STATE OF MICHIGAN

COURT OF APPEALS

KEVIN KROHN,

Plaintiff-Appellee,

v

HOME-OWNERS INSURANCE COMPANY,

Defendant-Appellant.

UNPUBLISHED
January 26, 2010

No. 283862
Lenawee Circuit Court
LC No. 06-002176-NF

Before: Fort Hood, P.J., and Cavanagh and K.F. Kelly, JJ.

FORT HOOD, J. (*dissenting*).

I would affirm the jury verdict, and therefore, I respectfully dissent.

On December 11, 2001, plaintiff was involved in a car accident during his drive to work. His car was coming up on a hill when a one-ton van hauling medical supplies hit plaintiff's vehicle head on. Plaintiff suffered serious injuries. His right arm was nearly severed, his ribs were punctured, a lung collapsed, and his spine was fractured at T-10 and T-11. This spinal fracture was just below plaintiff's midchest area. After the accident, plaintiff did not have any kind of sensation or function below the injury site. He could not touch his feet or move any part of his body below the injury. Plaintiff could not even determine when he needed to go to the bathroom. Eventually, plaintiff was moved to an inpatient rehabilitation program at the University of Michigan (U of M) to learn how to do transfers and other things necessary to accommodate his injuries. During his physical therapy program at the U of M, plaintiff did not obtain any improvement in his condition. Consequently, plaintiff was released to perform the rehabilitation and physical therapy on his own.

After the accident, plaintiff began investigating whether there was any reasonable option that would improve his situation for himself and his family. Through the rehabilitation program at U of M, plaintiff learned of procedures performed in different parts of the world. Plaintiff learned of a procedure in Lisbon, Portugal through a patient who had benefited from the procedure. The patient referred him to the Rehabilitation Institute of Michigan (the institute), a facility that offers intensive physical therapy and other medical rehabilitation to individuals with spinal cord injuries. Although there were other stem cell procedures, plaintiff had an ethical problem with the embryonic type of procedure. Therefore, he decided to pursue the stem cell procedure in Portugal to determine if it would give him a benefit.

In order to be considered as a candidate for the stem cell procedure, plaintiff had to submit an application in order to obtain an interview at the institute. After his application, Dr. Steven Hinderer interviewed plaintiff. At the institute, plaintiff was able to see the patient who had the surgery in Portugal. She was able to stand on a device similar to a treadmill and walk with braces. This experience at the institute caused plaintiff to pursue the surgery. Dr. Hinderer advised plaintiff that the procedure was experimental. However, in plaintiff's opinion, the doctor explained both the pros and cons of the procedure in a positive way. Legally, Dr. Hinderer was unable to recommend the surgery. Additionally, to comply with legal standards, the decision to have the surgery remained with plaintiff. Although the Food and Drug Administration (FDA)[1] in the United States did not approve the procedure, plaintiff was not concerned about having a procedure performed that was not yet accepted in the U.S. Plaintiff had relatives who worked in the medical field that advised him of other procedures that were not yet performed in the U.S. that were positive and beneficial to people.

With regard to insurance, plaintiff testified that he had health care insurance through Blue Cross and Blue Shield (Blue Cross). As his primary health insurance, Blue Cross paid for his medical bills first, and defendant provided secondary insurance. Benefits not covered by plaintiff's health insurance were submitted to defendant. Plaintiff contacted Raymond Mickus, defendant's representative, and explained the procedure that he wanted to have performed. After conducting an investigation, Mickus advised that defendant would pay for the testing to determine if plaintiff was a candidate for the surgery, but would not pay for the surgery itself. Despite this knowledge, plaintiff decided to proceed to Portugal and have the surgery.

Immediately after the surgery, plaintiff noticed a difference in his body below the injury site. He was able to push stool out on his own during a bowel movement. Previously, plaintiff would have to use a glove to physically remove the stool. Also, plaintiff could now determine when he needed to empty his bladder, something he was unable to do before the surgery. Plaintiff's inability to determine when he had to use the bathroom impacted his health. This inability created problems such as leaking and also caused plaintiff to suffer from frequent urinary tract infections. As a result of the surgery, leaking was limited, and plaintiff suffered from fewer infections.

Plaintiff's commitment to the surgery required him to engage in an intensive physical therapy program at the institute in Detroit. He traveled to the institute three days a week for a "grueling" physical therapy session that would last over four hours. This therapy involved repetitive motion, floor contact, and crawling. Before the surgery, plaintiff was unable to crawl. Now, he was able to crawl both forward and backwards. Before the surgery, plaintiff was unable to move any of the lower extremities. Now, there were times when plaintiff was able to voluntarily move his lower extremities. Plaintiff testified that the benefits of the surgery included control over his bladder and bowel movements, increased hip function and control over his hips that aided his transfers, and increased circulation and blood flow to the lower extremities

[1] An expert or representative from the FDA did not testify that this agency did or would in fact monitor and approve of this surgery.

and his heart that also helped him maintain his weight. Plaintiff testified that the surgery was worth it, and he owed it to himself and his family to do what was reasonable to improve his situation. He rejected the suggestion that he was desperate and willing to do anything to improve his situation. Rather, he testified that he performed the research and would not have any procedure that posed a danger in any way. The lack of FDA approval did not concern him. In light of his research and discussions with other patients, plaintiff knew that the surgery was not a scam. Furthermore, the surgery had met European guidelines. Therefore, plaintiff requested that defendant reimburse him for the amount of money that he paid out of pocket to have the surgery performed and the travel expenses.

Dr. Carlos Lima, a neurologist and neuropathologist at a public hospital in Lisbon, Portugal, was part of the team that performed the procedure on plaintiff.[2] He testified that the tissue located in the area between the upper nose and the outside of the brain was unusual because it was one of the few parts of the body that continued to grow in a mature individual. This tissue formed new neurons. Consequently, when transplanted into the part of the central nervous system where connection was lost because of a lesion, the tissue would perform as it did in the nasal area by forming new neurons and new connections.

Initially, Dr. Lima studied every pathology, but he began to focus on paralyzing injuries. When he started his research and the clinical trials, there existed experimental data that the nasal tissue, when transplanted to the spinal cord injury, will provide functional recovery of neurons. The tissue located in the olfactory stem consisted of several cells, not just stem cells but other ensheathing cells. The first studies began eighteen years earlier on guinea pigs. Stem cells had great potential because they could be used, not just in the central nervous system, but in other locations of the body and take on characteristics of the environment in which they were placed. Because of the use of an adult's own stem cells, ethical or technical issues were avoided.

In order to provide this treatment to people with spinal cord injuries, Dr. Lima had to obtain the approval of the public hospital where he worked. The government operated the hospital. Consequently, he had to apply to the hospital administration, which included the clinical director and the ethical committee. Although Portugal did not have "the FDA", there was an equivalent FDA institute in Europe with rules regarding cells and cell application on humans. He acknowledged that the European FDA was not in existence at the time he started the study in 2001. However, at the beginning of the study, he followed the principles for clinical trials on humans as set forth in the Helsinki Declaration, worldwide universally accepted guidelines. Dr. Lima obtained approval from the hospital and the government to perform the surgical procedures. He started treatment on humans in 2001, and the procedure continued to this day.

To be a candidate for the surgery, a patient had to fall within a particular set of criteria. The patient had to have a chronic spinal cord injury. That is, the person had to have been injured at least six months earlier and stabilized, and there was no anticipation that with rehabilitation

---

[2] Dr. Lima was deposed at the institute in Michigan. He was at the institute because he worked with patients and colleagues there to study spinal cord injuries.

that the patient would experience new signs of recovery. Secondly, the patient had to be less than 40 years of age. This age restriction was imposed because, as humans age, they lose stem cells from the nose. Lastly, the patient had to be completely immobile; there was no movement below the site of the injury. Both the U.S. and Portugal adopted the "ASIA" Scale for determining the severity of a spinal cord injury. To qualify for the surgery, the patient had to suffer from a severe injury, a level A or B on the ASIA Scale. Before traveling, the patient had to have medical tests on the spinal cord and nose. Between 2001 and the time of deposition, the surgery had been performed on 110 patients from all over the world.

After the surgery, the patient had to commit to physical therapy as part of the rehabilitation process. Physical therapy was important because the nervous system was permanently damaged, and the brain no longer recognized the damaged area of the body. For the surgery to be successful, the spinal cord connection to the brain had to be rewired so the body would learn to reuse what was damaged. Rehabilitation was essential to reverse the nonrecognition between the brain and the spinal cord as a result of the injury. Therefore, a rehabilitation known as "gait training" was utilized. Patients who had the surgery reported improvements in sensation below the injury site and were able to obtain greater improvements in bladder and bowel control. Patients who were continuing rehabilitation three to five years after the surgery continued to see improvements. However, patients who had undergone the surgery had not regained the ability to walk without the use of a walker. At that time, the results of the clinical study had not been published.

Plaintiff had the surgery on November 10, 2005. It was one of the most severe injuries that Dr. Lima had ever treated. Because of the degree of injury, the team not only had to remove the scar tissue in the spinal cord area, but also had to rebuild the normal anatomical structure of the area. After the surgery, Dr. Lima was advised of plaintiff's improvements and learned that he had improved from an ASIA level of A to a C. Dr. Lima was very happy with these results in light of the degree of the injury and the short period of time in which the improvements had occurred. The doctor acknowledged that, at this point, there was no complete recovery from such a severe lesion. That is, no patient had ever returned to pre-injury functioning levels. However, at this point in time, the surgery was necessary for plaintiff to have any chance of recovery. Additionally, rehabilitation was crucial to the recovery. If plaintiff underwent rehabilitation or physical therapy without the surgical procedure, there would be no recovery. Dr. Lima was currently working on pilot studies in other countries.

Dr. Lima acknowledged that the surgery was experimental, but he nonetheless opined that it was reasonably necessary because there was no other option available for a person with a chronic spinal cord injury. The lack of approval from the FDA did not change Dr. Lima's opinion. An autograft, or transfer of a person's own cells to another part of the body, was analogous to a burn patient who had skin transferred from a thigh to replace burned skin on the arm. The olfactory tissue was an extension of the brain and could be considered tissue of the nervous system.

On cross-examination, Dr. Lima acknowledged that he was not licensed to practice medicine in the U.S. He also acknowledged that he did not perform the surgery himself, but was part of the team that coordinated the project. The government of Portugal paid for the program for its citizens. Dr. Lima acknowledged that, to obtain FDA approval, the project had to present controlled studies of the effectiveness and risks of the surgery with peer review. At this point,

U.S. doctors had not applied for such approval. He also acknowledged that there was no controlled study distinguishing between the effectiveness of the surgery as opposed to intensive physical therapy. He noted that patients would obtain benefits from intensive physical therapy, and that the surgery would not return a patient to fully functioning or pre-injury condition. The doctor disputed defense counsel's characterization regarding government approval. Dr. Lima testified that the hospital was a government institute and the administration of the hospital had to approve the surgery. Therefore, governmental approval was obtained.

The jury concluded that the surgery was reasonable and necessary. Defendant appeals this determination.

I. Evidentiary Issue

As an initial matter, I note the majority sua sponte raises the issue of the admissibility of Dr. Lima's testimony and concludes that it was improperly admitted pursuant to MRE 702. Review of the lower court record reveals that this issue is not preserved for appellate review because it was not raised, addressed, and decided in the trial court. *Miller v Inglis*, 223 Mich App 159, 168; 567 NW2d 253 (1997). Counsel for defendant did not file a motion in the trial court challenging the qualifications and scientific data underlying Dr. Lima's factual conclusions and testimony. This Court, as an error correcting court, should not address unpreserved issues, *Burns v Detroit (On Remand)*, 253 Mich App 608, 615; 660 NW2d 85 (2002), and defendant did not brief the issue of the admissibility of Dr. Lima's testimony or the scientific reliability. Consequently, the trial court was never asked to act as the gatekeeper with regard to admission and did not conduct an evidentiary hearing to determine the scientific reliability underlying this testimony. See *Gilbert v DaimlerChrylser Corp*, 470 Mich 749, 780; 685 NW2d 391 (2004). Thus, plaintiff was never given the opportunity at a *Daubert* hearing[3] to demonstrate that the testimony met the reliability standards of Michigan evidentiary law. When reviewing an evidentiary issue, the proper role of the *trial* court is:

> to filter out expert evidence that is unreliable, not to admit only evidence that is unassailable. The inquiry is not into whether an expert's opinion is necessarily correct or universally accepted. The inquiry is into whether the opinion is rationally derived from a sound foundation. [*People v Unger*, 278 Mich App 210, 217; 749 NW2d 272 (2008), quoting *Chapin v A & L Parts, Inc*, 274 Mich App 122, 139; 732 NW2d 578 (2007) (opinion by Davis, J.).]

Scientific testimony need not be based on certainties. *Nelson v American Sterilizer Co (On Remand)*, 223 Mich App 485, 491-492; 566 NW2d 671 (1997). Rather, "[a]s long as the basic methodology and principles employed by an expert to reach a conclusion are sound and create a trustworthy foundation for the conclusion reached, the expert testimony is admissible no matter how novel." *Id*. at 492. Inferences or assertions in proposed testimony is acceptable provided the source rests in the application of scientific methods. *Id*. at 491.

---

[3] *Daubert v Merrell Dow Pharmaceuticals, Inc*, 509 US 579; 113 S Ct 2786; 125 L Ed 2d 469 (1993).

Although Dr. Lima had treated 110 patients, he did not testify in detail regarding each patient, the location of the lesion, the ASIA level of severity, the outcome following the procedure, and the prognosis. The doctor was never asked to provide a summation of the underlying applicable science, which had a foundation in treatment in animals, and was never asked to provide a summation of the scientific data regarding the 110 patients. If defense counsel had challenged the admission of Dr. Lima's opinion, the trial court would have had the opportunity to conduct a *Daubert* hearing to review the science. Despite the fact that an evidentiary hearing was not held, this Court conducts its own analysis based on the limited record. A reversal on the basis of an unpreserved issue when a request for an evidentiary hearing was not made to the trial court is inappropriate. *Burns, supra*. I would not sua sponte reverse a jury verdict premised on an unpreserved issue that was not briefed or raised as an error by the appellant.

II. Preserved Issues on Appeal

Defendant contends that the trial court erred in denying its motion for summary disposition because the experimental surgery was not reasonably necessary and it was not lawfully rendered. A trial court's ruling regarding a motion for a directed verdict is reviewed de novo. *Elezovic v Ford Motor Co*, 472 Mich 408, 418; 697 NW2d 851 (2005). When reviewing the trial court's decision, the evidence and all legitimate inferences are examined in the light most favorable to the nonmoving party. *Id*. The appellate court reviews the evidence presented up to the time of the motion and resolves any conflict in the evidence in favor of the nonmoving party to determine if a question of fact is presented. *Thomas v McGinnis*, 239 Mich App 636, 643-644; 609 NW2d 222 (2000). "A directed verdict is appropriately granted only when no factual questions exist on which reasonable jurors could differ." *Cacevic v Simplimatic Engineering Co (On Remand)*, 248 Mich App 670, 679-680; 645 NW2d 287 (2001). Application of disputed facts to the law present proper questions for the jury or trier of fact. *White v Taylor Distributing Co*, 482 Mich 136, 143; 753 NW2d 591 (2008).

Questions involving statutory interpretation present questions of law subject to de novo review. *Hunter v Hunter*, 484 Mich 247, 257; 771 NW2d 694 (2009). The language of the statute expresses the legislative intent. *Dep't of Transportation v Tomkins*, 481 Mich 184, 191; 749 NW2d 716 (2008). The rules of statutory construction provide that a clear and unambiguous statute is not subject to judicial construction or interpretation. *Id*. When a statute plainly and unambiguously expresses the legislative intent, the role of the court is limited to applying the terms of the statute to the circumstances in a particular case. *Id*. The fair and natural import of the terms employed in light of the subject matter of the law governs. *In re Wirsing*, 456 Mich 467, 474; 573 NW2d 51 (1998). The no-fault act is "remedial in nature and must be liberally construed in favor of the persons intended to benefit from it." *Turner v Auto Club Ins Ass'n*, 448 Mich 22, 28; 528 NW2d 681 (1995).

MCL 500.3107(1)(a) addresses personal protection insurance benefits and allowable expenses and provides:

> (1) Except as provided in subsection (2), personal protection insurance benefits are payable for the following: (a) Allowable expenses consisting of all reasonable charges incurred for reasonably necessary products, services and accommodations for an injured person's care, recovery, or rehabilitation. Allowable expenses

> within personal protection insurance coverage shall not include charges for a hospital room in excess of a reasonable and customary charge for semiprivate accommodations except if the injured person requires special or intensive care, or for funeral and burial expenses in the amount set forth in the policy which shall not be less than $1.750.00 or more than $5,000.00.
>
> MCL 500.3157 addresses treatment and rehabilitative training and provides:
>
> A physician, hospital, clinic or other person or institution lawfully rendering treatment to an injured person for an accidental bodily injury covered by personal protection insurance, and a person or institution providing rehabilitative occupational training following the injury, may charge a reasonable amount for the products, services and accommodations rendered. The charge shall not exceed the amount the person or institution customarily charges for like products, services and accommodations in cases not involving insurance.

First, defendant contends that the experimental surgery was not reasonably necessary. However, "entitlement to no-fault benefits is dependent on the facts and circumstances of each case." *Begin v Mich Bell Telephone Co*, 284 Mich App 581, 590; 773 NW2d 271 (2009). The plain and unambiguous language of MCL 500.3107 makes "both reasonableness and necessity explicit and necessary elements of a claimant's recovery[.]" *Nasser v Auto Club Ins Ass'n*, 435 Mich 33, 49; 457 NW2d 637 (1990). The claimant bears the burden of proof of demonstrating both reasonableness and necessity. *Id*. "Where a plaintiff is unable to show that a particular, reasonable expense has been incurred for a reasonably necessary product and service, there can be no finding of a breach of the insurer's duty to pay that expense, and thus no finding of liability with regard to that expense." *Id*. at 50.

The issue of whether personal injury protection expenses are reasonable and necessary generally presents a question of fact for the jury. *Begin, supra* at 597; *Rose v State Farm Mut Auto Ins Co*, 274 Mich App 291, 296; 732 NW2d 160 (2007). Although the issue of reasonable and necessary generally presents a question of fact, it is possible for the court to decide the issue as a matter of law. *Nasser, supra* at 55. "Thus, if it could be 'said with certainty' that an expense was both reasonable and necessary, the court could make the decision as a matter of law." *Id*. However, when the trial court makes the threshold determination as a matter of law, the evidence must be viewed in the light most favorable to the nonmoving party. *Id*.

In *Griffith v State Farm Mut Auto Ins Co*, 472 Mich 521, 534-535; 697 NW2d 895 (2005), the Supreme Court addressed the statutory use of the terms "care," "recovery," and "rehabilitation" to determine that food costs were not an appropriate expense for purposes of MCL 500.3107. With regard to defining the terms "recovery" and "rehabilitation," the Court stated:

> As an initial matter, it is important to note that the statute does not require compensation for any item that is reasonably necessary to a person's care in general. Instead, the statute specifically limits compensation to charges for products or services that are reasonably necessary "for an *injured person*'s care, recovery, or rehabilitation." (Emphasis added.) This context suggests that "care" must be related to the insured's injuries.

> This conclusion is supported by the fact that the statute lists "care" together with "recovery" and "rehabilitation." "Recovery" is defined as "restoration or return to any former and better condition, esp. to health from sickness, injury, addiction, etc." Random House Webster's College Dictionary (2001). "Rehabilitate" is defined as "to restore or bring to a condition of good health, ability to work, or productive activity." *Id*. Both terms refer to restoring an injured person to the condition he was in before sustaining his injuries. Consequently, expenses for "recovery" or "rehabilitation" are costs expended in order to bring an insured to a condition of health or ability sufficient to resume his preinjury life. [*Griffith*, *supra* at 534-535.]

Review of the record reveals that plaintiff presented sufficient facts and circumstances to present the issue of reasonableness and necessity to the jury. *Begin*, *supra*; *Nasser, supra*. Because the issue could be not decided as a matter of law "with certainty," the jury verdict must be affirmed.

Plaintiff testified that a serious car accident left him paralyzed from his midchest. He had no sensation or feeling below the location of the injury site. Consequently, plaintiff researched his options to improve his standard of living. He learned of a fellow patient at the institute that had the transfer of olfactory cells procedure at issue and saw that the patient could walk on a treadmill type device, albeit with braces. In his physical state as a result of the accident, plaintiff was limited in his mobility and could not even meet basic bathroom needs, causing him to experience leakage and bladder infections. The no-fault act provides for allowable expenses for reasonable charges incurred "for reasonably necessary products, services and accommodations for an injured person's care, recovery, or rehabilitation." MCL 500.3107(1)(a). As set forth in *Griffith*, *supra*, "recovery" is defined as "return to any former and better condition." The surgical procedure in Portugal provided plaintiff, as a paralyzed individual, with the only option to "return to any former and better condition." The accident in 2001 left plaintiff in a chronic state with continued physical therapy as his only progressive option. However, plaintiff did not experience any additional benefit from physical therapy and was merely continuing therapy at home on his own. Dr. Lima testified that because of the severe state of plaintiff's injury, plaintiff had no other option for recovery.[4] Indeed, plaintiff was in his late 30s at the time of the procedure and waiting for a consensus regarding approval[5] would eliminate this surgical

---

[4] The contention that there was no evidence regarding reasonableness and necessary is without merit. Dr. Lima was questioned about this issue and testified, "I mean, there's no – there's no possibility for [plaintiff] to have any recovery with such a lesion … which is not just functionally complete, but it was anatomically very destructive and complete also." Additionally, Dr. Lima testified that, without the surgery, plaintiff had no chance of recovery, stating, "No, [plaintiff] is a patient with almost four years with lesion before, and he was completely stabilized and without no further improvements." Dr. Lima further opined that the nature of the surgery, as experimental, did not alter his opinion regarding reasonable and necessary "because there's almost nothing in the world to help a patient with a spinal cord injury chronic before. There's nothing."

[5] As will be set forth later in this opinion, there was no evidence admitted by an individual with

(continued…)

procedure as a treatment option because the change of the status of the nasal cells in adults over the age of 40. In light of the above, the trial court properly submitted this issue to the jury for resolution.

Defendant next alleges that the surgery is not a covered benefit because it was not lawfully rendered. As previously stated, MCL 500.3157 provides in relevant part:

> A physician, hospital, clinic or other person or institution *lawfully rendering* treatment to an injured person for an accidental bodily injury covered by personal protection insurance, and a person or institution providing rehabilitative occupational training following the injury, may charge a reasonable amount for the products, services and accommodations rendered. [Emphasis added.]

Defendant submits that the surgical procedure was not lawfully rendered because it was not performed in the U.S., and it did not have FDA approval. However, the plain language of the statute places no qualification regarding the location of treatment or that FDA approval is required. Rather, the plain language of the statute provides that the treating physician or hospital must lawfully render treatment. The surgery occurred in a public hospital owned by the government in Lisbon, Portugal, by a team of medical professionals. The government of Portugal funded the hospital program for "Portuguese patients." Dr. Lima did not have any other type of funding or grant money from other entities or other foreign governments; rather, the Portuguese government funded his program for its citizens.[6] Dr. Lima's employment at a public hospital operated by the government meant that he had to obtain approval to take the procedure tested on animals and apply it to humans. Consequently, he had to apply to hospital administration that included the clinical direction committee and the ethical committee. With regard to standards and practices, Dr. Lima testified that, at the start of the project, there was no FDA equivalent in Europe. Consequently, his program initially followed the Helsinki Declaration on clinical trials for humans and later followed the European equivalent of the FDA that was created.

Based on the testimony of Dr. Lima, there was sufficient evidence to conclude that the surgical procedure at issue was lawfully rendered. Dr. Lima's program was funded by the government and was subject to oversight by the clinical direction and ethical committees. The program followed the Helsinki Declaration for clinical trials on humans and later followed the European equivalent that created rules regarding cells and cell application on humans during this ongoing program. As previously stated, there is no statutory limitation regarding the location of the service or the type of approval that is required.

Defendant urges this Court to adopt a standard that requires FDA approval.[7] However, to impose such a standard would require the inclusion of additional language not contained in the

(…continued)

personal knowledge that FDA approval is the standard.

[6] Visitors to the country were responsible for the costs of the procedure.

[7] Defendant questioned Dr. Hinderer extensively regarding FDA approval and the submission of documentation and peer review. However, the value of FDA approval is questionable. In late June 2009, the FDA held a joint meeting between three of its advisory committees to address

(continued…)

statute as written. That is, the statute would have to be rewritten to provide for coverage for treatment "lawfully rendered in the U.S. and approved by the FDA."[8] It is also important to note that the propriety of "FDA approval" was raised in questioning of Dr. Lima and Dr. Hinderer. However, Dr. Hinderer is the medical director at the Center for Spinal Cord Injury Recovery. He did not perform plaintiff's surgery. Additionally, although he described a four-stage process for obtaining FDA approval, it is unclear if he had the requisite expertise or underlying foundational knowledge to render such an opinion. Defendant urges this Court to adopt an FDA approval standard, but did not offer testimony from a representative of the FDA to attest that the agency monitors stem cell procedures or approves surgical procedures that do not involve the implantation of a medical device.[9] However, review of the function of the FDA reveals that it is

(…continued)

acetaminophen, a commonly used over the counter drug marketed under the brand name Tylenol and contained in other products. In the late 1990s, research began to demonstrate that acute liver failure was occurring as a result of accidental overdose of acetaminophen. Consequently, in 1998, the FDA finalized a regulation regarding acetaminophen products to contain a warning regarding product use and consumption of alcoholic beverages. In 2002, the FDA convened an advisory committee that recommended a specific liver toxicity warning and distinctive labeling on over the counter packages. In 2004, the FDA launched a public education campaign to help consumers use acetaminophen more safely. In 2004, the FDA sent communication to every state board of pharmacy asking them to "consider" labeling on prescription acetaminophen products. However, as of February 2008, no state had implemented the requested regulation. In 2006, the FDA proposed regulations for over the counter labeling of acetaminophen to include new safety information. The final version was still under review as of June 2009. Finally, in 2007, the FDA's Center for Drug Evaluation and Research (CDER) convened a multidisciplinary working group to continue to evaluate acetaminophen related liver injuries. The report of the working group was to be addressed at the June 2009 meetings. See www.fda/gov/AdvisoryCommittees/Calendar/ucm143083.htm (accessed December 16, 2009). Curiously, this report contains no statement regarding the number of accidental liver overdoses or liver injuries in the eleven-year period since this problem was first recognized and does not propose a definitive resolution for the problem. Therefore, I would not elevate FDA approval as the measure of whether a procedure is "lawfully rendered" in the absence of an express statutory requirement.

[8] Defendant also argues the role of policy and costs. However, I conclude that the issues raised in this case are appropriately resolved by examining the plain language of the statute. Moreover, defendant's argument regarding policy is one-sided. Although it is argued that FDA studies and peer review is necessary, defendant fails to recognize that research regarding stem cells has been limited by regulations and political viewpoints. Patients in need of need of new technology and therapies relying on stem cell research have been hampered by limitations that have been placed on scientists. Recently, human stem cell policy in the U.S. was altered. See Exec. Order No. 13505, 74 Fed. Reg. 46 (March 9, 2009) ("Removing Barriers to Responsible Scientific Research Involving Human Stem Cells"). However, the change in policy is of little benefit to individuals such as plaintiff who had a limited time period in which an autograft stem cell procedure is available because of the age of the stem cells. Perhaps that is why the statute at issue only requires that the treatment be "lawfully rendered" and contains no regulation regarding the location of the procedure or the type of approval necessary to have the procedure.

[9] The National Institutes of Health (NIH) is a division of the United States Department of Health and Human Services. Its mission is to uncover new knowledge to improve health. The NIH plans to achieve its mission by "conducting research in its own laboratories; supporting the

(continued…)

the federal agency "responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe."[10] The surgery at issue as described by Dr. Lima did not involve the implantation of a medical device, but rather, involved the surgery movement of plaintiff's stem cells from one location of his body to another. Whether FDA approval is the standard for this type of procedure was presumed in the record, and defendant did not present any representative of the FDA to testify regarding the agency's supervision of "experimental" surgeries. Consequently, irrespective of the language of the statute, I would not impose an FDA approval requirement when defendant failed to present evidence by individuals with personal knowledge of the FDA standards and the federal agency

(…continued)

research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country *and abroad*; helping in the training of research investigators; and fostering communication of biomedical information. See http://directory.psc.gov/nih/12.html (accessed December 22, 2009) (emphasis added). A portion of the NIH is devoted to registering clinical trials in the U.S. and around the world including the trial's purpose, participants, and location. See http://clinicaltrials.gov/ (accessed January 6, 2010). Therefore, because the parties did not submit evidence from the FDA, I would not conclude that FDA approval is the standard for acceptance of this or any other surgical procedure unless it involves the implantation of a medical device. In this case, Dr. Lima testified regarding the surgery and never testified that a medical device was implanted in plaintiff. Dr. Hinderer, as the director of rehabilitation, was not questioned regarding his interaction with the FDA, his personal knowledge of the surgery at issue and whether it involved implantation of a medical device, and whether he had ever applied to the FDA for approval of a surgical procedure. Without an examination of the foundation of an expert's opinion, the trier of facts' evaluation of the value of the opinion is necessarily circumscribed and the reliability of the ultimate determination correspondingly compromised. *People v Dobben*, 440 Mich 679, 697; 488 NW2d 726 (1992). Therefore, I would not sua sponte impose an FDA standard where the appropriate foundation for such a conclusion was not provided in the lower court record. The majority sua sponte questions the foundations underlying the opinion of Dr. Lima, but does not question the foundation provided by Dr. Hinderer and his knowledge of FDA approval.

[10] See http://www.fda.gov/AboutFDA/WhatWeDo/WhatFDARegulates/default.htm (accessed December 22, 2009).

charged with categorizing surgeries as experimental or standard. Therefore, on the record presented to the trial court, I would affirm the jury verdict.[11]

/s/ Karen M. Fort Hood

[11] I note that defendant asserts that an approval of insurance coverage for experimental surgeries will be cost prohibitive and lead to a flood of claims. The record does not support such a broad conclusion. The standard for determining the propriety of a claim for coverage is based on what is reasonable and necessary under the facts and circumstances of each individual case. Any affirmation of the jury verdict in this case does not lead to the conclusion that experimental surgeries are subject to payment upon request. Under the facts and circumstances of this case, there was sufficient evidence to submit the issue to the jury. That is the conclusion reached in this dissent. Furthermore, under a cost benefit analysis, defendant did not present proofs regarding the cost savings it will attain when a paralyzed individual suffering from mobility related issues obtains the ability to monitor their own hygiene levels. Also with regard to the assertion of costs, plaintiff's surgery performed by a team of doctors, his weeklong hospital stay, and his transportation for three individuals was approximately $51,000. There was no record evidence of the cost of the equivalent procedure if approved and performed in the U.S. In the absence of record evidence, it cannot be concluded the affirmation of this verdict will lead to defendant's fear of a flood of burdensome claims. Finally, the contention that success of the procedure is not an issue in this case is correct. Rather, this case hinges on the construction of the reasonableness and necessity of the procedure in relationship to the specific facts and circumstances of this case. *White, supra*.