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Admissibility of Informed Consent in Medical Malpractice Cases

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Special to the Legal

The admissibility of informed consent discussions and forms are a frequent issue in the trial of medical malpractice cases. While this evidence is obviously admissible in cases where the Plaintiff is asserting a claim for lack of informed consent, its admissibility in cases where there is no challenge to the patient's consent is less clear. In *Brady v. Urbas*, 80 A.3d 480 (Pa. Super. Ct. 2013), the Superior Court set forth a bright line rule that evidence of informed consent would not be admissible where, no lack of informed consent claim had been asserted. On appeal, the Pennsylvania Supreme Court affirmed the Superior Court decision, however, backed away from the bright line rule announced below. This left open that informed consent information "may" be relevant in a medical malpractice case. Because of the Supreme Court's holding in *Brady*, the admissibility of informed consent continues and will continue to be argued to and decided by trial courts in medical malpractice cases.

By way of background, a "consent form" refers to the signed form that authorizes a physician to perform an invasive or surgical procedure. In almost every medical negligence case involving a procedure, the plaintiff-patient's medical record will contain a signed consent to perform the procedure. These documents usually set forth a brief description of the procedure, the name of the physician, patient name, and may document certain medical complications or risks. The forms used vary widely by institution. Some include only a generic listing of serious medical complications that could conceivably happen in any procedure (i.e., cardiac arrest, death). Others include specific complications that have been known to occur in the specific medical procedure the patient is undergoing, often by way of blank lines that are filled in by the physician or an assistant at the time the consent is signed. Other forms include both preprinted generic risks and other more specific risks that the physician includes based on the specific procedure. Many forms include an acknowledgement that the physician has explained the risks of the procedure. These forms are signed patients, and usually, the physician and a third-party witness.

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> *"The problem with the purported relevance of informed-consent evidence to establish the standard of care is that a 'risk' of a procedure alone cannot help to define the standard of care.*

The potential persuasive effect of these forms and the surrounding conversations is obvious. Consent forms often include the harm that befell the patient on the list of risks associated with the procedure. This can be extremely harmful to a plaintiff-patient because it invites the jury to consider an improper assumption of the risk defense, that is, the plaintiff proceeded with the procedure despite being fully aware that a certain adverse outcome could occur.

Brady involved allegations that a podiatrist negligently performed several surgical procedures on the plaintiff's big toe resulting in a loss of bone and length in the toe. Notably, there were no allegations of lack of informed consent, only claims that the podiatrist deviated from standards of care in performing the surgery. Before each of the procedures, the physician discussed the risks and complications and a consent form was signed. The trial court

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Consent

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denied a motion in limine to preclude any consent related evidence at trial as irrelevant and/or unfairly prejudice. Evidence of the discussion of the risks of the surgery and the consent form came up throughout the trial and some of the consent forms were provided to the jury in deliberations. The jury returned a verdict in favor of the defendant-physician.

The Superior Court found that admission of the consent-related evidence was an abuse of discretion and reversed. The Superior Court succinctly stated "evidence of informed consent is irrelevant in a medical malpractice case." The court endorsed the rationale that while a patient may consent to the surgery they cannot consent to negligent care, in other words, the patient may acknowledge the risk but does not agree to negligent conduct that makes those risks occur. The court recognized that admission of this evidence could lead the jury to conclude that the patient-plaintiff accepted the risk regardless of the conduct that caused the risks to occur.

The Pennsylvania Supreme Court affirmed the Superior Court decision that the consent-related evidence was irrelevant. The Supreme Court recognized that there was no assumption of risk defense in medical negligence claim and that whether a patient agreed to a procedure in light of known risks does make it more or less probable that the physician met the standard of care in performing the operation. The Supreme Court refused, however, to adopt the Superior Court's "bright line rule." The decision found that some consent-related information may be relevant to the question of negligence. The court provided two examples—where the standard of

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care required certain risks be discussed and where evidence of certain risks, either in discussion or on the consent form, may be relevant to establishing the standard of care. The Supreme Court ultimately held that evidence that a patient affirmatively consented to treatment after being informed of the risks is "generally irrelevant in a cause of action sounding in medical negligence."

The Supreme Court's refusal to adopt the Superior Court's bright line rule left open the possibility that evidence of informed consent could be admitted at trial of a medical negligence case. The decision offered little explanation or guidance as to when consent-related information could be admitted. The first example, when disclosure of risks is required by the standard of care, merely leads back to an informed consent claim which was never included in the scope of the Superior Court's decision. The second example, that informed consent information may be relevant to "establish the standard of care" is more perplexing. Even more so, considering that the decision states that patient-plaintiff's agreement to the procedure is not relevant. How can the listing of possible complications on a form be probative of how the procedure is performed?

On further examination, the Pennsylvania Supreme Court appears to be drawing a distinction between medical expert testimony regarding risks of the procedure, generally, and the communication of those risks to a patient. *Hayes v. Camel*, 927 A.2d 880 (Conn. 2007), the case cited by *Brady* in support of the statement that evidence of risks may admissible to establish the standard of care was clearer in this distinction. *Hayes*, similar to *Brady*, concluded that admission of informed-consent communications and forms was an abuse of discretion. *Hayes* noted that expert testimony may be permitted about risks of a procedure, generally, separated from the communication of those risks to the patient. Indeed, following this approach would alleviate much of the confusion left by the *Brady* decision.

The problem with the purported relevance of informed-consent evidence to establish the standard of care is that a "risk" of a procedure alone cannot help to define the standard of care. Indeed, this proposition represents confusion between outcomes (risks) and methods (standards of care). The risks that are addressed in informed consent communications with a patient are outcomes, i.e. nerve injury, bowel injury, death, etc. They are merely adverse outcomes that have been associated with the procedure or surgical procedures in general. The standard of care for a procedure addresses the method for how the surgery is performed. Indeed, an adverse outcome, such as death, could be reached in any number of ways, some of which meet the standard of care and some which do not. For example, a patient could die during a procedure because there was an unknown and unpredictable allergic reaction to anesthesia. A patient could also die during the same procedure because the anesthesiologist failed to monitor the patient. Of course, whether "death" was listed on the consent form as a potential risk does not have any bearing on the standard of care for checking allergies or monitoring a patient.

There are few reported decisions that have applied *Brady*. In *Mitchell v. Shikora*, (C.C.P. Allegheny Cty. May 18, 2016),the judge permitted defense expert testimony that the injury suffered by the plaintiff was a "known risk or complication" of the procedure. Discussions about risks between the physician and patient were precluded. The opinion is silent on whether the consent form itself was specifically precluded. *Mitchell* appears to follow the distinction described in *Hayes*, above.

It appears clear from *Brady* that the patient-plaintiff's signing the form agreeing to the procedure is not relevant and should be precluded. Arguments, however, will be made that the inclusion of a specific risk makes it more likely that a given risk is a recognized "risk of procedure" and thus supports the expert testimony on this issue. While the logic of the argument that a "risk" is relevant to standard of care at all, is flawed, there are additional factors that may have bearing on the admissibility of a specific consent form. Whether the consent form is specific to a procedure, whether the form contains a preprinted or specific list of risks, and who was involved in the creation of the form, are all potential questions that could ultimately have bearing on the forms admissibility. Indeed, the underlying circumstances relevant to the form may further show that there is little relationship between the risks listed and the standard of care for the procedure. Going forward, the decision of whether consent forms are admissible in medical negligence case will most likely turn on whether these forms are relevant to the standard of care. •