[J-86-2007] IN THE SUPREME COURT OF PENNSYLVANIA EASTERN DISTRICT

CAPPY, C.J., CASTILLE, SAYLOR, EAKIN, BAER, BALDWIN, FITZGERALD, JJ.

CAROL FITZPATRICK AND THOMAS FITZPATRICK, H/W,	: No. 1 EAP 2007 :
Appellants v.	 Appeal from the Order of the Superior Court, No. 1448 EDA 2004, entered on December 13, 2005, affirming the order of the Court of Common Pleas of Philadelphia County entered on May 3, 2004, at No. 2642.
HOWARD NATTER, M.D., MEADOWBROOK NEUROLOGY, MICHAEL MUNZ, M.D., AND THE BRAIN AND SPINE INSTITUTE AT TEMPLE UNIVERSITY HOSPITAL,	ARGUED: October 15, 2007
Appellees	

OPINION

MR. CHIEF JUSTICE CASTILLE DECIDED: December 17, 2008

The primary issue in this appeal is whether a patient, seeking to prove a lack of informed consent claim in a medical malpractice case, may rely solely upon circumstantial evidence to demonstrate that the information that the physician allegedly failed to disclose would have been a substantial factor in the patient's decision to undergo the procedure. Specifically, we consider whether the substantial factor element of the claim may be

established solely through testimony of the patient's spouse.¹ The trial court and the Superior Court panel majority answered that question in the negative. For the following reasons, we determine that the testimony of the patient's spouse may be sufficient to prove the substantial factor element. For the reasons we explain below, we vacate the Superior Court's order and remand to that court to consider appellants' evidentiary claim, which the panel did not reach.

The evidence adduced at trial, viewed in the light most favorable to appellants as verdict winners, revealed the following. Appellant Carol Fitzpatrick was born in 1953, and was diagnosed with multiple sclerosis ("MS") when she was nineteen years old. MS is an incurable condition that attacks nerve fibers in the brain, spinal cord, and eyes, resulting in progressive physical deterioration that is often attended by muscle spasticity or flaccidity that eventually necessitates the use of a wheelchair. The progression of the disease is marked by "flare ups" of varying frequency that leave the patient progressively more disabled. Carol married appellant Thomas Fitzpatrick when the two were in their early twenties.

There are three types of treatment available to patients diagnosed with MS: (1) treatment for the "flare ups"; (2) symptomatic treatment; and, relevant to this case, (3) treatment to reduce disability. This third treatment typically involves the use of disease-modifying drugs that slow the progression of the disability, but do not eliminate it.

¹ We note at the outset that the testimony of Thomas Fitzpatrick, at issue here, is not classic "circumstantial evidence." Rather, Thomas purported to relate his first-hand knowledge of the considerations affecting his wife's medical decisions. Nevertheless, the parties have briefed the case in terms of the testimony being "circumstantial" because it was not the patient, Carol Fitzpatrick's, own testimony. For ease of exposition, we will accept their nomenclature and we use the term "circumstantial" evidence to describe evidence other than the testimony of the patient herself.

By 1977, Carol's MS had progressed to the point where she required a cane to walk, and was prescribed daily oral doses of Baclofen, an anti-spasticity drug. In 1990, due to the continuing progression of her disease, she was forced to terminate her employment and was hospitalized on numerous occasions. In 1994, Carol began using a Rascal motorized scooter. In 1998, Carol became a patient of Dr. Howard Natter, a neurologist at Meadowbrook Neurology. While taking her medical history, Dr. Natter noted that Carol was having difficulty walking, and had some incontinence, intermittent pain, and other symptoms. Instead of oral doses of Baclofen, Dr. Natter suggested that Carol consider undergoing surgery to have a subcutaneous pump implanted that would administer Baclofen continuously and uniformly. Dr. Natter provided appellants with manufacturerproduced information on the Baclofen pump, which included a videotape and pamphlet that outlined the use of the pump, as well as the benefits and risks associated with it.

At Carol's next appointment, Dr. Natter again suggested having the Baclofen pump implanted and appellants were receptive, agreeing to consider the procedure. In December of 1998, Dr. Natter referred appellants to appellee Dr. Michael Munz,² a neurosurgeon who performed pump implantation procedures. Appellee examined Carol, discussed the risks and benefits of the implantation with appellants, and stated that Carol was potentially a good candidate for the surgery, but would first have to undergo a test dose of Baclofen to gauge her reaction to the medication. After again reviewing the information they had received from the Baclofen pump manufacturer and discussing the surgery, appellants decided that Carol had "nothing to lose and everything to gain" from the procedure.

² Named appellee Brain and Spine Institute is no longer a party. As Dr. Munz is the sole appellee here, all references to appellee refer to him.

Carol signed two consent forms, one prior to undergoing the test dose, and a second prior to the surgery itself. The parties disputed later what occurred following the test dose procedure: Dr. Munz testified that, while Carol experienced some hypotonia, *i.e.*, extreme muscle flaccidity, her spasticity and function began to return within twelve hours and her walking was improved for several days after the test dose. Thomas testified that Carol had a severe reaction to the test dose, experiencing extreme hypotonia that robbed her of all function and lasting several days, well after her discharge from the hospital. Thomas testified that despite this reaction, Carol's ability to walk was improved after four to five days. Dr. Munz opined that Carol's response was favorable and confirmed that she was a good candidate for the procedure.

On May 12, 1999, Carol underwent surgery for the implantation of a Baclofen pump. After being discharged from the hospital, Carol was referred to physical therapy. While her condition improved for a period of time, in August of 1999 Carol was diagnosed with a urinary tract infection and, following the infection, her ability to walk decreased until she ultimately became wheelchair bound. Carol's condition continued to deteriorate to the point where she became paraplegic, incontinent, and wholly dependent upon Thomas for caretaking. In 1999, Thomas left his job to care for Carol full-time.

In 2001, appellants filed a civil action against Dr. Natter, Meadowbrook Neurology,³ the Brain and Spine Institute at Temple University Hospital,⁴ and appellee. Appellants

³ Meadowbrook Neurology is the practice group with which Dr. Natter was associated.

⁴ Dr. Munz was associated with the Temple Brain and Spine Institute. Appellants withdrew their claim against the Institute during trial, recognizing that the Institute was not responsible for obtaining the informed consent of patients. Notes of Testimony, 2/23/08. at 89.

claimed professional negligence or a breach of the standard of care, battery or a lack of informed consent, and loss of consortium.

A jury trial commenced on February 23, 2004, but limited to the claims of lack of informed consent and loss of consortium. Thomas testified that he and Carol made all medical decisions jointly and that, had the risks of the surgery been fully disclosed, Carol would not have undergone the procedure. Carol was present in the courtroom for most of the proceedings, but did not testify. While appellants now assert that Carol did not testify due to her deteriorated condition and cognitive dysfunction, Appellants' Brief at 11, 24, the record does not support that assertion. Appellants did not present any explanation or evidence at trial that Carol's failure to testify was due to her physical incapacitation. Meanwhile, appellee argues that Carol's failure to testify was strategic. Appellee notes that it was only after the defense case began and the court was considering a motion for compulsory nonsuit that appellants asked to re-open their case to present Carol's testimony. That request was denied by the trial court. In its opinion, the trial court found that appellants had made a conscious and strategic decision not to present Carol's testimony. The trial court found that the request was untimely and prejudicial to the defense. Trial Ct. Op. at 10, 19-21.

In order to prove the first element of the informed consent claim, that is, the undisclosed risk or alternative, appellants attempted to present two expert witnesses, an anesthesiologist and a neurologist. The trial court refused to permit the anesthesiologist, Dr. Atlas, to testify on informed consent, reasoning that an anesthesiologist was not qualified to testify against a neurosurgeon such as appellee. The neurologist, Dr. Grenell, was also barred from testifying as to the informed consent issue, the trial court reasoning that a neurologist was not necessarily qualified to testify regarding the benefits, risks, or complications associated with pump implantation surgery. Further, the trial court found Dr. Grenell unqualified to testify on this point because he had never personally performed a

surgery, had never secured a patient's consent for surgery, and had no experience with the Baclofen pump. Both experts were permitted to testify concerning the negligence case against Dr. Natter.

Thomas testified that he had questioned Dr. Munz about potential risks and side effects of the pump implantation, and that Dr. Munz had told him that it was an "extremely simple procedure." Thomas also stated that his understanding was that patients with MS should never undergo any procedure near the spinal cord, and that Dr. Munz had "shrugged that off," and stated that that was "a very conservative way of thinking" and that "none of [Dr. Munz's] patients ever suffered an attack or exacerbation; that's not something to worry about." Notes of Testimony ("N.T."), 2/24/04, at 26. Thomas testified that, prior to the procedure, Dr. Munz did not inform him and Carol that the pump implantation might not be successful in controlling Carol's spasticity, that it might cause weakness, or that it might exacerbate her incontinence.

Appellee testified at trial as to the risks of pump implantation. Appellee testified that the risks that should be disclosed to a patient before the surgery are the general risks associated with anesthesia and surgery, the risk that the procedure may not help the patient, and the risk of increased perceived weakness due to the decrease in spasticity brought about by the medication. Appellee testified that hypotonia and temporary loss of function are recognized potential side effects of Baclofen, but that those side effects were caused by the medication, and so could be dealt with by "turning the Pump off" and thereby ceasing the administration of the medication.

On February 27, 2004, the defense rested. During closing arguments, appellants argued that the undisclosed risks of the pump implantation were loss of the ability to walk due to too large a dosage of Baclofen, and that the procedure may not work due to an inability to correctly calibrate the dosage. As part of its jury charge, the trial court submitted a verdict sheet with seven questions to the jury. Questions three, four, five, and seven

addressed the case against Dr. Munz. Question three asked: "Do you find that [Dr. Munz] failed to obtain the informed consent of Carol Fitzpatrick for the operative procedure which he performed?" Question four read: "Do you find that the failure of [Dr. Munz] to obtain the informed consent of [Carol Fitzpatrick] was a substantial factor in her decision to undergo the implantation procedure?" Question five asked for a calculation of damages for the informed consent claim, and question seven for a calculation of damages on the loss of consortium claim.

On March 1, 2004, the jury answered yes to questions three and four, finding that appellee failed to obtain Carol's informed consent before performing the pump implantation surgery and that the missing information would have been a substantial factor in Carol's decision whether to undergo the surgery. The jury awarded damages in the amount of 1.5 million dollars on the informed consent claim, and 1.7 million dollars on the loss of consortium claim. Both awards were against Dr. Munz only.⁵

Dr. Munz filed post-trial motions for, *inter alia*, a new trial and judgment N.O.V. The trial court granted the motion for judgment N.O.V. In its Opinion, the trial court found that the informed consent claim failed on three distinct grounds. First, the trial court opined that the claim failed as a matter of law because the informed consent statute, 40 P.S. § 1301.811-A, required the patient herself to testify that the allegedly undisclosed information would have been a substantial factor in her decision to undergo the procedure. The trial court noted that Carol was present throughout the trial and capable of testifying, yet appellants instead strategically chose to rely solely on Thomas' testimony to establish the lack of informed consent. Without Carol's testimony, the trial court reasoned, the jury could only speculate what her thought process was and whether she had provided her informed

⁵ The jury found that Dr. Natter was not negligent in the care he rendered to Carol.

consent to the surgery. The court concluded that, as a matter of law, Carol's failure to testify rendered the jury's verdict "improper." Trial Ct. Op. at 10.

Second, the trial court determined that appellants had failed to prove that the allegedly undisclosed information would have been significant to Carol's decision because the evidence showed that other factors had completely dominated her election to go forward with the procedure. The "other factors" cited by the trial court included that, at the time she decided to undergo the procedure, Carol was suffering from frequent bouts of incontinence, falls, difficulty ambulating, and confinement to a scooter. Trial Ct. Op. at 13.

Finally, the trial court discussed its rulings barring the expert testimony of appellants' neurologist and anesthesiologist on informed consent. After first finding that the rulings were not in error, the trial court went on to conclude that appellants had failed to meet their burden of establishing the benefits, risks, and alternatives associated with the pump implantation procedure. The court recognized that appellants had attempted to rely on the testimony of Dr. Munz himself to meet their burden, but the trial court found that the record "was devoid of any expert opinion testimony on the risks involved, how likely the risks are to occur, and the nature of the harms inherent in these risks." Consequently, the trial court found that appellants had not introduced "sufficient expert testimony" to establish the elements of an informed consent claim.⁶ Trial Ct. Op at 18.⁷

Appellants appealed to the Superior Court, raising three claims: (1) the trial court erred as a matter of law in holding that a lack of informed consent claim must fail if the patient does not testify; (2) the trial court otherwise abused its discretion in granting judgment N.O.V. where the disputed evidence created a jury question; and (3) the trial

⁶ As our summary of the trial testimony above reveals, appellee in fact did testify to certain risks posed by the surgical procedure. <u>See</u> discussion <u>supra</u>.

⁷ The trial court also discussed a number of appellants' claims requesting a new trial. Those rulings are not before us in this appeal.

court abused its discretion in excluding testimony from appellants' experts. The Superior Court affirmed the grant of judgment N.O.V. in an unpublished, 2-1 panel opinion. The panel considered appellants' first two claims together. Appellants argued that the testimony of Dr. Munz was sufficient to prove the first element of their claim, respecting the material risks involved, even though the trial court barred their own experts. Appellants added that Thomas' testimony was then sufficient to prove the substantial factor element, and that the trial court erred in holding that Carol's testimony was required to prove this element.

The panel majority stated that the "essential issue" concerned the substantial factor element. The majority determined that Thomas' testimony was insufficient to prove that the allegedly undisclosed information would have been a substantial factor in Carol's decisionmaking. The majority reasoned that, while Thomas could testify as to what he understood the risks to be, or what he suggested to Carol regarding the potential risks, he could not testify about the significance Carol may have placed upon the information as compared to other factors playing into her decision. The majority found that, "[w]ithout Wife's testimony … the jury was left to speculate on whether the undisclosed information would have been a substantial factor in **Wife's** decision to undergo the procedure, given the circumstances of Wife's condition and the other factors favoring the procedure." Super. Ct. Op. at 14-15. The majority concluded that, considering the evidence in the light most favorable to appellants as verdict winners, appellants had failed to adduce sufficient evidence as a matter of law to sustain the jury verdict in their favor.

Although the bulk of the majority's discussion concerned the substantial factor element, in the midst of this analysis, the majority opined that: "[b]ased on the trial evidence, the jury could reasonably conclude that Appellee had failed to disclose the general risk that any surgical procedure might exacerbate Wife's MS." Super. Ct. Op. at 14-15. The majority's brief observation concerning the first element was contrary to the trial court's alternative finding that appellants had failed to establish, through the required expert testimony, the benefits, risks, and alternatives implicated by the surgical procedure. However, having found that the evidence was insufficient to establish the first element of the informed consent claim because of Carol's failure to testify, the majority declined to address appellants' third claim concerning the trial court's exclusion of appellants' expert testimony.

Judge Panella filed a brief dissenting statement. In the dissent's view, there was sufficient evidence, even without Carol testifying, to support the jury's conclusion that Dr. Munz's failure to disclose known risks was a substantial factor in Carol's decision to undergo surgery. The dissent further noted that "making guesses as to how the jury would have reviewed [the] evidence usurps the function of the jury." Super. Ct. Op. at 17 (Panella, J., dissenting).

This Court granted allocatur. Appellants now set forth four questions: (1) whether the panel majority below properly applied the informed consent statute; (2) whether the majority erred in "effectively ruling that circumstantial evidence cannot be used to prove elements of an informed consent claim;" (3) whether the testimony of a patient's husband is "competent" to satisfy the substantial factor element of an informed consent claim; and (4) whether the majority erred in "ignoring" the *stare decisis* value of <u>Rowinsky v. Sperling</u>, 681 A.2d 785 (Pa. Super. 1996), <u>alloc. denied</u>, 690 A.2d 237 (Pa. 1997). Because the questions are interrelated, we shall consider them together. As the overriding issue is one of law, our scope of review is plenary and our standard of review is *de novo*. <u>Coolspring</u> Stone Supply, Inc. v. County of Fayette, 929 A.2d 1150, 1151 n.1 (Pa. 2007).

The law of informed consent applicable to this 1999 case was codified at 40 P.S. §

1301.811-A^{,8} and provided, in relevant part:

(a) Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

(1) Performing surgery, including the related administration of anesthesia.

(4) Inserting a surgical device or appliance.

(b) Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted medical standards of medical practice would provide.

(c) Expert testimony is required to determine whether the procedure constituted the type of procedure set forth in subsection (a) and to identify the risks of that procedure, the alternatives to that procedure and the risks of these alternatives.

(d) A physician is liable for failure to obtain the informed consent only if the patient proves that receiving such information would have been a substantial factor in the patient's decision whether to undergo a procedure set forth in subsection (a).

40 P.S. § 1301.811-A (repealed).

Thus, to succeed on an informed consent claim, the patient must establish that: (1)

the doctor failed to disclose a relevant risk or alternative before obtaining the patient's

consent for a covered procedure, and (2) the undisclosed information would have been a

substantial factor in the patient's decision whether to undergo the procedure. See also

Hohns v. Gain, 806 A.2d 16, 19 (Pa. Super. 2002); accord Gouse v. Cassel, 615 A.2d 331,

⁸ 40 P.S. § 1301.811-A has been repealed in favor of 40 P.S. § 1303.504 (effective Mar. 20, 2002). The relevant portions of the new statute are materially the same as the old one.

333 (Pa. 1992) (construing prior version of statute). The purpose of the informed consent doctrine is to ensure that the patient is provided with the material information necessary to determine whether to undergo the given procedure or to remain in the present condition. <u>Sinclair by Sinclair v. Block</u>, 633 A.2d 1137, 1140 (Pa. 1993). For consent to be informed and valid, it must be clear that the patient understands the reasonably possible, as well as the expected, results. <u>See Gouse</u>, 615 A.2d at 333-34. Therefore, the patient must first prove the known, material risks of the procedure and the likelihood of their occurrence, and then prove that the doctor did not fully inform her about the known risks of and alternatives to the procedure; and finally, that such information would have factored substantially into her decisionmaking process. <u>Hohns</u>, 806 A.2d at 19-20. The patient need not show that she would have chosen differently had she possessed the missing information, but only that the missing information would have been a substantial factor in this decision. Whether the information would have been a substantial factor is a question of fact for the jury. If there were other factors that completely dominated the patient's decision to move forward with the procedure, the jury may find the element missing. <u>Id.</u>

As to the first element of this informed consent claim, appellants currently argue that Dr. Munz failed to disclose that surgery on a patient with MS -- any surgery -- carries a risk of damaging existing neurological function and consequently worsening the patient's condition. Appellants further argue that, because the jury found that they proved the first element of this claim, the only point in dispute in this appeal is whether what they call "circumstantial" evidence -- here, the testimony of Thomas Fitzpatrick -- was sufficient to prove the second element, *i.e.*, that the undisclosed information would have been a significant factor in Carol's decision whether to undergo the procedure. Appellants argue that the Superior Court erred by holding that this circumstantial evidence was insufficient to establish the substantial factor element. Appellants maintain that circumstantial evidence is competent to prove all issues of fact generally, and that it is therefore an acceptable

manner of proving the factual question of whether knowledge of an undisclosed risk of a medical procedure would have been a substantial factor in a patient's decision-making process.

Appellants note that they presented evidence that they made joint medical decisions, and Thomas testified that Carol followed his advice and that he would not have advised her to have the surgery if they had been informed of the risks. This evidence, appellants argue, provided a sufficient basis from which the jury could reasonably conclude that Carol would have considered the undisclosed information to be a substantial factor in her decision whether to undergo the surgery.

The fact that the jury had to draw inferences to conclude that Carol would have considered the undisclosed information to be significant, appellants argue, does not mean that such inferences were unreasonable and impermissibly speculative. Furthermore, the requirement that a patient must prove all elements of her claim is not, appellants urge, synonymous with a rule that the patient herself must testify. Rather, circumstantial evidence, which is generally competent to prove all elements of a factual claim under Pennsylvania law, may be presented, from which the jury may permissibly draw reasonable inferences. In this case, appellants argue, the jury properly inferred from the evidence presented that the undisclosed information would have been a substantial factor in Carol's decision. Appellants also assert that the use of circumstantial evidence to prove an informed consent case was approved in <u>Rowinsky v. Sperling</u>, supra, a case decided under the former version of the informed consent statute, in which a claim was brought by the wife of an incompetent patient. <u>Rowinsky</u>, 681 A.2d at 788.⁹

⁹ The patient in <u>Rowinsky</u> suffered severe cognitive impairment as a result of the procedure, and died between the filing of the complaint and the commencement of trial.

Appellants conclude that the trial court's granting of appellee's motion for judgment N.O.V. was inappropriate because appellants had established, through the testimony of Thomas Fitzpatrick, a *prima facie* case for lack of informed consent. Once a *prima facie* case was established, the resolution was exclusively a question for the jury. The trial court's legal ruling, appellants argue, effectively usurped the jury's role as fact finder.

Finally, appellants argue that restricting the type of evidence by which a plaintiff may prove an informed consent claim, as the lower courts have done, sets a dangerous precedent.¹⁰ To rule that a patient **must** testify in order to prove the second element of the informed consent claim would effectively bar claims in cases where the patient has died or has become incompetent to testify. In such cases, appellants argue, a patient (or the patient's survivors) could **only** prove the case by circumstantial evidence, so the rule accepted below would exclude an entire class of plaintiffs. In response to Dr. Munz's rejoinder that the executor of an estate or the patient's guardian could bring the action because of the "special legal relationship" that exists between them, appellants argue that imposing different evidentiary rules on cases brought by the executor of an estate or an incompetent patient's guardian is illogical and without precedent in Pennsylvania law.

In response, appellee argues that the panel majority below correctly determined that circumstantial evidence is not legally sufficient to prove the substantial factor element of an informed consent claim. Without the testimony of Carol, appellee submits, the jury inevitably was left to speculate as to what weight she would have given the allegedly undisclosed information. Appellee notes that to make the substantial factor determination, the number of other factors which contributed to the patient's consent necessarily must be considered. Appellee argues that appellants failed to prove that undisclosed information

¹⁰ Appellants' *amicus curiae*, the Pennsylvania Trial Lawyers Association, echoes this argument.

was a substantial factor in Carol's decision to undergo the procedure because Thomas could only testify as to the significance he would have placed on the information, and to what he would have advised Carol. Without the testimony of Carol herself, however, the jury was left to speculate as to her own thought process. In appellee's view, Thomas could not testify as to the significance Carol might have placed on the information as compared to other factors that influenced her decision. Appellee adds that, as a matter of law, a jury cannot base its verdict upon speculation or conjecture, citing <u>Kuisis v. Baldwin-Lima-Hamilton Corp.</u>, 319 A.2d 914, 922 (Pa. 1974) (plurality on this point) in support of this principle. Appellee concludes that the circumstantial evidence here was insufficient as a matter of law to prove that the allegedly undisclosed information concerning the surgical risk was a substantial factor in Carol's decision to undergo the procedure, which means that judgment N.O.V. was appropriate.

In response to the policy argument forwarded by appellants, appellee argues that requiring a patient to testify to establish her informed consent claim would not set a dangerous precedent because, when a patient is deceased or incompetent, a special legal relationship between the patient and the administrator of the estate or the guardian exists that allows the action to be brought for the patient by the executor, administrator, or guardian *ad litem*. <u>See</u> Pa.R.C.P. 2051-2075, 2201-2225. Appellee says that this "special legal relationship" negates the concerns that the jury will be forced to speculate as to the inner workings of the patient's mind.

Appellee also distinguishes <u>Rowinsky</u> on grounds that it was decided under the previous incarnation of the statute, which only required proof that a **reasonable person** would have considered the information important.¹¹ The 1996 version of the statute

¹¹ The statute at issue in <u>Rowsinsky</u>, 40 P.S. § 1301.103 (1992), required a physician to "inform[] the patient of the nature of the proposed procedure or treatment and of those risks (continued...)

applicable here, on the other hand, requires the patient to prove that the information was a substantial factor in the **patient's** decisionmaking. Thus, appellee argues that the patient's testimony was not essential under the reasonable person standard in the pre-1996 statute only because the patient's actual decision-making process was not at issue.

Turning to his own issues of public policy, appellee foresees endless battles if the fact finder must determine on a case-by-case basis whether a spouse is competent to testify to the substantial factor element. Appellee argues that a bright-line rule is necessary to avoid an untenable situation in which juries are forced to determine, on a case-by-case basis, whether a patient's relationship with a spouse or next of kin is sufficiently intimate that the relative may testify as to the inner workings of the patient's mind for purposes of informed consent.

Appellee also raises several alternative arguments, alleging appellants failed to prove other elements of their informed consent claim. Noting that this Court may affirm the judgment below on any grounds, appellee first cites the trial court's alternative holding that appellants failed to show that factors other than the allegedly undisclosed information did not dominate Carol's decision to have the pump implantation surgery. Appellee's Brief at 20-25 (citing <u>Commonwealth v. Fisher</u>, 870 A.2d 864, 870 n.11 (Pa. 2005); <u>Gilbert v. Korvette, Inc.</u>, 327 A.2d 94, 96 n.5 (Pa. 1974); <u>Sherwood v. Elgart</u>, 117 A.2d 899, 901 (Pa. 1955)). Appellee cites to the trial evidence indicating that other significant factors influenced Carol's decision to proceed with the surgery. Citing the Superior Court's <u>Hohns</u> decision, appellee posits that a causal connection must exist between the physician's failure to give the patient all relevant information, and the patient's decision to undergo the procedure. Appellee asserts that, in this case, the trial court properly found that other

^{(...}continued)

and alternatives to treatment or diagnosis that a reasonable patient would consider material to the decision whether or not to undergo treatment or diagnosis."

factors completely dominated Carol's decision; thus, as a matter of law, the absence of information regarding the risks of surgery cannot be deemed a substantial factor in that decision.

Next, appellee argues that appellants failed to prove the first element of their claim, *i.e.*, that there was a material undisclosed risk of the surgery. Appellee notes that appellants now argue that the allegedly undisclosed risk was that **any** surgical procedure could exacerbate Carol's MS symptoms. Any such claim is waived, appellee argues, because appellants failed to present that theory of liability at trial. To the contrary, appellee asserts, at trial appellants proceeded solely on the theory that appellee had failed to disclose the risk that it may prove impossible to correctly calibrate the Baclofen dosage administered by the pump to improve Carol's ability to walk.¹²

Underlying the informed consent doctrine is the fundamental recognition that a physician should not administer to, or operate upon, a mentally competent adult patient in non-emergency situations without his or her consent. <u>Festa v. Greenberg</u>, 511 A.2d 1371, 1373 (Pa. Super. 1986). Although the two basic elements of an informed consent claim are easily enough stated, the statute does not purport to address how to prove the substantial

¹² Also respecting the first element, appellee echoes the trial court's second alternative holding that appellants failed to produce the necessary expert testimony on the specific risks of the surgical procedure and the probability of harm. Appellee argues that the trial court properly barred appellants' expert neurologist, Dr. Grenell, from testifying as to the risk of pump implantation because the proposed testimony went beyond the scope of his pre-trial report and he was not qualified to render such an opinion. Furthermore, appellee points to Dr. Grenell's trial testimony and argues that he never testified that Carol's present, debilitated condition was a risk of the surgery, nor did he ever quantify the probability that the surgery could lead to this result. Finally, as to causation, appellee argues that the evidence demonstrates that Carol's deteriorated condition was not in fact caused by the surgery. The Superior Court, however, did not pass upon appellants' claim that the trial court erred in excluding their expert testimony. The validity of appellee's alternative argument is intertwined with the evidentiary question, which we will remand to the Superior Court.

factor question, and the case law provides little guidance as to the evidentiary means by which a patient may, or must, prove that element. The primary question posed here is whether the testimony of a person other than the patient can be sufficient to prove the substantial factor element. For the reasons that follow, we hold that, as in other areas of the law, circumstantial or indirect evidence may suffice for an informed consent patient to prove the elements of her claim. Therefore, a patient's decision to refrain from testifying at trial is not fatal to the claim.

As a general matter, a party bringing a civil action must prove, by direct or circumstantial evidence, facts by which the trier of fact can reasonably draw the inference urged by the plaintiff. <u>Noel v. Puckett</u>, 235 A.2d 380, 384-85 (Pa. 1967).¹³ Nonetheless,

Circumstantial evidence is entitled to as much weight as direct evidence, and is admissible to prove all elements of a negligence claim. See, e.g., Beers-Capitol v. Whetzel, 256 F.3d 120, 133 (3d Cir. 2001) ("[S]ubjective knowledge . . . can be proved by circumstantial evidence to the effect that the excessive risk was so obvious that the official must have known of the risk."); Leedy v. Hartnett, 510 F. Supp. 1125, 1127 (M.D. Pa. 1981), aff'd, 676 F.2d 686 (3d Cir. 1982) (circumstantial evidence sufficient to prove identity of assailant in civil assault and battery action); Commonwealth v. Chambers, 599 A.2d 630, 635 (Pa. 1991) (circumstantial evidence entitled to same weight as direct evidence); Brandon v. People's Natural Gas Co., 207 A.2d 843, 846 (Pa. 1965) (in trespass action, "[w]here proof is by circumstantial evidence the jury may not reach its verdict on the basis of speculation and conjecture; but the plaintiff is entitled to keep the verdict for him when the jury could have reasonably inferred the facts necessary to establish liability"); Dorofey v. Bethlehem Steel Co., 180 A.2d 562, 566 (Pa. 1962) ("Circumstantial evidence, with the inferences reasonably deducible therefrom, is adequate to establish the conclusion sought if it so preponderates in favor of the conclusion as to outweigh . . . any other evidence and reasonable inferences therefrom which are inconsistent therewith."); In re Escheat of (continued...)

¹³ <u>Noel</u>, as well as several other cases cited below, involved circumstantial evidence as a manner of proof in a negligence action. An informed consent action, of course, sounds in battery rather than in negligence. <u>Montgomery v. Bazaz-Sehgal</u>, 798 A.2d 742, 744 (Pa. 2002). Nevertheless, the distinction between a battery and a negligence tort is irrelevant to the evidentiary question of what sort of evidence is sufficient to establish an element of the claim; logically, the principles governing the admissibility of circumstantial evidence and the weight it may be accorded apply regardless of the nature of the case, and the parties do not argue otherwise.

there is a limit to the inferences that the jury may reasonably draw from such circumstantial evidence. Viewed as a whole, the "evidentiary threads" must be sufficient to "lift [the] contention out of the realm of speculation." <u>Kuisis v. Baldwin-Lima-Hamilton Corp.</u>, 319 A.2d 914, 923 (Pa. 1974) (plurality on this point). Thus, while the jury may draw reasonable inferences, it "may not be permitted to reach its verdict merely on the basis of speculation or conjecture, but . . . there must be evidence upon which logically its conclusion may be based." <u>Jones v. Treegoob</u>, 249 A.2d 352, 354 (Pa. 1969) (quoting <u>Smith v. Bell Tel. Co.</u>, 153 A.2d 477, 479 (Pa. 1959)). "Clearly this does not mean that the jury may not draw inferences based upon all the evidence and the jurors' own knowledge and experiences, for that is, of course, the very heart of the jury's function. It means only that the evidence presented must be such that by reasoning from it, without resort to prejudice or guess, a jury can reach the conclusion sought by [the] plaintiff, and not that the conclusion must be the **only** one which logically can be reached." <u>Id.</u> at 354-55.

Preliminarily, we note that the <u>Rowinsky</u> case, upon which appellants place great reliance, is of little help to our analysis because the <u>Rowinsky</u> court never considered or discussed the means of proof question at issue here. Rather, at issue in <u>Rowinsky</u> was the question of whether a patient seeking to recover on an informed consent claim was required to prove that the procedure in fact caused the injury.

Suffering from severe seizures that failed to respond to medication, Mr. Rowinsky elected to attempt to treat his seizures through a lobectomy, a surgery that removed a

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<u>\$92,800</u>, 86 A.2d 55, 56 (Pa. 1952) (in escheat action, "[a] fact can be established . . . by circumstances"); <u>In re Young's Estate</u>, 32 A.2d 901, 904 (Pa. 1943) ("[A]s [circumstantial] evidence commonly comes from several witnesses and different sources, a chain of circumstances is less likely to be falsely prepared and arranged, and falsehood and perjury are more likely to be detected and fail of their purpose.") (quoting <u>Commonwealth v.</u> <u>Webster</u>, 59 Mass. (5 Cush.) 295, 312 (1850)); <u>De Reeder v. Travelers Ins. Co.</u>, 198 A. 45, 47 (Pa. 1938) (circumstantial evidence is legal evidence in both criminal and civil cases).

portion of his brain. <u>Rowinsky</u>, 681 A.2d at 787. Unfortunately, the surgery not only failed to cure Rowinsky's seizures, but also resulted in severe memory and speech difficulties, which prevented him from returning to work. Rowinsky and his wife brought an informed consent claim against the physician, alleging that the physician neglected to inform them that the procedure carried a risk of speech or memory loss. <u>Id.</u> Rowinsky was incompetent to testify due to his memory and speech problems, and he died between the filing of the complaint and the trial. Instead, his wife testified and she claimed that the relevant information was withheld and that it would have been significant to Rowinsky's decision whether to undergo the procedure. <u>Id.</u> at 789.

The jury returned a verdict for the Rowinskys; however, the trial court granted the physician's motion for judgment N.O.V., holding that the evidence presented was insufficient to sustain the verdict. On appeal, the doctor did not claim that Mrs. Rowinsky's testimony was inadequate as a matter of law to prove the substantial factor element of the claim, and the Superior Court did not consider that issue. Rather, the only issue in <u>Rowinsky</u> was whether, after proving a failure to obtain informed consent, the Rowinskys were required to prove by expert evidence that the surgery actually caused the claimed injury. The Superior Court held that, once a plaintiff proves that he or she was not informed of material risks, recovery is permitted "regardless of causation and actual damages." 681 A.2d at 790 (emphasis omitted).

Appellants argue that the <u>Rowinsky</u> panel "tacitly approved" the use of circumstantial evidence to prove the informed consent claim. But the panel did no such thing; it decided the issue presented. Recitation of undisputed facts is not approval of a theoretical evidentiary question.

Although <u>Rowinsky</u> does not advance appellants' cause, the plain language of the informed consent statute is more helpful. Nothing in the plain language of the amended statute requires the evidentiary interpretation forwarded by appellee and adopted by the

courts below. Nor is there any suggestion that the General Assembly deemed this cause of action, unlike others, to be subject to special rules respecting reliance upon circumstantial or direct evidence. Section 1301.811-A(d) provided that a physician is liable for failing to obtain the patient's informed consent only when "the patient proves that receiving such information would have been a substantial factor in the patient's decision whether to undergo a procedure." 40 P.S. § 1301.811-A(d). Nowhere did the plain language of the statute include a requirement that the patient must testify that the missing information would have been significant to his or her decision-making process.

Of course, if the General Assembly intended to restrict so severely the evidence available to the plaintiff in informed consent cases, it could have done so explicitly.¹⁴ As circumstantial evidence generally is competent to prove factual issues, and the Informed Consent statute does not purport to provide otherwise, we will not create an evidentiary exception for informed consent claims. Assuming the evidence is not merely speculative, the strength or usefulness of the circumstantial evidence is then a question for the jury.

We find further support for our construction of the statute, and our understanding of informed consent cases, in the policy argument forwarded by appellants and their *amicus*. In medical malpractice cases, it is not uncommon for the patient to be deceased or so debilitated (as in <u>Rowinsky</u>) as to be unable to testify, either as a result of the underlying condition or the medical procedure, or some intervening cause. There is no reason in law or logic to adopt a shifting standard governing proof in informed consent cases, which

¹⁴ It is noteworthy that the General Assembly did set forth specific evidentiary requirements for how the plaintiff must prove the **first** element of an informed consent claim. Section 1301.811-A(c) stated that the plaintiff must present expert testimony to prove the risks of the procedure, and the likelihood that those risks will occur. The failure to restrict proof of the second element supports that the General Assembly did not intend a specialized restriction.

would have the acceptable manner of proof depend upon the testimonial availability of the patient. Neither the statute, nor the case law on informed consent, supports such a distinction.¹⁵

The fact that circumstantial evidence **may** be sufficient to prove a necessary point, of course, does not mean that the circumstantial evidence was in fact sufficient in a particular case. As we have emphasized above, proof, whether circumstantial or not, must be more than mere speculation.¹⁶ When the patient herself is available, competent, and able to testify, the better course of action probably is to call the patient to testify, and it is certainly fair game for the medical defendant to stress to the jury an available patient's failure to testify.

In the case *sub judice*, a related and central aspect of the reasoning on circumstantial evidence forwarded by the courts below, and appellee here, is that the circumstantial evidence in this case was simply insufficient to support the jury verdict on the substantial factor element. If that were so, and if there were no other issue respecting the evidence at trial, appellee would be entitled to judgment notwithstanding our finding on the legal question of the proper role of circumstantial evidence in informed consent cases. In

¹⁵ Appellee argues that holding that a patient may prove the second element of an informed consent claim through circumstantial evidence will result in an evidentiary morass, requiring informed consent juries to determine whether the relationship between the patient and the persons testifying as to the patient's decision-making process is sufficiently intimate. To the extent that appellee's concern may exist, we note that making such determinations is, of course, the core function of a jury. We decline to disturb that function by unnecessarily restricting the nature of the evidence available for the jury to consider.

¹⁶ Judgment N.O.V. may only be granted after the verdict winner has been given the benefit of every available inference of fact arising from the evidence. <u>Moure v. Raeuchle</u>, 604 A.2d 1003, 1007 (Pa. 1992). The trial court may not grant judgment N.O.V. simply because it would have preferred a different outcome, and in reviewing a grant of judgment N.O.V. the appellate court must reject all evidence which does not support the verdict. <u>Jemison v.</u> <u>Pfeifer</u>, 152 A.2d 697, 702-03 (Pa. 1959).

determining whether the knowledge of the undisclosed risks and/or alternatives would have been a "substantial factor" in the patient's decision-making process, the jury considers both the importance of the undisclosed information and the relative importance of other factors that may have influenced the patient's decision. <u>See Hohns</u>, 806 A.2d at 20.

Thomas Fitzpatrick largely testified as to questions and concerns that he raised during appellants' discussions with either Dr. Natter or appellee. But, Thomas did testify to a few questions raised by Carol herself. For example, Thomas testified that, during the first appointment with appellee to discuss the pump implantation, Carol was present and did not say "a whole lot," but that she was concerned that the placement of the pump would put pressure on her bladder. N.T., 2/24/04, at 28. Further, Thomas testified that the most important consideration for Carol was to preserve her current level of functioning -- he stated that Carol "enjoyed doing the things that she could do," that she was "proud of the things she was able to do" and "did not want to lose the ability to walk. She did not want to lose the ability to care for herself." Id. at 199-200. Thomas also testified that he and Carol made all medical decisions jointly, that he attended all doctor's appointments with her, and that she listened to his advice regarding medical treatment. He further testified that had he been in possession of the information regarding the procedure that he and Carol claimed was not disclosed, he would have considered it a substantial factor in their joint decisionmaking process. Id. at 199. In fact, Thomas testified that had he been informed that Carol could have lost existing function as a result of the implantation procedure, he would have advised her not to go ahead with the surgery. Id. Appellants essentially argue that, on this record, the jury could properly infer, from Thomas' testimony, that what would have been a substantial factor for Thomas would also have been a substantial factor for Carol. The predicate difficulty with appellants' argument concerning the substantial factor element as premised upon the existing trial record, however, is that it assumes there was competent evidence concerning an undisclosed risk of the surgical procedure, which could then be the

subject of the substantial factor analysis. In addition to arguing that other factors dominated Carol's decision to undergo the surgical procedure, appellee forwards a more elemental alternative argument -- one which was credited by the trial court on post-verdict motions -- that appellants failed to prove the first element of their informed consent claim, *i.e.*, they failed to prove, by expert testimony, the risks of the procedure, the alternative procedures, and the risks of the alternatives. <u>See</u> 40 P.S. § 1301.811-A(c).¹⁷ The determination of what risks would be material to the patient's decision is a jury question; however, in making that determination, the jury must be supplied with expert information not only as to the potential harm, but the likelihood of that harm occurring. <u>See Moure v.</u> <u>Raeuchle</u>, 604 A.2d 1003, 1008 (Pa. 1992).¹⁸

Appellee argues that appellants did not present or pursue the theory at trial that appellee neglected to inform them that, on a patient with MS, surgery itself carries a risk of damaging existing neurological function. Instead, appellee submits, appellants proceeded solely on the theory that Carol's deteriorated condition, and specifically her hypotonia, resulted from the inability to correctly calibrate the dosage of the Baclofen pump to achieve the proper balance between spasticity and flaccidity. Thus, appellee notes that appellants' primary trial theory was that hypotonia from too much Baclofen is an established risk of

¹⁷ It is settled, of course, that this Court may affirm the order of the court below if the result reached is correct, without regard to the grounds for decision relied upon by that court. <u>C.B. ex rel. R.R.M. v. Dep't of Pub. Welfare</u>, 786 A.2d 176, 178 n.1 (Pa. 2001). In this case, the alternative ground is one which appellee preserved below and urges on this appeal.

¹⁸ While <u>Moure</u> interpreted the previous version of the informed consent statute, the current version of the statute is identical concerning the purposes of expert testimony and the assessment of materiality of risk. Further, neither party disputes that expert testimony must be presented not only as to the possible harms, but as to the likelihood of their occurrence. Thus, <u>Moure</u> is binding on this point.

pump implantation, and that that specific risk was not disclosed to Carol prior to the surgery. Appellee also urges that, notwithstanding the Superior Court panel majority's offhand notation that the jury could reasonably conclude that appellee "had failed to disclose the general risk that any surgical procedure might exacerbate [Carol's] MS," in point of fact, **no** expert evidence was presented at trial from which the jury could find that such a risk actually exists, or that such a risk is likely and material enough that a reasonable physician would inform a patient of the risk prior to surgery.

Appellants respond by insisting that they proceeded at trial solely on the theory that appellee failed to disclose the risk that surgery alone could exacerbate Carol's MS symptoms. Appellants state that the trial court "misinterpreted" their theory of liability, and they maintain that they "did not present a claim for lack of informed consent in connection with the administration of Baclofen. Appellant[s] did not and [do] not raise an issue as to whether the risks of receiving Baclofen through a Pump were properly disclosed. It is Appellants' position that [appellee] failed to properly disclose the risks of surgery associated with a patient who suffers from [MS]"; and that "[t]he undisclosed risk in this case was the fact that surgery on a person with [MS] carries a risk of permanent and rapid neurological deterioration." Appellants' Brief at 17 n.5. Our careful review of the record corroborates appellee's assertion that there was no properly admitted expert testimony at trial to support appellants' current theory of liability -- *i.e.*, that any surgery on a patient with MS carries a risk of exacerbating that condition.¹⁹ The trial court noted that its evidentiary

¹⁹ The question of whether appellants "pursued" a theory premised upon the fact of surgery posing a risk of deterioration in Carol's condition is somewhat closer. Contrary to appellants' current assertion, they clearly argued for relief premised upon appellee's alleged failure to disclose the risk of hypotonia resulting from an inability to properly calibrate the doses of Baclofen as administered with the implanted pump.

On the other hand, Thomas testified at trial that he "understood that any kind of operation with an MS patient concerning the spinal cord . . . shouldn't be done." N.T., 2/24/04, at 78. (continued...)

rulings, which excluded the testimony of appellants' expert witnesses on the informed consent claim, left an evidentiary void as to the risks actually associated with pump implantation surgery and, by implication, the risks implicated in any surgery on a patient with MS. The record supports the trial court's view. Appellants' first expert, Dr. Atlas, was not permitted to testify as to the informed consent issue because the trial court reasoned that, as an anesthesiologist, he was not qualified to testify against a neurosurgeon such as appellee. Likewise, the trial court limited the testimony of the second plaintiffs' expert, Dr. Grenell, to the negligence case against Dr. Natter. N.T., 2/23/04, at 33. The trial court reasoned that Dr. Grenell, a neurologist, was not qualified to testify regarding any benefits, risks or complications associated with pump implantation because Dr. Grenell had never performed a surgery, had never secured a patient's consent for surgery, and had no experience with the Baclofen pump. In arguing that their existing expert evidence was in fact sufficient to prove the undisclosed risk necessary to their claim, appellants point primarily to the testimony of Dr. Grenell. Dr. Grenell indeed testified that Carol's condition was "worsened" by the implantation of the Baclofen pump because, in the secondary progressive phase of MS, "you wouldn't expect her to have sudden worsening unless there

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According to Thomas, Dr. Natter responded that "[t]hat's a very conservative way of thinking. This is done all the time." <u>Id.</u> Thomas further testified that he broached the same subject with Dr. Munz before the test dose procedure, and Dr. Munz informed him that "none of [Dr. Munz's] patients ever suffered an attack or exacerbation; that's not something to worry about." <u>Id.</u> at 27. Thomas further testified that Carol would not have gone ahead with the procedure had they been informed that the pump implantation might cause weakness in Carol's legs, exacerbate her incontinence, and have no effect on her spasticity. <u>Id.</u> at 376a. In addition, appellants' expert, Dr. Grenell, opined, *inter alia*, that acute attacks of MS can be "temporally associated" with surgical procedures, and that Carol's condition worsened as a result of the pump implantation. N.T., 2/23/04, at 46, 122. However, the fact remains, as we will explain below, that appellants produced no qualified expert testimony on the point.

was some smoking gun such as high fever or a urinary infection or an operation." N.T., 2/23/04, at 46. Dr. Grenell also opined that "multiple sclerosis patients can respond to injury by worsening multiple sclerosis" and that "surgery is a kind of controlled injury." <u>Id.</u> The difficulty in appellants' argument, however, is that the trial court specifically limited the jury's consideration of Dr. Grenell's testimony to the negligence case against Dr. Natter. Moreover, as appellee correctly notes, even if Dr. Grenell's testimony could be considered in the context of the informed consent claim, Dr. Grenell did not testify that permanent neurological deterioration is a recognized risk of surgery in a patient with MS, nor did he quantify the likelihood of such a "risk" occurring. Thus, Dr. Grenell's testimony did not serve to provide the expert testimony necessary to prove the undisclosed risks and alternatives element of the informed consent claim.

Appellants also cite to appellee's own testimony as filling the expert evidence void in their proof, but again, the record belies the claim. Appellee testified to risks associated with the pump implantation procedure, including the general risks associated with surgery and anesthesia, the risk of side effects from leaking spinal fluid, the risk that the procedure may not help the patient, and the risk of increased perceived weakness due to the decrease in spasticity brought about by the medication. Appellee also testified that hypotonia and temporary loss of function are recognized side effects of pump implantation, but that those effects could be addressed simply by "turning the Pump off" and ceasing the administration of Baclofen. N.T., 2/25/04, at 74-75. However, appellee did not testify to the likelihood of any of the acknowledged risks occurring, nor did he testify that a permanent loss of function is associated with any surgery on MS patients. Furthermore, as appellee emphasizes, appellants did not qualify appellee as an expert prior to asking him questions regarding the risks of the implantation. Finally, appellee is also correct in noting that an expert medical witness must testify to "a reasonable degree of medical certainty," <u>Barbour v. Dep't of Transp.</u>, 732 A.2d 1157, 1160 (Pa. 1999), and appellee never testified that his opinion

reached that level of certainty. In short, appellee did not testify to (nor was he asked) whether surgery itself carries a risk of permanent neurological deterioration in MS patients, nor did he quantify the likelihood of this supposed risk. Thus, on this trial record, appellee is correct (and the Superior Court's offhand comment was correspondingly incorrect) that appellants failed to carry their burden of proof on this necessary issue, and we cannot simply reinstate the jury verdict.

The fact that appellants did not adduce sufficient, qualified expert evidence to support their claim, however, does not end the case. As we have noted above, appellants' proof at trial was limited by the trial court's evidentiary ruling, which excluded the testimony of Drs. Atlas and Grenell on informed consent. Appellants objected to the evidentiary limitation, and they renewed the claim on direct appeal. Given its J.N.O.V. holding respecting the absence of testimony from Carol, however, the Superior Court panel did not reach the evidentiary issue. Furthermore, the evidentiary issue has not been briefed or argued to this Court. In such circumstances, the better course is to remand the matter to the Superior Court to consider the evidentiary issue in the first instance.

In summary, we find that the courts below erred in holding that the substantial factor element of an informed consent claim cannot be established by circumstantial evidence. We also remand the matter to consider appellant's evidentiary claim.

Vacated and remanded.

Former Chief Justice Cappy, and former Justices Baldwin and Fitzgerald did not participate in the decision of this case.

Messrs. Justice Saylor, Eakin and Baer join the opinion.