Kevin J. Shannon, et al. v. Mafalda Fusco et al., No. 57, September Term, 2013

**TORTS – NEGLIGENCE – INFORMED CONSENT – MATERIAL RISK**

In discerning which risks are "material," thereby requiring a physician to discloses them to effectively obtain a patient's informed consent, significant factors include the severity of the risk and the likelihood with which it will occur.

**TORTS – NEGLIGENCE – INFORMED CONSENT – NECESSITY FOR EXPERT TESTIMONY**

In an informed consent cause of action, expert testimony is necessary to establish the material risks of the medical treatment.

**TORTS – NEGLIGENCE - INFORMED CONSENT – EXPERT TESTIMONY – QUALIFICATIONS OF A PHARMACIST TO TESTIFY ABOUT MATERIAL RISKS**

In an informed consent cause of action involving the administration of a medication, a pharmacist may be qualified to testify about the likelihood and severity of the risks of the medication.

Circuit Court for Prince George's County
Case No. CAL-07-11137
Argued: February 7, 2014

IN THE COURT OF APPEALS OF MARYLAND

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No. 57

September Term, 2013

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KEVIN J. SHANNON, et al.
v.

MAFALDA FUSCO, et al.

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Barbera, C.J.
Harrell
Battaglia
Greene
Adkins
McDonald
Eldridge, John C. (Retired, Specially Assigned),

JJ.

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Opinion by Battaglia, J.
Eldridge, J., dissents.

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Filed: April 24, 2014

We are called upon to decide whether a trial judge abused his discretion in excluding the testimony of a pharmacist in a case in which it was alleged that a physician failed to obtain informed consent for the administration of radiation therapy and a drug, Amifostine,[1] to a patient, Anthony Fusco.

The Petitioners herein, Dr. Kevin Shannon and his medical practice, Hematology-Oncology Consultants, P.A. (hereinafter, "Dr. Shannon"), were sued in the Circuit Court for Prince George's County by the Estate of Anthony Fusco and Mr. Fusco's surviving children and widow, Respondents, in survival and wrongful death actions, sounding in informed consent.[2] In relevant part, the Complaint alleged:

> 17. On or about March 12, 2003, Fusco met with Dr. Kevin Shannon to discuss Amifostine as a cytoprotective agent.[3]
> 18. Between the dates of April 15, 2003 and May 15, 2003, Fusco received both radiotherapy and approximately 16 injections of 500mg of Amifostine and was monitored by Dr. Shannon. Dr. Shannon recorded in his follow-ups on Fusco's prostate carcinoma that he is tolerating the radiation and Amifostine during the external beam portion of his treatment well, having no nausea, dizziness or other symptoms, aside from some mild orthostatic symptoms if he does not change positions slowly.
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> * * * *
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> 51. Dr. Kevin Shannon owed to Deceased, Fusco a clear and adequate explanation of the nature, benefits and risks of, and alternatives to the administration of the drug, Amifostine and the administration of radiation in order to enable him to make an intelligent decision as to whether to proceed.

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[1] Amifostine "works by protecting against the harmful effects of chemotherapy medications and radiation treatment." *Amifostine Injection*, MedlinePlus, http://www.nlm.nih.gov/medlineplus/druginfo/meds/a696014.html (last visited April 23, 2014).

[2] Two other physicians were joined in the Complaint, but claims against them did not survive, and no appeal was taken. They are not a part of the instant action.

[3] Cytoprotective is a "descriptive of a drug or agent protecting cells from damage expected to occur." Stedman's Medical Dictionary 490 (28th ed. 2006).

> 52. Dr. Kevin Shannon failed to inform Fusco of the risks that accompany the administration of the drug, Amifostine and the administration of radiation and therefore did not provide an adequate explanation.
> 53. The adequacy of the explanation must be measured by the patient's need, and that need is whatever is material to the decision. A material risk is one which a physician knows or ought to know would be significant to a reasonable person in the patients position in deciding whether or not to submit to a particular medical treatment or procedure.
> 54. In the situation at hand, a patient under the same or similar circumstances as Fusco would most commonly have objected to the administration of Amifostine.
> 55. Deceased, Fusco would not have given his consent to the proposed administration of the drug, Amifostine and the administration of radiation, had full and adequate disclosure been made at the time consent was originally given.
> 56. As the direct and proximate result of Dr. Kevin Shannon's failure to obtain informed consent, Deceased Fusco was caused to sustain severe and conscious pain, permanent bodily injuries, substantial emotional pain and suffering and mental anguish and ultimately death which caused him to incur medical expenses, funeral expenses and other related expenses.

During the course of discovery, the Fuscos designated Dr. James Trovato, a pharmacist, as an expert witness, but the trial judge excluded Dr. Trovato's testimony based upon his deposition and proffer. Dr. Shannon and his practice group prevailed after a jury trial, and the Fuscos appealed, alleging, *inter alia*, error in the exclusion of Dr. Trovato's testimony.[4] In a reported opinion, the Court of Special Appeals reversed the judgment

[4] The questions presented to the Court of Special Appeals were:

> 1. Did the trial court improperly grant the appellees' motion to exclude the testimony of James Trovato, Pharm.D. on the basis that he was not able to testify as to the five elements of an informed consent case as outlined in *Sard v. Hardy*?
> 2. Did the trial court's consistent misapplication and misinterpretation of the holding in *University of Maryland Medical System Corporation v. Waldt* lead to the repeated erroneous denial of appellants' admission of evidence relating

and remanded the case for a new trial, having determined that Dr. Trovato may have been qualified to offer an opinion because he had substantial experience studying and advising patients regarding oncology medications, including Amifostine, and therefore, should have been permitted to testify. *Fusco v. Shannon*, 210 Md. App. 399, 428, 63 A.3d 145, 162 (2013). Dr. Shannon and Hematology-Oncology Consultants, thereafter, filed a petition for *certiorari*, which we granted, to consider the following questions:[5]

> 1. Whether the trial court properly exercised its broad discretion in granting Petitioners' Motion in Limine to preclude James Trovato's testimony at trial, and whether the Court of Special Appeals decision holding otherwise was error.
> 2. Whether the trial court properly exercised its broad discretion in precluding the use of, or reference to, the drug insert and FDA approval, and

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to the approved uses of Amifostine?

[5] We use the questions submitted in the Petitioner's brief, because they provide greater clarity than those submitted in the Petition for Certiorari, which were:

> 1. Whether the Court of Special Appeals erred in vacating the jury's verdict in favor of Petitioners in a medical lack of informed consent case when Respondents' case was void of any evidence that Dr. Shannon failed to disclose the "material risks, benefits, and alternatives" to the proposed treatment plan, and even on remand, will continue to be void of such evidence.
> 2. Whether summary judgment and/or judgment in Petitioners' favor was mandated as a matter of law on the informed consent claim.
> 2. Whether the Court of Special Appeals erred in vacating the judgment in Petitioners' favor by relying exclusively on an untimely "proffer" by Respondents' counsel which was provided in violation of discovery deadlines, rather than the witness' actual discovery and trial testimony.
> 4. Whether the Court of Special Appeals erred in vacating the judgment in Petitioners' favor when it failed to consider the question of relevance and/or prejudicial effect of the Pharmacist's limited testimony on remand.

> whether the Court of Special Appeals' decision holding otherwise was error.
> 3. Whether the trial court erred in denying Petitioners' Motion for Summary Judgment and/or whether the trial court erred in denying Petitioners' Motion for Judgment given that Respondents' did not adduce evidence that Dr. Shannon failed to advise Mr. Fusco of "material risks" to Amifostine, either in discovery or at trial.[6]

*Shannon v. Fusco*, 432 Md. 466, 69 A.3d 474 (2013).

After Anthony Fusco had been diagnosed with prostate cancer he consulted with a radiation oncologist and decided to undergo treatment, which involved a combination of hormone therapy and radiation. The radiation oncologist referred Mr. Fusco to Dr. Kevin Shannon, a physician who specialized in hematology[7] and oncology,[8] to administer Amifostine, a drug which, according to Dr. Shannon's trial testimony, was designed to protect the bladder and rectum from inflammation caused by radiation therapy. Mr. Fusco was later diagnosed with Stevens-Johnson Syndrome, a disease involving skin irritations and blisters, which ultimately causes the top layer of skin to die and shed,[9] and died shortly thereafter from pneumonia.

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[6] Because of our disposition of the first two questions, we need not address Petitioner's third question.

[7] Hematology is "[t]he medical specialty that pertains to the anatomy, physiology, pathology, symptomatology, and therapeutics related to the blood and blood-forming tissues." Stedman's Medical Dictionary 862 (28th ed. 2006).

[8] Oncology is "[t]he study or science dealing with the physical, chemical, and biologic properties and features of neoplasms, including causation, pathogenesis, and treatment." Stedman's Medical Dictionary, 1365 (28th ed. 2006).

[9] *Diseases and Conditions, Stevens-Johnson syndrome*, The Mayo Clinic, http://www.mayoclinic.org/diseases-conditions/stevens-johnson-syndrome/basics/definition/con-20029623 (last visited April 23, 2014).

The Estate of Anthony Fusco, Mr. Fusco's surviving children, Carmela Dent, Anthony J. Fusco Jr., and Michael A. Fusco; and Mr. Fusco's widow, Malfada Fusco (collectively, "the Fuscos"),[10] filed wrongful death and survival actions against Dr. Shannon and the medical group of which Dr. Shannon was a member at the time. The thrust of the informed consent action was that Dr. Shannon failed to disclose the material risks of administering radiation therapy as well as Amifostine before obtaining Mr. Fusco's consent to the treatment plan.

After the case was joined, a scheduling order was issued requiring the parties to identify any expert witness expected to be called at trial. In response[11] the Fuscos designated a pharmacist, Dr. James Trovato, in addition to a physician,[12] as an expert. Dr. Trovato was offered, in his deposition, as "an expert in drug therapy, generally and

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[10] The Complaint also named two of Mr. Fusco's other children, John and Paul Fusco, as plaintiffs. Their claims, however, were voluntarily dismissed and they are not parties to this appeal.

[11] In their "Plaintiffs' Designation of Experts", the Fuscos also indicated that they were designating experts pursuant to Rule 2-402(f) (2007), which provided:

> (f) **Trial preparation—Experts.** (1) Expected to be called at trial.
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> (A) Generally. A party by interrogatories may require any other party to identify each person, other than a party, whom the other party expects to call as an expert witness at trial; to state the subject matter on which the expert is expected to testify; to state the substance of the findings and the opinions to which the expert is expected to testify and a summary of the grounds for each opinion; and to produce any written report made by the expert concerning those findings and opinions. A party also may take the deposition of the expert.

[12] The other expert designated to testify at trial was Mohamed Al-Ibrahim, M.D., identified as an infectious disease specialist.

specifically in drug therapy as it applies to oncology."

Dr. Shannon, thereafter, moved for summary judgment, alleging that he was entitled to judgment as a matter of law because the Fuscos had failed to produce expert testimony to establish that Dr. Shannon had breached his duty to obtain Mr. Fusco's informed consent. In this first motion, Dr. Shannon alleged that Dr. Trovato was not qualified to offer an opinion on the standard of care a physician must exercise in obtaining the informed consent of a patient, because he was a pharmacist and had never obtained a patient's informed consent. The Fuscos opposed the motion, arguing that Dr. Trovato was not offered to testify about the standard of care in this case; he was offered, rather, to testify about Amifostine, including its risks and alternative treatments. They contended, moreover, that expert testimony is not required to establish a breach of the standard of care in an informed consent case. The motion was denied.

The Fuscos elected, pursuant to Rule 2-419(a)(4),[13] to take a video or *de bene esse*[14] deposition of Dr. Trovato, in lieu of having him appear at trial. During this deposition, Dr. Trovato offered his opinion that, "amifostine was inappropriately used or should not have

[13] Rule 2-419(a)(4) provides:

> Videotape deposition of expert. A videotape deposition of a treating or consulting physician or of any expert witness may be used for any purpose even though the witness is available to testify if the notice of that deposition specified that it was to be taken for use at trial.

[14] *De bene esse* is defined: "[a]s conditionally allowed for the present; in anticipation of a future need <Willis's deposition was taken *de bene esse*>." Black's Law Dictionary 430 (8th ed. 2009).

been used for the reason of a patient getting radiation therapy for prostate cancer." To support his opinion, Dr. Trovato testified that the Food and Drug Administration had not approved Amifostine to supplement radiation treatment in prostate cancer patients, but rather, only for two uses not applicable to Mr. Fusco's condition.[15] Likewise, Dr. Trovato explained that an insert contained in the Amifostine packaging provided by the manufacturer advised against its use in elderly patients, because its effects on an older population were not yet known. Additionally, he also testified that common side effects included nausea, vomiting, hypertension, dizziness, respiratory affects, and "various skin reactions," including Steven-Johnson's Syndrome. He did not testify about radiation therapy.

After the video deposition, Dr. Shannon filed a motion *in limine* to exclude Dr. Trovato's testimony, arguing, again, that Dr. Trovato was not qualified to render an opinion, because "he had no experience as a medical doctor, and has never diagnosed a patient; admitted a patient to a hospital; . . . prescribed medication to a patient" and because he had never obtained a patient's informed consent. In addition, Dr. Shannon alleged that Dr. Trovato's testimony addressed negligence, rather than informed consent and was, therefore, irrelevant. The Fuscos opposed the motion, contending that Dr. Trovato's status as a pharmacist did not disqualify him from offering an opinion in this matter: "Precisely because he is a pharmacist . . . Dr. Trovato, is eminently qualified and perhaps

[15] Dr. Trovato testified that approved FDA uses included: to decrease the toxicity in kidneys for patients being treated for ovarian cancer, and for head and neck cancer patients to prevent dry mouth.

more so than the defendant doctors themselves, to discuss the risks, benefits, and alternatives of Mr. Fusco's proposed course of treatment", Amifostine.

Dr. Shannon also renewed his earlier motion for summary judgment,[16] arguing that the Fuscos had failed to prove by expert testimony the material risks of Amifostine, reiterating many of the arguments set forth in the motion in limine, namely that Dr. Trovato was not qualified to offer an opinion in this matter. Additionally, Dr. Shannon argued that Dr. Trovato had not testified to the nature of the risks of Amifostine, the probability of success of Amifostine; the frequency of occurrence of risks of Amifostine, and the availability of alternatives to Amifostine, which Dr. Shannon asserted was required by this Court's decision in *Sard v. Hardy*, 281 Md. 432, 379 A.2d 1014 (1977).

The Fuscos countered, arguing that Dr. Trovato's testimony did meet *Sard's* criteria, and moreover, the "lack of clinical evidence regarding the use of Amifostine . . . in the treatment of prostate cancer in elderly patients . . . , the fact that Amifostine was not FDA-approved . . . and the knowledge of the then-known side effects of Amifostine amounted to a material risk such that a reasonable person in Mr. Fusco's position, having been fully informed, would have withheld consent to this form of treatment." They alleged, therefore, that a material dispute of fact existed as to whether Dr. Shannon had disclosed all material risks that rendered summary judgment inappropriate.

Judge Leo E. Green Jr. of the Circuit Court for Prince George's County decided

[16] The renewed motion for summary judgment was originally filed by the other two physicians that are not parties to this appeal. In a subsequent filing with the court, however, Dr. Shannon indicated that he was joining in the motion.

both motions and initially denied Dr. Shannon's renewed motion for summary judgment, but granted the motion in limine to exclude Dr. Trovato's *de bene essee* testimony. With respect to the latter, however, he left open the issue of whether Dr. Trovato could testify at trial. In so concluding, Judge Green reasoned that significant portions of Dr. Trovato's deposition were irrelevant and prejudicial in an informed consent case, because Dr. Trovato is not a medical doctor, did not address the standards of *Sard*, and his deposition addressed negligence rather than informed consent:

> The Court grants the motion for the following reasons. That's not to say I would exclude him at trial, okay. But the testimony as given gives a great indifference to relevance to the issue at hand. That is informed consent. Secondly, he doesn't testify as to the standard of an expert in an informed consent case. Third, there's no testimony in the transcript that's consistent with these standards. Four, his testimony is more in line in the totality when you take out all of the objections and everything else, testimony is more in line with negligence than that of informed consent. And as a result of this, it is more prejudicial than probative to the issue at hand. Lastly, but not - - and I use it as a last situation, is that he's a pharmacist, he's not a medical doctor. And he's not testifying with the five standards that are found in *Sard*. Information that must be communicated. The nature of the ailment. The nature of risk of a treatment. The probability of success. The frequency of occurrence of the risk. He never gets into that. Is it a Risk? Yes. But he doesn't give it and he doesn't testify as to what the available alternatives to the treatment are. He testifies as to the risk but he doesn't give a whole thing.
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> Now would he be - - he wouldn't be my choice of my main expert. And then again I'm not a Plaintiffs lawyer any more. But this is a tough call. As it in a totality counsel, right now, I'm not precluding you from calling him at trial, live and not memorex, so to speak.

With the possibility remaining that Dr. Trovato could testify at trial, Dr. Shannon requested his proffer, arguing "if he is going to remain consistent with his deposition testimony and his de bene esse deposition and there are no new opinions, then we would again move in

limine for him testifying at trial." Judge Green granted the request for a proffer, and thereafter, the Fuscos submitted a written proffer, stating Dr. Trovato would testify to, *inter alia*, the risk factors associated with Amifostine; that Amifostine has only been proven to benefit patients suffering from head, neck and kidney cancer; that the efficacy of Amifostine in treating prostate cancer was unknown; that the package insert cautions against use in elderly patients; that there are no other known alternatives to Amifostine, and that Amifostine was not approved by the Food and Drug Administration for the treatment of prostate cancer:

> 1. Dr. Trovato is an associate professor with the Department of Pharmacy Practice & Science at the University of Maryland School of Pharmacy and is the Director of the University's Residency program. Dr. Trovato is board certified in oncology pharmacy practice.
> 2. In addition to his teaching responsibilities, Dr. Trovato has a clinical practice which focuses on "insur(ing) appropriate or safe use of medication in oncology patients."
> 3. As a part of his teaching and clinical responsibilities, Dr. Trovato educates and advises patients on the appropriate and safe use of oncology medications, including the use of Amifostine. Dr. Trovato plays a pivotal role in educating patients and physicians about the risks and side effects of particular modes of treatment as well as the potential benefits of the treatment and, ultimately, in selecting said treatment. Dr. Trovato makes recommendations to the physicians and patients as to what drug therapy is best for each patient, and plays a direct role in obtaining informed consent from a patient.
> 4. Dr. Trovato will testify that the risk factors associated with Amifostine include nausea, vomiting, low blood pressure or hypotension, skin changes, allergic or immunologic reactions including a rash, hives, toxic necrolysis, and Stevens-Johnson Syndrome, fever, shortness of breath, and dizziness.
> 5. Dr. Trovato will testify that the most common risks of Amifostine are hypotension, nausea, vomiting and skin changes.
> 6. Dr. Trovato will explain the properties of Amifostine as a cytoprotective agent and how it is used to protect certain normal tissues from damage either from chemotherapy or from radiation therapy. Dr. Trovato will testify that

> Amifostine has been proven to provide this type of benefit to normal tissues in patients **only with head and neck cancer and kidney cancer**.
> **7.** Dr. Trovato will testify that it is unknown whether or not Amifostine protects the normal cells of a patient with prostate cancer.
> 8. Dr. Trovato will explain that there have only been phase I and phase II clinical trials relative to the administration of Amifostine in patients with prostate cancer. Therefore, he will testify that there is no medical literature or clinical trials that demonstrate the efficacy of Amifostine for treatment in prostate cancer, only its toxicity.
> 9. Dr. Trovato will testify that "the risks of using Amifostine in this particular patient (Mr. Fusco) outweigh the potential benefits ..." and "there is no evidence to support the benefit of Amifostine in this patient, but we do have evidence of the toxicities or adverse effects of this agent".
> 10. Dr. Trovato will testify that the package insert of Am.ifostine gives a precaution as to the administration of the drug to an elderly patient, like Plaintiff, because the toxic effects of the drug have not been tested on an elderly population.
> 11. Dr. Trovato will testify that the alternative to the administration of Amifostine is to refrain from its administration and treat solely with radiation therapy. He will further testify, based upon his experience in making treatment recommendations and engaging in the informed consent process with patients, that there is no detriment to advising the patient fully about the risks associated with this medication.
> 12. Dr. Trovato will testify that there are no known alternative cytoprotective agents for prostate cancer.
> 13. Dr. Trovato will testify about the approved FDA uses at the time that Amifostine was administered to Anthony Fusco.

(emphasis in original) (citations omitted).

After receiving the proffer, Judge Green notified the parties that he would not permit Dr. Trovato to testify at trial. Dr. Shannon then filed a second motion for summary judgment, arguing that, pursuant to *Sard*, expert testimony was required to establish the nature of the risks inherent in a particular treatment, the probabilities of therapeutic success, the frequency of the occurrence of the particular risks, and available alternatives, which were no longer available. At the hearing, the Fuscos opposed the motion,

contending that their claims could survive summary judgment because "there's really one person . . . , one doctor, who talks about the five factors more than anybody else and that's Dr. Shannon," and thus, they could read to the jury portions of Dr. Shannon's deposition in which he discussed, among other things, the risks of Amifostine and their likelihood of occurrence. Judge Green agreed that Dr. Shannon's deposition testimony did create a genuine dispute of material fact as to the materiality of the risks of Amifostine, stating "at this stage of the proceeding I do have some, there is in my view a dispute as to a material fact, i.e. is whether or not that's a material risk or not."

At the hearing, Judge Green also explained his reasons for precluding Dr. Trovato from testifying at trial. Initially, he referred to the Fuscos' allegation regarding the lack of informed consent regarding the "complete treatment plan" of radiation and Amifostine, about which Dr. Trovato, as a pharmacist, was not qualified to offer an opinion. Additionally, Judge Green noted that Dr. Trovato's testimony was not consistent with our opinion in *Sard*. He also noted that the proffered testimony of Dr. Trovato sounded in negligence and would, therefore, confuse the jury:

> And first and foremost, we must remember that this is a trial that does not have a negligence count. It has a simple count of a lack of informed consent. This is important in the Courts consideration. And the Court looks very carefully and has already given one opinion on this matter already.
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> And I adopt what I said earlier and will add to it today as for my reasons. I don't want to belabor the point but when I ended my opinion before, I looked at the question of what the status of Dr. Trovato was as to what he was. And he quite frankly, he's a pharmacist. He's not a medical doctor. And as such, when you look and you review of what, under Maryland Rule 5-701 and 5-702, what an expert is.

In this matter it is not just the sole issue of the medicines that were used. But it is a sole and complete treatment plan that is before the Court. It is not just that sole issue that we have before us. And remember is that the pharmacist is dealing only with a small part of the treatment plan, the medications. And that is where his expertise is. It's not in the complete treatment plan. So he only deals with medication.

There is an entirety to the informed consent and that is not just the medications, but the entire treatment. And as such, a pharmacist does not, in the Courts opinion, have the ability to give the full demarcation of what is involved in informed consent.

Quite frankly, he's never given an informed consent. He's not trained in informed consent. And he, quite frankly, he is very limited in what he does with patients. And the final call is not his. It is always the doctor. That's the way the medical system is set up.

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In these matters we have to look at what exactly it is that has to be testified to. And it said in the *Sard* case at page 447 "We are not to be holding as understood as holding however, that expert medical testimony can be dispensed with entirely in cases of informed consent. Such expert testimony would be required, one to establish the nature of the risk inherent in a particular treatment."

And that's key to me is treatment because it has to do with material risks that are involved. Two, "The probabilities of the therapeutic success." Again, the pharmacist is really only dealing with a small part of that.

* * *

Further I go back to the same things that I would say that I said before. And not in particular order is that testimony is more in line, after I read it, in negligence rather than informed consent. And therefore, would be prejudicial rather than probative to the trier of fact.

It would not - - I think in other ways it would confuse and disenchant the jury in their ability to determine what the doctrine of informed consent really is if they listen to this sole expert on pharmacology. The testimony that Dr. Trovato both in the proffer and in the *de bene esse* deposition touches upon the five criteria that I listed in *Sard* but doesn't completely analyze, completely give a completeness to what has to be done to this patient. That's another reason why I'm disallowing him.

And again I go back to the relevance of where that particular experts expertise is relevant but not material to the material risks that involved in this matter. So for these reasons and the reasons that I gave when we were before the Court on December 21, 2010, Court will disallow the testimony of James Trovato, a doctor of pharmacology, at trial for those reasons.

Just prior to opening statements, Dr. Shannon moved *in limine* to exclude the introduction into evidence of a package insert included with Amifostine, as well as any reference to the fact that the Food and Drug Administration had not approved Amifostine for treatment of prostate cancer patients, relying on our decision in *University of Maryland Medical System Corp. v. Waldt*, 411 Md. 207, 983 A.2d 112 (2009), to claim that, "to the extent that counsel intends to articulate what the approved FDA uses were for [A]mifostine, we would argue and ask that they be excluded in opening statements as irrelevant." Judge Green granted the motion *in limine*, but the two issues were resurrected when the Fuscos offered portions of Dr. Shannon's deposition in which he had responded to questions regarding the use of Amifostine for treatment of prostate cancer and its efficacy in an elderly population.[17] Dr. Shannon objected again and argued that *Waldt*

[17] The specific portions of Dr. Shannon's deposition pertaining to approved uses of Amifostine that Dr. Shannon objected to were:

> [COUNSEL FOR THE FUSCOS]: Do you know whether or not the FDA has approved Amifostine in the treatment of prostate cancer?
> [DR. SHANNON]: I do know.
> [COUNSEL FOR THE FUSCOS]: What is the answer to that question?
> [DR. SHANNON]: The indications are for conditions that don't include prostate cancer.
> [COUNSEL FOR THE FUSCOS]: Okay. So the FDA has not approved Amifostine as a drug for prostate cancer. I'm not saying it can't be used off label, but it's not a drug that the FDA has approved for that use, is that correct?
> [DR. SHANNON]: That's correct.

The relevant portions of Dr. Shannon's deposition related to the package insert were:

> [COUNSEL FOR THE FUSCOS]: Does the drug insert . . . indicate that this drug

precluded such evidence, with which Judge Green agreed. The jury returned a verdict in favor of Dr. Shannon, by answering that a reasonable person, having been informed of the material risks of Amifostine, would not have refused treatment.[18] The Fuscos filed a timely notice of appeal to the Court of Special Appeals, challenging the exclusion of Dr. Trovato's testimony, as well as evidence related to FDA approved uses of Amifostine and

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> should not be used on elderly patients because there has been inadequate clinical studies?
> [DR. SHANNON]: The drug insert indicates that there are several shoulds. Shoulds are not musts. We should run six times a day. That doesn't mean we're going to.
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> * * *
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> [COUNSEL FOR THE FUSCOS]: [D]id you advise him . . . [t]hat the drug manufacturer recommended that it not be used because it hasn't been fully tested on elderly patients yet?
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> * * *
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> [DR. SHANNON]: No, I didn't and there is additional reason why I don't. We are giving in terms of a dosage spectrum as we just spoke of we're really on the low end. . . .

[18] The jury answered "no" to the following question:

> Do you find by preponderance of the evidence that a reasonable patient, having been informed of the material risks and complications associated with Amifostine therapy, would have refused to consent to its use.

Other questions presented to the jury on the verdict sheet, that were not answered, were:

> Do you find by a preponderance of the evidence that Kevin Shannon, MD failed to obtain Anthony Fusco, Sr.'s informed consent as to Amifostine therapy?
>
> Do you find by preponderance of the evidence that Amifostine was a cause of injury to Anthony Fusco, Sr.?

the package insert.

In a reported opinion, the Court of Special Appeals reversed, concluding that the trial judge erred in excluding not only Dr. Trovato's testimony, but also references to the FDA-approved uses of Amifostine and the package insert. With respect to the issue of whether Dr. Trovato should have been permitted to testify, the intermediate appellate court opined that, "the issue is not whether Dr. Trovato was qualified to opine about Dr. Shannon's advisement to obtain informed consent, but whether he, as a pharmacist, was qualified to testify regarding Amifostine," *Fusco*, 210 Md. App. at 427, 63 A.3d at 161-62, and reasoned that Dr. Trovato was, because he had prior experience teaching and counseling patients regarding oncology medications, including Amifostine:

> Dr. Trovato testified that he had "counselled [sic] some patients on Amifostine. It was like a handful of cases . . . ." In appellants' proffer, they indicated that Dr. Trovato would have testified that "as part of his teaching and clinical responsibilities, [he] educate[d] and advise[d] patients on the appropriate and safe use of oncology medications, including the use of Amifostine." Although Dr. Trovato was not a medical doctor, he proffered that he was familiar with Amifostine therapy. Thus, we hold that the trial court abused its discretion in ruling that Dr. Trovato did not qualify as an expert witness on the issue.

*Id.* at 428, 63 A.3d at 162 (alterations in original). The intermediate appellate court, however, stated that, on remand, Dr. Trovato could not testify as to material risks and alternative treatment plans, because it would exceed the extent of his expertise:

> On remand, although Dr. Trovato indicated that he counseled and educated patients on the use of oncology medications, including Amifostine, informed consent encompasses more than the potential benefits and risks of Amifostine. There is an overall treatment plan, which the record indicated, including the patient's past medical, social, and family history, tobacco and

> alcohol intake, physical examinations, laboratory studies, anatomy demonstrations via diagrams and pictures, x-ray films, and lifestyle management, all of which are a part of a recommended course of treatment. Hence, we note that portions of Dr. Trovato's proffered testimony regarding informed consent were not admissible, as exceeding the scope of his expertise in an informed consent case. In that regard, Dr. Trovato's testimony regarding the nature of the material risks associated with the particular regimen of treatment provided to Mr. Fusco, and any alternative treatment options, would exceed the extent of Dr. Trovato's expertise relative to informed consent.

*Id.* at 437-38, 63 A.3d at 168.

The trial judge also erred, according to the Court of Special Appeals, in excluding evidence relating to the FDA's approved uses of Amifostine as well as the package insert that contained information regarding the use of Amifostine in elderly patients, explaining that, "this information could have been a material consideration regarding Mr. Fusco's decision whether to consent to the use of Amifostine." *Id.* at 436, 63 A.3d at 167.

Before us, Dr. Shannon contends that because Dr. Trovato is not a medical doctor and has never obtained a patient's informed consent, he is unable to offer an opinion as to whether Dr. Shannon breached his duty to warn Mr. Fusco about the material risks of Amifostine; even assuming Dr. Trovato was qualified to offer an opinion, he alternatively argues that Dr. Trovato's testimony focused on an inappropriate use of the drug, which, they contend, may be relevant in a negligence action, but not in an informed consent case. Dr. Shannon argues, moreover, that Judge Green properly excluded evidence pertaining to the package insert and FDA-approval status of Amifostine, because such evidence is not relevant in an informed consent cause of action.

The Fuscos disagree, contending that although Dr. Trovato is not qualified to offer an opinion as to whether Dr. Shannon breached his duty to inform Mr. Fusco of the material risks inherent in Amifostine therapy, he is qualified, as a pharmacist, to testify about the nature and frequency of the risks of Amifostine, probabilities of its success, and the available alternatives to the use of the drug, all of which, they argue, are relevant in an informed consent action. They assert, also, that Judge Green erred in excluding evidence pertaining to the package insert and the FDA-approval status of Amifostine, reasoning that such information is a necessary component of an informed consent discussion, because it is information that a reasonable person in Mr. Fusco's position would want to know.

We considered the doctrine of informed consent in the seminal case of *Sard*, 281 Md. 432, 379 A.2d 1014, in which a patient alleged that her surgeon failed to disclose to her the potential failure rate and alternative treatment options to a surgical sterilization procedure called a tubal ligation. The trial court had granted a motion for judgment at the end of the plaintiff's case, because it had concluded that a written consent form signed by the patient barred her recovery. In considering the propriety of the trial judge's decision, we elucidated the various elements of an informed consent cause of action, which, generally, include the duty to disclose to the patient material information that "a physician knows or ought to know would be significant to a reasonable person in the patient's position in deciding whether or not to submit to a particular medical treatment or procedure"; breach of that duty by failing to make an adequate disclosure; and that the breach was the proximate cause of the patient's injuries. *Sard*, 281 Md. at 444, 379 A.2d

at 1022.

In *Sard* we opined that informed consent is predicated on the notion that a patient has a right to exercise control over her own body. Because a patient, however, generally does not possess the expertise necessary to understand the consequences of submitting to a particular medical treatment, she, necessarily, relies on the physician for such information. Accordingly, the doctrine of informed consent imposes on a physician a duty to disclose material information that "a physician knows or ought to know would be significant to a reasonable person in the patient's position in deciding whether or not to submit to a particular medical treatment or procedure," *id.* at 444, 379 A.2d at 1022, including "the nature of the ailment, the nature of the proposed treatment, the probability of success of the contemplated therapy and its alternatives, and the risk of unfortunate consequences associated with such treatment." *Id.* at 440, 379 A.2d at 1020.

We then adduced the scope of a physician's duty, rejecting a standard embraced by some of our sister courts by which a physician must disclose information that is customarily disclosed by other physicians.[19] We, rather, adopted a more patient-oriented standard by which a physician must disclose "material risks", those risks "which a physician knows or ought to know would be significant to a reasonable person in the patient's position in deciding whether or not to submit to a particular medical treatment or procedure." *Id.* at 444, 379 A.2d at 1022. We further explained that, under the material risk standard, a physician is not "burdened with the duty of divulging *all* risks" of which he

[19] *See, e.g.*, *Roberts v. Young*, 119 N.W.2d 627, 630 (Mich. 1963).

knew or should have known, but rather, only those that are necessary to the rendering of an intelligent decision by a reasonable patient. *Id.* at 444, 379 A.2d at 1022 (emphasis in original).

In *Wilkinson v. Vesey*, 295 A.2d 676 (R.I. 1972), a case upon which we relied in *Sard* to define material risks, the Rhode Island Supreme Court identified two factors of significance in the discernment of what is a material risk, those being "the severity of the risk and the likelihood of its occurrence." *Id.* at 689. In *Sard*, we also consulted Jon R. Waltz & Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 NW. L. Rev. 628, 640-41 (1970), which described the material risk factors, stating:

> [T]he basic factors to be considered are the nature of the overall risk, its severity and its likelihood of occurrence. Each factor must be weighed in combination with the others to determine whether a particular risk is material and therefore subject to disclosure . . . .

*Id.* at 640-41. Many of our sister courts with the same patient-centric view of informed consent have embraced the same factors. *See, e.g.*, *Flatt v. Kantak*, 687 N.W.2d 208, 213 (N.D. 2004) ("The materiality of information about the risk of a potential injury is a function of the severity of the potential injury and of the likelihood it will occur."); *Feeley v. Baer*, 679 N.E.2d 180, 181 (Mass. 1997) ("The materiality of information about a potential injury is a function not only of the severity of the injury, but also of the likelihood that it will occur.", quoting *Precourt v. Frederick*, 481 N.E.2d 1144 (Mass. 1985)).

Since *Sard*, we have opined that, while a cause of action for informed consent

sounds in negligence, it is distinct from a medical negligence claim:

> In a count alleging medical malpractice, a patient asserts that a healthcare provider breached a duty to exercise ordinary medical care and skill based upon the standard of care in the profession, . . . while in a breach of informed consent count, a patient complains that a healthcare provider breached a duty to obtain effective consent to a treatment or procedure by failing to divulge information that would be material to his/her decision about whether to submit to, or to continue with, that treatment or procedure.

*McQuitty v. Spangler*, 410 Md. 1, 18-19, 976 A.2d 1020, 1030 (2009). Because the two causes of action are distinct, we have also opined, in *dicta*, that evidence that a medical procedure or treatment is contraindicated for a patient is not relevant in an informed consent action. In *Waldt*, the patient underwent a procedure to treat an aneurysm in her brain in which a device called a neuroform stent was used, which caused Mrs. Waldt to suffer a stroke. Mrs. Waldt and her husband filed an action against the surgeon based upon a lack of informed consent. In support of their claim, the Waldts offered a neuroradiologist as an expert witness, but the trial judge excluded him from testifying, because the neuroradiologist lacked sufficient evidence. On appeal, the Court of Special Appeals concluded that the propriety of the trial judge's decision to exclude the neuroradiologist from testifying was not preserved for appellate review pursuant to Rule 5-103,[20] because the only proffered testimony was that the stent had not been approved by

[20] Rule 5-103 provides in relevant part:

> **Rulings in evidence.**
>
> (a) **Effect of erroneous ruling.** Error may not be predicated upon a ruling that admits or excludes evidence unless the party is prejudiced by the ruling, and . . . (2) Offer of proof. In case the ruling is one excluding evidence, the substance of the

the Food and Drug Administration for the treatment of the type of aneurysm from which Mrs. Waldt had suffered. *Waldt v. Univ. of Maryland Med. Sys. Corp.*, 181 Md. App. 217, 261, 956 A.2d 223, 248 (2008).

We granted *certiorari* to consider, among other issues, whether the issue had properly been preserved for appeal. We then quoted with approval the Court of Special Appeals's opinion, in which our brethren had stated whether a procedure is contraindicated may be relevant in a negligence action to establish that a physician's conduct fell below the standard of care, but not relevant to a cause of action in informed consent:

> The Waldts' proffer was that Dr. Debrun would testify about the approved uses of the neuroform stent. The intermediate appellate court explained,
>
> > The excerpts from the record the Waldts argue constituted a proffer reveal that the only proffered (albeit vaguely) substantive testimony of Dr. Debrun was that the neuroform stent device was not approved for use on Mrs. Waldt's type of aneurysm. This is not a proffer of a risk inherent to the procedure that Mrs. Waldt underwent. It is a proffer of expert testimony that the procedure was contraindicated for Mrs. Waldt, and therefore should not have been performed on her. That expert testimony would be relevant to an ordinary negligence claim, *i.e.*, that the doctors breached the standard of care in their treatment of Mrs. Waldt by performing a contraindicated procedure on her. It is not relevant to an informed consent claim.

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> evidence was made known to the court by offer on the record or was apparent from the context within which the evidence was offered.

*Waldt*, 411 Md. at 235-56, 983 A.2d at 130, quoting *Waldt*, 181 Md. App. at 261–62, 956 A.2d at 248, 249. Affirming on procedural grounds, we agreed with the intermediate appellate court that the issue had not been properly preserved for appellate review because "no testimony was proffered concerning the material risks of the procedure that would make out a *prima facie* case for informed consent." *Id.*[21]

The issue queued up by the instant case is whether Dr. Trovato, a pharmacist, was qualified to testify in this informed consent action against Dr. Shannon. We begin by addressing the necessity of expert testimony in an informed consent action, specifically with respect to material risks, because we have not squarely addressed this issue in the past. In *Sard* we opined in *dicta* that, "[s]uch expert testimony would be required to establish the nature of the risks inherent in a particular treatment, the probabilities of therapeutic success, the frequency of the occurrence of particular risks, the nature of available

[21] In the wake of *Sard*, we have also determined that the choice of surgeon, *Dingle v. Belin*, 358 Md. 354, 749 A.2d 157 (2000), as well as that a surgeon is infected with the AIDS virus, *Faya v. Almaraz*, 329 Md. 435, 620 A.2d 327 (1993), may be material to the issue of informed consent. We also determined in *Goldberg v. Boone*, 396 Md. 94, 126-27, 912 A.2d 698, 717 (2006), that the availability of more experienced surgeons to perform a surgery than the treating physician, at least when the surgery is complex and the treating physician had only performed it three time previously, may be material information that needs to be disclosed.

In *McQuitty v. Spangler*, 410 Md. 1, 976 A.2d 1020 (2009), we held that lack of informed consent outside of a surgical context could be actionable. We reasoned that the gravamen of an informed consent claim is a violation of a physician's duty to communicate adequately with the patient so as to enable her to make an intelligent decision about whether to consent to treatment, and therefore, "requiring a physical invasion to sustain an informed consent claim contravenes the very foundation of the informed consent doctrine—to promote a patient's choice." *Id.* at 31, 976 A 2d at 1038.

alternatives to treatment and whether or not disclosure would be detrimental to a patient." *Sard*, 281 Md. at 448, 379 A.2d at 1024. Likewise, in *Waldt*, we opined, again in *dicta*, that, "[e]xpert testimony is necessary to establish the material risks and other pertinent information regarding the treatment or procedure", and observed that the Waldts had relied on the neurologist to establish the material risks of the neuroform stent procedure. *Waldt*, 411 Md. at 232, 983 A.2d at 127.

Although our pronouncements in *Sard* and *Wadt* were *dictum*, it is clear, nevertheless, that expert testimony is necessary to assist the trier of fact in understanding the severity and the likelihood of a risk so that the trier of fact may assess the material risks of the proposed treatment. Pursuant to Rule 5-702,[22] "[e]xpert testimony may be admitted, in the form of an opinion or otherwise, if the court determines that the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue." Likewise, in *Blackwell v. Wyeth*, 408 Md. 575, 971 A.2d 235 (2009), we opined, when "'complex medical issue[s]'" . . . are in question, we have required a specificity of

[22] Maryland Rule 5-702 provides in its entirety that:

> **Testimony by experts.**
> Expert testimony may be admitted, in the form of an opinion or otherwise, if the court determines that the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue. In making that determination, the court shall determine (1) whether the witness is qualified as an expert by knowledge, skill, experience, training, or education, (2) the appropriateness of the expert testimony on the particular subject, and (3) whether a sufficient factual basis exists to support the expert testimony.

knowledge, skill, experience, training, or education for qualification." *Id.* at 623, 971 A.2d at 264, quoting *In re Yve S.*, 373 Md. 551, 615-16 819 A.2d 1030, 1068 (2003). The likelihood that certain risks will occur when medicine is administered and the severity of such risks are complex medical matters that will generally fall outside the scope of lay knowledge, and thus, expert testimony is necessary to "assist the trier of fact . . . to determine a fact in issue", —the material risks of proposed medical treatment.[23] Rule 5-702.

Addressing whether a pharmacist, Dr. Trovato, is "qualified as an expert by knowledge, skill, experience, training, or education" under Rule 5-702 to opine regarding material risks of Amifostine, is, of course, our main inquiry. Dr. Shannon asserts that because Dr. Trovato is not a physician and has never obtained a patient's informed consent, he cannot opine as to what information needed to be disclosed before administering Amifostine. The Fuscos react negatively to this *per se* argument, alleging that Dr. Trovato was uniquely qualified to opine about the material risks of Amifostine.

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[23] Our sister courts utilizing the same patient-centric standard also have opined that expert testimony is necessary to define a material risk. *See, e.g.*, *White v. Leimbach*, 959 N.E.2d 1033, 1040 (2011), quoting *Univ. of Maryland Sys. Corp. v. Waldt*, 411 Md. 207, 232, 983 A.2d 112 (2009) ("[E]xpert testimony is necessary to establish the material risks . . . regarding the treatment or procedure."); *Thibodeaux v. Jurgelsky*, 898 So.2d 299, 314 (La. 2005) (noting that expert testimony is necessary to establish the risks, the harm, and the likelihood of occurrence); *Marsingill v. O'Malley*, 58 P.3d 495, 504 (Alaska 2002) (requiring expert testimony on the existence, nature, and likelihood of the risk to establish the material risks); *Flatt v. Kantak*, 687 N.W.2d 208, 213 (N.D. 2004) ("Expert testimony may be necessary under the lay standard, at least to establish the existence of a risk, its likelihood of occurrence, and the type of harm in question." (internal citations and quotations omitted)).

As a basis for excluding Dr. Trovato from testifying at trial, the trial judge opined that Dr. Trovato's expertise did not extend to the "complete treatment plan" involved in the treatment of Mr. Fusco's cancer:

> I looked at the question of what the status of Dr. Trovato was as to what he was. And he quite frankly, he's a pharmacist. He's not a medical doctor. And as such, when you look and you review of what, under Maryland Rule 5-701 and 5-702, what an expert is.
>
> In this matter it is not just the sole issue of the medicines that were used. But it is a sole and complete treatment plan that is before the Court. It is not just that sole issue that we have before us. And remember is that the pharmacist is dealing only with a small part of the treatment plan, the medications. And that is where his expertise is. It's not in the complete treatment plan. So he only deals with medication.

Apparently, in this determination, the trial court considered that Dr. Trovato would necessarily have to be qualified with respect to radiation therapy rather than just with the material risks of the administration of Amifostine, which was the foundation of the informed consent action against Dr. Shannon who was not responsible for the radiation therapy.

The Court of Special Appeals, on the other hand, opined that Dr. Trovato could qualify as an expert regarding the material risks of the administration of Amifostine and that he did offer such testimony. *Fusco*, 210 Md. App. at 428, 430, 63 A.3d at 162. We agree that Dr. Trovato may have been qualified to testify about the material risks of the administration of Amifostine, but disagree that he rendered such an opinion in his *de bene esse* deposition or in the proffer of his trial testimony.

In concluding that Dr. Trovato may have been qualified, we note that he stated in his

proffer and in his *de bene esse* deposition that he had substantial experience and knowledge pertaining to oncological medications. He testified in his *de bene esse* deposition that he taught and lectured to pharmacy students at the University of Maryland and also served as an "oncology clinical specialist" at the University of Maryland Greenebaum Cancer Center, in which he provided "direct patient care activities and other clinical services", including "rounding with the medical oncology team to help provide appropriate and safe use of medications, oncology related medications". He further explained:

> I also work with physicians, oncologists at the cancer center in terms of supportive care issues for oncology patients. So, oncology patients that develop complications related to oncology related treatments, chemotherapy, as well as complications related to the cancer itself. I do help to manage these complications, things, for example, like pain management . . . things like nausea/vomiting, I also provide a lot of education, patient education, educating patients on oncology related medications, educating patients on adverse effects of chemotherapy, I provide education to medical residents, pharmacy residents, physicians and nursing staff at the cancer center in terms of new oncology drugs. I also play a role in terms of the development of guidelines and policies and procedures related to oncology medication at the cancer center. I also do play a role in formulating addition of oncology related drugs at cancer center. So, in terms of reviewing literature and developing drug monographs and helping to develop guidelines for safe, appropriate use of oncology related medications.[24]

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[24] Dr. Trovato's subsequent written proffer similarly stated:

> 1. Dr. Trovato is an associate professor with the Department of Pharmacy Practice & Science at the University of Maryland School of Pharmacy and is the Director of the University's Residency program. Dr. Trovato is board certified in oncology pharmacy practice.
> 2. In addition to his teaching responsibilities, Dr. Trovato has a clinical practice which focuses on "insur(ing) appropriate or safe use of medication in oncology patients."
> 3. As a part of his teaching and clinical responsibilities, Dr.

Based on his qualifications, he was offered as an expert in "drug therapy, generally and specifically in drug therapy as it applies to oncology." Thereby he may have been qualified to testify about the likelihood and severity of risks caused by the administration of Amifostine.

In so concluding, we find succor in the decision of *Parker v. Harper*, 803 So.2d 76, 78 (La. Ct. App. 2001), in which the Louisiana intermediate appellate court reversed a trial court's grant of summary judgment in favor of a physician in an action alleging lack of informed consent for administration of the drug Dilantin for seizures. The plaintiff had contracted Stevens-Johnson Syndrome and alleged that the treating physician had failed to warn her of the material risks of Dilantin, including Stevens-Johnson Syndrome. *Id.* at 79. In opposition to the physician's motion for summary judgment, the plaintiff attached an affidavit of a pharmacist, who attested that Stevens-Johnson Syndrome, a potentially fatal disease, and other skin rashes were risks of Dilantin which occurred in two-to-five percent of its users. *Id.* at 84. The pharmacist's affidavit, the appellate court reasoned, was sufficient to provide the requisite expert testimony to establish the material risks of the drug. In addressing the pharmacist's qualifications under Article 702 of the Louisiana

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> Trovato educates and advises patients on appropriate and safe use of oncology medications, including the use of Amifostine. Dr. Trovato plays a pivotal role in educating patients and physicians about the risks and side effects of particular modes of treatment as well as the potential benefits of the treatment and, ultimately, in selecting said treatment.

Code of Evidence, [25] which stated that a witness may be qualified by "knowledge, skill, experience, training, or education," the court opined that he was qualified to offer an opinion about the risks, their nature, and the likelihood with which they occur:

> Though we recognize that he is not a neurologist, the potential development of Stevens-Johnson syndrome is not peculiar to the practice of neurology. Mr. Stewart does not need to have treated patients with neurological problems to discuss the frequency of risks associated with Dilantin. His opinions represent to this court that he is an "other qualified expert" with regard to drugs and potential reactions thereto and is capable of judging what risk exists, its nature, and the likelihood of its occurrence. There would be a serious question as to the sufficiency of Mr. Stewart's affidavit if he were opining regarding Dr. Harper's compliance with a neurologist's standard of care. However, we do not view his affidavit as being employed for this purpose.

*Id.* [26]

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[25] Louisiana Code of Evidence, Article 702 provides in its entirety:

> **Testimony experts.**
> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

[26] Dr. Shannon directs us to a number of cases relied upon by the Court of Special Appeals in which some of our sister states determined that a pharmacist or a pharmacologist was not qualified to testify against a physician in a negligence cause of action. *See Hollabaugh v. Arkansas State Med. Bd.*, 861 S.W.2d 317, 318 (Ark. Ct. App. 1993); *Chandler v. Koenig*, 417 S.E.2d 715, 716 (Ga. Ct. App. 1992); *Bell v. Hart*, 516 So.2d 562, 565 (Ala. 1987); *Rodriguez v. Jackson*, 574 P.2d 481, 486 (Ariz. Ct. App.1977). In all of these cases, however, our sister courts opined that the pharmacist was not qualified to testify about the *standard of care* in a negligence cause of action. As we have explained, negligence and informed consent are distinct causes of action, and moreover, Dr. Trovato was *not* testifying about whether Dr. Shannon's informed consent discussion fell below the standard of care. We, therefore, find these cases inapposite.

Accordingly, we reject Dr. Shannon's argument that a pharmacist is *per se* unqualified to testify in an informed consent action when a physician has been sued. Dr. Trovato was never offered as an expert to testify about the types of information Dr. Shannon had a duty to disclose to effectively obtain Mr. Fusco's informed consent, and thus, his lack of experience in obtaining informed consent is not a bar to his testimony in the instant case.[27] The relevant inquiry, rather, is whether Dr. Trovato had the requisite expertise to testify about the material risks of the administration of Amifostine; he did.

Despite agreeing with our intermediate appellate court that Dr. Trovato may have been *qualified* to testify about the material risks of the administration of Amifostine, we part ways with our brethren regarding whether Dr. Trovato's testimony addressed the material risks of the administration of Amifostine. The intermediate appellate court

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The Court of Special Appeals did, however, rely on a number of other negligence cases in support of its conclusion that Dr. Trovato was qualified to testify in this case. *See, e.g.*, *Sinkfied v. Oh et al.*, 495 S.E.2d 94, 95-96 (Ga. Ct. App. 1997); *Tidwell v. Upjohn Co.*, 626 So.2d 1297, 1300 (Ala. 1993). Because negligence and informed consent are two distinct causes of action, we do not, so as to avoid blurring the line between the two.

[27] Dr. Shannon's assertion that Section 3-2A-02(c)(1) of the Courts and Judicial Proceedings Article, Maryland Code (1974, 2013 Repl. Vol.), part of the Health Care Malpractice Claims Act, renders a pharmacist *per se* unqualified to testify in an informed consent action against a physician is without merit. Section 3-2A-02(c)(1) provides that "the health care provider is not liable for the payment of damages unless it is established that the care given by the health care provider is not in accordance with the standards of practice among members of the same health care profession". Dr. Shannon posits, therefore, that because Dr. Trovato is not a member of the same health care profession as Dr. Shannon, he is not qualified to testify as an expert. In this, Dr. Shannon conflates negligence with informed consent, thus blurring the distinction between these two causes of action.

emphasized that the proffer of Dr. Trovato's testimony expressed his opinion regarding the material risks of the administration of Amifostine:

> Dr. Trovato would testify regarding "the risk factors associated with Amifostine[,] includ[ing] nausea, vomiting, low blood pressure or hypotension, skin changes, allergic or immunologic reactions[,] including a rash, hives, toxic necrolysis, and Stevens–Johnson [S]yndrome, fever, shortness of breath, and dizziness." He would have opined concerning the properties of Amifostine as a cytoprotective agent, and how Amifostine therapy was only successful regarding patients diagnosed with head, neck, and kidney cancer, but not prostate cancer. Furthermore, Dr. Trovato would have asserted that the alternative to Amifostine was radiation therapy; and ". . . that the package insert of Amifostine [gave] a precaution as to the administration of the drug to an elderly patient, like [Mr. Fusco], because the toxic effects of the drug have not been tested on an elderly population."

*Id.* at 434-35, 63 A.3d at 166 (alterations in original).

We disagree that Dr. Trovato, in his *de benne esse* deposition or the proffer of his trial testimony, addressed the severity and the likelihood of the risks of the administration of Amifostine; rather, he opined in both only about the existence of risk:

> [COUNSEL FOR THE FUSCOS]: What are some of the risk factors that are - - what are the risk factors that are included in the drug insert that has been approved by the FDA?
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> * * *
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> [DR. TROVATO]: The most common clinical side effects do include nausea/vomiting, they include low blood pressure or hypotension, there are various skin reactions, such as cutaneous reactions associated with amifostine, some of these could be mild rash to, again, very severe skin eruptions, things that we mentioned like Stevens-Johnson, TEN, are side effects of amifostine. There also could be some central effects in terms of dizziness with amifostine. There could be some respiratory effects, shortness of breathe, for example. So, there's a variety of different systems that could be affected by amifostine. But, again, the more common ones include the skin changes and the nausea/vomiting and hypotension.
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> * * *
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> [COUNSEL FOR THE FUCSOS]: Could you explain to the ladies and

> gentlemen of the jury what Stevens-Johnson syndrome is?
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> * * *
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> [DR. TROVATO]:Stevens-Johnson Syndrome is basically a severe rash that forms on the patient's skin. So, that basically a skin eruption, presents as red, it could involve peeling of skin or itching.
> [COUNSEL FOR THE FUSCOS]: What is TEN?
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> * * *
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> [DR. TROVATO]: TEN stands for toxic epidermal necrolysis. So, it implies that the severity of the skin damage can progress to the point that the patient can experience necrosis, tissue - permanent tissue death of the skin, sloughing of the skin, and so forth due to that reaction.

In his written proffer, Dr. Trovato simply enumerated the myriad of risks associated with the drug:

> 4. Dr. Trovato will testify that the risk factors associated with Amifostine include nausea, vomiting, low blood pressure or hypotension, skin changes, allergic or immunologic reactions including a rash, hives, toxic necrolysis, and Stevens-Johnson Syndrome, fever, shortness of breath, and dizziness.
> 5. Dr. Trovato will testify that the most common risks of Amifostine are hypotension, nausea, vomiting and skin changes.

Because Dr. Trovato did not opine about the likelihood and severity of the risks implicated in the administration of Amifostine,[28] we cannot say that Judge Green abused his

[28] Severity and likelihood of risk are defined by the use of empirical data and are phrased in terms of statistical probability. Severity of illness is defined as "the degree of . . . risk of disease manifested by patients, based either on clinical data from the medical records or on hospital discharge/billing data." Stedman's Medical Dictionary 947 (28th ed. 2006). Likelihood, moreover, relates to the chance or probability that an injury or consequence will occur. *See Precourt v. Frederick*, 395 Mass. 689, 694-95, 481 N.E.2d 1144, 1148 (Mass. 1985) ("The materiality of information about a potential injury is a function not only of the severity of the injury, but also of the likelihood that it will occur. Regardless of the severity of a potential injury, if the probability that the injury will occur is so small as to be practically nonexistent, then the possibility of that injury occurring cannot be considered a material factor in a rational assessment of whether to engage in the activity that exposes one to the potential injury."); *see also Harbeson v. Parke Davis, Inc.*, 746 F.2d 517, 523 (9th Cir. 1984) (opining that testimony about empirical research that

discretion in excluding Dr. Trovato's testimony. [29]

We address, next, Judge Green's decision to exclude evidence pertaining to the package insert accompanying the Amifostine and evidence regarding the use of Amifostine in an off-label manner. Evidence pertaining to the package insert was offered three times, the first of which occurred with Dr. Trovato's *de bene esse* testimony in which he testified:

> [COUNSEL FOR RESPONDENT]: [D]oes the drug insert . . . speak to the use of amifostine in elderly patients?

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indicated that certain birth defects are two-to-three times more likely to occur in those taking the drug Dilantin supported the trial court's conclusion that the birth defect was a material risk); *Barcai v. Betwee*, 50 P.3d 946, 962-63 (Haw. 2002) (opining that expert testimony that the allegedly undisclosed risk manifested itself in one out of every eight thousand patients provided the necessary expert testimony regarding likelihood to submit the question of whether the undisclosed risk was material to the jury).

Dr. Trovato's testimony embraced only the relative terms of "most common," when he opined about which adverse effects were "most common," and "severe," when he described certain adverse effects as "very severe skin eruptions." The terms "most common" and "severe" are relative terms, lacking foundation in empirical research and definition in statistical realities. In this regard, we find helpful the Massachusetts Supreme Court's decision in *Precourt*, 481 N.E.2d at 1149, in which the court opined that expert testimony that the allegedly undisclosed risk of the drug Prednisone, aseptic necrosis, was "high," was "no evidence of the likelihood that a person would develop aespectic necrosis after taking Prednisone," because "'[h]igh' is a relative word. It could mean one in ten, but it could just as well mean one in a million."

[29] We also would note that, both Dr. Trovato's *de bene esse* testimony and written proffer pertained, primarily, to his opinion that Amifostine was inappropriately administered to Mr. Fusco, because of the fact that the FDA had not approved Amifostine to supplement treatment of undergoing radiation therapy for prostate cancer and that the package insert warned against use in an elderly population, because its effects were not yet known. As a basis for excluding Dr. Trovato's testimony, Judge Green reasoned that the testimony would confuse the jury because it sounded in negligence. We agree. As we explained, *supra*, informed consent and negligence are distinct causes of action and whether a treatment is contraindicated for a patient may be relevant evidence that the physician's actions in treating the patient fell below the standard of care, but it is not relevant in an informed consent action. *See Waldt*, 411 Md. at 236, 983 A.2d at 128-29.

* * *

> [DR. TROVATO]: Yes, it does speak to that.
> [COUNSEL FOR RESPONDENT]: What does it say relative to the use of amifostine in elderly patients?
>
> * * *
>
> [DR. TROVATO]: There's actually - - there's actually a precaution in the product package insert people with drug – amifostine studied in elderly patients who – should use precaution in those patients since we don't know what the effects might be in those patients.[30]

At trial, moreover, the Fuscos offered a copy of the package insert itself. In a dialogue with the judge, Dr. Shannon argued that the package insert was irrelevant, pursuant to our decision in *Waldt*, because it listed the approved uses of Amifostine, which, Dr. Shannon asserted were not relevant pursuant to *Waldt*. Judge Green agreed that *Waldt* precluded admission of the package insert, and the insert was never admitted into evidence.

Finally, the Fuscos sought to introduce Dr. Shannon's deposition testimony, in which he stated that he had not advised Mr. Fusco about warnings on the package insert pertaining to use in an elderly population:

> [COUNSEL FOR THE FUSCOS]: Does the drug insert . . . indicate that this drug should not be used on elderly patients because there has been inadequate clinical studies?
> [DR. SHANNON]: The drug insert indicates that there are several shoulds. Shoulds are not musts. We should run six times a day. That doesn't mean we're going to.
>
> * * *

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[30] The subsequent written proffer similarly stated:

> 10. Dr. Trovato will testify that the package insert of Amifostine gives a precaution as to the administration of the drug to an elderly patient, like Plaintiff, because the toxic effects of the drug have not been tested on an elderly population.

> [COUNSEL FOR THE FUSCOS]: [D]id you advise him . . . [t]hat the drug manufacturer recommended that it not be used because it hasn't been fully tested on elderly patients yet?
>
> * * *
>
> [DR. SHANNON]: No, I didn't and there is additional reason why I don't. We are giving in terms of a dosage spectrum as we just spoke of we're really on the low end. . . .

Again, relying on *Waldt*, Judge Green excluded such testimony.

Dr. Shannon contends that evidence pertaining to the package insert was properly excluded, because Dr. Trovato testified about the warnings only in support of his ultimate conclusion that Amifostine was inappropriately *used*, and thus, the testimony sounded in negligence, and was, therefore, irrelevant. The Fuscos disagree, arguing that the warnings in the package insert "could have been a material consideration regarding Mr. Fusco's decision whether to consent to the use of Amifostine." Dr. Shannon counters, arguing that there was no expert testimony or evidence adduced that the insert's warning was a "material risk" of the administration of Amifostine, and therefore, there was no evidentiary basis from which a jury could conclude that the insert's warnings required disclosure.

Our intermediate appellate court agreed with the Fuscos, citing our decision in *Nolan v. Dillon*, 261 Md. 516, 276 A.2d 36 (1971) and decisions from other courts in which package inserts have been admitted in negligence cases, to conclude that this information could have been material to Mr. Fusco's decision to consent to the use of Amifostine. *See Fusco*, 210 Md. App. at 431-32, 63 A.3d at 167.

We disagree with the Court of Special Appeals and agree with Judge Green that, based on *Waldt*, evidence regarding the package insert, which pertained solely to the fact

that it warned against use in an elderly population, was properly excluded. In *Waldt*, in *dicta*, we cited with approval language from the intermediate appellate court that had opined that, whether a procedure or treatment is contraindicated is relevant and admissible evidence in a negligence cause of action, but not in informed consent case. Although it was *dicta*, our pronouncement finds support in our jurisprudence. In *McQuitty*, we elucidated the distinction between negligence and informed consent; in a negligence cause of action, the relevant inquiry is whether the physician "breached a duty to exercise ordinary medical care and skill based upon the standard of care in the profession," whereas, in an informed consent cause of action, the focal point is whether the physician made an adequate disclosure of information regarding the procedure or treatment. *McQuitty*, 410 Md. at 18-19, 976 A.2d at 1030. With regard to the administration of pharmaceutical drugs, one commentator has observed, "[a] typical medical malpractice claim in the prescription drug realm would deal with the administration of the wrong medicine, the incorrect dosage, or some other similar error. Negligence under informed consent, by contrast, is based on the theory that the patient was not apprised of all material risks, and was therefore unable to properly consent to the administration of drugs". John G. Culhane et al., *Toward a Mature Doctrine of Informed Consent: Lessons From A Comparative Law Analysis*, 1 Brit. J. Am. Legal Stud. 551, 567 (2012). The package insert's warning, which suggested that Amifostine should not be administered to an elderly patient, may have supported a claim of negligence in the administration of the drug to Mr. Fusco.[31]

[31] We note, in this regard, that the Court of Special Appeals relied only on

We address, finally, Judge Green's decision to exclude evidence regarding the FDA-approved uses of Amifostine. The issue was first presented in Dr. Trovato's *de bene esse* deposition, in which he testified:

> [COUNSEL FOR RESPONDENT]: Let's go back and clear this up. Did the FDA approve the use for amifostine in the treatment of cancer?
>
> * * *
>
> [DR. TROVATO]: Yes, the FDA did do so.
>
> [COUNSEL FOR RESPONDENT]: What is the FDA approved use of

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negligence cases to support its conclusion that evidence regarding the package insert was admissible in an informed consent case. *See Fusco v. Shannon*, 210 Md. App. 399, 431-33, 63 A.3d 145, 164-65 (2013). In *Nolan*, the plaintiff filed a negligence cause of action against a physician after an injection of a drug called Sparine allegedly caused portions of three of the plaintiff's fingers to become gangrenous and later amputated. The trial judge gave a jury instruction that the jury was permitted to consider warnings and other information contained in the package insert as evidence of whether the treating physician fell below the standard of care. We granted *certiorari*, to consider, *inter alia*, whether the instruction was proper. We concluded that the package insert of a drug "does not standing alone establish a standard of care," but rather, was "prime facie proof of proper use," and thus, concluded that the jury instruction was "quite proper." *Nolan v. Dillon*, 261 Md. 516, 540, 276 A.2d 36, 49 (1971). In the other cases cited by the intermediate appellate court relative to the package insert, many of our sister courts also opined that the package insert is relevant and admissible in a negligence case as to the standard of care. *See Garvey v. O'Donoghue*, 530 A.2d 1141, 1146 (D.C. 1987) (opining that package inserts of medication "are relevant and probative evidence of the medical standard of care for selecting, administering, and monitoring the drug"); *Thompson v. Carter*, 518 So.2d 609, 613 (Miss. 1987) ("[T]he package insert . . . should not be taken as conclusive evidence of the physician's standard of care, nor should a departure from the directions contained in the package insert be considered to establish a prima facie case of negligence. However, . . . the package insert contains prima facie proof of the proper method of use . . . and, for those purposes, was admissible at trial."); *Rodriguez*, 574 P.2d at 486 ("While the package insert is admissible into evidence, it does not establish conclusive evidence of the standard or accepted practice in the use of the drug by physicians and surgeons, nor that a departure from such directions is negligence."). As these cases clearly demonstrate, the package insert's warnings are relevant evidence as to whether the treating physician's conduct fell below the standard of care in prescribing or administering medication, an issue of no relevance in an informed consent action.

amifostine in the treatment of cancer?

* * *

[DR. TROVATO]: There are only two FDA approved indications for amifostine. One of them is to decrease the risk of nephrotoxicity or kidney toxicity in patients receiving specifically cisplatin, which is therapy agent, that was approved in ovarian cancer patients. It's also approved for use in head and neck cancer patients receiving radiation therapy to protect their prod glands, you know, from – basically, the end result is to prevent dry mouth in patients receiving radiation therapy to their head and neck.
[COUNSEL FOR RESPONDENT]: Is there any FDA approved usage of amifostine for prostate cancer?

* * *

[DR. TROVATO]: There is no FDA approved indication for use of amifostine in prostate cancer.[32]

The issue of FDA-approval then was resurrected when the Fuscos sought to introduce the deposition testimony of Dr. Shannon at trial, in which he had testified that he was aware that Amifostine was not approved by the FDA for the treatment of prostate cancer patients:

[COUNSEL FOR THE FUSCOS]: Do you know whether or not the FDA has approved Amifostine in the treatment of prostate cancer?
[DR. SHANNON]: I do know.
[COUNSEL FOR THE FUSCOS]: What is the answer to that question?
[DR. SHANNON]: The indications are for conditions that don't include prostate cancer.
[COUNSEL FOR THE FUSCOS]: Okay. So the FDA has not approved Amifostine as a drug for prostate cancer. I'm not saying it can't be used off label, but it's not a drug that the FDA has approved for that use, is that correct?
[DR. SHANNON]: That's correct.

As with the package insert, Judge Green relied on *Waldt* to determine that such evidence was not admissible.

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[32] Dr. Trovato's written proffer similarly stated that "Dr. Trovato will testify about the approved FDA uses at the time that Amifostine was administered to Anthony Fusco."

The parties advance similar arguments pertaining to the admissibility of Amifostine's FDA-approval status as they did to the package insert. Dr. Shannon asserts that the FDA-approval status was only offered in support of Dr. Trovato's opinion that Amifostine was inappropriately *used*, and thus, sounded in negligence and argues, moreover, that pursuant to our decision in *Waldt*, FDA-approval status is irrelevant in an informed consent cause of action. As with the warnings in the package insert, the Fuscos contend that the regulatory status of a drug may be material information that a reasonable patient would want to know prior to consenting to treatment. The Court of Special Appeals agreed that FDA-approval or lack thereof could have been a material consideration to Mr. Fusco's decision to consent to treatment involving the administration of Amifostine. *Fusco*, 210 Md. App. at 436, 63 A.3d at 167.

As we have explained, our decision in *Waldt* was based on the procedural inadequacy of the proffer of expert testimony, and thus, language quoted from our intermediate appellate court, which opined that the FDA-approval status is not relevant in an informed consent cause of action, is *dicta*. In *Waldt*, we quoted the following language from our intermediate appellate court:

> The excerpts from the record the Waldts argue constituted a proffer reveal that the only proffered (albeit vaguely) substantive testimony of Dr. Debrun was that the neuroform stent device was not approved for use on Mrs. Waldt's type of aneurysm. This is not a proffer of a risk inherent to the procedure that Mrs. Waldt underwent. It is a proffer of expert testimony that the procedure was contraindicated for Mrs. Waldt, and therefore should not have been performed on her. That expert testimony would be relevant to an ordinary negligence claim, *i.e.*, that the doctors breached the standard of care in their treatment of Mrs. Waldt by performing a contraindicated procedure

on her. It is not relevant to an informed consent claim.

*Waldt*, 181 Md. App. at 236, 956 A.2d at 248. Although *dicta*, as we opined earlier, we find the language persuasive and consistent with our informed consent jurisprudence.

In the context of medical devices, many of our sister courts have opined that the FDA-regulatory status is not relevant to an informed consent cause of action. *See, e.g.*, *Blazoski v. Cook*, 787 A.2d 910, 913 (N.J. Super. 2002); *Alvarez v. Smith*, 714 So.2d 652, 653 (Fla. Dist. Ct. App. 1998). Indeed, in the instant case, although our intermediate appellate court determined that the FDA-approval status is a pertinent part of an informed consent discussion, it cited to only one case that considered the relevance of the FDA's regulatory status in an informed consent cause of action that came to the opposite conclusion, *Southard v. Temple University Hospital*, 781 A.2d 101, 102 (Pa. 2001), in which the Supreme Court of Pennsylvania considered "the issue of whether the doctrine of informed consent requires surgeons to advise their patients of the Food and Drug Administration's . . . regulatory status of a medical device." In concluding that no such obligation exists, the Pennsylvania court reasoned:

> The category into which the FDA places the device for marketing and labeling purposes simply does not enlighten the patient as to the nature or seriousness of the proposed operation, the organs of the body involved, the disease sought to be cured, or the possible results. The FDA administrative label does not constitute a material fact, risk, complication or alternative to a surgical procedure. It follows that a physician need not disclose a device's FDA classification to the patient in order to ensure that the patient has been fully informed regarding the procedure.

*Id.* at 107 (citation omitted). Although addressing the regulatory status of a surgical

device, the Supreme Court of Pennsylvania's reasoning is equally applicable to the regulatory status of a drug; it also is not a "material fact, risk," or "complication" of a drug.

The Fuscos argue, however, that simply because the FDA-status is not a "risk," such as nausea and vomiting, it is nonetheless relevant, because in Maryland, physicians are required to disclose "other pertinent information regarding the treatment or procedure". Likewise, the intermediate appellate court opined:

> Although "patients generally do not base their decision to purchase a prescription medication on the instructions for its consumption or use or any information contained in the informational pamphlet accompanying the prescription drug." *Rite Aid Corp. v. Levy–Gray*, 391 Md. 608, 640, 894 A.2d 563 (2006) (Harrell, J., dissenting), we disagree with our sister states, and perceive that this information could have been a material consideration regarding Mr. Fusco's decision whether to consent to the use of Amifostine. *See Waldt II*, 411 Md. at 241, 983 A.2d 112 (Adkins, J., dissenting) (stating, "[i]nformation about the lack of FDA approval is something that a patient could reasonably want to consider in deciding whether to place her confidence and trust in [his or] her physician about the treatment [he or] she is about to undertake.").

*Fusco*, 210 Md. App. at 436, 63 A.3d at 167 (footnote omitted) (alterations in original).

A review of the "other pertinent information" that we have determined may require disclosure as part of an informed consent discussion, however, reveals that this information is limited to that which, in some way, will impact the medical treatment. *See, e.g.*, *Faya v. Almaraz*, 329 Md. 435, 448-50, 620 A.2d 327, 334 (1993) (opining that a surgeon may need to disclose his HIV-status as part of an informed consent discussion, because, *inter alia*, it was foreseeable that the physician might transmit the HIV virus to the patient during surgery); *Dingle v. Belin*, 358 Md. 354, 370-71, 749 A.2d 157, 165-66

(2000) (opining that the identity of the physician who will be performing a surgery may require disclosure as part of an informed consent discussion); *Goldberg v. Boone*, 396 Md. 94, 125-27, 912 A.2d 698, 717 (2006) (opining that that the availability of more experienced surgeons to perform a surgery than the treating physician, at least when the surgery is complex and the treating physician had only performed it once in the previous three years, may be material information that needs to be disclosed).

Information pertaining to an "off-label" use provides the patient with no information about the treatment itself. As the Pennsylvania court recognized in *Southard*, "'[t]he mere fact that the FDA has not cleared a product for a particular use does not mean that the product is not in fact suitable for that purpose; it simply means that the FDA has not cleared it.'" *Southard*, 781 A.2d at 107, quoting *Holland v. Smith & Nephew Richards, Inc.*, 100 F.Supp.2d 53 (D. Mass. 1999). Because it provides no information regarding the medical treatment, it cannot, therefore, be considered material information to an informed consent discussion.[33] We note, finally, with respect to this issue, that the FDA-approval status does not provide any information regarding the materiality of the risks of the administration of Amifostine; it does not inform the fact-finder of the likelihood or severity of any risk.

Having concluded that Judge Green did not abuse his discretion in excluding Dr.

[33] Having determined that the FDA-approval status of a drug need not be a necessary part of an informed consent discussion, we find no merit to the Fuscos' contention that, because Dr. Shannon testified in his deposition that he advised Mr. Fusco that the drug was being prescribed in an off-label manner, its FDA-status was necessarily relevant evidence.

Trovato's testimony nor in excluding evidence related to the package insert or the FDA-approval status of Amifostine, we reverse the judgment of the Court of Special Appeals and affirm the judgment of the Circuit Court.

**JUDGMENT OF THE COURT OF SPECIAL APPEALS REVERSED; CASE REMANDED TO THAT COURT WITH INSTRUCTIONS TO AFFIRM THE JUDGMENT OF THE CIRCUIT COURT FOR PRINCE GEORGE'S COUNTY. COSTS TO BE PAID BY RESPONDENT.**

Circuit Court for Prince George's County
Case No. CAL-07-11137
Argued: February 7, 2014

IN THE COURT OF APPEALS OF MARYLAND

No. 57

September Term, 2013

KEVIN J. SHANNON, et al.
v.

MAFALDA FUSCO, et al.

Barbera, C.J.
Harrell
Battaglia
Greene
Adkins
McDonald
Eldridge, John C. (Retired, Specially Assigned),

JJ.

Dissenting Opinion by Eldridge, J.

Filed: April 24, 2014

I dissent. *See Univ. of Md. Medical Systems Corp. v. Waldt*, 411 Md. 207, 238-242 (Adkins, J., dissenting), 250 (Raker, J., joined by Eldridge, J., dissenting), 983 A.2d 112, 130-133, 138 (2011).