[J-77-2018] [MO: Todd, J.]
IN THE SUPREME COURT OF PENNSYLVANIA
WESTERN DISTRICT

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 the Court of Common Pleas of Allegheny County entered February 22, 2016 at No. GD 13-023436, and remanding
v.	:	
EVAN SHIKORA, D.O., UNIVERSITY OF PITTSBURGH PHYSICIANS D/B/A WOMANCARE ASSOCIATES, MAGEE WOMENS HOSPITAL OF UPMC,	:	ARGUED: October 23, 2018
Appellants	:	

CONCURRING AND DISSENTING OPINION

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

I agree with the learned Majority that evidence of the known risks and complications of a medical procedure may be (but are not always) admissible in medical negligence actions. In particular, I agree with the Majority that this evidence is admissible where it assists in establishing the requisite standard of care. *See* Majority Op. at 16-17 (stating "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," and holding that such evidence "may be admissible in a medical negligence action for these purposes").[1] I disagree, however,

[1] The Majority points to several decisions from other jurisdictions as showing support for this conclusion. *See* Majority Op. at n.10. Every one of these cases, however, involved the question of whether evidence of a patient's informed consent was admissible in a medical negligence action. While each case held that informed consent evidence was

with the Majority's finding that such evidence was relevant and thus admissible in the case at bar.

The Majority relies heavily on *Brady v. Urbas*, 111 A.3d 1155 (Pa. 2015), for its conclusion regarding the admissibility in medical malpractice cases of evidence of known risks of a medical procedure. In my view, *Brady* cautions against the broad rule announced by the Majority and otherwise does not support it. In *Brady*, we granted allowance of appeal to review the propriety of the Superior Court's per se ban on evidence of a patient's consent in a medical negligence action. *Id.* at 1160. Recognizing the multi-faceted nature of informed consent evidence, the *Brady* Court found that a per se ban was not warranted, envisioning hypothetical circumstances wherein specific of the facets of informed consent evidence could potentially be relevant. Addressing one component of informed consent evidence, the risks of surgery, the Court stated:

> 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*, 283 Conn. 475, 927 A.2d 880, 890 (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). 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*, 330 Or. 444, 8 P.3d 204, 207–08 (2000). Accordingly, we decline to endorse the Superior Court's broad pronouncement to the degree it may be construed to hold that

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inadmissible, the court went on to state, in pure dicta, that evidence of the risks of the procedure would be admissible. Moreover, as discussed herein, although the cases cited to by the Majority were decided in the same context as *Brady v. Urbas*, 111 A.3d 1155 (Pa. 2015), unlike our *Brady* decision, none of these decisions from other jurisdictions included any analysis as to when evidence of risks and complications of a procedure would be admissible or provided any limiting circumstances. Thus, in my view, these cases are neither helpful nor persuasive.

> all aspects of informed-consent information are always "irrelevant in a medical malpractice case."

Id. at 1161-62 (footnote and some citations omitted).

In a footnote integral to this excerpt, the *Brady* Court "envisioned other scenarios in which this information [i.e., the risks of a procedure] could be germane, such as where the standard of care differs from one geographic region to another (the 'locality rule')," for example, if the defendant physician worked in a medical office in a remote area that lacked advanced medical equipment that would typically be present in a large metropolitan area. *Id.* at 1162 n.5 (citing, inter alia, *Thierfelder v. Wolfert*, 52 A.3d 1251, 1265 (Pa. 2012)).

As is evident from this passage and example, the *Brady* Court clearly recognized that evidence of the risks and complications of a medical procedure is not always relevant to the standard of care but, potentially, it may be germane to the issue. In addition to the example used in *Brady*, I can envision other circumstances where risk and complication evidence "could be germane to establishing the standard of care." As an example, it may be relevant in a two schools of thought case, i.e., a case wherein a doctor exercised his or her judgment to choose "one of two or more accepted courses of treatment where competent medical authority is divided as to the proper course," *Passarello v. Grumbine*, 87 A.3d 285, 297 (Pa. 2014) (citing *Pringle v. Rapaport*, 980 A.2d 159, 166-67 (Pa. Super. 2009) (en banc)). Further, evidence of known risks of a procedure "could be germane" in cases involving new, experimental or developing surgeries, as such evidence would serve to establish the standard of care where one otherwise does not yet exist. Additionally, evidence of known risks would also be relevant to defend against res ipsa loquitur claims in medical negligence cases, as this evidence would be relevant to show that the injury could have happened in the absence of negligence. *See Quinby v. Plumsteadvill Family Practice, Inc.*, 907 A.2d 1061, 1071 (Pa. 2006) (explaining res ipsa loquitur as

establishing that an injury would not have happened in the absence of the defendant's negligence). In each of these scenarios, the evidence of known risks establishes or explains the standard of care and is relevant to the conduct of the doctor in performing the medical procedure.

As this evidentiary issue was discussed in *Brady*, and as I view it, the evidence of risks and complications of a medical procedure is admissible, in limited and discrete circumstances, where it establishes the standard of care. The circumstances of the case at bar do not remotely qualify. This case involved a routine medical malpractice case. Plaintiff's expert opined on the proper standard of care for a laparoscopic hysterectomy,[2] the procedure that resulted in Lanette Mitchell's injury. The defense expert disagreed and further opined that the severed colon suffered by the Plaintiff was a known risk and complication of the procedure. The known risks of this procedure did nothing to assist in the establishment of the standard of care for the procedure. Thus, in my view, the evidence was irrelevant and inadmissible in this medical negligence action.

The record from the trial explicitly establishes that this is not a case where the risks of the procedure informed the standard of care.[3] The plaintiff's testifying expert, Dr.

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[2] A laparoscopic hysterectomy is a procedure to remove a woman's uterus using a very small incision. The surgeon inserts a tiny camera, called a laparoscope, into the incision and watches the images from the camera on a television in the operating room while he or she performs the surgery. It is a minimally invasive procedure that is associated with shorter hospital stays, less blood loss, quicker recoveries and fewer abdominal infections as compared to an abdominal hysterectomy. *See* Jon I. Einarsson, MD, MPH, and Yoko Suzuki, MD, *Total Laparoscopic Hysterectomy: 10 Steps Toward a Successful Procedure*, Reviews in Obstetrics & Gynecology, 57 (Winter 2009). In the case at bar, the injury occurred during the incision and prior to the insertion of the laparoscope.

[3] Prior to trial, on January 25, 2016, Plaintiff filed a motion in limine to exclude evidence of, inter alia, the risks or complications of the surgery, asserting that such evidence was irrelevant to the medical negligence action. *See generally* Plaintiff's First Motion in Limine: to Exclude Consent/Risk Related Evidence, 2/9/2016. The trial court denied the motion in pertinent part, holding that "Defendants can introduce evidence and/or testimony that certain things are known risks and complications of surgery." Trial Court

Vadim Morozov, provided a detailed description of the standard of care for a laparoscopic hysterectomy. He testified that the procedure begins with an incision that opens up the skin at the base of the bellybutton. N.T., 2/2/2016, at 170. The surgeon excises the subcutaneous layers of the abdominal wall, including several layers of fat and the fascia (the "tough layer on the anterior wall that keeps our belly flat"). *Id.* at 164, 166. This reveals the peritoneum, which he described as "a very thin structure," and defined it as "a shiny membrane that lines out entire abdominal cavity" that operates "like a big sac" that goes "all the way around the bowel, the kidneys, the fatty apron." *Id.* at 163-64, 179. The surgeon then uses two hemostats (small clamps) to lift and "tent" the peritoneum, elevating it with a "small bulge." *Id.* at 179.

At this point in the surgery, prior to opening the peritoneum, Dr. Morozov testified that the standard of care requires the "crucial step" of "transvisualization," which involves the surgeon looking into the abdomen, through the peritoneum, to assure that the cut that he or she is about to make is safe. *Id.* at 179, 181. The surgeon uses the tips of the surgical scissors to push the peritoneum to the side to ensure that he or she "can clearly see through the membrane" and identify the organs and anatomical structures thereunder. *Id.* at 181, 241. Once transvisualization is complete, the surgeon then takes the scissors and makes a tiny cut (approximately three or four millimeters) into the peritoneum to continue the surgery. *Id.*

Dr. Morozov acknowledged that complications occur during surgery in the absence of negligence, and that for a laparoscopic hysterectomy, most complications arise during entry into the peritoneum. *Id.* at 228. According to Dr. Morozov, however, cutting into the

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Order, 1/29/2018. Because of this evidentiary ruling, Defendants were able to repeatedly state during opening and closing arguments that the injury was simply a "complication" of surgery and was just "a part of medicine." *See, e.g.,* N.T., 2/1/2016, at 115, 129, 131; N.T., 2/5/2016, at 737, 740.

peritoneum without first transvisualizing is a violation of the standard of care for this procedure. *Id.* at 185. It was his opinion that the failure to identify a patient's bowel before cutting into the peritoneum, as happened here, is not a complication of surgery, but a breach of the standard of care. *Id.* at 203.

The defendants' expert, Dr. Charles Asher-Walsh, acknowledged that there was no evidence that the surgeons who performed the surgery, Dr. Evan Shikora (the attending physician) and Dr. Karyn Hansen (the surgical resident), transvisualized the peritoneum prior to cutting into it. N.T., 2/5/2016, at 711. *See also* N.T., 2/2/2016, at 294 (Dr. Hansen testifying that she did not transvisualize what was under the peritoneum before cutting). He disagreed, though, that the failure to transvisualize prior to cutting the peritoneum constituted a violation of the standard of care for a laparoscopic hysterectomy. According to Dr. Asher-Walsh, "at least half the time, if not more, the tissue is much thicker" and the surgeon cannot see through it. N.T., 2/5/2016, at 700. Further, he testified that in cases of an overweight individual (as the patient was here), "99 percent of the time, when … going through that … depth of tissue, you can almost never transvisualize the peritoneum because you are in such a confined space, it is just almost impossible to see through the peritoneum." *Id.* at 723-24. *See also* N.T., 2/2/2016, at 291-92 (Dr. Hansen testifying that for a patient with a high body mass index (BMI), she usually does not even try to pull up and transvisualize the peritoneum, and that the patient in question had a BMI "in the 30s"). In either case, Dr. Asher-Walsh testified that this does not mean that the surgery is not performed, but that the surgeon just needs to ensure that he or she is "pulling up the thinnest amount of tissue … hoping that there isn't anything on the other side." N.T., 2/5/2016, at 701. As stated by Dr. Asher-Walsh, because there is "always something right on the other side" of the peritoneum, "whether it is large intestine or small intestine[, i]t is always an incision where there can be injury,"

even in the absence of negligence. *Id.* He did not view the doctors' performance in the case at bar as falling below the applicable standard of care, but was of the opinion that the colon injury that occurred was a complication of the surgical procedure. *Id.* at 702, 706.

Most notably for purposes of this appeal, Dr. Asher-Walsh 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 have happened as a result of negligence or not. *Id.* at 707. To the contrary, Dr. Asher-Walsh agreed that the occurrence of a bowel injury "doesn't really tell us much about the standard of care."[4] *Id.*

Liability in the case at bar depended upon whether the surgeons' failure to transvisualize prior to incising the peritoneum constituted a breach of the standard of care. Plaintiff's expert opined that this was the standard of care and continuing without transvisualizing breached that standard. Defendants' expert testified, in substance, that transvisualization (or even an attempt to transvisualize, as was the case here) was not required. According to the defense expert, if transvisualization is not possible (or simply not done), proceed with caution and hope for the best. *Id.* at 701; *see also id.* at 694 (Dr. Asher-Walsh testifying that "every time I make [the] incision [into the peritoneum], I hold my breath[] because you never know 100 percent that that is going to be okay"). Focused appropriately on the conduct of the defendant physician, the question for the jury was whether transvisualization was required or not. If so, the failure to do so was negligent; if not, it was not. These questions should have been decided exclusively on this evidence

[4] I do not view this as a "'gotcha' moment on the stand," as the Majority suggests. *See* Majority Op. at 20. Instead, I view this as honest testimony from the defense expert that the occurrence of a bowel injury during a laparoscopic hysterectomy does not inform the standard of care for the procedure.

of what was expected of the surgeon in this case. Again, as this Court has made clear, the focus in a malpractice case is on the **conduct of the physician**. *Passarello*, 87 A.3d at 299, 305.

Informing the jury that a particular injury is one that can occur during the procedure does not make it more or less likely that the injury occurred as a result of the doctor's negligence, rendering it entirely irrelevant. *See* Pa.R.E. 401 (defining relevant evidence as that which has a tendency to make a fact of consequence to the action more or less probable). Instead, as the Majority recognizes, permitting the admission of evidence of known risks "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[.]" Majority Op. at 18. This was precisely the concern that led the *Brady* Court to exclude evidence of a patient's informed consent – the risk of juror confusion. Like the evidence at issue in *Brady*, informing the jury of known risks of a procedure that are irrelevant to the standard of care could cause the jury to "lose sight of the central question pertaining to whether the defendant's actions conformed to the governing standard of care[.]" *Brady*, 111 A.3d at 1162. Because evidence of the known risks of a laparoscopic hysterectomy was irrelevant here, it was inadmissible. Pa.R.E. 402 ("Evidence that is not relevant is not admissible."). Respectfully, if the Majority is correct that known risk evidence was germane in the case at bar, it is difficult to imagine a circumstance where such evidence would be inadmissible. To be clear, the fact that cutting through a patient's colon is a known risk of a laparoscopic hysterectomy does not shed any light on the crucial issue of whether this defendant physician performed the procedure in compliance with the standard of care.

The Majority is critical of the Superior Court below, believing that the lower court "blurred the distinction between informed-consent evidence … and evidence regarding

the risks and complications of medical procedures." Majority Op. at 15. It further accuses the Superior Court of creating a per se "bar on evidence of the risks of a procedure itself," and asserts that the decision is "inconsistent" with the principle that injuries can happen in the absence of negligence. *Id.* at 15, 18 n.11. Respectfully, my review of the Superior Court's opinion finds no support for the Majority's assertions. To the contrary, the Superior Court recognized *Brady*'s holding that "evidence of risks and complications of a surgical procedure may be admissible to establish the relevant standard of care," but found that "**in this case**, such evidence was irrelevant in determining whether [Appellants], specifically Dr. Shikora, acted within the applicable standard of care." *Mitchell v. Shikora*, 161 A.3d 970, 975 (Pa. Super. 2017) (emphasis added). As the Superior Court found (correctly, in my view), "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." *Id.*; *see, cf., Brady*, 111 A.3d at 1162 (observing that a patient proceeding with a procedure knowing the risks does not make it more or less probable that the doctor was negligent in performing the procedure). Saliently, and as previously explained, the Superior Court's conclusion tracks precisely the opinion of the defense expert. N.T., 2/5/2016, at 707.

In announcing its conclusion that evidence of risks and complications was admissible in the case at bar, the Majority recognizes that "medical negligence cases involve a classic confrontation among experts, each testifying as to the appropriate standard of care[.]" Majority Op. at 17. As stated hereinabove, the confrontation between the experts in this matter was their disagreement as to whether transvisualization was a necessary step in performing a laparoscopic hysterectomy. By allowing the jury to be

informed that a bowel laceration – the precise injury that occurred in this case – was a known risk of the procedure, the court allowed the jury to effectively conclude that the injury was not the result of negligence regardless of whether transvisualization was required. This is particularly troubling because as even the defense expert admitted, the fact that a bowel injury occurred here was irrelevant to the standard of care. *See* N.T., 2/5/2016, at 707.

I also disagree with the Majority's conclusion that the absence of evidence of known risks of a medical procedure in this case would encourage the jury "to infer that a physician is a guarantor of a particular outcome." Majority Op. at 18, 23; *see also* 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."). Respectfully, the Majority's concern on this point is misplaced and unfounded. The legal precept that a physician is not a guarantor of any particular outcome is baked into the trial of every medical malpractice case. As the Majority acknowledges, the jury is informed of this principle by way of a standard jury instruction. *See* Majority Op. at 11 (quoting Pa.S.S.J.I. (Civ) 14.10); *see also Commonwealth v. Aikens*, 168 A.3d 137, 143 (Pa. 2017) ("jurors are presumed to follow the court's instructions"). Limiting the evidence to that which is relevant to establishing the standard of care does not limit the availability of this jury instruction on a principle of law. However, interjecting the risks or complications of a procedure into a medical malpractice case where it does nothing to establish the standard of care shifts the focus of the jury's inquiry away from the conduct of the physician to the outcome of the surgery.

The question of whether the physician breached a duty depends on whether the physician acted within the established standard of care for a given procedure. *See Toogood v. Owen J. Rogal, D.D.S., P.C.*, 824 A.2d 1140, 1145 (Pa. 2003) (plurality)

(defining medical malpractice "as the unwarranted departure from generally accepted standards of medical practice resulting in injury to a patient"). When a jury concludes that a physician met the applicable standard of care and an injury nonetheless occurred, the court's instructions will have made clear that the physician is not liable to the plaintiff. Evidence of risks and complications of the procedure in this case, comingled with evidence of the standard of care, did not help to clarify the jury's function but instead muddled it.

For the foregoing reasons, I would affirm the decision of the Superior Court. On that basis I respectfully dissent.

Justice Dougherty joins this concurring and dissenting opinion.