2013 WL 7089298 (Md.) (Appellate Brief)
Maryland Court of Appeals.

Kevin J. SHANNON, M.D., et al., Petitioners,
v.
Mafalda FUSCO, et al., Respondents.

No. 57.
September Term, 2013.
October 15, 2013.

On appeal from the Court of Special Appeals of Maryland (No. 2819, Sept. 2010 Term)

Petitioners' Brief

Robert J. Farley, Esq., Michelle R. Mitchell, Esq., Wharton, Levin, Ehrmantraut & Klein, P.A., 104 West Street, Annapolis, Maryland 21404, (410) 263-5900, rjf@wlekn.com, mrm@wlekn.com, Counsel for Petitioners.

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*1 STATEMENT OF THE CASE

This appeal arises from a medical malpractice action filed against Kevin J. Shannon, M.D., Hematology-Oncology Consultants, (hereinafter Petitioners or "Dr. Shannon"), Walid Mufarrij, M.D., and Lawrence Shombert, M.D. based on medical care provided to then eighty-three (83) year-old Anthony Fusco in 2003. Dr. Mufarrij was Mr. Fusco's urologist, directing treatment options for his prostate cancer. Dr. Shombert was Mr. Fusco's radiolgic-oncologist and Dr. Shannon was Mr. Fusco's hematologic-oncologist. The allegations against all physicians sounded in lack of informed consent only. No allegations of medical negligence were waged against any of these providers.

Respondents identified two expert witnesses in an effort to support their lack of informed consent claim against the Petitioners and other physicians: Dr. Al-Ibrahim, an infectious disease physician, and James Trovato, a pharmacist. Dr. Trovato's trial testimony was conducted via videotaped de bene esse deposition on November 30, 2009. [E.132-162]. Shortly thereafter, Petitioners filed a Motion in Limine to Exclude James Travato's Testimony at Trial. [E.110-178]. The basis for that Motion was essentially twofold: First, Dr. Trovato was a pharmacist, not a physician, and accordingly, was not qualified to offer opinions about what a physician was required to advise a patient to obtain informed consent. Second, Dr. Trovato's de bene esse testimony offered criticisms sounding in standard of care (i.e., whether it was appropriate to use Amifostine), not as to informed consent (i.e., whether the appropriate information about the risks, benefits and alternatives to Amifostine were provided to the patient). The trial court granted Petitioners Motion in Limine and precluded Respondents from utilizing James Trovato's testimony at trial.

Petitioners also filed a Renewed Motion for Summary Judgment on the basis that Respondents failed to adduce the requisite evidence to establish that the risk of ***2** Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis Syndrome (TENS) [1]

was a material risk to the use of Amifostine requiring a physician to disclose this information for purposes of informed consent. Without such evidence, Petitioners maintained that they were entitled to summary judgment on the lack of informed consent claim as a matter of law. The trial court denied Petitioners Motion for Summary Judgment on December 21, 2010. [E.534]. Accordingly, this matter proceeded to trial before a jury from January 10 - January 19, 2011.

On January 19, 2011, the jury returned a verdict in favor of Petitioners. [E.1713-1714]. Specifically, the jury unanimously concluded that a reasonable patient, having been informed of the material risks and complications associated with Amifostine would not have refused to consent to its use. [2] *Id.* Respondents filed a timely notice of appeal to the Court of Special Appeals, and Petitioners filed a conditional Cross-Appeal. The following questions were presented to the Court of Special Appeals for consideration: (a) whether the trial court properly precluded James Trovato's testimony at trial; (b) whether the trial court properly precluded reference to FDA approval and use of the drug's package insert at trial; and on cross-appeal, (c) whether the trial court erred in denying Petitioners' Motion for Summary Judgment given Respondents' failure to adduce evidence that the "material risks" were not disclosed to Mr. Fusco.

***3** On March 20, 2013, the Court of Special Appeals reversed the judgment in Petitioners' favor in a reported opinion captioned, Fusco v. Shannon, 210 Md. App. 399, 63 A.3d 145 (2013). [Apx. 003-037]. A timely Petition for Writ of Certiorari was filed. Having established good cause for this Court's review and consideration of the intermediate court's opinion, this Court granted certiorari on July 3, 2013, and the following issues are now presented for consideration:

STATEMENT OF QUESTIONS PRESENTED ON APPEAL

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.

Whether the trial court properly exercised its broad discretion in precluding the use of, or reference to, the drug package insert and FDA approval, and whether the Court of Special Appeals' decision holding otherwise was error.

Whether the trial court erred in denying Petitioners' Motion for Summary Judgment and/or whether the trial court erred in denying Petitioners' Motions 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.

STATEMENT OF FACTS

A. Pertinent Medical Treatment

Petitioner Dr. Shannon first saw the decedent, Mr. Fusco, on March 12, 2003. At that time, Mr. Fusco was approximately 83 years old and was in early stage localized prostate cancer, Tic with a Gleason score of 6. Mr. Fusco's prostate cancer had been diagnosed by a Dr. Kumar in 2001, and at that time Mr. Fusco opted for "watchful waiting." Apparently, it was Mr. Fusco's discomfort with this "watchful waiting" strategy that ultimately led him to discuss alternative avenues with Drs. Mufarrij and Shombert, his urologist and radiologic-oncologist, respectively.

According to Dr. Mufarrij's office note of February 21, 2003, Mr. Fusco and his family "did not feel comfortable with watchful waiting" and were therefore provided three options: 1) continue watchful waiting; 2) hormone therapy with ***4** radiation; or 3) hormone therapy without radiation. Mr. Fusco opted for the hormone therapy with radiation.

Co-defendant Dr. Shombert was Mr. Fusco's treating radiation-oncologist; after discussions with Mr. Fusco about radiation therapy, Dr. Shombert referred Mr. Fusco to Dr. Shannon at Hematology-Oncology Consultants, P.A., for additional discussions regarding a supplemental medication regimen commonly utilized for patients undergoing radiation; specifically, Amifostine therapy (also known as Ethyol). [E.1428]. During his visit with Dr. Shannon, Mr. Fusco was educated about how, in an effort to counter cancer, radiation also can collaterally attack non-cancerous elements of the body's immune system. [E.1413-15]. Thus, cancer patients are often prescribed a "radiation-protectan" such as Amifostine, as a prophylactic against collateral damage to the body's healthy structures. [E.1419-20]. During this discussion, in which Dr. Shannon utilized explanatory diagrams and photographs, Mr. Fusco was advised of the potential side effects of the radiation protectant medication. [E. 1444-45]. Dr. Shannon discussed with the patient that Amifostine needed to be given every day prior to radiation, [E. 1424-25], and advised that the material risks to this medication included the nausea, lowering of blood pressure, and dermatologic reactions. [E. 1438-39, 1445][Apx.001-002].

Ultimately, Mr. Fusco underwent approximately 23 treatments with Amifostine between April 15 and May 16, 2003. During these treatments, Mr. Fusco was seen by Petitioners and Dr. Shombert. Following a course of Amifostine treatment on May 16, 2003, Mr. Fusco presented to Doctors Hospital with an acute rash on May 17, 2003. Dr. Shannon examined Mr. Fusco at the hospital and believed that the decedent's acute rash may have been caused by Amifostine. Accordingly, he recommended that antihistamines and other various medications be given to counteract the allergic reaction.

Ultimately, Mr. Fusco was transferred to Bayview on May 20, 2003, for treatment of his dermatologic problems, which advanced to a rare condition known as Stevens Johnson Syndrome and Toxic Epidemal Necrolysis (TENS). Mr. Fusco ***5** recovered from TENS and was discharged to Magnolia Nursing Home in August, 2003.

Although Mr. Fusco's dermatologic problems resolved, [E.1327, 1331], Mr. Fusco was admitted to Doctors Hospital with respiratory problems in late October, 2003. Despite efforts to improve Mr. Fusco's respiratory distress over the ensuing weeks, he developed and succumbed to a stroke on December 4, 2003. [E.1330]. No autopsy was performed on Mr. Fusco, nor requested by Respondents; accordingly, the precise cause of death was never determined.

B. Respondents' Lack of Informed Consent Claim

Respondents filed this lawsuit against Petitioners (and his other healthcare providers) alleging that Petitioners failed to appropriately advise Mr. Fusco of the material risks, benefits and alternatives to Amifostine in Mr. Fusco's cancer treatment regimen, and failed to obtain the requisite informed consent of Mr. Fusco.

The following point is significant to this Court's evaluation of the issues on appeal, just as it was significant to the lower court: Respondents waged no complaints or causes of action sounding in medical negligence against Dr. Shannon. Meaning to say, there were no allegations that Dr. Shannon's (or Dr. Shombert's) recommendation to use Amifostine in Mr. Fusco's treatment plan was inappropriate or a breach in the standard of care. Respondents' claims were limited exclusively to lack of informed consent.

C. Respondents' Pharmacists' Testimony

As summarized above, Petitioners identified two expert witnesses in this matter. An infectious disease expert, Dr. Mohamed A1-Ibrahim, was identified to testify as to issues of causation only. [E.85]. Specifically, Dr. Al-Ibrahim was identified to testify that the Amifostine taken in May 2003 caused Mr. Fusco's death from pneumonia approximately seven months later (and four months post-recovery from TENS). [E.86]. He provided no opinions as to lack of informed consent issues.

***6** Respondents also identified a pharmacist, [3] James Trovato, to testify as to "whether the use of Amifostine was appropriate in the care and treatment of Anthony Fusco." [E.86]. Similarly, Dr. Trovato's discovery deposition confirmed that his opinions were confined to the belief that "the use of Amifostine for this patient, I feel is not justified or inappropriate." [E.402].

In lieu of appearing live at trial, Dr. Trovato's testimony was taken via de bene esse on November 30, 2009. At this de bene esse, both Dr. Trovato's qualifications to testify regarding a physician's informed consent process, as well as the substance of Dr. Trovato's opinions were challenged. Additionally, Petitioners objected to Dr. Trovato's use of a package insert from another manufacturer of Amifostine, as well as reference to literature on Amifostine clinical trials and FDA approval. A pertinent summary of his testimony is provided herein:

1. *Dr. Trovato's (lack of) qualifications*

Dr. Trovato is not a physician. [E.140]. He did not attend medical school. Rather, he received his doctorate in pharmacy. [E.137]. Dr. Trovato did not complete a Residency or Fellowship, as Dr. Shannon did. [E.1391-92]. He is not board certified in Internal Medicine, as Dr. Shannon is. [E.140][E.1391-92]. He did not take additional specialized training to become board-certified in Hematology, as Dr. Shannon did. Id. He did not take additional specialized training to become board-certified in Oncology, as Dr. Shannon did. Id.

Dr. Trovato is not licensed to practice medicine. [E.139]. He does not have privileges at any hospital, he cannot admit patients to the hospital, and he cannot prescribe medications. [E.140]. He has never sat down with a patient and written a prescription for medication at any time. [E.143]. Dr. Trovato does not diagnose ***7** patients, and the ultimate therapy determined for a patient is up to the medical physician. [E.143]. He conceded that his “involvement” with patients is solely one of collaborating with the physician about medication options. [E.143]. He has never used and never administered an injection to a patient, and certainly never used or administered Amifostine. [E.143].

Dr. Trovato has never obtained a patient's consent to treatment, and in particular, to the use of Amifostine. [E.157, 160]. Dr. Trovato does not have a separate office where he actually sees patients in an office setting for purposes of rendering care, treatment and medical management. [E.156]. Dr. Trovato has never been in attendance at any session or meeting between a medical doctor, like Dr. Shannon, where that medical doctor has sought to obtain a consent from a patient regarding the use of Amifostine. [E.157]. In fact - he has never, in his career, been asked for his opinion as to whether Amifostine was appropriate for the use in any patient. [E.158]. Dr. Trovato conceded that he did not know the potential benefits to the drug in a patient like Mr. Fusco. [E.160]. Most notably, when asked whether he understood the term “material risks” - Dr. Trovato responded that he did not. [E.143].

2. *Dr. Trovato's opinions were unrelated to informed consent.*

In addition to Dr. Trovato's lack of qualifications to testify as to informed consent, the substance of Dr. Trovato's testimony (both in deposition and in his videotaped trial testimony) was irrelevant given that Dr. Trovato's opinions centered on the ***inappropriate use of Amifostine rather than the inadequate information*** provided to the patient about Amifostine.

Notably, Dr. Trovato explicitly affirmed the purpose of his testimony at the inception of his de bene esse deposition: “my understanding is that I'm here to testify as to the appropriate use of Amifostine in this case.” [E.139] This was the precise explanation that he previously provided about the substance of his opinions in his discovery deposition: “My opinions in terms of the use of Amifostine for this patient, I feel is not justified or inappropriate. Again, Amifostine in terms of how it's being used in this patient's case, this specific patient's case. That's my opinion.” [E.402]. ***8** Accordingly, nothing changed over the course of discovery vis-a-vis Dr. Trovato's opinions: his criticisms related to the use of the drug as opposed to the information conveyed about the drug.

During the course of the video-taped trial testimony, the focus of Dr. Trovato's testimony was on the inappropriate use of Amifostine. In support of those opinions, Dr. Trovato discussed the FDA approval process relating to drugs, how clinical trials are utilized in the drug approval process, and how Amifostine had not yet been formally approved for prostate cancer.

[E.147-151, 152-53]. Dr. Trovato then was merely taken through the "package insert" for Amifostine (over objections based on form, foundation, relevance and hearsay), and asked about the "hypersensitivities" to the drug. [E.150]. Dr. Trovato reaffirmed that his testimony pertaining to the clinical trials and the manufacturer's package insert formed the basis for his opinions that Amifostine ***should not have been used*** in this case. [E. 151-152, E.155].

The *only* questions asked on direct examination, to a reasonable degree of medical probability, pertained to Dr. Trovato's opinions on the ***appropriateness of the use*** of the drug Amifostine in a patient with prostate cancer.

Q: In this particular case, the radiation for prostate cancer. Would that be a logically - do you have an opinion within reasonable medical certainty likes [sic] Amifostine in a patient if you chose the use for prostate cancer?

Mr. McManus: Objection.

Mr. Farley: Objection.

Mr. Goodson: Objection. Form and foundation.

A: That would not be logical. Typically the radiation therapy is directed to the pelvic area for prostate cancer, so it's not going to affect the glands, if that's what you're asking.

[E.151, Tr. Pg. 67].

Q: Do you have an opinion within a reasonable medical certainty or probability as to *whether or not it was appropriate to administer* Amifostine for - while being given radiation treatment for prostate cancer?

***9** Mr. Farley: Objection. Form, foundation, relevancy.

Mr. Goodson: Same objection.

A: I do have an opinion

Q: What is your opinion?

A: My opinion is that Amifostine was **inappropriately used or should not have been used** for the reason of a patient getting radiation therapy for prostate cancer.

[E.151, Tr. Pg. 69].

The only testimony remotely pertaining to "informed consent" occurred when Dr. Trovato was asked where the patient gets information to make a decision about treatment. His response: "it can come from other health care professionals. There are various sources. But generally, for the most part, health care professionals will communicate to the patient the risk/benefits of a particular treatment, and then again, it's the patient's decision..." [E.152].

In short, Dr. Trovato provided no opinions as to what information, specifically, was required to be disclosed by Dr. Shannon that would constitute "material risks, benefits, and alternatives" to this drug.

To the extent this Court believes there to be any ambiguity on this issue, on cross-examination, Dr. Trovato emphasized, again, that his opinions pertained to the decision to use Amifostine for Mr. Fusco: "I did not come across literature that was pertinent in this case,... *the case being, the use of Amifostine* to prevent cystitis proctitis in prostate cancer patients." [E.156]. Dr. Trovato

readily reiterated that his opinion was that *use of Amifostine in this situation was inappropriate."* [E.158]. Furthermore, he restated that the bases for his opinion that the use of Amifostine was inappropriate were that the drug was not FDA approved for prostate cancer patients, there was a lack of clinical trials for use in prostate cancer patients, and there was a lack of data for use in **elderly** patients (as stated in the package insert). [E.158-59]. In ***10** short, Dr. Trovato verified on cross-examination that the entirety of his opinions pertained to the alleged inappropriate use of Amifostine and the bases in support thereof. Id. Dr. Trovato reiterated again that his ultimate opinion in this case was that Amifostine should not have been used. [E.160]. It was wrong to use Amifostine. [E.161]. Period.

It was only on redirect, that Respondents' counsel attempted to ask a question about what a patient should be advised (in a leading manner, no less) :

Q: If a patient is going through a clinical trial, should they be advised of the risks as well as the benefit?

Mr. Goodson: Objection.

Mr. Farley: Objection, beyond the scope of direct, form, foundation and relevancy.

A: Yes.

[E.162]. Even that inappropriate question, which was well-beyond the scope of direct or cross-examination, failed to elicit the necessary testimony as to the material risks that Dr. Shannon was obligated to advise Mr. Fusco.

Accordingly, the entirety of Dr. Trovato's *de bene esse* trial testimony pertained to his opinion about the misuse of Amifostine. Meaning to say, Dr. Trovato's opinion was that the use of Amifostine was improper, or negligent. He offered no opinions that information that Dr. Shannon provided Mr. Fusco was insufficient information on which informed consent could be given by the patient.

D. The Trial Court's Ruling on Petitioners' Motion in Limine

For these reasons, Petitioners filed a Motion in Limine seeking to preclude the jury from hearing the irrelevant and otherwise objectionable testimony of Dr. Trovato.

On December 21, 2010, Judge Green heard argument on Petitioners' Motion. The trial court correctly noted that Dr. Trovato's testimony failed to discuss informed consent, i.e., **"where is his testimony about informed consent?"** [E.550]. When Respondent's counsel pointed to the one page where Dr. Trovato discussed the ***11** common risks to the drug (which he essentially listed from the package insert), the trial judge astutely noted "[t]hat's talking about the risks. Not talking about material risks." [E.550](emphasis added). The court expounded that Dr. Trovato "doesn't testify as to what the material risks are. And that gets to the meat of it. There are risks in everything. I walk out here and walk down the step, I could trip on my robe. That's a risk, but it's not a material risk." *Id.*

Additional grounds were raised in support of precluding Dr. Trovato's testimony and in fact, the trial acknowledged that there were additional problems with Dr. Trovato's testimony, above and beyond the fact that the substance did not relate to informed consent. [E.547-48]. For example, to support his opinion, Dr. Trovato relied heavily upon a package insert from Amifostine; however, the package insert on which he relied post-dated 2003 (the year of the incident in this case) and was an insert from a different manufacturer (Immunex) than the one utilized in 2003 (Medimmune). [E.160, E.553]. Accordingly, Dr. Trovato's recitation of the "risks" was inappropriate given that he utilized a package insert that was created by a different manufacturer and post-dated the use of the drug in this case.

After hearing argument on Petitioners' Motion in Limine, the trial court ruled as follows:

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 is 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, 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 the 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 ***12** to the treatment are. He testifies as to the risk but he doesn't give a whole thing." [E.558-59].

At a subsequent hearing related to Dr. Trovato's testimony, the lower court revisited the grounds for his ruling to preclude the *de bene esse*, and reiterated as follows:

"... 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 Court's consideration....

... I adopt what I said earlier and will add to it today as for my reasons... I looked at the question of what the status of Dr. Trovato was... and he quite frankly, ***he's a pharmacist.*** He's not a medical doctor. And as such, when you look and you review what, under Maryland Rule 5-701 and 5-702, what an expert is. In this matter, it is not just the sole issue of what medicines were used. But it is a sole and complete treatment plan that is before this Court. It is not just that sole issue that we have before us. And remember 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 the medications.

... informed consent... is not just the medications, but the entire treatment. And as such, a ***pharmacist does not, in the Court's opinion, have the ability to give the full demarcation as to 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."

[E.575-76](emphasis added). The court acknowledged that Dr. Trovato was well-qualified in the area of pharmacy, but correctly noted that "this is a different area." [E.579]. Accordingly, it wasn't his lack of qualifications, per se, but his lack of qualifications as it related to the "nature of this case." [E.580]. In short, "informed consent is not in his field." [E.580].

In support of his ruling, the trial court went on to discuss, at length, the ***13** standards outlined in *Sard v. Hardy*, 281 Md. 432 (1977), *Mahler v. Johns Hopkins Hospital, Inc.*, 170 Md. App. 293 (2006) and *University of Maryland Medical System v. Waldt*, 411 Md. 207 (2009), and maintained that "these cases are controlling in [the court's] decision to disallow Dr. Trovato to testify." [E.578].

Finally, the court reiterated, again, that Dr. Trovato's testimony "is more in line, after I read it, in negligence rather than informed consent," and thus, it would not be probative to the trier of fact. [E.578]. Judge Glenn believed that "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 pharmacy [sic]." [E.578]. Furthermore, his testimony did not provide an understanding as "to what has to be done with this patient," which was "another reason why I'm disallowing him." [E.578].

E. Petitioners' Motion for Summary Judgment and Motions for Judgment.

Prior to trial, Dr. Shannon moved for summary judgment on the grounds that Respondents did not produce any (qualified) expert to testify that Dr. Shannon failed to advise Mr. Fusco of the material risks, benefits and alternatives to Amifostine so as to constitute proper informed consent. Dr. Shannon maintained that under Sard, and it's progeny, expert testimony is required to establish the material risks necessary in an informed consent discussion, and "material" is defined as "what a physician knows or should have known would be significant to a patient." *University of Maryland Medical System v. Waldt,* 411 Md. 207, 232, 983 A.2d 112, 127 (2009); Sard v. Hardy, 281 Md. 432, 443-444, 379 A.2d 1014, 1022 (1977). Nevertheless, the Court believed that "at this stage of the proceedings" there was some dispute as to material fact, and thus, he denied the Petitioners' Motion for Summary Judgment. [E.533]. The matter proceeded to trial.

At the close of Respondents' case, and again at the close of the evidence, Petitioners moved for judgment on several grounds. [E.1259, 1543]. Petitioners maintained that Respondents did not establish a prima facie case of lack of informed ***14** consent, in that there was no evidence that Dr. Shannon failed to advise the patient of the material risks to the treatment. [E.1260-61]. Maryland law required some evidence that Dr. Shannon failed to convey a material risk to the patient to sustain an informed consent claim; Respondents adduced no such evidence, either in their case-in-chief, or over the course of the trial. [E.1264-1267]. The trial court denied Petitioners' Motions for Judgment [E.1275, 1554], and the matter was tendered to the jury for deliberations. The jury returned a verdict in favor of Petitioners on January 19, 2011. [E.1713-1714].

F. The Erroneous Opinion by the Court of Special Appeals

The Court of Special Appeals vacated the judgment in favor of Petitioners based upon what it deemed to be an improper exclusion by the lower court of the pharmacist's testimony. The impropriety of the intermediate court's opinion is revealed by the fact that the Court of Special Appeals vacated the jury's verdict on the basis that a pharmacist is qualified to testify about the nature of and risks to a medication, yet the intermediate court ultimately held that "on remand,... [the pharmacist's] testimony regarding the nature of the material risks associated with the particular regimen of treatment provided to Mr. Fusco... would exceed the extent of [his] expertise relative to informed consent." Fusco, 210 Md. App. at 437, 63 A.3d at 168.

Notably, this holding is entirely consistent with the reasons that the lower court excluded the pharmacist's testimony below, as well as Petitioners' position throughout discovery, trial and appeal. It was error, however, for the intermediate court to vacate the judgment in Petitioners' favor on the grounds that the pharmacist should be permitted to testify about the medication, generally, even though, on remand, the pharmacist would not be capable or qualified to testify as to any of the requisite elements of informed consent, i.e., "regarding the nature of the material risks of the particular treatment regimen provided to Mr. Fusco." *Id.* Accordingly, the intermediate court's suggested permissible testimony would be largely irrelevant and/or prejudicial; however, the Court of Special Appeals failed to address these other ***15** legitimate evidentiary bases for the lower court's preclusion of Dr. Trovato's testimony. In addition, the intermediate appellate court also disregarded standing precedent from this Court on the issue of use of FDA approval information, as espoused in *University of Maryland Medical System v. Waldt,* 411 Md. 207, 983 A.2d 112 (2009). Finally, the Court of Special Appeals completely ignored Petitioners' position that summary judgment and/or judgment in their favor was warranted given Respondent's failure to make a prima facie case of lack of informed consent, a dispositive void which will remain on remand.

The intermediate court's vacatur of the judgment in Petitioners favor was unsupported by the facts of this case and inconsistent with both Maryland law on informed consent and fundamental rules of evidence. Petitioners now seek redress with this Court.

ARGUMENT

I. Dr. Trovato's Trial Testimony Sounded in Negligence, Not Informed Consent, and Therefore, the Trial Court's Exclusion was Proper.

The Court of Special Appeals devoted the vast majority of its opinion to Dr. Trovato's purported qualifications and merely glossed over the actual substance of his testimony, provided in both discovery deposition and de bene esse trial testimony,

which sounded in negligence, not informed consent. To the extent that the Court of Special Appeals considered Dr. Trovato's testimony at all, it relied exclusively on the untimely "proffer," which itself is wrought with error.

A. The Court of Special Appeals Reliance on a "Proffer" of Testimony that, Itself, Constituted a Discovery Violation Was Improper.

Dr. Trovato not only provided his substantive opinions in a discovery deposition, but he also provided his trial testimony by way of de bene esse deposition. Accordingly, the trial court had the benefit of knowing exactly the substance of Dr. Trovato's trial testimony when it was considering whether to preclude that testimony. Given that Dr. Trovato's discovery deposition and trial testimony consisted of ***16** opinions sounding entirely in negligence, not lack of informed consent, Petitioners filed a Motion in Limine to preclude his testimony and a Motion for Summary Judgment. Well after these dispositive voids were pointed out, and on the eve of trial, Respondents quickly crafted a "proffer" of Dr. Trovato's additional opinions which they argued sounded in informed consent. Putting aside, momentarily, Petitioner's position that the "proffer" still failed to make out a prima facie case of informed consent and failed to proffer any testimony regarding material risks which Dr. Shannon was purportedly obligated to disclose, the "proffer" was a blatant discovery violation. To the extent that the proffer is read as sounding in informed consent (as Respondents maintain), Dr. Trovato had never before testified as such in discovery deposition, nor in his own trial testimony.

It is noteworthy that after Petitioner's initial Motion for Summary Judgment was denied, the trial of this matter was postponed at Respondent's request. When Judge Smith granted the postponement in the trial, resetting the dates to January 2011, he included in his Order, "no further discovery." [E. 47, docket entry 093]. In addition to violating basic discovery rules, Respondent's proffer also violated Judge Smith's explicit Order prohibiting further discovery.

Quite tellingly, in briefs and argument to the intermediate court, Respondents' relied almost exclusively on the proffer they drafted after counsel recognized the dispositive gaping holes in Dr. Trovato's discovery and trial testimony. Likewise, in considering the admissibility of Dr. Trovato's opinions, the Court of Special Appeals exclusively relied upon a "proffer" crafted by Respondents after Petitioners had (a) completed Dr. Trovato's discovery deposition, (b) completed Dr. Trovato's trial testimony via de bene esse, (c) moved to preclude Dr. Trovato's testimony and (d) moved for summary judgment.

The Court of Special Appeals completely ignored Respondents' discovery violation and failed to even acknowledge Petitioners' preserved objection to the proffer. [E.562-63]. As this Court stated in *Rodriguez v. Clarke*, "the fundamental objective of discovery is to advance the sound and expeditious administration of ***17** justice by eliminating, as far as possible, the necessity of any party to litigation going to trial in a confused or muddled state of mind, concerning the facts that gave rise to the litigation." *Rodriguez v. Clarke*, 400 Md. 39, 57, 926 A.2d 736, 747 (2007). Providing a "proffer" on the eve of trial containing additional opinions of an expert that were not provided in his previously videotaped trial testimony is the clearest violation of the discovery rules. It runs afoul of every fundamental objective to discovery espoused by this Court. The preclusion of evidence in these scenarios is not only authorized by the Maryland Rules but has been affirmed by Maryland courts. *See id.* at 66, 926 A.2d at 752.

The Court of Special Appeals had an obligation to at least address the properly preserved objection that Petitioners made regarding the proffer, which alone provided an independent basis to support the preclusion of Dr. Trovato and/or consideration of the proffer altogether. Instead, the Court of Special Appeals sidestepped this issue and in so doing, the court not only embraced Respondents' discovery violation, it rewarded such conduct with a new trial. Maryland courts should not condone such antics by litigants. If new opinions by way of 'proffer' on the eve of trial are permitted to be admitted - particularly after dispositive voids have been highlighted in a motion for summary judgment - the rules of discovery lose meaning and effect, compliance with discovery becomes a nicety rather than a requirement, and the tool of summary judgment serves not to dispose of cases, but to merely highlight voids for nonmoving parties to bandage. The discovery process is intended to serve a purpose - the orderly, fair, and expeditious administration of justice. Yet, the Court of Special Appeals' opinion promotes the opposite by flaunting the benefit of violating discovery: a reversal of the judgment below and a new trial.

Respondent's proffer violates the rules of discovery, generally, and Judge Smith's "no further discovery" order specifically. As such, it should not have been considered by the Court of Special Appeals, and certainly, it should not have been relied upon as the sole basis to support its reversal of judgment in Petitioner's favor.

***18 B. The Substance of Dr. Trovato's Opinions Sounded in Negligence, Not Lack of Informed Consent, and Was Therefore Not Relevant.**

As this Court espoused in *McQuitty v. Spangler, supra,* "[b]reach of informed consent and medical malpractice claims both sound in negligence, but are separate, disparate theories of liability." McQuitty, 410 Md. at 18, 976 A.2d at 1030. Maryland law is replete with cases in which that distinction was not only upheld but illuminated: *Landon v. Zorn,* 389 Md. 206, 230, 884 A.2d 142, 156 (2005)(upholding a trial judge's decision to instruct the jury on a medical malpractice theory of liability, but not on an informed consent theory); *Reed v. Campagnolo,* 332 Md. 226, 240-41, 630 A.2d 1145, 1152-53 (1993)(holding that a failure to recommend a diagnostic procedure is properly an allegation of medical malpractice, not one of breach of informed consent); *Faya v. Almaraz,* 329 Md. 435, 447-51, 620 A.2d 327, 333-35 (1993) (holding that patients stated a proper cause of action when they alleged that the physician breached a duty to obtain their informed consent by failing to inform them that he was infected with the AIDS virus before operating, without alleging that physician breached the standard of care in performing the procedure); *see also Zeller v. Greater Baltimore Medical Center,* 67 Md. App. 75, 81-82, 506 A.2d 646, 650 (1986) ("The rendering of medical services absent informed consent, if pled properly, constitutes a separate and new count of negligence.").

The distinction between these claims has been explained as follows: "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, 410 Md. at 18-19, 976 A.2d at 1030 (internal citations and quotations omitted)(emphasis added). See also, Schwartz v. Johnson, 206 Md. App. 458, 484, 49 A.3d 359 (2012).

19** This Court explained that "unlike the traditional action of negligence, a claim for lack of informed consent focuses not on the level of skill exercised in the performance of the procedure itself but ***on the adequacy of the explanation given by the physician in obtaining the patient's consent." *Dingle v. Belin,* 358 Md. 354, 36970, 749 A.2d 157, 165 (2000)(emphasis added).

Dr. Trovato's testimony, in both deposition and his videotaped trial testimony, unequivocally reveals his opinion that it was inappropriate for Dr. Shannon to use Amifostine in Mr. Fusco given his age and given that his cancer involved the prostate, (as opposed to kidney, bladder, ovarian, head or neck cancer). Dr. Trovato's opinions clearly sounded in negligence (malpractice) as opposed to lack of informed consent:

o "My opinions in terms of the use of Amifostine for this patient, I feel is not justified or inappropriate. Again, Amifostine in terms of ***how it's being used*** in this patient's case, this specific patient's case. That's my opinion." [E.402](discovery deposition)

o "Amifostine-Ethyol was inappropriate in this patient." [E.402] (discovery deposition)

o Dr. Trovato agrees that his opinion is that the use of Amifostine was not justified or appropriate. [E.403] (discovery deposition)

o "I think my concern is there is no evidence to support its efficacy for its use in this case." [E.405] (discovery deposition)

o "there is no evidence to support its use, its efficacy. There is a known toxicity. Again, when we look at the risk-benefit, I guess I don't see a benefit to the drug." [E.407] (discovery deposition)

o "my understanding is that I'm here to testify as to the appropriate use of Amifostine in this case." [E.139](*de bene esse*)

o "My opinion is that Amifostine was ***inappropriately used or should not have been used*** for the reason of a patient getting radiation therapy for prostate cancer." [E.151, Tr. Pg. 69] (de bene esse).

o "I did not come across literature that was pertinent in this case,... the case being, the use of Amifostine to prevent cystitis proctitis in prostate cancer patients." [E.156] (de bene esse).

***20** o Dr. Trovato readily reiterated that his opinion was that "the use of Amifostine in this situation was inappropriate." [E.158] (de bene esse).

o Dr. Trovato reiterated that his ultimate opinion in this case was that Amifostine should not have been used. [E.160] (de bene esse).

o Dr. Trovato believed that it was wrong to use Amifostine. [E.161] (de bene esse).

In fact, when Dr. Trovato was asked to provide the basis for his opinions, he reiterated that the bases for his opinion that Amifostine should not have been used in this case included: the lack of FDA approval in prostate cancer patients specifically, the limited clinical trials on prostate cancer patients, and the limited studies in the **elderly** (as espoused in the manufacturer package insert). [E.151-152, E.155, E.158-59, E.403-405]. Accordingly, all of Dr. Trovato's opinions adduced in discovery pertained to the alleged misuse of Amifostine, and all of the bases he cited were in support of the alleged misuse of Amifostine. Put simply, Dr. Trovato's opinion was that the use of Amifostine was improper, or negligent. He offered no testimony that Dr. Shannon provided Mr. Fusco with insufficient information on which informed consent could be given by the patient. For these reasons, the lower court's ruling was proper and should have been affirmed by the Court of Special Appeals. The Court of Special Appeals' reversal was contrary to Maryland law, which has consistently reinforced the distinct theories of liability that are negligence and informed consent.

C. The Trial Court Properly Held that Dr. Trovato's Opinions were Not Relevant and/or Confusing and Misleading to the Jury

The trial court properly concluded that the substance of Dr. Trovato's testimony (which sounded in negligence) was not relevant to the cause of action at hand, i.e., lack of informed consent. [E.558-59, E.575-76]. To the extent that Dr. Trovato touched on the common side effects or potential adverse reactions to Amifostine, those opinions similarly do not carry the day for Respondents. The trial court correctly noted: "your guy [Dr. Trovato] doesn't testify as to what the material risks are. And ***21** that gets to the meat of it. There are risks in everything. I walk out here and walk down the step, I could trip on my robe. That's a risk, but it's not a material risk." [E.550]. As the lower court stated, the fact that risks may exist is not relevant in an informed consent case, the pertinent question is whether those risks were *material* to the treatment proposed and thus, warranted disclosure by Petitioners. *Id.*

For example, the fact that Dr. Trovato can pull a (post-dated) package insert from a (different) manufacturer of Amifostine and read the myriad of listed possible adverse reactions does not mean that Dr. Shannon had a *duty to disclose* each and every one of those risks to Mr. Fusco. Dr. Trovato never identified which risks were *material* to an informed consent discussion with a patient; Dr. Trovato never testified that Dr. Shannon needed to disclose material risk "x" or material risk "y" to constitute informed consent. Respondents never adduced this requisite evidence in discovery; nor did Respondents adduce this requisite testimony at trial.

Evidence that is not relevant is not admissible. See MD. RULE 5-402. Furthermore, even if relevant, when the probative value of that evidence is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, the evidence may be excluded. See MD. RULE 5-403. A ruling on relevance of evidence is quintessentially within the wide discretion of the trial court. *See Phoenix Services, Ltd. v. Johns Hopkins Hospital*, 167 Md. App. 327, 892 A.2d 1185 (2006).

Appellate courts will not disturb a trial court's decision to admit or exclude evidence absent an **abuse** of discretion. *See Ruffin Hotel Corp. of Maryland, Inc. v. Gasper*, 418 Md. 594, 619, 17 A.3d 676, 690 (2011). Appellate courts utilize a "clearly erroneous" standard of review when assessing a lower court's ruling as to whether the evidence has "probative value." *Id.* at 620.

The trial court's determination that Dr. Trovato's opinions lacked probative value and was otherwise outweighed by the prejudicial effect was well-supported and soundly analyzed. After reviewing the pleadings, conducting two separate hearings on the matter, reading the deposition testimony of Dr. Trovato, the de bene esse of Dr. Trovato, the proffer by Respondents' counsel and multiple cases from our appellate ***22** courts, Judge Green found that Dr. Trovato's testimony gave ***"great indifference to relevance to the issue at hand.*** That is informed consent." [E.558-59]. The court emphasized that Dr. Trovato's "testimony is more in line with negligence than that of informed consent." *Id.* Testimony by a pharmacist about the existence of risks does not equate to "material risks" for purposes of an informed consent discussion and would only serve to confuse the issues, mislead the jury and cause unfair prejudice to Petitioners. See MD. RULE 5-403: The jury was tasked with determining whether "material risks" were discussed with the patient, not whether any or all risks and side effects were discussed. Not only was there little probative value to general information on Amifostine, any value to that evidence was substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. For this reason, Dr. Trovato's "proffered" testimony was properly precluded.

Curiously, the Court of Special Appeals reversed the judgment below and remanded for a new trial to permit Dr. Trovato to testify, but then (correctly) held that, on remand, Dr. Trovato would be *precluded* from offering testimony "regarding the nature of the material risks associated with the particular regimen of treatment provided to Mr. Fusco, and any alternative treatment options," because it would "exceed the scope of [Dr. Trovato's] expertise in an informed consent." Fusco, 210 Md. App. at 437, 63 A.3d at 168. This holding, while correct, begs the question - on what grounds is the Court of Special Appeals basing its vacatur of the judgment and a remand for new trial? The only testimony that Dr. Trovato may be permitted to provide on remand is the very testimony that the trial court correctly deemed to be irrelevant and/or prejudicial below. The Court of Special Appeals performed no analysis to counter the lower court's ruling on this basis, nor any analysis to explain it's decision to disturb the wide discretion afforded trial courts for evidentiary rulings. Dr. Trovato cannot offer testify as to material risks for informed consent discussion - that is undisputed. Thus, on remand, what could Dr. Trovato offer that isn't (a) irrelevant or (b) confusing and misleading, or (c) a discovery violation, or (d) all of the above? Not a thing. Reading to the jury from a package insert containing a myriad of ***23** possible risks to a drug is not relevant to a jury's consideration of an informed consent cause of action. Furthermore, testimony of a litany of possible risks, as the lower court correctly pointed out, is both confusing to the jury and misleading, rendering any probative value far outweighed by the prejudicial effect. See Md. Rule 5-403.

In short, the Court of Special Appeals failed to explain how Dr. Trovato's very limited testimony on remand, i.e. opinions relating to potential risks, albeit not "material risks," (a) would be relevant to a jury's determination of the elements of lack of informed consent and (b) would not be outweighed by the risk of confusing or otherwise misleading the jury as to the elements they were tasked to consider, i.e. "material risks" as opposed to any risk. At a minimum, the Court of Special Appeals had an obligation to consider the basic rudimentary issues of relevance and probative value / prejudicial effect before stripping the verdict from Petitioners and granting a new trial. This they failed to do.

Had the intermediate appellate court considered these issues, it is clear that Dr. Trovato's proffered testimony would be deemed both irrelevant and prejudicial, and therefore, precluded under Rules 5-402 and 5-403.

II. Dr. Trovato Lacked the Requisite Experience and Qualifications to Opine as to What Disclosures were Required for Informed Consent.

Assuming that this Court gets past the lack of relevance and/or prejudicial effect of the substance of Dr. Trovato's testimony, Dr. Trovato's testimony on the issue of informed consent remains inadmissible given that he lacks the necessary training and experience in the informed consent process to opine on what material risks must be disclosed by a physician. In fact, Dr. Trovato conceded that he did not understand "material risks," period. [E.143].

Maryland Rule 5-702, which governs testimony by expert witnesses, provides as follows:

> "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 ***24** 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."

As mentioned above, one of the bases for the lower court's preclusion of Dr. Trovato's testimony was that Dr. Trovato lacked the necessary experience and training about informed consent processes between a physician and patients under Maryland Rule 5-702. As to this particular subject matter, i.e., informed consent, the court found that Dr. Trovato's testimony would be inappropriate. [E.575-76].

As this Court is aware, the admissibility of expert testimony is an area which the trial court is given broad discretion, and it rarely constitutes grounds for reversal. *See Globe Sec. Systems Co. v. Sterling*, 79 Md. App. 303, 308, 556 A.2d 731 (1989). In fact, so broad is the trial court's discretion that it will not be disturbed on appeal unless it has been shown to be manifestly erroneous. *See Troja v. Black & Decker Mfg. Co.*, 62 Md. App. 101, 110, 488 A.2d 516, 520 (1985). Precluding Dr. Trovato from rendering opinions at trial as to Dr. Shannon's duty to advise Mr. Fusco of certain risks to constitute informed consent was proper and well-within the trial court's broad discretion. The trial court's ruling is consistent with Maryland Rule 5-702, and well-supported by the record, as well as statutory and case law.

A. Dr. Trovato Lacks the Necessary Training, Experience and Qualifications in Informed Consent Pursuant to Rule 5-702.

The following facts are undisputed: Dr. Trovato is a pharmacist, not a medicine, hematology, and oncology. [E.140, 1391-92]. Dr. Trovato was not trained to evaluate, diagnose and treat oncologic patients in a clinical setting like Dr. Shannon. *Id.* Dr. Trovato is not licensed to practice medicine. [E.139]. He doesn't prescribe medications, recommend treatment regimens, discuss alternative therapies, ***25** or consider the totality of a patient's condition in making recommendations for patient treatment. [E.143, 156]. He has never consented a patient for any treatment regimen, including Amifostine. [E.157, 160]. Given that Dr. Trovato is not licensed to practice medicine, he cannot prescribe medications, including the Amifostine at issue in this case. [E.140]. He has never sat down with a patient and written a prescription for medication at any time. [E.143]. Given that Dr. Trovato is not licensed to practice medicine, naturally, **he's never himself obtained a patient's consent to treatment,** and in particular, to the use of Amifostine. [E.157, 160]. It is no surprise then, that Dr. Trovato **did not understand the term "material risks."** [E.143].

In University of Maryland Medical System Corp. v. Waldt, 411 Md. 207, 983 A.2d 112 (2009), this Court upheld the trial court's preclusion of Dr. Debrun for reasons similar to the trial court's preclusion of Dr. Trovato in the case sub judice. The trial judge in Waldt evaluated Dr. Debrun's qualifications and concluded that "he did not have a sufficient factual basis on which to render an expert opinion on informed consent." Id. at 237, 983 A.2d 130. This Court agreed that "[g]iven Dr. Debrun's limited experience with similar procedures and his failure to disclose any specific scientific or factual underpinnings for any knowledge about the material risks of the neuroform stent coiling procedure, the court did not err or **abuse** its discretion in excluding his testimony on this issue." Id. (citing Waldt, 181 Md. App. at 267-68, 956 A.2d at 252). Accordingly, this Court upheld the ruling of the trial judge, who precluded the expert from testifying under Rule 5-702.

Similar to Dr. Debrun in *Waldt*, Dr. Trovato had "limited experience" (read: none) with the informed consent process for an oncologic patient like Mr. Fusco; and he failed to disclose any specific "factual underpinning for any knowledge about the material risks" of the treatment regimen proposed. See id. The trial court ruled that Dr. Trovato's area of expertise

was not germane to the issues in this case. His expertise is "not in the complete treatment plan... he only deals with the medications." [E.575-76]. The court additionally noted that "he's never given an informed consent. ***26** 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." Id. Accordingly, the lower court ruled that Dr. Trovato, as a pharmacist, ***"does not have the ability to give the full demarcation as to what is involved in informed consent."*** *Id.* The trial court's exclusion of Dr. Trovato was consistent with Rule 5-702, and at a minimum, was not an **abuse** of discretion.[4] This Court may uphold the trial court's ruling on this basis alone, although additional support is found in statutory and case law.

B. Maryland Statutory Law Supports the Trial Court's Preclusion of Dr. Trovato's Testimony

1. Dr. Trovato is Not Authorized to Obtain Informed Consent

Recommending a treatment course - *and obtaining informed consent for that treatment course* - constitutes the practice of medicine. As discussed above, Dr. ***27** Trovato is not a licensed physician; accordingly, he *cannot* obtain informed consent from a patient, as doing so would constitute an unauthorized practice of medicine. The unauthorized practice of medicine constitutes grounds for discipline in Maryland under Health Occupation Title, §§ 14-301, 14-601, 14-602(a) and 14-606, See MD. CODE ANN. (1981, 2009 Repl.Vol.), Health Occ. Art. §§ 14-301, 14-601, 14-602(a) and 14-606, If one is prohibited, by law, from consenting a patient on a proposed treatment regimen, he/she should likewise be prohibited from offering opinions at trial that a licensed physician breached his duty to sufficiently inform the patient of the material risks, benefits and alternatives to a proposed treatment in the course of obtaining informed consent.

Thus, Maryland's statute defining the authorized practice of medicine supports the propriety of the lower court's exclusion of Dr. Trovato on the basis of qualifications and experience. [E.575-76].

2. Dr. Trovato is Not a Member of Dr. Shannon's Profession, and thus, is Not Qualified per the Health Care Malpractice Claims Act to Testify.

As this Court is aware, any claim by a person against a health care provider for a medial injury falls under the provisions of the Health Care Malpractice Claims Act, Section 3-2A-01, et. seq. of the Courts and Judicial Proceedings Article. (hereinafter, "Act"). The Act applies to any claim for medical injury, which includes lack of informed consent. Section 3-2A-02(c)(1) outlines the requirements for establishing liability of a health care provider. It provides as follows:

> (c)(1) In any action for damages filed under this subtitle, *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* with similar training and experience situated in the same or similar communities at the time of the alleged act giving rise to the cause of action.

Pursuant to this provision, Respondents must establish that Dr. Shannon's care in the context of his informed consent discussion with Mr. Fusco, was "not in accordance ***28** with the standards of practice among members of the same health care profession with similar training and experience." See §3-2A-02(c)(1). A pharmacist is not qualified to testify about the standards of practice among triple-board certified physician; he is not in the same "health care profession" and does not have "similar training and experience." *Id.* Section 3-2A-02(c)(1), alone, supports the trial court's preclusion of Dr. Trovato, given that he is not a member of the same health care profession as Dr. Shannon and thereby lacks the requisite statutory qualifications. [E.575-76].

The next section, Section 3-2A-02(c)(2) specifies the required qualifications for those experts who attest to departures from the standard of care, whether by certificate or testimony: This provision requires the attesting expert to have similar clinical experience in the field of health care in which the defendant provided treatment and, if the defendant is board-certified, the

expert must be the same or a related specialty as the defendant. See §3-2A-02(c)(2), Cts. & Jud. Pro. Art. Therefore, subsection (c)(2) provides additional support for the court's preclusion of Dr. Trovato, given that he clearly did not possess the equivalent board certifications that Dr. Shannon possessed.

The Court of Special Appeals stated that Respondents were not required to establish a breach in the duty through a similarly qualified expert per the Health Care Malpractice Claims Act because this was an informed consent action, not a negligence action. *See Fusco,* 210 Md. App. at 413, 63 A.3d at 153-54. The Court of Special Appeals' incorrectly carried the exemption for informed consent cases found in Section 3-2A-04(b)(pertaining to when certificates of qualified experts are necessary) [5], to the qualifications provisions of Section 3-2A-02(c). As this Court has confirmed, when conducting statutory interpretation, the primary goal is always to "discern the legislative purpose, the ends to be accomplished, or the evils to be remedied by a particular provision, be it statutory, constitutional or part of the Rules." General Motors Corp. v. Seay, 388 Md. 341, 352, 879 A.2d 1049, 1055 (2005). The analysis ***29** begins by first looking to the normal, plain meaning of the language of the statute, reading the statute as a whole to ensure that "no word, clause, sentence or phrase is rendered surplusage, superfluous, meaningless or nugatory." *Mayor & Town Council of Oakland v. Mayor & Town Council of Mountain Lake Park,* 392 Md. 301, 316, 896 A.2d 1036, 1045 (2006).

In analyzing the Act, it is noteworthy that, if the General Assembly felt that informed consent claims should be exempt from the statutory requirements for experts espoused in Section 3-2A-02(b), the General Assembly would have expressly limited their applicability to negligence claims. Evidence of their ability to do precisely that is seen in Section 3-2A-04(b), wherein the General Assembly expressly dispenses with the Certificate of Qualified Expert requirement for lack of informed consent cases. See Section 3-2A-04(b). Accordingly, if the General Assembly wanted to exclude informed consent claims from the provisions which mandate certain qualifications for experts who offer testimony against a health care provider, it could have likewise done so in Section 3-2A-02(c). Instead, while the Act permits claims to proceed through the arbitration process without a Certificate of Qualified Expert when the case sounds in lack of informed consent only, the General Assembly made no such distinction in Section 3-2A-02(c), when outlining the requisite qualifications for experts who testify against a health care provider.

Given that Dr. Trovato is not a member of the same health care profession as Dr. Shannon, and given that he does not have similar training or experience, Dr. Trovato is not qualified to render opinions that the informed consent discussion was *"not in accordance with the standards of practice among members of the same health care profession." See* Section 3-2A-02(c); [E.575-76]. Once again, there exists clear statutory support for the lower court's preclusion of Dr. Trovato, and likewise, clear evidence of error by the Court of Special Appeals in overturning the court's ruling.

***30 C. Maryland Case Law Supports the Trial Court's Preclusion of Dr. Trovato.**

1. Maryland courts have defined the duty to disclose "material risks" in an informed consent case as grounded in physician's knowledge.

Maryland case law also supports the trial court's ruling on Dr. Trovato's lack of qualifications. It is well recognized that lack of informed consent claims sound in negligence, thereby triggering the concept of "duty." *See e.g., Dingle v. Belin,* 358 Md. 354, 368, 749 A.2d 157, 164-65 (2000). In informed consent claims, the physician has a "duty" to impart certain information to a patient. As the Sard Court explained, "the doctrine of informed consent imposes on a physician, before he subjects his patient to medical treatment, the duty to explain the procedure to the patient and to warn him of any material risks or dangers inherent in or collateral to the therapy, so as to enable the patient to make an intelligent and informed choice about whether or not to undergo such treatment." *Id.* at 439, 379 A.2d at 1020 (emphasis added). Given that the duty is imposed on a physician, the only logical person qualified to testify about that duty is another physician. Dr. Trovato is not authorized to do what Dr. Shannon did in this case, i.e., obtain Mr. Fusco's informed consent, and therefore, should not be permitted to testify about that "duty" in a court of law.

The very definition of "material risk" likewise dictates who is qualified to opine on material risks. A material risk is defined as "one which a physician knows or ought to know would be significant to a reasonable person in the patient's position in deciding whether to submit to a particular medical procedure." *See Sard v. Hardy*, 281 Md. 432, 444, 379 A.2d 1014, 1022 (1977). Accordingly, the definition of material risk mandates consideration of what a physician knows or should know, not what a pharmacist knows or should know. As the lower court correctly noted, Dr. Trovato -as a pharmacist - had never obtained informed consent on a patient, let alone in the specific setting in which Dr. Shannon found himself, i.e., with a prostate cancer patient undergoing radiation and requiring a radiation-protectant medication. For these ***31** reasons, (among others), Dr. Trovato lacked the necessary qualifications to testify as to any duty owed by Dr. Shannon in the informed consent discussion with his patient. The lower court's ruling is supported by Maryland case law; by the same token, the Court of Special Appeals' reversal of the lower court is contrary to it.

2. The Corollary to the "Learned Intermediary Doctrine" Provides Support for the Trial Court's Preclusion of Dr. Trovato.

Maryland case law involving the scope of duty for a pharmacist also provides support for the trial court's preclusion of Dr. Trovato. Specifically, courts have established a corollary to the learned intermediary rule[6] which extends the defense from drug and device manufacturers to pharmacies and pharmacists. In explaining the extension of this defense to pharmacists, the Court of Special Appeals noted that physicians possess the "knowledge of the range of possible choices among prescription drugs and of the patient's particular condition," and further, "have the duty to warn of potential adverse consequences." *See Rite Aid Corp. v, Levy-Gray*, 162 Md. App. 673, 687, 876 A.2d 115, 123 (2005). For these reasons, courts have held that "the duty of pharmacists is to dispense the drug in accordance with physicians' prescriptions, generally without injecting themselves into the physician-patient ***32** relationshi." *Id.*

In fact, this Court has held that a pharmacist may not substitute his judgment for that of a physician writing a prescription. *See People's Service Drug Stores v. Somerville*, 161 Md. 662, 158 A. 12, 13 (1932). Likewise, the Fourth Circuit, applying Maryland law, has held that a pharmacist has no duty to warn a customer when filling a doctor's prescription, noting that:

> "[i]f the law is going to require... that the physician be second-guessed by the pharmacist... only danger could result. A pharmacist... who advised a patient not to take a drug prescribed by a physician might easily cause death or serious injury, and we think the practice of medicine by pharmacists... is not a field in which we should even encourage them to engage, much less require it...."

See Hofherr v. Dart Industries, Inc., 853 F.2d 259, 263-64 (4th Cir.1988). The Fourth Circuit's opinion in Hofherr adopted the same rationale that this Court espoused in *People's Service Drug Stores*, to wit: it is unwise to impose liability on a pharmacist for filling a prescription signed by a physician, because the physician is in a better position to evaluate the patient's medical needs. This principle is likewise applicable to the case *sub judice:* a physician - armed with the knowledge of the possible medication options as well as the knowledge of a particular patient's medical condition - is in the best position to propose a treatment regimen and provide the risks, benefits and alternatives to the same. Maryland courts would appear quite contrarian to hold, on the one hand, that pharmacists have no duty to warn a patient filling a prescription, but on the other hand, permit that pharmacist to testify about the propriety of a physician's warnings in a court of law. Accordingly, the trial court's ruling is well suorted b and consistent with Marland case law.

D. The Court of Special Appeals Ruling was Inconsistent with the Maryland Rules of Evidence, Maryland Case Law and Maryland Statutory Law.

The irony with the Court of Special Appeals' opinion is that while its reversal of the judgment below was erroneous, at least part of it's holding was correct. While the Court of Special Appeals held that Dr. Trovato should have been permitted to ***33** testify, the Court ultimately held that Dr. Trovato was not qualified to testify on informed consent and material risks, benefits

and alternatives of a particular treatment regimen. See Fusco, 210 Md. App. at 437, 63 A.3d at 168. With respect to this latter position, Petitioners wholeheartedly agree. Certiorari was necessary, however, given the myriad of other errors with the Court of Special Appeals' analysis and potential precedential impact. First, the Court of Special Appeals utilized loose language in several parts of its reported opinion, which may be (mis)interpreted in the future as granting the court's imprimatur on the acceptance of pharmacists as experts in lack of informed consent cases. Even a hint of such position sets a dangerous precedent in this State. Second, the Court of Special Appeals completely glossed over the myriad of other bases upon which the trial court excluded Dr. Trovato's testimony, including relevance, prejudicial effect, and discovery violations, among others, all of which support the affirmance of judgment in Petitioners' favor. Third, the Court of Special Appeals departed from standing law on various evidentiary issues (as will be discussed in further detail in Section IV). Finally, finding Dr. Trovato qualified to discuss Amifostine, generally, does not eliminate the other dispositive voids in Respondent's case, i.e., a *prima facie* case for informed consent requires expert testimony of the "material risks."

For inexplicable reasons, the Court of Special Appeals stepped away from the germane issue before it below, namely, whether Dr. Trovato possessed the necessary qualifications to opine on the propriety of an informed consent discussion between a physician and a patient, to a more generalized question of whether Dr. Trovato was "qualified to testify regarding Amifostine." Id. at 412. Quite frankly, nobody disputed that Dr. Trovato would be qualified to generally discuss the drug Amifostine from a pharmacy perspective. That was never the pivotal issue before the lower court, nor the intermediate court. Possessing general knowledge about a drug does not equate to knowing the material risks, benefits and alternatives of a proposed treatment regimen in the context of an informed consent discussion. Random information about a drug may be either not relevant or confusing and misleading to a jury tasked with ***34** determining the propriety of a physician's discussion with a patient. The trial court's justifiable concern in this matter was not ensuring that the jury learned every nuance of Amifostine, including its various phases of clinical trials and results therefrom. To the contrary, the issue with which the jury was tasked was much more narrowly focused: did Dr. Shannon discuss the material risks, benefits and alternatives to Amifostine with Mr. Fusco to constitute informed consent. Thus, the pivotal question was not, "whether Dr. Trovato has sufficient experience with Amifostine," as the Court of Special Appeals claimed; the question was whether Dr. Trovato has sufficient experience with informed consent discussions relating to Amifostine for patients with Mr. Fusco's medical condition to opine on the propriety of Dr. Shannon's disclosure. To this latter question, the answer is unequivocally, No.

Curiously, the Court of Special Appeals' overtly disregarded Maryland case and statutory law supporting the trial court's rulings, but eagerly cited any out-of-state case law, no matter how remotely related to the issue at hand. In fact, the extra jurisdictional cases which the intermediate court claims demonstrate that a pharmacist is qualified to testify in an informed consent action are easily distinguishable from the case at hand. Some involved permitting a pharmacologist (not a pharmacist) to testify on causation, *see Sinkfield v. Oh et al.*, 229 Ga. App. 883, 495 S.E.2d 94, 95 (1997)(holding that a pharmacologist / toxicologist expert was qualified to testify as to the scientific effects or causes resulting from the medication administration); *Tidwell v. Upjohn, Co.*, 626 So. 2d 1297, 1299 (Ala. 1993)(holding that the expert's education, training and experience in pharmacology rendered him qualified to testify whether the drug caused or contributed to the suicide); some involved permitting a pharmacologist to testify in a negligence action, *see Goodman et al. v. Lipman et al.*, 197 Ga. App. 631, 399 S.E.2d 255, 256 (1990)(agreeing that a pharmacologist could not render standard of care opinions, but could testify generally with regard to the pharmacokinetics and pharmacodynamics of the drug, Coumadin); *Garvey v. O'Donoghue*, 530 A.2d 1141, 1142 (D.C.1987)(permitting a pharmacologist to testify about the proper dosing and monitoring of a particular drug for standard of care ***35** purposes); and some involved permitting testimony pertaining to the very nature of a pharmacy practice, i.e., the dispensing of drugs, *see United States v. Smith*, 573 F.3d 639, 653 (8th Cir. 2009)(permitting a pharmacist who had helped the Government identify over 1,500 "rogue pharmacies," testify against a physician in a case alleging conspiracy to distribute and dispense controlled substances without an effective prescription). While citing this inapposite case law, the Court of Special Appeals also acknowledged that several Other jurisdictions held the opposite, i.e., that a pharmacist could not testify against a physician. *See Fusco*, 210 Md. App. at 421-23, 63 A.3d at 158-60. Ironically, the court summarily dismissed these cases because they involved negligence, not informed consent cases, even though some of the cases it cited as ostensibly supportive of its position were likewise negligence cases. *Id.* at 424, 63 A.3d at 160.

Regardless, the Court of Special Appeals opted to disregard Marylan's case law, statutory law, and rules of evidence and turn to outside case law in an effort to support its end goal. The cliché, “trying to fit a square peg in a round hole,” comes to mind. Petitioners request that this Court reverse the Court of Special Appeals and affirm the rulings and judgment of the lower court.

III. Given Respondent's Failure to Adduce Evidence that Dr. Shannon Failed to Apprize Mr. Fusco of the “Material Risks” of Amifostine, Summary Judgment or Judgment Should have been Granted in Petitioners Favor.

Petitioners maintain that the facts adduced in discovery mandated an entry of summary judgment on their behalf prior to commencement of trial. [E.356, E.534]. Additionally, Petitioners moved for judgment at the close of Respondents' case [E.1259-1268] and at the close of evidence. [E.1543-1551]. Given Respondents' failure to establish a *prima facie* case of lack of informed consent, judgment should have been entered in Petitioners' favor at any of those junctures.

Remarkably, the Court of Special Appeals failed to address this issue - despite the fact that its very holding affirmed that Dr. Trovato could not testify as to “material ***36** risks, benefits and alternative to the proposed treatment regimen.” See Fusco, 210 Md. App. at 437, 63 A.3d at 168. Accordingly, even on remand, Respondent's case will be faced with the same dspostive void. The Court of Special Appeals should have considered the merits of Petitioners' Motion for Summary Judgment and Motion for Judgment based upon Respondent's failure to establish a prima facie case of lack of informed consent and should have mandated that judgment be entered in Petitioners' favor.

A. Standard of Review

Summary judgment is appropriate when, after viewing the motion and the response in favor of the non moving party, there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *See Messing v. Bank of America, N.A.,* 143 Md. App. 1, 10, 792 A.2d 312, 317-18 (2002); MD. RULE 2501(e). When considering the propriety of a trial court's grant or denial of summary judgment, the appellate courts review the matter de novo to determine “whether the trial court was legally correct.” *Heat & Power Corp. v. Air Prods, & Chems., Inc.,* 320 Md. 584, 591, 578 A.2d 1202 (1990); *see Mamsi Life & Health Ins. Co. v. Callaway,* 375 Md. 261, 825 A.2d 995 (2003):

Given the paramount importance of disputed facts in the summary judgment process, when sufficient grounds for summary judgment have been set forth by the moving party, “the party opposing the motion must show with ‘some precision’ that there is a genuine dispute as to material fact.” *Bond v. NIBCO, Inc.,* 96 Md. App. 127, 135, 623 A.2d 731 (1993) (quoting *Seaboard Sur. Co. v. Richard F. Kline, Inc.,* 91 Md. App. 236, 243, 603 A.2d 1357 (1992)) (emphasis omitted). The opposing party “cannot rely on formal denials or general allegations.” Bond, 96 Md. App. at 135, 623 A.2d 731. Rather, the opposing party must produce evidence upon which the jury could reasonably find in his favor. Furthermore, trial courts “should not be reluctant to grant a motion for summary judgment in an appropriate case... a motion for summary judgment, although not a substitute for trial, is nevertheless not disfavored. A proper summary judgment motion is to be granted unless the parties truly dispute a material ***37** fact, i.e., the evidence is such that a fair minded jury could return a verdict for the nonmovant.” *Bond v. NIBCO, Inc.,* 96 Md. App. 127, 134-35, 623 A.2d 731, 735 (1993) (quoting Seaboard Surety Co. v. Richard F. Kline, Inc., 91 Md. App. 236, 244, 603 A.2d 1357 (1992) (internal citations omitted) (emphasis in original)).

Even assuming the truth of the evidence adduced by Respondents, Respondents could not sustain a legal cause of action for lack of informed consent given that Respondents failed to adduce any evidence of material risks that were not disclosed to Mr. Fusco. Additionally, even assuming Respondents were premitted to introduce the evidence pertaining to the package insert and the lack of FDA approval, none of this evidence would cure the dispositve defect in Respondents' case given that there was no expert testimony to equate those issues to “material risks” to the use of Amifostine. Respondents' claims in this regard were legally deficient. Accordingly, this is precisely the “appropriate case” for which a grant of summary judgment was proper as a matter of law.

Likewise, in reviewing the denial of a motion for judgment, the appellate courts utilize a de novo standard of review. Specifically, appellate courts consider whether, on the evidence presented, a reasonable fact-finder could find the elements of the cause of action by a preponderance of the evidence. *See University of Maryland Medical System v. Gholston,* 203 Md. App. 321, 329, 37 A.3d 1074 (2012). Given that Respondents did not adduce any evidence that Dr. Shannon failed to inform Mr. Fusco of material risks to Amifostine, no reasonable finder of fact could conclude that the elements of lack of informed consent had been established; thus, Petitioners were entitled to judgment in their favor.

Therefore, under either mechanism (summary judgment or judgment), the trial court's failure to enter judgment on behalf of Petitioners was erroneous. Likewise, the Court of Special Appeals' failure to enter judgment, let alone consider these issues, was erroneous.

***38 B. Evidence as to "Material Risks" are necessary to establish a Prima Facie case of Lack of Informed Consent**

Informed consent, as applied today, was first established in *Sard v. Hardy,* 281 Md. 432, 379 A.2d 1014 (1977). In Sard, the Court of Appeals stated that "the doctrine of informed consent imposes on a physician, before he subjects his patient to medical treatment, the duty to explain the procedure to the patient and to warn him of any material risks or dangers inherent in or collateral to the therapy, so as to enable the patient to make an intelligent and informed choice about whether or not to undergo such treatment." *Id.* at 439, 379 A.2d at 1020 (emphasis added). Furthermore, "the scope of the physician's duty to inform is to be measured by the materiality of information to the decision of the patient." Id. at 444, 379 A.2d at 1022.

As with any negligence action, there exists a duty of care and a breach of that care. In an informed consent case, "the proper test for measuring the physician's duty to disclose risk information is whether such data will be material to the patient's decision... a material risk is one 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." Sard, 281 Md. at 443-444, 379 A.2d at 1022. Cases subsequent to Sard have continued to define the physician's duty in informed consent cases to that which a physician knows or ought to know would be significant to a reaonable patient. *See McQuitty,* 410 Md. at 21, 976 A.2d at 1032; *Zeller v. Greater Baltimore Med. Center,* 67 Md. App. 75, 84, 506 A.2d 646, 651 (1986). Thus, "material risks" is the fundamental question in establishing duty in an informed consent claim, the scope of which is defined as ***that which a physician knows or ought to know.***

Furthermore, the Court of Appeals has made clear ***"expert testimony is necessary to establish the material risks*** and other pertinent information regarding the treatment or procedure." *Waldt,* 411 Md. at 232, 983 A.2d at 127. The determination of what constitutes a "material risks" should not be left to the jury. Maryland law affirms that a physician is not obligated to disclose risks that are insiginficant or ***39** infintesimal. See McQuitty, 410 Md. at 12, 976 A.2d at 1032 (stating that a healthcare provider is not burdened with the duty of divulging all risks, but only those which are material to the intelligent decision of a reasonably prudent patient)(internal citations omitted). The science of medicine, as well as the practice of medicine, are complex and generally well beyond the understanding of lay jurors. This is particularly so in cases like Mr. Fusco's where complex oncologic patients are being treated in a multifaceted manner (radiation, hormone therapy, drugs), and the particular drug at issue - Amifostine - is not a drug commonly utilized by members of the populous. Additionally, the alleged resulting injury to the patient was one of the most rare diseases and occurrences: the undisputed testimony in this case established that the risk of SJS or TENS from Amifostine is between 6-9 cases per 10,000, for a statistical rate of 0.06 to 0.09. [E.1547-48].

To leave to the jury, in a case like this, the ability to define what consitutes a "material risk" to Amifostine in a patient with Stage Tic prostate cancer who voluntarily opted for radiation and hormone therapy, is nonsensical and quite frankly, unjust. For these very reasons, Maryland law adheres to the principle that a physician is not obligated to disclose risks that are infintesimal. See McQuitty v. Spangler, 410 Md. 1, 12, 976 A.2d 1020, 1032 (2009). Thus, the nature of that which constitutes "material risks" is the pivotal question in establishing duty in an informed consent claim, and the scope of that of which is defined as ***that which a physician knows or ought to know.***

The pivotal issue before this Court can be boiled down to this: to establish a *prima facie* case of lack of informed consent, does Maryland law require that plaintiffs adduce evidence that a material risk was not disclosed to the patient. Applied to the case at hand, the specific question becomes: did Mr. Fusco adduce any evidence (in discovery or trial) that Stevens Johnson Syndrome / Toxic Epidermal Necrolysis was a material risk to the use of Amifostine which Dr. Shannon failed to disclose. The answer to that question is an resounding and unqualified - no.

Respondents produced no expert testimony on the issue of material risks to ***40** Amifostine.[7] No expert testified that TENS was a material risk to Amifostine; no expert testified that Stevens Johnson Syndrome was a material risk to Amifostine; no expert testified that off-label use was a material risk to Amifostine; no expert testified that limited clinical trials on prostate cancer or **eldery** patients was a material risk to Amifostine. On every level conceivable, Respondents' failed to establish a *prima facie* case of lack of informed consent.

Given that Respondents had no qualified expert witness to testify as to the material risks to the use of Amifostine, Respondents failed to adduce evidence to establish duty, or breach thereof, as it pertains to informed consent. Even if this Court somehow affirms the intermediate court and allows the pharmacist to testify to Amifostine, generally, Dr. Trovato will still fail to offer any opinions as to that which constituted a "material risk" of Amifostine requiring disclosure by Dr. Shannon in order to satisfy the doctrine of informed consent. Dr. Trovato never rendered those opinions in his deposition, nor in his de bene esse videotaped trial testimony, nor in his proffer. The lack of evidence on "material risks" was a dispostive gap in Respondents' case below, and will continue to be a dispositve gap upon remand.

Ironically, the Court of Special Appeals discussed the correct elements of the informed consent cause of action in its opinion:

> "For a complainant to establish a *prima facie* case of failure to obtain informed consent, the complainant must illustrate (1) an existence of a material risk, which the physician must explain to the patient; (2) the failure of the physician to inform the patient of the material risk; (3) the physician knew or ought to have known of the material risk; and (4) a causal connection between the lack of informed consent and the harm. ***41** *See generally Schwartz,* 206 Md.App. at 484, 49 A.3d 359; Sard, 281 Md. at 444, 379 A.2d 1014 (citing Miller, 522 P.2d at 863); *Goldberg, et al. v. Boone,* 396 Md. 94, 123, 912 A.2d 698 (2006) (citing Sard, 281 Md. at 448, 379 A.2d 1014)."

See Fusco, 210 Md. at 411, 63 A.3d at 152. The Court of Special Appeals also correctly noted that "an expert witness is *required* to ascertain the material risks and other significant factors concerning the medical therapy." *Id.* (citing *Univ. of Maryland Med. Sys. Corp. v. Waldt,* 411 Md. 207, 232, 983 A.2d 112 (2009)(emphasis added).

Juxtaposing those two legal principles alone - (a) that a material risk is defined as that which a *physician* knows or ought to know, and (b) that an expert is required to testify as to material risks -leads to the obvious and natural conclusion that Respondents must adduce some evidence, through qualified expert testimony, that a material risk was not disclosed. Putting aside the question of who is qualified to testify to material risks, for a moment, the most glaring void in Respondent's case is that they have nobody to testify as to material risks, an element which the Court of Special Appeals, itself, affirmed was required to establish informed consent. *Id.*

The Court of Special Appeals' holding in this matter reinforces the dispositive void: the intermediate court held (appropriately so) that Dr. Trovato could not testify as to the "material risks" of the treatment regimen given that such testimony would exceed his qualifications and expertise. Given this holding, the intermediate court should have also held that summary judgment and/or directed judgment should have been entered in Petitioners' favor. Petitioners request that this Honorable Court reverse the Court of Special Appeals and enter judgment in Petitioners' favor.

IV. The Trial court properly granted Petitioners' motions in Limine pertaining to the Drug's Package Insert and Reference to FDA approved uses of Amifsotine; the Court of Special Appeals Erroneously Reveresed the Trial Court.

***42 A. Standard of Review**

Evidentiary rulings, particularly those hinging on relevance, are entrusted to the wide discretion of the trial judge. *See Merzbacher v. State,* 346 Md. 391, 404, 697 A.2d 432, 439 (1997). An appellate court will not second-guess such a decision absent a clear **abuse** of the trial court's discretion. *See Smallwood v. Bradford,* 352 Md. 8, 27, 720 A.2d 586, 595 (1998); *North River Ins. Co. v. Mayor and City Council of Baltimore,* 343 Md. 34, 89-90, 680 A.2d 480, 508 (1996); *Armstead v. State,* 342 Md. 38, 66, 673 A.2d 221, 235 (1996).

In addition, to prevail on appeal when contesting a court's evidentiary ruling, the aggrieved party must establish that the error "was ***both manifestly wrong and substantially injurious."*** *See Beahm v. Shortall,* 279 Md. 321, 331, 368 A.2d 1005, 1011 (1977)(quoting *Rotwein v. Bogart,* 227 Md. 434, 437, 177 A.2d 258, 260 (1962))(emphasis added); *See also Benik v. Hatcher,* 358 Md. 507, 537, 750 A.2d 10, 26 (2000)("It is well settled that a civil judgement will not be reversed unless the complaining party shows both error and prejudice."). Meaning, error by the lower court alone will not suffice. Substantial injury must also be established. Unless the aggrieved party establishes substantial injury, there the verdict will stand. *See Harris v. Harris,* 310 Md. 310, 319, 529 A.2d 356, 360 (1987); *McQuay v. Schertle,* 126 Md. App. 556, 587, 730 A.2d 714, 730-31 (1999)(quoting *Beahm, supra,* 279 Md. at 331, 368 A.2d at 1011).

The evidentiary rulings made by the trial court below which (a) precluded the use of a drug package insert from Amifostine, and (b) precluded discussion of whether or not Amifostine was FDA approved for use in prostate cancer patients, were neither manifestly wrong nor substantially injurious. The Court of Specials Appeals' reversal was legally incorrect and factually unsupported by the record.

B. The package insert's precautionary statement that there had been limited clinical trials involving elderly patients was properly excluded by the trial court.

At the outset, it is significant to note that Dr. Trovato only raised the package ***43** insert's precautionary statements regarding the limited testing in the **elderly** as support for his opinions that the use of Amifostine was inappropriate, i.e., a basis for his opinions sounding in negligence. [E.158-59, 160, 161] Respondents never adduced any evidence in discovery that the limited testing in the **elderly** was a material risk to Amifostine which Dr. Shannon needed to disclose to obtain informed consent. Likewise, Dr. Trovato's trial testimony never included opinions that limited testing in the **elderly** was a material risk requiring disclosure. In fact, even Respondents' untimely post-discovery proffer failed to contend that the lack of testing in the **elderly** was a material risk to the drug. [E.488] The proffer merely states that Dr. Trovato will testify that the package insert gives a precaution as to the administration of the drug to the **elderly** since the effects have not been tested extensively in the **elderly** population. [E.488]. In that manner, the proffer continues to sound in negligence, i.e., the propriety of administering the drug on an **elderly** patient, and not informed consent. Id.

Accordingly, despite never having elicited any testimony that disclosing that Amifostine had limited clinical trials in the **elderly** was a required component of an informed consent discussion with a patient, the Court of Special Appeals nevertheless stripped Petitioners of the verdict in its favor so as to permit Respondents the opportunity to attempt to elicit on remand that which they failed to elicit during discovery deposition, trial testimony or their untimely proffer. Stated differently, there is absolutely no factual predicate for the Court of Special Appeals' reversal. An appellate court should not be permitted to superimpose upon the record evidence that did not exist below to support an outcome that it apparently desires, but ironically, even on remand, cannot obtain. Recall that the Court of Special Appeals (correctly) held that Dr. Trovato was not qualified to testify as to the material risks, benefits and alternatives to a treatment regimen for an informed consent discussion. On remand, therefore, Dr. Trovato could not testify that the limited clinical testing equated to a material risk; to the contrary, his testimony on remand would

simply be that there were limited clinical trials in the **elderly**. Without more, however, such testimony still falls ***44** victim to the considerations of relevancy and prejudicial effect, and would be precluded under either Maryland Rule 5-402 or 5-403.

Furthermore, the Court of Special Appeals completely ignored the multiple problems with the package insert on which Dr. Trovato and Respondents relied. First, the package insert post-dated the drug that was actually used by Mr. Fusco. [E.540]. Second, the package insert was from a different manufacturer of Amifostine than the manufacturer who developed the Amifostine utilized by Mr. Fusco. Id. Third, the package insert was not authenticated and contained hearsay. [Not even Dr. Trovato's proffer provides authentication]. Finally, as previously stated, there was no expert testimony to establish that a precautionary notification in a package insert about the limited clinical trials of Amifostine in **elderly** patients was equivalent to a "material risk" to the use of the drug, such that Dr. Shannon had a duty to disclose this "material risk" to Mr. Fusco.

Had Respondents presented a package insert from the appropriate manufacturer and from the appropriate time period, and had Respondents produced a qualified expert who would testify that the package insert was reasonably reliable within Dr. Shannon's field, and had Respondents produced a qualified expert who offered timely opinions that limited clinical testing equated to a material risk, and had Respondents produced a qualified expert who offered timely opinions that Dr. Shannon breached his duty to obtain informed consent by failing to disclose this information about limited testing on the **elderly**, -- then, Respondents may have been entitled to elicit such testimony. Given that Respondents possessed none of the above factors, the trial court's ruling precluding the use of the package insert (and the information contained therein) was entirely appropriate. [8] The Court of Special Appeals' reversal of the same ***45** is unsupported by the factual record, contrary to the Maryland Rules, and legally improper.

C. Evidence regarding the lack of FDA approval specific to prostate cancer was properly excluded by the trial court.

1. Respondents never adduced any evidence that the FDA status was required to be disclosed in an informed consent discussion.

As previously discussed, Dr. Trovato's testimony throughout discovery and de bene esse trial testimony was that the use of Amifostine was inappropriate in this case. Another basis for his opinion that it was wrong to ***use*** Amifostine in Mr. Fusco's care was that the FDA had not specifically approved Amifostine in prostate cancer patients. (Note: Amifostine had been approved as a "radiation protectorate" for other types of cancer, including head, neck, ovarian, and kidney cancer; regarding prostate cancer, however, the drug was in the second phase of clinical trials). Once again, Dr. Trovato's opinions in this regard sounded in negligence and not lack of informed consent. Dr. Trovato's trial testimony was unequivocally clear: that the lack of FDA approval supported his opinion that the drug should not have been used. [E.147]. And once again, even Respondent's proffer only provides that Dr. Trovato will explain that there is "no medical literature or clinical trials that demonstrate the efficacy of Amifostine for treatment in prostate cancer." [E.488]. As with the **elderly** issue above, the proffer still sounds in negligence, i.e., the usefulness of the drug for a prostate cancer patient. Id. Regardless, there was no proffer that Dr. Trovato would equate the lack of data for prostate cancer patients to a material risk to the use of the drug for Mr. Fusco which must be disclosed in an informed consent discussion.

Despite having *never* adduced any evidence in discovery deposition, trial testimony or untimely proffer, Respondents argued that the trial court erred by not permitting them to disclose to the jury the lack of FDA approval for prostate cancer ***46** and argue that Dr. Shannon should have disclosed the same. [9] Meaning to say, without any factual predicate and without any expert witness testimony to support it's relevance to informed consent, Respondents wanted to be able to argue the FDA issue to the jury. Remarkably, the Court of Special Appeals agreed.

Petitioners objected to the introduction of evidence on FDA approval, not only on the grounds that Respondents lacked any evidentiary support or factual predicate for their position, but also on the basis that Maryland case law established that the approval, or lack thereof, by the FDA of a particular drug or product was relevant to a negligence claim, not a lack of informed consent claim. Specifically, the case of *University of Maryland Medical System v. Waldt*, 411 Md. 207, 983 A.2d 112 (2009) is analogous and controlling. There, the trial court received a proffer from plaintiffs' expert that the device (a neuroform stent) was

not approved by the FDA for use on Mrs. Wald's type of aneurysm. The trial court concluded that such evidence was not a proffer of an inherent risk to the procedure that Mrs. Waldt underwent; rather, it was a proffer of expert testimony that the procedure was contraindicated for Mrs. Waldt, and therefore should not have been performed on her. *Id.* at 235-36. This Court agreed and stated that this "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." *Id.* at 236. In short, that aspect of the expert's proffered opinions was ruled irrelevant and inadmissible. *Id.*

It is indisputably clear that Dr. Trovato's trial testimony, i.e. that Amifostine should not have been used in Mr. Fusco because it was not yet FDA approved for prostate cancer, was only relevant to an ordinary negligence claim. A close review of Dr. Trovato's proffer likewise reveals that it continues to sound in negligence. The ***47** proffer merely advises that Dr. Trovato will testify that while the FDA has approved the drug for various other cancers, the FDA is in its second (of three) phases of clinical trials relative to prostate cancer. [E.488]. As it relates to the FDA issue, Dr. Trovato's proffer is virtually identical to the proffer this Court considered in Waldt. In Waldt, plaintiffs' expert proffered that the device (a neuroform stent) was not approved by the FDA for use on Mrs. Waldt's type of aneurysm. In the case sub judice, Dr. Trovato proffered that the drug was not approved by the FDA for use on Mr. Fusco's type of cancer. In both cases, the off-label use of the product would be relevant only to an ordinary negligence claim. Yet, the Court of Special Appeals attempts to explain away it's departure from *Waldt* by remarking that the proffer was insufficient in Waldt, but was somehow sufficient in this case. *Id.* at 434-45, 63 A.3d at 166. Upon close comparison of the FDA portion of these proffers, however, the speciousness of this position becomes evident. In both Waldt and this case, the proffered testimony boils down to: the FDA has not approved this product for this type of ailment.

Dr. Trovato's proffered testimony as to the FDA approval issue must meet the same fate as Dr. Debrun's proffered testimony in Waldt and be deemed irrelevant and inadmissible on the issue of informed consent. The testimony concerning off-label use of Amifostine goes to just that: it's use. Such evidence is not relevant to an informed consent claim, particularly given that Respondent's expert never testified that lack of FDA approval specific to prostate cancer was a material risk or necessary component of an informed consent discussion. [10] The trial judge correctly ruled that such statements would confuse the jury given that there was no testimony to link it to any component of informed consent. For these reasons, the trial court was entirely correct to refuse to allow Respondents' counsel to discuss the FDA approval issue with the jury in opening statements, or otherwise adduce evidence pertaining to it at trial. ***48** [E.602].

The Court of Special Appeals had no factual predicate to support the extreme recourse of reversing a judgment, particularly when based upon on evidentiary grounds where **abuse** of discretion is the standard of review. The fact is, the Court of Special Appeals relied exclusively on an *untimely* proffer by an *unqualified* witness which still contained opinions sounding in negligence and *not* informed consent. There was simply no basis to strip the judgment from Petitioners and remand for a new trial. Petitioners request that this Court reverse the Court of Special Appeals and affirm the judgment below.

2. The FDA status of a drug should not be a required component of an informed consent discussion.

While Respondents will attempt to convince this Court otherwise, the record is clear: Dr. Trovato, nor any expert for that matter, never testified that disclosing the FDA status of Amifostine (for prostate cancer) was required to constitute informed consent. Accordingly, this Court need not delve into the merits of whether FDA status must be disclosed in an informed consent discussion.

Out of an abundance of caution, however, Petitioners briefly address the merits of this issue. Our sister states have squarely considered the issue whether the FDA status must be disclosed in an informed consent discussion, and determined that such disclosure is not required for informed consent The Supreme Court of Pennsylvania found "no reason to expand the information that surgeons traditionally impart to their patients to encompass a device's FDA regulatory status." *See Southard v. Temple University Hosp.*, 781 A.2d 101, 107 (Pa. 2001). The Southard Court explained that "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 ***49** patient has been fully informed regarding the procedure." *Id.*

New Jersey courts have likewise "endorse[d] the majority opinion as expressed by the court in *Southard, [supra]." See Blazoski v. Cook,* 787 A.2d 910, 919 (N.J. Super. App. Div. 2002). The Blazoski Court explained that the issue in informed consent cases is whether the physician failed to disclose material information surrounding a particular treatment to the patient; "[i]n contrast, the FDA regulatory status does not speak directly to the medical issues surrounding a particular [treatment]." *Id.* (citations omitted). The *Blazoski* Court noted that the "FDA's concern is to regulate the marketing and labeling of medical drugs and devices, not to intrude upon the practice of medicine or redefine the doctrine of informed consent." *Id.* The court further discussed the "sound policy reasons" why the FDA status need not be disclosed:
"Further, there are sound policy reasons why the FDA status need not be disclosed. Requiring disclosure may necessitate a pre-surgery discourse by the physician on the mechanics of the FDA approval process which may dilute the significance of material, medical risks related to the procedure.

Patients... would be distracted from learning about the nature, risks, and benefits of their treatments by regulatory information of de minimus value. Such information would accentuate the errant notion that all off-label use is by definition inherently risky, novel, or investigational. By implying risk or novelty when there is none, these disclosures could frighten patients away from the very therapies that actually are best for the treatment of their conditions."

Id. at 920. To the extent this Court considers the issue of whether FDA status is a required component of an informed consent discussion (despite the lack of factual predicate for such consideration), Petitioners maintain that the majority view, as espoused in our sister states, *supra,* is consistent with Maryland law and promotes sensible public policy.

The Federal Food, Drug and Cosmetic Act (FDCA) expressly disclaims any intent to directly regulate the practice of medicine through the FDA labeling process, see 21 U.S.C. § 396 (1994 ed., Supp. V). The United States Court of Appeals for the ***50** District of Columbia Circuit noted that, "[a] physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA.... [furthermore,] it is undisputed that the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties." See Washington Legal Foundation v. Henney, 202 F.3d 331, 333 (D.C. Cir. 2000)(internal citations and quotations omitted). The U.S. Supreme Court recognized that "off-label" usage of medical devices "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." See Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 350, 121 S.Ct. 1012 (2001). In fact, off-label use is frequently "state-of-the-art treatment," given that medical advances routinely outpace the FDA's regulatory process. See V. Henry, "Off-Label Prescribing: Legal Implications," 20(3) J. LEG. MEDICINE 365, 365 (Taylor & Francis Sep. 1999)(noting that "off-label use has become an important part of mainstream, legitimate medical practice. Many off-label uses are recommended by medical textbooks, research institutes, and professional organizations, as well as standard pharmaceutical reference works. According to some estimates, almost half of the United States population currently may be taking a medication prescribed for an unapproved reason."); see also U.S. Gen. Accounting Office, Report to the Chairman, Comm. on Labor and Human Resources, U.S. Senate, Off-Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies at 11 (1991).

The science of medicine and practice of medicine are inherently complex arenas. Physicians should not be required to add to the complexity of a treatment proposal explanations about the internal approval processes of the FDA, the interplay between drug manufacturers and the FDA, the various phases of clinical trials of a drug, and the results or implications thereof. As succinctly stated by the *Blazoski* court above, patients "would be distracted from learning about the nature, risks, and benefits of their treatments by regulatory information of de minimus value." *Blazoski,* 787 A.2d at 920. Furthermore, such disclosures would imply "risk or novelty when there ***51** is none,... [and] could frighten patients away from the very therapies that actually are best for the treatment of their conditions." *Id.* To the extent this Court intends to weigh in on the FDA disclosure issue, sound

policy favors holding that physicians are not required to make disclosure in the context of providing the patient with information on the material risks, benefits and alternatives to the treatment proposed.

CONCLUSION

In conclusion, the trial court's preclusion of Dr. Trovato and its evidentiary rulings below were proper and well within its broad discretion. As a result, the rulings below should be upheld and the judgment in favor of Dr. Shannon should be affirmed.

Furthermore, given that the Court of Special Appeals correctly held that the pharmacist, on remand, could not provide testimony "regarding the nature of the material risks associated with the particular regimen of treatment... and any alternative treatment options," there is no basis upon which the judgment in Petitioner's favor should have been vacated. Without any testimony, whatsoever, on the material risks associated with the treatment regimen proposed by Dr. Shannon, Respondents failed to adduce the requisite evidence to sustain an informed consent action, a failure that will linger on remand. To the extent that the trial court erred, it did so in denying summary judgment and/or judgment on behalf of Petitioners given that Respondents' case was void of any evidence that Dr. Shannon failed to disclose a material risk to Mr. Fusco in obtaining informed consent. Even if this matter is remanded due to some error below, this Court should remand with instructions to enter judgment in favor of Petitioners given that Respondents continue to lack the necessary evidence to support a prima facie case of lack of informed consent.

Regardless of the avenue, the Court of Special Appeals mandate should be reversed and judgment in favor of Petitioners affirmed.

Appendix not available.

Footnotes

1 SJS and TENS are very rare skin conditions in which cell death causes the dermis to separate from the epidermis. [E.1145-45]. The majority of causes are idiopathic, but the known causes are allergic reactions or hypersensitivities to medications, infections, and in rare cases, cancer.

2 The jury was unable to reach a unanimous conclusion as to question (1) pertaining to whether Dr. Shannon advised Mr. Fusco of the material risks, benefits and alternatives to the Amifostine drug. The jury provided a note to the lower court indicating that while they could not reach a unanimous conclusion to question (1), they were unanimous as to question (2) which would conclude their deliberations. [E.1711]. For this reason, the trial court elected to take the verdict. The lower court's decision to take the verdict is not an issue before this Court, nor was it an issue raised in the Court of Special Appeals below.

3 Curiously, Respondents repeatedly mischaracterized Dr. Trovato as a "pharmacologist" rather than his true profession as a "pharmacist" in their Briefs to the Court of Special Appeals below. Dr. Trovato is a *pharmacist.* [E.136]. The training programs and licensing programs for pharmacology and pharmacy are different and distinct.

4 Along those lines, the Court of Special Appeals' reliance on *Wantz v, Afzal,* 197 Md. App. 675, 14 A.3d 1244 (2011) below is misplaced. The disputed testimony in the Wantz case involved opinions by a neurosurgeon as to causation, i.e., the outcome a patient would have had if she had been immobilized prior to the spinal fusion. *Id.* at 684, 14 A.3d at 1249-50. The neurosurgeon was excluded on the basis that he hadn't actually performed the type of spinal fusion at issue. The intermediate court correctly pointed out that the neurosurgeon's testimony was not being offered for standard of care relating to the conduct of the spinal fusion procedure, rather, "the thrust of [the neurosurgeon's] testimony was that 'immobilization and immediate surgery, would have prevented Mrs. Reynolds' paralysis... [and] had she not been paralyzed at the time of surgery, her chances of success were good...." Id. Thus, the neurosurgeon had ample relevant experience in dealing with the timing of spinal surgeries and the likelihood of good outcomes after paralysis had already set in. Therefore, his inexperience with performing the specific spinal fusion surgery did not disqualify him from offering testimony regarding the pre-operative cause of paralysis (i.e., the delay in operating). *Id.* at 685, 688.

The *Wantz* opinion is distinguishable from the case at hand. Unlike the neurosurgeon in *Wantz,* who possessed relevant experience and training on the issue of causation, (the subject matter for which he was proffered), Dr. Trovato lacks any requisite experience in or knowledge about informed consent discussions between a physician and a patient and what constitutes a "material risk" for purposes of that discussion. Thus, the Court of Special Appeals' reliance on Wantz is misplaced.

5 Section 3-2A-04(b) mandates when Certificates of Qualified Experts are necessary, and the very first line of this subsection states, "(b) Unless the sole issue in the claim is lack of informed consent...." See MD. CODE, §3-2A-04(b), Cts. & JUD. PRO. ART.

6 The traditional "learned intermediary rule" provides that drug and medical-device manufacturers are liable only when their products contain manufacturing defects or are sold without adequate instructions and warnings to prescribing and other health-care providers. *See* Restatement (Third) of Torts: Products Liability § 6, "Liability Of Commercial Seller Or Distributor For Harm Caused By Defective Prescription Drugs And Medical Devices." *See also*, *Gourdine v. Crews*, 405 Md. 722, 731, 955 A.2d 769 (2008).
"The rationale supporting this 'learned intermediary' rule is that ***only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy.*** The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy. " *See Rite Aid Corp. v. Levy-Gray*, 162 Md. App. 673, 686-87, 876 A.2d 115 (2005)(quoting Restatement (Third) of Torts: Products Liability, § 6, comment b)(emphasis added).

7 In response to the motions for judgment, Appellants claimed that Dr. Shannon testified as to material risks and therefore, they met the obligation to have expert testimony on material risks. [E.1261] Naturally, as the defendant-physician in the case, Dr. Shannon testified about the material risks that he discussed with Mr. Fusco. Dr. Shannon never testified, however, that there were certain material risks to Amifostine that he failed to disclose. Quite to the contrary, the only evidence adduced both in discovery and in trial as to "material risks" established that Dr. Shannon disclosed all material risks to Amifostine, i.e. he complied with the duty of care for informed consent.

8 In spite of the lower court's explicit instruction not to mention the warnings in the package insert about **elderly** patients, [E.911], Respondent's counsel, several times in opening statements, mentioned that the medication "had a warning" that it had not been tested for use in the **elderly** and further, that Mr. Fusco was not advised of that warning. [E.924, 929, 934]. Accordingly, through argument by counsel, this information was improperly presented to the jury.

9 Dr. Shannon testified in deposition that it was his custom and practice to advise a patient when a proposed drug or medical device would be used in an off-label manner. [E.983]. Given the lower court's ruling in limine on the FDA issue, Petitioners did not raise this testimony with Dr. Shannon at trial so as not to "open the door" to impermissible evidence about the FDA approval process.

10 Had Respondents adduced such testimony, there may be a factual predicate to challenge the holding in *Waldt.* In this case, however, and with these facts, no such predicate exists; only wishful and revisionist thinking on the parts of Respondents and our intermediate appellate court.

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