case but his of this therapeutic medication allegedly causing irreversible kidney failure.

Instead, Matthew has simply responded that the Food and Drug Administration's adverse event reporting system is voluntary and that no one is required to provide that agency with any information of an adverse drug reaction. Dr. Fraser reminds the Court that zero complaints/reports concerning Ketorolac and this specific type of injury is still significant. Why? It is meaningful because there are no reports that would alert a medical practitioner, like Dr. Fraser, that a single injection of this commonly-used pain medication could lead to the type of irreversible renal injury that is at issue in this case – i.e., even if Matthew's theory of the case is correct, (which is not conceded), it was not foreseeable to Dr. Fraser at the time of treatment.

Moreover, the Ketorolac package insert that was available to Dr. Fraser at the time of her treatment of Matthew (attached hereto as Exhibit H; ROA, pp. 783-794) was also silent on any possibility of the medication causing an irreversible kidney failure in the patient. In the

⁴ Since there was no avowal submission on what Dr. Gold would have said on rebuttal, it makes great sense to apply the harmless error doctrine and to reinstate the jury verdict in favor of Dr. Fraser.

“INDICATIONS AND USAGE” section of the package insert (page 6 of 12), the following language is found: “The safety and effectiveness of single doses of Ketorolac Tromethamine Injection have been established in pediatric patients between the ages of 2 and 16 years.” Matthew was sixteen and a half years old when he was seen by Dr. Fraser and even his standard of care witness, Dr. Denham, agreed that medically Matthew was in his seventeenth year at the time at issue in this case (which means he was not subject to pediatric dosage requirements). (See Trial CD 8-1-11-CD-70.1, May 4, 2011 at 01:59:12-02:01:50). In addition, in the “OVERDOSAGE” section of the package insert (page 11 of 12), it is stated: “Single overdoses of ketorolac tromethamine have been variously associated with abdominal pain, nausea, vomiting, hyperventilation, peptic ulcers and/or erosive gastritis and renal dysfunction which have resolved after discontinuation of dosing.” (Emphasis added).

Thus, Dr. Fraser and other practitioners are told in the package insert by the manufacturer that the drug in single doses is effective even for pediatric patients and that if a single administration causes complications to the patient, including renal dysfunction, any such complication would resolve after discontinuation of dosage (i.e., it would be reversible). There is no language from the manufacturer in the package insert that a single dose of this medication could lead to irreversible kidney failure.

Indeed, even Matthew’s treating nephrologist, Dr. Tracy Hunley of Vanderbilt, who saw him after he treated with Dr. Fraser, testified that he initially expected Matthew’s kidney function would get better and return to normal. (Deposition of Dr. Hunley, p. 83). In addition, Dr. Hunley wrote an e-mail to Matthew’s school describing his kidney injury as “unforeseen”. (See Exhibit I attached). These statements by one of Matthew’s own experts corroborate the unforeseeability of the injury at the time of Dr. Fraser’s treatment of the patient.

Finally, the Court is again referred to the testimony of Dr. Fraser's nephrology expert, Dr. Richard Johnson⁵, who testified by deposition that Toradol/Ketorolac has never before been reported to cause irreversible renal cortical necrosis. (Deposition of Dr. Johnson, September 23, 2010, pp. 15-19, 104). Dr. Johnson testified that the type of irreversible kidney failure experienced by Matthew cannot be caused by non-steroidal medication such as Ketorolac. Rather, Dr. Johnson opined that Matthew's irreversible renal failure was caused by his pancreatitis. None of the expert witnesses retained by Matthew can point the Court to any other case of irreversible renal cortical necrosis caused by the administration of a single dose of Ketorolac in an otherwise healthy individual. Thus, Matthew was not successful in his attempt to establish any proof of foreseeability based upon his receipt of a single dose of Ketorolac and as such, the trial judge erred in allowing the breach of duty and causation issues to go to the jury.

The Court must decide whether Matthew's injury and his causation theory were foreseeable to Dr. Fraser at the time of treatment. If they were not foreseeable, then there was no duty to prevent his irreversible kidney failure and his negligence claim fails as a matter of law. "Under Kentucky law, it is clear that the existence of the duty of care to plaintiff and its underlying foreseeability inquiry, is a pure question of law for the court." *Lee v. Farmer's Rural Electric Co-Op Corp.*, 245 S.W.3d 209, 218 (Ky. App. 2007) (citing *Mullins v. Commonwealth Life Ins. Co.*, 839 S.W.2d 245, 248 (Ky. 1992); *Sheehan v. United Services Auto. Ass'n*, 913 S.W.2d 4, 6 (Ky. App. 1996)). "No party is required to guard against what a reasonably prudent person would not anticipate." David J. Leibson, *13 Kentucky Practice: Tort Law*, 2nd Ed., § 10.3 (Thompson-West 2008). "[F]oreseeability is to be determined by viewing the facts as they

⁵ Dr. Johnson is the editor of the top-selling clinic nephrology textbook in the world and is one of the top three clinical nephrologists cited in the medical literature. (Deposition of Dr. Johnson, September 23, 2010, pp. 8-10).

reasonably appear to the party charged with negligence, not as they appear based on hindsight.”
Lee, 245 S.W.3d at 212 (internal citation omitted).

In addition, Matthew’s alleged one-of-a-kind reaction to Ketorolac cannot be deemed foreseeable by Dr. Fraser. *See Gordon v. Proctor Gamble Distrib. Co.*, 789 F.Supp. 1384, 1385 (W.D. Ky. 1992) (“The unusual susceptibility of the [plaintiff] is generally recognized as a complete defense where the [defendant] did not know and had no reason to know that a very few users of his product might be injured”) (citation omitted); and *Halfways, Inc. v. Hammonds*, 113 S.W.3d 85, 90-91 (Ky. 2003) (defendant’s duty to know “pertinent matters” in terms of foreseeable risk is limited to characteristics and capacities of things commonly known at the time and in the community and even if deemed foreseeable, the risk must be unreasonable for liability to attach).

There has been some discussion in this case, particularly at the March 16, 2011 hearing on Dr. Fraser’s motion for summary judgment, that Matthew was an eggshell plaintiff which would remove the case from the traditional foreseeability analysis. Dr. Fraser submits that even if Matthew is thusly characterized, the threshold determination of foreseeability still applies. The following cases are cited in support of that position.

In *City of Jackson v. Estate of Stewart ex rel. Womack*, 908 So.2d 703 (Miss. 2005), the Supreme Court of Mississippi held as a matter of law that the plaintiff, an elderly woman who slipped and fell while exiting a city-owned bus and suffered a massive stroke, had experienced an injury that was unforeseeable to the defendant municipality. In so ruling, the Court held as follows:

...the Estate also urges us to find that Mrs. Stewart was an “eggshell plaintiff.”
The “eggshell plaintiff” theory does not obviate the necessity to show foreseeability. It simply provides that plaintiffs who are far more susceptible to particular harm than the average person may nonetheless recover their full

damages without reduction. In other words, you take the plaintiff as find him or her. Applying the 'eggshell plaintiff' theory to this case, if stroke were a foreseeable consequence of the City's negligence then the City would be liable for all damages related to the stroke, even if Mrs. Stewart was far more susceptible to a stroke than the average person. But we do not reach the 'eggshell plaintiff' analysis without first satisfying the question of foreseeability.

Because the unchallenged expert testimony at trial established that stroke is not a foreseeable consequence of the alleged negligence which led to Mrs. Stewart's fall, we held that the Estate may not recover damages related to the stroke, whether or not it was caused by the fall on August 11, 1997.

Id. at 715 (underlined emphasis added). *See also Mountain v. Procter Gamble Co.*, 312 F.Supp. 534 (E.D. Wis. 1970) (plaintiff could not recover where allergic reaction was 1 of only 3 reported instances out of 225,000 products sold); *Booker v. Revlon Realistic Prof'l Prods., Inc.*, 433 So.2d 407 (La. Ct. App. 1983) (plaintiff could not recover where allergic reaction was 1 of only 4 reported complaints out of 7 million products sold); and *Adelman-Tremblay v. Jewel Cos., Inc.*, 859 F.2d 517 (7th Cir. 1998) (plaintiff could not recover for allergic reaction which was the only reported complaint out of 1 million products sold).

Thus, even if Matthew is considered an eggshell plaintiff and even if his one-of-a-kind causation theory is accepted, he must still establish that his ultimate injury was foreseeable to Dr. Fraser at the time of treatment. He cannot do so. Being the only person to experience irreversible kidney failure after receiving one shot of Ketorolac (out of nearly seven million units given in the time at issue) is the very definition of unforeseeability.

Dr. Fraser and other medical practitioners were not warned of even the remote possibility of this type of irreversible kidney failure being caused by a single dose of this medication: (1) in the medical literature; (2) from reports of the drug's prior adverse events; or (3) by the warnings given by the manufacturer in the package insert. Even when viewing all facts in the like most favorable to Matthew, his injury was unforeseeable to Dr. Fraser at the time of treatment. The

Court should conclude, just as was done in a similar NSAID case, *Jordan v. Geigy Pharmaceuticals*, 848 S.W.2d 176 (Tex. Ct. App. 1992), that the ultimate injury to the patient was unforeseeable to the physician and that there was no actionable negligence claim as a matter of law.

Based on all of these facts, the trial court erred in overruling Dr. Fraser's motions for summary judgment and directed verdict on the issue of foreseeability and by allowing the negligence claim to proceed to a jury disposition.

CONCLUSION

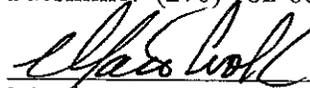
Respectfully, the Court of Appeals panel overstepped its bounds by reversing the jury verdict and ordering a new trial. The panel ignored Matthew's failure to preserve either of the issues he raised for appellate review. Moreover, the trial judge ruled correctly on both issues -- it must be remembered that Matthew failed to disclose any expert witness who would testify in support of his purported lack of informed consent claim (even by avowal) and that Dr. Gold did testify for Matthew in his case-in-chief on the issue of the pancreatitis causation theory. Finally, both issues are subject to the harmless error doctrine and a new trial is not warranted on either claim because of the jury's specific finding that Dr. Fraser did not cause Matthew's injury.

It is terribly unfortunate that Matthew developed a rare type of kidney failure and required a transplant. However, the fact that this occurred does not mean Dr. Fraser was negligent. The jury carefully considered the facts and the applicable law and reached a fair and impartial verdict in favor of Dr. Fraser. The Court of Appeals panel improperly wiped that verdict away. This Court is urged to reverse that decision and to reinstate the jury's verdict. In the alternative, the Court is asked to reverse the Court of Appeals panel and remand to the trial

court with instructions to enter a directed verdict for Dr. Fraser based on unforeseeability. The entry of a consistent opinion is respectfully prayed.

Respectfully submitted,

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APPENDIX

APPENDIX INDEX

Exhibit A – Kentucky Court of Appeals Panel Opinion, December 7, 2012

Exhibit B – Consent Form

Exhibit C – Plaintiff's Expert Disclosures, Rule 26 Discovery Responses and Pre-trial Compliance Filings

Exhibit D – Plaintiff's Proposed Jury Instructions

Exhibit E – Warren Circuit Court Trial Order and Judgment, May 13, 2011

Exhibit F – Plaintiff's Supplemental Expert Disclosure of Dr. Craig Denham

Exhibit G – Deposition Transcript of Dr. Craig Denham, April 7, 2011

Exhibit H – Ketorolac Package Insert

Exhibit I – E-mail from Dr. T.E. Hunley, February 26, 2008