

[J-99-2014]
IN THE SUPREME COURT OF PENNSYLVANIA
MIDDLE DISTRICT

CASTILLE, C.J., SAYLOR, EAKIN, BAER, TODD, STEVENS, JJ.

MARIA A. BRADY AND ROBERT BRADY, JR.,	:	No. 74 MAP 2014
	:	
Appellees	:	Appeal from the Order of the Superior Court, dated 11/12/13, at No. 3470 EDA 2012, vacating and remanding the
v.	:	judgment of the Delaware County Court of Common Pleas, Civil Division, of
	:	12/5/12 and entered on 1/16/13, at No.
WILLIAM M. URBAS, D.P.M.,	:	10-15584
	:	
Appellant	:	
	:	ARGUED: November 18, 2014

OPINION

MR. CHIEF JUSTICE SAYLOR

DECIDED: March 25, 2015

In this appeal by allowance involving alleged medical negligence, we consider whether a doctor may introduce evidence that the patient was informed of and acknowledged various risks of surgery, although the complaint does not assert a cause of action based on a lack of informed consent.

Appellee, Maria Brady, had a lengthy history of foot problems. By 2007, both of her feet were in pain due to toe deformities. Appellee's podiatrist, William Urbas, D.P.M., successfully treated toes on her left foot with surgery; he then turned his attention to her right foot. Regarding that foot, one of Appellee's primary complaints pertained to a hammer-toe condition of her second toe (next to the big toe). This deformity caused the middle of Appellee's second toe to rise above the plane of the foot, which in turn caused rubbing and pain when Appellee wore shoes.

To address this condition, Dr. Urbas performed a total of four operations between March 2008 and January 2010. Before each surgery, he explained the risks and complications that could occur, and Appellee signed a consent form acknowledging her awareness of these possible outcomes. The first surgery entailed removing approximately one centimeter of bone from the proximal phalanx of the second toe in an effort to straighten the toe. The parties agree that Dr. Urbas was not negligent as to that surgery. Unfortunately, however, this first operation did not finally alleviate Appellee's condition because, in the post-operative timeframe, certain internal tissues contracted, pulling the toe upward once again. Dr. Urbas eventually performed three more surgeries, each involving, among other things, the removal of additional bone material with the expectation that the foot would, over time, generate soft tissue to fill the gap and provide flexibility. Nevertheless, Appellee's pain persisted and, in the end, her toe was less stable and significantly shorter than it had been initially.

In August 2010, Appellee consulted a different podiatrist, Dr. Harold Schoenhaus, who performed a bone-graft operation which returned the toe to approximately ninety percent of its original length. This procedure also had the effect of restoring some of the toe's stability and substantially reducing the pain. Appellee testified that she was pleased with the outcome of Dr. Schoenhaus' surgery and that she returned to all levels of activity.

In December 2010, Appellee filed a complaint against Dr. Urbas, alleging that he negligently treated her toe in the three follow-up surgeries performed after March 2008. She averred that she could not have reasonably discovered the harm she suffered until after the fourth surgery because "Dr. Urbas' advice, assurances and recommendations . . . lulled [her] into a false sense of security and concealed the true nature of [her] condition[.]" Complaint at ¶18. As to the alleged negligence, Appellee asserted, *inter*

alia, that Dr. Urbas failed to determine the cause of her original toe condition, and recommended and performed procedures that were counter-indicated. See *id.* at ¶¶22.¹ Notably, the complaint did not include a cause of action for lack of informed consent.²

Appellee filed a motion *in limine* to exclude any consent-related evidence at trial, including the surgical consent forms she signed before each procedure. Appellee argued that such evidence was not relevant to whether Dr. Urbas performed within the appropriate standard of care. Further, she maintained that the probative value of this evidence was outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. Dr. Urbas responded that the risks and complications of surgery would be relevant to Appellee's credibility as a witness and to her state of mind at the time of the surgeries, and that the evidence of consent would not be used to prove or disprove informed consent. The trial court denied the motion and permitted admission of the consent-related evidence.

At the jury trial, experts for both sides testified that the complications Appellee experienced after the first surgery were common, although they differed as to whether Dr. Urbas was negligent in his recommendations, care, and treatment of Appellee. Dr. Urbas testified that he informed Appellee of the possible complications from the surgery and that the follow-up procedures were reasonable to alleviate these problems. At various other points during the trial, Appellee's consent to surgery and her knowledge of the risks involved were discussed.

¹ The complaint also stated a loss-of-consortium claim on behalf of Appellee's husband.

² Under the informed-consent doctrine, a physician must disclose those risks "that a reasonable person in the patient's situation would consider significant in deciding whether to have the operation." *Gouse v. Cassell*, 532 Pa. 197, 203, 615 A.2d 331, 334 (1992). A lack-of-informed-consent claim sounds in battery rather than negligence. See *Montgomery v. Bazaz-Sehgal*, 568 Pa. 574, 585, 798 A.2d 742, 748-49 (2002).

During deliberations, the jury asked to review the consent forms, stating that they needed to know “what [Appellee] agreed to.” N.T., Nov. 9, 2012, at 251. The court provided the forms. Shortly thereafter, the jury returned a defense verdict, specifically finding that Dr. Urbas was not negligent in his care and treatment of Appellee. In light of this finding, the jury did not reach the issues of causation or damages. See Dkt. No. 34 (completed verdict form); see *also* N.T., Nov. 9, 2012, at 233-35 (reflecting the trial court’s explanation of the verdict form); *id.* at 253 (reflecting the jury’s finding that Dr. Urbas was not negligent).

After unsuccessfully moving for a new trial on the basis that the trial court erred in admitting the consent evidence, Appellee lodged a timely appeal. In its Rule 1925(a) opinion, see Pa.R.A.P. 1925(a), the trial court expressed that “[t]he risks and complications associated with the alleged negligent procedures and the course of treatment to alleviate those complications were relevant to determine if Dr. Urbas was negligent.” *Brady v. Urbas*, No. 10-15584, *slip op.* at 6 (C.P. Delaware March 8, 2013). The court continued:

The probative value of the consent forms listing the possible results from the procedures described therein outweighed any prejudicial impact. Moreover, as aptly and repeatedly clarified before the jury by both [Appellee] and her counsel, [Appellee] never signed a consent form which identified one of the risks as “negligent surgery.” [Appellee] never authorized Dr. Urbas to negligently perform surgery on her.

Id.

In a published opinion, the Superior Court vacated and remanded for a new trial. See *Brady v. Urbas*, 80 A.3d 480 (Pa. Super. 2013). In concluding that the trial court had abused its discretion, the intermediate court adopted the reasoning of the Supreme Court of Virginia regarding the relevancy of consent evidence in a medical malpractice case. In particular, the Virginia court stated:

[The plaintiff's] awareness of the general risks of surgery is not a defense available to [a defendant physician] against the claim of a deviation from the standard of care. While [the plaintiff] or any other patient may consent to risks, she does not consent to negligence. Knowledge by the trier of fact of informed consent to risk, where lack of [in]formed consent is not an issue, does not help the plaintiff prove negligence. Nor does it help the defendant show he was not negligent. In such a case, the admission of evidence concerning a plaintiff's consent could only serve to confuse the jury because the jury could conclude . . . that consent to the surgery was tantamount to consent to the injury which resulted from that surgery. In effect, the jury could conclude that consent amounted to waiver, which is plainly wrong.

Wright v. Kaye, 593 S.E.2d 307, 317 (Va. 2004), *quoted in Brady*, 80 A.3d at 484 (ellipsis added).

The court further explained that Appellee's consent to the procedures and her knowledge of the risks did not make the existence of any fact of consequence more or less probable. See Pa.R.E. 401. Thus, the Superior Court established a per se rule of exclusion mirroring that of the Virginia court, explaining that "evidence of informed consent is irrelevant in a medical malpractice case." *Brady*, 80 A.3d at 484. The court added, in the alternative, that even if such proofs had some marginal relevance in the present case, they "could have misled or confused the jury by leading it to believe that [Appellee's] injuries simply were a risk of the surgeries and that she accepted such risks, regardless of whether Dr. Urbas' negligence caused the risks to occur." *Id.* Finally, the intermediate court reasoned that the trial court's error was prejudicial, since the consent evidence constituted a central component of Dr. Urbas' defense and the jury reviewed the consent forms during deliberations. See *id.* at 484-85. Accordingly, the court remanded for a new trial.

We allowed further review on a limited basis primarily to address whether the Superior Court's bright-line exclusionary rule should be sustained. See *Brady v. Urbas*, ___ Pa. ___, 96 A.3d 988 (2014).

Dr. Urbas argues that consent-related communications between himself and Appellee regarding the purpose, nature, and risks of surgery were relevant in that they helped establish the applicable standard of care. Relatedly, he proffers that his testimony regarding his views prior to the surgery as to possible outcomes and complications lent credence to his position at trial that he met the standard of care, as the injuries occurred from the procedures' known complications rather than negligence. He further notes that the parties centrally disagreed about the necessity of the three follow-up surgeries, and that Appellee alleged in her complaint that he had given her assurances which "lulled [her] into a false sense of security." Thus, he argues that his testimony was needed to rebut such allegation and, again, to demonstrate that the injuries Appellee suffered stemmed from ordinary risks associated with the operations.

Additionally, Dr. Urbas criticizes the Superior Court's use of a per se rule, reasoning that this deviates from the abuse-of-discretion standard applicable to a trial court's evidentiary rulings. As applied here, Dr. Urbas claims that the intermediate court failed to afford sufficient deference to the trial court's reasonable explanation as to why it viewed the informed-consent evidence as relevant. He maintains that the Superior Court also failed to engage in an appropriate balancing analysis under evidentiary rule 403, essentially concluding that any risk of unfair prejudice automatically outweighs probative value.³

Appellee responds that the Superior Court appropriately recognized the lack of relevance and prejudicial nature of informed consent evidence in a negligence case, and that its reasoning is consistent with that of courts in other jurisdictions. See Brief for Appellee at 19-22 (summarizing cases). She maintains that consent evidence only

³ Dr. Urbas also argues that any error in admitting the consent-related evidence was waived when Appellee failed to request a cautionary instruction. This issue is not subsumed within our limited grant of allocatur.

serves to confuse jurors because they might conclude that consent to the surgery was consent to the injury. Appellee posits that the jurors in the present trial appear to have labored under this misconception, as they clarified that their purpose in requesting the consent sheets during deliberation was to see what Appellee had agreed to. As well, Appellee reasons that, where, as here, the form contains an extensive list of risks and complications, allowing the jury to consider it presents an unduly high obstacle to recovery for medical negligence. Appellee finally takes issue with Dr. Urbas' argument that the Superior Court failed to apply the proper standard of review or evidentiary balancing test. She indicates that the record reflects that Dr. Urbas used the consent forms and related testimony, not as evidence of adherence to the standard of care or lack of causation, but to show that Appellee understood and accepted the risk of her injuries – thereby demonstrating that the trial court abused its discretion in permitting the introduction of such proofs.

The Pennsylvania Association for Justice, as *amicus curiae* favoring affirmance, adds that: (a) Appellee's state of mind in consenting to risks is immaterial to the issue of whether Dr. Urbas' treatment conformed to the proper standard of care; (b) such standard should be established via testimony by an expert familiar with current practices in the defendant's area of specialization; and (c) the establishment of a general precept of evidentiary exclusion is not necessarily improper, as some types of evidence are so prejudicial or confusing that they should never be admitted.⁴ The Association concludes

⁴ The Association references cases in which this Court has established general exclusionary precepts. See Brief for the Association at 19 (citing *Martin v. Soblotney*, 502 Pa. 418, 420, 466 A.2d 1022, 1023 (1983) (concluding that evidence of medical expenditures is irrelevant to the calculation of damages for pain and suffering and is inadmissible for such purpose), *Commonwealth v. Vandivner*, 599 Pa. 617, 639, 962 A.2d 1170, 1183 (2009) (“[P]sychiatric evidence that a defendant lacked the ability to control his actions or that he acted impulsively is irrelevant and inadmissible on the issue of the defendant's specific intent to kill.” (internal quotation marks omitted)), and (...continued)

that, even if this Court rejects the Superior Court’s general rule of preclusion, we should affirm its order because the jury’s verdict was rendered on an improper basis.

Evidence is relevant if it has “any tendency to make a fact [of consequence] more or less probable than it would be without the evidence.” Pa.R.E. 401. Irrelevant evidence is inadmissible, and relevant evidence “is admissible except as otherwise provided by law.” Pa.R.E. 402. The “except as otherwise provided by law” qualifier includes the principle that relevant evidence may be excluded “if its probative value is outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” Pa.R.E. 403.

This appeal involves review of an evidentiary decision made by the trial court in light of the above rules. Such decisions are reviewed for an abuse of discretion. See *Commonwealth v. Wright*, 621 Pa. 446, 472, 78 A.3d 1070, 1086 (2013). An abuse of discretion occurs where the trial court “reaches a conclusion that overrides or misapplies the law, or where the judgment exercised is manifestly unreasonable, or is the result of partiality, prejudice, bias, or ill will.” *Id.* at 462, 78 A.3d at 1080. To the degree the issue of whether the law has been misapplied involves a purely legal question, it is reviewed *de novo*. See *Hoy v. Angelone*, 554 Pa. 134, 144, 720 A.2d 745, 750 (1998) (noting that this Court is the final arbiter of state law); *cf. In re N.C.*, ___ Pa. ___, ___, 105 A.3d 1199, 1210 (2014) (observing that, although the standard of review for evidentiary rulings is abuse-of-discretion, whether the admission of evidence

(continued...)

Commonwealth v. Vallejo, 532 Pa. 558, 561, 616 A.2d 974, 976 (1992) (excluding proofs of the defendant’s alleged low intelligence in a prosecution for possession with intent to deliver illegal drugs, as such information would “focus the jury’s attention upon a red herring that has . . . no connection with the defendant’s guilt or innocence”)).

violates the Confrontation Clause is a question of law and, as such, is reviewed *de novo*).

To prevail on a claim of medical negligence, the plaintiff must prove that the defendant's treatment fell below the appropriate standard of care. See *Scampone v. Highland Park Care Ctr.*, 618 Pa. 363, 387, 57 A.3d 582, 596 (2012); see also *Toogood v. Rogal*, 573 Pa. 245, 254, 824 A.2d 1140, 1145 (2003) (plurality opinion) (“[M]edical malpractice can be broadly defined as the unwarranted departure from generally accepted standards of medical practice resulting in injury to a patient[.]”). We therefore consider whether informed-consent evidence is probative of that question. In undertaking this inquiry, it is important to recognize that such information is multi-faceted: it reflects the doctor's awareness of possible complications, the fact that the doctor discussed them with the patient, and the patient's decision to go forward with treatment notwithstanding the risks.

Some of this information may be relevant to the question of negligence if, for example, the standard of care requires that the doctor discuss certain risks with the patient. See, e.g., *Viera v. Cohen*, 927 A.2d 843, 868-69 (Conn. 2007) (finding that a trial court reasonably admitted evidence of informed consent where the applicable standard of care obligated the doctor to discuss particular risks). Evidence about the risks of surgical procedures, in the form of either testimony or a list of such risks as they appear on an informed-consent sheet, may also be relevant in establishing the standard of care. See *Hayes v. Camel*, 927 A.2d 880, 890 (Conn. 2007) (acknowledging the potential relevance of such enumerated risks in establishing the standard of care and stating that evidence of the same may be introduced so long as it is not admitted in the

context of communications with the plaintiff).⁵ In this regard, we note that the threshold for relevance is low due to the liberal “any tendency” prerequisite. Pa.R.E. 401 (emphasis added); *accord Macy v. Blatchford*, 8 P.3d 204, 207-08 (Or. 2000). Accordingly, we decline to endorse the Superior Court’s broad pronouncement to the degree it may be construed to hold that all aspects of informed-consent information are always “irrelevant in a medical malpractice case.” *Brady*, 80 A.3d at 484.⁶

Still, the fact that a patient may have agreed to a procedure in light of the known risks does not make it more or less probable that the physician was negligent in either considering the patient an appropriate candidate for the operation or in performing it in the post-consent timeframe. Put differently, there is no assumption-of-the-risk defense available to a defendant physician which would vitiate his duty to provide treatment according to the ordinary standard of care. The patient’s actual, affirmative consent, therefore, is irrelevant to the question of negligence. *Accord Warren v. Imperia*, 287 P.3d 1128, 1132 (Or. Ct. App. 2012) (“Evidence of plaintiff’s awareness of [information

⁵ Although we need not explore the issue in detail, we can envision other scenarios in which this information could be germane, such as where the standard of care differs from one geographic region to another (the “locality rule”). See *Incollingo v. Ewing*, 444 Pa. 263, 276 n.5a, 282 A.2d 206, 214 n.5a (1971), *abrogated on other grounds by Kaczowski v. Bolubasz*, 491 Pa. 561, 421 A.2d 1027 (1980); *Thierfelder v. Wolfert*, 617 Pa. 295, 319, 52 A.3d 1251, 1265 (2012) (applying the locality rule to general practitioners). This could occur, for example, if the defendant physician worked in a medical office in a remote location that lacked advanced equipment that would ordinarily be present in a large metropolitan area. See *generally Crosby v. U.S.*, 48 F. Supp. 2d 924, 932 (D. Alaska 1999) (observing that medical care must sometimes “be delivered in remote locations which cannot make all potentially beneficial tests and procedures available at anything approaching a reasonable cost”).

⁶ Except in the most obvious cases of negligence (such as where a gauze pad is left inside a patient’s body), expert testimony is necessary to establish the standard of care. See *Hightower-Warren v. Silk*, 548 Pa. 459, 463 & n.1, 698 A.2d 52, 54 & n.1 (1997). It does not follow, however, that other types of proofs tending to establish the standard are precluded.

about the nature of the procedure, its inherent risks, or available alternatives] would neither have assisted plaintiff in proving negligence nor have assisted defendant in showing that he was not negligent.”); *Wright*, 593 S.E.2d at 317 (same); *Baird v. Owczarek*, 93 A.3d 1222, 1232 (Del. 2014) (expressing that “assumption of risk is not a valid defense to a medical negligence action”). Moreover, and as the trial court observed, assent to treatment does not amount to consent to negligence, regardless of the enumerated risks and complications of which the patient was made aware. See *Brady*, No. 10-15584, *slip op.* at 6; *accord Hayes*, 927 A.2d at 889 (quoting *Wright*, 593 S.E.2d at 317); *Patten v. Gayle*, 69 So. 3d 1180, 1187 (La. Ct. App. 2011); *Gross v. Robinson*, 218 S.W. 924, 926-27 (Mo. Ct. App. 1920).⁷ That being the case, in a trial on a malpractice complaint that only asserts negligence, and not lack of informed consent, evidence that a patient agreed to go forward with the operation in spite of the risks of which she was informed is irrelevant and should be excluded.

⁷ The concept that a patient’s authorization to perform a surgery may comprise consent to negligent treatment is inherently suspect for multiple reasons. For one, there is a marked disparity in medical knowledge as between the doctor and the patient. See *Schwartz v. Johnson*, 49 A.3d 359, 372 (Md. Ct. Spec. App. 2012) (collecting cases). As well, consent to negligence “would be specious when considered against the strict legal, ethical and professional standards that regulate the healthcare profession.” *Storm v. NSL Rockland Place, LLC*, 898 A.2d 874, 884 (Del. Super. Ct. 2005).

The *Storm* court expressed that the only exception it could envision would arise where the patient agrees to “an experimental medical procedure where the standards of care have not yet been fully developed or consents to treatment modalities known to be outside of the medical mainstream.” *Id.* at 884 n.41 (citing *Boyle v. Revici*, 961 F.2d 1060 (2d Cir. 1992), and *Schneider v. Revici*, 817 F.2d 987 (2d Cir. 1987)). Along these lines, *Schneider* recognized that an assumption-of-the-risk defense may be available in such cases, so long as there is evidence that the plaintiff expressly consented to any particular risks associated with the unconventional or experimental treatment. See *Schneider*, 817 F.2d at 995-96. While we do not foreclose a similar ruling in the future, the issue is not presently before the Court.

Nor are we convinced by Dr. Urbas' argument he needed to use evidence of Appellee's affirmative consent to rebut her allegation of having been "lulled into a false sense of security." When viewed in context, this allegation was included in the complaint to support its timeliness under the discovery rule, *see generally Crouse v. Cyclops Industries*, 560 Pa. 394, 404, 745 A.2d 606, 611 (2000) (explaining that the discovery rule tolls the statute of limitations until the plaintiff knows or should know that she has been injured by another party's conduct), and it was not material to the substantive questions on which liability depended.⁸

Evidence of the patient's consent also tends to confuse the issue because, as the Virginia Supreme Court noted, the jury might reason that the patient's consent to the procedure implies consent to the resultant injury, *see Wright*, 593 S.E.2d at 317, and thereby lose sight of the central question pertaining to whether the defendant's actions conformed to the governing standard of care. Indeed, the present case illustrates the point: the defense questioned Appellee at length about her having signed the consent forms, elicited testimony from Dr. Urbas on the topic, and made references to the fact of

⁸ To the extent Dr. Urbas' argument suggests a need to use the information for impeachment, *see* Appellant's Brief at 19 (emphasizing Appellee's testimony that she was "shocked" to learn for the first time, only after the fourth surgery, that her toe might be shortened); Appellant's Reply Brief at 7-8 (same), nothing in this opinion should be understood to preclude impeachment if the plaintiff adduces evidence that she did not consent to a particular risk. However, any impeachment use of the consent evidence was minimal compared to its use to prove a lack of negligence.

As previously noted, moreover, in Pennsylvania, lack of informed consent is treated as a distinct claim under a battery rubric. *See supra* note 2. However, in some jurisdictions informed consent is considered to be a negligence concept. Under such a framework, the consent may be relevant in a medical negligence dispute. *See, e.g., Downs v. Trias*, 49 A.3d 180, 188 (Conn. 2012) (expressing that a physician's failure to adhere to the standard of medical care with respect to communicating risks to a patient may be relevant to a negligence claim).

Appellee's consent during its summation – all in an effort to rebut the allegation of negligence. See N.T., Nov. 9, 2012, at 204 (reflecting defense counsel's argument to the jury that Dr. Urbas was not negligent because he had listed a particular risk on one of the consent forms and talked to Appellee about it). The jury, for its part, ultimately focused its attention on what Appellee "had agreed to" and, shortly thereafter, returned a verdict finding that Dr. Urbas was not negligent. There is a substantial possibility, then, that the jury's verdict rested on an improper consideration.

Accordingly, we hold that evidence that a patient affirmatively consented to treatment after being informed of the risks of that treatment is generally irrelevant to a cause of action sounding in medical negligence.

The Superior Court's order vacating the judgment and remanding for a new trial is affirmed.

Former Chief Justice Castille did not participate in the decision of this case.

Messrs. Justice Eakin and Baer, Madame Justice Todd and Mr. Justice Stevens join the opinion.