1-23-2009

Coombs v. Curnow Respondent's Brief Dckt. 35157

IN THE SUPREME COURT OF THE STATE OF IDAHO

MELINDA COOMBS, natural mother of Michael Hall, deceased, and the ESTATE OF MICHAEL HALL, as represented by Melinda Coombs, personal representative,

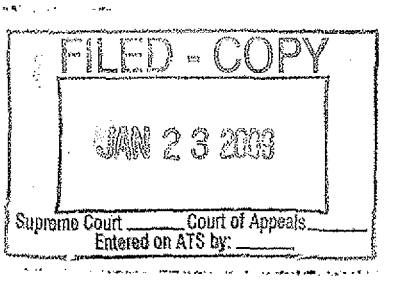
Plaintiffs/Appellants,

vs.

ADRIAN CURNOW, M.D., and RUSSELL GRIFFITHS, M.D.,

Defendants/Respondents.

Supreme Court No. 35157



RESPONDENT'S BRIEF

Appeal from the District Court of the Fourth Judicial District of the State of Idaho in and for the County of Ada

Honorable Deborah A. Bail, presiding

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I. STATEMENT OF THE CASE

A. Nature of the Case.

This is an appeal from a Decision and Order granting the defendants' Motions for Judgment Notwithstanding the Verdict entered by the district court on March 28, 2008, and the subsequent Amended Judgments entered in favor of each defendant. Plaintiffs' claim is based on the June 28, 2002, death of 35-month-old Michael Hall. Michael had suffered a dog bite that removed a significant portion of tissue from his face. Defendant Russell Griffiths, M.D. performed a complicated and delicate procedure in an effort to re-attach the tissue that had been removed, and Dr. Curnow was the pediatric general surgeon and acting pediatric intensivist assisting in Michael's care.

Because of the need to give the tissue graft a chance to re-implant, it was necessary to keep Michael completely sedated for an extended period of time so that he would not move or touch the tissue. Following a consultation with an anesthesiologist at St. Alphonsus, Dr. Griffiths ordered propofol, a sedative, at a specified dosage. The effort to re-attach the cheek graft eventually failed, and Dr. Curnow began to consider what was next in Michael's care. Because the wound had to be debrided, the decision was made to continue Michael on propofol for sedation and Fentanyl for pain management for a short while longer. However, Michael developed ventricular tachycardia of unknown origin and became hemodynamically unstable. Following a neurological exam on July 27, Michael's pupils were found fixed and dilated, signifying brain death. Michael's parents decided to remove him from the ventilator, and he died

on June 28, 2002. The cause of death was listed as cerebral edema. Aside from the brain injury, no other organ or tissue damage was noted.

Plaintiffs initiated this suit, claiming that the defendants breached the standard of care and proximately caused the death of Michael Hall by keeping him sedated on propofol for a period of between 76 and 92 hours. The district court granted defendant's Motion for Judgment N.O.V., holding that there was no substantial evidence presented at trial to support the jury's verdict that the long-term use of propofol was the actual or proximate cause of Michael Hall's death and that the plaintiffs had failed to establish that the defendants breached the applicable standard of care at the time that care was rendered.

B. Course of the Proceedings.

Plaintiffs filed their original Verified Complaint and Demand for Jury Trial on December 17, 2004. R., Vol. I, p. 20. Following a lengthy discovery process and several motions by all parties, including dispositive motions filed by both defendants, this matter proceeded to a jury trial commencing September 4, 2007. R., Vol. I, p. 36. At the close of evidence, defendants moved for entry of directed verdict, and the district court reserved ruling. The matter was submitted to the jury, which returned a verdict in favor of plaintiffs, finding defendants equally liable and setting damages at $750,000. R., Vol. I, pp. 75-77.

After the jury's verdict was entered, defendants moved for judgment notwithstanding the verdict. R., Vol. I, pp. 82, 85. Following hearing on defendants' motions, the district court issued its Decision and Order Re: Motions for Judgment Notwithstanding the Verdict on March 28, 2008, granting the requested relief. R., Vol. I, p. 111. Judgment was

entered on behalf of Dr. Curnow on April 11, 2008. R., Vol. I, p. 145. An Amended Notice of Appeal was filed by plaintiffs on May 14, 2008. R., Vol. I, p. 151.

C. Statement of Facts.

1. Medical care and treatment of Michael Hall.

On June 22, 2002, Michael Hall, a 35-month-old boy, was at a party when he reached for some food that had been dropped. R., Vol. 1, p. 112. At the same time that he reached for the food, the host's golden retriever went for the same food. When Michael tried to take the food away, the dog bit his face. *Id.* The dog's bite tore away a significant portion of Michael's face—the majority of his cheek, including a portion of the commissure of his lip. The detached skin and tissue was preserved by a member of Michael's family, and he was rushed to St. Alphonsus Regional Medical Center ("St. Al's"). *Id.* The bite was critical and put Michael at serious risk. *Id.*

Michael was admitted at St. Al's by defendant Adrian J. Curnow, MD, a pediatric surgeon who was also serving as a pediatric intensivist at St. Al's at the time. R., Vol. I, p. 113; Tr., Vol. I, p. 1839, L. 7 – p. 1840, L. 6. At the time the care was rendered, Dr. Curnow and his partner, Dr. Ellen Reynolds, were the only two pediatric surgeons in Idaho. R., Vol. I, p. 113. Because of the severity of the wound to Michael's face, Dr. Curnow asked Russell Griffiths, M.D., a pediatric plastic surgeon specializing in craniofacial surgery and microvascular surgery, to come in and treat Michael. *Id.* The evidence at trial confirmed that Dr. Griffiths was the only pediatric plastic and craniofacial surgeon in Idaho. *Id.*

After assessing the wound, Dr. Griffiths discussed the various options available to Michael with his parents, including the possibility of re-implantation. *Id.*; Tr., Vol. I, p. 1114, L. 3 – p. 1117, L. 13. Ms. Coombs consented to re-implantation of the severed tissue and all attendant care, having been advised of the risks, including death. Tr., Vol. I, p. 1113, L. 25 – p. 1117, L. 24; p. 1121, L. 22 – p. 1123, L 16; p. 1125, L. 4 – p. 1127, L 5; p. 589, L. 4 – p. 592, L. 4. She recognized that if re-implantation was not attempted, Michael would face multiple future surgeries, the attendant risks of multiple general anesthesia and infection, the likelihood of permanent facial disfigurement, and the possibility of significant psychological harm. *Id.* Once re-implantation was selected, Dr. Griffiths performed a difficult and intricate surgery, re-attaching the severed tissue one dermal layer at a time and reconnecting the available blood supply all the way up the stratus of the detached cheek. R., Vol. I, p. 113; Tr., Vol. I, p. 1118, L. 9 – p. 1126, L. 7. Post-surgically, any disturbance whatsoever to the surgical site would have destroyed the sutures and caused the re-implantation to fail. Tr., Vol. I, p. 2174, L. 23 – p. 2176, L. 13. Because of the significant risk that the tissue graft would fail if Michael were to touch or rub his cheek in any way, it was necessary to keep him completely sedated for several days post-op, to give the re-implantation a chance. Tr., Vol. I, p. 2175, L. 7. Dr. Griffiths asked the anesthesiologist assisting with the surgery for his recommendation on a post-surgical sedative agent. Tr., Vol. I, p. 1793, LL. 14-19. Dr. Smagula, the anesthesiologist, recommended propofol. Tr., Vol. I, p. 1133, LL. 7-16; p. 2186, LL. 12-13. Even though Dr. Griffiths had not used propofol for long-term sedation of a pediatric patient, he was aware that an alternative, Versed, carried the risk of an idiosyncratic reaction, where the patient actually becomes excitable

rather than sedated. Tr., Vol. I, p. 2185, L. 2 – p. 2186, L. 13. After his consultation with Dr. Smagula, Dr. Griffiths wrote the order for propofol. Tr., Vol. I, p. 1085, LL. 7-13. In addition to propofol, Dr. Griffiths ordered Heparin, an anti-coagulant, and medical leeches to draw blood away from the graft, since no patent vein had been found in the cheek tissue. Tr., Vol. I, p. 1109, L. 25 – p. 1110, L. 7; p. 2170, LL. 5-7.

After the surgery was over, Dr. Reynolds and then Dr. Curnow acted as intensivists with respect to Michael's care in the ICU. Dr. Reynolds saw Michael on the morning of June 23, 2002. Tr., Vol. I, p. 708, L. 19 – p. 709, L. 24. She noted that Michael was to return that day to the operating room for "re-exploration" of the cheek flap, and that he was "[t]o remain sedated on [the] vent[ilator] for the next few days." Tr., Vol. I, p. 709, LL. 18-20. Dr. Reynolds did not express any concern about the administration of propofol at any time. Tr., Vol. I, p. 710, LL. 4-9. Dr. Curnow thereafter resumed Michael's care.

Dr. Curnow testified that in June 2002, he was current on the medical literature regarding propofol, that he had used it several times himself for short-term sedation, and that he had been part of a care team that had provided propofol to a pediatric patient for long-term sedation even though he did not use propofol as part of his regular practice.[1] Tr., Vol. I, p. 1942, LL. 7-24; p. 1838, LL. 5-14. Based on that prior experience, Dr. Curnow was aware of the need

[1] When acting as a pediatric general surgeon, and when acting as a pediatric intensivist, Dr. Curnow relied on the recommendations of the anesthesiologist and/or the primary sub-specialist surgeon for post-operative sedation.

to frequently monitor the patient for known side effects of propofol, and Michael was monitored accordingly. Tr., Vol. I, p. 1943, LL. 14-17.

In June 2002, the medical literature noted a concern with the use of propofol in patients under three years of age. Problems had been observed and were hypothesized to stem from the fact that propofol was infused as an emulsion, suspended in fats or lipids. Tr., Vol. I, p. 1844, LL. 6-10. Dr. Curnow was aware of this issue, and of the corresponding need to "account for that when managing patients who are on Propofol for long-term sedation, that you would need to take into account the lipid content in the Propofol and make sure that you did not give an excess – excessive amount of lipids to the child during that interval of time." Tr., Vol. I, p. 1838, L. 24 – p. 1839, L. 5; *see also* Tr., Vol. I, p. 1996, LL. 17-24.

Not only did Dr. Curnow monitor Michael's lipid metabolism, he frequently monitored Michael's complete hemodynamic status, particularly given the known features of Propofol-Related Infusion Syndrome ("PRIS"). Medically speaking, a "syndrome" is a cluster of symptoms and is used to describe an association between those symptoms **when there is no proof of any causal nexus**. R., Vol. I, p. 116. *See also* Tr., Vol. I, p. 476, L. 15 – p. 477, L. 3. PRIS is a rare, though often fatal, progressive disorder characterized by certain "hallmark" features, including bradycardia (decreased heart rate), rhabdomyolysis, decreased renal function, irreversible (or "refractory") metabolic acidosis, and sometimes lipemia and hematic steatosis. R., Vol. I, p. 116. Dr. Ross Reichard, a forensic pathologist who testified at trial, provided a consistent description of the features of PRIS. Tr., Vol. I, p. 1255, L. 12 – p. 1256, L. 24.

Plaintiffs' counsel examined Dr. Curnow at length about the extent to which he monitored Michael while sedated on propofol:

> Q. And when you say that you monitor the patient very closely, what does "monitor" mean in your mind?
>
> A. This child was on a continuous heart monitor. He was on a blood pressure monitor that was taking his blood pressure every three to five minutes automatically.
>
> He was on a pulse oximeter, monitoring his oxygen level in his blood. He was having blood tests drawn to monitor his bleeding so that he could get replacement of his blood and blood products with his bleeding, and he had laboratory tests that monitored his acid level in his body as far as the bicarbonate in his body.

Tr., Vol. I, p. 1043, L. 18 – p. 1044, L. 6.

In addition to the monitoring of Michael's heart, blood pressure, oxygen saturations, blood and blood products and metabolism, Dr. Curnow testified concerning other testing that was being conducted:

> Q. Are the side effects in addition – you were here during Dr. Hammer's testimony, I think.
>
> A. Yes.
>
> Q. And he mentioned other side effects, such as contractility of the heart, and such as lipemia. Were you aware of those side effects when you were taking care of Michael?
>
> A. I was aware of lipemia, and contrary to Dr. Hammer's –
>
> Q. Well, let –
>
> A. – understanding of the amount of lipids that he was getting –

* * * *

Q. You were aware of lipemia. Were you also aware of the effect of contractility of the heart?

A. That is correct.

Q. And so you were closely monitoring Michael yourself by coming into the ICU and reading the reports and digesting all of the information that you learned about Michael, were you?

A. That's correct.

Tr., Vol. I, p. 1044, L. 16 – p. 1045, L. 20.

Based upon this testimony, the district court found that Dr. Curnow was familiar with propofol and was aware of its possible side effects, and that he took specific steps to limit the possibility of lipemia in Michael. R., Vol. I, p. 114. The court further noted that Dr. Curnow was aware of PRIS, its connection with multiple organ damage and heart failure, that extensive monitoring of Michael's blood pressure and hemoglobin was provided, and that he was monitored for metabolic acidosis as well. *Id.*

Despite the skilled efforts of Dr. Griffiths, the re-implantation of Michael's cheek failed. On June 25, Dr. Griffiths removed the tissue graft. Tr., Vol. I, p. 1102, L. 14 – p. 1105, L. 13. As a part of the graft removal, the wound needed to be debrided, an exceptionally painful procedure. Therefore, when he was returned to the ICU, Michael continued to be sedated with propofol per Dr. Griffiths' order. R., Vol. I, p. 114. While Dr. Curnow had intended to lighten up the propofol by this point, because of the tissue failure and debridement, he maintained the propofol at the prior levels to help manage the pain Michael faced from debridement and the pain

he would unavoidably experience with subsequent dressing changes. Dr. Ellen Reynolds was examined on this subject, and testified as follows:

> Q. And do you see there where he said he will lighten up sedation over the next 24 to 48 hours?
>
> A. Yes.
>
> Q. Did you and he [Dr. Curnow] have a discussion about that plan?
>
> A. Yes.
>
> Q. Please tell the jury about that discussion.
>
> A. He just said that the flap was debrided, it wasn't on his face anymore, and that we would wean his medication – you can't just stop it, because you have some withdrawal when you stop a medication, like both Propofol and Fentanyl.
>
> And so that we would lighten it up over the next 24 to 48 hours and see if he could tolerate the dressing changes, since he now still had an open wound without any – you know, much medication.
>
> Q. And that was a very painful open wound?
>
> A. Yes.
>
> Q. So the plan – now, when Dr. Curnow left, did he discuss with you the patient, the plan, and everything that was going on?
>
> A. Yes.
>
> Q. Did you feel that you were fully informed about the patient?
>
> A. Yes. I was comfortable taking care of him.

Tr., Vol. I, p. 710, L. 19 – p. 711, L. 23.

Following this consultation, Dr. Curnow left and Dr. Reynolds resumed Michael's care. As the district court noted, Michael's blood pressure and hemoglobin were low on June 25. R., Vol. I, p. 115. Although a transfusion of packed red blood cells resolved the low hemoglobin, Michael's blood pressure remained low. Testimony was provided by plaintiffs' primary expert, Dr. Gregory Hammer, that while propofol will decrease blood pressure, so will any sedative agent, including Dr. Hammer's own drug of choice, Versed. *See, e.g.*, Tr., Vol. I, p. 506, L. 12 – p. 507, L. 22.

The next day, after Dr. Reynolds had assumed Michael's care, he began to show signs of ventricular tachycardia (accelerated heart rate) ("V-Tach"). Tr., Vol. I, p. 679, L. 11 – p. 680, L. 23. Dr. Reynolds was immediately called by the nursing staff, and she ordered laboratory work. Tr., Vol. I, p. 677, LL. 11-14. The lab results indicated low albumin and calcium, for which she ordered supplemental potassium and calcium, and the EKG changes responded positively. Tr., Vol. I, p. 677, L. 23 – p. 678, L. 7. The V-Tach returned later that day, and Dr. Reynolds consulted a pediatric cardiologist, Dr. Michael Womack. Tr., Vol. I, p. 678, LL 8-16. The cardiologist ordered an EKG, which again indicated ventricular tachycardia. Tr., Vol. I, 679, L. 5 – p. 681, L. 1. Following treatment with adenosine, Michael's heart rate returned to normal. Tr., Vol. I, p. 681, LL. 2-17. Dr. Womack testified at trial that Michael Hall's heart rhythm changes were **not** consistent with those associated with PRIS. Tr., Vol. I, p. 1207, LL. 1-10.

During the afternoon of June 26, Dr. Reynolds decided to follow Dr. Curnow's earlier recommendation and begin weaning Michael off of the propofol. Tr., Vol. I, p. 682,

LL. 2-18. As she was doing so, Michael's abnormal heart rate recurred, and Dr. Reynolds discontinued the propofol at 8:00 p.m. on June 26. By the following morning Michael exhibited a "normal sinus rhythm." Tr., Vol. I, p. 681, L. 23 – p. 682, L. 1; p. 683, LL. 12-19. At 8:00 a.m. on June 27, a neurological exam of Michael showed "normal" pupillary reaction. Tr., Vol. I, p. 686, LL. 11-14. Another neuro check was conducted at noon, and again, pupillary reaction was normal. Tr., Vol. I, p. 686, LL. 18-21. The neurological exam conducted at 4:00 that afternoon, however, showed that Michael's pupils were fixed and dilated. Tr., Vol. I, p. 688, LL. 13-16. A CT of the head was immediately taken, which revealed bilateral cerebellar infarcts. Tr., Vol. I, p. 689, L. 4 – p. 690, L. 1. Michael was declared to be brain dead, and arrangements were made to remove him from the ventilator. Tr., Vol. I, p. 692, LL. 16-23. Following removal of the life support equipment, Michael died on June 28, 2002.

An autopsy was conducted, and Michael was found to have had cerebral edema with global hypoxic changes. Tr., Vol. I, p. 149, LL. 16-18. This was the sole abnormal finding. All other organs and systems were normal. Tr., Vol. I, p. 178, L. 2 – p. 179, L. 11. Dr. Groben, the forensic pathologist who conducted the autopsy for Ada County, testified that Michael's liver, kidneys and heart were all normal on gross and microscopic examination. Tr., Vol. I, p. 202, L. 25 – p. 206, L. 9. Dr. Groben found no evidence of rhabdomyolysis, the breakdown and release of muscle fibers into the bloodstream. Tr., Vol. I, p. 206, LL. 12-22. While cerebral edema has never been disputed as the ultimate cause of Michael's death, the central issue at trial was what had caused the cerebral edema.

2. Evidence introduced at trial.

Judge Bail observed that there was only one witness at trial who had testified that the long-term sedation of Michael Hall with propofol was the proximate cause of death: plaintiffs' expert, Dr. Gregory Hammer. R., Vol. I, p. 115. She also noted, however, that "all other witnesses testified that it was not possible to determine the cause of cerebral edema." *Id.* Dr. Hammer is a board certified pediatrician and anesthesiologist with a sub-specialty in pediatric critical care medicine who practices at Lucille Packard Children's Hospital in Palo Alto, California. Tr., Vol. I, p. 303, LL. 20-23. Dr. Hammer, along with every other expert who testified at trial, acknowledged that there are **no scientific studies** that show the presence of cerebral edema or cerebral cytotoxicity alone following long-term sedation with propofol. R., Vol. I, p. 116. For example, Dr. Hammer testified:

> Q. Okay. And if you turn to Page 80 of your deposition, again, the opinion you have given the jury today is that Propofol caused this cerebral edema in Michael Hall.
>
> And on Page 80 at Line 18, did I ask you the following question, and did you give the following answer?
>
> "Question: Okay, are you aware of any articles in peer or non-peer-reviewed journals that correlate long-term high-dose use of Propofol for sedation in pediatric patients under the age of three with cerebral edema resulting in death?
>
> "Answer: I'm not aware of that precise association."
>
> Was that your testimony on that date, doctor?
>
> A. Yes.
>
> Q. Okay.

A. That's still my testimony.

Tr., Vol. I, p. 466, L. 20 – p. 467, L. 13. Later, when asked a similar question on cross-examination, he testified:

> A. . . . I'm not aware of a direct association in the literature.
>
> There would be nothing interesting or new about that to publish, so yes, there are **no** articles, if I understand your question, directly saying Propofol causes cerebral edema directly.

Tr., Vol. I, p. 880, L. 25 – p. 881, L. 5 (emphasis added).

One of the preeminent and most knowledgeable physicians on the use and study of propofol is Dr. Michael Reed, a pediatric clinical pharmacologist (Pharm D.). Dr. Reed's entire career has been focused on both clinical and academic pediatric practice. Tr., Vol. I, p. 1660, LL. 6-8. He spent the majority of his career at Rainbow Babies and Children's Hospital, an affiliate of Case Western Reserve University in Cleveland, Ohio, practicing as an academic-based clinician with over 23 years of research studying new drugs used in children and helping to establish the pediatric pharmacology and critical care division. Tr., Vol. I, p. 1660, L. 19 – p. 1663, L. 17. In connection with his practice, Dr. Reed has conducted a number of studies of propofol, beginning in 1991 and continuing through approximately 2000. Tr., Vol. I, p. 1677, L. 18 – p. 1684, L. 15. While those studies were being conducted, Dr. Reed was part of the care team involved in the administration of propofol in doses of 150 to 200 micrograms per kilogram[2] per minute to pediatric patients under the age of three.[3] Tr., Vol. I, p. 1684, L. 16 – p. 1685, L. 4.

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[2] Michael was receiving between 100 to 125 mcg/kg. Tr., Vol. I, p. 1085, LL. 4-13.

Also among the studies conducted by Dr. Reed was the "multicenter clinical trial" referred to in the 2002 Physicians' Desk Reference ("PDR") entry for Diprivan, the brand name for propofol. Tr., Vol. I, p. 1694, L. 18 – p. 1695, L. 9; p. 1703, L. 16 –p. 1704, L. 13.

Addressing the lack of any scientific studies showing only cerebral cytotoxicity or cerebral edema from the use of propofol, the district court pointed to the "anecdotal reports of serious adverse events and death in pediatric patients" and the negative outcomes in a small clinical study as reported in the 2002 PDR. R. Vol. I, p. 116. That clinical study in particular, Judge Bail observed, showed a "possible **association**" between propofol and death in a small number of pediatric patients, but she recognized that there was no evidence of causation. *Id.* That "association," labeled as PRIS, was observed in 29 pediatric patients. *Id.* Dr. Reed provided extensive testimony at trial describing these "associations" commonly linked to PRIS:

> And the Propofol Infusion Syndrome –
>
> Q. What are its principal characteristics?
>
> A. It's just that. It is what is most often described – and I think it's important to recognize that the definition of the Propofol Infusion Syndrome has come out of experience in 29 pediatric patients from case reports.
>
> It's primarily a progressive disorder that is characterized by cardiovascular hemo–instability, cardiovascular instability, an evolving rhabdomyolysis, an evolving decrease in renal function,

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[3] Plaintiff may argue that Dr. Reed monitors creatinine kinase ("CK") enzymes when propofol is being administered in pediatric patients, and based thereon suggest that Dr. Curnow did not know how to monitor Michael Hall's propofol administration. However, that argument is a red herring, because high CK levels indicate muscle breakdown, *e.g.* rhabdomyolysis, which Michael Hall did not have.

> and when you start adding – all of those things interplay on each other.
>
> But when you get to that part of the syndrome, as your renal function decreases, you can't eliminate from your body the acids, so you become more acidotic, and it's sort of like acid begets acid, the electrolyte abnormalities – another characteristic in many of the cases is that when these components or when these abnormal physiologic events occur, they were refractory to treatment. And then –
>
> Q. Meaning?
>
> A. Which means that you would treated – you would try to treat that disorder with what you normally treat that disorder with and the patient didn't respond.

Tr., Vol. I, p. 1705, L. 25 – p. 1707, L. 1.

Dr. Reed further testified that in all his research and first-hand experience observing the use of propofol in pediatric patients over an eight- to nine-year period, he has **never** seen a case where cerebral edema was described in the literature on PRIS. Nor has Dr. Reed ever seen **any** reports or participated in any case where patients sedated over an extended period died and **cerebral edema was the only abnormal finding**. Tr., Vol. I, p. 1707, L. 18 – p. 1708, L. 3. Defendants also called Dr. Martin Johnston, a pediatric hematologist and oncologist. He testified that even though he has been using propofol since 1997, none of the medical literature he reviewed mentioned an association between the use of propofol and an isolated global ischemic event, *e.g.*, an event that would cause cerebral edema. Tr., Vol. I, p. 1312, LL. 4-7; p. 1315, LL. 6-16.

The evidence presented at trial showed that while Michael had acidosis at one point during his sedation, that acidosis responded to treatment with routine sodium bicarbonate

and therefore was not the type of "refractory" acidosis associated with PRIS. *See* Tr., Vol. I, p. 1886, LL. 10-19; p. 1889, LL. 12-20. The forensic pathologists who testified at trial both agreed that Michael's liver, kidneys and heart and skeletal muscles were all normal on gross and microscopic examination, and there was no evidence of rhabdomyolysis. Tr., Vol. I, p. 202, L. 25 – p. 206, L. 22; p. 1255, L. 7 – p. 1257, L. 21; p. 1269, L. 20 – p. 1270, L. 6. As the district court found, **none** of the hallmark signs of PRIS were present in the autopsy of Michael Hall. R., Vol. I, p. 116.

Despite the lack of any features associated with PRIS in the medical literature, Dr. Hammer insisted that the long-term sedation with propofol directly caused the cerebral edema that killed Michael Hall. His conclusion was that propofol contributed to hypotension, thereby decreasing blood flow to vital organs, including the brain, heart, liver and other vital tissues. Tr., Vol. I, p. 355, LL. 7-11. He went on to theorize that the propofol caused a buildup of fatty acids, which in turn impacted the energy generation of cells in Michael's body. Tr., Vol. I, p. 355, LL. 12-17. These factors, combined, allegedly resulted in diminished oxygen delivery to the brain, causing cerebral edema and inadequate oxygen delivery to other organs. Tr., Vol. I, p. 355, L. 18 – p. 356, L. 3. As support for this "oxygen utilization" theory, Dr. Hammer relied upon **only** two sources: the 2002 PDR entry for Diprivan and an article on PRIS published in Italy on August 6, 2003, entitled "*The Pathophysiology of Propofol Infusion Syndrome: A Simple Name for a Complex Syndrome.*" R., Vol. I, p. 117.

Referring to the 2003 article, Dr. Hammer agreed that it defined PRIS as "a rare and often fatal syndrome originally described in critically ill children undergoing long-term,

greater than 48 hours, Propofol infusion in high doses, greater than 4 milligrams per kilogram per hour," where "severe metabolic acidosis, rhabdomyolysis, renal failure, and fatal cardiac failure are the features." Tr., Vol. I, p. 518, LL. 2-10. The 2003 article did not describe any cases where death was due solely to cerebral edema, and Dr. Hammer repeatedly acknowledged in his testimony that there are "no articles . . . saying Propofol causes cerebral edema directly." Tr., Vol. I, p. 881, LL. 3-5. Dr. Reed confirmed that the 2003 article said nothing which would support his theory that the administration of propofol could cause a patient to have edema only in the brain causing multiple infarcts and ultimately death. Tr., Vol. I, p. 1719, LL. 13-24.

Just as the 2003 study utilized by Dr. Hammer failed to support his oxygen utilization theory, the 2002 PDR reference to the "multicenter clinical trial" which reported that propofol "is not indicated for sedation in pediatric patients until further studies have been performed to document its safety in that population" was shown at trial by the report's author, Dr. Michael Reed, to be statistically insignificant. Tr., Vol. I, p. 1694, L. 14 – p. 1695, L. 23. Dr. Reed testified that "when the data was subjected to statistical analysis, there was **no statistical difference**" between the patients who died after receiving propofol and those who died after receiving a different sedative agent. Tr., Vol. I, p. 1704, LL. 14-19 (emphasis added).

Propofol is described in the PDR as not being "indicated for use in pediatric patients for ICU or for MAC sedation . . . as safety and effectiveness have not been established" (Tr., Vol. I, p. 471, LL. 1-14), but there was substantial testimony at trial establishing that there is a key difference between a drug being "contraindicated" for a particular use, and its being "not indicated" for certain uses. Dr. Hammer described this difference as follows:

A. Yes. As I think we talked about in my deposition, 70 per cent of the drugs that we use in pediatric anesthesia and critical care are off-label.

It's the difference between the PDR, saying something is not specifically indicated or it is off-label, or actually issuing a warning saying that there is a caution against its use. . . .

The language is that it is not indicated.

Q. Right.

A. But it's not a warning against using it under those circumstances.

Tr., Vol. I, p. 471, LL. 18-25; p. 472, LL. 14-18.

The district court found that when a drug is "not indicated" for use in a pediatric patient, there was "universal agreement by all of the physicians who testified" that it could nonetheless be used in a pediatric patient because "not indicated" does **not** mean "contraindicated," and it certainly does not rise to the level of a "black box" warning—the strongest negative offered in the PDR. R., Vol. I, p. 118.

Because the sources relied upon by Dr. Hammer in formulating and offering his theories at trial were not supportive of his opinions and conclusions, or were otherwise proven to have been statistically insignificant, the district court determined that there was no substantial admissible evidence to support the jury's verdict that the long-term use of propofol was the proximate cause of Michael's death. R., Vol. I, p. 133. The district court also concluded that since there was **no reported data** in the medical field showing that propofol had **ever** caused death from cerebral edema alone without the other hallmark signs of PRIS, plaintiffs had failed to prove a breach of the local standard of care by Dr. Curnow in his use of propofol for

Michael's sedation. Absent these elements, the court felt compelled to grant the defendants' respective Motions for Judgment Notwithstanding the Verdict.

II. ISSUE PRESENTED ON APPEAL

1. Whether the district court correctly determined that plaintiffs failed to present admissible evidence that, to a reasonable degree of medical certainty, Dr. Curnow caused Michael Hall's death.

III. ADDITIONAL ISSUE PRESENTED ON APPEAL

1. Dr. Curnow is entitled to an award of attorney fees on appeal.

IV. ARGUMENT

The district court properly granted Dr. Curnow's Motion for Judgment Notwithstanding the Verdict. Although plaintiffs have submitted lengthy factual arguments calculated to sway the Court's sympathy, and the loss of a child is indeed a tragedy unlike any other, the simple and undisputed fact remains that at trial, plaintiffs' expert witness on both causation and the standard of care premised his opinions on scientific data that was unavailable at the time care was rendered. Even if the underlying scientific data had been available in June 2002, the research relied upon by plaintiffs' expert fails to establish a causal connection between long-term sedation with propofol and cerebral edema as the **sole cause of death**. There was no substantial evidence introduced at trial proving that the care rendered by Dr. Curnow caused Michael Hall's death, or that Dr. Curnow breached the local standard of health care practice as it existed in June 2002. Given the lack of evidence, entry of judgment n.o.v. was the appropriate remedy.

A. Standard of Review.

The function of I.R.C.P. 50(b) is "to give the trial court the last opportunity to order the judgment that the law requires." *Quick v. Crane*, 111 Idaho 759, 764, 727 P.2d 1187, 1192 (1986). In determining whether a judgment n.o.v. should have been granted, the Idaho appellate courts apply "the same standard as does the trial court which passed on the motion originally." *Quick*, 111 Idaho at 763, 727 P.2d at 1191. The question of whether a verdict should have been directed "is purely a question of law," and in such matters, the "parties are entitled to full review by the appellate court without special deference to the views of the trial court." *Id.* at 764. This Court is obligated to review the record of the trial below and determine if there was "substantial evidence to justify submitting the case to the jury." *Id.* The question is "not whether there is literally no evidence supporting the party against whom the motion is made, but whether there is substantial evidence upon which the jury could properly find a verdict for that party." *Quick*, 111 Idaho at 763 (citing *Mann v. Safeway Stores, Inc.*, 95 Idaho 732, 736, 518 P.2d 1194, 1198 (1974)).

B. Plaintiffs Failed at Trial To Present Substantial Evidence Proving That Dr Curnow's Care and Treatment of Michael Hall Was an Actual or Proximate Cause of His Death.

1. Plaintiffs' burden of proof.

A plaintiff in a medical malpractice action must establish both a breach of the applicable standard of care and that the breach was the proximate cause of the injury. *Sheridan v. St. Luke's Reg'l Med. Ctr.*, 135 Idaho 775, 25 P.3d 88 (2001). Proximate cause consists of two elements: actual cause and proximate cause, which is also referred to as "legal cause." *Newberry*

v. Martens, 142 Idaho 284, 288, 127 P.3d 187, 191 (2005). Actual cause is comprised of the factual question of "whether a particular event produced a particular consequence." *Id.* Proximate cause "focuses upon legal policy in terms of whether responsibility will be extended to the consequences of conduct which has occurred." *Munson v. State, Dep't of Highways*, 96 Idaho 529, 531, 531 P.2d 1174, 1176 (1975).

2. Evidentiary requirements for proving causation.

While there are statutory requirements expressly identifying the elements of duty and breach in a medical malpractice case, proximate cause in such cases "is governed by the rules of evidence regarding opinion testimony by lay witnesses and experts under Idaho Rules of Evidence 701 and 702." *Sheridan*, 135 Idaho at 785. Proximate cause can be shown either by direct evidence, or it may be shown "from a 'chain of circumstances from which the ultimate fact required to be established is reasonably and naturally inferable. *Id.* (citing *Formont v. Kircher*, 91 Idaho 290, 296, 420 P.2d 661, 667 (1965)).

Idaho Rule of Evidence 701 states:

> If the witness is not testifying as an expert, the testimony of the witness in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b) helpful to a clear understanding of the testimony of the witness or the determination of a fact in issue, **and (c) not based on scientific, technical or other specialized knowledge within the scope of Rule 702.**

(Emphasis added.)

Idaho Rule of Evidence 702 states:

> **If scientific, technical, or other specialized knowledge will assist the trier of fact** to understand the evidence or to determine a

> fact in issue, **a witness qualified as an expert** by knowledge, skill, experience, training, or education, **may testify thereto** in the form of an opinion or otherwise.

(Emphasis added.)

The Rules of Evidence recognize that when scientific or other specialized knowledge is necessary, it must come in the form of expert testimony. This Court has long held that there are instances where expert testimony is necessary in order to prove causation in a medical malpractice case. Concerning the *Sheridan* court's finding that proximate cause in a medical malpractice case could be inferred through a "chain of circumstances" this Court later explained:

> When doing so, we did not hold that expert testimony is never necessary in order to prove causation in a medical malpractice case. We simply held that expert testimony that the nurses' negligence was a proximate cause of the child's injuries was not required **under the facts of that particular case**.

Swallow v. Emergency Med. of Idaho, P.A., 138 Idaho 589, 596, 67 P.3d 68, 75 (2003) (emphasis added).

The clarification offered in *Swallow* confirmed the holding of this Court made some thirteen years earlier: namely, that the medical cause of injury or death is wholly scientific and therefore requires the testimony of a competent expert. *See, e.g., Evans v. Twin Falls County*, 118 Idaho 210, 214, 796 P.2d 87, 91 (1990). The rationale employed by the *Evans* court has been consistently applied in other cases as well. *See, e.g., Flowerdew v. Warner*, 90 Idaho 164, 172, 409 P.2d 110, 115 (1965) (lay opinion testimony is inadmissible to prove the cause of a plaintiff's condition); *Kolln v. St. Luke's Reg'l Med. Ctr.*, 130 Idaho 323, 329-30, 940 P.2d

1142, 1148-49 (1997) (holding that as a lay person, the plaintiff in a medical malpractice case was not competent to testify about the cause of her injury).

There can be no question (and indeed, plaintiffs have never disputed) that the issue of whether long-term sedation using propofol can cause death in children without the classic signs of PRIS is an issue that requires scientific or other specialized knowledge to assist the trier of fact in determining the facts in issue. Expert testimony was necessary in this case in order to establish a link between the use of propofol and Michael Hall's death.

3. Expert testimony, where required, must be reliable.

Having established that expert testimony is necessary on the issue of causation, the Court must then determine if there was substantial expert testimony introduced at trial that was sufficiently sound so as to be admissible. Idaho law precludes the introduction of expert opinions that are "speculative, conclusory, **or unsubstantiated by facts in the record,**" since any such testimony would be "of no assistance to the jury in rendering its verdict and, therefore, is inadmissible as evidence." *Bromley v. Garey*, 132 Idaho 807, 811, 979 P.2d 1165, 1169 (1999) (emphasis added). The admissibility of evidence is a threshold question left to the sound discretion of the district court. *See Weeks v. E. Idaho Health Servs.*, 143 Idaho 834, 838, 153 P.3d 1180, 1184 (2007). The trial court also has discretion to determine whether or not there is a scientific basis for an expert' opinions. *Swallow*, 138 Idaho at 592.

Judge Bail correctly noted that the Idaho appellate courts have "not fully adopted" the standard set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). R. Vol. I, 122. The Idaho appellate courts have, however,

"followed a similar analytical method and tested the expert testimony based upon factors which tended to show the reliability of the studies that underlay the expert opinion." *State v. Konechny*, 134 Idaho 410, 417-18, 3 P.3d 535, 542 (Ct. App. 2000). If the "reasoning or methodology underlying [an expert's] opinion is not scientifically sound, then the opinion will not assist the trier of fact to understand the evidence or determine a fact in issue." *Swallow*, 138 Idaho at 592. Under this paradigm, it is the trial judge's function to "distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs." *Konechny*, 134 Idaho at 417 (citing *Ryan v. Beisner*, 123 Idaho 42, 46, 844 P.2d 24, 28 (Ct. App. 1992)). To assist the trial court in this duty, "[t]he *Daubert* standards of whether the theory can be tested and whether it has been subjected to peer-review and publication have been applied. . . ." *See Weeks*, 143 Idaho at 838. The permitted application of these standards contains an inherent recognition that "[s]cientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry." *Daubert*, 509 U.S. at 593. Bearing these standards in mind, the evidence presented by plaintiffs at trial failed to meet the minimum requirements of reliability.

4. Plaintiffs' expert testimony was unreliable.

The district court noted that plaintiffs presented "no studies which point to the use of propofol causing death solely by cerebral edema in a young child who shows no other signs of PRIS." R., Vol. I, 125. There was ample testimony offered during trial which established that PRIS is routinely associated with certain "hallmark" signs, such as rhabdomyolysis, cardiac

bradycardia, refractory metabolic acidosis, hepatic steatosis and/or renal failure. *See, e.g.*, Tr., Vol. I, p. 478, L. 1 – p. 481, L. 14; p. 508, LL. 14-24 (Dr. Hammer), Tr., Vol. I, p. 1705, L. 25 – p. 1707, L. 6 (Dr. Reed), and Tr., Vol. I, p. 1312, L. 13 – p. 1314, L. 21 (Dr. Johnston). Plaintiffs' sole expert on causation, Dr. Hammer, repeatedly acknowledged that he was unaware of any correlation in the medical literature between the use of propofol and death caused exclusively by cerebral edema where none of the hallmark signs of PRIS were found. *See, e.g.*, Tr., Vol. I, p. 466, L. 20 – p. 467, L. 13; p. 563, LL. 5-22. Defense experts Dr. Michael Reed and Dr. Martin Johnston provided similar testimony. When asked if cerebral edema was described in **any** of the medical literature addressing PRIS, Dr. Reed stated that he had "**never** seen that." Tr., Vol. I, p. 1707, L. 25 – p. 1708, L. 3. Dr. Johnston was asked if, in his research into PRIS, he had found any articles that associated PRIS with **only** "a global ischemia of the brain," to which he answered "no." Tr., Vol. I, p. 1315, LL. 6-16.

Given the foregoing trial testimony, the district court aptly noted:

> **[T]his is not a case in which the scientific community is split** with some articles concluding that propofol can cause the type of harm experienced in this case and some articles disputing that conclusion. **There are no articles** in which it is proposed that long-term high dose use of propofol is fatal in children without the presence of some of the signs of PRIS.

R. Vol. I, p. 125 (emphasis added).

Despite the lack of any scientific support for his opinions in the medical literature, Dr. Hammer insisted that propofol was the cause of Michael Hall's fatal cerebral edema. Judge Bail observed that the sole bases for Dr. Hammer's opinions were excerpts from the 2002

Physicians' Desk Reference and a 2003 article published in the Italian journal, Intensive Care Medicine. *See* R., Vol. I, pp. 125-26.

a. Dr. Hammer's conclusion regarding oxygen utilization is contrary to the article upon which it was allegedly based.

As noted above, Dr. Hammer's theory of causation was that the propofol administered to Michael contributed to an unsafe drop in blood pressure, which in turn decreased the blood flow to vital organs, thereby decreasing energy production from the mitochondrion, ultimately resulting in diminished oxygen delivery to the brain that caused fatal cerebral edema. *See* Tr., Vol. I, p. 355, L. 7 – p. 356, L. 3; p. 365, LL. 2-20. Dr. Hammer concluded that these factors then caused "lethal organ injury, including brain injury" (Tr., Vol. I, p. 356, LL. 15-17) and/or "multi-organ injury" (*id.*, p. 366, LL. 19-22). He thereby conceded that propofol-related death necessarily involves multiple organ injury, but in his efforts to "avoid" the PRIS factors absent in Michael Hall (Tr., Vol. I, p. 464, L. 17), he continued to maintain that the use of propofol was itself capable of causing fatal cerebral edema **without any other signs of organ injury**.

The article chosen by Dr. Hammer to support his conclusion was published on August 6, 2003, in an apparent effort to "crystalize a central hypothesis" for what was causing PRIS (*see* Tr., Vol. I, p. 1720, LL. 12-13) and theorized that one of the "key pathogenetic mechanism[s]" was the "imbalance between energy demand and utilization." R., Vol. I, p. 126. From this discussion of the imbalance between energy demand and utilization, Dr. Hammer

determined that propofol resulted in cellular toxicity due to its "effect on [the] mitochondrion." Tr., Vol. I, p. 365, LL. 16-20.

Even though the oxygen utilization theory espoused by Dr. Hammer originated in the Italian study, when that study is viewed in its full context, it is clear that it does not support Dr. Hammer's opinions. The article concludes instead that "**cardiac and peripheral muscle necrosis**" are the result of the decreased mitochondrial activity, **not** cerebral edema resulting in death. R., Vol. I, p. 126 (emphasis added). The finding of "cardiac and peripheral muscle necrosis" was classified by the study's authors as a "critical illness **cardiac failure** and **rhabdomyolysis**." *Id.* (emphasis added). The Italian study implicitly acknowledged that even if oxygen utilization is the operative mechanism for injury, the end result nevertheless **must include** the "hallmark" signs of rhabdomyolysis and cardiac failure. The evidence presented at trial **unequivocally** established that neither cardiac nor peripheral muscle necrosis were present in Michael Hall. Dr. Reichard testified that he specifically looked at the pathological evidence, including heart and muscle tissue that even Dr. Groben had not seen and noted that there were no signs of rhabdomyolysis. Tr., Vol. I, p. 1251, LL. 9-20; p. 1256, LL. 4-18; p. 1259, L. 25 – p. 1260, L. 13. Given the conclusion that cardiac and peripheral muscle necrosis—and **not** cerebral edema—are the direct result of decreased mitochondrial activity, the article upon which Dr. Hammer chiefly relied at trial does not support his conclusion that the administration of propofol caused Michael's death by cerebral edema alone, without any other signs of PRIS.

b. The study referenced in the 2002 PDR, upon which Dr. Hammer further based his opinions, was shown at trial by its author to be statistically insignificant in establishing causation.

In addition to the 2003 Italian journal, Dr. Hammer's opinions were founded on a multi-clinic study referred to in the 2002 PDR. Tr., Vol. I, p. 318, LL. 19-21; p. 443, LL. 11-14. The 2002 PDR entry was admitted as an exhibit at trial and was exhaustively addressed by witnesses for all parties. The passage cited most regularly by Dr. Hammer in support of his claim that propofol was the proximate cause of death read as follows:

> There have been anecdotal reports of serious adverse events and death in pediatric patients with upper respiratory infections receiving [propofol] for ICU sedation.
>
> In one multicenter clinical trial of ICU sedation in critically ill pediatric patients that excluded patients with upper respiratory tract infections, the incidence of mortality observed in patients who received [propofol] was 9% while that for patients who received standard sedative agents was 4%. While **causality has not been established**, [propofol] is not indicated for sedation in pediatric patients until further studies have been performed to document its safety in that population.

R., Vol. I, pp. 126-27 (emphasis added).

Dr. Curnow presented expert testimony at trial from Dr. Reed, whose qualifications in the field of propofol study as set forth above are second to none and who was the principal designer and author of the study referenced in the 2002 PDR. Tr., Vol. I, p. 1695, LL. 1-9; p. 1703, L. 19 – p. 1704, L. 8. Dr. Reed not only testified that the multi-center clinical trial did not show any statistical significance between the use of propofol and pediatric mortality, but he also stated that in **none** of the patients who died following administration of propofol was

cerebral edema the **only** finding. Tr., Vol. I, p. 1704, LL. 14-19; p. 1707, LL. 3-6, 18-20. In fact, cerebral edema was not described in **any** of the referenced case studies. Tr., Vol. I, p. 1707, LL. 20-21.

5. Idaho law does not allow speculative or unsupported opinions.

The lack of any statistical or other clinical correlation between the administration of propofol and patient death, where cerebral edema was the only finding, is significant. The court in *Bromley, supra*, plainly held that expert opinions that are "unsubstantiated by the facts in the record" are of "no assistance to the jury in rendering its verdict." *Bromley*, 132 Idaho at 811. This Court has also expressly rejected the notion that causation can be established solely by a temporal relation between the use of a particular drug and an adverse health consequence. *See Swallow*, 138 Idaho at 597. As the *Swallow* court established, whether or not the taking of a drug causes injury "is a matter of science that is far removed from the usual and ordinary experience of the average person." *Id.* at 598. Thus, "without the assistance of expert testimony establishing that [propofol] can cause [death due to cerebral edema alone], any finding in that regard would be based upon speculation." *Id.* The foundation required for admission of opinion testimony based on scientific knowledge "includes both that the witness is an expert in the field **and that there is a scientific basis for the expert's opinion.**" *Id.* at 593 (citing *State v. Gleason*, 123 Idaho 62, 844 P.2d 691 (1992)) (emphasis added). As a part of its gate-keeping role in deciding if a proper foundation has been laid for the admission of opinion evidence, the trial court "has discretion to determine both whether the expert is qualified as an expert in the field **and whether there is a scientific basis for the expert's opinion.**" *Id.* The scientific basis

needed for admission of an expert's opinion has been held to include whether the underlying data was "statistically significant." *See Swallow*, 138 Idaho at 594. The *Swallow* court upheld the district court's exclusion of expert testimony where the plaintiff's expert failed to show "what percentage of Cipro patients [were] represented [and where] there [was not] any showing that [those] events were **statistically significant**." *Id.* [4] (emphasis added).

Even though Dr. Hammer failed to present a reliable scientific basis for his opinions, the district court acknowledged that there were still circumstances in which his testimony could have been admissible. Referring to the rationale adopted by the Ninth Circuit, Judge Bail observed that "if there are few opportunities for scholarly research and the scientific basis of the testimony was the use of a differential diagnosis in which all hypotheses which might explain a patient's symptoms or mortality were identified," the testimony might still be allowed. R., Vol. I, p. 129 (citing *Clausen v. M/V New Carissa*, 339 F.3d 1049 (9th Cir. 2003)). Dr. Hammer clearly established that he did **not** employ a differential diagnostic approach, in that he neither discussed nor ruled out any alternative possible causes for Michael's death. He also testified that he did not make **any** study of PRIS in connection with his opinions in this matter or otherwise. Tr., Vol. I, p. 464, LL. 15-20. Dr. Hammer said that he "tried to avoid" PRIS altogether (Tr., Vol. I, p. 464, L. 17), and instead relied entirely upon excerpted portions of the 2003 Italian study and the multi-center study referenced in the 2002 PDR. As discussed more

[4] Defendants objected, upon multiple bases, to the admissibility of Dr. Hammer's testimony. Tr., Vol. I, p. 410, LL. 13-17; Augmented Record, Ex. 11; Augmented Record, Ex. 12.

fully in Section IV.B.4, *supra*, neither of those studies support Dr. Hammer's opinions. According to the district court, "[a]ll that has been shown based upon the evidence submitted in this case is that there is an *association* between the use of propofol for long term sedation in children and a few cases showing that it could possibly be linked to cardiac failure, rhabdomyolysis, severe metabolic acidosis and renal failure." R., Vol. I, p. 130 (emphasis in original). However, "[t]here are no studies at all which show that long term use of propofol is even associated with cerebral edema as the sole cause of death." *Id.* A mere association is not sufficient to establish proximate cause. *See Swallow*, 138 Idaho at 597 (citing *Blocking v. Albertson's, Inc.*, 129 Idaho 844, 847, 934 P.2d 17, 20 (1997) ("The temporal relationship between the taking of the insulin blend and the onset of more frequent and severe seizures was not sufficient to prove causation").

6. Conclusion re: causation.

The entirety of the evidence introduced at trial established that while there have been unspecified coincidences between the long-term use of propofol in pediatric patients and death, in every reported study, such deaths were marked by rhabdomyolysis, cardiac arrhythmia/bradycardia, refractory metabolic acidosis, hepatic steatosis and/or renal failure. *See, e.g.*, Tr., Vol. I, p. 478, L. 1 – p. 481, L. 14; p. 508, LL. 14-24; p. 1705, L. 25 – p. 1707, L. 6; and p. 1312, L. 13 – p. 1314, L. 21. There was considerable trial testimony establishing that **none** of these symptoms were found in Michael Hall. Dr. Groben, the forensic pathologist offered by plaintiffs, testified at length regarding the physical systems he examined at autopsy, including the entire cardiovascular, pulmonary, gastrointestinal, genito-urinary, hematopoietic, endocrine

and central nervous systems. Tr., Vol., I, p. 178, LL. 2-25. After gross and hematologic examination of these systems, he found nothing wrong with any organ other than Michael's brain. *Id.*, p. 179, LL. 8-12; p. 202, L. 25 – p. 207, L. 6. Dr. Groben further testified regarding Michael's death as follows:

> Q. All right. Bottom line, Doctor, even though you had researched Propofol, it had been brought to your attention, even though you looked for the effects of it and learned about Propofol Infusion Syndrome, you cannot testify to a reasonable degree of medical certainty that Propofol caused the death, can you Doctor?
>
> A. Propofol itself? No, I cannot.

Tr., Vol. I, p. 209, LL. 2-9. Dr. Reichard added to the testimony of Dr. Groben and the lack of any findings associated with propofol:

> Q. Okay. Based on your review of the literature, did you feel that you had knowledge of what to look for in determining whether Propofol Infusion Syndrome played a role in the death of Michael Hall, the young man whose medical records and tissue slides were sent to you?
>
> A. Yes.
>
> Q. Okay. Can you explain to the jury what you were looking for, based upon your independent review of the literature?
>
> A. Well, I mean, you are looking to integrate both the clinical and the autopsy findings. And so Propofol or Propofol-related Infusion Syndrome has certain hallmark features, including irreversible or refractory metabolic acidosis, or where your blood gets – the PH of your blood is lowered.
>
> Clinically they might have low heart rate, or bradycardia and, ultimately, they will have necrosis or death of their skeletal muscle. And they can also have changes in their heart muscle which, obviously, correlate with the low heart rate and other changes.

Tr., Vol. I, p. 1254, L. 25 – p. 1255, L. 22. Upon noting these factors, Dr. Reichard specifically found no necrosis of the skeletal muscle tissue (Tr., Vol. I, p. 1256, LL. 7-18), no steatosis (fatty buildup) in the liver (*id.*, p. 1256, LL. 19-21), no myocytolysis, or, necrosis of the cells in the heart muscle (*id.*, p. 1256, L. 22 – p. 1257, L. 1), and no evidence of renal failure (*id.*, p. 1269, L. 20 – p. 1270, L. 6). The only significant findings in the autopsy were "the changes in the brain that demonstrate a lack of blood or oxygen to the brain, and then the important negative findings were the normal organs." Tr., Vol. I, p. 1271, LL. 7-21.

The district court was correct in concluding that there was "not substantial evidence to support the jury's verdict that the long term use of propofol was the proximate cause of Michael Hall's death," which was ultimately caused by cerebral edema and no other modality (R., Vol. I, p. 133), and the judgment N.O.V. should be affirmed.

C. Plaintiffs Failed To Present Substantial Evidence at Trial That Dr. Curnow Breached the Applicable Standard of Health Care Practice at the Time That Care Was Provided.

1. Idaho law requires expert testimony to establish that a physician breached the local standard of health care practice.

A plaintiff in a medical malpractice case must also prove, as part of his or her case in chief, that the defendant physician failed to meet the standard of care owed by like practitioners. The prerequisites for admission of testimony establishing a breach of such duty are set forth at Idaho Code Sections 6-1012 and 6-1013. Section 6-1013 requires that any testimony regarding the standard of care must be offered through a competent expert witness. An expert testifying about the standard of care must show that he is familiar with the standard for a

particular health care professional for the relevant community **during the relevant time frame.**

See Kolln v. St. Luke's Reg'l Med. Ctr., 130 Idaho 323, 331, 940 P.2d 1142, 1150 (1997).

Idaho Code Section 6-1012 provides:

> **6-1012. Proof of community standard of health care practice in malpractice case.** In any case, claim or action for damages due to injury to or death of any person, brought against any physician and surgeon or other provider of health care . . . on account of the provision of or failure to provide health care or on account of any matter incidental or related thereto, such claimant or plaintiff must, as an essential part of his or her case in chief, affirmatively prove by direct expert testimony and by a preponderance of all the competent evidence, **that such defendant then and there negligently failed to meet the applicable standard of health care practice of the community in which such care allegedly was or should have been provided, as such standard existed at the time and place of the alleged negligence of such physician and surgeon, hospital or other such health care provider and as such standard then and there existed with respect to the class of health care provider that such defendant then and there belonged to and in which capacity he, she or it was functioning.** Such individual providers of health care shall be judged in such cases in comparison with similarly trained and qualified providers of the same class in the same community, taking into account his or her training, experience, and fields of medical specialization, if any. If there be no other like provider in the community and the standard of practice is therefore indeterminable, evidence of such standard in similar Idaho communities at said time may be considered. As used in this act, the term "community" refers to that geographical area ordinarily served by the licensed general hospital at or nearest to which such care was or allegedly should have been provided.

(Emphasis added.)

As defined by the statute, "the term 'community' refers to that geographical area ordinarily served by the licensed general hospital at or nearest to which such care was or

allegedly should have been provided." *Id.* A testifying expert must have "**actual knowledge of the applicable said community standard.**" IDAHO CODE § 6-1013 (emphasis added). However, "**statements that are conclusory in nature**" do not satisfy the requirement of admissibility or competency. *See Ramos v. Dixon*, 144 Idaho 32, 156 P.3d 533, 536 (2007) (emphasis added). Where the expert does not possess **actual knowledge** of the applicable standard, the witness **is not competent** to testify regarding the applicable standard of care. In addition to demonstrating personal knowledge of the local community standard of health care practice, the standard of care for physicians is evaluated based upon what the practitioner knew or should have known **at the time the care was rendered.** IDAHO CODE § 6-1012. This Court has previously held that in light of Idaho Code Section 6-1012, the medical malpractice statute "is both **site and time specific.**" *Gubler v. Boe*, 120 Idaho 294, 296, 815 P.2d 1034, 1036 (1991).

At the time of Michael's treatment, Dr. Curnow was one of only two pediatric surgeons in Idaho. Given the professional association between Dr. Curnow and Dr. Ellen Reynolds, the other pediatric surgeon in defendant's office, both doctors were properly treated as a single provider under the statute. *See Hoene v. Barnes*, 121 Idaho 752, 754, 828 P.2d 315, 317 (1992). As such, the standard of health care practice in the community served by these doctors would be indeterminable, thereby allowing the plaintiffs' experts to look at similar localities or communities outside the state. *Id.* at 756, 828 P.2d at 319.

2. Dr. Curnow demonstrated knowledge of and compliance with the standard of care for long-term use of propofol in June 2002.

Plaintiffs retained an anesthesiologist from Palo Alto, California, Dr. Gregory Hammer, who stressed the standard of care required a physician to be familiar with the properties of medications ordered for patients. Tr., Vol. I, 349:8-12. Upon cross-examination by plaintiffs' counsel, Dr. Curnow testified that prior to his care and treatment of Michael Hall, he had personal knowledge of the properties of propofol in both short- and long-term sedation of pediatric patients. Tr., Vol. I, p. 1942, L. 7 – p. 1943, L. 2. Dr. Curnow had testified earlier that he had specific experience with the administration of propofol in the pediatric ICU setting for a period of at least 36 to 48 hours. Tr., Vol. I, p. 1838, LL. 5-17. He also testified that in 2002, he knew what was then contained in the medical literature regarding PRIS. Tr., Vol. I, p. 1996, LL. 14-24. Dr. Curnow agreed that when using propofol, the physician needs to monitor carefully for known side effects, and that he did in fact provide careful monitoring in this case. Tr., Vol. I, p. 1943, LL. 14-17. For example, he stated that because propofol was administered in a fatty emulsion, additional care needed to be taken in order to account for lipid metabolism. Tr., Vol. I, p. 1838, L. 20 – p. 1839, L. 5. Dr. Curnow then provided extensive testimony concerning the specific care taken in this regard with Michael. Tr., Vol. I, p. 1850, L. 24 – p. 1851, L. 17.

a. The scientific data regarding PRIS in June, 2002 made no mention of cerebral edema or deficiencies in oxygen utilization as potential causes of death.

It should also be noted that there was no evidence introduced at trial establishing that propofol actually causes PRIS. Instead, the evidence put forth by the parties suggested, at most, that there is a coincidental association between long-term sedation using propofol and the

constellation of symptoms known as PRIS. According to Dr. Hammer, because PRIS is a "syndrome," it is by very definition incapable of being tied to any causal nexus. *See* Tr., Vol. I, p. 476, L. 15 – p. 477, L. 3. Dr. Hammer described what he agreed were the "hallmarks" of PRIS, including: rhabdomyolysis (Tr., Vol. I, p. 478, L. 19 – p. 479, L. 3); refractory metabolic acidosis (*id.*, p. 480, L. 1 – p. 481, L. 14); lipemia associated with propofol (*id.*, p. 508, LL. 7-13); and bradycardia (*id.*, p. 508, LL. 14-21). Perhaps more significant was Dr. Hammer's acknowledgment that the 2003 article that formed the primary basis for his opinions at trial referred to PRIS as "a rare and often fatal syndrome" where "severe metabolic acidosis, rhabdomyolysis, renal failure, and fatal cardiac failure are the features." Tr., Vol. I, p. 518, LL. 1-12. Conspicuously absent from the list of "features" of PRIS in the 2003 article chosen by Dr. Hammer is any mention of cerebral edema. Michael Hall had **none** of the findings identified in the 2003 article.

After acknowledging this list of PRIS' "features," Dr. Hammer was asked at length if any of those features had been found in Michael Hall. He testified that according to the autopsy report submitted by plaintiffs, Michael's liver was normal (Tr., Vol. I, p. 520, LL. 24-25), there was no rhabdomyolysis (*id.*, p. 521, LL. 1-5), there was no cardiomyopathy or cardiac damage (*id.*, p. 521, LL. 20-25), and no metabolic acidosis (*id.*, p. 523, L. 25 – p. 524, L. 2). Dr. Groben, called by plaintiffs as a testifying expert, also established that none of the "features" described in the 2003 article were present in Michael. For example, he testified that all of Michael's organs were of normal weight, that he had no liver damage, no damage to the kidneys,

no rhabdomyolysis, and that Michael's low albumin was what would be expected in a child who had received fluids and lost a lot of blood. Tr., Vol. I, p. 203, L. 17 – p. 207, L. 6.

b. Dr. Curnow was familiar with all known risks associated with PRIS when he cared for Michael Hall in 2002.

While there was substantial evidence offered at trial concerning (1) PRIS and its hallmark signs as of June 2002; (2) Dr. Curnow's familiarity with PRIS in June 2002; and (3) the prevailing concerns over the use of propofol in pediatric patients at that time, there was no evidence whatsoever establishing a risk of cerebral edema after prolonged use without the other indications of PRIS. The evidence relied upon by Dr. Hammer was either non-existent in June 2002, or had otherwise proven to be "statistically insignificant" in terms of establishing a causal link between the use of propofol for long-term sedation of pediatric patients in the ICU setting and patient mortality. The Italian study chiefly used by Dr. Hammer was not published until August 2003. There was no evidence at trial establishing that the standard of care for the administration of propofol in Boise, Idaho in June 2002 included a need to monitor mitochondrial activity or the alleged oxygen utilization theory introduced by Dr. Hammer. The only other support for Dr. Hammer's opinions, as discussed more fully above, was the 2002 PDR and its reference to the "multi-center study" designed by Dr. Reed, who testified that the results of that study were statistically insignificant in correlating the use of propofol and mortality. Tr., Vol. I, p. 1704, LL. 14-19.

Plaintiffs introduced **no evidence** at trial establishing that in June 2002 there were **any studies** linking the long-term administration of propofol to cerebral edema. Dr. Michael

Reed testified that he had never seen cerebral edema described in any literature discussing PRIS. Tr., Vol. I, p. 1707, L. 25 – p. 1708, L. 3. Dr. Martin Johnston testified that in all of his research into propofol and PRIS, he had never found any articles that associate PRIS with any global ischemic events, including cerebral edema. Tr., Vol. I, p. 1315, LL. 6-16. More importantly, however, plaintiffs' own expert testified that he was not aware of any articles correlating the long-term use of propofol for sedation in pediatric patients with cerebral edema resulting in death. Tr., Vol. I, p. 466, L. 20 – p. 467, L. 13. While Dr. Hammer attempted to qualify that testimony, opining that he "imagined" that some patients would have had cerebral edema, that effort was couched in terms that were entirely speculative, and he stated that he could not recall any such findings in the published reports. Tr., Vol. I, p. 467, LL. 16-18.

By way of contrast, Dr. Curnow provided considerable testimony concerning his monitoring of Michael Hall:

> Q. And when you say that you monitor the patient very closely, what does "monitor" mean in your mind?
>
> A. This child was on a continuous heart monitor. He was on a blood pressure monitor that was taking his blood pressure every three to five minutes automatically.
>
> He was on a pulse oximeter, monitoring his oxygen level in his blood. He was having blood tests drawn to monitor his bleeding so that he could get replacement of his blood and blood products with his bleeding, and he had laboratory tests that monitored his acid level in his body as far as the bicarbonate in his body.

Tr., Vol. I, p. 1043, L. 18 – p. 1044, L. 6. Dr. Curnow provided ample testimony elsewhere about the hemodynamic monitoring of Michael's condition, including serum samples to monitor

for lipemia, complete blood counts, placement and monitoring of a central line, additional CBC and Chem-7 blood panels at regular intervals, urine output and blood gases, bicarbonates, monitoring and treatment of metabolic acidosis, cardiac monitoring and pulse oximeters, and regular blood pressures. *See generally* Tr., Vol. I, pp. 1870-94.

3. The district court correctly found no breach by Dr. Curnow of the local standard of health care practice.

After hearing all of the evidence, the district court noted that the "defendant physicians were monitoring Michael for signs of the only known risks associated with propofol at the time care was rendered, which was PRIS." R., Vol. I, p. 136. Even if Dr. Hammer's conclusion that cellular toxicity caused cerebral edema in Michael Hall without any other signs of PRIS is assumed to be correct, the physicians' conduct must still be judged within the standard of care that existed in June 2002. Dr. Hammer's opinions were, according to the district court, "based upon extrapolation from research which was reported" in August 2003—over one year after the care in this case was rendered. *See id.* Evidence seeking to establish a violation of the standard of care owed by a physician based upon subsequently developed information is impermissible under Idaho Code Section 6-1012 and the decisions of this Court which long predated that statute. This Court held nearly one hundred years ago that "a physician or surgeon is bound to exercise such reasonable care and skill as is possessed and exercised by physicians and surgeons generally in good standing of the same system or school of practice or treatment in the locality and community of his practice, **having due regard to the advanced state of the school or science of treatment at the time of such treatment.**" *State v. Smith*, 25 Idaho 541,

550, 138 p. 1107, 1109 (1914) (emphasis added). The requirement that the standard of care also include the state of science in existence at the time of treatment was codified at Idaho Code Section 6-1012 in 1976 and has repeatedly been upheld by this Court since.

Plaintiffs in this case failed to establish at trial that the defendants breached the local standard of health care practice as it existed in June 2002. The expert testimony offered by plaintiffs was premised upon scientific data that did not exist at the time care was rendered and upon scientific studies that were expressly deemed to be of no statistical significance in correlating long-term sedation with propofol and mortality. Because plaintiffs failed to offer competent expert testimony establishing a breach of the standard of care as it existed in June 2002, they failed to establish a necessary part of their case at trial, and the judgment n.o.v. should be affirmed.

V. ATTORNEY FEES ON APPEAL

Respondent requests attorney fees on appeal pursuant to Rules 35 and 41, Idaho Appellate Rules, and Idaho Code Section 12-121. Under Idaho law, attorney fees may be awarded on appeal pursuant to Idaho Code Section 12-121 if the "Court is left with the abiding belief that the appeal was brought or pursued frivolously, unreasonably, and without foundation." *See Rowley v. Fuhrman*, 135 Idaho 105, 110, 982 P.2d 940 (1999). This Court has long held that attorney fees "are awardable if an appeal does no more than simply invite an appellate court to second-guess the trial court on conflicting evidence, or if the law is well settled and appellant has made no substantial showing that the district court misapplied the law." *Johnson v. Edwards*, 113 Idaho 660, 662, 747 P.2d 69 (1987). When a "dispassionate view of

the record discloses that there is no valid reason to anticipate reversal of the judgment below," attorney fees should be awarded. *Rueth v. State*, 103 Idaho 74, 81, 644 P.2d 1333 (1982).

In this case, plaintiffs have simply asked this Court to re-evaluate the evidence or second-guess the district court's well-reasoned decision granting defendant's motion for judgment n.o.v. No substantial legal argument has been presented, and defendant should be awarded attorney fees on appeal.

VI. CONCLUSION

For the foregoing reasons, respondent respectfully requests this Court to affirm the district court's entry of judgment in favor of Dr. Curnow and award defendant his attorney fees on appeal.

DATED this 23rd day of January, 2009.

MOFFATT, THOMAS, BARRETT, ROCK & FIELDS, CHARTERED

By _____
Patricia M. Olsson – Of the Firm
Attorneys for Respondent
Adrian Curnow, M.D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 23rd day of January, 2009, I caused a true and correct copy of the foregoing **RESPONDENT'S BRIEF** to be served by the method indicated below, and addressed to the following:

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IN THE SUPREME COURT OF THE STATE OF IDAHO

MELINDA COOMBS, natural mother of Michael Hall, deceased, and the ESTATE OF MICHAEL HALL, as represented by Melinda Coombs, personal representative,

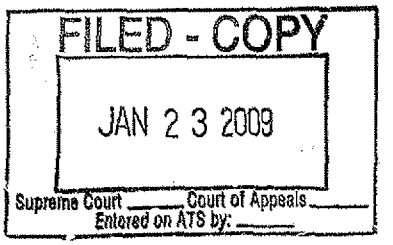
Plaintiffs/Appellants,

vs.

ADRIAN CURNOW, M.D., and RUSSELL GRIFFITHS, M.D.,

Defendants/Respondents.

Supreme Court No. 35157



RESPONDENT'S BRIEF

Appeal from the District Court of the Fourth Judicial District of the State of Idaho in and for the County of Ada

Honorable Deborah A. Bail, presiding

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I. STATEMENT OF THE CASE

A. Nature of the Case.

This case arises from the tragic and unfortunate death of a young three-year-old boy, Michael Hall. Michael was attacked by a dog which caused a los of most of the left side of Michael's face. The bitten off tissue was retrieved and taken with Michael to St. Alphonsus Regional Medical Center ("SARMC"). Michael was taken by ambulance to SARMC and admitted to the Trauma Service and subsequently underwent plastic surgery to reattach the retrieved tissue, performed by a pediatric plastic surgeon, Dr. Russell Griffiths, who had been called in to assist the primary care providers. After surgery, Michael was cared for in the intensive care unit, but subsequently, the reattachment failed and Dr. Griffiths was no longer providing care. Two days following the failure of the tissue reattachment, Michael Hall died.

This matter dealt with the medical care and treatment provided to Michael Hall and his subsequent death at SARMC.

B. Course of Proceedings.

1.	12/17/04	Complaint filed.
2.	9/21/06-3/28/08	Defendants' multiple motions for summary judgment and to strike Affidavit of Gregory B. Hammer, M.C.
3.	3/1/07	Judge Deborah Bail is assigned to case
4.	9/4/07	Jury Trial Commences
5.	9/19/07	Jury Verdict
6.	9/19/07	Oral Motions for JNOV

7.	9/28/07	Defendants' Motions for Judgment Notwithstanding the Verdict
8.	1/23/08	Oral argument for Motion for JNOV
9.	3/28/08	Decision and Order Re: Motions for JNOV
10.	3/31/08	Appeal filed
11.	4/16/08	Memorandum of Costs
12.	5/14/08	Oral argument for costs
13.	6/19/08	Amended Judgment

C. Statement of Facts.

1. Admitted Evidence of the Medical Care and Treatment of Michael Hall.

This case was filed by Melinda Coombs, the mother of Michael Hall, who died as a result of a horrific dog bite which severed most of the left side of his face. R. Vol. I, p. 112. At the time of the attack, June 22, 2002, Michael was almost three years old and was attending an outdoor party at a family member's home. R., Vol. 1, p. 112. The family who hosted the party had a dog. *Id.* During the party, Michael was carrying a bowl of potato chips and was feeding the dog chips from the bowl. *Id.* At one point, Michael spilled some chips onto the ground and Michael and the dog went for the chips at the same time, which resulted in injury to Michael's face, which amputated a large portion of the left side of Michael's face. Tr., Vol. I, p. 1061, L. 23 – p. 1063, L. 22. Following the injury, Michael was transported by ambulance in serious condition to the trauma hospital for Boise, SARMC. R. Vol. I, p. 112.

Upon arrival at the hospital, Michael was admitted to the trauma service. R., Vol 1, p. 113, Tr., Vol. 1, p. 1065, L. 14 – p. 1067, L. 7; p. 1839, L. 7 - p. 1840, L. 6. Someone in the

family brought the severed facial tissue to the hospital. R., Vol. I, p. 113; Tr., Vol. I, p. 1065, L. 14 – p. 1067, L. 7; p. 1839, L. 7 – p. 1840, L. 6. That day, Dr. Adrian Curnow was on call for pediatric trauma and assumed the role of Michael's primary physician. Tr., Vol 1, p. 707, L. 7 – p. 708, L. 18; p. 713, L. 24 – p. 714, L. 15; Tr., Vol. II, p. 1866, 1981, L. 14 to 1982, L. 19. Dr. Curnow and his partner, Dr. Ellen Reynolds, were the only pediatric surgeons in Idaho. R. Vol. I, p. 113. They filled the duties of pediatric intensivists and had the trauma contract for pediatrics at SARMC. Tr., Vol. I, p. 1065, L. 14 – p. 1067, L. 4; p. 1839, L. 7 – p. 1840, L. 1.

After Dr. Curnow evaluated the severity of the wound and the volume of tissue severed, he determined that he could not perform the necessary surgery. Tr., Vol. I, p. 1061, L. 20 – p. 1064, L. 10. Dr. Curnow gave Michael's mother the option of having Michael transferred to Salt Lake City, or he could try to locate Dr. Russell Griffiths, a Boise pediatric craniofacial plastic surgeon. Mrs. Coombs chose to keep Michael in Boise at SARMC, if Dr. Griffiths, who was off duty at the time, was located and agreed to perform the surgery. *Id.*

At the time of Michael's admission to SARMC, Dr. Griffiths and his family were boating on Lucky Peak. Tr., Vol. I, p. 1113, LL. 7–24. After notification, using a pay phone, Dr. Griffiths called in and agreed to examine Michael. *Id.* At the time of the call, Dr. Griffiths informed the hospital that before he would be in he needed to take his family home. *Id.*

When Dr. Griffiths reached the hospital, he went directly to Michael's room and met with Michael, Mrs. Coombs, Kenneth Coombs, and other family members. Tr., Vol. I., p. 1114, L 3 – p. 1117, L. 13. Dr. Griffiths examined the wound, trauma, and severed tissue. Tr., Vol. I, p. 1113, L. 25 – p. 1114, L. 9; p. 1115, LL. 18-20. He also discussed the situation at

length with Michael's mother and her husband, Kenneth Coombs. Tr., Vol. I, p. 591, L. 8 – p. 592, L. 15. Dr. Griffiths told them that they had a number of options. They could do nothing to the wound except supportive care and allow the wound to heal, however, that would leave the left side of Michael's face severely scarred and disfigured, Tr., Vol. I, p. 1114, L. 15 – p. 1116, L. 19; or, after healing had occurred, they could re-build the left side of Michael's face which would take multiple surgeries, but this option would also look disfigured, *Id.*; or, they could attempt a reattachment of the severed tissue, which would require a delicate exploration of the severed tissue and wound to discern whether any vessels could be located and if located, the surgery could go forward to reattach the tissue. This alternative was not guaranteed, but would decrease the number of surgeries necessary and would save Michael's natural face. *Id.* Both re-building/reattachment alternatives would require post operative and a long-term sedative to keep Michael completely still to avoid any facial, head or neck movement, or disruption of the tissue. *Id.* The sedation would also require that a ventilator be used to breath for Michael. *Id.*
Dr. Griffiths explained that the mere re-building option would require multiple surgeries, sedatives, and ventilator support, but if the free/severed tissue could be reattached that could be done in this one setting and avoid the multiple surgeries required by the other option. *Id.*

Dr. Griffiths explained as part of his informed consent that the re-building options both included the risk of death. Tr., Vol. I, p. 1139, L. 12 – p. 1140, L. 12. Knowing all the risks to include death, Mrs. Coombs chose to have Dr. Griffiths try to reattach the severed tissue. Tr., Vol. I, p. 1117, LL. 3–13. The anesthesiologist, Dr. Smagula, was present for the informed consent. Tr., Vol. I, p. 1117, L. 14 – p. 1118, L. 4.

Dr. Griffiths then proceeded to the O.R. with Michael, explored the tissue and the wound and found one artery but no vein. Tr., Vol. I, p. 1118, L. 5 – p. 1121, L. 1. Vessels retract when there is a tearing of the tissue because of a severe dog bite, the tissues and vessels do not have a clean cut, but rather are knurled, twisted, and torn. Tr., Vol. I, p. 1063, LL. 9 – 22; Tr., Vol. II, p. 2170, L. 18 – p. 2171, L. 8.

After Dr. Griffiths had microscopically explored the tissues, he called Michael's mother from the O.R. to inform her of his findings. Tr., Vol. I, p. 1121, L. 22 – p. 1127, L. 5. Dr. Griffiths told Mrs. Coombs that he had found only one artery, and no vein, therefore, the risks of this reattachment had increased. *Id.* Not only was there greater risk of failure, but there was also a greater risk to Michael's overall well being, because since there was no vein to reattach, the blood that was delivered to the graft would not have a vein to remove the used blood from the graft. *Id.* This inability, if not provided for, would cause the graft to engorge, vessels would block, and the graft would quickly fail. *Id.* To avoid engorgement and vascular blockage, he would use medical leeches and heparin. *Id.* Use of heparin and medical leeches would cause an ongoing loss of blood and would require ongoing replacement transfusions. *Id.*

After Dr. Griffiths explained all of the risks, to include death, the procedures, and care needed, and while still in the operating room, he asked Mrs. Coombs if she wanted him to go forward with surgery and attempt the reattachment. Tr., Vol. I, p. 1123, L. 9 – p. 1127, L. 5; p. 1139, L. 12 – p. 1140, L. 12. The full O.R. crew, to include Dr. Smagula, heard this conversation on the speaker phone, including the explanation of the risks. *Id.* After Dr. Griffiths received Mrs. Coombs' informed consent, he proceeded with the lengthy microsurgery. *Id.*

By the time Dr. Griffiths had completed the reattachment surgery, it was after 3:00 a.m. and Drs. Griffiths and Smagula were Michael's only doctors present, therefore, Dr. Griffiths needed to write a bridging order to get Michael admitted to ICU. Tr., Vol. I, p. 1128, L. 14 – p. 1131, L. 2; p. 1131, L. 15 – p. 1133, L. 19. This bridging order would cover Michael's care until Drs. Curnow or Reynolds arrived. As part of the bridging order, he needed to order sedation, and at that time, Dr. Griffiths turned to Dr. Smagula for recommendation. Tr., Vol. I., p. 1117, LL. 14–24; Tr. Vol. II, p. 2174, L. 23 – p. 2175, L. 11. During the operation, Dr. Griffiths had discussed with everyone in the O.R. the care that Michael would require in ICU. Tr., Vol. I, p. 1132, L. 8 – p. 1133, L, 8; *Id.* When Dr. Griffiths asked for his assistance, Dr. Smagula went into the O.R. library and returned with two references. Tr., Vol. II, p. 2186, LL. 5-24. Dr. Smagula verbally dictated the order for Propofol as well as the dosage range to use to the circulating nurse and she wrote the order down word for word. Tr., Vol. I, p. 1130, L. 7 – p. 1133, L. 19; Vol. II, p. 2186, LL. 5-24. Contained in the bridging order was an order for anesthesia, to monitor Michael, which he as in the ICU. Tr., Vol. I, p. 1131, L. 15 – p. 1132, L. 4. The bridging ICU orders were prepared during the latter aspect of the surgery, while Dr. Griffiths was consulting with Dr. Smagula. Tr., Vol. I., p. 1128, L. 14 – p. 1130, L. 6. After surgery was completed, Dr. Curnow resumed Michael's care. Tr., Vol. I, p. 708, L. 19 – p. 709, L. 24.

Before this case, Dr. Griffiths had not personally ordered Propofol for long-term sedation of a pediatric patient but was aware of its use. Tr., Vol. I, p. 2185, L. 2 – p. 2186, L. 13. He also knew and relied on the fact that the clinical pharmacist assigned to ICU, Drs. Curnow

and Reynolds, and the anesthesiologist group would all review the bridging orders. Tr., Vol. I, p. 1086, L. 25 – p. 1087, L. 1. After the initial surgery, Dr. Griffiths slept at the hospital near ICU to be available for Michael should he need his immediate care. Tr., Vol. II, p. 2182, L. 16 – p. 2183, L. 6.

During this hospitalization, Michael was being cared for by the anesthesiologist group, the ICU clinical pharmacists, Dr. Reynolds, Dr. Curnow, Dr. Griffiths, and the staff of SARMC. Tr., Vol. I, p. 1086, L. 25 – p. 1087, L. 1.

Dr. Reynolds evaluated Michael the morning of June 23, 2002, wrote a progress note indicating she knew Michael would be sedated with Propofol on a long term basis, and left the Propofol order in place. Tr., Vol. I, p. 708, L. 19 – p. 710, L. 9. Drs. Reynolds and Curnow were the primary doctors for Michael for his entire hospitalization. *Id.*

The pharmacy at SARMC also received Dr. Griffiths ICU admission bridging orders. Tr., Vol. I, p. 1133, L. 20 – p. 1135, L. 19. The policies and procedures of SARMC require that the pharmacy review all physician orders and not fill the orders for medications if the ordered drug or dosage are unsafe. Trial Exh. 2008; Tr., Vol. II, p. 1501, L. 24 – p. 1504, L. 11; p. 1539, L. 21 – p. 1540, L. 18. If the pharmacy deems that the order places the patient at an unacceptable risk, then they must also call the doctor and record that call in the medical record. *Id.*

The pharmacy has a clinical pharmacist on duty in the ICU. Tr., Vol. II, p. 1501, L. 24 – p. 1504, L. 11; p. 1539, L. 21 – p. 1540, L. 18. The pharmacist in the ICU receives all

ICU orders, all ICU requests to refill medications, consults on all pediatric patients, and directs all ICU clinical pharmacology issues identified. *Id.*

The sedative order for Propofol was also an "off label" use for that drug. *Id.* When medications are ordered for off-label use, prior to filling the order, the policies and procedures of the pharmacy at SARMC had an additional required review of the specific physician order to ensure that the order is safe, the medication and dosage are appropriate and indicated. *Id.* Once this second review of the drug is completed, if the pharmacist can not fill the medication because he does not deem the medication safe, he must call the physician and recommend different medication or dosage. *Id.* This contact must also be documented in writing in the patient chart. *Id.* This required double-check was completed, and such was indicated by the pharmacist progress note and dosage change for another medication. *Id.* The pharmacy did not recommend any change to the Propofol order. Tr., Vol. I, p. 1132, L. 20 – p. 1135, L. 19.

As the care proceeded, Michael needed numerous blood infusions, laboratory testing, medication changes, ventilator monitoring, and was neurologically evaluated by the nurses each shift. Tr., Vol. I, p. 1043, L. 18 – p. 1044, L. 9.

On June 25, 2002, Dr. Griffiths determined that the graft had failed. Tr., Vol. I, p. 1136, L. 19 – p. 1137, L. 11; Vol. II, p. 2200, L. 25 – p. 2201, L. 8. On that day, Dr. Griffiths removed the leeches, debrided the graft, stopped heparin, and informed the parents and all health care professionals that it would be necessary to start dressing changes and follow the alternative course of treatment. Tr., Vol. I., p. 1136, L. 19 – p. 1138, L. 17; Vol. II, p. 2201, L. 10 – p.

2202, L. 4. When Dr. Griffiths debrided Michael's wound at 7:00 p.m. on June 25, 2002, Michael appeared neurologically normal because he reacted to the pain of the debridement. *Id.;* Tr., Vol. I, p. 1102, L. 13 – p. 1105, L. 17; Tr., Vol. I, p. 1136, L. 19 – p. 1138, L. 17; Vol. II, p. 2213, L. 22 – p. 2214, L. 25. On June 25, 2002, at 7:00 p.m., Dr. Griffiths' assistance was no longer needed for the acute care of Michael. *Id.* Dr. Griffiths spoke to the family, Dr. Reynolds, as well as providing a written "sign out" in the physician progress notes. *Id.*, Tr., Vol. II, p. 2215, L. 1 – p. 2217, L. 13. At the time Dr. Griffiths signed out, Michael appeared neurologically normal. Tr., Vol. I, p. 1136, L. 19 – p. 1138, L. 17. After debridement, the graft site continued to cause pain and, therefore, Michael was maintained on pain medication and Propofol as Dr. Curnow and Dr. Reynolds felt Michael needed medication for the pain and also wanted to use a weaning regimen. R. Vol. I, p. 115.

Michael began experiencing cardiac tachycardia, and had one episode of metabolic acidosis that was treated and reversed. *Id.* On each neurological evaluation, Michael was assessed as within normal range, until 4:00 p.m. on June 27, 2002. *Id.* On that day and time, the nurses assessed that Michael's pupils were non-reactive, fixed, and dilated. *Id.* After Michael's pupils became fixed and dilated, Dr. Reynolds called a neurosurgeon into assist, and it was found that Michael was suffering from cerebral edema. *Id.*

When Dr. Griffiths learned of Michael's turn for the worse, he came to the hospital to review the chart and to meet with Mrs. Coombs. Tr., Vol. I, p. 2217, L. 14 – p. 2220, L. 17. Dr. Griffiths told Mrs. Coombs that he had reviewed the chart and could not determine the cause of Michael's decline. *Id.* Michael died on June 28, 2002. R., Vol. I, p. 115.

2. Evidence Admitted at Trial

Dr. Hammer testified that he did not have any criticism of Dr. Griffith's care, decisions, or treatment through and up to the completion of the second surgery, which would include Dr. Griffiths' informed consent, discussions of the risks, and writing the bridging order. Tr., Vol. I, p. 803, L. 25 – p. 805, L. 3; R. p. 118, p. 1082, LL. 16-20. Dr. Hammer rendered the opinion that the only error or violation of the standard of health care practice as to Dr. Griffiths was the manner in which he wrote the Propofol order, and if Dr. Smagula knew that Propofol was to be used on Michael for greater than 12 hours, then Dr. Griffiths could rely on that recommendation. Tr., Vol. I, p. 543, L. 10 – p. 544, L. 1.

Dr. Hammer, as well as all other experts asked about the issue, opined that more than 70 percent of all drugs used in pediatrics are drugs not recommended for children, termed off-label use. Tr. Vol. I, p. 532, L. 13 – p. 533, L. 5.

Dr. Hammer agreed that he would defer to a neuroradiologist regarding Michael's brain C.T. Tr. Vol. I, p. 831, L. 18 – p. 832, L. 12.

Dr. Hammer admitted that he could not site to even one scientific medical study or peer-reviewed article to support his opinion that the long-term use of Propofol in children will cause cerebral edema, or that Propofol alone can cause death due to cerebral edema. Tr., Vol. I, p. 563, L. 5-22; R., Vol. I, p. 116.

He also admitted that he had not received the policies and procedures for the pharmacy at SARMC. Tr., Vol. I, p. 534, L. 9 – p. 536, L. 4; p. 544, LL. 2-7, p. 822, LL. 14-18. He also testified that physicians could rely on pharmacy consults and the recommendation of

other physicians. *Id.*; Tr., Vol. I, p. 829, LL. 13-18. Pharmacy consults were required at SARMC. R., Vol. I, p. 118.

Treating pediatric surgeon, and acting pediatric intensivist at SARMC, Dr. Ellen Reynolds, testified that she had reviewed and agreed with Dr. Griffiths' bridging order regarding Propofol. Tr., Vol. I, p. 708, LL. 4-18.

Dr. Smith was an expert plastic surgeon called to testify by Dr. Griffiths and is in private practice in Twin Falls, Idaho. Tr., Vol. II, p. 2058, L. 25 – p. 2059, L. 18. Dr. Smith opined that Dr. Griffiths met the applicable standard of health care practice in his care and treatment of Michael Hall. Tr., Vol. II, p. 2068, L. 1 – p. 2069, L. 6. He rendered the opinion that Dr. Griffiths' order written at about 0320 on June 23, 2002 was a bridging order to allow Michael's admission to the ICU. Tr., Vol. II, p. 2093, L. 10-22. Dr. Smith further opined that it was obvious that the anesthesiologists knew that Michael was to be sedated long term. Tr., Vol. II, p. 2095, L. 4 - p. 2096, L. 25. He also testified that Dr. Griffiths' care did not cause harm to Michael. Tr., Vol. II, p. 2107, LL. 9-19.

Dr. Womack, who was called in by Dr. Reynolds, as a cardiac consultant, and opined that Michael's cardiac response was not due to Propofol and he ruled out PRIS as a cause of Michael's death. Tr., Vol. I, p. 1237, L. 5 – p. 1238, L. 7.

Dr. Michael Reed, an expert for Dr. Griffiths, is a well respected clinical pharmacologist and clinical researcher from Rainbow Children's Hospital, an affiliate of Case Western University. Tr., Vol. I, p. 1660, LL. 6-8.. Dr. Reed is a pre-eminent pharmacological researchers and has conducted clinical research on Propofol. Tr., Vol. I, p. 1660, L. 19 – p.

1663, L. 17; Tr., Vol. I, p. 1677, L. 18 – p. 1684, L. 15. At Rainbow Children's Hospital he has been instrumental in establishing the ongoing protocols for sedation, in include Propofol. *Id.* He also testified that he had reviewed the world's medical literature, and found no citations that support Dr. Hammer's opinion that the long-term use of Propofol, such as was used in Michael Hall, could cause cerebral edema or death due to cerebral edema. R., Vol. I, p. 116; Tr., Vol. I, p. 1707, L. 18 – p. 1708, L. 3.

Dr. Martin Johnston, a pediatric hematologist and oncologist testified that he had used Propofol since 1997, and in all the medical literature he had reviewed on Propofol there was no association between the use of Propofol and an isolated global ischemia event that resulted in cerebral edema. Tr., Vol. I, p. 1312, LL. 4-7, p. 1315, LL. 6-16.

Dr. Richard Latchaw is a pediatric neuro-radiologist who is also involved in medical research and teaching. Tr., Vol. II, p. 1562, L. 16 – p. 1566, L. 17. Dr. Latchaw reviewed all neurological images of Michael Hall as well as the world's medical literature regarding Propofol. Tr., Vol. II, p. 1567, L. 16 – p. 1568; p. 1647, LL. 5-14. Dr. Latchaw opined that Michael died as a result of cerebral edema and that there is absolutely no scientific medical basis to support a premise that Propofol caused Michael's cerebral edema. Tr., Vol. II, p. 1647, LL. 5-14, p. 1618, L. 22 – p. 1619, L. 25. Dr. Latchaw opined that Michael died due to a cytotoxic exposure, from a substance other than Propofol. *Id.*

Dr. Ross Reichard is a neuro-pathologist from New Mexico and rendered an expert opinion that the tissue from Michael's autopsy did not support findings of the effects of Propofol or PRIS. Tr., Vol. I, p. 1255, L. 7 – p. 1257, L. 21; p. 1269, L. 20 – p. 1270, L. 6.

Dr. Griffiths is a cranio-facial plastic surgeon with specialty in pediatrics. Tr., Vol. II, p. 2144, L. 15 – p. 2146, L. 17. He is in private practice in Boise, Idaho. Tr., Vol. II, p. 2148, LL. 6-15. He testified that he met the applicable standard of health care practice as it pertained to his care of Michael Hall in Boise, Idaho in June 2002. Tr., Vol. II, p. 2220, L. 18 – p. 2221, L. 6. Dr. Griffiths testified that he warned Michael's mother, Mrs. Coombs, on at least two different times of all the significant risks of the surgery and post care to include the risk of death. Tr., Vol. I, p. 1113, L. 25 – 1117, L. 24. Kenneth Coombs was present during one of the warnings and recalls that Dr. Griffiths did warn them that death was a risk associated with Michael's care. Tr., Vol. I, p. 589, L. 4 – 592, L. 4. Dr. Griffiths testified that the risk of death is present no matter which option Mrs. Coombs chose for re-building Michael's face. Tr. Vol. I, p. 1140, LL. 5-12. He further testified that nothing he did caused Michael's death. *Id.*

II. ADDITIONAL ISSUES PRESENTED ON APPEAL

1. Whether Dr. Griffiths is entitled to attorney's fees on appeal.

III. ARGUMENT

The District Court's Judgment Notwithstanding the Verdict ("JNOV") should be upheld because Plaintiffs: (1) failed to present substantial and credible evidence that their proposed medical expert, Gregory Hammer, M.D., possessed actual knowledge of the applicable standard of care as to Dr. Russell Griffiths in Boise, Idaho for the year 2002. As such, Dr. Hammer was not competent to testify pursuant to the requirements set forth in Idaho Code Sections 6-1012 and 6-1013 , Idaho Rules of Evidence 701, 702, 703, and the precedent case law for the State of Idaho; and (2) failed to present substantial and credible evidence establishing a

causal connection between the use of Propofol for the post-surgery sedation of Michael Hall and the care and treatment rendered by Dr. Griffiths to Michael Hall and the cause of his subsequent death.

Because Plaintiffs have failed to present substantial and credible evidence on the issues discussed above, they have failed to establish a prima facie case of medical negligence and proximate cause. The District Court's Judgment Notwithstanding the Verdict should be affirmed. Defendant Griffiths submits the following in support of the District Court's ruling.

A. Standard and Scope of Review.

A Judgment notwithstanding the verdict ("JNOV") may be granted only when there was no substantial evidence to support the jury's verdict. *Jeremiah v. Yanke Machine Shop, Inc.*, 131 Idaho 242, 247, 953 P.2d 992, 997 (1998); *O'Neil v. Schuckardt*, 112 Idaho 472, 480, 733 P.2d 693, 701 (1986); *Quick v. Crane,* 111 Idaho 759, 763, 727 P.2d 1187, 1191 (1986); *Dawson v. Olson*, 94 Idaho 636, 641, 496 P.2d 97, 102 (1972); *Evans v. State*, 135 Idaho 422, 430, 18 P.3d 227, 235 (Ct. App. 2001). For evidence to be considered substantial, the evidence must "be of such sufficient quantity and probative value that reasonable minds could conclude that the verdict of the jury was proper." *Mann v. Safeway Stores, Inc.*, 95 Idaho 732, 736, 518 P.2d 1194, 1198 (1974). "The question is not whether there is literally no evidence supporting the party against whom the motion is made, but whether there is substantial evidence upon which the jury could properly find a verdict for that party." *Pocatello Auto Color, Inc. v. Akzo Coatings Inc.*, 127 Idaho 41, 45, 896 P.2d 949, 953 (1995) (quoting *Quick*, 111 Idaho at 763-64, 727 P.2d at 1191-92). This question is a matter of law to be decided by the trial court.

Quick, 111 Idaho at 764, 727 P.2d at 1192; *Litchfield v. Nelson,* 122 Idaho 416, 419-20, 835 P.2d 651, 654-55 If, after reviewing the evidence in the manner set forth above, the Court finds that there is substantial evidence to show that reasonable minds could have reached the same conclusion as did the jury, then the jury's verdict will be upheld. *Hudson v. Cobbs,* 118 Idaho 474, 478, 797 P.2d 1322, 1326 (1990); *Evans*, 135 Idaho at 430, 18 P.3d at 235.

As such, the moving party is not required to show that no evidence supports the verdict, but rather must merely show that there is a lack of substantial evidence. *Karlson v. Harris,* 140 Idaho 561, 567, 97 P.3d 428, 434 (citations omitted, emphasis added). "The question is not whether there is literally no evidence supporting the party against whom the motion is made, but whether there is substantial evidence upon which the jury could properly find a verdict for that party." *Pocatello Auto Color, Inc. v. Akzo Coatings Inc.*, 127 Idaho 41, 45, 896 P.2d 949, 953 (1995) (quoting *Quick,* 111 Idaho at 763-64, 727 P.2d at 1191-92). This question is a matter of law to be decided by the trial court. *Quick,* 111 Idaho at 764, 727 P.2d at 1192; *Litchfield*, 122 Idaho at 419-20, 835 P.2d at 654-55.

A JNOV may be used by a trial court to correct a prior decision to deny a directed verdict. *Hudson v. Cobbs*, 118 Idaho 474, 478-79, 797 P.2d 1322, 1326-27 (1990) (citation omitted). After reviewing the evidence in the manner set forth above, if the Court finds that there is substantial evidence to show that reasonable minds could have reached the same conclusion as did the jury, then the jury's verdict will be upheld. *Hudson*, 118 Idaho at 478, 797 P.2d at 1326; Evans, 135 Idaho at 430, 18 P.3d at 235.

"The standard of review of a grant or denial of a motion for JNOV is the same as that of the trial court when ruling on the motion." *Hall v. Farmers Alliance Mutual Ins. Co.,* 145 Idaho 313, 324, 179 P.3d 276, 287 (2008) (citing *Gillingham Constr., Inc. v. Newby-Wiggins Constr., Inc.*, 142 Idaho 15, 20, 121 P.3d 946, 951 (2005)). "In reviewing a grant or denial of a motion for JNOV the court may not reweigh evidence, consider witness credibility, or compare its factual findings with that of the jury." *Johannsen v. Utterbeck* 196 P.3d 341, 346 -347 (Idaho, 2008), citing *Hall*, 145 Idaho at 324, 179 P.3d at 287 (2008) (citing *Gillingham Const., Inc. v. Newby-Wiggins Const., Inc.*, 142 Idaho 15, 20, 121 P.3d 946, 951 (2005)). *Id.* The court must "review all the evidence and draw all the reasonable inferences therefrom in the light most favorable to the non-moving party." *Schwan's Sales Enters., Inc. v. Idaho Transp. Dept.*, 142 Idaho 826, 830, 136 P.3d 297, 301 (2006) (citation omitted).

Dr. Griffiths respectfully submits that the quantity, probative value and credibility of the evidence offered by the Plaintiffs regarding the applicable standard of health care practice in 2002 for Dr. Griffiths and proximate cause thereof was inadmissible, inadequate, and without probative value to support the jury's verdict. Accordingly, the District Court's granting defendant's JNOV motion should be affirmed.

B. Plaintiffs Failed To Establish That Dr. Griffith Breached the Applicable Standard Of Health Care Practice.

1. The statutory requirements necessary to establish a violation of the applicable standard of health care practice for a physician defendant.

Idaho Code Sections 6-1012 and 6-1013 set forth the requirements that the Plaintiffs must meet to establish the standard of care and a violation thereof in a medical malpractice action. Idaho Code Sections 6-1012 and 6-1013 provide:

> **6-1012. Proof of community standard of health care practice in malpractice case.** In any case, claim or action for damages due to injury to or death of any person, brought against any physician and surgeon or other provider of health care . . . on account of the provision of or failure to provide health care or on account of any matter incidental or related thereto, such claimant or plaintiff must, as an essential part of his or her case in chief, affirmatively prove by direct expert testimony and by a preponderance of all the competent evidence, that such defendant then and there negligently failed to meet the applicable standard of health care practice of the community in which such care allegedly was or should have been provided, as such standard existed at the time and place of the alleged negligence of such physician and surgeon, hospital or other such health care provider and as such standard then and there existed with respect to the class of health care provider that such defendant then and there belonged to and in which capacity he, she or it was functioning. Such individual providers of health care shall be judged in such cases in comparison with similarly trained and qualified providers of the same class in the same community, taking into account his or her training, experience, and fields of medical specialization, if any. If there be no other like provider in the community and the standard of practice is therefore indeterminable, evidence of such standard in similar Idaho communities at said time may be considered. As used in this act, the term "community" refers to that geographical area ordinarily served by the licensed general hospital at or nearest to which such care was or allegedly should have been provided.
>
> **6-1013. Testimony of expert witness on community standard.-** The applicable standard of practice and such a defendant's failure

> to meet said standard must be established in such cases by such a plaintiff by testimony of one (1) or more knowledgeable, competent expert witnesses, and such expert testimony may only be admitted in evidence if the foundation therefore is first laid, establishing (a) that such an opinion is actually held by the expert witness, (b) that the said opinion can be testified to with reasonable medical certainty, and (c) that such expert witness possesses professional knowledge and expertise coupled with actual knowledge of the applicable said community standard to which his or her expert opinion testimony is addressed; provided, this section shall not be construed to prohibit or otherwise preclude a competent expert witness who resides elsewhere from adequately familiarizing himself with the standards and practices of (a particular) such area and thereafter giving opinion testimony in such a trial.

IDAHO CODE §§ 6-1012-13.

As provided in the statutes, in order for an expert to testify in a medical malpractice case, the expert must be deemed competent to testify by satisfying certain standards prior to presenting evidence to the jury. Specifically, the proffered expert must adequately demonstrate that he has actual knowledge of the local standard of care. IDAHO CODE § 6-1013; *Ramos v. Dixon,* 144 Idaho 32, 156 P.3d 533 (2007).

The District Court ruled in this matter that the use of Propofol by these defendants was within the applicable standard of health care practice. In doing so, the Court cited to learned and expert testimony that was supported by medical science, peer reviewed literature, research of the world's study in Propofol, and the fact that Propofol is a drug that has been used for many years, therefore, any problem with its use would have had more than enough time to enter the world's medical literature and study.

The Court also analyzed the opinion of the Plaintiffs' expert Dr. Gregory Hammer. Dr. Hammer was the **only** medical doctor to testify that the use of Propofol for long term sedation violates the standard of health care practice or that Propofol caused the cerebral edema that lead to Michael Hall's death. When the Court looked at Dr. Hammer's testimony with a learned eye, the Court found that the opinion was merely theory and not admissible opinion. Dr. Hammer could not support his theory with any actual knowledge from the community and he could not support the causation theory through acceptable juried medical literature or studies. Just because Dr. Hammer testifies that the standard of health care practice is a certain thing, does not make it truth. Standard of health care practice is more than theory or personal opinion. In Idaho, standard of health care practice is based on actual knowledge, practice that can be proved by facts, known to be true and known personally by the physician that is testifying.

Idaho law does not impose an enormous burden for an expert to render an opinion to an Idaho jury. It imposes a burden that safeguards Idaho juries. The burden does not allow expert opinions to guide a jury that are not soundly based.

The Court, in analyzing the facts, the actual knowledge, and the statutory requirements was correct in finding that Dr. Hammer's opinions on standard of health care practice and causation did not meet the requirements imposed by law.

2. Plaintiffs' expert, Dr. Gregory Hammer, failed to establish that he familiarized himself with the applicable standard of health care practice.

In order to be competent to testify, Plaintiffs' expert, Dr. Hammer, must have shown that: (1) He did familiarize himself with the applicable standard of health care practice applicable for the care provided to Michael Hall by Dr. Griffiths in Boise, Idaho for the year 2002; and (2) how he familiarized himself with that standard. It is not sufficient to simply state whom he spoke with and what conclusions he reached. *Kolln v. St. Luke's Reg'l Med. Ctr.*, 130 Idaho 323, 331, 940 P.2d 1142, 1150 (1997). Instead, there "must be evidence showing that the . . . physician [with whom he spoke] knows the applicable standard of care." *Ramos v. Dixon*, 144 Idaho 32, 37, 156 P.3d 533, 538 (2007).

In the "unique situation" where there is no local specialist to consult, experts must gain an actual knowledge of the applicable standard in other similar localities or communities. See *Hoene v. Barnes*, 121 Idaho 752, 757, 828 P.2d 315, 320 (1992). Further, the expert at a very minimum, must determine whether the applicable standard varies from the national standard for that specialty. *Dulaney v. St. Alphonsus Reg'l Med. Ctr.*, 137 Idaho 160, 166, 45 P.3d 816, 822 (2002).

In *Morris* by and through *Morris v. Thomas*, 130 Idaho 138, 937 P.2d 1212 (1997), the Idaho Supreme Court explained its prior holding in *Hoene v. Barnes*, 121 Idaho 752, 828 P.2d 315 (1992). Specifically, the Court stated that a plaintiff must first demonstrate that there is no health care provider other than the defendant or his or her business associates practicing in the local community, thus making a local standard indeterminable. *Id.* at 147,

93713:2d at 1221. At that point, the plaintiff must turn to similarly situated communities in other locations in the state of Idaho as provided by Idaho Code §6-1012. *Id.*

Here, Plaintiffs failed to present substantial and credible evidence showing that Dr. Hammer met this strict standard as it pertains to Dr. Griffiths. Plaintiffs failed to satisfy the requirement that a "health care [provider] shall be judged in such cases in comparison with similarly trained and qualified providers of the same class in the same community," which is defined by the statute as "that geographical area ordinarily served by the licensed general hospital at or nearest to which such care was or allegedly should have been provided." IDAHO CODE § 6-1012. *Id.* Furthermore, Idaho Code Section 6-1013 requires that the testifying expert must have "actual knowledge of the applicable said community standard." (emphasis added). Thus, where the expert does not possess actual knowledge of the applicable standard of health care practice for specific care provided by a physician in Dr. Griffiths' capacity, the witness is not competent to testify regarding the applicable standard of health care practice for that defendant physician.

3. Plaintiffs expert, Dr. Hammer, did not have actual knowledge of Dr. Griffiths' specialty in pediatric cranio-facial plastic surgery.

In order to render an opinion in Idaho, an expert must demonstrate actual knowledge of the standard of health care practice for the defendant physician's specific field or specialty. *Dulaney v. St. Alphonsus Reg. Med. Ctr.*, 137 Idaho 160, 168, 45 P.3d 816, 824 (2002) (quoting *Clark v. Prenger*, 114 Idaho 766, 769, 760 P.2d 1182, 1185 (1988)).

With respect to the issue of specialization, the Idaho Supreme Court stated:

> Recognizing the complexity of knowledge required in the various medical specialties, more than a casual familiarity with the specialty of the defendant's physician is required. The witness must demonstrate a knowledge acquired from experience or study of the standards of the specialty physician sufficient to enable him to give an expert opinion as to the conformity of the defendant's conduct to those particular standards, and not to the standards of the witness's particular specialty if it differs from that of the defendant.

Clark, 114 Idaho at 769, 760 P.2d at 1185 (quoted by *Dulaney*, 137 Idaho at 168, 45 P.3d at 824 and discussing IDAHO CODE §§ 6-1012 and 6-1013). As such, experts must show that they "adequately familiarized" themselves with the standards and practices of the defendant's specialty. *Dulaney,* 137 Idaho at 168, 45 P.3d at 824.

The Idaho Supreme Court has repeatedly affirmed the statutory requirement of expert testimony on the standard of health care practice admissible to a defendant health care provider. *See Gubler v. Boe*, 120 Idaho 294, 815 P.2d 1034 (1991); *Strode v. Lenzi*, 116 Idaho 214, 775 P.2d 106 (1989); *Dekker v. Magic Valley Reg'l Med. Ctr.*, 115 Idaho 332, 767 P.2d 1213 (1988); *Frank v. E. Shoshone Hosp.*, 114 Idaho 480, 757 P.2d 1199 (1988); *Grimes v. Green*, 113 Idaho 519, 746 P.2d 978 (1987); *Maxwell v. Women's Clinic, RA.,* 102 Idaho 53, 625 P.2d 407 (1981); *LePelley v. Grefenson*, 101 Idaho 422, 614 P.2d 962 (1980).

For instance, in Strode v. *Lenzi*, the plaintiffs filed suit against Dr. William Lenzi, alleging that he negligently failed to detect carotid artery disease prior to conducting a shoulder operation to repair plaintiff Donald Strode's rotator cuff injury. 116 Idaho at 214, 775 P.2d at 106. Following surgery, Mr. Strode suffered a stroke, allegedly resulting in partial paralysis and brain damage. *Id.* Dr. Lenzi subsequently moved for summary judgment supported by an

affidavit in which he stated that he was familiar with the standard of care applicable to orthopedic surgeons in Boise, Idaho, in 1984 and had complied with the local standard with respect to his care and treatment of Mr. Strode. *Id.* at 215, 775 P.2d at 107.

The plaintiffs countered with two affidavits from Dr. Robert Hall, an orthopedic surgeon from Chicago, Illinois. Dr. Hall's first affidavit did not demonstrate that he was qualified to testify regarding the local standard of care. The plaintiffs attempted to remedy this defect by submitting a second affidavit containing the following information regarding Dr. Hall's perceived knowledge of the local standard of care:

> The standard of care for a board-certified orthopedic surgeon in Boise is that set by the American Academy of Orthopedic. Surgeons and is the same standard under which I practice in Chicago, Illinois. I am, therefore, familiar with what is expected of a board certified orthopedic surgeon in Boise.

Id. The trial court, however, held that Dr. Hall's affidavit testimony was not sufficient to establish a prima facie case because Dr. Hall's affidavit failed to demonstrate that he had any "actual personal knowledge" of the local standard of care for a Boise orthopedic surgeon as required by the express language of Idaho Code § 6-1012. *Id.* Accordingly, the trial court granted summary judgment in favor of Dr. Lenzi. *Id.*

The plaintiffs appealed, contending that an out-of-state board-certified orthopedic surgeon was competent to testify regarding the standard of care of a similar specialist in Boise, Idaho, without first demonstrating that he possessed "actual knowledge" of the local standard. *Id.* The Idaho Supreme Court disagreed, however, noting that Idaho Code Sections 6-1012 and 6-

1013 specifically require that an expert outside of the local community must demonstrate that he has "actual knowledge" of the local standard of care. *Id.* at 216; 775 P.2d at 108.

Similarly, in *Frank v. East Shoshone Hospital*, the Idaho Supreme Court affirmed the trial court's summary judgment in a medical malpractice case because the plaintiffs' expert witness failed to display "actual knowledge" of the applicable community standard. 114 Idaho at 481; 757 P.2d at 1199. In *Frank*, plaintiffs alleged medical malpractice from the treatment Mrs. Shirley Frank received at East Shoshone Hospital for a broken ankle. The defendant physician, Dr. Glenn Faith, moved for summary judgment on the ground that the plaintiffs' expert, Dr. Blaisdell, was not familiar with the standard of care in Dr. Faith's community. *Id.* The deposition testimony of Dr. Blaisdell reflected a general knowledge of medical practice in the region known as "Silver Valley" in northern Idaho, but no "detailed" understanding of the standard of care. pertaining to the treatment of the particular problem which arose in that case. Moreover, Dr. Blaisdell admitted that he had not discussed the standard of care in any detail with any physicians who practiced in Dr. Faith's community.

As the Court's decisions in *Strode* and *Frank* demonstrate, plaintiffs must establish by competent expert testimony the applicable standard of health care practice for a health care provider as well as Dr. Griffiths' failure to meet that specific standard. There is no such thing as a "national" standard of care. Such expert testimony can only be admitted after a foundation is first laid which establishes that the witness possesses the requisite level of expertise, that the witness has actual knowledge of the applicable community standard, that the standard of health care practice in Boise, Idaho for 2002 as it applied to the facts and

circumstances of this matter were the same or specifically similar as those held by a physician similarly situated who adheres to a "national" standard of health care practice, that the expert actually has an opinion regarding whether or not there was a breach of the applicable standard of health care practice, and that such opinion is held to a reasonable degree of medical certainty.

The facts in the instant matter show that Plaintiffs' expert, Dr. Hammer, neither testified regarding Dr. Griffiths' specialty at trial, nor testified that he had actual knowledge of the applicable standard of health care practice for Dr. Griffiths' specialty.

4. Plaintiffs proffered no evidence that Dr. Hammer's familiarizing physicians, Dr. Seifert and Dr. Kahn, have actual knowledge of the local standard of health care practice applicable to Dr. Griffiths' field of specialty in care of Michael Hall.

Expert testimony must show that the expert has "actual knowledge of the applicable community standard of health care practice." *Dulaney v St. Alphonsus Reg'l Med. Ctr.*, 137 Idaho 160, 164, 45 P.3d 816, 820 (2002) (citing Morris ex rel. *Morris v. Thomson*, 130 Idaho 138, 937 P.2d 1212 (1997); *Rhodehouse v. Stutts*, 125 Idaho 208, 868 P.2d 1224 (1994); Dunlap ex rel. *Dunlap v. Garner*, 127 Idaho 599, 903 P.2d 1296 (1994)). Therefore, the expert must show that he or she is familiar with the standard of health care practice for a particular defendant health care professional in the geographical community in which the care was provided and for the specific year the care was rendered. *Id.* (citing *Perry v. Magic Valley Reg'l Med. Ctr.*, 134 Idaho 46, 995 P.2d 816 (2000); *Rhodehouse v. Stutts*, 125 Idaho 208, 868 P.2d 1224 (1994)). The medical expert need not practice in the same specialty as the defendant. *Id.* at

168, 45 P.3d at 624. Nevertheless, and most importantly, the expert must have "more than a casual familiarity" with the defendant's specialty. *Id.*

Significantly, where an out-of-area expert attempts to familiarize himself or herself through a local specialist, the local specialist also must have an actual knowledge of the applicable standard of health care practice. See *id.* at 168, 45 P.3d at 824.

The Court's holding in *Dulaney* is particularly relevant to the case at bar. In *Dulaney*, the district court granted summary judgment to two defendant physicians after striking portions of the Affidavits from plaintiff's out-of-state experts. *Id.* at 163, 45 P.3d at 819. One of the defendants was an emergency room physician and the other was an orthopedic surgeon. *Id.* at 162, 45 P.3d at 817. Accordingly, in *Dulaney*, the plaintiff hired Dr. Mengert, an out-of-state emergency room physician. Subsequently, Dr. Mengert attempted to familiarize himself with the local standard of health care practice for emergency room physicians in Boise, Idaho. His attempt consisted of consulting Dr. Smith, a Boise physician who had the specialty of an internist. *Id.*

At summary judgment, the district court found no evidence that the local internist was "himself familiar with the local standard of care for E.R. physicians practicing in Boise at the relevant time." *Id.* On appeal, the Idaho Supreme Court agreed, holding that the district court did not error in striking the Affidavit. Specifically, the Court held there were no specific facts showing that the internist had knowledge of the applicable standard of health care practices for E.R. physicians in Boise, Idaho for the relevant period of time. *Id.*

Also in Dulaney, the Court upheld the trial court's decision to strike the Plaintiffs' proffered testimony of a Dr. Stump, who was an out-of-state physician with a specialty in neurology. Dr. Stump testified that he telephoned another neurologist, Dr. Adornato, who alleged to have practiced neurology in Idaho around the time of the alleged malpractice. *Id.* at 167, 45 P.3d at 823. Dr. Stump stated that he called Dr. Adornato to learn the local standard of care for emergency room physicians and orthopedic surgeons in Boise. *Id.* at 168, 45 P.3d at 824. In affirming the trial court's decision to strike Dr. Stump's testimony, the Idaho Supreme Court again recognized that there were no facts showing that the familiarizing neurologist, Dr. Adornato, had an actual knowledge of the defendants' specialties. *Id.*

Likewise in *Dulaney*, the Court affirmed the trial court's decision to strike Dr. Stump's Supplemental Affidavit. *Id.* at 169, 45 P.3d at 825. The facts reveal that the Plaintiffs' expert, Dr. Stump, contacted an anonymous professor of orthopedics. The anonymous professor allegedly was familiar with the applicable standard of health care practice in 1994 for orthopedic surgeons in Boise, Idaho. *Id.* The anonymous professor expert further alleged that the standard in Boise at that time was the same as the national standard. *Id.*

On appeal, the Court recognized that Dr. Stump's Affidavit did not allege specific facts showing that the anonymous professor was familiar with the standard of care for orthopedic surgeons in Boise, Idaho, in August of 1994. *Id.* Notably, the professor stated he maintained professional relationships with the physicians in Boise, Idaho. *Id.* Nevertheless, there were no specific facts set forth by Dr. Stump that these physicians whom the professor relied upon practiced E.R. care or orthopedic surgery in August of 1994. *Id.* As a result, the Court held the

anonymous professor's knowledge of the local standard of care was "simply not sufficient." *Id.* (citing *Strode v. Lenzi*, 116 Idaho 214, 775 P.2d 106 (1989).

In this matter, Plaintiff did not satisfy the requirement that Dr. Hammer's familiarizing physicians, Drs. Seifert and Kahn, had actual knowledge of Dr. Griffiths' specialty.

5. Negligence or violation of the applicable standard of health care practice cannot be established based on a particular result.

The mere fact that a particular result is not achieved by health care treatment is not in and of itself proof of negligence. In Idaho, the prima facie elements for medical negligence are clear. Before causation becomes relevant, the Plaintiff must first prove the applicable standard of health care practice that applies to the specific physician defendant in the geographical community in which the case was rendered and for the relevant time period in which it was rendered. Then the Plaintiff must prove that the Defendant physician violated that applicable standard of health care practice. Only after the Plaintiff has established the applicable standard of health care practice and the Defendant's violation of said standard does causation become relevant.

For instance, in *LePelley v. Grefenson*, the defendant physician dropped a bone fragment in the surgical site while performing surgery on the bones of the plaintiff's ear. 101 Idaho 422, 424, 615 P.2d 962, 964 (1980). The remaining bone fragment caused dizziness, hearing loss, and nausea, which eventually resulted in the permanent loss of hearing in the plaintiff s ear. *Id.* The plaintiff's experts testified by deposition and affidavit that the dropping of a bone fragment was a surgical risk and that the defendant had performed the surgery within the

standard of care for Twin Falls, Idaho, the community in which the surgery was performed. *Id* at 429, 614 P.2d at 965. In affirming summary judgment on the issue of negligence, the Idaho Supreme Court stated:

> The appellants indicated that Dr. Goltry and Dr. Thomas were the experts that they intended to rely on in presenting their case. However, neither doctor testified to any negligence on the part of the respondent. In fact, both indicated in affidavits submitted on behalf of the respondent, that the respondent had performed the operation within the standard of care of the community. **Nothing is offered to refute this testimony other than the facts that a bone fragment was dropped and that the operation was not a success. However, these facts do not show that the doctor performed the operation negligently.** Therefore in the absence of even an offer to supply expert testimony in their favor, appellants cannot complain about a dismissal of their case as far as count H.

Id. (citations omitted) (emphasis added).

If liability could be predicted on a perceived "bad" result, without more, strict liability - rather than negligence - would be the standard. *Campbell v. United States*, 904 F.2d 1188, 1194 (7th Cir. 1990). Health care providers, however, are not insurers of the correctness of their diagnosis or treatments. *Willis v. W. Hosp. Assoc.*, 67 Idaho 435, 182 P.2d 950 (1947). Health care is neither a perfect nor an exact science. Physicians are required to meet the applicable standard of health care practice when making decisions and rendering care.

Thus, in this case, Plaintiffs must show that Defendant Griffiths failed to meet the applicable standard of health care practice, and, as discussed *supra*, and that specific failure proximately caused the very damages that the Plaintiff alleges. Plaintiffs have done neither.

C. Plaintiffs Failed To Establish Any Causal Connection Between the Use of Propofol and the Death of Michael Hall.

The District Court's ruling should be affirmed because Dr. Hammer's opinion on causation is without` scientific basis, is in opposite of all existing literature/research on the subject, is not supported by the clinical evidence, and is not supported by evidence learned at autopsy.

1. Plaintiffs failed to admit substantial evidence that Michael Hall's death was actually or proximately caused by Propofol.

Proximate cause is composed of two components; actual cause and proximate cause, also referred to as 'legal cause." *Newberry v. Martens*, 142 Idaho 284, 288, 127 P.3d 187, 191 (2005). Actual cause is comprised of the factual question of "whether a particular event produced a particular consequence." *Id.* Proximate cause "focuses upon legal policy in terms of whether responsibility will be extended to the consequences of conduct which has occurred." *Munson v. State Dept. of Highways*, 96 Idaho 529, 531, P.2d 1174, 1176 (1975) (quoting *Henderson v. Cominco Am., Inc.*, 95 Idaho 690, 695, 518 P.2d 873, 878 (1973)).

Plaintiffs must further prove proximate cause pursuant to Rule 701 (and Rule 702) of the Idaho Rules of Evidence. *Sheridan v. St Luke's Reg'l Med. Ctr.*, 135 Idaho 775, 25 P.3d 88 (2001). Idaho Rule of Evidence 701 states:

> If the witness is not testifying as an expert, the testimony of the witness in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b) helpful to a clear understanding of the testimony of the witness or the determination .. of a fact in issue, and (c) not based on scientific, technical or other specialized knowledge within the scope of Rule 702.

An opinion regarding medical causation is beyond the ken of a lay juror, and may only be established through expert medical testimony. *See, e.g., Flowerdew v. Warner*, 90 Idaho 164, 172, 409 P.2d 110, 115 (1965) (lay opinion testimony is inadmissible to prove the cause of a plaintiff s condition); *Kolln v. St. Luke's Reg'l Med. Ctr.,* 130 Idaho 323, 329-30, 940 P.2d 1142, 1148-49 (1997) (holding that as a lay person, the plaintiff in medical malpractice case was not competent to testify about the cause of her injury).

To allow expert opinion testimony on the ultimate issue at trial, the Court is required to decide two distinct threshold questions on admissibility. Rules 702 and 703 of the Idaho Rules of Evidence set forth foundational requirements necessary for the admission of expert testimony:

> (1) If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Idaho Rule of Evidence 702.

> (2) The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. <u>If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.</u>

Idaho Rule of Evidence 703.

Once a witness is qualified as having sufficient expertise, a witness may only offer opinion testimony if his specialized knowledge will assist the trier of fact to understand the evidence or determine a fact in issue. *See State v. Konechny*, 134 Idaho 410, 417, 3 P.3d 535,

542 (Ct. App. 2000) citing Idaho Rule of Evidence 702, The trial court's function in determining the validity of proposed expert testimony is to "distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs." *Konechny*, 134 Idaho at 417, citing *Ryan v. Beisner*, 123 Idaho 42, 46, 844 P.2d 24, 28 (Ct. App. 1992).

The Court of Appeals specifically discussed these two decisions that the District Court must make prior to admission of an expert opinion in *Ryan,* 123 Idaho at 46, 844 P.2d at 28. The Court of Appeals in *Ryan* found that the admissibility of expert testimony cannot rest on speculation and conjecture. The expert opinion is inadmissible if the opinion is speculative, conclusory, or unsubstantiated by the facts and the record so that the opinion is of no assistance to the jury in rendering its verdict because a verdict cannot rest on such speculation and conjecture. *Id.* at 46, 844 P.2d at 30. The admissibility of expert opinion testimony depends on the expert's ability to explain pertinent scientific principles and to apply those principles to the formulation of his or her opinion. Thus, the key to admission of the opinion is the validity of the expert's reasoning and methodology. In resolving these issues, the trial court should not substitute its judgment for that of the relevant scientific community. The court's function is to distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs. *Ryan,* at page 46, citing *Landrigan v. Celotex Corp.*, 127 NJ. 404, 605 A. 2d 1079, 1084 (1992). (Emphasis added.)

Further, in the *Ryan* decision, the Court of Appeals held that in order for expert opinion testimony to be admissible, the party offering evidence must show to the trial court by

factual evidence that the expert is a qualified expert in the field and thereafter, the trial court must make a factual determination that the expert proffered indeed is a qualified expert in the field. *Ryan,* 123 Idaho at 47, 844 P.2d at 29. In determining whether these foundational requirements have been satisfied, the trial court must make various factual determinations; i.e. whether the expert is qualified, whether the evidence would be of assistance to the finder of fact, whether the facts upon which the expert's testimony is based are of the type other experts in the field would reasonably rely, and whether the probative value of the evidence is outweighed by its prejudicial effect. *Id.*

As exemplified in *State v. Johnson*, 119 Idaho 852, 856, 810 P.2d 1138, 1142 (Ct. App. 1991), where an expert witness doctor had no expertise in the area in which he would testify, this state's appellate court upheld the objection to foundation. *Daubert v. Merrill Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993) is also instructional in this matter. The *Daubert* decision held that speculative expert testimony is inadmissible. While the *Daubert* case dealt specifically with expert scientific testimony as opposed to expert medical testimony, such as in this case, the U.S. Supreme Court cautioned litigants as to the reliance and basis of Federal Rule of Evidence 702, which is virtually identical to Idaho Rule of Evidence 702. Both Rules cover all types of expert testimony. As the United States Supreme Court noted in Daubert:

> The word knowledge connotes more than subjective belief or unsupported speculation. The term applies to any body of known facts or to any body of ideas inferred from such facts or accepted as true on good grounds.

Id. at 590, 113 S. Ct. at 2795. The *Daubert* court further held that the proposed testimony must be supported by appropriate validation, i.e. good grounds based on what is known. *Id.*

In this case, Dr. Hammer's opinion did not comport with these essential requirements.

2. Dr. Hammer's opinion lacked a scientific basis.

Dr. Hammer testified that the Propofol Michael Hall received did not cause Propofol Infusion Syndrome, or PRIS. PRIS is manifested by a patient with severe and untreatable metabolic acidosis, severe damage to skeletal muscle tissue, an arrhythmia of the heart (termed bradycardia or abnormally slow heart rate), lipedemia, liver damage, and the break down of skeletal muscle. Dr. Hammer proffered testimony during the Plaintiff's prima facie case that Michael Hall did not die due to PRIS. In fact, all the experts and treating physicians that opined on causation agreed with Dr. Hammer, that Michael Hall did not die due to PRIS.

Dr. Hammer admitted that Michael Hall died due to cerebral edema, which is a medical finding that is **not** cited in any peer review or scientific study to occur as a result of the long-term use of Propofol. Further, cerebral edema is not cited in any peer reviewed article or of scientific study as one of the findings in PRIS.

Under Idaho law a medical expert must not only be qualified, but there must be a scientific basis for the expert's opinions. *Swallow v. Emergency Med. of Idaho, P.A.*, 138 Idaho 589, 592, 67 P.3d 68, 71 (2003) (citing *State v. Faught*, 127 Idaho 873, 908 P.2d 566). In addition, the underlining theory or methodology advanced by the expert must possess "sufficient indicia of reliability." *City of McCall v. Seubert*, 142 Idaho 580, 585, 130 P.3d 1118, 1123

(2006); *State v. Merwin*, 131 Idaho 642, 646, 962 P.2d 1026, 1030 (1998). Thus, expert opinion is not allowed if the methodology or reasoning underlying that opinion is not scientifically sound. *Swallow*, 138 Idaho at 592, 67 P.3d at 71.

While Idaho has not expressly adopted all of the standards set forth in *Daubert*, the Idaho Supreme Court recently recognized that the Daubert standards of "whether the theory can be tested and whether it has been subjected to peer-review and publication" have been applied by Idaho Courts. *Weeks v. E. Idaho Health Servs.*, 143 Idaho 834, 838, 153 P.3d 1180, 1184 (2007). As such, where an opinion is based upon scientific medical knowledge, there must be a scientific basis for that opinion. *Id.* (citing *Swallow*, 138 Idaho at 592, 67 P.3d at 71). Dr. Hammer's opinion that Michael's cerebral edema was caused by Propofol lacks any scientific basis.

a. Dr. Hammer's opinion had not been subjected to any form of peer review.

In this matter, it was undisputed that Michael Hall died due to cerebral edema. Dr. Hammer provided no published peer review medical studies that showed that Propofol caused cerebral edema which led to death. In fact, Dr. Hammer could not cite to any scientific or peer reviewed study that Propofol is known to cause cerebral edema. In his testimony on causation, Dr. Hammer relied upon an anecdotal study and a non-peer-reviewed article, neither of which supported the premise that Propofol caused cerebral edema. In fact, these two articles were discussed in great detail by the Defendants' experts and were shown to be inapplicable to

the cause of death for Michael Hall. Specifically, neither study showed that Propofol caused cerebral edema of the brain or PRIS (Propofol Infusion Syndrome).

In an effort to excuse the lack of scientific medical foundation, Plaintiffs rely upon the holding in *Weeks v. Eastern Idaho Health Services*, 143 Idaho 834, 838, 153 P.3d 1180, 1184 (2007) . This reliance is misplaced. Weeks involved the "rare" situation where no peer-reviewed articles were available. In this case, unlike *Weeks*, it is clear that peer-reviewed articles **are** available and **were** utilized by Defendants' experts at trial. In fact, Defendant brought Dr. Reed to trial to testify, who is one of the recognized researchers of Propofol and offered intimate knowledge as to the medical applicability, risks, and side effects of Propofol, or lack thereof. Dr. Reed cited to a substantial amount of peer-reviewed research and findings as well as his own actual knowledge regarding the long-term use of Propofol in pediatric patients.

Dr. Hammer was not able to cite to **even one** published medical study to support his opinion that Propofol would cause cerebral edema, the very damage suffered by Michael Hall. Instead, he relied on an anecdotal study cited in the PDR and an article published a year after the care was provided to Michael. Those two sources were also discussed in detail by all defense witnesses. The overwhelming evidence established that the PDR anecdotal study, even if deemed an appropriate foundational basis for an expert opinion, **did not apply** to the medical findings of Michael Hall's death. That anecdotal study dealt with Propofol Infusion Syndrome, which Dr. Hammer testified was not present in Michael Hall. The 2003 study relied on by Dr. Hammer was not even available at the time of Michael's care, and even if it was used, did not establish that Propofol would cause cerebral edema in a patient, let alone in Michael Hall.

Neither of the studies established that Propofol could, cause edema of the brain, especially in the absence of damage to any other organ or muscle, or any evidence of Propofol Infusion Syndrome. (PRIS).

b. Dr. Hammer's opinion is based only on a temporal relationship.

More importantly, Dr. Hammer's opinions do not constitute substantial evidence because the only basis for his opinion on causation is the temporal relationship between the use of Propofol and Michael Hall's death. *See Weeks*, 143 Idaho at 838, 153 P.3d at 1184 (citing Swallow, 138 Idaho 593-94, 67 P.3d at 72-73). In fact, after listing the chain of events allegedly leading up to the Decedent's condition, Dr. Hammer states: "I think all these things happen together in a predictable way to produce his death." See Appellants' Brief at 10. Dr. Hammer further testified that the "basic issues surrounding the care" of the Decedent somehow caused his death. See Appellants' Brief at 11. Dr. Hammer's use of timing, or a temporal relationship, is not proper evidence of causation. *See Weeks*, 143 Idaho at 838, 153 P.3d at 1184.

In the case of Michael Hall, many medications were needed and used, but Dr. Hammer only identified Propofol as a cause of Michael Hall's death.

Evidently, because Dr. Hammer could not rely on any scientific or peer-reviewed medical basis, the only avenue left to Dr. Hammer was the fact that Propofol was used as a sedative in Michael Hall's care and that Michael Hall died.

Defendant, Dr. Griffiths, had warned the parents prior to the reattachment surgery that one of the known risks of the surgery and after care was death. He explained the sedation and ventilation was necessary to try to re-establish blood flow to the bitten-off tissue and also re-

establish blood return from the tissue. To allow this re-vascularization to occur takes time and during that time the child must be completely still, even a grimace could disrupt the process, let alone movement of the head, scratching at the tissue, or any other movement or disruption to the tissue. Dr. Griffiths explained death as known risk due to the extensive surgical time, the subsequent bleeding that will be necessary which would cause substantial blood loss and the need for blood transfusions, the long term sedation that would be necessary to keep the child from moving, as well as the need to place the child on a ventilator because he would not be able to breathe on his own.

D. What Caused Michael to Die.

There is no dispute that Michael died due to the effects of cerebral edema. Dr. Hammer agrees with that finding, as do all the defendants' witnesses who opined on causation. The only question on causation at trial was the cause of cerebral edema. The Plaintiff proffered the opinion of Dr. Gregory Hammer that the sedative needed to monitor Michael in a quiet state in the ICU was the proximate cause of the cerebral edema. Dr. Hammer rendered this opinion without any medical or scientific basis whatsoever. Dr. Hammer did not have one case study, article, reported finding, research, text book, or even personal experience to support the opinion.

The defendants rebutted the opinion of Dr. Hammer, by requiring him to admit that Michael died due to the effects of cerebral edema, that he had no basis nor had he ever seen Propofol cause cerebral edema in someone without any other Propofol side effects.

The defendants' experts searched the world medical literature, case studies, reported medical research and found not **one** piece of medical literature to support Dr. Hammer's opinion. Defendants then proffered Michael's treating physician, experts, medical literature and studies which evidence that Michael did not die due to Propofol. The Defendants proffered the opinion of Dr. Richard Latchaw, re-known and world known pediatric neuro-radiologist. In forming his opinion on Michael's course of death, he had studied all the images of Michael's brain and body, he too had conducted his own research of the world's medical literature, and also utilized his own expertise, education and experience. It was Dr. Latchaw's opinion that Michael died of a cyto-toxic brain event. He also reviewed similar brain damage and damage patterns in the cerebellum of the brain of other patients that were similar to Michael's images. In those brain images he reviewed, to include Michael's, Michael's damage pattern was similar. The other cases, in which he compared to Michael's damaged brain, had died due to a toxic injury to the brain which resulted in cerebral edema, not from Propofol action directly on the brain, hypotension or low blood flow, but rather from a toxic event, Tr. Vol. I, p. 1607, L. 4, caused by something other than Propofol, hypotension, or low blood flow. Tr. Vol. I, p. 1607, L. 4 – p. 1619, L. 25.

The cerebellum damage can go undetected for 2-5 days, or until the swelling becomes so great that the pressure in the brain exceeds its limits of normal function. Tr., Vol. I, p. 1621, L. 7 – p. 1624, L. 20.

This case had a tragic outcome, even though all the health care professionals worked diligently to save Michael. Death was a risk to this surgery and after care, but no one wanted that outcome from this horrific dog bite.

E. Dr. Griffiths Is Entitled to Costs and Attorney's Fees on Appeal.

Dr. Griffiths requests costs and attorney fees on appeal pursuant to Rules 41(a) and 11.1, Idaho Appellate Rules, and Idaho Code Section 12-121. Attorney fees and costs may be awarded on appeal when the "court is left with the abiding belief that the appeal was brought, pursued or defended frivolously, unreasonably or without foundation." *Minich v. Gem State Developers, Inc.*, 99 Idaho 911, 918, 591 P.2d 1078, 1085 (1979) at 918. Moreover, attorney fees and costs "are awardable if an appeal does no more than simply invite an appellate court to second-guess the trial court on conflicting evidence." *Johnson v. Edwards*, 113 Idaho 660, 662, 747 P.2d 69 (1987), citing *Booth v. Weiser Irrigation Dist.*, 112 Idaho 684, 735 P.2d 995 (1987). When a "dispassionate view of the record discloses that there is no valid reason to anticipate reversal of the judgment below," attorney fees and costs should be awarded. *Rueth v. State*, 103 Idaho 74, 81, 644 P.2d 1333, 1340 (1982).

In this case Plaintiffs, without identifying any clear error by the district court, have asked this Court merely to second-guess the district court's well-supported decision to grant Dr. Griffiths' motion for a judgment notwithstanding the verdict. Dr. Griffiths respectfully submits that he is entitled to costs and attorney's fees.

IV. CONCLUSION

In this case, the District Court found that Plaintiffs failed to provide competent expert testimony from a qualified witness to testify regarding the applicable standard of care, and failed to present substantial evidence establishing a causal connection between Propofol and the death of Michael Hall. As set forth in the District Court's Memorandum, and supported in Respondent's Brief herein, that the District Court's ruling of JNOV was based on the law of the State of Idaho and should be affirmed. Dr. Griffiths respectfully requests this Court affirm the District Court's ruling granting his Motion for Judgment Notwithstanding the Verdict.

DATED this 23rd day of January, 2009.

MOFFATT, THOMAS, BARRETT, ROCK & FIELDS, CHARTERED

By _____ ISB# 7093
Nancy J. Garrett – Of the Firm
Attorneys for Respondent
Russell Griffiths, M.D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this _____ day of January, 2009, I caused a true and correct copy of the foregoing **RESPONDENT'S BRIEF** to be served by the method indicated below, and addressed to the following:

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