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UNPUBLISHED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.

PER CURIAM.

In this action to recover first-party no-fault benefits, defendant appeals by right a judgment, entered after a jury trial, which awarded plaintiff his expenses associated with experimental stem cell surgery performed in Portugal. Specifically, defendant argues on appeal that the trial court erred in failing to grant its motion for directed verdict following plaintiff's proofs. We agree for two reasons: (1) plaintiff's treating physician expert witness did not testify that the experimental stem cell surgery performed in Portugal was either "reasonable" or "necessary" and (2) the trial court erred in failing to determine the scientific reliability of the experimental surgery before admitting any testimony regarding the procedure. Accordingly, we reverse.

I. Basic Facts and Procedural History

On December 11, 2001, plaintiff was involved in a head-on collision with a van on his way to work. Plaintiff suffered multiple injuries including a severe spinal fracture just below his mid-chest area. After the accident, plaintiff participated in intensive physical therapy at the University of Michigan in an attempt to regain function in his chest and mid-level area. However, plaintiff was not able to regain any sensation below his injury site.

During this time, plaintiff began investigating different treatment options. He learned about an experimental medical procedure being performed in Portugal which involved surgery, followed by intensive physical therapy. The surgery involved the transplantation of olfactory mucosa, a tissue found in the sinus cavities containing stem cells, into the injury site. The theory behind the procedure is that the stem cells will develop into spinal cord nerves with the right stimuli. This procedure is not approved by the United States Food and Drug Administration (FDA) and cannot be performed in the United States. The FDA approval process involves

extensive review of exiting research, controlled studies, peer review, and publication. No one has applied for FDA approval of the procedure or to begin a controlled study.

In March 2005, plaintiff went to the Rehabilitation Institute of Michigan (RIM) and discussed the procedure with Dr. Steven Hinderer, who specializes in physical medicine and rehabilitation. Dr. Hinderer is the medical director of The Center for Spinal Cord Injury Recovery Program (CSCIRP). According to the medical literature from CSCIRP regarding the experimental surgery:

> There has been very little scientific data collection of the efficacy and long-term outcomes of these procedures. As a result, CSCIRP will be offering medical screening to any individuals who choose to pursue these alternative surgical procedures. In this way, we can begin to advance scientific knowledge by enrolling you as a potential research candidate. Following the surgery, patients will agree to enroll in RIM's clinical research study to evaluate the effectiveness of these procedures.

Plaintiff decided to have the procedure done, and submitted a request for coverage to his primary care insurer, Blue Cross Blue Shield (BCBS). After BCBS denied his request, plaintiff sought to have defendant cover the cost of the surgery and related travel expenses. Defendant determined it would cover the costs of testing and physical therapy, but denied coverage for the surgery because it was experimental, lacked FDA approval, and was unlawful to be performed in the United States. According to Raymond Marcus, defendant's claim specialist, defendant was not under an obligation to fund experimental research where there was no evidence "regarding the efficacy and long term outcome of the surgery." Plaintiff elected to travel to Portugal to have the surgery and he paid for it himself. Plaintiff then filed this suit to recover his out of pocket costs.

After the proofs were presented at trial, defendant moved for a directed verdict arguing that the surgery was not covered by the no-fault act because it was not reasonably necessary or lawfully rendered. The trial court denied the motion and this appeal followed.

II. Standard of Review

We review de novo a trial court's decision on a motion for a directed verdict. *Coble v Green*, 271 Mich App 382, 385; 722 NW2d 898 (2006). This Court reviews the evidence and all legitimate inferences in the light most favorable to the nonmoving party to determine if the evidence fails to establish a claim as a matter of law. *Sniecinski v Blue Cross & Blue Shield of Michigan*, 469 Mich 124, 131; 666 NW2d 186 (2003). In determining whether a question of fact existed that would preclude a directed verdict, this Court draws every reasonable inference in favor of the nonmoving party, while recognizing the trial court's superior opportunity to observe witnesses. *Coble*, *supra* at 386.

III. Applicable Law

As a matter of public policy of this state, "the existence of no-fault insurance shall not increase the cost of health care." *Dean v Auto Club Ins Ass'n*, 139 Mich App 266, 274; 362

NW2d 247 (1984). As this Court stated in *McGill v Automobile Ass'n of Michigan*, 207 Mich App 402, 407; 526 NW2d 12 (1994):

> Indeed, the no-fault act was as concerned with the rising cost of health care as it was with providing an efficient system of automobile insurance. To that end, the plain and ordinary language of [MCL 500.3107] requiring no-fault insurance carriers to pay no more than reasonable medical expenses, clearly evinces the Legislature's intent to place a check on health care providers who have no incentive to keep the doctor bill at a minimum. [Citations and internal quotations omitted.]

Accordingly, under the no-fault act, an injured person is entitled to payment of personal protection insurance (PIP) benefits only for "[a]llowable expenses consisting of all reasonable charges incurred for reasonably necessary products, services, and accommodations for an injured person's care, recovery, or rehabilitation." MCL 500.3107(1)(a). For an expense to qualify as an "allowable expense" under the no-fault act, (1) the charge must be reasonable, (2) the expense must be reasonably necessary, (3) the expense must be incurred, and (4) the expense must be for an injured person's care, recovery, or rehabilitation. *Griffith v State Farm Mut Auto Ins Co*, 472 Mich 521, 532 n 8; 697 NW2d 895 (2005); *Nasser v Auto Club Ins Ass'n*, 435 Mich 33, 50; 457 NW2d 637 (1990). Thus, a no-fault insurer is not liable for medical expenses that are not reasonably necessary. *Nasser*, *supra* at 49. The question whether an expense is reasonably necessary is generally one of fact for the jury, although "it may be in some cases possible for the court to decide the question of the reasonableness or necessity of particular expenses as a matter of law in much the same way that under certain circumstances it may decide whether a plaintiff has sustained a threshold injury under [MCL 500.3135] of the act." *Id*. at 55.

In the context of this case, because the question of whether this surgical procedure was reasonably necessary involves medical judgment, expert testimony was required to support plaintiff's claim. See *Bryant v Oakpointe Villa Nursing Ctr Inc*, 471 Mich 411, 423; 684 NW2d 864 (2004). And, whether the medical testimony is admissible is a preliminary question to be determined by the trial court. As we held in *SPECT Imaging, Inc v Allstate Ins Co*, 246 Mich App 568, 578; 633 NW2d 461 (2001):

> The party proffering the evidence bears the burden of demonstrating its acceptance in the medical community. Pursuant to MRE 702, the trial court is required to determine the evidentiary reliability or trustworthiness of the facts and data underlying an expert's testimony before the testimony may be admitted. To determine whether the requisite standard of reliability has been met, the court must determine whether the proposed testimony is derived from recognized medical knowledge. To be derived from recognized medical knowledge, the proposed testimony must contain inferences or assertions, the source of which rests in an application of medical methods. Additionally, the inferences or assertions must be supported by appropriate objective and independent validation based on what is known, e.g., scientific and medical literature. [Citations and alternations omitted.]

Thus, a trial court must first make a preliminary determination whether the proposed treatment has gained general acceptance in the medical community as to be admissible under

MRE 702. *Id*. at 578-579, citing *Stitt v Holland Abundant Life Fellowship (On Remand)*, 243 Mich App 461, 468; 624 NW2d 427 (2000). Then, only *after* the procedure has been demonstrated to have gained general acceptance in the medical community will the question of whether it is an "allowable expense" become a question of fact for the trier of fact. *Id.*

IV. Analysis

Defendant argues that it was entitled to a directed verdict because plaintiff's surgery was not reasonably necessary. We agree. First, plaintiff's own treating physician expert, Dr. Hinderer, did not testify that the procedure was either reasonable or necessary. Second, even assuming that Dr. Carlos Lima[1] was properly qualified as an expert witness, even he conceded that the surgery has not gained general acceptance in the international medical community, let alone in the United States.

A. Reasonably Necessary

In support of his claim for recovery of the costs associated with the surgical procedure, plaintiff presented the testimony of Dr. Hinderer. Dr. Hinderer testified that he does not prescribe the experimental surgery for his patients and did not do so for plaintiff. Not only does he not prescribe the surgery, CSCIRP does not recommend it. In fact, to the best of his knowledge, the surgery has never been prescribed for any patient from the United States. It is not part of the standard clinical care for patients suffering from spinal cord injuries, particularly in light of its experimental nature and he believed that "many physicians would not recommend [it] or agree that it is necessary." Further, if a patient opts to have this procedure done, it might disqualify the patient from later spinal cord treatment advances. Finally, he testified that the procedure is not regarded as necessary in his field but rather is an understandable personal choice. With respect to whether the surgery benefited the plaintiff, he testified that he would not be able to determine whether any improvement was due to the surgery, the aggressive physical therapy he prescribed for plaintiff, or a combination of both, and acknowledged that the aggressive rehabilitation itself can produce improvements.

After our review of Dr. Hinderer's testimony in a light most favorable to the plaintiff, it is clear that it does not reflect a reasoned medical opinion on the potential health benefits of the subject medical procedure. His testimony did not elicit any facts that would demonstrate that the surgery was either reasonable or necessary. At most, it is merely evidence of a physician carrying out his role as a health care professional providing support to his patient in a decision the patient independently made regarding his own treatment.[2]

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[1] Dr. Lima is a neurologist licensed in Portugal. While he did not participate in plaintiff's surgery, he is part of the team that supervises the human clinical trials in Portugal. He is not licensed to practice medicine in the United States.

[2] Further, we also note that the trial court's ruling appears to conclude that the surgery was an allowable expense because plaintiff benefited from the surgery. We stress, however, that such evidence does not provide a basis for the trial court's conclusion. The use of the words (continued…)

Given the considerable lack of medical testimony or evidence, there was no question of fact on the reasonableness and necessity of the surgery. Rather, taken as a whole, Dr. Hinderer's testimony established that the surgery was not "a reasonably necessary product, service and/or accommodation[]" for plaintiff's "care, recovery or rehabilitation," see MCL 500.3107(1)(a), and the fact that plaintiff may have benefited from the procedure was an irrelevant inquiry in determining whether the surgery was an allowable expense. Thus, the trial court erred in not granting defendant's motion for directed verdict. When a plaintiff fails to show that the surgery is a reasonably necessary product or 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." *Nasser*, *supra* at 50.

B. Scientific Unreliability

We further emphasize, that on this record, even if Dr. Hinderer had recommended or prescribed the surgery, it still could not be considered an allowable expense. An insurer is only liable for scientifically proven medical tests or procedures. *SPECT*, *supra* at 579; see also *Miller v State Farm*, 168 Mich App 238, 246; 424 NW2d 31 (1988). Plaintiff did not establish that the surgery had any current acceptance as a reliable treatment method, even in Portugal. Rather the evidence merely established that the clinical study in Portugal was conducted under the theory that the procedure could *potentially* produce a viable treatment option. Further, the experimental surgery fails to meet any nationally recognized standard and has not been approved by the FDA. There have been no controlled studies; no peer review; no published research materials; or any follow up studies. Even Dr. Lima testified that at the time of plaintiff's surgery, no studies had been published as it was so new. The first "paper" published after plaintiff's surgery only referenced seven patients. Even plaintiff's surgical results could not be included in subsequent published studies as he would need to be followed for a minimum of two years. Dr. Hinderer also testified that because the surgery is such a new procedure, by any scientific standards, the outcomes are unknown and potential results were speculative. Accordingly, the trial court erred in admitting Dr. Lima's testimony regarding the surgery. See MRE 702.

V. Conclusion

Defendant's motion for a directed verdict should have been granted because the evidence established that the surgery was not prescribed by any licensed medical professional; no medical professional testified that it was reasonably necessary; and it has not been shown to be

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(…continued)

"reasonably necessary" within the statute mandates a review by an objective standard rather than a subjective, insured based perspective. *South Macomb Disposal Authority v American Ins Co*, 225 Mich App 635, 657-659; 572 NW2d 686 (1997). In other words, a subjective positive outcome of a medical procedure is not the ultimate fact essential to determining what is an allowable expense within the context of the no-fault act. Solely relying on such evidence in this manner would violate the plain language of the statute, as it would premise cost recovery simply based upon actual success, even if viewed objectively, of a medically accepted treatment. This would mean that any unsuccessful treatment would not be covered even though the medical treatment was universally accepted as "reasonably necessary." This is a result we cannot sanction because it is contrary to the plain language and purpose of the statute.

scientifically reliable such that it has gained general acceptance within the medical community.[3] We reject the argument that defendant is required to pay for the costs of experimental surgery that is part of an experimental human clinical trial still in its infancy in another country. Accepting such an argument would require insurance companies to accept their insured's unilateral health care treatment decisions, reached without medically accepted support or judgment, thereby obliterating the cost-containment and policing functions of the no-fault act. Clearly, the Legislature did not intend no-fault insurers to pay any claim submitted without either reviewing the claim for lack of coverage or having legitimate, properly supported contested claims submitted to a properly instructed fact-finder. *McGill*, *supra* at 408, citing *Lewis v Aetna Cas & Surety Co*, 109 Mich App 136, 139; 311 NW2d 317 (1981).

Reversed and remanded for judgment in favor of defendant. We do not retain jurisdiction.

/s/ Mark J. Cavanagh
/s/ Kirsten Frank Kelly

[3] Because of our resolution of this issue, we do not reach defendant's additional argument that the treatment was not lawfully rendered.