June 20, 2019

Unanswered Questions in *Mitchell vs. Shikora*

Justice Debra Todd wrote the majority Opinion in *Mitchell vs. Shikora*, decided June 18, 2019. The Court indicated that it was following its prior decision in *Brady vs. Urbas*, 111 A.3d 1155 (Pa. 2015), and found that evidence of the risks and complications of a surgery "may be" admissible at trial. Note the emphasis on the words "may be." The Superior Court was reversed and the trial court opinion reinstated.

Dr. Shikora was performing a laparoscopic hysterectomy on Lynette Mitchell when he severely cut her bowel. The doctor's defense was that in performing a laparoscopic hysterectomy, the first cut is "blind."

The opinion, permitting evidence of the risks and complications of a surgery, seems to be grounded on the Pennsylvania Standard Jury Instruction 14.10 Subcommittee Note that: "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." That observation by the Committee appeared to serve as the basis for the logical underpinning in *Mitchell vs. Shikora*.

The Court reiterated the proposition that evidence of a patient's informed consent to a procedure is "generally relevant" to the issues of the standard of care and breach of duty and may confuse the jury. However, the Court distinguished informed consent from evidence of the risks of the procedure "themselves" which the court said may be relevant and admissible.

Justice Todd went so far as to suggest that testimony or a list of risks, as they appear on an informed-consent sheet, may be relevant in establishing the standard of care. It does appear, from later reasoning, that such evidence would have to be carefully circumscribed.

What remains irrelevant is informed consent or lack of informed consent. Evidence that a patient agreed to go forward with the operation in spite of the risks is still irrelevant, if informed consent has not been pled.

The majority opinion acknowledged that while evidence that a specific injury is a known risk or complication does not definitively disprove negligence, it does not necessarily establish it either. The Court does not discuss the proposition that if a risk is well known, the doctor may be required to function at an enhanced level to avoid it.

We have found, for example, in laparoscopic cholecystectomy cases that the risks are so well known that the standard of observation on the part of the doctor as to location of the anatomy should be elevated. The Court makes a leap of faith by stating, without any citation, that risks and complications "may assist a jury in determining whether the harm suffered was more or less likely to be the result of negligence."

Opinion Page 16. How is that so? What about the fact that 2% of all colonoscopies result in a colon perforation proves that a colon perforation is not negligent? Do the risks of colon perforation during a colonoscopy prove that the doctor should have been more careful knowing of the risks and that such a perforation was negligent? There are many reasons why certain procedures result in more injuries than others. In *Mitchell*, the excuse was that the doctor must cut blind during a laparoscopic hysterectomy which would lead to the conclusion that any bowel injury at the beginning of such surgery would be justified as non-negligent. In *Mitchell*, there was also evidence that the anatomy was irregular in terms of the location of the bowel. The Court discussed that virtually not at all.

Of greater interest is that the Court did not give any examples of why risks or complications being "known" are less likely to point to negligence. Precisely why is that? Permitting evidence of "known risks and complications" consists of making a very unevidentiary assumption that whenever a procedure is accompanied by an increased number of injuries to patients, there must be a smaller chance of negligence. In fact, the opposite may be true. If a particular procedure results in many injuries to patients, far above the norm for surgeries in general, perhaps there is something wrong with the way the surgery is done. Are laparoscopic procedures dangerous because they are inherently blind? What about robotic surgeries which, in certain situations, may even be more blind?

The problem with *Mitchell vs. Shikora* is that by permitting evidence of known risks and complications, it assumes that the quantity of injuries concerning a particular procedure is presumptively evidence of non-negligence. The logic goes that if there are a lot of injuries for a particular procedure, then the problem must be the patient, bad luck or the forces of evil. If a patient has a high risk of a heart attack because of cardiac problems, should a particular procedure be undertaken, that risk factor should be admissible if there is a lawsuit concerning the occurrence of the heart attack. The patient will claim that the doctor or the hospital should have been aware of his/her cardiac condition and take additional precautions. However, none of that suggests that the mere occurrence of risks or complications is a get out of jail free card.

The Court in *Mitchell vs. Shikora* may have erroneously concluded that risks and complications correlate with lack of negligence. The Court denies that and in fact recognized 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." The Court then goes on to say that it nevertheless will permit risks and complications into evidence because "we believe that the significant consequences of a prohibition on such evidence tip the scales in favor of admissibility." What does that mean? The consequences of prohibiting miscellaneous risks and complications tipped the scales in favor of admissibility for what reason? The Court does not answer that.

One of the effects this decision will have is to cause healthcare providers to give a laundry list of possible risks and complications regardless of whether those risks and complications are seriously identified in the literature as being pertinent. Is it a risk that a doctor may not be fully trained or may have a drinking problem? Undoubtedly "no."

Finally, in a scrap to the patient, the Court states: "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 Court offers no indication as to what the jury should be told.

Perhaps juries will need to be told that risks and complications of surgery might mean that the event was not negligent, but it also might mean that the doctor, knowing of such risks and complications, was not careful enough. It could go either way. The jury needs to be provided the balance which the Supreme Court indicates it would like to see.

Justice Todd also stated: "[A]s noted above, such evidence may be admissible, subject to traditional concerns of relevancy, reliability and disqualifying considerations such as undo prejudice." At what point is a jury prohibited from hearing a risk and complication because of "disqualifying considerations?" What might those "disqualifying considerations" be? Will there have to be a *Frye* hearing as to the science and whether it is novel or junk every time a defense relies upon risks and complications or every time the plaintiff says that risks and complications should have placed the doctor on heightened guard? Probably the court did not have that in mind, although *Frye* snuck in this case in Footnote 12.

Reading the majority Opinion together with the concurring and dissenting views one inevitably arrives at the determination that the concept of risks and complications is a salon door that might swing both ways. If it is going to be relied upon and utilized by either party, to exculpate the doctor or to demonstrate that the doctor should have been more prudent, the jury is going to need significant understanding and instruction, in addition to careful scrutiny of the evidence by the trial court. Certainly, the argument will not be permitted, under the language of this decision, that no negligence is simply demonstrated by the heightened risk or complication rate as testified to by an expert, shown on a "risk list" or that appears in some arcane medical literature.

Mitchell vs. Shikora may not be the panacea that defense lawyers think it is and although plaintiffs' lawyers will hear about risks and complications in every case, it is a concept that increasingly will be subject to scrutiny and restrictions.

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