[J-77-2018]
IN THE SUPREME COURT OF PENNSYLVANIA
WESTERN DISTRICT

SAYLOR, C.J., BAER, TODD, DONOHUE, DOUGHERTY, WECHT, MUNDY, JJ.

LANETTE MITCHELL,	:	No. 55 WAP 2017
	:	
Appellee	:	Appeal from the Order of the Superior
	:	Court entered May 5, 2017 at No. 384
	:	WDA 2016, reversing the Judgment of
v.	:	the Court of Common Pleas of
	:	Allegheny County, Civil Division,
	:	entered February 22, 2016 at No. GD
EVAN SHIKORA, D.O., UNIVERSITY OF	:	13-023436, and remanding.
PITTSBURGH PHYSICIANS D/B/A	:	
WOMANCARE ASSOCIATES, MAGEE	:	ARGUED: October 23, 2018
WOMENS HOSPITAL OF UPMC,	:	
	:	
Appellants	:	

OPINION

JUSTICE TODD **DECIDED: JUNE 18, 2019**

In this appeal by allowance, we consider the admissibility of evidence regarding the risks and complications of a surgical procedure in a medical negligence case. For the reasons that follow, and consistent with our recent decision in *Brady v. Urbas*, 111 A.3d 1155 (Pa. 2015), we find that evidence of the risks and complications of a surgery may be admissible at trial. Thus, we reverse the order of the Superior Court.

In May 2016, Appellant, Dr. Evan Shikora, was to perform a laparoscopic hysterectomy on Appellee Lanette Mitchell. Dr. Shikora, assisted by resident physician, Dr. Karyn Hansen, began the operation by making an incision into Mitchell's abdomen;

however, while they were opening the sheath of the peritoneum,[1] the doctors detected fecal odor.[2] Dr. Shikora realized that Mitchell's colon had been severely cut; thus, he abandoned the hysterectomy and consulted with a general surgeon, Dr. Anita Courcoulas, who performed an emergency loop ileostomy,[3] which ultimately was successful in repairing the bowel. Mitchell, however, was required to wear an external ileostomy pouch for a short period.

In December 2016, Mitchell filed the instant medical negligence action against Dr. Shikora, University of Pittsburgh Physicians d/b/a WomanCare Associates, and Magee Women's Hospital of UPMC (collectively, "Appellants"). Mitchell alleged Dr. Shikora breached his duty of care by, *inter alia*, "failing to take reasonable precautions to prevent [Mitchell] from suffering complications, injuries and/or damages in connection with the surgery." Complaint, 12/6/13, ¶ 25(b). Mitchell's theory was that Dr. Shikora's failure to identify her colon before making an incision into her abdomen constituted a breach of the applicable medical standard of care. Mitchell did not plead a claim for battery or lack of informed consent.

Prior to trial, Mitchell filed a motion *in limine* to exclude evidence of her informed consent regarding the risks of the procedure, which included perforation of the colon, as well as evidence of the risks themselves, as irrelevant, unfairly prejudicial, or confusing. Following a hearing, the trial court granted Mitchell's motion with respect to evidence of

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[1] The peritoneum is a membrane that lines the abdominal cavity and covers the organs in the abdomen. Stedman's Medical Dictionary 1353 (27th ed. 2000).

[2] While both physicians were involved in the surgery, it appears Dr. Hansen made the incision. N.T., 2/2/16, at 261.

[3] An ileostomy is a surgical procedure used to create an opening in the abdomen in which a piece of lowest part of the small intestine (the ileum) is "brought outside the abdominal wall to create a stoma through which digested food passes into an external pouching system." United Ostomy Association of America, Inc., Ileostomy Facts, https://www.ostomy.org/ileostomy/. A temporary ileostomy, usually constructed with a "loop" stoma, is used when a surgical site requires time to heal. *Id*.

her informed consent regarding the risks of the procedure, as she had not raised such a claim. However, with respect to whether a bowel injury was a known risk or complication of the surgery, *i.e.*, with respect to the allowance of evidence of the risks or complications themselves, the trial court denied the motion to preclude such evidence.

The parties proceeded to a jury trial before the Honorable Paul F. Lutty, Jr. Mitchell offered testimony from a medical expert, Dr. Vadim Morozov, who explained the anatomy of the abdomen, testified regarding performing a proper and safe laparoscopic hysterectomy, which he stated included identification of the body structure before making an incision, and provided his opinion that cutting into the colon without proper identification of the anatomy below the incision breached the relevant standard of care. N.T., 2/1/16, at 183-85, 202-04, 245-46. Mitchell also called Dr. Hansen, and testified herself. Mitchell was not questioned regarding her pre-operation discussions with Dr. Shikora as to the risks and potential complications of the surgery, or the informed-consent process.

For Appellants, Dr. Shikora testified, acknowledging that injury to the bowel is a recognized complication of surgery and that the riskiest part of the procedure is entry into the abdominal cavity, "[b]ecause it is blind" and the surgeon "can't see beyond the skin and the layers below it." N.T., 2/4/16, at 593. Appellants also provided the testimony of an expert, Dr. Charles Ascher-Walsh, who offered that Dr. Shikora and Dr. Hansen complied with the standard of care applicable to laparoscopic hysterectomies; he testified that, in making the initial incision, a physician often cannot see through the tissue, and, thus, the surgeon does not know what is behind the peritoneum, and that this is when complications may occur, which can be unavoidable and can occur absent surgical negligence. N.T., 2/5/16, at 694-95, 697, 701-02. Thus, Appellants introduced evidence of the risks of the procedure, including perforation of the colon, which may occur with a

properly performed laparoscopic hysterectomy. Furthermore, according to Appellants, Mitchell's colon was in an unanticipated location in the middle of her abdomen, which led to it being cut. Following closing arguments, the jury returned a verdict for Appellants.

Mitchell filed a post-trial motion for a new trial on the ground that the trial court erred in denying her motion *in limine* in part. The trial court denied the motion, and Mitchell appealed. In its ensuing Pa.R.A.P. 1925(a) opinion, the trial court justified its ruling on the ground that, in *Brady v. Urbas*, 111 A.3d 1155 (Pa. 2015), discussed in detail below, this Court held that evidence of a patient's informed consent is generally irrelevant in medical negligence actions unless lack of consent is at issue, but evidence of the risks themselves may be relevant to establish the applicable standard of care, or to establish whether the physician breached the same. Specifically, the trial court explained that the evidence that the risks of a laparoscopic hysterectomy included perforation of the colon was relevant to establish the standard of care and whether Dr. Shikora breached that standard.

In a unanimous, published opinion, authored by the Honorable John L. Musmanno, a three-judge panel of the Superior Court reversed and remanded for a new trial. *Mitchell v. Shikora*, 161 A.3d 970 (Pa. Super. 2017). After reciting the applicable abuse-of-discretion standard of review, the court looked to the relevant law regarding the admission of known risks and complications evidence as set forth in our decision in *Brady*. The Superior Court quoted operative language from *Brady*, which considered whether informed-consent evidence was probative of the appropriate standard of care or the breach thereof. Recognizing that the *Brady* Court rejected the notion that informed-consent information is always irrelevant, the court nevertheless determined that, "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." *Id.* at 973 (quoting *Brady*, 111 A.3d at 1162-63).

After surveying the expert testimony offered by both parties, the court found that the trial court erred in denying Mitchell's motion *in limine* with respect to evidence of the risks and complications of the procedure, reasoning that such evidence was irrelevant, misleading, and confusing:

> Here, while evidence of risks and complications of a surgical procedure may be admissible to establish the relevant standard of care, in this case, such evidence was irrelevant in determining whether [Appellants], specifically Dr. Shikora, acted within the applicable standard of care. . . . The fact that one of the risks and complications of the laparoscopic hysterectomy, *i.e.*, the perforation of the bowel, was the injury suffered by Mitchell does not make it more or less probable that Dr. Shikora conformed to the proper standard of care for a laparoscopic hysterectomy and was negligent. . . .
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> Moreover, the evidence would tend to mislead and/or confuse the jury by leading it to believe that [Mitchell's] injuries were simply the result of the risks and complications of the surgery.

Id. at 975 (citations omitted).

The court further found that the trial court's error resulted in prejudice, observing that the evidence was central to Appellants' theory of the case, as demonstrated by their opening and closing statements. Thus, the court concluded that the risks and complications evidence was irrelevant to the issue of whether Appellants' treatment of Mitchell met the appropriate standard of care, and remanded the matter for a new trial.

In response to Appellant's petition, we granted allocatur limited to the issue, as framed by Appellants, of "[w]hether the Superior Court's holding directly conflicts with this Honorable Court's holdings in *Brady v. Urbas*, 111 A.3d 1155 (Pa. 2015), which permits

evidence of general risks and complications in a medical negligence claim?" *Mitchell v. Shikora*, 174 A.3d 573, 573-74 (Pa. 2017) (order).

Appellants argue that evidence of the risks and complications of a procedure is relevant and admissible in a medical negligence case, as explained in *Brady*, because it informs the inquiry regarding the standard of care and whether it was breached, as well as causation. Specifically, Appellants contend that evidence of the risks and complications is necessary to explain a physician's decision-making with respect to his or her actions, which in turn informs the standard of care. According to Appellants, here, the first incision in laparoscopic surgery involves an increased risk of complications as the initial incision is undertaken "blind;" thus, it follows that, if a bowel injury during abdominal entry is a well recognized risk or complication of laparoscopic surgery, it is less likely that the standard of care was breached. Appellants submit that, given that complications may arise even when proper care is provided, evidence of risks and complications must be presented to the jury to allow for a complete picture of the applicable standard of care.

As to causation, Appellants maintain that defendants in a negligence action are entitled to offer evidence as to alternative causes of injury, and, here, it is permissible for a physician to introduce evidence suggesting another cause of the injury, such as routine medical complications. Appellants stress that a physician is neither a warrantor of a cure, nor a guarantor of a result. Thus, Appellants offer that evidence of risks or complications addresses not only whether a physician's conduct fell below the standard of care and caused injury, but is relevant to dispel a finding of negligence with respect to an injury which may have occurred despite the exercise of reasonable care. Appellants urge that prohibiting such explanatory evidence would prevent a physician from presenting alternative causes, and, in effect, transform physicians into guarantors of a cure.

Appellants further argue that the Superior Court misunderstood the holding of *Brady* and erroneously conflated two distinct concepts: evidence of patient consent (which is not admissible in a pure medical negligence case) and evidence of general medical risks and complications (which is admissible). Appellants assert that the *Brady* Court did not hold that evidence of surgical risks and complications is irrelevant or cannot be considered. Rather, according to Appellants, *Brady* stands for the proposition that, in medical negligence cases, risks and complications evidence is relevant, while patient consent evidence is not relevant. Here, Appellants claim the trial court properly applied *Brady*, excluding the informed-consent evidence, but permitting expert testimony regarding risks and complications. Finally, Appellants contend that policy concerns require the reversal of the Superior Court, because its decision undermines the tenet that physicians are not guarantors of a cure, and effectively imposes strict liability upon medical professionals. This, according to Appellants, will act to discourage high-risk procedures and will impact other legal doctrines, such as the "two schools of thought" doctrine[4] and *res ipsa loquitur* claims.[5] [6]

[4] The "two schools of thought" doctrine serves as a defense to a claim of negligence. Specifically, "[w]here competent medical authority is divided, a physician will not be held responsible if in the exercise of his judgment he followed a course of treatment advocated by a considerable number of recognized and respected professionals in his given area of expertise." *Jones v. Chidester*, 610 A.2d 964, 969 (Pa. 1992).

[5] The doctrine of *res ipsa loquitur* allows an inference of negligence where it can be established that an event would not ordinarily occur absent negligence, and may establish whether a medical professional is responsible for causing an injury. *Toogood v. Rogal*, 824 A.2d 1140, 1148-49 (Pa. 2003) (plurality).

[6] A variety of medical organizations in Pennsylvania, including the American Medical Association and the Pennsylvania Orthopaedic Society, among others, filed *amicus* briefs in support of Appellants, largely reiterating their arguments. *Amici* also indicate that the Superior Court's decision could adversely impact healthcare in Pennsylvania by deterring healthcare providers from providing higher risk healthcare services, or new healthcare services, and from treating high-risk patients, as well as exposing healthcare providers to a vast new swath of liability, thereby resurrecting the concerns that led to the MCARE Act and other tort reform measures.

Mitchell counters that, under *Brady*, informed-consent evidence is generally inadmissible in medical malpractice cases, and she characterizes evidence of the risks and complications of a procedure as such evidence. Appellee's Brief at 17. Mitchell maintains that Appellants overstate their argument by claiming the Superior Court in this matter determined that risks and complications evidence was always inadmissible. Rather, Mitchell asserts that the Superior Court's decision is entirely consistent with *Brady*, as such admissibility decisions are to be made on a case-by-case basis, and, here, the Superior Court determined that risks and complications evidence was not probative of whether Appellants treatment of Mitchell fell below the standard of care. Mitchell adds that the Superior Court properly found that testimony regarding risks and complications would mislead and confuse the jury. According to Mitchell, evidence about complications is not probative of whether *her* bowel injury occurred in the absence of negligence, as generalized risks and complication studies do not usually indicate what percentage of complications resulted from negligent care. Mitchell presses that a jury should not be allowed to conclude that the occurrence of a known complication demonstrates the absence of negligence in a particular case.

Mitchell also rejects Appellants' assertion that informing jurors of risks of a certain procedure would facilitate their understanding of the overall technical challenges inherent in such surgery. Mitchell initially asserts such argument is waived; as to its merits, she contends an overall understanding of the risks is irrelevant, as she had a right to expect that the surgery would be performed in accordance with the applicable standard of care, whether during a high-risk stage of the surgery or not. Mitchell claims that she was prejudiced, and the jurors were misled, when they were told that incision into the abdomen

was one of the riskier parts of the surgery and that a bowel injury was a known complication that could happen in the absence of negligence.[7] [8]

As this case involves the admission of evidence, a brief recitation of the law in this area is helpful. Generally, relevant evidence is admissible and irrelevant evidence is inadmissible. 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. The threshold for relevance is low given the liberal "*any* tendency" prerequisite. *Id*. (emphasis added). Relevant evidence "is admissible, except as otherwise provided by law." Pa.R.E. 402. One such exception is 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.

Decisions regarding the admissibility of evidence are vested in the sound discretion of the trial court, and, as such, are reviewed for an abuse of discretion. *See Commonwealth v. Wright,* 78 A.3d 1070, 1086 (Pa. 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 1080. To the degree the issue of whether the law has been

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[7] Mitchell also argues that Appellants improperly raised issues of whether the Superior Court created a strict liability standard in medical malpractice cases and whether it usurped the trial court's discretion, as beyond our limited grant of allocatur. We disagree, and find that these arguments are related, albeit tangentially, to the central issue on which we granted review. In conjunction therewith, Mitchell's Application for Leave to File Post-Submission Communication, which raises these same contentions, is hereby denied.

[8] The Pennsylvania Association for Justice and American Association for Justice filed an *amicus* brief in support of Mitchell, largely reiterating her arguments. They also advance an argument that, although evidence of the risks of a procedure may be relevant to the issues of standard of care, breach, or causation, it is prejudicial, as it confuses the jury. Finally, *amici* challenge Appellants' and their associated *amici*'s policy arguments, reasoning that the Superior Court's decision is a boon to patient safety, decreases overall healthcare system liability, and stems the cost-shifting of medical errors to victims.

misapplied involves a purely legal question, it is reviewed *de novo. See Hoy v. Angelone*, 720 A.2d 745, 750 (Pa. 1998).

In order to establish a *prima facie* case of malpractice, the plaintiff must establish: (1) a duty owed by the physician to the patient; (2) a breach of that duty; (3) that the breach of duty was the proximate cause of the harm suffered by the patient; and (4) that the damages suffered were a direct result of that harm. *See Hightower-Warren v. Silk*, 698 A.2d 52, 54 (Pa. 1997). Stated another way, to prevail on a claim of medical negligence, the plaintiff must prove, *inter alia*, that the defendant's treatment fell below the appropriate standard of care — that is, varied from accepted medical practice. *See Scampone v. Highland Park Care Ctr.*, 57 A.3d 582, 596 (Pa. 2012); *see also Toogood*, 824 A.2d at 1145 ("[M]edical malpractice can be broadly defined as the unwarranted departure from generally accepted standards of medical practice resulting in injury to a patient[.]").

A plaintiff in a medical negligence matter is required to present an expert witness who will testify, to a reasonable degree of medical certainty, regarding the standard of care (duty); that the acts of the physician deviated from the standard or care (breach); and that such deviation was the proximate cause of the harm suffered. *Hightower-Warren*, 698 A.2d at 54. Expert testimony in support of the plaintiff's claim is an indispensable requirement in establishing a plaintiff's right of action, as the treatment and injury typically involved are such that the common knowledge or experience of a layperson is insufficient to form the basis for passing judgment. *Collins v. Hand*, 246 A.2d 398, 401 (Pa. 1968). We must therefore consider whether risks and complications evidence is probative of any of the above requirements.

Initially, we note that, "a physician is neither a warrantor of a cure nor a guarantor of the result of his treatment." *Collins,* 246 A.2d at 400-01; 40 P.S. § 1303.105 ("In the

absence of a special contract in writing, a health care provider is neither a warrantor nor a guarantor of a cure."). Specifically, there is no "presumption or inference of negligence merely because a medical procedure terminated in an unfortunate result which might have occurred despite the exercise of reasonable care." *Collins*, 246 A.2d at 401; *Toogood*, 824 A.2d at 1150 ("There is no requirement that [a physician] be infallible, and making a mistake is not negligence as a matter of law. In order to hold a physician liable, the burden is upon the plaintiff to show that the physician failed to employ the requisite degree of care and skill."). Indeed, the idea that complications may arise through no negligence of a physician is so ingrained in our jurisprudence that it is often included as part of the instructions to the jury. *See* Pennsylvania Suggested Civil Jury Instruction 14.10, subcommittee note ("In the absence of a special contract, a physician is neither a warrantor of a cure, nor a guarantor of the result of his treatment" (citation omitted)).

Furthermore, evidence of an individual's consent to undergo surgery is not evidence of consent to a physician acting below the accepted standard of care: "It has long been the law in Pennsylvania that a physician must obtain informed consent from a patient before performing a surgical or operative procedure. . . . The rationale underlying requiring informed consent for a surgical or operative procedure and not requiring informed consent for a non-surgical procedure is that the performance of a surgical procedure upon a patient without his consent constitutes a technical assault or a battery because the patient is typically unconscious and unable to object." *Morgan v. MacPhail*, 704 A.2d 617, 619-20 (Pa. 1997). Thus, an action asserting a lack of informed consent is distinct from a claim of medical negligence. That being the case, admitting evidence that a patient is informed of certain risks in a pure negligence action can erroneously suggest to the jury that the patient has consented to negligence. Additionally, such

evidence can confuse the jury and cause it to stray from assessing the central question of whether the physician's actions conformed to the applicable standard of care.

Our Court addressed these legal principles in our 2015 opinion in *Brady*, authored by Chief Justice Saylor, and joined by all participating Justices. In *Brady*, Dr. William Urbas performed four operations on the second toe of Maria Brady's right foot. The first surgery was successful; however, the three follow-up procedures resulted in her toe being significantly shorter. Brady later alleged that Dr. Urbas failed to determine the cause of her deformed toes and negligently treated her by performing improper procedures. In doing so, Brady asserted a claim of medical negligence, but did not sue for battery or for a lack of informed consent. Prior to trial, Brady filed a motion to exclude all evidence related to her informed consent to the surgery on the ground that it was irrelevant, unfairly prejudicial, or confusing. The trial court denied Brady's motion, reasoning that the risks of the surgeries were relevant to the issue of negligence and admitting evidence regarding the risks was not unfairly prejudicial or confusing. The jury returned a defense verdict, finding that Dr. Urbas was not negligent.

The Superior Court vacated and remanded for a new trial, adopting a *per se* rule, and reasoning that evidence of informed consent is always irrelevant to the issue of negligence and could suggest to the jury that consent to the surgery was tantamount to consent to the injury which resulted from that surgery, and that, in the alternative, such evidence could mislead the jury by leading it to believe that the plaintiff's injuries were simply a risk of the surgeries, regardless of negligent conduct by Dr. Urbas. Dr. Urbas sought, and we granted, review.

On appeal, we held that, although evidence of a patient's informed consent to a procedure is generally irrelevant to the issues of standard of care and breach of duty and may confuse the jury, evidence of the risks of the procedure themselves may be relevant

and admissible. Specifically, our Court made a distinction between the admission of informed-consent evidence — such as consent forms, or communications between a physician and a patient regarding the purpose, nature, and risks of surgery — and the admission of evidence of the risks and complications of surgery:

> To prevail on a claim of medical negligence, the plaintiff must prove that the defendant's treatment fell below the appropriate standard of care. ("[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 multifaceted: 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.
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> 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. ***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. In this regard, we note that the threshold for relevance is low[.] 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."***
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> 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.*** 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. ***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***. . . .
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> Evidence of the patient's consent also tends to confuse the issue because, . . . the jury might reason that the patient's consent to the procedure implies consent to the resultant injury, and thereby lose sight of the central question pertaining to whether the defendant's actions conformed to the governing standard of care. . . .
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> 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.

Brady, 111 A.3d at 1161-64 (emphasis added) (citations omitted).

As becomes evident from the above quoted passage, our Court in *Brady* spoke in terms of two discrete categories of evidence: (1) informed-consent evidence; and (2) risks and complications evidence. As to the first category, the Court plainly held that manifestations of a patient's actual, affirmative consent to surgery, and the risks thereof, are irrelevant to the question of negligence. *Brady*, 111 A.3d at 1162. Thus, where a patient's action is limited to medical negligence, and not a lack of informed consent, all 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. *Id*. at 1162-63.

However, the Court contrasted this with other types of evidence, such as evidence of risks and complications. Indeed, the *Brady* Court specifically rejected the Superior

Court's *per se* rule that "all aspects of informed-consent information are always 'irrelevant in a medical malpractice case.'" *Id*. at 1162. Rather, evidence of the risks and complications of a surgical procedure, "in the form of either testimony or a list of such risks as they appear on an informed-consent sheet" could be "relevant in establishing the standard of care." *Id*.[9]

The Superior Court's approach in the matter *sub judice* is inconsistent with our decision in *Brady*, as it blurred the distinction between informed-consent evidence — showing a patient's actual, affirmative consent to surgery — and evidence regarding the risks and complications of medical procedures. Contrary to *Brady*, the Superior Court suggested that all evidence of the risks of a procedure is forbidden, and, in doing so, conflated *Brady*'s bar on evidence of informed consent to the risks of a procedure with a bar on evidence of the risks of a procedure itself. Thus, the Superior Court went beyond *Brady*'s limit on informed-consent evidence by barring evidence of complications known to be a risk even of non-negligent treatment. The Superior Court appropriately recited the core analysis in *Brady* – that evidence of the risks of a procedure may be relevant in particular cases. Yet, the court nevertheless effectively set forth a bright-line rule, determining in this case that evidence that one of the risks of a laparoscopic hysterectomy is perforation of the colon, even if the surgery is performed with due care, is irrelevant to the issues of standard of care and breach of duty. *See Mitchell*, 161 A.3d at 975 ("The fact that one of the risks and complications of the laparoscopic hysterectomy, *i.e.*, the

[9] While the *Brady* Court offered that a list of such risks "as they appear on an informed-consent sheet" may be relevant with respect to the standard of care, we interpret this to mean the generic offering of such risks, and not the informed-consent sheet itself. *Id.* at 1161. Indeed, to offer into evidence the informed-consent sheet itself would undermine the clear distinction made in *Brady* between informed consent evidence and risks and complications evidence, and such a proffer, absent special justification, would unnecessarily risk the very dangers regarding a jury receiving irrelevant informed consent evidence warned of in *Brady*.

perforation of the bowel, was the injury suffered by Mitchell does not make it more or less probable that Dr. Shikora conformed to the proper standard of care for a laparoscopic hysterectomy and was negligent.").

The complex nature of the practice of medicine — requiring, in the litigation realm, expert testimony for virtually all aspects of a plaintiff's burden to prove negligence, as well as in defense to those allegations — is central to our admissibility inquiry. Determining what constitutes the standard of care is complicated, involving considerations of anatomy and medical procedures, and attention to a procedure's risks and benefits. Further, a range of conduct may fall within the standard of care. While evidence that a specific injury is a known risk or complication does not definitively establish or disprove negligence, it is axiomatic that complications may arise even in the absence of negligence. We emphasize that "[t]he art of healing frequently calls for a balancing of risks and dangers to a patient. Consequently, if injury results from the course adopted, where no negligence or fault is present, liability should not be imposed upon the institution or agency actually seeking to assist the patient." *Toogood*, 824 A.2d at 1150. As a result, risks and complications evidence may clarify the applicable standard of care, and may be essential to provide, in this area, a complete picture of that standard, as well as whether such standard was breached. Stated another way, risks and complications evidence may assist the jury in determining whether the harm suffered was more or less likely to be the result of negligence. Therefore, it may aid the jury in determining both the standard of care and whether the physician's conduct deviated from the standard of care. We recognized as much in *Brady*. *See Brady*, 111 A.3d at 1161-62 ("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."). As such, we hold that evidence of the risks and complications of a procedure may be admissible in a medical negligence case for these purposes.[10]

Indeed, medical negligence cases involve a classic confrontation among experts, each testifying as to the appropriate standard of care, any breach of that standard, and whether such breach caused injury. The weighing of this evidence is for the jury, not the court. Such evidence, and, indeed, any evidence, is to be liberally admitted at trial, and 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. Importantly, the process commands not that evidence be reliable, but that reliability be assessed in a particular manner: by "testing in the crucible of cross-examination." *Crawford v. Washington*, 541 U.S. 36, 61 (2004). Cross-examination, according to Professor John Henry Wigmore, is "beyond any doubt the greatest legal engine ever invented for the discovery of truth." 5 Wigmore, *Evidence,* § 1367; *Heddings v. Steele*, 526 A.2d 349, 351 (Pa. 1987). Thus, the expert testimony, and any additional evidence, in a medical negligence case will be vetted

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[10] Case law from our sister states supports our conclusion. *See McDaniel v. UT Medical Group*, 2018 WL 774770, *2 (W.D. Tenn. February 7, 2018) ("This order does not prevent UTMG from presenting evidence of the surgical and post-operative risks. . . . UTMG may present this evidence in the form of general testimony by the defendant[] or nonparty expert witnesses" (citations and internal quotations omitted)); *Hillyer v. Midwest Gastrointestinal Associates*, 883 N.W.2d 404, 416 (Neb. App. 2016) ("To avoid confusion and inappropriate prejudice, evidence of the risks of a procedure is instead properly admitted in the form of general testimony by the defendants or nonparty expert witnesses. The defendant or nonparty expert witnesses can testify about the risks of the relevant surgical procedures generally (e.g., that perforations are a risk of colonoscopies), but cannot testify that the patient was informed of such risks prior to the procedure."); *Hayes v. Camel*, 927 A.2d 880, 890 (Conn. 2007) ("Thus, although evidence of the risks of a surgical procedure is relevant in the determination of whether the standard of care was breached, it was unduly prejudicial to admit such evidence in the context of whether and how they were communicated to the plaintiff."); *Waller v. Aggarwal*, 688 N.E.2d 274, 276 (Ohio App. 1996) (in addressing contention that bladder injuries may occur during laparoscopic procedures in the absence of negligence, court opined that "this theory could easily be demonstrated without confusion through the testimony of an expert, rather than through the introduction of the consent form.").

through direct and cross-examination. Ultimately, it is for the jury to determine whether a patient's injury is the result of negligence. We find that, without the admission of testimony of known risks or complications, where appropriate, a jury may be deprived of information that a certain injury can occur absent negligence, and, thus, would be encouraged to infer that a physician is a guarantor of a particular outcome.[11] [12] While we recognize that this determination allows for the potential that a jury might mistakenly conclude that an injury was merely a risk or complication of a surgery, rather than as a result of negligence, we believe that the significant consequences of a prohibition on such evidence tip the scales in favor of admissibility; moreover, we are confident that trial judges will serve their evidentiary gate-keeping function in this regard and, through instruction and comment, ensure that juries understand the proper role of such evidence at trial.

The dissent takes a contrary view, first accusing the majority herein of enacting a *per se* rule that risks and complications evidence is always admissible in medical

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[11] The Superior Court's alternative view — focusing solely on the injury, and deeming irrelevant to the negligence inquiry any consideration of whether the injury could have occurred in the absence of negligence, *see Mitchell*, 161 A.3d at 973 ("The evidence would tend to mislead and/or confuse the jury by leading it to believe that Mitchell's injuries were simply the result of the risks and complications of the surgery.") — is inconsistent with the principle that certain injuries happen even in the absence of negligent conduct. While the occurrence of a known complication does not preclude a finding of negligence, conversely, negligence may not be inferred merely from the occurrence of a complication when such complication is known to occur without negligence.

[12] We reject Mitchell's contention that defense expert testimony relying on studies regarding known risks and complications should be inadmissible because such studies may not distinguish between injury due to known risks and those caused by negligence. Any such challenges go to the weight, not the admissibility, of the evidence. It is for the jury to accept or reject a defendant's testimony as credible, and the jury may believe all, part, or none of the testimony of any witness. *In the Interest of: J.B.*, 189 A.3d 390, 408 (Pa. 2018). If an expert's testimony is based upon a flawed study, it will be subjected to cross-examination, impeached, and dismissed by a jury. Additionally, such testimony may be challenged under *Frye v. United States*, 293 F.2d 1013 (D.C. Cir. 1923) where there is reason to believe that "an expert witness has not applied accepted scientific methodology in a conventional fashion in reaching his or her conclusions." *Betz v. Pneumo Abex, LLC*, 44 A.3d 27, 53 (Pa. 2012).

malpractice cases. See Dissenting Opinion (Donohue, J.). Respectfully, this is not our determination. As noted above, such evidence may be admissible, subject to traditional concerns of relevancy, reliability, and disqualifying considerations such as undue prejudice.

The dissent further claims that evidence of risks and complications is irrelevant in this case, as it does not speak to whether Dr. Shikora acted within the applicable standard of care. Respectfully, the dissent takes too circumscribed a view of such evidence and how it relates to the standard of care or breach thereof. First, the critical inquiry in a medical malpractice action is whether the physician's treatment fell below the appropriate standard of care — i.e., was there an unwarranted departure from generally accepted standards of medical practice resulting in injury to the patient. *Brady*, 111 A.3d at 1161. In attempting to resolve these questions, evidence is freely admitted because, as we discussed, 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. Again, our decision in *Brady* fully supports our approach as we stressed the low threshold for relevance when discussing the admission of the risks of surgical procedures. *Brady*, 631 A.3d at 1162. Here, evidence of the risks and complications of the initial incision in laparoscopic surgery, as conveyed by Appellants' expert, is broader than suggested by the dissent. As set forth in greater length below, and distilled to its essence, Appellants' expert offered that: this type of incision is undertaken blind; as a result, it involves a known increased risk of cutting of the bowel; such injury can occur in the absence of negligence; and Appellants did all they could do to avoid the injury and acted within the applicable standard of care. Thus, as such risks and complications of this incision are well-recognized, and can occur in the absence of negligence, it would be less probable that the standard of care was breached in making such a first blind cut. This evidence

provides a fuller picture of the proper standard, and whether a physician's conduct fell below that standard. While a plaintiff could refute such evidence and standard, ultimately, it would be for a jury, considering all relevant facts, to determine the standard of care and resolve whether such standard was breached.

In support of its position, the dissent makes much of the expert testimony from Appellants' expert, Dr. Ascher-Walsh, and specifically that he "admitted that the fact that Mitchell suffered a colon injury, which is a known risk of a laparoscopic hysterectomy, provides no insight into whether the surgeons who performed the procedure were negligent and breached the standard of care - the injury could happen as a result of negligence or not," Dissenting Opinion (Donohue, J.) at 6-7, and that Dr. Ascher-Walsh agreed that the known risks of the surgery did not clarify the applicable standard of care, *id*. at 9. Making the point again, the dissent further presses that "Dr. Asher-Walsh testified that evidence of known risks in the case at bar was irrelevant to the standard of care." *Id*. Yet, despite the dissent's repeated urgings, it fails to appreciate the exact question proffered to Dr. Asher-Walsh, his entire testimony, and the point that risks and complications evidence involves more than the injury itself. In this exchange with Mitchell's counsel, rather than speaking to specific conduct, or whether an injury could occur in the absence of negligence, Dr. Asher-Walsh was asked *only* about the injury itself:

> Q. [Mitchell's Counsel] So, in fact, the injury, the bowel injury itself, doesn't really tell us much about the standard of care, does it?
>
> A. [Dr. Asher-Walsh] That's correct.

N.T., 2/5/16, at 707.

Based upon the specific question asked of him, Dr. Ascher-Walsh merely stated the obvious: that the exact injury suffered — the cutting of Mitchell's bowel — may have

resulted from negligence, or not from negligence. This passage was not, as implied by the dissent, a "gotcha" moment on the stand. Rather, risks and complications evidence goes beyond the specific injury at issue and includes the conduct of the physician and circumstances surrounding that conduct, as exemplified by Dr. Ascher-Walsh's testimony:

> Q. [Appellants' Counsel] Would you just take it, if you will, from there. Explain to the jury, I'll interrupt you if I need to, why you hold that opinion to a reasonable degree of medical certainty?
>
> A. I think that really the only place in this case where one can find fault is in the initial incision into the abdomen, and during that incision is the one time during the surgery -- I think you have seen pictures of how narrow a site you are going down -- it is the one time in the surgery when you are making an incision into a space where you can't really see where you are going.
>
> You know, you are cutting through tissue that occasionally you can see through it, but very often you can't see through it at all. Everybody is very different. Most of the time, especially going through a little incision, the more fat, the deeper the longer that incision is. That initial incision, I've done over 8,000 case[s] and every time I make that incision, I hold my breath[] because you never know 100 percent that that is going to be okay. I feel much better once you are inside and seeing, but that initial incision is when you can't be sure.
>
> The benefit of doing it that way is that the patient will recover faster, have less pain, sort of both the surgeons and patients are happy to take that risk because it is going to benefit them in the long run; but there is going to be those times where that incision is going to cause a problem like in this case.

N.T., 2/5/16, at 694-95.

Indeed, Dr. Ascher-Walsh did not simply testify that a specific injury is a risk of laparoscopic surgery, but provided a full explanation regarding whether such injury may occur in the absence of negligence and why:

> A. [Dr. Ascher-Walsh] Half the time that doesn't work, half the time you just have to make sure you are pulling up the thinnest amount of tissue you possibly can after you make that cut and you are hoping that there isn't anything on the other side.
>
> Q. [Appellants Counsel] Again, that's why the entry in the laparoscopic procedures, sometimes in the terminology they use is it is blind if you will?
>
> A. Correct.
>
> Q. It is not really that it is blind, it is just at that one stage the surgeon doesn't know exactly what is behind the peritoneum. Is that a fair statement?
>
> A. That's exactly correct.
>
> Q. And furthermore, if a structure were to be behind where it is not -- in a position where it's not supposed to be, is that when complications can occur unfortunately?
>
> A. Absolutely. Absolutely. I mean there's always something behind the peritoneum there. There's not like there is free space. There's not gas in your abdomen naturally. There's always bowel, there's always something right on the other side of that, whether it is large intestine or small intestine. It is always an incision where there can be injury.
>
> Q. In the best of possible care?
>
> A. Correct.

N.T., 2/5/16, at 700-01. Dr. Ascher-Walsh continued in this vein tying the physician's conduct to the standard of care, to the fact that an injury may occur in the absence of negligence.

> Q. [Appellants' Counsel] In your review, Dr. Ascher-Walsh, did you see anything by way of Dr. Shikora and Dr. Hansen's approach that suggests to you that they did not proceed in this case, that is proceed down through those layers, proceed to the peritoneum, proceed with the entry that was at all below the standard of care?
>
> A. No.

N.T., 2/5/16, at 702. He later added:

> A. It is a complication in this case.
>
> Q. [Mitchell's Counsel] I see. And, doctor, as far as the literature is concerned -- well, strike that. I think you had

> indicated in your report that the injury that Miss Mitchell sustained was unavoidable. That's what you said?
>
> A. Correct.
>
> Q. If it was unavoidable it would happen every time, wouldn't it?
>
> A. No.
>
> Q. Well, I don't understand if it is unavoidable, wouldn't it happen every time?
>
> A. Not necessarily. It is unavoidable in the sense that he did everything he could to avoid it, yet it still happened, so, therefore, it was unavoidable.

N.T., 2/5/16, at 721.

Indeed, Dr. Ascher-Walsh was entirely consistent in his ultimate conclusion, based upon the above, as to whether the standard of care was breached:

> Q. [Appellants' Counsel] Now, with respect to those opinions, Dr. Ascher-Walsh, do you have an opinion as to whether on May 16th of 2012, Dr. Shikora, along with his assistant, Dr. Hansen met the standard of care?
>
> A. I do.
>
> Q. And what is your opinion in that regard?
>
> A. I feel like they absolutely met the standard of care.

N.T. 2/5/16, at 694.

In our view, the above expert testimony, taken *in toto*, concerning risks and complications was both relevant and admissible regarding the proper standard of care and whether there was a breach thereof. Related thereto, the difficulty with the dissent's approach is that it would prevent a jury from obtaining a complete understanding of the applicable standard of care and the possible breach of that standard. Ultimately, the dissent's approach undermines the foundational tenet that injuries may occur in the absence of negligence and would work a radical change in medical malpractice jurisprudence, making physicians virtual guarantors of a result or warrantors of a cure — neither of which, as a matter of fact or law, is supportable.

Indeed, the dissent's position — that risks and complications evidence is inadmissible because it does not speak to the proper standard of care in *this* case, with respect to *this* physician — proves too much. The dissent, after concluding such evidence was inadmissible in this matter, concedes that, in certain circumstances, such evidence is relevant, such as cases involving "new, experimental or developing surgeries, as such evidence would 'establish the standard of care' where one otherwise does not exist." Dissenting Opinion (Donohue, J.) at 3 n.3. Yet, applying the dissent's logic, even in this scenario, the risks and complications of a procedure would not make it more or less probable that the particular physician conformed to the proper standard of care in *that* case. The dissent does not explain how this approach regarding the admissibility of risks and complications evidence would be inadmissible in this matter, but potentially admissible in other instances. The inescapable conclusion is that faithful application of the dissent's approach and logic would render such evidence inadmissible in all cases.

Here, Mitchell's expert testified that the proper standard of care for performing a laparoscopic hysterectomy included identification of the underlying body structures before making an incision by looking into the abdomen, and contended that cutting into the colon underneath the peritoneum without proper identification of the anatomy below the incision site violated the relevant standard of care. N.T., 2/1/16, at 183-85, 202-04, 245-46. Appellants' expert testified that complications are often unavoidable; that the initial incision was the most dangerous part of the procedure; that, half the time, the abdominal tissue is too thick to see through; that when a patient's bowel is in an unanticipated location an injury may occur while making the initial incision even with the best possible care; and, ultimately, that the manner in which Dr. Shikora and Dr. Hansen proceeded did not fall below the standard of care. N.T., 2/5/16, at 694, 697, 700-02. After the

introduction of this contrasting expert testimony, the jury found Appellants' defense more credible and, thus, entered judgment in their favor.

Accordingly, we find that the trial court herein properly distinguished between informed-consent evidence, which it did not admit, and surgical risks and complications evidence, which it admitted. In finding this risks and complications evidence to be inadmissible, the Superior Court erred. Therefore, we reverse the Superior Court's order, and reinstate the judgment on the verdict entered in favor of Appellants.

Chief Justice Saylor and Justices Baer and Mundy join the opinion.

Justice Wecht files a concurring opinion.

Justice Donohue files a concurring and dissenting opinion in which Justice Dougherty joins.