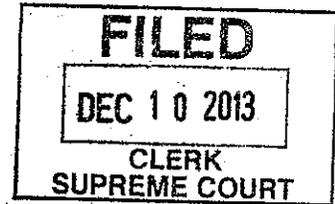


COMMONWEALTH OF KENTUCKY  
SUPREME COURT  
CASE NO. 2012-SC-000829



COURT OF APPEALS  
CASE NOS. 2011-CA-00084 AND 2011-CA-000905

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

AMBREEN FRASER, M.D.

APPELLANT

V.

MATTHEW MILLER

APPELLEE

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**BRIEF ON BEHALF OF APPELLEE, MATTHEW MILLER**

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**CERTIFICATE OF SERVICE**

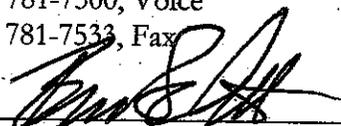
This will certify that ten copies of this brief on behalf of Appellee, Matthew Miller, were on this the 6<sup>th</sup> day of December, 2013, placed in the U. S. Mail postage prepaid registered mail to: Susan Stokley Clary, Clerk, Kentucky Supreme Court, 700 Capitol Avenue, Room 209, Frankfort, KY 40601-3488 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, KY 40601; Hon. Steve A. Wilson, Judge, Warren Circuit Court, Division I, Warren County Justice Center, 1001 Center Street, Suite 404, Bowling Green, KY 42101; and Matthew P. Cook, John David Cole, Frank Hampton Moore, Jr., Cole & Moore, P.S.C., 921 College Street-Phoenix Place, P. O. Box 10204, Bowling Green, KY 42102-7240.

This is to further certify that the Record on Appeal was not withdrawn from the Clerk's office by the Appellee herein.

Respectfully submitted this the 6<sup>th</sup> day of December, 2013.

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BRIAN SCHUETTE

## INTRODUCTION

Appellee Matthew Miller's medical negligence case is before this Court on discretionary review of a unanimous, designated-to-be-published opinion of the Court of Appeals reversing a verdict in favor of Appellant Dr. Ambreen Fraser and remanding the matter for a new trial.<sup>1</sup>

The Court of Appeals held that the Trial Court committed reversible error in ruling that Matthew was not entitled to present a claim for informed consent. Additionally, the Court of Appeals held that the Trial Court erred in refusing to allow Matthew to recall his causation expert to respond to a question posed by of the jurors; however, the lower court declined to address whether this constituted an abuse of discretion.

At trial, Matthew sought to prove that he developed irreversible kidney failure from the improper administration of a double-dose of a powerful non-steroidal anti-inflammatory medication ordered by Dr. Fraser. He was diagnosed with complete kidney failure within hours of receiving the medication. As a result, Matthew was required to undergo fifteen months of dialysis followed by a deceased-donor kidney transplant. At the time of trial, he had incurred more than one-and-a-half million dollars in medical expenses and faced an estimated five million dollars in future medical care. Further, Matthew's life expectancy has been reduced by 20 years and his work-life expectancy has been reduced by a similar amount.

Dr. Fraser's arguments for reversal of the Court of Appeals may be summarized as follows:

- 1) Preservation of issues for appellate review:
  - a. Dr. Fraser contends that the Court of Appeals erred in holding that Matthew preserved the informed consent issue;
  - b. Dr. Fraser contends that the Court of Appeals erred in holding that Matthew preserved the issue relating to his efforts to recall Dr. Benjamin Gold, his causation expert, to address a question raised by a juror;

---

<sup>1</sup> *Miller v. Fraser*, 2012 Ky. App. Unpub. LEXIS 1050. Copy attached at Tab 1.

- 2) Dr. Fraser contends that the Court of Appeals erred in holding that Matthew was entitled (through his parents) to render informed consent to the administration of a double-dose of a drug known to cause kidney damage;
- 3) Dr. Fraser contends that that the Court of Appeals erred in holding that Matthew was entitled to present additional testimony by Dr. Benjamin Gold to address a question raised by a juror;
- 4) Dr. Fraser contends that the Court of Appeals erred in rejecting her argument that the Trial Court's refusal to allow Matthew the opportunity to present additional testimony by Dr. Benjamin Gold was "harmless"; and
- 5) Dr. Fraser contends that the Court of Appeals erred in rejecting her argument that Matthew's kidney failure was not a "foreseeable" result of the administration of a double-dose of a drug known to cause kidney damage.

For the reasons that follow, the decision of the Court of Appeals should be affirmed in all respects and this matter should be remanded for a new trial.

**STATEMENT CONCERNING ORAL ARGUMENT**

The Appellant believes that Oral Argument would aid the Court in deciding the issues on appeal and requests same.

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## COUNTERSTATEMENT OF THE CASE

On January 8, 2008, Matthew Miller ("Matthew") sought treatment for symptoms of nausea, vomiting and a headache at Urgent Care of Bowling Green, where Dr. Ambreen Fraser works as a physician.<sup>2</sup> Dr. Fraser diagnosed him with gastritis and chose to treat him with an antibiotic, an anti-nausea medication and twice the recommended dose of an injected non-steroidal anti-inflammatory drug (NSAID) known as Toradol (brand name) or Ketorolac Tromethamine (generic version) (hereinafter "Toradol" or "Ketorolac"). Ketorolac is available only by prescription and carries with it strong warnings about potentially serious side effects, including kidney damage<sup>3</sup>.

Within 24 hours of receiving the double-dose of Ketorolac at Dr. Fraser's direction, Matthew developed kidney failure<sup>4</sup> that turned out to be permanent:

Greenview Regional Hospital 1801 Ashley Circle Bowling Green, KY 42102	Name: MILLER, MATTHEW JOEL Attending Dr: Kelly, Kevin M. DOB: 06/23/1991 Age: 16 Sex: M Acct: AAD803955244 Loc: RA.411 A Exam Date: 01/09/2008 Status: ADM IN Radiology No: 00207858 Unit No: AAD0208622
Phone #: (270) 793-2150 Fax #: (270) 793-2155	

Exams: 000398956 CT ABDOMEN W/NO CONTRAST,  
000398957 CT PELVIS W/NO CONTRAST

CT OF THE ABDOMEN AND PELVIS WITH AND WITHOUT CONTRAST:

CLINICAL DATA: Abdominal pain, nausea, vomiting.

FINDINGS: Axial CT images through the abdomen and pelvis were obtained both prior to and following IV contrast administration.

The imaged lung bases show no mass or consolidation. The liver, spleen, pancreas, gallbladder, and adrenal glands show no acute or focal findings. The kidneys show no cortical enhancement or excretions at ten minutes post injection. This suggests acute renal failure. These findings were immediately discussed with the patient's referring physician, Dr. Grace. There is moderate abdominal and pelvic ascites. There is no adenyopathy. There is mild fecal retention. The vermiform appendix is normal in appearance.

IMPRESSION - ABDOMEN:

1. APPARENT ACUTE RENAL FAILURE WITH MODERATE ASCITES.

IMPRESSION - PELVIS:

1. NO BLADDER FILLING WITH CONTRAST OR SIGN OF URINARY FUNCTION.  
THERE IS ASCITES.

\*\* Electronically Signed by Kevin Burner on 01/09/2008 at 1726 \*\*  
Reported by: DR. KEVIN BURNER  
Signed by: Burner, Kevin

(emphasis added)

<sup>2</sup> A detailed description of Matthew's medical treatment may be found in the Record on Appeal ("ROA"), Plaintiff's Trial Exhibit 2.

<sup>3</sup> A more detailed description of the warnings relating to Ketorolac, including the risk of kidney damage, is attached at Tab 2.

<sup>4</sup> Copy attached at Tab 3.

As a result, he was required to undergo fifteen months of dialysis and a deceased donor kidney transplant. His medical expenses as of the time of trial exceeded one-and-a-half million dollars and he faced future medical care estimated to exceed five million dollars<sup>5</sup>. In addition, his life expectancy is reduced by twenty years with a similar reduction in his work life.

According to Matthew's treating pediatric kidney specialists at Vanderbilt Children's Hospital<sup>6</sup>, his irreversible kidney failure is the result of receiving an excessive dose of Ketorolac while dehydrated from multiple episodes of vomiting.<sup>7</sup> After Matthew's kidney failure was discovered, it was determined that he also had a case of pancreatitis (a recognized complication of the administration of Ketorolac)<sup>8</sup>, which Dr. Fraser strenuously argued was the true cause of his kidney failure.

In anticipation of this argument, Matthew presented at trial the testimony of Dr. Benjamin Gold, a Pediatric Gastroenterologist practicing in Atlanta. Dr. Gold treats children with various digestive issues, including pancreatitis, that are often complicated by kidney problems. Dr. Gold explained to the jury that pancreatitis is rarely associated with irreversible kidney failure and does not cause it, except under circumstances where the pancreatitis is so severe that it causes damage to the organ itself. With regard to Matthew's pancreatitis, Dr. Gold measured its severity utilizing several

<sup>5</sup> Matthew's damages are outlined in the Plaintiff's Trial Exhibit 3 (Summary of Medical Expenses) (Copy attached at Tab 4) and Plaintiff's Trial Exhibit 17 (Future Medical Expenses/Life Care Plan) (Copy attached at Tab 5).

<sup>6</sup> The *Curriculum Vita* of Matthew's treating Pediatric Nephrologists, Dr. T.E. Hunley and Dr. Kathy Jabs, may be found in the ROA as Plaintiff's Trial Exhibit 7 and the ROA as Defendant's Trial Exhibit 6, respectively. Dr. Gold's *Curriculum Vitae* may be found in the ROA as Plaintiff's Trial Exhibit 8.

<sup>7</sup> A discussion of the medical evidence of Matthew's state of dehydration at the time he presented to Urgent Care is attached at Tab 6).

<sup>8</sup> The drug labeling for Ketorolac (ROA, Plaintiff's Trial Exhibit 14) includes the following information for prescribers:

**The Following Adverse Events Were Reported From Postmarketing Experience:**

<b>Body as a Whole:</b>	hypersensitivity reactions such as anaphylaxis, anaphylactoid reaction, laryngeal edema, tongue edema (see Boxed <b>WARNING, WARNINGS</b> ), angioedema, myalgia
<b>Cardiovascular:</b>	hypotension, flushing
<b>Dermatologic:</b>	Lyell's syndrome, Stevens-Johnson syndrome, exfoliative dermatitis, maculopapular rash, urticaria
<b>Gastrointestinal:</b>	peptic ulceration, GI hemorrhage, GI perforation (see Boxed <b>WARNING, WARNINGS</b> ), melena, acute pancreatitis, hematemesis, esophagitis
<b>Hemic and Lymphatic:</b>	postoperative wound hemorrhage (rarely requiring blood transfusion—see Boxed <b>WARNING, WARNINGS</b> and <b>PRECAUTIONS</b> ), thrombocytopenia, leukopenia
<b>Hepatic:</b>	hepatitis, liver failure, cholestatic jaundice
<b>Nervous System:</b>	convulsions, psychosis, aseptic meningitis
<b>Respiratory:</b>	asthma, bronchospasm
<b>Urogenital:</b>	acute renal failure (see Boxed <b>WARNING, WARNINGS</b> ), flank pain with or without hematuria and/or azotemia, interstitial nephritis, hyponatremia, hyperkalemia, hemolytic uremic syndrome

well-recognized scoring systems. Each severity score, regardless of the system utilized, showed that Matthew's pancreatitis was mild and, therefore, not of sufficient severity to cause irreversible renal failure. Moreover, Matthew had no damage to the pancreas itself<sup>9</sup>.

Dr. Gold concurred with the opinions of Matthew's treating physicians from Vanderbilt, Drs. Hunley and Jabs, that Ketorolac was the cause of Matthew's renal failure.

On the day after Dr. Gold was excused as a witness, a juror approached the bench during a break (but while the proceedings were still on the record) with a question:

TRANSCRIPT OF COURT PROCEEDINGS JUDGE J. S. FRANK May 5, 2011 (Holding Courtroom)			
Time	Digital Time	Speaker	
11:50:09	01:00:14	Juror	Judge
		Judge	Yes, mam
		Juror	You said something about if there was a question
		Judge	What
		Juror	There is a question
		Judge	Can I ask you, can I get the attorneys because they need to hear this better than I do. Ah, Brian, Hamp, Mr. Cole ... come over here.... She had a question of me and I just asked her for you all to step in
		Juror	I just hadn't heard the question and I was wondering about the answer and unless there is another section that comes with these people
		Judge	What is the question?
		Juror	The question is <b>"How long does pancreatitis have to be present in order for kidney failure to happen?"</b>
		Judge	OK, so that's your question.
		Juror	Uh, huh
		Judge	Ok, thank you
		Juror	Uh, huh
		Mr. Moore	<b>We will try to answer it, Judge.</b>
11:50:33	1:00:38	Judge	Thank you. The Jury has left the Courtroom

<sup>9</sup> See testimony of Dr. Gold, ROA, May 4, 2011 at 17:04:59/00:59:06.

<sup>10</sup> All references in this transcript are to Record on Appeal, Video Transcript.

Recognizing the potential impact of this previously unaddressed issue, plaintiff's counsel requested the opportunity to present by deposition the rebuttal testimony of Dr. Gold<sup>11</sup>. If permitted to testify, Dr. Gold would have explained that the length of time that one has pancreatitis is not a factor in its association with renal failure—the severity of the disease is the key consideration. The trial court denied this request, on the stated grounds that Dr. Gold had already covered this issue. However, the record reflects that Dr. Gold did not address the length-of-time-factor with respect to pancreatitis in his direct testimony.

TRANSCRIPT OF COURT PROCEEDINGS MILLER VS. PRASEK COURT RULING ON REBUTTAL BY GOLD (MAY 6, 2010)			
Time	Digital Time	Speaker	
9:15:54	7:57	Schuetze	Also, I haven't mentioned this to you yet, too much going on this morning, but I have arranged for Dr. Gold to be available on Monday afternoon @ 4:00 in Atlanta, ah, I will arrange a Court Reporter, videographer, and, what not, to take some testimony from him. My first effort to use it will be in response to that juror's question. If that is objectionable and the court sustains that objection then at a minimum, I think that I can use that in my rebuttal case. So what I am asking the Court to do, and I have not asked Mr. Moore if he is willing to do this and he may be, but is for Mr. Moore and I to get into a room with a speakerphone. Dr. Gold in the room with a Court Reporter and speakerphone and then we question him on just that issue and then if I perceive the need to do anything else by way of rebuttal to put that in as well.
		Judge	I don't know.
		Moore	<b>I object.</b>
		Judge	I just don't know. I will have to think that through. I don't know about that.
		Schuetze	Well I need to make those arrangements quickly, if ah
		Judge	I'm not all that satisfied that we—I am not clear as to why you want to recall
		Schuetze	The juror asked the question, 'How long does acute-how long pancreatitis has to be present to cause renal failure—

<sup>11</sup> Plaintiff's counsel had made preliminary arrangements for Dr. Gold to be questioned telephonically by counsel while there was a court reporter, videographer and a speakerphone at his office in Atlanta. This was to take place on Monday, May 9<sup>th</sup>, a day on which the trial was in recess. It could have been accomplished without any burden upon Defense Counsel or the Court.

	irreversible renal failure. That goes to the very heart of the defense. They are going to hear a parade of witnesses who I think will at least attempt—I will object—who will attempt to draw the connection between Matthew's mild pancreatitis and his renal failure, ok. That goes to the very heart of the defense and at a minimum
Judge	I thought he had already testified as to that
Schuette	Well apparently it didn't make it.
Judge	Well that's, that's not going to be the governing aspect
Schuette	Well no, but I can still call him on rebuttal irrespective of that.
Judge	If its proper
Schuette	Hmmm
Judge	If it's proper.
Schuette	Well, if they talk about it in their case in chief then I can bring back rebuttal.
Judge	Well, I think he has already talked about that.
Schuette	No, I am talking about in my rebuttal case.
Moore	He testified last September.
Schuette	Who did?
Moore	Dr. Johnson.
Schuette	We're not talking about Johnson. I am talking about Gold.
Judge	No, No, I mean that issue. He testified about it couldn't be pancreatitis.
Mr. Cole	That's what he said.
Judge	I mean that's his whole basis, it can't be pancreatitis.
Schuette	Right. But I think, I think I should be entitled to introduce, even if it's a 5 or 10 minute deposition, his further explanation of that point. We told the jurors they could ask a question.
Judge	A further explanation of the point, so you understand that you made the point.
Schuette	Well, I thought we had made it.
Judge	<b>Well, just because one juror has a question, that doesn't mean—that doesn't mean anything.</b>
Schuette	Well, but I can still recall a witness
Cook	If he allows him to.
Judge	If I allow you to.
Cook	That's right
Schuette	And you should, Come on. . .
Mr. Cole	It's your rebuttal in . . . .
Judge	No, I understand gentlemen. I've not been in the civil end, but I've had a few criminal cases when I wanted to.. I would really like to really re-emphasize the point. I mean, Dr. Gold could not have been any clearer that pancreatitis did not cause, ah, Matthew Miller's injuries.
Cook	That's what closing is for.

		Judge	And I'm sure I am going to hear that plenty of times. I understand Dr. Gold (no one is here for the purposes of the record). Dr. Gold did a heck of a job as a witness and I understand why you would want to call him but I am not convinced that you get him on rebuttal, ok, but I don't want to make that decision right not because I would like to go ahead and get the jury back right now.
		Schuette	<b>OK. Well can we at least leave open the scheduling part of this so that if we can do it at 4:00 on Monday because I have to reserve his time and make sure Mr. Moore is available or somebody from his office.</b>
		Moore	<b>I can't do it by agreement but if Judge Wilson orders me to do it, I would. But, I continue to object to any effort to recall Dr. Gold.</b>
		Schuette	I understand and I
		Moore	Your case is still open, for the record, your case is still open.
		Schuette	Well, let me call him back then.
		Moore	I object to you calling him back. You said that's all my questions and he got up and walked out of the courtroom.
		Schuette	Well we were under extraordinary time pressure and the juror didn't ask the questions until it was too late to respond.
		Judge	And jurors ask questions all the time about different things and one juror may be informed by the other jurors, you know. That's, that's the part of the living, breathing aspect of the trial and I understand that you want to dot every I and every dot. I understand that and if I felt like I was keeping something from this jury, I would be more inclined to let Dr. Gold, you know, you recall him. But, I've said. Brian, he could have not been more clearer that pancreatitis did not shut down this boy's kidneys.
		Schuette	Ok. Well, I just wanted to make my request for the record and I will wait for the Court's ruling.
		Judge	And, ah I will give you a final ruling after I kind of think about it for a few minutes.
		Schuette	Fair enough. Thank you.
9:20:46	12:50	Judge	But ah, we'll go from there.
11:57:14	57:09	Schuette	Have you made a decision about Dr. Gold?
		Judge	Huh
		Schuette	Have you made a decision about Dr. Gold, whether I can call him in my rebuttal case
		Judge	Yes, I am not.
		Schuette	I can't even call him in my rebuttal case?
		Judge	Well, you haven't told me anything new he is going to say yet.
		Schuette	Well, I haven't heard all their case yet.
		Judge	I know that's why
		Schuette	Well, I've heard part of it-I don't know if they will have any

			more witnesses today. I may want him to respond to some of these things I don't know yet. <b>I really want him to answer the juror's question.</b>
		Judge	I understand but, I am satisfied he's answered that question, so.
		Schuette	Ok
		Judge	Ok
		Schuette	<b>I've made my request, so I will stop talking about it now.</b>
		Judge	<b>You've made your request 3 times now. So</b>
		Schuette	<b>Yes sir, thank you. I just want to make sure</b>
		Judge	<b>Have I made the same response each time?</b>
		Schuette	<b>Ah, my recollection is that you have.</b>
11:58:07	57:52	Judge	<b>All right. Thank you.</b>

The Trial Court's decision to disallow the rebuttal testimony of Dr. Gold was a fateful one for Matthew.

After approximately four hours of deliberation, the jury returned a verdict in favor of Dr. Fraser. The verdict was based upon a single finding: Dr. Fraser's decision to give Matthew a double-dose of a powerful drug known to cause kidney damage in dehydrated patients was not a "substantial factor" in causing his kidney failure and resulting legal damages.

**Do you believe from the evidence that Ambreen Fraser, M.D. failed to comply with her duty in treating Matthew Miller on January 8, 2008?**

Yes \_\_\_\_\_ No \_\_\_\_\_

**If you believe that Ambreen Fraser, M.D. failed to comply with her duty in treating Matthew Miller on January 8, 2008, do you believe that such failure was a substantial factor in causing Matthew Miller's injuries?**

Yes \_\_\_\_\_ No  \_\_\_\_\_

The Court of Appeals examined this issue and its opinion states as follows:

We believe *sub judice* that the juror's question, which was relevant to the issue of causation, warranted the opportunity for Miller to present further testimony, this being "good reasons in furtherance of justice." We disagree with the court that such

a singular question from a juror, which was relevant, "doesn't mean anything."  
(emphasis added)

*Miller v. Fraser*, at page 9.

The Court of Appeals declined to address the question of whether the Trial Court abused its discretion in this regard "in light of [its] remand for a new trial" based upon the informed consent issue. *Id.*

The second issue addressed by the Court of Appeals in its opinion was the Trial Court's refusal to allow Matthew to present his claim for failure to obtain informed consent, even though it was undisputed at trial that Dr. Fraser did not advise Matthew's parents<sup>12</sup> of the risks of Ketorolac before ordering it. The Defendant objected to presentation of this claim on the grounds that an informed consent claim does not apply to nonsurgical procedures. The Trial Court sustained the objection and disallowed this claim<sup>13</sup>.

Both of Matthew's parents testified on avowal<sup>14</sup> that at no time were they informed of the substantial risks associated with the administration of Ketorolac. They further testified that if they had been advised of the danger that Ketorolac posed to Matthew's kidneys, the treatment would have been declined, especially in light of the fact that Ketorolac was for pain and Matthew was reporting his pain as a "3" on a scale of "1" to "10", (with the latter being the most intense).

On this point, the Court of Appeals held that the Trial Court committed reversible error and stated as follows:

While our current jurisprudence concerning informed consent has only addressed cases involving medical procedures, this does not mean its application is limited to cases involving medical procedures. Thus, we hereby recognize that the issue of informed consent is not limited to surgery as argued by Dr. Fraser; instead, the question becomes whether such disclosures are required under the applicable professional standard of care upon which Miller was prepared to offer evidence of

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<sup>12</sup> Matthew was a minor at the time Dr. Fraser treated him.

<sup>13</sup> The Trial Court's ruling may be found at ROA 05/06/11 at 9:09:11/00:01:18.

<sup>14</sup> The avowal testimony of Mark Miller may be found at 05/05/11 at 17:07:15/01:04:46; the avowal testimony of Tammy Miller may be found at 05/05/11 at 18:11:51/00:00:10.

such via Dr. Denham and which Dr. Fraser would be free to contest. Accordingly, the trial court erred in disallowing Miller to assert his claim of negligence for lack of informed consent, necessitating reversal of the jury verdict and remand for a new trial on all issues.

*Miller v. Fraser*, at 10.

For the reasons that follow, the Court of Appeals should be affirmed and Matthew should have an opportunity to present fully his claims against Dr. Fraser at a new trial.

## ARGUMENT

### I. DR. FRASER'S ARGUMENT THAT MATTHEW FAILED TO PRESERVE THE PERTINENT ISSUES FOR APPEAL IS REBUTTED BY THE RECORD.

#### a. MATTHEW PRESERVED THROUGH TESTIMONY OF HIS PARENTS THE INFORMED CONSENT ISSUE.

Matthew preserved for appellate review the informed consent issue by the avowal testimony of his parents, both of whom testified that they would not have consented to the administration of Ketorolac for his mild to moderate pain if they had been advised of its risks.<sup>15</sup> By offering this testimony, Matthew complied with KRE 103, which states in relevant part as follows:

(a) Error may not be predicated upon a ruling which admits or excludes evidence unless a substantial right of the party is affected; and

\* \* \*

(2) Offer of proof. If the ruling is one excluding evidence, the substance of the evidence was made known to the court by offer or was apparent from the context within which questions were asked. (emphasis added)

KRE 103(a)(2).

His compliance in this regard does not appear to be disputed.

Dr. Fraser contends, however, that in addition to the avowal testimony of his parents Matthew was required to offer expert testimony on this issue. This position is contrary to this Court's holding in *Keel v. St. Elizabeth Medical Center*, Ky., 842 S.W.2d 860 (1992).

In *Keel*, a patient underwent a diagnostic procedure that involved the injection of dye (*i.e.* contrast). After receiving the injection, Keel developed a condition known as thrombophlebitis (inflammation of a vein). He brought suit against St. Elizabeth Medical Center alleging failure to obtain informed consent prior to the procedure. The trial court granted summary judgment because

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<sup>15</sup> The avowal testimony of Mark Miller may be found at 05/05/11 at 17:07:15/01:04:46; the avowal testimony of Tammy Miller may be found at 05/05/11 at 18:11:51/00:00:10.

the plaintiff did not present expert medical proof regarding the informed consent process. On appeal, the Court of Appeals affirmed.

On discretionary review, this Court reversed the Court of Appeals and Trial Court, holding that Keel's claim should have gone to the jury.

We must agree with St. Elizabeth that, in most cases, expert medical evidence will likely be a necessary element of the plaintiff's proof in negating informed consent. In view of the special circumstances of this case, however, we believe that neither *Holton* nor KRS 304.40-320 requires Keel to produce expert testimony on this issue. With respect to *Holton*, we answer the question left open there, and hold that expert evidence is not required in all instances where the claim is lack of informed consent. Here, we find it significant that St. Elizabeth offered Keel no information whatsoever concerning any possible hazards of this particular procedure, while at the same time the hospital admits that it routinely questions every patient about to undergo a dye injection as to whether he/she has had any previous reactions to contrast materials. If we are to analogize consent actions to negligence actions, **we must also acknowledge that a failure adequately to inform the patient need not be established by expert testimony where the failure is so apparent that laymen may easily recognize it or infer it from evidence within the realm of common knowledge.** Cf. *Jarboe v. Harting*, Ky., 397 S.W.2d 775 (1965); *Butts v. Watts*, Ky., 290 S.W.2d 777 (1956). In the present case, a juror might reasonably infer from the non-technical evidence that St. Elizabeth's utter silence as to risks amounted to an assurance that there were none, whereas its own questions to patients regarding reactions to this specific procedure demonstrate that St. Elizabeth itself, as the health care provider performing the treatment, recognized the substantial possibility of complications, and whereas (subject to further proof) a complication did in fact result. These inconsistencies are apparent without recourse to expert testimony; we believe this evidence was sufficient to satisfy the standards of *Holton*, supra, and of KRS 304.40-230, and to protect the plaintiff from adverse summary judgment. (emphasis added)

*Keel* at 862.

The *Keel* decision is directly on point and stands for the proposition that where a healthcare provider gives a patient "no information whatsoever" and "the failure is so apparent that laymen may easily recognize it or infer it from evidence with the realm of common knowledge," expert testimony is not required. *Id.* This rule of law makes perfect sense: if a doctor has the obligation to obtain informed consent from her patient and provides no information whatsoever, a jury does

not need to be told that she failed to do so—it is obvious and “within the realm of common knowledge.”

If Dr. Fraser had offered some information about the dangers of Ketorolac and the question was whether she had adequately informed her patient, it would make sense to require expert testimony. But that is not the case here. Rather, she offered her patient nothing and the jury should have been permitted to determine if she violated the standard of care in this regard.

Based upon the application of KRE 103 and this Court’s holding in *Keel v. St. Elizabeth Hospital*, Matthew properly preserved this issue for appeal.

**b. MATTHEW PRESERVED THE ISSUE RELATING TO ADDITIONAL TESTIMONY FROM DR. GOLD BY MAKING CLEAR TO THE TRIAL COURT WHAT THAT TESTIMONY WOULD BE.**

Dr. Fraser contends that Matthew failed to preserve for appellate review the issue relating to his efforts to offer additional testimony from Dr. Gold. The gist of her argument is that failure to make an avowal is fatal on appeal. Under these facts, however, that is not the law of Kentucky.

As with the question of preserving the informed consent issue, KRE 103 is the applicable rule. The portion of the rule relevant to this issue is as follows:

(a) Error may not be predicated upon a ruling which admits or excludes evidence unless a substantial right of the party is affected; and

\* \* \*

(2) Offer of proof. If the ruling is one excluding evidence, the substance of the evidence was made known to the court by offer or was apparent from the context within which questions were asked. (emphasis added)

KRE 103(a)(2).

In *Weaver v. Commonwealth*, Ky., 298 S.W.3d 851 (2009), a published decision rendered just four years ago, this Court explained in a footnote the proper application of the KRE 103(a)(2):

<sup>12</sup> HN11 Kentucky Rules of Evidence (KRE) 103(a)(2) provides that the issue of a trial court's ruling excluding evidence is properly preserved for review if "the substance of the evidence was made known to the court by offer or was apparent from the context within which questions were asked." Given defense counsel's oral remarks that the expert **[\*\*16]** testimony was offered to show that Weaver did not know what he was doing at the time of commission of the offense and the filing of Dr. Fabian's report stating that he offered an opinion concerning KRS 501.080 and a voluntary intoxication defense, this issue was properly preserved under the current version of KRE 103. (The trial took place in 2008, one year after the current version of KRE 103 became effective.)

In contrast to earlier versions of KRE 103, the current version does not require the presentation of avowal testimony to preserve the issue of a trial court's exclusion of testimony.

*Weaver* at 857.

As set forth above in the Counterstatement of the Case, there was very specific colloquy between the Trial Court and counsel concerning Matthew's need to recall Dr. Gold. The record demonstrates that the purpose of recalling Dr. Gold was to allow him to respond to the juror question about the duration of pancreatitis necessary to cause irreversible renal failure.

The exchange between counsel and the Trial Court provided adequate information concerning the substance of the evidence that Matthew intended to offer.

It is significant to note that it was a practical impossibility for Matthew to present Dr. Gold's proposed testimony by way of avowal. This is true because the witness had already returned to Atlanta. The only way to provide additional testimony was through a deposition. Dr. Frasier's counsel refused to participate in a deposition unless ordered to do so by the Trial Court, something the Trial Court declined to do. For Matthew's counsel to have proceeded with such a deposition would have been contemptuous conduct under the circumstances. More importantly, the law did not require him to do so.

Based upon the application of KRE 103 and this Court's holding in *Weaver v. Commonwealth*, Matthew properly preserved this issue for appeal.

## II. MATTHEW WAS ENTITLED TO PRESENT HIS INFORMED CONSENT CLAIM IN ACCORDANCE WITH KRS 304.40-320 AND KEEL V. ST. ELIZABETH MEDICAL CENTER.

The Court of Appeals properly found that Matthew was entitled to present a claim for Dr. Fraser's failure to obtain his parent's informed consent to the administration of Ketorolac, a drug known to cause kidney damage. This holding is based upon well-established Kentucky law, including KRS 304.40-320 and *Keel v. St. Elizabeth Medical Center*.

While the main issue on appeal in *Keel* was whether expert testimony is required, the case is also significant for its recognition of the right of a patient to bring an action arising out of the failure of a healthcare provider to obtain informed consent in connection with a nonsurgical procedure. KRS 304.40-320 also applies to the question of informed consent and identifies the broad scope of procedures to which this requirement applies: "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: . . ." Thus, Kentucky law recognizes a cause of action against a healthcare provider for failure to obtain informed consent for "treating," "examining" or "operating" on a patient.

The Court of Appeals did nothing more than recognize that under KRS 304.40-320 patients are entitled to render informed consent. In the section of its opinion addressing Dr. Fraser's foreseeability arguments, the Court of Appeals observed that: "Clearly, injecting medication into a person and having an injury result therefrom was foreseeable."<sup>16</sup> If injury is a foreseeable result of the treatment—whether surgical, diagnostic or "therapeutic"—the opportunity to learn of the risks and weigh those against the corresponding benefits is an essential right that every patient should enjoy.

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<sup>16</sup> *Miller v. Fraser* at 19-20.

The decision of the lower court in this case is consistent with precedents established by this Court and should be affirmed.

**III. IT WAS ERROR FOR THE TRIAL COURT TO DENY MATTHEW THE OPPORTUNITY TO RECALL DR. BENJAMIN GOLD TO ADDRESS A QUESTION RAISED BY A JUROR AND THE COURT OF APPEALS WAS CORRECT IN SO HOLDING; FURTHER, THIS ERROR WAS FAR FROM HARMLESS.**

It was Matthew's position in the Court of Appeals that the first and most important issue on appeal was the Trial Court's refusal to allow Matthew to introduce additional testimony from Dr. Gold to address the juror question concerning the length of time necessary for pancreatitis to cause irreversible renal failure. A reading of the lower court's opinion shows that it agreed that the Trial Court erred in this regard; however, the Court of Appeals chose not to address the question of whether this error was an abuse of discretion since it had already held that Matthew was entitled to a new trial on the informed consent issue.

Examining this issue in light of the following authorities leads to but one conclusion: irrespective of the lower court's characterization, the Trial Court's disallowance of additional testimony was an abuse of discretion.

**A. THE CIVIL RULES CONTEMPLATE THE INTRODUCTION OF REBUTTAL TESTIMONY IN A CIVIL CASE.**

The order of proceeding in a civil trial is governed by CR 43.02, which specifically addresses the subject of rebuttal evidence:

**CR 43.02 ORDER OF PROCEEDING IN TRIAL**

When the jury has been sworn, the trial shall proceed in the following order, unless the court, for special reasons otherwise directs:

(a) The plaintiff must briefly state his claim and the evidence by which he expects to sustain it.

(b) The defendant must then briefly state his defense and the evidence he expects to offer in support of it.

(c) The party on whom rests the burden of proof in the whole action must first produce his evidence; the adverse party will then produce his evidence. The party who begins the case must ordinarily exhaust his evidence before the other begins. But the order of proof shall be regulated by the court so as to expedite the trial and enable the tribunal to obtain a clear view of the whole evidence.

(d) The parties will then be confined to rebutting evidence, unless the court, for good reasons in furtherance of justice, permits them to offer evidence in chief.

(e) The parties may submit or argue the case to the jury. In the argument, the party having the burden of proof shall have the conclusion and the adverse party the opening. If there be more than one speech on either side, or if several defendants having separate defenses appear by different counsel, the court shall arrange the relative order of argument.

(emphasis added)

By operation of this rule, a plaintiff should ordinarily be permitted to present evidence in rebuttal, subject only to the discretion of the Trial Court. Such decisions are reviewable on appeal and "abuse of discretion is the proper standard of review of a trial court's evidentiary rulings." *Goodyear Tire & Rubber Co. v. Thompson, Ky.*, 11 S.W.3d 575, 577 (2000).

In determining whether a trial court has abused its discretion, the reviewing court applies the following test: "The test for abuse of discretion is whether the trial judge's decision was arbitrary, unreasonable, unfair, or unsupported by sound legal principles. 5 Am.Jur.2d *Appellate Review* § 695 (1995); cf. *Kuprion v. Fitzgerald, Ky.*, 888 S.W.2d 679, 684 (1994)." *Commonwealth v. English, Ky.*, 993 S.W.2d 941 (1999). (emphasis added).

Stated differently, unless the Trial Court's evidentiary ruling is rational, reasonable, fair and supported by sound legal principles, it is subject to reversal.

In this case, the Trial Court based its ruling on the erroneous observation that Dr. Gold had already testified concerning the issue raised by the juror question. However, a review of the record demonstrates that while he opined that Matthew's pancreatitis did not cause his irreversible renal failure, Dr. Gold did not even touch upon the question of how long one must have pancreatitis in

order to develop this condition. Because the question was important enough for the inquiring juror to pose, it was most certainly the proper subject of rebuttal testimony. The Court of Appeals disagreed with the Trial Court's statement that just because one juror asks a question "doesn't mean anything."<sup>17</sup> In this case, it obviously meant everything.

Further, since the question arose after Dr. Gold had been excused as a witness, the only way that Matthew could fairly and reasonably address this issue was by recalling his only causation expert. Instead, the jury heard from seven different defense experts, five of whom asserted that pancreatitis was not the cause of Matthew's renal failure. And from Matthew, they were permitted to hear nothing.

It was neither reasonable nor fair to deprive Matthew of the opportunity to offer evidence to aid the jury in answering this complex medical question. Rather, it was a clear abuse of discretion and the Court of Appeals was right to reverse and remand, even if it did not characterize the Trial Court's error as an "abuse of discretion."

**B. EVEN UNDER THE USUALLY DEFERENTIAL "ABUSE OF DISCRETION" STANDARD OF REVIEW, THE ONLY PROPER CONCLUSION IN THIS CASE IS THAT THE TRIAL COURT ABUSED ITS DISCRETION AND THEREBY COMMITTED REVERSIBLE ERROR.**

Appellate courts have shown a strong willingness to reverse the judgment of a Trial Court when a party is improperly denied the opportunity to present rebuttal testimony.

The jury in this case rendered its verdict in Dr. Fraser's favor in spite of the fact that two of Matthew's treating pediatric nephrologists from Vanderbilt Children's Hospital were strongly of the opinion that his irreversible kidney failure was the result of an excessive dose of Ketorolac given when he was dehydrated. Both stated that pancreatitis was not the cause.<sup>18</sup>

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<sup>17</sup> *Miller v. Fraser* at 9-10.

<sup>18</sup> See testimony of Dr. T.E. Hunley at May 4, 2011, 14:38:24/00:01:15 and Dr. Kathy Jabs at May 5, 2011, 10:54:57/00:05:02.

Nevertheless, the jury returned a verdict that suggests that it did not believe that Ketorolac was the culprit. To be sure, a jury is not required to accept as gospel the opinions of treating physicians. But any time a jury rejects the opinions of two highly accomplished treating physicians (both of whom are on the faculty of a pre-eminent medical school) whose opinions were formed at the outset of treatment, the matter bears close examination.

In this case, one need not go far to identify the reason behind this seemingly anomalous verdict: the pancreatitis argument.

Throughout the case, the defense strenuously argued that Matthew's irreversible kidney failure was the result of pancreatitis. While there are rare circumstances in which pancreatitis is associated with irreversible renal failure, those are instances in which the pancreatitis is so severe that it results in readily discernable damage to the organ itself. That was not the case with Matthew's pancreatitis. His case was mild and in the opinion of Dr. Gold, the only gastroenterologist who testified, Matthew's pancreatitis was not capable of producing irreversible kidney injury.

Although there are no on-point Kentucky decisions rendered on facts similar to this case, numerous federal circuit courts have addressed the issue, including cases decided by the United States Courts of Appeal for the 6<sup>th</sup>, 10<sup>th</sup>, 5<sup>th</sup> and 2<sup>nd</sup> Circuits. It is appropriate for this court to consider federal cases where the state rule being considered is essentially identical to its federal counterpart. As recently stated by this court in the case of *Curtis Green & Clay Green, Inc. v. Clark*, Ky. App., 318 S.W.3d 98 (2010): "[i]t is well established that Kentucky courts rely upon Federal caselaw when interpreting a Kentucky rule of procedure that is similar to its federal counterpart. See, e.g., *Newsome By and Through Newsome v. Lowe*, 699 S.W.2d 748 (Ky. App. 1985)."<sup>19</sup>

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<sup>19</sup> While CR 43.02 has no direct federal counterpart, the cases cited herein make clear that what is codified in Kentucky's civil rules is embodied in the federal authorities cited below. In other words, while the state and federal rules do not codify these legal principles in the same way, they are substantively the same. Thus, there is sufficient similarity between Kentucky law and federal law to render consideration of federal case law both useful and appropriate in this matter.

The case of *Benedict v. United States*, 822 F.2d 1426 (6<sup>th</sup> Cir., 1987), involved a claim against the United States under the Federal Tort Claims Act in which the plaintiff/appellant alleged injury as a consequence of receiving the Swine Flu Vaccine. The sole issue on appeal was whether the trial court erred by refusing to allow the plaintiff to present certain rebuttal testimony from one of her medical experts. As with all FTCA claims, the matter was tried before a judge without a jury. The specific issue in *Benedict* related to the use of epidemiological data in determining whether a patient developed Guillain-Barre Syndrome (GBS), a neurological disorder, as a result of receiving a vaccination.

During her case in chief, the plaintiff presented the testimony of a single expert who testified that she contracted GBS approximately 9½ weeks after receiving the vaccine. Relying upon published epidemiological studies, the plaintiff's expert testified that the period during which a vaccine recipient is at risk for developing GBS is 10 weeks. Based upon the temporal relationship between the vaccine and the onset of GBS, the expert opined that the plaintiff's GBS was probably the result of the vaccine.

The defendant then proceeded to introduce the testimony of three experts, all of whom expressed the opinion that subsequent epidemiological studies supported the conclusion that the period during which a vaccine recipient was exposed to the risk of developing GBS was 8 weeks and, therefore, the plaintiff's GBS was not causally related to the vaccine. In response to this testimony, the plaintiff sought to introduce rebuttal testimony from Dr. Goldfield, a second expert, to rebut the defense expert's testimony regarding the epidemiological data.

The trial court refused to permit the testimony on the grounds that it should have been presented during the plaintiff's case in chief. The 6<sup>th</sup> Circuit reviewed the decision of the trial court on an abuse of discretion standard, the same standard that applies in this case. In holding that the trial court had abused its discretion, the reviewing court explained its decision as follows:

A trial judge's determinations regarding the order of proof and scope of rebuttal testimony will not be disturbed absent an abuse of discretion. *Geders v. United States*, 425 U.S. 80, 86, 47 L. Ed. 2d 592, 96 S. Ct. 1330 (1976). As succinctly stated by this court in *Martin v. Weaver*, 666 F.2d 1013 (6th Cir. 1981), cert. denied, 456 U.S. 962, 72 L. Ed. 2d 485, 102 S. Ct. 2038 (1982):

In the exercise of sound discretion, the district court may limit the scope of rebuttal testimony, *Geders v. United States*, *supra*; *United States v. Algie*, 503 F. Supp. 783, 793 (E.D.Ky. 1980), to that which is directed to rebut new evidence or new theories proffered in the defendant's case-in-chief. See, e.g., *Bowman v. General Motors Corp.*, 427 F. Supp. 234, 240 (E.D. Pa. 1977). However, "where . . . [the] evidence is real rebuttal evidence, the fact that it might have been offered in chief does not preclude its admission in rebuttal." *National Surety Corp. v. Heinbokel*, 154 F.2d 266, 268 (3d Cir. 1946). Furthermore, with respect to "real rebuttal evidence," the plaintiff has no duty to anticipate or to negate a defense theory in plaintiff's case-in-chief. *Weiss v. Chrysler Motors Corp.*, 515 F.2d 449, 458-59 (2d Cir. 1975).

*Id.* at 1020.

*Benedict v. United States*, 822 F.2d at 1428.

Applying the forgoing analysis, the 6<sup>th</sup> Circuit reasoned that, "Dr. Goldfield's testimony regarding the accuracy of the methodology would have "served the permissible rebuttal function of counteracting the testimony of the opposing expert witness." " (Citing, *United States v. Posey*, 647 F.2d 1048, 1052 (10th Cir. 1981)). *Benedict v. United States*, 822 F.2d at 1429.

The court went on to explain:

In sum, Dr. Goldfield's testimony which would have attacked the reliability of Dr. Nathanson's data was proper rebuttal. The district court partially based its decision on its finding of fact that the government's studies were reliable. It concluded that the Benedicts had not supported their attack on those studies with "hard data." These circumstances force us to conclude that the court's failure to permit the Benedicts the opportunity to rebut the government's data regarding this critical issue was an abuse of discretion. (emphasis added)

*Benedict v. United States*, 822 F.2d at 1430.

The facts of the *Benedict* case are substantially similar to those in this case in that both involved presentation of a complex medical causation question. Just as the *Benedict* trial court abused

its discretion by disallowing the plaintiff's causation expert's rebuttal testimony, the Trial Court in this case did so by refusing to allow Dr. Gold to testify concerning a critical and ultimately dispositive issue on rebuttal.

Another case in which a reviewing court reversed a defense verdict was that of *Bell v. AT&T*, 946 F.2d 1507 (10<sup>th</sup> Cir., 1991). *Bell* was a Title VII employment discrimination case in which the plaintiff/appellant contended that she was discharged in a reduction in force for racially discriminatory reasons. In reversing the trial court's judgment in favor of the employer/appellee, the reviewing court focused on the trial court's refusal to allow the plaintiff to call on rebuttal a former co-worker for purposes of establishing that the employer's proffered reason for discharge was a mere pretext for discrimination. Holding that the plaintiff should have been permitted to introduce this important rebuttal evidence and that the district court abused its discretion by refusing her the opportunity to do so, the appellate court reversed the judgment and remanded the matter for further proceedings.

In the case of *Rodriguez v. Olin Corp.*, 780 F.2d 491 (5<sup>th</sup> Cir., 1986) the 5<sup>th</sup> Circuit reversed a verdict in a wrongful death and product liability action based upon the trial court's refusal to permit introduction of rebuttal testimony on a technical causation question. The underlying action was brought by the estate of Rodriguez, a delivery driver who died as a consequence of exposure to a toxic emission at an Olin Corp. plant, the company to which he was making the delivery. The estate also sued Smith Valve Corporation, the manufacturer of a valve that failed, leading to the emission. The plaintiff's claims were settled and the case proceeded to trial to determine responsibility as between Olin and Smith. These parties agreed that the emission occurred when four corroded bolts that held the valve together broke, causing the valve to come apart and thereby allowing toxic gas to escape.

The issue in contention was what caused the bolts to corrode and this was the battleground for the opposing experts. Each side of the dispute presented expert witness testimony in its case-in-chief. Thereafter, Olin sought to introduce additional testimony from its expert on rebuttal. The trial court disallowed the proffered rebuttal testimony and the jury returned a verdict in favor of Smith. Upon review, the 5<sup>th</sup> Circuit reviewed the trial court's refusal to permit rebuttal testimony on an abuse of discretion standard. The court reversed the trial court's judgment on the grounds that it was an abuse of discretion to disallow the expert's rebuttal testimony, observing as follows:

We note that evidentiary matters in trials involving a "battle of experts" are often difficult, and, as the learned judge below recognized, often lead to "reversible error." Although the district judge acted within the appropriate bounds of discretion in almost every instance, we conclude that his decision to refuse Olin the opportunity to rebut and discredit Smith's corrosion fatigue entrapment theory must be reversed.

*Rodriguez v. Olin Corp.*, 780 F.2d at 497

Solely on the basis of this ruling by the trial court, the 5<sup>th</sup> Circuit reversed the judgment and remanded the matter for a new trial.

The present case was without question a "battle of the experts" and the battle should have been allowed to proceed in a fair and evenhanded manner. Not permitting Dr. Gold to address the juror's question placed Matthew at an unfair disadvantage and the Trial Court's ruling was exactly the sort of "reversible error" to which the *Rodriguez* court was referring.

The case of *Pitasi v. Stratton Corp.*, 968 F.2d 1558 (2<sup>nd</sup> Cir., 1992) was a personal injury action by a skier against a ski resort in which the plaintiff alleged that the resort was negligent in failing to rope off the sides of a closed trail on which he was injured. Federal jurisdiction was based on diversity of citizenship, with the state law of Vermont applying to substantive matters, including Vermont's modified comparative negligence scheme (which bars recovery by a plaintiff whose comparative fault is equal to or greater than that of the defendant).

One of the issues in the trial was whether the resort had roped off the sides of the closed slope in prior years. In response to the resort's contention that it had not, the skier sought to introduce on rebuttal the testimony of a former resort employee to establish that the trail had been roped off when closed in prior years. The trial court sustained the defendant's objection and refused to allow the testimony. In reversing the trial court, the 2<sup>nd</sup> Circuit explained:

It is well-settled that a trial court's determination concerning the order of proof and the scope of rebuttal testimony will not be disturbed absent an abuse of discretion. E.g., *Geders v. United States*, 425 U.S. 80, 86, 47 L. Ed. 2d 592, 96 S. Ct. 1330 (1976). However, such discretion should be tempered greatly where the probative value of proffered evidence is potentially high and where such evidence, though admissible on the case in chief, was unnecessary for the plaintiff to establish in its prima facie case. *Weiss v. Chrysler Motors Corp.*, 515 F.2d 449, 457-58 (2d Cir. 1975) (holding that district court abused its discretion by precluding rebuttal testimony); see also *Benedict v. United States*, 822 F.2d 1426 (6th Cir. 1987) (same).

The testimony that the Pitasis sought to elicit was not necessary for its prima facie case. Rather, it would have served the permissible rebuttal function of impeaching Stratton's witnesses, who had testified during its case-in-chief that the side entrances to this trail had never been closed. See, e.g., *Federal Aviation Administration v. Landy*, 705 F.2d 624, 632 (2d Cir.) (holding that testimony tending to impeach was proper rebuttal), cert. denied, 464 U.S. 895, 78 L. Ed. 2d 232, 104 S. Ct. 243 (1983); *United States v. Windham*, 489 F.2d 1389, 1391 (5th Cir. 1974) (same). This testimony plainly was not collateral but central to the issue of Stratton's negligence in failing to rope off East Meadow's side entrance. Because this testimony was highly relevant and material to impeach the credibility of defendant's employees, we hold that the district court erred in excluding it. See *Weiss*, 515 F.2d at 457-58. (footnotes omitted) (emphasis added)

*Pitasi v. Stratton Corp.*, 968 F.2d at 1561.

In this case, Matthew recognized the highly probative value of Dr. Gold's proposed testimony. After all, what can be more important than responding to a juror's specific (and proper) question? As the verdict demonstrated in this case, there was nothing more important. Nevertheless, the Trial Court arbitrarily slammed the door on Dr. Gold and sent the jury to

deliberate without the benefit of competent and highly relevant testimony from a well-qualified expert.

The decision of the 2<sup>nd</sup> Circuit in *Weiss v. Chrysler Motors Corp.*, 515 F.2d 449 (2<sup>nd</sup> Cir., 1975), was the foundation for that court's decision in *Pitasi*. In *Weiss*, plaintiff brought a product liability action against Chrysler Motors after she suffered serious injuries in a wreck. She asserted that a defective steering mechanism broke and caused her to veer off the road and strike a tree. In support of this contention, the plaintiff presented the testimony of an expert who opined that a rod in the steering mechanism fractured before the wreck and caused the plaintiff to veer off the road and, thereafter, that there was an additional rod fracture upon impact with the tree. Chrysler's experts contended that both fractures were a result of the wreck. When the plaintiff sought to introduce additional testimony from her expert on rebuttal to respond to the assertions of Chrysler's experts, the trial court excluded the testimony. The jury returned a verdict in favor of Chrysler and the plaintiff appealed.

The *Weiss* Court held that the trial court abused its discretion by disallowing expert rebuttal testimony and reversed the judgment of the trial court. In doing so, the court focused on the fact that the excluded testimony went to the central issue in the case and "in this battle of experts might have changed the verdict." *Weiss v. Chrysler Motors Corp.*, 515 F.2d at 460-61.

Surely it is evident that Dr. Gold's testimony "might have changed the verdict" in this matter. In fact, it seems clear that the jury's decision was based on a determination that pancreatitis was the cause of Matthew's kidney failure. It should not have been allowed to reach this conclusion without the benefit of Dr. Gold's rebuttal testimony. This erroneous ruling alone is more than sufficient basis to justify reversal, just as it was in *Benedict*, *Bell*, *Rodriguez*, *Pitasi* and *Weiss*.

As these cases illustrate, a fair opportunity to present rebuttal testimony is of such importance to the notion of fairness in civil litigation that reviewing courts frequently reverse trial

court judgments, in spite of the fact that the standard of review is abuse of discretion. This further illustrates that respect for the unique role of a trial court must yield to the necessity of providing litigants the even playing field that the rules require. In service to this principle, reviewing courts have reversed judgments based in actions ranging from those under the Federal Tort Claims Act to Title VII to product liability cases to simple negligence claims.

This Court should apply the sound reasoning of the foregoing authorities to the present case and determine that the Trial Court abused its discretion. Further, the judgment of the Court of Appeals should be affirmed.

**IV. THE COURT OF APPEALS WAS RIGHT TO REJECT DR. FRASER'S ARGUMENT THAT MATTHEW'S KIDNEY FAILURE WAS NOT A "FORESEEABLE" RESULT OF THE ADMINISTRATION OF A DOUBLE-DOSE OF A DRUG KNOWN TO CAUSE KIDNEY DAMAGE.**

**A. THE ABSENCE OF PREVIOUSLY REPORTED CASES OF IRREVERSIBLE RENAL FAILURE FROM A SINGLE ADMINISTRATION OF KETOROLAC DOES NOT SUGGEST THAT MATTHEW'S RENAL FAILURE WAS UNFORESEEABLE OR THAT IT WAS CAUSED BY PANCREATITIS.**

Dr. Fraser seeks to advance a very misleading argument when she contends that the absence of previously reported cases of irreversible renal failure from a single administration of Ketorolac proves that Matthew's renal failure was a result of pancreatitis. Her argument is similarly misleading with regard to whether irreversible renal failure was foreseeable at the time she ordered a double-dose of the drug for Matthew when he was dehydrated and at risk for losing more fluid volume.

The gist of Dr. Fraser's argument is that because there were no known cases of irreversible renal failure from a single administration of Ketorolac, Matthew's kidney failure was either caused by something else or was not a foreseeable risk. This argument is misleading because according to the literature and the expert who testified at trial, there is not enough reported data from which to draw a conclusion.

Matthew presented at trial the deposition of Dr. Andrew Osiak<sup>20</sup>, the Associate Director for Global Pharmacovigilance for Baxter Pharmaceuticals, which manufactured the Ketorolac that Matthew received on January 8, 2008.

Dr. Osiak testified by video deposition and responded to a series of questions about the Food and Drug Administration's Adverse Event Reporting System (hereinafter "AERS"), a program for conducting post-marketing surveillance of risks and complications relating to the administration of drugs. (See Depo of Dr. Osiak 13-20). He correctly described the AERS as a voluntary reporting system that, by virtue of its non-mandatory reporting guidelines, gathers limited data. (See Depo of Dr. Osiak 20:2-7).

Importantly, Dr. Osiak expressed agreement with the medical literature, which concludes that because the voluntarily reported data is so limited, it does not provide a valid scientific basis upon which to draw conclusions:

2           Q.   Well, and as the commentators or the  
3           medical journal article writers suggest, that  
4           has the effect of producing a fairly limited  
5           pool of data with regard to adverse events, is  
6           that fair?  
7           A.   Yes.  
8           Q.   And I've seen in more than one place --  
9           and please tell me if you think this is a fair  
10          assertion -- that because of the limited nature  
11          of the data, you really can't draw any  
12          conclusions as a scientist as to how frequently  
13          adverse events occur?  
14          A.   In general, I think that that's a fair  
15          statement.

Depo of Dr. Owsiak 20:2-15.

A recent article published in the Archives of Internal Medicine<sup>21</sup> cites the following statistic:

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<sup>20</sup> See Trial Testimony of Dr. Osiak, beginning May 4, 2011, 9:13:40/00:07:55.

Estimates of what fraction of serious events were reported to the AERS vary between 0.3% and 33%,<sup>4,16</sup> depending on event, period, and drug. However, the re-

A January 2000 report to the United States Congress by the General Accounting Office underscores the inadequacy of data regarding adverse drug events in its very title: *ADVERSE DRUG EVENTS: The Magnitude of Health Risk Is Uncertain Because of Limited Incidence Data.*<sup>22</sup> The report states:

FDA's current postmarketing data collection systems for approved drugs are intended to compensate for the limitations of information from clinical trials by detecting the existence of previously unidentified ADEs. However, because FDA's Adverse Event Reporting System (AERS) relies on voluntary reports from physicians, pharmacists, patients, and others, it can uncover instances of problems but it cannot determine their incidence.

(emphasis added)

"Incidence" is precisely what Dr. Fraser is attempting to argue in her brief, essentially saying that *because there are no reported cases of Ketorolac causing irreversible renal failure, pancreatitis is the only explanation for what caused Matthew's renal failure.* However, as is abundantly clear from the medical experts who analyze such data, there is no scientifically competent or logically valid way to draw this conclusion.

Further, this argument ignores completely the likelihood that most physicians heed the Boxed Warnings against giving Ketorolac to dehydrated patients, especially giving double the recommended dose.

Presumably, Dr. Fraser's spurious arguments are calculated to divert the Court's attention from the Trial Court's erroneous refusal to allow Dr. Gold to address on rebuttal the "duration of pancreatitis" question raised by the jury.

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<sup>21</sup> *Serious Adverse Drug Events Reported to the Food and Drug Administration, 1998-2005*, ARCH INTERN MED/VOL 167 (NO. 16), SEP 10, 2007. Attached to Depo of Dr. Osiak as Exhibit 2. (Copy attached at Tab 7)

<sup>22</sup> A copy of this document is attached to Depo of Dr. Osiak as Exhibit 4. (Copy attached at Tab 8)

This Court should reverse the Judgment of the Trial Court and remand this case for a new trial.

**B. THE MANUFACTURER'S PACKAGE INSERT FOR KETOROLAC INCLUDES WARNINGS THAT MAKE IRREVERSIBLE RENAL FAILURE FROM A SINGLE ADMINISTRATION OF KETOROLAC ENTIRELY FORESEEABLE.**

Baxter included in its package insert warnings about Ketorolac that render irreversible renal failure entirely foreseeable. In order to understand the manufacturer's warnings, it is important to note the following about dehydration and renal blood flow:

- People who vomit without replacing lost fluid volume become volume depleted, *i.e.* dehydrated.
- Dehydration impairs renal function and, most importantly, renal perfusion, *i.e.* blood flow to the kidneys.
- The body has a substance used to overcome poor renal perfusion and it is called "prostaglandin," which promotes blood flow to the kidneys when a person is dehydrated.
- Ketorolac blocks the action of prostaglandin so that it cannot help the body compensate for compromised renal blood flow resulting from dehydration.

These simple medical principles were undisputed at trial.

The package insert for the Ketorolac provides strong warnings about possible kidney damage:

**Renal Effects**

- Ketorolac tromethamine is CONTRAINDICATED in patients with advanced renal impairment and in patients at risk for renal failure due to volume depletion (see WARNINGS).

The package insert goes on to state in the CONTRAINDICATIONS section:

- Ketorolac tromethamine is CONTRAINDICATED in patients with advanced renal impairment or in patients at risk for renal failure due to volume depletion (see WARNINGS for correction of volume depletion).

These warnings mean DON'T GIVE THIS DRUG TO VOLUME DEPLETED PATIENTS. The manufacturer even explains why patients at risk for renal failure should not receive Ketorolac before their volume depletion is corrected:

**Ketorolac tromethamine should be used with caution in patients with impaired renal function or a history of kidney disease because it is a potent inhibitor of prostaglandin synthesis.** Renal toxicity with ketorolac tromethamine has been seen in patients with conditions leading to a reduction in blood volume and/or renal blood flow where renal prostaglandins have a supportive role in the maintenance of renal perfusion. In these patients administration of ketorolac tromethamine may cause a dose-dependent reduction in renal prostaglandin formation and may precipitate acute renal failure. Patients at greatest risk of this reaction are those with impaired renal function, dehydration, heart failure, liver dysfunction, those taking diuretics and the elderly. Discontinuation of ketorolac tromethamine therapy is usually followed by recovery to the pretreatment state.

(emphasis added)

Because Matthew vomited three times without significant fluid replenishment before receiving Ketorolac, he was unquestionably dehydrated and, therefore, among those at greatest risk for "renal toxicity."

Even a casual reading of the language of the warning demonstrates the misleading nature of Dr. Fraser's argument: "[d]iscontinuation of . . . therapy is usually followed by recovery to the pretreatment state." "Usually," by definition, does not mean "always."

So, when properly read, the warning tells *prudent* physicians:

- Do not to give this drug to dehydrated patients.
- Giving this drug to dehydrated patients this drug poses a risk of causing renal toxicity.
- Discontinuation of the therapy does not necessarily result in a return to the patient's pretreatment state, *i.e.* irreversible kidney damage is possible.

Ultimately, the jury's verdict demonstrates that whether irreversible renal failure was foreseeable had no bearing on the outcome of the case, since the jurors could not reach a conclusion on the question of whether Dr. Fraser deviated from the standard of care. Rather, the verdict

appears to be based upon the jury's acceptance of the pancreatitis argument and this conclusion would very likely have been different if Dr. Gold had been permitted to address the juror question on rebuttal and otherwise respond to Dr. Fraser's evidence in chief.

For these reasons, the Court of Appeals properly rejected Dr. Fraser's arguments on her cross-appeal below and its decision should be affirmed.

**C. SINCE THE MECHANISM OF INJURY THAT CAUSES REVERSIBLE RENAL FAILURE IS THE SAME AS THAT WHICH CAUSES IRREVERSIBLE RENAL FAILURE, THE LATTER IS JUST AS FORESEEABLE AS THE FORMER.**

As explained above, Dr. Johnson agreed that the mechanism of injury for reversible ischemic kidney injury and irreversible ischemic kidney injury is the same. It is really just a matter of degree, which leads to this question: if the mechanism of injury for reversible and irreversible forms of kidney injury is the same, how can one possibly argue that irreversible renal failure is not a foreseeable result of receiving a double dose of a Ketorolac?

The simple answer to this question is that one cannot logically make this argument. Therefore, Dr. Fraser's argument that Matthew's irreversible renal failure was not foreseeable is in direct conflict with the warning contained in the manufacturer's package insert as well as some of her own expert's testimony.

**D. THE CONCEPT OF FORESEEABILITY DOES NOT REQUIRE THAT A DEFENDANT KNOW THE PRECISE MANNER IN WHICH INJURY CAN OCCUR.**

Dr. Fraser seems to be arguing that because she could not foresee the precise manner in which her treatment decision would harm Matthew, she cannot be held legally responsible. Even if one ignores the obvious conflict between her assertion and the manufacturer's clear warnings, the

legal conclusion is the same: Dr. Fraser is not entitled to escape responsibility based upon a supposed lack of foreseeability.

A recent decision handed down by United States District Court for the Southern District of New York provides a useful analysis of the issue of foreseeability. The plaintiffs in that action contended that a drug manufacturer was liable for place a drug for osteoporosis on the market that caused some patients to develop severe deterioration of the jawbone. In rejecting the manufacturer's argument that it should not held liable because such a complication was unforeseeable, the court offered the following analysis:

Merck contends that it is entitled to judgment as a matter of law because there was no scientific evidence during the time Plaintiff used Fosamax from which it could have foreseen the risk of ONJ.

With regard to Plaintiff's negligence claim, the foreseeability of ONJ bears on the issue of proximate causation. For Merck's failure to design a safe product to be a proximate cause of Plaintiff's injury, she must show that "prudent human foresight would lead one to expect that similar harm is likely to be substantially caused by the specific act or omission in question." *McCain v. Fla. Power Corp.*, 593 So.2d 500, 503 (Fla.1992); *Stzenski v. Tennant Co.*, 617 So.2d 344, 346 (Fla.Dist.Ct.App.1993) ("In determining whether the action of the defendant is a proximate cause of the injury, the test is to what extent the defendant's conduct foreseeably and substantially caused the specific injury that actually occurred."). That burden is rather light in that Plaintiff need not show that the precise manner in which the injury occurred or the extent to which the injury was foreseeable. See *Stzenski*, 617 So.2d at 347. "[A]ll that is necessary in order for liability to arise is that the tortfeasor be able to foresee that some injury will likely result in some manner as a consequence of his negligent acts." *Crislip v. Holland*, 401 So.2d 1115, 1117 (Fla.Dist.Ct.App.1981). The proximate cause inquiry typically is an issue of fact for the jury, one that can be decided as a matter of law only "where evidence supports no more than a single reasonable inference." *McCain*, 593 So.2d at 504; *Palma v. BP Prods. N. Am., Inc.*, 594 F.Supp.2d 1306, 1310-11 (S.D.Fla.2009); see also *Lindsey v. Bell South Telecomms., Inc.*, 943 So.2d 963, 966 (Fla.Dist.Ct.App.2006) ("The circumstances under which a court may resolve proximate cause as a matter of law are extremely limited.").

*In re Fosamax Prods. Liab. Litig.*, 742 F. Supp. 2d 460, 473 (S.D.N.Y. 2010)

Kentucky law is substantially identical to the cases cited by the *Fosamax* court as illustrated by the Kentucky Supreme Court's opinion in the case of *Isaacs v. Smith*, Ky., 5 S.W.3d 500 (1999):

We think it is clear that so far as foreseeability enters into the question of liability for negligence, it is not required that the particular, precise form of injury be foreseeable—it is sufficient if the probability of injury of some kind to persons within the natural range of effect of the alleged negligent act could be foreseen.

*Miller v. Mills*, Ky., 257 S.W.2d 520, 522 (1953) (citing \*503 *Morton's Adm'r v. Kentucky-Tennessee L. & P. Co.*, Ky., 282 Ky. 174, 138 S.W.2d 345 (1940); *Dixon v. Ky. Utilities Co.*, Ky., 295 Ky. 32, 174 S.W.2d 19 (1943)).

*Isaacs* at 502-03.

The case of *Lee v. Farmer's Rural Electric Co-Op Corp.*, Ky. App., 245 S.W.3d 209 (2007), curiously cited by Dr. Fraser in her brief, further supports Matthew's argument. In *Lee*, the estate of a pilot sued a power company for failing to mark its electrical power lines, which the pilot struck while flying. The Trial Court granted summary judgment on the grounds that the incident was not foreseeable. The Court of Appeals reversed, explaining the concept of foreseeability as follows:

Foreseeability inquiries are often complicated by the tendency to confuse foreseeability and proximate cause. Whether a harm was foreseeable in the context of determining duty depends on the general foreseeability of such harm, not whether the specific mechanism of the harm could be foreseen. *See, e.g., Bolus v. Martin L. Adams & Son*, 438 S.W.2d 79, 81 (Ky. 1969) ("It is not necessary, to impose liability for negligence, that the defendant should have been able to anticipate the precise injury sustained, or to foresee the particular consequences or injury that resulted. It is enough that injury of some kind to some person could have been foreseen."); *Eaton v. Louisville & N.R. Co.*, 259 S.W.2d 29 (Ky. 1953) (precise form of [\*213] injury need not be foreseen). In determining whether an injury was foreseeable, we look to whether a reasonable person in a defendant's position would recognize undue risk to another, not whether a reasonable person recognized the specific risk to the injured party. In *Pathways, Inc. v. Hammons, supra*, [\*\*8] our Supreme Court held:

Foreseeable risks are determined in part on what the defendant knew at the time of the alleged negligence. "The actor is required to recognize that his conduct involves a risk of causing an invasion of another's interest if a reasonable man would do so while exercising such attention, perception of the circumstances, memory, *knowledge of other pertinent matters*, intelligence, and judgment as a reasonable man would have." Restatement (Second) of Torts § 289(a) (emphasis added); *see also Mitchell v. Hadl*, Ky., 816 S.W.2d 183, 186 (1991). (Holding that liability for negligence is based on what the defendant was aware of at the time of the alleged negligent act and not on what the defendant should have known in hindsight.) The term "knowledge of pertinent matters" is explained by Restatement (Second) of Torts § 290, which states:

For the purpose of determining whether the actor should recognize that his conduct involves a risk, he is required to know (a) the qualities and habits of human beings and animals and the qualities, characteristics, and capacities of things and forces in so far as they are matters of common knowledge at the time and in the community; and [\*\*9] (b) the common law, *legislative enactments*, and general customs in so far as they are likely to affect the conduct of the other or third persons.

*Pathways, supra*, at 90.

*Lee v. Farmer's Rural Electric Co-Op Corp.*, at 212-13.

The *Lee* court makes the precise point that Matthew has argued ever since this issue was raised by Dr. Fraser's motion for summary judgment: "foreseeability" does not mean the ability to know in advance the precise injury that may be sustained. The difference between reversible and irreversible renal failure caused by the same mechanism of injury is merely a matter of degree. This is well within the scope of foreseeability as contemplated by *Lee* and the other authorities cited by Matthew.

Thus, Dr. Fraser's hair-splitting foreseeability arguments must fail in light of the reasoning of the *Fosamax*, *Isaacs* and *Lee* courts. She was not entitled to summary judgment at the trial stage nor did the Court of Appeals err in rejecting her arguments.

## CONCLUSION

Medical negligence cases are difficult for patients who have been harmed as a result of substandard medical care. One of the greatest challenges is to communicate technical medical concepts in a way that is understandable to juries. Since the plaintiff has the burden of persuasion, it is critical that he strike that important balance between providing too much and too little information. When the jury poses a question that provides a window into its thought process, it is essential that the parties pay attention and seek to respond.

Under the circumstances of this case, the jury made known through its duration-of-pancreatitis question that it was struggling to understand the medical causation issue. Recognizing this, Matthew attempted to provide additional, helpful testimony from one of his key causation experts—one that happened to be the only gastroenterologist who testified in the whole case. Refusing him this opportunity was a clear abuse of discretion that placed Matthew at a profoundly unfair disadvantage.

Accordingly, this Court should affirm the decision of the Court of Appeals and remand this case to the Warren Circuit Court for a new trial.

Respectfully submitted,

By: \_\_\_\_\_



Brian Schuette

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