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

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

CERTIFICATE OF SERVICE

This will certify that ten copies of this reply brief were on this 17th day of December, 2013 forwarded by overnight Federal Express 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.

COLE & MOORE, P.S.C.
921 College Street – Phoenix Place
P.O. Box 10204
Bowling Green, KY 42102-7240
Telephone: (270) 782-6666
Facsimile: (270) 782-8666

Matthew P. Cook
Frank Hampton Moore, Jr.
Counsel for Appellant, Ambreen Fraser, M.D.

STATEMENT OF POINTS AND AUTHORITIES

Appellant, Ambreen Fraser, M.D., by counsel, for her reply brief, states as follows:

Dr. Fraser submits this reply brief to correct the factual misstatements in Matthew Miller's brief and to further demonstrate the reversible errors in the Court of Appeals' panel opinion ("the Panel Opinion"), a copy of which is attached as Exhibit A.

EXPLAINING THE DISPUTED FACTUAL ISSUES

Several times in his brief, Matthew attempts to convince the Court that he was clinically dehydrated when he presented to Dr. Fraser for treatment and further, that Dr. Fraser improperly gave him a double dose of the therapeutic pain medication, Ketorolac. However, the proof at trial on both of these points was in sharp dispute. The jury heard the lay and expert testimony from both parties at trial and concluded, well within its discretion, that Dr. Fraser's treatment – specifically, her decision to give Matthew one 60 mg shot of Ketorolac for his pain – did not cause him to subsequently develop irreversible kidney failure.

Dr. Fraser testified without equivocation that Matthew was not dehydrated at the time of examination. Her record and the subsequent test results, which are attached hereto as Exhibit B, provide the proof that Matthew was not dehydrated while at Urgentcare. Matthew had a normal pulse, blood pressure and pH level of his urine. He also had normal respiration and moist mucous membranes upon examination. (*See* Trial CD 8-1-11-CD-70.4, 5/10/11 at 09:27:40-09:49:06). Importantly, the radiologist who performed the CT scan on Matthew after Dr. Fraser saw him found that the blood flow to his renal arteries (kidneys) was normal. (Deposition of Dr. Kevin Burner, p. 11). This means that Ketorolac was not contraindicated for Matthew.

In addition, the various expert witnesses presented by Dr. Fraser at trial all supported her contention that Matthew was not dehydrated at the time of her treatment of the patient and that

the 60 mg dose was appropriate given Matthew's age and weight – he was 16 and a half years old and 144 pounds – i.e., he was much closer to an adult than a child.

Specifically, Dr. Richard Johnson, Dr. Fraser's nephrology expert, testified: "Matthew, had several episodes of vomiting; you know, he probably was – had probably lost some volume. But he didn't really clinically appear very significantly volume depleted ... And I think, you know, with a short-term illness in a 16-year-old, who walks in, who was teaching after school, has only vomited a couple times, has normal pulse, I think all those things go against him being significantly volume depleted." (Deposition of Dr. Johnson, September 23, 2010, pp. 22, 24).

In addition, Dr. Marcus Patton, Dr. Fraser's anesthesiology expert, opined that the 60 mg dose of Ketorolac was within the acceptable range given Matthew's age and weight and that he was not volume-depleted enough to make the use of this drug problematic.[1] Dr. Patton's testimony is found in the record at Trial CD 8-1-11-CD-70.3, 5/6/11 at 02:55:25004:09:59.

Finally, perhaps the most convincing testimony on the issue of dehydration came from Dr. Gary Howerton, Dr. Fraser's emergency room physician expert. Dr. Howerton's trial testimony is found in the record at Trial CD 8-1-11-CD-70.5, 5/11/11 at 11:28:15-02:02:00. Dr. Howerton used a visual demonstration with water jugs to demonstrate the amount of water in the human body and what would need to be lost for a person to become clinically dehydrated. Dr. Howerton opined that it was "impossible" that Matthew was dehydrated at the time of his presentation for treatment to Dr. Fraser at Urgentcare.

On the issue of dosage, Matthew's own standard of care expert witness, Dr. Craig Denham, agreed that Matthew was in his seventeenth year of life at the time of treatment with Dr. Fraser. (*See* Trial CD 8-1-11-CD-70.1, 5/4/11 at 01:59:12-02:01:50). This is important

[1] In addition, one of Matthew's expert witnesses, Dr. Benjamin Gold, confirmed that in his deposition he gave the opinion that Matthew "was not volume depleted" on the day in question. (*See* Trial CD 8-1-11-CD-70.1, 5/4/11 at 05:51:45-05:52:20).

because it means that Matthew was not subject to pediatric dosage requirements. The Ketorolac package insert is attached hereto as Exhibit C. On page 12 of 12 of the package insert the drug manufacturer discusses the recommended IM dose and states: "Patients <65 years of age: One dose of 60 mg." Dr. Fraser followed this and gave Matthew one 60 mg dose of Ketorolac.

The package insert also addresses the dosage to be given to pediatric patients, who are described as 2 to 16 years of age, and states that one 30 mg IM dose is appropriate. The testimony of Dr. Marcus Patton, the anesthesiologist described above, is important on this point. Dr. Patton opined that the adult dose of 60 mg was appropriate for Matthew given his age and his weight. In other words, there was expert testimony for the jury to rely on in determining that the dosage Matthew received was correct and not a deviation from the standard of care.

Another factual error from Matthew's brief is the statement that his pancreas had no damage. (*See* Matthew's Brief at p. 3). This statement was made in an attempt to discount the defense pancreatitis causation theory. However, after his treatment with Dr. Fraser, Vanderbilt University physicians noted that Matthew had a "severe case of pancreatitis." (*See* Vanderbilt document attached as Exhibit D). In addition, there is attached as Exhibit E a telling Vanderbilt document which states that Matthew's pancreas was "atrophic."

THE INFORMED CONSENT ISSUE

Despite his protest to the contrary, Matthew was required to (and failed to) preserve the lack of informed consent issue with expert testimony. The Panel Opinion incorrectly states that Matthew's standard of care expert, Dr. Craig Denham, was prepared to testify that "Dr. Fraser deviated from the standard of care by failing to obtain informed consent." (Panel Opinion, p. 8).

Respectfully, there is nothing in the record stating that Dr. Denham was prepared to opine on this topic. There was no testimony from any Plaintiff expert witness, including Dr.

Denham, in a deposition or at trial (or even by avowal) on this point. Matthew did not address the lack of informed consent claim in his expert disclosures or in his written summary judgment responses and his counsel stated 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 this claim or object to the trial court's jury instructions.

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 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.").

Neither *Keel* 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. 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).[2]

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. The holding in *Keel* is the rare exception to the recognized rule that expert proof is needed by a plaintiff to establish a jury issue on a claim of lack of informed consent.

An important Kentucky case which analyzed the holding in *Keel* is *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. The Court applied Kentucky law and discussed the *Keel* decision at length in explaining the ruling for the physician, stating: "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.

[2] Matthew's argument that he preserved the informed consent issue for appellate review by his parents' avowal testimony that they would have declined the single dose of Ketorolac had they been advised of its risks is incorrect. Kentucky law is clear that expert testimony is needed on this topic. Matthew's failure to present expert testimony precludes appellate review of this claimed error.

The same holding should follow in the instant matter. 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 falls within the general rule announced in *Keel* that expert proof is required to make out an actionable lack of informed consent claim.

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. Since the proposed informed consent claim sounds in negligence, Judge Wilson did not abuse his discretion by refusing a separate informed consent negligence instruction for lack of expert proof. *See Harris v. Commonwealth*, 313 S.W.3d 40, 50 (Ky. 2010).

Even if there was an error made on the issues raised by Matthew, 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. In applying the harmless error doctrine, 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 again 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." *Id.*

THE REBUTTAL WITNESS ISSUE

Likewise, the same defenses apply to Matthew's other issue raised on appeal – whether or not the trial judge abused his discretion in refusing to allow one of his experts, Dr. Benjamin Gold, to return to testify again on rebuttal against the defense pancreatitis theory. First, Matthew failed to preserve the issue with avowal testimony on what Dr. Gold would have said on rebuttal and thereby waived the issue. Second, the trial judge did not abuse his discretion in declining the invitation to let Dr. Gold testify for a second time on rebuttal. Third, the harmless error doctrine would also apply here since the jury determined that Dr. Fraser did not cause Matthew's injury.

Matthew's brief incorrectly states that the Panel Opinion found that the trial judge erred in refusing his request to recall Dr. Gold on rebuttal. However, the panel did not reach the issue of whether Judge Wilson abused his discretion on this issue because it had already determined (incorrectly) to reverse on the informed consent issue. (Panel Opinion, pp. 7-8).

The trial judge was fair to both parties in limiting what could be said by witnesses in response to the juror's question on pancreatitis. In addition to denying Matthew's request to recall Dr. Gold, Judge Wilson also refused to let Dr. Fraser testify on this issue. Specifically, he sustained an objection from Matthew's counsel when Dr. Fraser was asked how soon renal failure could occur due to pancreatitis. (*See* Trial CD 8-1-11-CD-70.4, 5/10/11 at 10:19:50-10:30:59).

Moreover, Matthew's suggestion that he had no opportunity to put in avowal testimony from Dr. Gold is incorrect. The statement that he faced contempt from the trial judge if he

proceeded to depose Dr. Gold for avowal is erroneous. There was no suggestion at all that that would occur. In point of fact, Matthew's counsel did not request to put anything in the record from Dr. Gold by avowal once the ruling was made that the witness could not be called again on rebuttal. Thus, Matthew waived this issue for appellate review. The Court cannot guess what this witness might have said on rebuttal nor can Matthew now advise what he might have said.

Likewise, Matthew cites no on-point Kentucky case to show that Judge Wilson abused his discretion in declining the proposed rebuttal testimony and the cases he cites from foreign jurisdictions are readily distinguishable. For example, in Benedict v. United States, 822 F.2d 1426 (6th Cir. 1987), the trial court's decision to refuse rebuttal testimony from a new expert who had not testified for a plaintiff in the case-in-chief was reversed because one of the defense experts changed his testimony at trial. That is not the case here. Dr. Fraser's pancreatitis causation theory was well known to Matthew and his attorney well before trial and there was ample time to prepare to respond to it. Dr. Gold testified during Matthew's case-in-chief and gave the opinion that pancreatitis did not cause his irreversible kidney failure. Thus, the trial judge was within his discretion to deny the request to repeat this testimony.

Likewise, in Bell v. AT&T, 946 F.2d 1507 (10th Cir. 1991), the proposed rebuttal witness had not testified during the plaintiff's case-in-chief. In fact, the opinion notes that the proposed rebuttal witness had not even been subpoenaed to testify when the trial judge ruled. Id. at 1511, fn 2. That is in direct contrast to Dr. Gold who had already testified in-chief for Matthew and articulated his opinions about pacreatitis.

In Rodriguez v. Olin Corp., 780 F.2d 491 (5th Cir. 1986), the appellate court only allowed that part of the proposed rebuttal which was deemed necessary to address a new "corrosion fatigue entrapment" causation theory raised by a defense expert for the first time at trial. As

indicated above, that is not the case here. In the instant matter, the pancreatitis theory was not newly raised at trial. In fact, the defense expert nephrologist, Dr. Johnson, did not testify live at trial so there was no opportunity for him to voice new theories.

In Pitasi v. Stratton Corp., 968 F.2d 1558 (2d Cir. 1992), the trial judge was reversed because the proposed rebuttal testimony was held to be proper to impeach a defense witness who had testified at trial that the side entrances to a ski trail were never closed. The rebuttal witness would have testified that the trail had been closed the year before due to weather conditions, including the side entrances at issue in the case. We have no such factual issue here. Dr. Gold was not being offered to impeach a new factual statement by a defense witness.

In Weiss v. Chrysler Motors Corp., 515 F.2d 449 (2d Cir. 1975), the appellate court reversed a defense trial judgment in an automobile products liability case where the defendant utilized a new causation theory at trial that had not been previously disclosed to the plaintiff in discovery. That is not the case in the instant matter. As indicated, Dr. Johnson's pancreatitis causation theory was subject to pre-trial discovery by Matthew and both Dr. Gold and Matthew's treating nephrologist gave opinion testimony in Matthew's case-in-chief attempting to dispel it. The trial judge did not abuse his discretion in refusing to allow Dr. Gold to testify again.

Finally, the harmless error doctrine applies to save the jury verdict from being reversed. The jury made the specific finding, after hearing Dr. Gold and the other Plaintiff experts, that Dr. Fraser did not cause Matthew's injury. Bringing Dr. Gold back to testify again would not have changed the jury's verdict.. The jury's verdict was properly supported and should be reinstated.

MATTHEW'S INJURY WAS UNFORESSEABLE

If we accept Matthew's theory of causation, he is the first otherwise healthy person to suffer irreversible kidney failure after receiving a single dose of Ketorolac. The medical

literature does not document such a case nor does the package insert warn of this possibility. The package insert notes that if the drug is overdosed and causes kidney dysfunction, the condition will resolve upon discontinuation of dosing. Likewise, the product manufacturer testified that it had received no other reports of this condition occurring from a single dose of this drug (out of millions of doses dispensed).

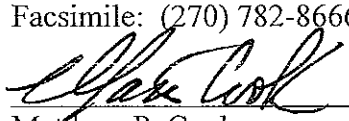
Dr. Fraser was not on notice that this type of irreversible injury could occur when she gave the single dose of Ketorolac to Matthew for his pain. Because the ultimate injury was not foreseeable at the time of administration, a directed verdict for Dr. Fraser was required.

CONCLUSION

Dr. Fraser shares in the hope for Matthew's continued good health. In addition, the fact that a person undergoes a health challenge does not, in and of itself, mean that the person's physician was negligent. Here, the science points to pancreatitis as the cause of Matthew's kidney failure. There is no suggestion that Dr. Fraser could or should have been able to diagnose pancreatitis when she saw Matthew. The jury decided, well within its discretion, that Dr. Fraser did not cause the kidney failure. That jury verdict should be respected and reinstated.

Based on all of the foregoing, Dr. Fraser urges the Court to reverse the Panel Opinion and to reinstate the trial judgment in her favor. Alternatively, she asks that the case be remanded with instructions to enter a directed verdict for her on the foreseeability issue.

COLE & MOORE, P.S.C.
P.O. Box 10204
Bowling Green, KY 42102-7240
Telephone: (270) 782-6666
Facsimile: (270) 782-8666



Matthew P. Cook
Frank Hampton Moore, Jr.
Counsel for Appellant, Ambreen Fraser, M.D.

APPENDIX

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