[Cite as *Harden v. Univ. of Cincinnati Med. Ctr.*, 2004-Ohio-304.]

IN THE COURT OF CLAIMS OF OHIO

GRETCHEN G. HARDEN, et al. :

Plaintiffs : CASE NO. 98-11405
Judge J. Warren Bettis

v. :

DECISION

UNIVERSITY OF CINCINNATI MEDICAL CENTER :

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Defendant

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Plaintiffs brought this action against defendant, University of Cincinnati Medical Center (UCMC), alleging claims of medical malpractice, loss of consortium, and breach of contract. The issues of liability and damages were bifurcated and the case proceeded to trial on the issue of liability.

In 1994, plaintiff,[1] Gretchen Harden, was diagnosed with an aneurysm (a swelling or bulge in the wall of a blood vessel) located in the left internal carotid artery in an area of the brain behind the left eye described as the cavernous sinus. Because of its location, the aneurysm was difficult either to repair or to remove surgically. Plaintiff did not require treatment until 1997, when she began to experience excruciating pain and double vision. Plaintiff was admitted to UCMC on April 17, 1997, with a diagnosis of left internal carotid artery aneurysm. Upon admission, plaintiff's attending physician, Dr. Harry vanLoveren, referred her to Dr. Tomsick, an interventional radiologist, for treatment of the aneurysm. Dr. Tomsick recommended that plaintiff undergo a procedure which was being conducted as part of his medical research study of cerebral aneurysms, whereby a catheter would be

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[1] Throughout this decision, "plaintiff" shall refer to Gretchen Harden.

threaded over a wire inserted through plaintiff's femoral artery and advanced through the aorta up to the carotid artery. Small, inflatable, and detachable silicon balloons would then be introduced and inflated at a location in the blood vessel to seal off the aneurysm. In order to be included in Dr. Tomsick's study, plaintiff signed a document which was called an "Informed Consent Statement."

To accomplish balloon occlusion of the aneurysm site, Dr. Tomsick inserted sheaths into plaintiff's left and right femoral arteries. A guidewire was threaded through each side and a catheter was advanced from the left femoral artery to the left internal carotid artery. Another guidewire was similarly positioned into the vessels on the right side of plaintiff's neck to study collateral circulation. Prior to permanently occluding the artery on the left side, Dr. Tomsick performed a diagnostic angiogram of the right vertebral and right internal carotid arteries to ascertain that there was sufficient blood flow through the right anterior and posterior cerebral circulation to adequately supply the entire brain. Dr. Tomsick temporarily blocked the blood flow on the left side by inflating a balloon, then injected contrast dye through a separate catheter advanced into the right internal carotid and right vertebral arteries, and finally took serial films of these vessels. The vessels were noted to be patent but they were markedly tortuous. Plaintiff also underwent a radioactive isotope test called a single positive electron computed tomography or SPECHT study to verify that she had sufficient perfusion to both hemispheres of the brain from the right side during occlusion of the flow through the left internal carotid artery. Once the cerebral perfusion was determined to be adequate, Dr. Tomsick returned to the left side, released a total of three inflated balloons and permanently occluded the blood flow to the aneurysm site. Dr. Tomsick then opted to recheck the vessels on the right side where he noticed that a small dissection had already occurred in the right vertebral artery. He terminated the procedure and transported plaintiff to the Intensive Care Unit for monitoring during her recovery. The entire procedure spanned several hours. Post-procedure orders included administrating anticoagulants and keeping plaintiff's blood pressure elevated for 60 hours.

According to the testimony presented at trial, plaintiff was awake and communicating with staff and her family after the procedure. Plaintiff's husband testified

that plaintiff was somewhat confused. The nurses' notes record that plaintiff was restless and forgetful at times. Plaintiff was treated with Heparin, an anticoagulant, to inhibit the formation of blood clots around the area of the dissection. She also underwent two more SPECHT studies: one on July 19, and one on July 21 after her blood pressure was allowed to return to normal. Each showed adequate perfusion to both hemispheres of the brain.

On the morning of July 22, 1997, plaintiff was noted to have a sudden change in her condition with flaccid extremities on the left side and changes in her pupils consistent with symptoms of a stroke. Plaintiff was taken for an angiogram to determine if the vertebral artery dissection had resulted in clot formation or occlusion of the vessel. The exam revealed instead that plaintiff had suffered a near complete occlusion of the right internal carotid artery. Plaintiff was taken emergently to surgery for a bypass graft of the occluded area. The bypass attempt eventually failed and plaintiff suffered permanent injuries from the lack of sufficient blood flow to the brain.

Plaintiffs assert that Dr. Tomsick was negligent in his care and treatment of plaintiff because of the dissection of her right vertebral artery and right internal carotid artery which eventually led to the stroke. Plaintiffs argue that the standard of care required Dr. Tomsick to perform a completion angiogram after permanent balloon occlusion had taken place to ensure the patency of the right internal carotid artery and that if Dr. Tomsick had done so, he would have discovered the second dissection. Plaintiffs further assert that the failure to timely diagnose plaintiff's impending stroke prevented plaintiff from participating in selecting the choice of treatment from the available options.

Plaintiff's husband has presented a claim for loss of consortium. Finally, plaintiffs contend they entered into a contract with defendant, that such contract was contained in the language of the consent form, and that defendant breached the contract by refusing to provide long-term health care to plaintiff.

In order to prevail on a claim of medical malpractice or professional negligence, plaintiffs must first prove: 1) the standard of care recognized by the medical community; 2) the failure of defendant to meet the requisite standard of care; and 3) a direct causal connection between the medically negligent act and the injury sustained. *Wheeler v. Wise*

(1999), 133 Ohio App.3d 564; *Bruni v. Tatsumi* (1976), 46 Ohio St.2d 127. The appropriate standard of care must be proven by expert testimony. *Bruni* at 130. That expert testimony must explain what a medical professional of ordinary skill, care, and diligence in the same medical specialty would do in similar circumstances. Id.

Plaintiffs presented the expert testimony of Dr. Gerard DeBrun (DeBrun), a specialist in interventional radiology. He explained that the wall of an artery is composed of three layers, an outer or external wall, a median layer and an inner or intimal wall; and that either the guidewire or the catheter can pierce the intimal lining and cause a small dissection or elevation of a flap. DeBrun stated that the injury may heal on its own or the dissection may continue to progress as either blood or contrast dye collects under the flap eventually occluding the lumen or allowing a clot to form. He related that once the dissection creates a diminished flow of blood the patient may exhibit neurological changes from insufficient oxygen to the brain, and if a clot forms, a piece of clot may break loose and lodge in another smaller vessel of the brain.

DeBrun acknowledged that there was no evidence of a right internal carotid artery dissection on the films taken prior to permanent occlusion. DeBrun also noted that there was no way to verify when the dissection of the right internal carotid artery occurred because there were no films or records documenting that Dr. Tomsick viewed this vessel after permanent balloon occlusion took place. However, DeBrun maintained that since dissection does not occur spontaneously, the right internal carotid artery dissection must have occurred at some point during the balloon placement procedure. DeBrun reasoned that the dissections probably occurred as a result of manipulation of the guidewire or the catheter. In addition, DeBrun stated that plaintiff's history of cigarette smoking may have been an aggravating factor in causing the vessel damage. DeBrun testified that he believed the occurrence of a dissection was a deviation from the standard of care. DeBrun stated that were he performing a procedure, it was his belief that if a dissection occurred, it would indicate that he had made a mistake. DeBrun maintained this opinion throughout the trial even though he conceded that dissection is recognized as a known risk/complication any time a guidewire is passed through a vessel.

DeBrun opined that the standard of care required Dr. Tomsick to perform a completion angiogram on the opposite side after permanent balloon occlusion was achieved to document adequate blood flow through the right internal carotid artery. On cross-examination, DeBrun admitted that this standard of care was his own personal standard; that once a balloon has been released there is no simple way to retrieve it; and that there is always a chance for injury to the inner wall with each pass of the guidewire or catheter through a vessel. DeBrun also opined that it would be within the standard of care to treat a dissection by administering plaintiff anticoagulants and by keeping her blood pressure elevated immediately post-procedure.

Dr. Rand, also plaintiff's expert, who is board-certified in neurosurgery, provided testimony by deposition based on his review of plaintiff's medical records. Rand stated that he has performed the balloon occlusion procedure on humans to treat a cavernous sinus fistula, but that he had not executed the procedure as treatment for an aneurysm. Rand testified that the dissections were most likely caused by the guidewire or the catheter; that the blood flow through the right internal carotid artery should have been checked after permanent occlusion; and that the risk of injury to the vessel by inserting the guidewire or catheter was outweighed by the need to verify that the remaining internal carotid artery was patent and uninjured.

In contrast to DeBrun's and Rand's opinions, defendant presented the expert testimony of Dr. Mary Jensen (Jensen), an interventional radiologist who appeared at trial and Dr. Thomas Flynn (Flynn), a board-certified neurosurgeon who testified via videotape deposition. Both Jensen and Flynn related that a dissection can be caused by mechanical trauma from the guidewire, the catheter, or from the force used to inject the dye. Jensen advised that plaintiff's vessels were so tortuous that the operator would have been required to frequently manipulate the guidewires to the left and right in order to position the catheter to visualize the cerebral circulation. Both Jensen and Flynn testified that dissections can occur even when the physician exercises due care and diligence. Flynn opined that the occurrence of a dissection did not imply substandard care. Jensen opined that Dr. Tomsick performed the procedure on plaintiff within the accepted standard of care. Both of

defendant's experts stated that dissections can occur where there has been an absence of negligence.

Jensen advised that the standard of care did not require the doctor to perform a completion angiogram after permanent occlusion because the circulation had already been checked during temporary occlusion. Jensen also opined that Dr. Tomsick met the standard of care during the procedure because the films taken during temporary occlusion depict equal and adequate blood flow to the anterior and posterior portions of the brain with no obstruction of flow on plaintiff's right side. Moreover, Jensen observed that after recognizing the dissection, Dr. Tomsick responded appropriately by placing plaintiff on an anticoagulant, Heparin, and by ordering repeat SPECHT scans to verify perfusion to both hemispheres of the brain. Both Jensen and Flynn explained that whether there was one dissection or two, the anticoagulation therapy remains the same. The dose of Heparin is regulated by the length of time it takes a sample of plaintiff's blood to clot and therefore is not dependent on the degree of vessel damage.

Dr. Tomsick and Jensen both testified that dissections can begin very slowly and develop over time. Thus, the injury to the lining of the vessel may initially be undetectable. They both insisted that since adequate perfusion had been documented during plaintiff's temporary occlusion, and since the presence of a second dissection might be undetectable, it was unnecessary to recheck the collateral perfusion after permanent occlusion and that to do so would pose a needless risk to the patient without appreciable benefit.

At trial, plaintiffs raised an issue regarding the absence of a series of films or runs that might have shown the area of the second dissection. However, Dr. Tomsick testified that he did not recheck the right internal carotid artery. In addition, the technician who transferred the films onto an optical disc testified that there was no practical way to delete runs or individual images from the computer or the optical disc and that there was no handwritten record that a view of the right internal carotid artery was taken after permanent occlusion. Upon review of the evidence, and testimony presented, the court finds that plaintiffs failed to prove these views were actually attempted; that the alleged missing

images were captured on film; or that the absence of sequential films creates a negative inference with respect to liability.

As to plaintiff's allegation of negligence in failing to timely diagnose the impending stroke, DeBrun testified that based on his inspection of the films provided to him for review, there is no radiographic evidence showing the internal carotid artery dissection prior to July 22, 1997. DeBrun advised that there was no extrinsic evidence in the record documenting that plaintiff was suffering from a stroke prior to the onset of symptoms plaintiff experienced in the early morning hours of July 22, 1997. DeBrun characterized the stroke as being of "sudden onset." Nonetheless, both DeBrun and Rand opined that Dr. Tomsick should have checked the right internal carotid artery after permanent balloon placement; that had he done so he would have recognized the second dissection; and that he should have offered a choice to plaintiff to have a stent placed, or to undergo surgery to directly repair or to bypass the injured area of the vessel.

Defendant contends that there was no deviation from the standard of care. Defendant argues further that the second dissection, even if diagnosed, would not have resulted in any different treatment plan. Both Jensen and Flynn testified that invasive treatment of dissections does not have any better outcome statistically than anticoagulation. Flynn also emphasized that there is no evidence in the literature that surgical intervention after dissection, whether it is performed early or late, improves the patient's outcome. Drs. vanLoveren and Tomsick stated that stents were not approved for use in the carotid arteries in 1997, and that even if such use could have been attempted, plaintiff's vessels were so tortuous as to prevent safe passage of a hard metal stent to the areas of dissection. Both Jensen and Flynn testified that plaintiff did not display signs of insufficient cerebral blood flow prior to the abrupt onset of the stroke in the early morning hours of July 22. Jensen attributed plaintiff's restlessness and confusion to the known side effects to the medications plaintiff received for pain and sedation. Even defendant's expert DeBrun testified that there was nothing in plaintiff's medical records to suggest that the second dissection had occurred prior to the sudden deterioration of plaintiff's condition noted on July 22.

Upon review of the testimony and evidence presented, the court finds that plaintiffs have failed to prove defendant was negligent with respect to the right vertebral or right internal carotid artery dissections. The expert testimony established that tears of the inner wall of a vessel do occur in the absence of negligence as a result of the methods employed to visualize remote areas of the body via angiography. The experts all agreed that contact either from the guidewire or the catheter or from the force used to inject the dye can create a tear in the delicate structure of the arterial lining. Radiographic images displayed at trial illuminated the tortuous nature of plaintiff's vessels. The court concludes that plaintiff suffered the dissections during the normal course of the balloon occlusion procedure and that plaintiffs have failed to prove the dissections occurred as a result of negligence.

The court further finds that the evidence and expert testimony does not support a finding that a completion angiogram was required as part of the standard of care or in response to the events occurring with plaintiff. DeBrun stated that the standard of care he referred to was his own personal standard and the court finds this is not sufficient under *Bruni,* supra, to meet plaintiffs' burden of proof. In addition, the court is persuaded by Dr. Jensen's opinion that further exploration of the right-sided blood vessels after discovery of the right vertebral tear posed significant risk without appreciable benefit to plaintiff. The experts agreed that anticoagulation was an appropriate treatment method for dissection, whether one or two. The court finds that plaintiffs failed to show that, had the second dissection been diagnosed before July 22, the use of stents or invasive surgery would have been successful such that plaintiff's outcome would have been improved.

For the foregoing reasons, the court finds that plaintiffs failed to prove by a preponderance of the evidence that defendant was negligent with respect to the care and treatment rendered to plaintiff.

Plaintiffs asserted a cause of action for breach of contract based on the language contained in the informed consent document. The form consists of five pages divided into various sections such as Introduction, Objectives of the Study, Procedures, Risks, Compensation, Fiscal Responsibility, etc. The language plaintiffs rely on states as follows: "Participation in the study will include one year of follow-up, although long-term care will be

offered for an indefinite period." Plaintiffs argue that the form consisted of a set of promises and representations that created a contract between the parties and to which defendant is now bound. Plaintiffs insist that defendant promised to provide long-term care to plaintiff indefinitely; that defendant has since refused to honor such promise; and that defendant's refusal constitutes a breach of the contract. Defendant maintains that the document in question was merely a consent form and that no contract was ever intended or executed between the parties.

A cursory review of the consent form confirms to this court that the writing does not constitute a contract. "A contract is a promise or a set of promises for the breach of which the law gives a remedy, or the performance of which the law in some way recognizes a duty." *Ford v. Tandy Transp., Inc.* (1993), 86 Ohio App.3d 364, 380, citing Restatement of the Law 2d, Contracts (1981) 5, Section 1. A contract consists of an offer, an acceptance, and consideration. Without consideration there can be no contract. Under Ohio law, consideration consists of either a benefit to the promisor or a detriment to the promisee. *Carlisle v. T&R Excavating, Inc.* (1997), 123 Ohio App.3d 277. (Citations omitted.) In order for a party to be bound to a contract, the party must consent to its terms, the contract must be certain and definite, and there must be a meeting of the minds of both parties. *Episcopal Retirement Homes, Inc. v. Ohio Department of Indus. Relations* (1991), 61 Ohio St.3d 366, 369.

Considering both plaintiffs' and defendant's arguments, the court is persuaded that no contract existed between the parties which would have required that defendant provide long-term care to plaintiff in the manner now contemplated by plaintiffs. The court is convinced that there was no meeting of the minds nor was there any evidence presented in the instant action that defendant and plaintiff bargained for any such benefit. It is apparent from a reading of the document in the instant claim that defendant intended the document to serve as notice of informed consent to treatment that included participation in a research project. On page two of the document it states that "Clinical follow-up will be performed at 4 weeks, 6 months, and one year *** to confirm shrinkage of the aneurysm *** [and] to determine the condition of the balloons ***." Based on this language, the court concludes

that defendant was notifying plaintiffs that the outcome of the procedure would be evaluated for up to one year in order to track the long-term effect of balloon occlusion on cerebral aneurysms. Defendant did not consent to provide anything to plaintiff other than an opportunity to follow up with her regarding the status of the aneurysm and the silicon balloons. Moreover, any long-term care was limited to following up in regard to the procedure performed. No reasonable interpretation of the language referenced by plaintiffs could support the conclusion that defendant would provide for all of plaintiff's medical needs for the rest of her life in exchange for her participation in the research study.

For the foregoing reasons, the court finds that plaintiffs have failed to prove by a preponderance of the evidence that they are entitled to relief on any of the claims presented. Furthermore, since plaintiffs have failed to prevail on any of the claims asserted herein, the loss of consortium claim must also be denied. *Bowen v. Kil-Kare, Inc.*(1992), 63 Ohio St.3d 84. Judgment shall be rendered in favor of defendant.

This case was tried to the court on the issue of liability. The court has considered the evidence and, for the reasons set forth in the decision filed concurrently herewith, judgment is rendered in favor of defendant. Court costs are assessed against plaintiffs. The clerk shall serve upon all parties notice of this judgment and its date of entry upon the journal.

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J. WARREN BETTIS
Judge

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SJM/cmd
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