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Coombs v. Curnow Appellant's Brief Dckt. 35157

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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,

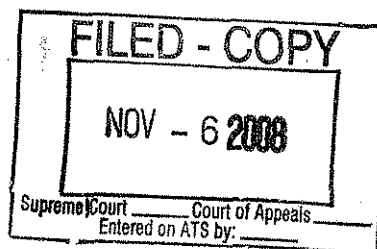
Plaintiffs/Appellants,

vs.

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

Defendants/Respondents.

DOCKET NO. 35157



APPELLANTS' BRIEF

Appeal from the District Court of the
Fourth Judicial District of Ada County

Honorable Deborah A. Bail
District Judge, Presiding

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I. ISSUES ON APPEAL

There is but one issue in this appeal:

- A. Was there substantial, competent evidence to support the jury's verdict?

II. STATEMENT OF THE CASE

A. Nature of the Case:

This is a medical malpractice action brought against two Boise physicians. They failed to adequately care for a child not yet three years of age after placing him in an intensive care unit following non-life threatening surgery and sedating him for 92 hours with a drug which was unfamiliar to them and not indicated for the long-term sedation of children. Due to the neglect and willful ignorance of the physicians, the boy's oxygen needs were compromised to the point where brain death occurred.

His mother brought this wrongful death action against the two physicians. At the conclusion of an eleven-day trial a jury verdict was rendered against the physicians in the amount of \$750,000. Post trial, and some six months later, the district court granted the physicians' motions for judgment notwithstanding the verdict with the district court ruling incorrectly that there must be peer-reviewed, published journal articles supporting an expert's opinion in order for that opinion to be acceptable. This appeal followed.

B. The Course of Proceedings

1. Complaint filed December 17, 2004

2. Defendants' multiple motions for summary judgment and to strike affidavit of Gregory B. Hammer, MD, 9/21/06 - 3/28/08.
3. Jury Verdict, 9/19/07
4. Defendants' Motions for Judgment Notwithstanding the Verdict, 9/28/07.
5. Decision and Order Re: Motions for JNOV, 3/28/08.
6. Appeal filed, 3/31/08.

C. Statement of Facts

Michael Hall was a little boy just under three years of age who, in 2002, tangled with a large dog. The dog took a bite out of Michael's cheek and both Michael and the tissue (described in the coroner's report as approximately 2" x 2"), Tr. p. 147, ll. 6-17, were rushed to St. Alphonsus Regional Medical Center. The dog bite, while serious, was not a mortal wound and should not have caused Michael's death. Tr. p., 175, ll. 9-14.

Dr. Curnow, a pediatric surgeon, took control of the case and called in Defendant Griffiths, a pediatric plastic surgeon, to work with him in attempting a tissue reattachment on Michael's face. Everyone agrees that the wound was not life-threatening and that Michael was certainly not expected to die. Eg., Dr. Curnow, Tr. p. 1056, ll. 12-15; Dr. Georgeson, Tr. p. 2036, ll. 21-24.

In fact, Michael was described by Defendant Curnow as a well-developed, well nourished, almost three-year-old boy, Tr. p., 1027, ll. 3-6. Dr. Curnow testified that Michael's heart, lungs and brain were in good condition, he had no known allergies and he

was a good surgical candidate. Tr. p. 1926, ll. 3-18. He had no hepatitis, (Tr. p. 1978, ll. 10-12,) no jaundice (Tr. p. 1981, ll. 11-13). He had had all of his immunizations. (Tr. p. 1027, ll. 14-20).

Dr. Groben, the Ada County Coroner's pathologist who conducted the autopsy, observed that Michael was in "good condition" and a "normal little boy." with no signs of child abuse or neglect. *Id.* "There was no cardiac reason for him to die." Tr. p. 161, ll. 9-10. Examination of Michael's organs revealed no pathology or disease or sickness. Tr. p. 164, ll. 13-18. Tr. p., 145, ll. 6-22. No trauma or bruising was noted. Tr. p. 147, ll. 2-5. The anesthesiologist, Dr. Smagula, testified that, aside from the dog bite, Michael was a healthy child, Tr 1809, ll. 1-3. One of the defendants' primary experts testified "There was nothing systemically abnormal about this boy." Dr. Latchaw, Tr. p. 1643, ll. 1-3. In short, all of the medical doctors agreed that Michael was a healthy and normal little boy, a little smallish perhaps, but within the parameters of expected growth and development as measured by weight and height.¹

With the consent of his mother, Michael was taken to surgery and Dr. Griffiths stitched the tissue back on to Michael's face. A second surgery followed within a matter of hours and Michael was then sent to the ICU to be monitored both by Dr. Griffiths and

¹ He was between the 5th and the 10th percentile for height and weight. Tr. p. 821, ll. 2-3.

by Dr. Curnow to see if the tissue would revascularize and “take.”²

During the two surgeries Michael was sedated with a drug known as Propofol. Propofol is often used for short periods of time for sedation both with children and adults. According to its manufacturer, however, and confirmed by the testimony of Plaintiffs’ experts and the 2002 Physician’s Desk Reference (PDR), Propofol is not indicated to be used for the long term sedation of children in the ICU.³ In 2002, the time in question, the long term use of Propofol was very, very uncommon Tr. p. 322, ll. 14-20 and only done with extremely close monitoring of the patient.⁴

The Propofol was initially chosen by an anesthesiologist, Dr. Smagula, in consultation with Dr. Griffiths for the short-term purposes of the initial surgery. Dr. Smagula, the anaesthesiologist, and Dr. Griffiths, the surgeon, had never met before. *Id.*, l. 13 and it was only happenstance that brought them together in the operating room at the same time, *Id.*, ll. 14-17. Put otherwise, Dr. Smagula was a stranger to Dr. Griffiths. Tr. p. 1810, ll. 6-8. There was no extended discussion about the Propofol that was to be used

² The defense spent much unnecessary trial time discussing this procedure, how difficult it was, how the procedure was necessary to avoid disfigurement of Michael in his later life, the tools used in the procedure, the skills demonstrated by Dr. Griffiths and the like. All of this was totally unnecessary as Michael’s mother was never in the slightest way critical of either defendant for undertaking or performing the procedure. Tr., p. 1082, ll. 5-20. This case focused instead on what the defendants did or did not do after the surgery and while Michael was in the ICU under their care.

³ The 2002 Physician’s Desk Reference (PDR) while not technically admitted into evidence was quoted from extensively and the entry on Propofol was frequently displayed for the jury’s benefit. The district court accurately noted the entry most frequently discussed at trial. R. p. 126.

⁴ “Long term” was defined as more than 24 hours. Tr. p. 855, ll. 16-22.

with Michael in the operating room. Significantly, this anesthesiologist was not asked by either of the defendants to look after Michael after the surgery, to make rounds on him, or to check up on Michael's care while he was being sedated on a long term basis. Dr. Smagula was not asked to give any advice with respect to the long term sedation of Michael with Propofol. He had no discussion with Dr. Griffiths about the length of time that Propofol would be administered to Michael in the ICU. His advice was never sought regarding how long Michael should remain on Propofol. He was never asked about the reduction of the dosage after Michael entered the ICU. (Tr. pp. 1811-1812). Dr. Smagula denied emphatically ever approving or recommending Michael being kept on Propofol for 92 hours in the ICU at St. Alphonsus, Tr. p. 1813, ll. 9-16.

Neither Dr. Griffiths, Tr. p. 2238, ll. 12-19, nor Dr. Curnow, Tr. p. 1041, ll. 14-24; Tr. p. 1042, ll. 5-10 had ever used Propofol for the long term sedation of children prior to Michael's death. Nevertheless, Dr. Griffiths, with Dr. Curnow's knowledge and concurrence, signed the order for the indefinite, long-term use of Propofol. For approximately 92 hours Michael was kept sedated on the drug. The reason he was placed in the ICU was to keep him quiet so that he could not disturb the attempted reattachment of the tissue. He was intubated, on a ventilator, unable to speak, and sedated to the point of unconsciousness. The initial dosage and order of Dr. Griffith for the administration of Propofol was never changed from the time Dr. Griffiths first gave it to the time when he discontinued his care of Michael some days later upon determining that the attempt to

reattach the tissue was a failure. Tr. p. 1107, l. 22 - p. 1108, l. 3; Tr. p. 1975, ll. 13-21.

Virtually every expert on both sides agreed that a physician is supposed to know the properties and contraindications of drugs which he or she orders for the patients.⁵ "Would you agree with me that a medical doctor who uses a drug ought to know generally the properties and contraindications of the drug? A. Yes." Dr. Curnow's testimony, Tr. p. 1050, ll. 19-22.

Even the nursing staff knew better than to keep this boy on Propofol on a long term basis in the ICU. Nurse Crockett, a St. Alphonsus employee, made an entry in the hospital nursing notes which read as follows:

06/25 9:30 MD Contact By: Tamela R. Crockett, RN
Dr. Curnow at bedside, asked by this nurse re: contraindications of propofol use in children. Responds, "no I use propofol in kids all the time. The trouble comes of concurrent use of propofol and lipids with parenteral nutrition, and I'm not going to put any lipids in the TPN." Patty Soran, Pediatric Clinical Case Manager in attendance. Ex. 1, p. 195.

Even after being warned by Nurse Crockett Dr. Curnow did not do any research about this drug with which he was unfamiliar, Tr. p. 1052, ll. 17-21.⁶ He admitted that the use of Propofol for long-term sedation was totally outside the realm of his practice, Tr. p. 1049, ll. 2-4. Dr. Curnow admitted further that although Michael was a complex pediatric

⁵ Dr. Griffiths, Tr. p. 1092, ll. 12-17; Dr. Curnow, Tr. p. 1050, l. 19-22; Dr. Vestal, Tr. p. 1536, l. 24 - p. 1537, l.4; Dr. Smith, Tr. p. 2109, ll. 15-19. Dr. Reed, Tr. 1736, ll. 1-5.

⁶ Dr. Curnow admitted that Nurse Crockett was a nurse with whom he was familiar and that he regarded her as a competent nurse. Tr. p. 1051, ll. 9-13.

patient he never requested a pediatric intensivist to follow Michael in spite of the fact that Dr. Christiansen, a pediatric intensivist known to Dr. Curnow, was available. Tr., p. 1045, I. 21 - p. 1046, I. 1; Dr. Christiansen, the pediatric intensivist, was a good physician in the opinion of Dr. Curnow, Tr. p. 1047, II. 19-22 and available but was not even consulted. This in spite of the fact that with respect to the drug Propofol Dr. Curnow testified "I don't use it for long term sedation . . . I just don't use it . . ." Tr., p. 1041, II. 18-24. Dr. Curnow was not even aware of what the dosage of Propofol should be if used long term with children. Tr. p. 1042, II. 5-10.

Dr. Curnow agreed that both defendants were equally responsible for the care of Michael while he was in the ICU. Curnow Tr. p.1042, II. 11-15

Dr. Griffiths who signed the order for Propofol also admitted that when a doctor of medicine orders a drug for a patient he or she should know generally the properties and contraindications of the drug. Tr. p. 1092, II. 12-17. Although he signed the order for the administration of Propofol on a long term basis, although he had never ordered Propofol for the long term sedation of any children in the ICU prior to Michael's case (Tr. p. 2238, II. 12-19) and although he had no advice from any anesthesiologist that this order was appropriate, Dr. Griffiths did not look up any information on Propofol prior to Michael's death. Tr. p. 1093, II. 14-18. Although he, too, had never used Propofol for the long term sedation of children in the ICU, Dr. Curnow similarly did nothing to research or to educate himself about the drug before or even after Michael's death. Tr. p. 1944, II. 6-8. The

testimony from both plaintiffs' and defendants' experts was that a computer search on Propofol could have been done easily and very quickly.⁷ Had either physician done so he would have quickly learned that Propofol was not indicated for the long-term sedation of children and that there was a FDA warning against its use. Defendants' expert agreed that the PDR entry on Propofol provided a "caution" and a "flag." Tr. p. 1738, ll. 5-22. As the trial court observed, (R. p. 126):

The entry most frequently discussed at trial provided:

[propofol] is not indicated for use in pediatric patients for ICU sedation or for MAC sedation for surgical, nonsurgical or diagnostic procedures as safety and effectiveness have not been established.

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 . . . 2002 PDR exhibit 6.

Both Dr. Griffiths and Dr. Curnow followed Michael in the ICU. Michael's vital signs and lab reports, were recorded and available to them around the clock. Tr. p. 1095, ll. 14-24.

The tissue that Dr. Griffiths had reattached to Michael's face did not "take". The technical term is "revascularization" but the tissue, without an adequate blood supply, did

⁷ Dr. Groben, Tr. p. 156, ll. 22-24; Dr. Reichard: "Probably within a minute." Tr. p. 1275, l. 22.

not adapt and had to be removed after about the fourth day that Michael was in the ICU. The tissue was removed, the wound was debrided and the next day, June 26th, Dr. Griffiths left town leaving Michael in the ICU and still on the Propofol drip. Tr. p. 1105, ll. 14-25. Dr. Griffiths never saw Michael again while Michael was alive. Tr. p. 1107, ll. 7-11. Even, after it was apparent that the tissue would not reattach, Dr. Griffiths still did not take the time to look up anything about Propofol on the hospital computers although such were available, Tr. p. 1093, ll. 14-18 and admitted that as to the team taking care of Michael there was no "quarterback." Tr. p. 1112, ll. 4-9. Similarly, Dr. Curnow went on vacation the morning of June 26th leaving Michael still sedated on Propofol, intubated and on a ventilator in the ICU. Tr. p. 1060, ll. 8-10.

In addition to the initial and continuing selection of Propofol for the sedation of this little boy, his vital signs and laboratory reports showed that he was experiencing difficulties which were either ignored or not recognized or not appropriately treated. Tr. p. 446, ll. 5-15. Michael's blood pressure from the beginning of the administration of Propofol to the point where it was stopped just prior to his death was extremely and abnormally low. [Ex. 1054] That blood pressure was graphically displayed on a time line for the jury and is provided as an appendix to this brief. It essentially was in the range of 60/20 with some, but not much, movement up and down. In addition, the values for the oxygen-carrying components of the blood -- the hemoglobin and hemocrit -- were very low sometimes reaching "panic" values. Ex. 1052; Tr. p. 1430, l. 16 - p. 1431, l. 8. Additionally, the liver

enzymes escalated from the normal range of approximately 20 to 50 to 899 over time indicating a seriously-compromised liver. Ex. 1052. Michael's temperature was also elevated over time which increased his brain's and body's need for oxygen. Tr. p. 868, l. 21 - p. 869, l. 19.

All of these deficits were apparent to the defendant physicians who were responsible for monitoring Michael. It was they who ordered the lab reports and it was they who reviewed these lab reports. Tr. p. 2231, ll. 18-24. These values were tell-tale signs that Michael was in distress but inadequate steps were taken to relieve that distress including, but not limited to, the discontinuance of the Propofol which was keeping him sedated without an appropriate oxygen supply to his brain. There were many indications for decreasing the dose or turning it off altogether. The lab reports were available. Tr. p. 2232, ll. 14-18. But the Propofol was never discontinued by the defendants.

Propofol is a toxic drug with toxic side effects. Tr. p. 245, ll. 10-25. Loring Beals, a registered clinical chemist and toxicologist, testified that Propofol lowers the blood pressure, interferes with the uptake of certain fatty acids necessary for the body's energy production [Tr. p. 246, ll. 1-3] and causes "oxygen deprivation throughout the body and liver function problems can arise with prolonged use." Tr. p. 246, l. 23 - p. 247, l. 1. Propofol interferes with the pumping of the heart and reduces the contractile strength of the heart muscle "so that when it beats you do not get an -- effective circulation of the blood." *Id.* ll. 13-16. The liver manufactures proteins necessary for the maintenance of the

circulation of blood and which are also involved in the body's metabolism where hemoglobin -- the red pigment in red cells -- is being manufactured. The liver also manufactures albumin which, if decreased, reduces circulation. This scientific explanation and the consequences of the administration of Propofol were stated clearly:

So first the heart is not pumping well because it doesn't have the contractile strength to really -- to do that, and one of the things that you observe as a result of that is what is a -- the jargon for it is hypotension, which just simply means the blood pressure that is too low, so you can get the failure of the blood to circulate in an appropriate satisfactory manner.

When the heart puts the squeeze on the blood, if you want to think of it that way, and the arterial blood is being forced under pressure out to the tissues, you get the blood which has just been circulated through the lungs and has picked up oxygen from the breathing process, and it's attached to the hemoglobin that I referred to, and it's distributed through all of the tissues.

And as the arteries break down into smaller and smaller vessels called arterials and finally into tiny, tiny little vessels called capillaries, and through the walls of those capillaries fluid moves out of the blood circulation and into the cells, into the tissues, and it carries the nutrient molecules, it carries the oxygen to the tissues, and if this is not going well, the oxygenation of the tissues is failing, and then the cells begin to break down.

I alluded to the albumin and the globulin, particularly the protein made by the liver, which itself now after a period of time is being damaged from lack of oxygen, and the liver cells, then, cannot make albumin well, and so you have a lowering of the albumin level in the circulation. Tr. p. 248, l. 10 - p. 249, l. 18.

Mr. Beals went on to explain the dangers of hypotension [Tr. p. 730] and the function of the liver in manufacturing proteins necessary for the production of hemoglobin and albumin. Tr. p. 732, ll. 16-25. The albumin produces what is called an "osmotic" tension. When the blood goes through the heart, arteries and capillaries, both oxygen and nutrient material is delivered to the cells through the cell membranes along with certain

fluids. After the fluid has distributed its oxygen and nutrients carbon dioxide should flow out of the cell for eventual elimination by the body. But "if the albumin is present in too low a concentration, the fluid does not return properly -- some of it does, but it doesn't do it well enough, and accumulative effect of that is that fluid is retained in the tissues and the word for that is edema, swelling and fluid buildup in the tissues." Tr. p. 734 - 735, l. 1.

The brain is particularly sensitive to the edema caused by a reduced blood flow, reduced oxygen, and reduced albumin because "the swelling has nowhere to go. It's enclosed in your skull, and this is a problem." Tr. p. 735, ll. 5-8. This oxygen deficiency is called "hypoxia."

In this case it was undisputed that Michael died from "brain cerebral edema and global hypoxic changes." Tr. p. 149, ll. 16-17. That is something Dr. Groben, the pathologist, "was able to see by looking at the brain." Tr. p. 149, ll. 16-22. Dr. Groben stated that the brain hypoxia and cerebral edema were not related to the dog bite. "The dog bite itself didn't cause the cerebral edema." Tr. p. 150, ll. 17-18. The defendants' expert pathologist, Dr. Reichard, agreed that Michael died of a cerebral global hypoxic ischemic event. Tr. p. 1276, ll. 1-4.

Dr. Groben determined that Michael's brain was "structurally normal" but evidenced "changes that are consistent with lack of oxygen, the hypoxia and the cerebral edema" Tr. p. 164, ll. 22-24.⁸ Dr. Groben also noted that there were "some questions" about the use

⁸ Defendants' expert pathologist, Dr. Reichard, showed tissue slides taken from Michael's brain evidencing "shrunken dead neurons." and added "so when there is a lack of blood flow and oxygen to the

of Propofol with Michael as he initially got a post mortem call from Risk Management at St. Alphonsus questioning whether the Propofol should have been used on Michael. Tr. p. 165, l. 23 - p. 166, l. 9. In Dr. Groben's opinion, the edema in Michael's brain was the immediate cause of death because the swelling cuts off the blood supply to the brain and the brain "swelled up so much that it impinged upon the vessels that are coming up through the bottom of the skull into the brain, and I think it actually cut the blood supply off and resulted in lack of blood flow to the brain."

Gregory Hammer, M.D. , a pediatric intensivist and anesthesiologist, then brought these threads together and connected the dots between the application of Propofol, the clinical signs and symptoms while Michael was in the ICU at St. Alphonsus, the failure of the defendants to learn about their drug of choice, the failure of the defendants to address the alarming clinical signs and symptoms in the ICU and the ultimate death. Dr. Hammer applied his scientific and medical knowledge to connect these dots and his testimony was grounded not in fiction or speculation but on scientific fact.

Dr. Hammer appropriately focused on the care provided to Michael by his two physicians after his surgery, i.e., during the time that Michael was sedated in the ICU. He provided a foundational showing of expertise which enabled the court to allow him to state opinions both as to standard of care and causation. He was double-board certified by the American Board of Anesthesiology and the American Board of Pediatrics as well as having

brain, the neurons or the nerve cells will die." Tr. p. 1267, ll. 16-18.

a sub-board certification in critical care medicine. Tr. p. 304, ll. 10-19. He has authored 70 to 80 journal articles, 25 or 30 book chapters on anesthesia and pediatric critical care "with the focus on pharmacology, that is the study of and science of drug disposition in children." Tr. p. 306, ll. 7-15. He has worked extensively with pediatric surgeons and was recruited to teach at Stanford University. Tr. p. 308, l. 17 - p. 309, l. 8. Much of his work is done in the pediatric ICU and in the OR with pediatric surgeons, pediatric plastic surgeons as well as other medical specialists. Tr. p. 313 - p. 314, l. 12.

Having studied the medical records of both defendants and the hospital records including all lab reports, Dr. Hammer summarized his opinions as to causation on cross-examination as follows:

Q. BY MS GARRETT: In 2002, isn't it true that there was no causal relationship for the use of Propofol and brain edema or that led to brain death?

A. No. I would strongly disagree with that statement.

Q. You would?

A. Right, because Propofol causes hypotension, which was seen in this patient, when, especially in combination with the low hemoglobin and the elevated temperature, that contributes to hypoxia ischemia of the brain and predisposes to cerebral edema and brain death, and there is no question in my mind that that was operative in this case.

And also, Propofol contributes to an elevated concentration of lipids in the bloodstream, which was clearly observed in this case, and the amount of lipids that was being administered was extremely high to this patient, and the amount of sugar was very low, and that condition is also well-known to cause cellular toxicity. So those two findings, I think, are indisputable, in my mind.

The third cause of brain injury related to Propofol is the mitochondrial toxicity, but that would be No. 3 on the list, and I believe it's almost certainly true that that contributed. But that would be an exacerbating factor to, I think, relatively indisputable causes No. 1 and 2 that aren't related to the infusion syndrome but just are an effect -- adverse effects of Propofol.

So I think it's undisputable that Propofol led to the development of brain swelling and death in this patient. Tr. p. 812, l. 5 - p. 813, l. 14.

Dr. Hammer actually gave a clinic about the physiology of the human body, involving microbiology and chemistry including the body's utilization of oxygen which he described in a diagram drawn for the benefit of the jury entitled "Oxygen Utilization 101, the entry-level class." Tr. p. 817, ll. 16-17. Dr. Hammer continued:

A. So, the mitochondria need substrate, which is oxygen and glucose in this case, so the things that failed were inadequate delivery of substrate related to inadequate hemoglobin and low flow, low blood pressure, so there was not enough blood pressure, so those were diminished.

And in addition to that, there was actually an excess of fatty acids present because of all the lipids in the Propofol, which causes toxicity; and Propofol specifically, in addition to that, blocks uptake of fatty acids and the utilization of fatty acids inside the mitochondrion for production of ATP, so there is actually a whole number of steps related to hypotension, anemia, hyperlipidemia.

And then I believe in this mitochondrial toxicity associated with Propofol, I think this is the part of it you are saying is controversial, but all of these other steps here are not controversial.

These are Basic Cell Physiology 101 in oxygen utilization that clearly failed because of the conditions of low hemoglobin, low blood pressure, too much lipid in the bloodstream and not enough glucose administration. Tr. p. 817, l. 25 - p. 818, l. 24.

Speaking directly to the drug Propofol, Dr. Hammer testified that it was well known in 2002 -- the time of the occurrence -- that Propofol causes the blood pressure to drop by depressing heart function and dilating blood vessels. That leads to less return of blood to the heart and less blood for the heart to pump out to the arteries in the body and a consequential lowering of blood pressure. "So by all of those mechanisms, by dilating the veins, causing the heart muscle itself to relax, that is not pumping as vigorously, and also

dilating the arteries in the body, the blood pressure will drop.” Tr. p. 326, ll. 9-13. Propofol not only promotes hypotension but also creates additional fat which, as it breaks down into fatty acids, becomes dangerous. And, additionally, the mitochondrion’s function is compromised and energy production becomes depressed and cellular death can follow. That is to say, when ATP production is diminished, the integrity of the cell is diminished because the inadequate energy means that the cell cannot pump fluids out of the cell, the cell has become swollen and this leads to cell death. In an enclosed compartment like the head the pressure inside the head goes up and there “becomes a runaway cycle of swelling, pressure, death, etc.” All of these are the disadvantages and effects of Propofol.

The record is replete with page after page after page of scientific explanation as to these intricate functions within the body. At Tr. p. 341 - 343, Dr. Hammer testified in great detail about the adverse effects of Propofol and how a physician taking care of a patient who is being administered Propofol should carefully monitor for and detect the signs and symptoms of problems for the patient. Dr. Hammer’s testimony was neither speculative nor unsupported by science as he stated:

I think everything I have said so far is quite basic, things we learned in medical school, things we think about directly or indirectly every day, especially in the intensive care unit, where we are thinking a lot about making sure that the tissues in the body have enough oxygen, the right amount of glucose, the laboratory values are monitored, blood pressure is very important, these sorts of things. Tr. p. 353, ll. 6-14.

Dr. Hammer expected board-certified surgeons to know these basic scientific principles that he explained to the jury so carefully and in so much detail. *Id.* ll. 15-18.

The record showed that Michael began to suffer from cardiac arrhythmias which were precipitated by inadequate blood flow, inadequate or low hemoglobin and the toxic effects of the Propofol combined. Tr. p. 354, ll. 1-10. The Propofol definitely caused or contributed to the low blood pressure (hypotension) and definitely cause the lipemia and in all likelihood caused toxicity to cells in the body. *Id.* ll. 21-25. Ultimately, the Propofol caused or contributed significantly to the hypotension therefore decrease in blood flow to vital organs in the body, including the brain, the heart, the liver and other vital tissues. As summarized by Dr. Hammer:

And these are all in combination, especially with the low hemoglobin that the Propofol did not cause, but these events taking place simultaneously all resulted like a triple or quadruple whammy where they all resulted in diminished oxygen delivery to the brain which ultimately caused the brain swelling and also caused inadequate oxygen delivery to other organs in the body for which there is evidence so I think all of these things happened together in a predictable way to produce his death. Tr. p. 355, l. 18 - p. 356, l. 17.

III. ARGUMENT

A. Scope of Review

In reviewing the lower court's ruling on a judgment notwithstanding the verdict the Appellate Court exercises free review of the record, without deference to the views of the trial court, to determine whether the verdict can be supported under any reasonable view of the evidence. *Litchfield v. Nelson*, 122 Idaho 416, 420, 835 P.2d 651, 654 (Ct. App. 1992). This is purely a question of law, the question being whether there is substantial evidence upon which the jury could properly find a verdict in favor of the Appellant, *Quick*

v. Crane, 111 Idaho 759, 763, 727 P.2d 1187, 1191 (1986). As to a decision on whether to admit expert testimony, the standard of review defers to “the sound discretion of the trial court and will not be overturned except on a showing of abuse of discretion.” *Grover v. Smith*, 137 Idaho 247, 249, 46 P.3d 1105, 1107 (2002).

B. A Summary of the Argument

The trial court impermissibly weighed the evidence in ruling on the Motion for Judgment Notwithstanding the Verdict. What is in the record must be regarded as true and all inferences from that evidence are to be drawn in favor of the party opposing the motion. There was substantial, competent, evidence to support the jury’s verdict and reasonable minds could conclude that the jury’s verdict was proper. That was as far as the court needed to go. Moreover, the trial court’s focus on the evidence was misguided and far too narrow with the court holding that an expert’s opinion must be supported by peer-reviewed publication in scientific journals.

C. Argument

This evidence then -- all of it -- is true and must be remembered as true for the purposes of this appeal. From the Respondents’ point of view the evidence is arguable.⁹ But such argument should not be accommodated with the four corners of this appeal.

It is well-established in Idaho jurisprudence that the party making a motion for

⁹ In the response to this Appellants’ Opening Brief no time should be spent in discussing the evidence which defendants believe rebuts or defeats plaintiffs’ evidence. The sole question is whether the *plaintiffs’* evidence was substantial and competent.

judgment notwithstanding the verdict must admit the truth of all adverse evidence and every inference that may legitimately be drawn therefrom. *Litchfield, supra*.

Quick v. Crane, 111 Idaho 759, 727 P.2d 1187, 1191 (1986) is a seminal decision regarding post-trial motions. There, the Idaho Supreme Court stated clearly with reference to Rule 50(b) that “in making the motion, the defendants necessarily admitted the truth of all of the plaintiffs’ evidence and every legitimate inference that could be drawn therefrom in the light most favorable to the plaintiff.” At 763, citing *Stephens v. Sterns*, 106 Idaho 249, 252-253, 678 P.2d 41, 44-45 (1984). *Quick v. Crane* goes on to state with respect to Rule 50(b) that “The trial judge is not free to weigh the evidence or pass on the credibility of witnesses and make [her] own separate findings of fact and compare them to the jury’s findings as [she] would in deciding on a motion for new trial.” *Id.* Citing *Gmeiner v. Yacte*, 100 Idaho, 1, 4, 592 P.2d 57, 60 (1979).

The Idaho Supreme Court has observed that in most jury trials ending in a verdict there will be conflicting evidence. The response to that observation is that “Where there is conflicting evidence, the court is required [under Rule 50(b)] to construe all of the evidence in favor of the jury verdict, including all reasonable inferences therefrom, to determine whether there is substantial evidence to support the verdict.” *Watson v. Navistar International Transportation Corporation*, 121 Idaho 659, 661, 827 P.2d 656, 699 (1992). The requisite standard is whether the evidence preceding the verdict is of sufficient quantity and probative value that reasonable minds could reach the same conclusion as the jury did in the case under consideration. *Id.*

When the evidence set forth at some length above is considered, its truth admitted and all inferences are legitimately drawn from that evidence then there certainly is a body of "substantial evidence" upon which the jury could have relied and which compels the conclusion that reasonable minds could reach the same conclusion as did the jury in this case. Whether the defendants reach the same conclusion is not important in this regard.

The defendants both argue, each in his own way, that the plaintiffs failed to provide substantial evidence that Propofol was a cause of Michael Hall's death (Dr. Griffiths' position) or, more broadly, that the defendants' care was an actual cause or proximate cause of Michael Hall's death. (Dr. Curnow's position). They neglect, however, to concede that IRE 702 allowed much expert testimony against both positions.

"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." We know from *Sheridan v. St. Luke's Regional Medical Center*, 135 Idaho 775, 785, 25 P.3d 88, 96 (2001) that no specific statute requires causation in a medical malpractice case to be proven by expert testimony. Instead, "unlike the elements of duty and breach of duty, there is no statutory requirement explicitly stating proximate cause in medical malpractice cases must be shown by direct expert testimony. Therefore, testimony admissible to show proximate cause in a medical malpractice case, like any other case, is governed by the rules of evidence regarding opinion testimony by lay witnesses and experts under Idaho Rules of Evidence 701 and 702." *Id.*

It was no accident or random selection that caused plaintiffs to call Dr. Groben from the Ada County Coroner's Office and Mr. Beals as witnesses prior to Dr. Hammer's testimony. Dr. Groben and Mr. Beals both provided foundation for Dr. Hammer's causation opinions. Dr. Groben performed the autopsy on Michael's still-warm corpse and testified clearly regarding his findings regarding brain swelling as the immediate cause of death. He also negated the presence of any underlying pathology which could explain the death. Dr. Groben explained his autopsy findings which included the clinical history of hypotension, cerebral edema and global hypoxic changes in the brain. He stated clearly that Michael suffered an anoxic brain injury leading to brain death and, most significantly, ruled out any evidence of medical diseases.

Mr. Beals, a registered clinical chemist and toxicologist with many years of local experience at St. Alphonsus and the VA Medical Center testified specifically regarding Propofol and its properties and effects on the human body. Mr. Beals explained the process of an "osmotic effect" where cells become swollen as their ability to cast out fluids diminishes because of a complex physiological process involving cellular function deficiency. Mr. Beals also commented on the toxicity of Propofol referencing, in part, the 2002 Physician's Desk Reference data contained in that publication. Mr. Beals also spoke to liver damage which could be caused by Propofol.

By the time Dr. Hammer took the stand and began his critical examination of empirical evidence it was obvious that plaintiffs had provided a substantial body of

evidence which allowed the linking of the action and inaction of the defendants to the death of Michael by means of a "chain of circumstances from which the ultimate fact required to be established is reasonably and naturally inferable." See, *Formont v. Kircher*, 91 Idaho 290, 296, 420 P.2d 661, 667 (1965) (quoting *Reinhold v. Spencer*, 53 Idaho 668, 690, 26 P.2d 796, 798 (1933) (citations omitted) -- cases cited in the *Sheridan* case, *supra*, at 783 as support for the Supreme Court's holding there.

In the *Formont* case -- a medical malpractice action -- the plaintiff had a leg infection which, when untreated, led to the amputation of the limb. The trial court concluded that there was not enough proof as to proximate causation but on appeal the court reversed the trial court stating the rule approved in *Sheridan*:

Respondent was not required to prove his case beyond a reasonable doubt, nor by direct and positive evidence. It was only necessary that he show a chain of circumstances from which the ultimate fact required to be established as reasonably and naturally inferable. *Formont* at 296 (citations omitted).

In *Sheridan, supra*, the Supreme Court cited *Formont* in holding that "... proximate cause can be shown from a 'chain of circumstances from which the ultimate fact required to be established is reasonably and naturally inferable.'" citing *Formont* at 667. Then, in reviewing St. Luke's appeal from the court's refusal to direct a verdict under the same standard applicable to a Rule 50(b) motion, the court added:

The evidence in this case was not uncontroverted; however, from our review of the record of the trial below, *and drawing all inferences from the evidence in a light most favorable to the non-moving party*, there was substantial evidence regarding proximate cause and damages to justify submitting the case to the jury. At 786, emphasis added.

Here, plaintiffs did have “direct and positive” evidence of a causal connection between the conduct on the part of the defendants which included, but was not limited to, the selection and continued use of a toxic drug not indicated for the long-term sedation of children in the ICU.

The causal connection is between the conduct of the defendants and the global hypoxic ischemic event which was the immediate cause of Michael’s brain death. That conduct did not stop with the initial selection of a sedative drug, Propofol, which was not supposed to be used for the long-term sedation of children in the ICU. It was not merely the continuation of that sedative drug in sedating a helpless, intubated, mute small child. It was not merely the initial and continued ignorance of both defendants in not doing even the slightest amount of research on their sedative drug of choice – even though neither of them had ever previously used this drug for pediatric long-term sedation.¹⁰ It was not just the refusal to heed the warnings of Nurse Crockett who confronted Dr. Curnow and cautioned him about the use of this drug and then went so far as to make a self-protective entry in the nursing notes. It was not merely the failure of the defendant physicians to deal with consistent and extreme hypotension, fever, low hemoglobin, low hemocrit, each one being a marker of low amounts of oxygen available for utilization by Michael. Rather, it was a constellation of these things which caught the attention of the jury and caused the verdict

¹⁰ As the evidence showed, the PDR was readily available and computers were similarly available for a quick discovery of the dangers and non-suitability of the use of Propofol as it was being used on Michael hour after hour, day after day.

against these treating physicians. Astra Zeneca, the manufacturer of Propofol was not a defendant here because Propofol is not inherently fatal. It is a useful drug which was *misused* in Michael's case and became a proximate cause of death.

The defendants convinced the trial court that when there is a drug involved, there must be a series of peer-reviewed journal articles or studies which confirm the testimony of an expert who opines that a certain drug produced a certain result. Exhibit A for this defense argument was a 2003 decision by this Court involving a plaintiff who suffered a heart attack after taking a drug called Cipro.

The district court took note of *Swallow v. Emergency Medicine of Idaho*, 138 Idaho 589, 67 P.3d 68, (2003) and used the case as precedent for her reversal of the jury's verdict. But *Swallow* certainly does not control here and is not even particularly relevant.

First, *Swallow* considered the district court's ruling which declared the opinions of a cardiologist and a pharmacologist inadmissible. In the case under consideration, the trial court overruled objections and *admitted* the opinions of plaintiffs' experts into evidence. The jury heard this evidence and were never instructed to ignore it or to give it no weight. This evidence was admitted after and in the face of long and strenuous argument by the defendants. The record here evidences extended colloquies between the court and counsel where the court ruled clearly that Dr. Hammer was qualified to state his opinion as to both causation and standard of care and that there was adequate foundation for his opinions. There was no abuse of discretion in admitting this evidence. It is there in the

record and has not been stricken.

Second, the experts in *Swallow* really did not have a good scientific explanation for the effect of Cipro on Mr. Swallow and how it caused his heart attack. The cardiologist stated that in order to cause a heart attack Cipro “would have either a vasoactive or pro-coagulative effect, and he did not know whether Cipro had either effect.” At 593. The witness could not explain the pathophysiology at issue and was mistaken in his interpretation of the PDR entry on Cipro. *Id.* This caused the trial court to observe that this proffered testimony “really amounts to nothing more than speculation based on a temporal concurrence of events.” At 594. The same reasoning precluded the admission of the opinion of the pharmacologist. At 595.

Contrast this lack of expert knowledge in *Swallow* to the evidence offered by Dr. Hammer and Mr. Beals and allowed into evidence by the trial court. Dr. Hammer did know how a combination of causes resulted in the global hypoxic event which was the immediate cause of death. The “chain of circumstances” leading to the cerebral edema was explained by Dr. Hammer, link by link. Working backwards from the obvious and well-documented hypoxia, Dr. Hammer applied his knowledge of several branches of medical science including cellular biology, chemistry, physiology, anesthesiology, pathology, anatomy, toxicology, oxygen utilization, metabolic reactions and the like. Propofol played a large part in the ultimate result. But so did the lack of red blood cells necessary to oxygenate the brain, the malfunction of the liver, the cardiac arrhythmias, the extremely low

blood pressures and the relatively high-dose, continued, relentless, unchanged use of Propofol. The lab reports told of a boy in distress. The defendants missed the signs and symptoms which should have told them -- had they bothered to look up the properties and contraindications of Propofol -- to reduce the dosage of Propofol or to discontinue it altogether. This was *not* "nothing more than speculation based on a temporal occurrence of events." *Swallow* at 594. It was an opinion or series of opinions based on direct and positive evidence in the record which led to a well-explained, reasonable and defensible conclusion.

Swallow does not say that a medical doctor cannot use analytical deductive and inductive logic in determining cause and effect. Medical doctors do this every day. Medicine is an applied science or grouping of branches of scientific knowledge.

The defendants argue with great vigor that there are no "scientific studies" which link Propofol to cerebral edema. This confuses "scientific evidence" with scientific studies. The jury seemed to be convinced that nobody in the United States has put a small child who was not critically-ill on Propofol and kept him sedated for 92 hours without knowledge of the properties of the drug and without taking the child off of the drug when lab tests demonstrated that the child was evidencing an adverse reaction to the sedation. One cannot conduct an experiment and ethically submit small boys to 92 hours of sedation with Propofol. The lack of literature is a function of the lack of similar, negligent behavior by physicians elsewhere. It is no accident that the defendants and their experts (Drs.

Lachtaw, Georgeson, Reichard, Johnston, Vestel, Reynolds, Womack, Smith and Smagula) have not used Propofol for the long-term sedation of children in the ICU. Under the circumstances surrounding Michael's death there was no precedent.¹¹ We do not need a peer-reviewed journal article about gravity-induced death because of parachute failure.

Dr. Hammer stated repeatedly that he was not utilizing "rocket science" in formulating his opinions. On the contrary he spoke to basic scientific principles found in the medical textbooks that doctors study in medical school. Tr. p. 353, ll. 6-14. There was substantial evidence produced at trial and the truth of that evidence must be assumed here.

This was not an "iffy" situation as seen in *State v. Konechny*, 134 Idaho 410, 3 P.3d 535 (2000) where social workers were attempting to interpret a child's testimony so as to testify that sexual abuse had occurred.

The proffered testimony in *Konechny* was to give expert opinions regarding the reliability of a child's account and other circumstantial evidence that sexual abuse had occurred. Apparently this expert testimony focused on psychological theories and the therapeutic and investigative roles of mental health professionals. That type of situation is a far cry from the testimony provided by Dr. Groben, Mr. Beals, Dr. Hammer and the

¹¹ Michael Reed, Pharm D., testified that Propofol is used on a long-term basis in his hospital in Cleveland, Ohio but that patients receiving Propofol have to be closely monitored, Tr. p. 1249, ll. 15-23, that he did not know if any of the top children's hospitals in the USA used Propofol for pediatric long-term sedation and that the FDA has not approved Propofol for the long-term sedation of children in the ICU. Tr. p. 1774, ll. 6-12.

medical records themselves which set forth, page after page, hard data showing what Michael's condition was for a period of time exceeding 92 hours measured at fairly rapid and distinct intervals. This provided foundation for testimony involving and applying the exact sciences of toxicology, chemistry, biology, microbiology as well as basic medicine.

The appellate court in *Konechny* observed there that the admissibility of expert opinion is governed by IRE 702 which measures the qualification of an expert by five factors: knowledge, skill, experience, training or education. Dr. Hammer and the toxicologist, Mr. Beals, qualified on all five factors as outlined in the Statement of Facts in this brief. Both men were eminently qualified¹² to bring to the jury scientific evidence and need to interpret that evidence through their knowledge of a variety of scientific specialties such as toxicology and microbiology. They did so. That evidence was admitted and covered several hundred pages of detailed testimony.

The district court's misapplication of case law illustrates the fact that the court seemed to assume that Propofol -- not the conduct of the defendant physicians -- was on trial. The court cited, for example, at R. p. 127 the *Swallow* case which has already been reviewed here. Also cited is *Bloching v. Albertson's, Inc.*, 129 Idaho 844, 934 P.2d 17 (1977) where an action brought by a diabetic who switched from one insulin to another

¹² Even the district court was impressed with Dr. Hammer's presentation, background and scientific learning: "Dr. Hammer is a board-certified pediatrician and anesthesiologist with a sub-board in pediatric critical care. He is on the faculty of the Stanford Medical School where he is a professor of anaesthesiology and pediatrics. He is the author of numerous articles and a text book on pediatric intensive care." [R. 116] He is a gifted and well-trained physician who practices and teaches at one of the foremost medical centers in the world." [R. 133]

upon the pharmacist's recommendation immediately began to suffer seizures. In *Bloching*, Bloching's physician said that it was "possible" that the new insulin could have caused a reaction. However, that opinion was so unsupported by any data that the district court refused to admit the evidence. That was upheld by the Idaho Supreme Court and the summary judgment was affirmed. The *Daubert* case, *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579, 113 S. Ct. 2786 (1993) itself involved the drug Bendectin and its linkage with serious birth defects. There was a great deal of data on both sides regarding millions of pregnant women who had taken the drug to control morning sickness. There, scientific studies could be and were undertaken which led to the ultimate holding, recognized by the district court here at R. p. 123 that "trial courts have a 'gatekeeper' function to make sure that scientific or technical knowledge is sufficiently grounded so that it's admission would aid a jury in determining issues before it." ¹³

A third case cited by the district court is *Kemp v. State*, 809 A.2d 77 (2002) where the New Jersey Supreme Court grappled with the connection between the rubella virus vaccine to a pregnant woman which allegedly caused the child to develop serious problems. Again, there was much data based upon a large population that had been administered the rubella vaccine. The court refused to admit the expert opinion into evidence. Thus all of the cases cited by the district court in support of her decision involve

¹³ In this instance, the gatekeeper opened the gate and allowed the evidence in. That is a second reason why *Daubert* would not be applicable here.

cases where the drug and not the conduct of the defendant was directly at issue and where the proffered evidence was not admitted. Neither of those situations exist here.

One can disagree with the conclusions expressed by plaintiffs' experts. The defendants did disagree for days on end at trial, in post-trial briefing and, it is expected, will do so in their reply to this brief. But that disagreement with and disappointment in the jury's verdict does not negate the truth of the competent and substantial evidence admitted at trial. And once that truth is assumed then that should be the end of the argument on the Rule 50(b) motion.

The principal issue was why Michael died. The defendants and their many experts drawn from around the United States stated that they did not know why Michael's brain became swollen to the point where he died. Dr. Hammer testified that he knew why the cerebral edema developed. His testimony was based not on a mere temporal connection as occurred in *Swallow v. Emergency Med of Idaho, supra*, but upon deductive reasoning utilizing empirical data and applying the various branches of medical science with which he was very familiar. This approach in a case involving brain swelling in a two-year old boy resulting in death was allowed by the trial court and seemingly approved by this Court. *State v. Merwin*, 131 Idaho 642, 644, 962 P2d 1026, 1028 (1998). Experts disagreed as to causation but the defendants' conviction was upheld on the basis of medical testimony from physicians.

The district court's memorandum decision clearly evidences an impermissible

weighing of the evidence as lacking “scientific reliability”, R. 125. Ignoring the foundation and logic of Dr. Hammer’s opinions as to causation, the district court incorrectly stated that “Dr. Hammer relied only on two sources in forming his opinion . . .”, R.125, those being the Physicians Desk Reference (PDR) and a 2003 study in a medical journal. If this were the only foundation for Dr. Hammer’s opinions on causation the case would not have taken 2-½ weeks to try.

What was apparently forgotten by the district court in the intervening six months between the jury’s verdict and the court’s decision regarding that verdict was the application by Dr. Hammer of basic medical science. That, too, is a scientific approach. Just as one does not expect medical journals to write about gravity-induced death related to the failure of parachutes, neither does one expect articles about the application of Propofol at a relatively high dosage rate to a not critically ill and not-yet three year old boy for 92 straight hours.

The defendants took some eight days in their presentation of evidence. Nowhere in that presentation did they show that a small boy was ever sedated with the dosage Michael experienced and kept sedated for 92 hours with Propofol while experiencing at the same time terribly low blood pressure, low hemoglobin, low hemocrit, spiking body temperature and cardiac arrhythmias. The district court seemingly wanted scientific research papers to be written about this grouping of events and linking them to Propofol.

But how can scientific studies be conducted about situations which don't occur because of the standard care in the ICU which prevents this scenario from occurring? Where are there opportunities for scholarly research? In *Manning v. Twin Falls Clinic & Hospital*, 122 Idaho 47, 50, 830 P.2d 1185, 1118 (1992) a medical doctor was able to testify that oxygen deprivation was the proximate cause of death of a 67 year old man without any mention of peer-reviewed published journal articles. The Idaho Supreme Court had no difficulty accepting this testimony.

Weeks v. Eastern Idaho Health Services, 143 Idaho 8343, 153 P.3d 1180 (2007), addresses the very situation that is presented to this Court and comments that in very "rare" circumstances experts can testify in the absence of peer-reviewed published studies. The Court in *Weeks* was confronted with a situation where a catheter had been placed in Weeks' head to drain excess fluid from her brain. Medications that were intended to be injected into her intravenously were instead injected into the drainage catheter causing an infusion -- rather than drainage -- of fluid into Weeks' brain. As a result of this error Weeks' condition was worsened by these actions. Dr. Smith, a board-certified neurosurgeon with thirty years experience, testified as an expert on behalf of Weeks. The substance of that testimony was summarized as follows by the Idaho Supreme Court:

In this case Dr. Smith testified that the infusion was a substantial factor in causing Evelyn's death to a reasonable medical probability, but he was unable to determine the exact effect of the medication on Evelyn's brain. He testified that the mechanical aspect of fluid buildup could not be separated from the chemical aspect of the composition of the fluid, and he was not certain whether the chemicals themselves, the volume of fluid, or the combination of the two caused her death. Dr. Smith stated that it was

impossible to tell the exact hydrodynamic, autoimmune, and biochemical effects of the infusion because that would require a series of controlled experiments or laboratory studies which would never be performed. No research has been done based upon this exact type of occurrence, and the effects of administering dopamine and amiodarone directly into the central nervous systems of humans or animals have never been studied. However, Dr. Smith was clear that infusion of this volume of fluid, whether over an eight hour period or a period of a few minutes, would cause a deleterious effect "just from the fact of fluid going in when it should be going out." This is not speculation and is based on more than a temporal concurrence. 143 Idaho at 839, 153 P.3d at 1185.

The Idaho Supreme Court then held that Dr. Smith's expert testimony was properly admitted notwithstanding the fact there was no peer-reviewed published information supporting his conclusions. The Court cited to the Ninth Circuit's decision in *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1060 (9th Cir. 2003) for the proposition that when there are few opportunities for scholarly research the lack of published studies should not bar otherwise scientifically valid testimony.

Dr. Smith's expert testimony in *Weeks* established that, "the mechanical aspect of fluid buildup could not be separated from the chemical aspect of the composition of the fluid, and he was not certain whether the chemicals themselves, the volume of fluid, or the combination of the two caused her death." The Idaho Supreme Court upheld this statement as admissible expert testimony.¹⁴

To the same effect is the testimony of Dr. Hammer in this case summarizing his

¹⁴ *Weeks* is not new law. See, e.g., *Formont v. Kirchen*, 91 Idaho 290, 296, 420 P.2d 661, (1966) citing *Reinhold v. Spencer*, 53 Idaho 688, 26 P.2d 796 (1933) regarding the rule that medical negligence and causation need not be proved by "direct and positive" evidence, the only necessity being that of establishing a "chain of circumstances from which the ultimate fact required to be established is reasonably and naturally inferable."

opinion as to causation:

A. Again, the Propofol caused or contributed significantly to the hypotension, and therefore, decrease in blood flow to vital organs in the body, including the brain, the heart, the liver and other vital tissues.

It is incontrovertible that Michael Hall suffered from severe hypotension throughout his stay in St. Alphonsus. His blood pressure was extremely low on a consistent basis and his heart rate was very high for long periods of time. Tr. p. 363, ll. 19-20. The lab values supported multi-organ injury. *Id.* There was solid evidence of liver injury connected to the Propofol. Tr. p. 364-365. Dr. Peck, a local radiologist, commented that Michael's brain scan showed "extensive ischemic injury likely secondary to hypotension" Exhibit 1, p. C00114. Michael also experienced cardiac arrhythmias which are a known effect of Propofol in some patients. Michael's hemoglobin was consistently far below the norm. The same may be said for his hemocrit as documented in the laboratory tests as well as his albumin which contributed to the inhibited osmotic effect discussed by plaintiffs' expert toxicologist.

While Dr. Hammer did testify concerning his opinions regarding Propofol and its effects, Dr. Hammer also addressed himself to very basic issues surrounding the care of Michael Hall while a patient of the defendants. These basic items had to do with the failure to control the extremely low blood pressures, the failure to insure adequate oxygenation of the tissues, the inability of the blood to provide enough oxygen to the brain, all combining with the known, documented, toxic effects of Propofol to ultimately cause the

brain swelling and death.

In stark contrast to plaintiffs' proof, the defendants really had nothing to explain the death and no good argument that they did not cause the death. Neither of the defendants and none of their experts from all around the United States came up with an opposing theory which would indicate why or how Michael died. Yet the death of Michael is something beyond argument. He died. In the face of that death it does not seem that the defendants themselves did anything to investigate alternative causes of that death. Instead, people who were friendly with Dr. Curnow (Dr. Johnston) or under whom he had studied (Dr. Georgeson) were called to testify even though they had no experience with Propofol being used on a long term basis for the sedation of children in the ICU. Similarly, Dr. Griffiths called as his principal experts, Dr. Reichard, a pathologist, who freely admitted that his examination showed a global hypoxic ischemic event which caused the brain to swell, Dr. Latchaw who had absolutely no experience with Propofol or the ICU care of children and Dr. Smith from Twin Falls who similarly had no experience with Propofol nor any opinion whatsoever as to why Michael Hall died.

It is submitted that the combination of Dr. Groben, Mr. Beals, and Dr. Hammer set forth their opinions based upon verifiable, observable and documented facts upon which they were competent to utilize their expertise and testify under IRE 702. Weighing the testimony of expert witnesses is uniquely within the competence of the trier of fact. *City of McCall v. Seubert*, 142 Idaho 580, 585, 130 P.3d 1118, 1123 (2006). The Court's

instructions to the jury did not state that Propofol (or anything else) had to be “the” proximate cause of Michael Hall’s death but only that the negligence of the defendants had to be “a” proximate cause.¹⁵ Dr. Hammer testified that he was able to state his ultimate conclusion as to both actual cause and proximate cause. Tr. p. 451, l. 8 - Tr. p. 452, l. 11. He did that with a clarity and demeanor that was persuasive to the jury. It is respectfully submitted that this is the type of testimony which supports the proposition that reasonable minds could reach the same conclusion as did the jury in this case. That is the test under Rule 50(b) and the plaintiffs clearly met that test.

STANDARD OF CARE

Both defendants continue to insist -- for the fourth or fifth time in this case -- that Dr. Hammer was not sufficiently knowledgeable about the post-operative standard of care existing in Boise, Idaho, in 2002 so as to offer an opinion with respect to the violation of that standard. In so doing the defendants must convince this court that there was an abuse of discretion in allowing Dr. Hammer to testify on the standard of care. *Grover v. Isom*, 137 Idaho 770, 774, 53 P.3d 821, 825 (2002) states clearly that in a medical malpractice case “Whether a witness is qualified as an expert is reviewed for an abuse of discretion.”

¹⁵ At R. 00127 the court erroneously stated in her Memorandum Decision that the use of a drug has to be “the” proximate cause of a negative health outcome. That is incorrect as a matter of law and shows the court’s overly narrow focus in this case.

There were multiple efforts by the defendants to exclude Dr. Hammer's testimony both as to causation and as to the defendants' breach of the standard of care. All of those efforts were to no avail. The court allowed Dr. Hammer's opinions in evidence. Those opinions must be seen now as true under Idaho law. *Litchfield, supra*, at 419.

In the six months between the jury's verdict and the district court's Order granting the JNOV motion the district court must have forgotten much of the evidence. That is understandable as there is no suggestion that the district court had a full trial transcript.¹⁶ If the district court had had the transcript a review of the then six-month old testimony would have revealed no basis for court's determination that Dr. Hammer was assessing the conduct of the defendants "based upon research which was reported after the care is rendered." R. p. 136. That is incorrect. Dr. Hammer testified that the FDA promulgated information in 2002 which contraindicated the use of Propofol for the long-term sedation of children in the ICU. Tr. p. 841, ll. 16-21. The FDA assessment was national and not limited to any particular locality. Tr. p. 840, ll. 2-8. There were journal articles published in 2002 that indicated that Propofol should not be used for the long-term sedation of children in the ICU. Tr. p. 842, l. 20 - p. 843, l. 11. Michael was infused with a dosage of Propofol at more than double the rate of a 2002 study where Dr. Hammer was sure that the Propofol infusion rate would have been turned "down or off if the blood pressure was

¹⁶ If the court had such a transcript then there would have been no reason for the court reporter to have taken three months from the time of ordering to prepare the transcript nor to charge the plaintiff \$7,700.00 for the preparation thereof.

low.” Tr. p. 837, l. 21 - p. 838, l. 14. Dr. Hammer stated that this is basic medicine.

The district court stated that Michael was being monitored in the ICU. R. p. 135. That is true. But it is just as true that the defendants did not recognize the importance of the results of that monitoring. The blood pressure was “dangerously low” (Tr. p. 869, l. 18) and Michael had a fever which causes the brain to require much more oxygen. Tr. p. 372, ll. 4-17. Yet the Propofol dose was not decreased. *Id.* ll. 1-19.

Dr. Hammer testified directly that his opinions are “based on medical science, physiology.” Tr. p. 867, ll. 6-11 and he explained the clinical signs and symptoms which were either ignored or not recognized by the defendants. There were signs of organ toxicity but the sedative drug was not modified. Tr. p. 446, ll. 5-15. This, too, was a breach of the standard of care for both physicians. *Id.* They did not know what everyone agreed was their responsibility to know, i.e., the contraindication and properties of the drug they were using on Michael coupled with clinical signs of unacceptable patient distress.

A simple literature search in 2002 would have yielded the defendants a series of articles, editorials and other publications regarding the hazards of Propofol in children for long-term sedation. Tr. p. 875, ll. 5-9. But no attempts were made by the defendants to learn about their drug of choice.

Any blood pressure for Michael below 75 over 40 or 45 would have been low and 70 over 30 would be considered “to be a critically low pressure in a child this age.” Tr. p. 878, ll. 1-9. Yet, Michael’s blood pressure was consistently even lower than this critical

level and nothing was done to bring it up. Exhibit 1054 (Appendix A-1)

Thus the defendants' performance was not, as the district court put it in her memorandum decision at R. p. 136, being judged "at a particular point in time from the vantage point of later research."

Plaintiffs stated in opening statements, throughout the trial and in closing argument that the malpractice being alleged had nothing to do with surgery, either plastic surgery or pediatric plastic surgery or pediatric surgery. Rather, since the defendants were each trained in basic medicine before specializing in other areas they are held to the standard of care of physicians who are following a pediatric patient in the ICU over an extended period of time while being sedated with a drug which is not indicated for that particular use. Dr. Hammer was not called to comment, one way or the other, on the surgical skills of either Dr. Griffiths or Dr. Curnow. It was abundantly clear at trial that Dr. Hammer focused exactly where the plaintiff drew the attention of the jury -- on what happened after the surgery was complete starting with the ill-advised and unconditional order for the use of Propofol which was signed by Dr. Griffiths and for which both he and Dr. Curnow must bear the responsibility. Further, "There is no requirement in [I.C. §§ 6-1012 and 6-1013] that an expert witness whose testimony is offered to establish a case of medical malpractice against a board-certified physician must also be board-certified in the same specialty." *Pearson v. Parsons*, 114 Idaho 334, 337, 757 P.2d 197, 199 (1988). Indeed, a physician can even testify about the standard of care of registered nurses in this state. *Manning*,

supra, at 52.

The foundation for Dr. Hammer's opinion was broad and covered a multitude of areas. The court ruled at trial that Dr. Hammer's testimony was admissible as it met applicable statutory and evidentiary standards relying, in part, on Dr. Hammer's sworn affidavits submitted earlier.

The evidence did show that in order to familiarize himself with the "local" standard of care Dr. Hammer did the following:

- He examined the process of the Idaho State Board of Medicine by which physicians are admitted to practice in Idaho.
- He reviewed policies and procedures at St. Alphonsus Regional Medical Center.
- He conferred with Dr. Avery Seifert who was the chief-elect of the medical staff at St. Luke's Regional Medical Center and who had practiced in Boise in 2002.
- He conferred with Dr. David Christiansen who was a pediatric intensivist working at St. Luke's Regional Medical Center in 2002.
- He conferred with Dr. David M. Kahn, a plastic surgeon specializing in pediatrics in 2002.
- He conferred with Dr. Mark L. Silan, professor of surgery and pediatrics and the head of pediatric surgery at the Oregon Health and Science University

in Portland, Oregon who stated that he was familiar with the standard of postoperative care in communities of a similar size in Oregon, to wit, Salem, Medford and Eugene and that, indeed, it was a national standard in those communities of a size similar to Boise.

- He read the deposition of Dr. Griffiths.
- He read the deposition of Dr. Reynolds.
- He read the deposition of Dr. Curnow.
- He conferred with his peers on a national basis throughout his professional practice at seminars, conventions and continuing medical education.
- He read the documentation contained in the 2002 PDR -- a document used in all 50 states and which warns, among other things, that Propofol is not indicated for the long-term sedation of children in the ICU.
- He read the product insert published by the manufacturer, Astra Zeneca, in effect in 2002.
- He read the deposition of Dr. Dell Smith, a plastic surgeon from Twin Falls who admitted that when a physician prescribes a drug for a patient he should know generally the properties and contraindications of that drug.¹⁷
- He read the deposition of Dr. Keith E. Georgeson, a pediatric surgeon from

¹⁷ "An out-of-state expert can become familiar with the local standard of care by review of depositions." *Perry v. Magic Valley Reg'l Med. Ctr.*, 134 Idaho 46, 51, 995 P.2d 816, 821 (2000).

Birmingham, Alabama, who was unaware of any surgeon in his area of the country using Propofol for the long term sedation of children in the ICU.

- He read the deposition of Dr. Michael Reed from Cleveland, Ohio.
- He read the deposition of Dr. J. Martin Johnston from Boise, Idaho who agreed that a physician's duty is to know generally the properties and contraindications of a drug which he prescribes.
- He read the deposition of Dr. Sarah Hirsch who practices with Dr. Curnow as a pediatric surgeon.
- He, himself, has used Propofol for the short term sedation of children.
- He, himself, has written a text book, many chapters in other text books and many journal articles involving the pediatric care of children. Propofol is among the topics covered.
- He, himself, worked in 2002 on a routine basis in the critical care area in an ICU taking care of pediatric patients.
- He was aware of the 2002 FDA contraindications as to the use of Propofol for the long term sedation of children in the ICU. Those were, in 2002, applicable throughout the United States.¹⁸

¹⁸ Some of this is not in the trial testimony but may be found in the pretrial affidavits submitted by Dr. Hammer and in a proceeding outside of the presence of the jury. Beginning at Tr. p. 377, l.22 the court called a recess upon the defendants' objections when plaintiffs had Dr. Hammer on direct testimony and began to ask him foundational questions as to how he had familiarized himself with the "local" standard of care. At this point in the trial the court had ruled, since there were no other pediatric surgeons or pediatric plastic surgeons in the state of Idaho (other than Dr. Curnow's partner) that the standard of

The defendants will argue that Dr. Hammer relied exclusively upon Dr. Silan. That is not true as evidenced by the above recitation of Dr. Hammer's foundation. Moreover, inquiring of a local physician regarding the local standard of care is only one method of obtaining knowledge of the local standard of care. *Perry, supra*, at 51-52.

Regardless, Dr. Hammer did testify as to what Dr. Silan told him. The question was posed:

- Q. And I heard you say to Mr. Lojek, and I am not sure if I wrote it down correctly, that you spoke to Dr. Silan, and I am sure that he was familiar with the standard of care in Medford and Salem, Oregon; correct?
- A. And Eugene. That's what he told me.
- Q. And Eugene, okay. Now, he told you he was familiar with the standard of care in Medford and Eugene and Salem?
- A. Yes.
- Q. Okay, the reason I ask was, you said "I'm sure he was," and I didn't know whether he had told you that or whether you had assumed he was.
- A. No, no, he told me that he was. I'm not sure if he operates there, he has clinics there, he works with physicians in those communities, but that's what he told me.

Tr. p. 455, l. 12 - p. 456, l. 5.

Additionally, Dr. Hammer testified that we were not talking about "rocket science"

care is that which applies to communities similar to Boise. This ruling followed *Hoene v. Barnes*, 121 Idaho 752, 828 P.2d 315, (1992), At Tr. p. 385-393.

The undersigned recited the things Dr. Hammer had done to familiarize himself with the standard of care by way of an offer of proof. The defendants objected to Dr. Hammer's proposed testimony at Tr. p. 393-437 with the court ultimately ruling that "the plaintiff has met the necessary burden [under I.C. §§ 1012 and 1013] to offer the [opinion] testimony for the jury's considerations . . ." and Dr. Hammer, with that ruling, was allowed to testify regarding the defendants' failure to meet the applicable standard of care.

in this case but, rather, basic medicine which conforms to a national standard. Dr. Hammer stated at Tr. 353, ll. 6-14.

I think everything I have said so far is quite basic, things we learned in medical school, things we think about directly or indirectly every day, especially in the intensive care unit, where we are thinking a lot about making sure that the tissues in the body have enough oxygen, the right amount of glucose, the laboratory values are monitored, blood pressure is very important, those sorts of things.

Q. By Mr. Lojek: In 2002 would you expect a board certified surgeon to know these things that you have been telling the jury?

A. Yes.

Q. Any question about that in your mind?

A. No.

There is also a common sense factor in this case which cannot be ignored by anyone. There was no evidence that either Dr. Griffiths or Dr. Curnow or Dr. Reynolds or Dr. Hirsch or Dr. Johnston or Dr. Smith or Dr. Georgeson or Dr. Latchaw or Dr. Vestal ever used Propofol for the long term sedation of children in the ICU. These are all defendants' physician experts. Their non-use of Propofol for the long-term sedation of children in the ICU itself says something about the standard of care in Boise in 2002. Additionally, neither Dr. Griffiths nor Dr. Curnow did anything after Dr. Griffiths signed the order for the use of the drug for long term sedation by way of research or any inquiry. In plain fact, they were both unaware of the properties and long-term effects of Propofol when used in a manner not indicated by the PDR and prohibited in 2002 on a national basis by the FDA.¹⁹

¹⁹ Then, of course, they could not have been monitoring for the adverse effects associated with the Propofol infusion syndrome as the district court erroneously stated at R. 135.

Yet, every expert cross-examined by plaintiffs' counsel, including direct testimony from plaintiffs' experts, indicated that physicians are expected to know generally the contraindications and properties of the drugs which they prescribe for their patients. There was no evidence to the contrary and that, in itself, would constitute a standard of care established by expert testimony on both sides. That standard was clearly violated by both Dr. Griffiths and Dr. Curnow who were inexperienced and ignorant about the long term effects of the drug which one ordered and the other approved. Even when Dr. Curnow was questioned by Nurse Crockett regarding the contraindications of Propofol, Dr. Curnow's response was to brush her off by saying that he used Propofol "all the time." Yet, Dr. Curnow had to admit that he had *never* used Propofol for the long term sedation of children in the ICU at any point in his practice, either before or after 2002.

With specific reference to Dr. Griffiths, Dr. Hammer was, based on 2002 standards, critical of the signing of an order for the extended use of Propofol without any time limits or guidance as to what to watch for in the ICU in terms of toxicity or low blood pressure. The consult with the anesthesiologist, Dr. Smagula, would have been appropriate, according to Dr. Hammer, if sufficient information was exchanged. However, when Dr. Smagula testified, it was apparent that Dr. Griffiths' plan of care was not revealed, that Dr. Smagula was never formally consulted, that Dr. Smagula was not asked to follow the patient and that Dr. Smagula neither recommended long term sedation in the ICU for Michael nor did he give advice concerning the propriety for the use of Propofol on a long

term basis in response to any inquiry.

When Dr. Griffiths did not bother to do any research whatsoever regarding the properties and contraindications of Propofol, even though that research could have been easily accomplished as testified to by Dr. Groben, Dr. Hammer, Mr. Beals, Dr. Georgeson and admitted by Dr. Griffiths himself, he put Michael at risk. As stated by Dr. Hammer, the standard of care applicable to Dr. Curnow “was violated principally by the choice of Propofol in the dose used for the duration of time used, without appropriate laboratory monitoring and adjustments in the dose according to what was happening with the child over time.” Tr. p. 448, ll. 6-10. Dr. Griffiths, too, was at the bedside frequently. He saw the lab reports and blood pressure readings; yet he never altered his order for Propofol at relatively high dosages and then left town with that order still in place, Michael still helpless and sedated, and critical lab tests necessary to monitor organ toxicity still unordered. Tr. p. 861, ll. 1-7; Tr. p. 873, ll. 6-20.

IV. CONCLUSION

The district court’s ruling centered on the erroneous idea that an expert in a medical malpractice case needs peer-reviewed published studies in order to validate his or her opinion. That is not the law in this or any jurisdiction. In this case plaintiffs’ experts’ opinions were admitted into evidence and the jury could and presumably did consider them. The Respondent physicians will no doubt, argue the weight of the evidence was in their favor and that the jury’s verdict was incorrect. But jury arguments are over. The only question before this Court is whether the ruling on the Defendants’ single motion for APPELLANTS’ BRIEF - 46

judgment notwithstanding the verdict was proper.

The test for that question does not invite a second-guessing of the jury's verdict or rearguing the evidence. Neither the district court nor this court can act as the 13th juror, weigh the evidence and "decide" the case as this appeal is framed. Instead the test is whether there was substantial competent evidence before the jury to support its verdict. That is the only test. Appellants passed that test.

Indeed, there was competent, substantial evidence in abundance. This matter should therefore be remanded to the district court with instructions to enter judgment in favor of the appellants, *nunc pro tunc*.

RESPECTFULLY SUBMITTED this 4th day of November, 2008.

LOJEK LAW OFFICES, CHTD.




Donald W. Lojek - Of the Firm
Attorneys for Plaintiffs/Appellants

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 6th day of November, 2008, a true and correct copy of the foregoing instrument was served on the following by the method indicated below, and addressed as follows:

- | | | |
|-------------------------------------|-----------------------------|--|
| <input type="checkbox"/> | Hand Delivery | Patricia M. Olsson |
| <input checked="" type="checkbox"/> | U.S. Mail, postage paid | Jason G. Murray |
| <input type="checkbox"/> | Overnight Express Mail | Nancy Jo Garrett |
| <input type="checkbox"/> | Facsimile Copy:
385-5384 | Moffatt, Thomas, Barrett, Rock & Fields,
Chtd.
101 S. Capitol Blvd., 10 th Floor
PO Box 829
Boise, ID 83701 |

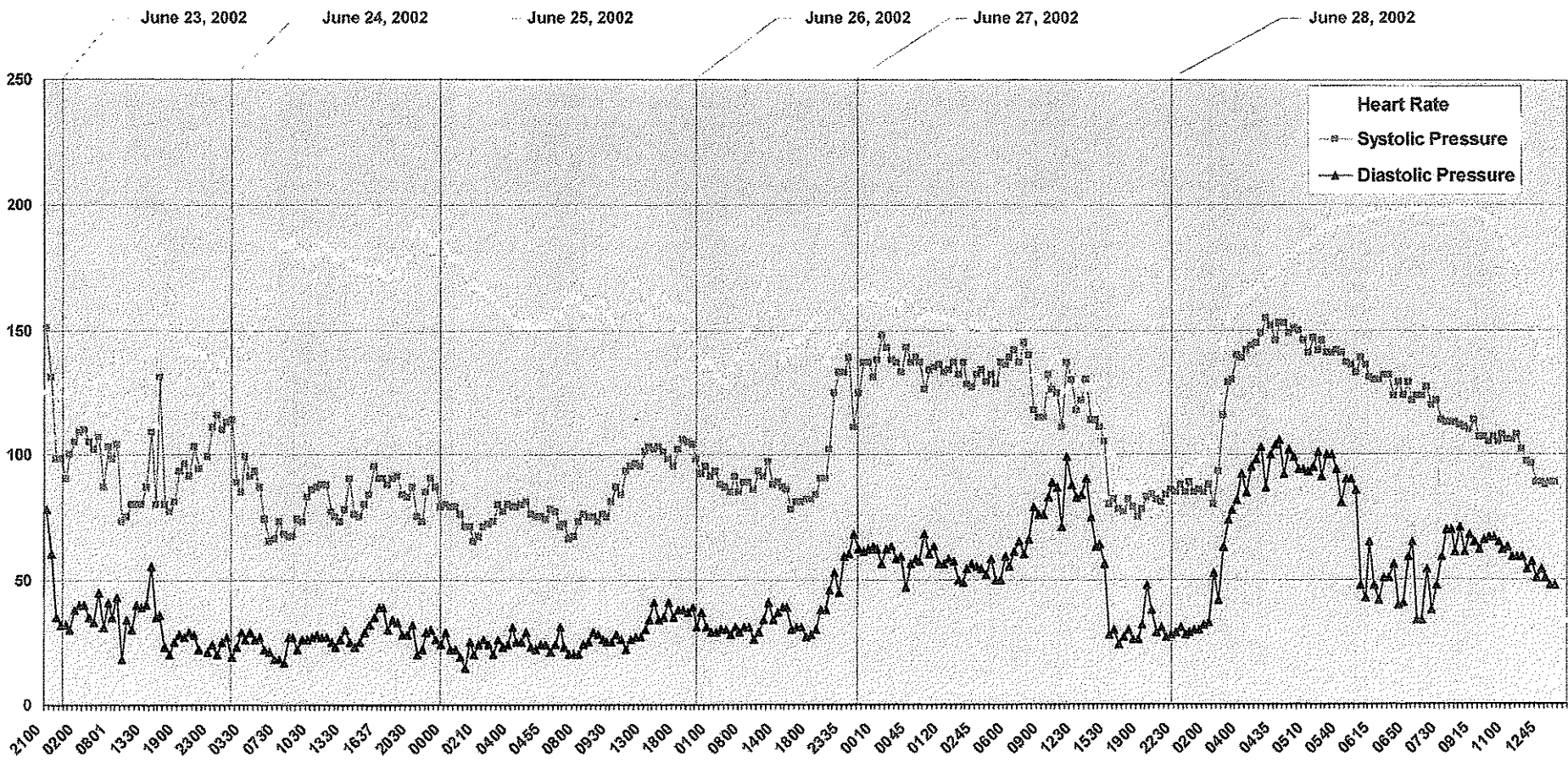
Attorneys for Respondents



Donald W. Lojek

APPENDIX A1

Michael Hall's Blood Pressure Graphically Displayed on a Time Line Ex. 1054



Heart Rate and Blood Pressure Timeline for
 Michael Hall from
 June 22, 2002 – June 28, 2002

