2011 WL 7308627 (Md.App.) (Appellate Brief)
Maryland Court of Special Appeals.

Mafalda FUSCO, et al., Appellants,
v.
Kevin J. SHANNON, M.D., et al., Appellees.

No. 02819.
September Term, 2010.
December 2, 2011.

Appeal from the Circuit Court for Prince George's County
(The Honorable Leo E. Green, Jr.)

Brief of Appellant

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***1 STATEMENT OF THE CASE**

In April of 2007 the Appellant Mafalda Fusco, along with Anthony Fusco's surviving children, filed suit in the Circuit Court for Prince George's County against the Defendants Walid Mufarrij, M.D., Lawrence Shombert, M.D. [1] and Kevin Shannon, M.D. as well as Dr. Shannons practice, Hematology-Oncology Consultants, following the death of their husband and father, Anthony Fusco. (E. 60). Mr. Fusco died of complications from the drug Amifostine used during his cancer treatment. In the Complaint, the Appellants brought survival and wrongful death actions solely on the basis of lack of informed consent against Drs. Mufarrij, Shombert and Shannon and actions in *respondeat superior* against Hematology-Oncology Consultants. (E. 60). Following multiple motions and a denied Motion for Summary Judgment, all Defendants filed a Joint Motion in Limine to exclude the testimony of the Appellants' expert James Trovato, Pharm.D. at trial. (E. 110). Prior to a ruling on the Defendants' Joint Motion in Limine, on December 7, 2009 the Appellants filed a Motion for Postponement of Trial due to health concerns of counsel. As a result of the Appellants' motion, the trial was postponed almost a year.

On November 8, 2010, Defendants Mufarrij and Shombert, with Defendant Shannon joining later by line, filed a renewed Motion for Summary Judgment. (E. 179, E. 356). Their renewed Motion was almost identical to their previously denied Motion for Summary Judgment. However, in their renewed Motion, the Defendants maintained that ***2** a recently decided Court of Appeals case, *McQuitty v. Spangler*, served as "new law" and was directly applicable to the instant case. *McQuitty v. Spangler*, 410 Md. 1, 976 A.2d 1020 (2009). In response, the Appellants filed an Emergency Motion to Strike and Motion for Sanctions, contending that the Defendants' prior Motion for Summary Judgment, which had been denied by a different judge, contained substantially similar, if not identical, language to the renewed Motion. Further, Appellants posited that the Defendants' interpretation of *McQuitty* as "new law" was misguided, averring that the cited portion of the decision only reaffirmed the language of prior decisions. Following their emergency Motion, the Appellants also filed an Opposition to the Defendants' Renewed Motion for Summary Judgment. (E. 361). Further, the Appellants filed a Response to the Defendants' Joint Motion in Limine to exclude the de bene esse testimony of their expert, Dr. Trovato, at trial. (E. 436).

On December 21, 2010, all parties attended a motions hearing in the Circuit Court for Prince George's County, with the Honorable Leo E. Green, Jr. presiding. (E. 493). Despite the clear similarities, and seemingly identical language between the Defendants' prior denied Motion for Summary Judgment and their Renewed Motion for Summary Judgment, the trial court denied the Appellants' Motion to Strike and proceeded to hear arguments on the issues presented. Additionally, the court heard arguments regarding the Motion in Limine to exclude the testimony of Dr. Trovato, a motion that was essentially an expansion on the Defendants' arguments in their Renewed Motion for Summary Judgment. Defendants argued that they were entitled to summary judgment because, ***3** without the testimony of Dr. Trovato, the Appellants would be unable to allege a prima facie case of informed consent. Ultimately, the trial court denied the Defendants' Renewed Motion for Summary Judgment. However, the trial court granted their Motion in Limine to exclude the de bene esse testimony of Dr. Trovato, with the caveat that the Appellants would have the opportunity to file a proffer of Dr. Trovato's testimony if he were to testify live at trial, rather than through the already stricken video.

On December 27, 2010 Appellants submitted a detailed proffer of Dr. Trovato's testimony. (E. 486). Following the proffer, a second motions hearing was conducted on January 7, 2011. (E. 574). At that hearing, the trial court made the final determination that Dr. Trovato would not be permitted to testify on the basis that, despite his extensive qualifications as a pharmacologist, he was not a medical doctor and did not have experience providing informed consent. Following the exclusion of Dr. Trovato, the Defendants renewed their Motion for Summary Judgment, however, the trial court denied the motion and the case proceeded to trial.

The trial spanned nine days, from January 10 to January 19, 2011. The Appellants claimed that Mr. Fusco was not provided with adequate informed consent regarding the drug Amifostine. The Appellee claimed that he was. During the entirety of the trial, the Appellants' efforts to introduce evidence regarding the material risks of Amifostine, risks which had allegedly not been conveyed to Mr. Fusco, were repeatedly denied.

The culmination of these rulings created a domino effect which resulted in the jury receiving so little information to consider in deliberations that they were unable to follow ***4** and answer the jury sheet in the requisite manner. Ultimately, the jury rendered a unanimous decision on question two (2) that, by a preponderance of the evidence, a reasonable patient, having been informed of the material risks and complications associated with Amifostine would not have refused to consent to its use. (E. 649). However, the jury noticeably was unable to reach a unanimous verdict on the first question, which asked whether Dr. Shannon failed to obtain Anthony Fusco, Sr.'s informed consent as to Amifostine therapy. The jury was instructed on the verdict sheet not to deliberate on question two (2) before it reached a unanimous verdict on question one (1).

QUESTIONS PRESENTED

I. Did the trial court improperly grant the Appellees' Motion to Exclude the testimony of James Trovato, Pharm.D. on the basis that he was not able to testify as to the five elements of an informed consent case as outlined in *Sard v. Hardy?*

II. Did the trial court's consistent misapplication and misinterpretation of the holding in *University of Maryland Medical System Corporation v. Waldt* lead to the repeated erroneous denial of Appellants' admission of evidence relating to the approved uses of Amifostine?

STATEMENT OF FACTS

In 2001, Anthony Fusco, Sr., an eighty-two year old retiree, was diagnosed with a slow-growing type of prostate cancer. (E. 60). Despite the diagnosis, Mr. Fusco was able to continue his daily activities with minimal effects. (E. 219). In February of 2003, Mr. Fusco attended an appointment with his urologist, Dr. Mufarrij, accompanied by his adult ***5** son, Michael Fusco, to discuss his treatment options. (E. 214). He was given three options to choose from: (1) watchful waiting; (2) hormone therapy; or (3) a combination of hormone and radiation therapy. (E. 214). At the conclusion of the appointment, Mr. Fusco chose to move forward with option three, a combination of hormone therapy and radiation. (E. 215).

The treatment plan chosen by Mr. Fusco involved the use of Amifostine, a cytoprotective agent that is intended to protect certain normal tissues from damage, either from chemotherapy or radiation therapy. (E. 263). Amifostine was administered by way of an injection. (E. 264).

At the time of Mr. Fusco's treatment, Amifostine had been proven to provide relief only to patients with head and neck cancer and kidney cancer. (E. 268, E. 340). Amifostine was not approved for use in the treatment of prostate cancer and, in fact, little clinical testing had been conducted for such use. (E. 268, E. 340). In addition, minimal clinical testing had been performed relative to the use of Amifostine in **elderly** patients. (E. 341, E. 268). The package instructions, provided to the physicians, contained a warning for use in **elderly** patients. (E. 341). The most common risk factors associated with Amifostine included nausea, vomiting, and, most importantly in this case, allergic or immunologic reactions, including a rash, hives, toxic necrolysis and Stevens-Johnson Syndrome ("SJS"), a life-threatening skin condition in which the epidermis separates from the dermis. (E. 341).

***6** All parties recall that Michael Fusco, Anthony's son, was present at the relevant visits prior to the initial injection of Amifostine. Moreover, Michael Fusco contends he was present during all relevant conversation concerning the administration of Amifostine. (E. 217, E. 262). Appellants contend that Mr. Fusco's radiologist oncologist, Lawrence Shombert, M.D., simply told him that a "cocktail shot" would be administered to help reduce nausea and replenish blood cells depleted during his rigorous course of radiation treatment. (E. 216). Furthermore, it is the position of the Appellants that his hematologist oncologist, Kevin Shannon, M.D., the administering doctor and the Appellee in this case only informed Mr. Fusco that Amifostine was a drug to help with nausea and replenishing blood cells and nothing more. (E. 217). Appellee contends that he had a lengthy discussion with Mr. Fusco wherein he informed him of the material risks of Amifostine. Appellee contends he informed Mr. Fusco that there were three pertinent side effects which include hypotension, nausea, and skin side effects and states he went on to explain each possible side effect in turn. (E. 263-68). Most importantly, Appellee contends that he prefaced his conversation

about Amifostine with Mr. Fusco by stating that Amifostine is only approved in head and neck cancer. (E. 268). Appellants contend that Appellee never went into detail about the aforementioned risks associated with Amifostine, never informed Mr. Fusco that this drug was not approved for the use in the treatment of prostate cancer because of inadequate testing, and never informed Mr. Fusco about the warning in **elderly** patients. (E. 217).

***7** Equipped with little information regarding the dangers of these injections, or the fact that that its' benefits were largely unknown, Mr. Fusco agreed to undergo radiation and hormone therapy with the use of Amifostine. (E. 218). On May 16, 2003, after nearly five weeks of radiation therapy, in conjunction with injections of Amifostine, Mr. Fusco developed a skin rash that marked the beginning of his severe decline in health. The following day, Mr. Fusco also developed a dangerously high fever, swollen lips and lesions covering his entire body. Extremely concerned, his family rushed him to the emergency room at the Doctor's Community Hospital, where he was admitted into the Intensive Care Unit ("ICU"). (E. 222). It was in the ICU that Mr. Fusco was given the devastating diagnosis of SJS. Following the diagnosis, the Appellee met the Fusco family at the hospital, where he informed the family that Mr. Fusco's condition was a direct result of the administration and use of Amifostine. (E. 224-25).

Following his diagnosis of SJS, Mr. Fusco's condition continued to deteriorate. On May 20, 2003, his condition had progressed into Toxic Epidermal Necrolysis Syndrome ("TENS"), a more severe form of SJS. (E. 226-27). During the summer of 2003, Mr. Fusco's condition deteriorated further, as he was shuttled to various hospitals and nursing facilities, all the while enduring excruciating pain from the effects of TENS. (E. 460). Ultimately, Mr. Fusco was transferred to Doctor's Community Hospital where he died on December 4, 2003. Mr. Fusco's transfer diagnoses and death summary notes resulted in a summary diagnosis of arteriosclerotic cardiovascular disease with the additional and substantial contributing factor of TENS. (E. 387-89). It is the position of the Appellants ***8** that Mr. Fusco's death was caused by TENS, which he developed as a result of his treatment with Amifostine. (E. 460).

Amifostine was a drug that had not been approved for use in prostate cancer patients, or even substantially tested for such use. (E. 268). Furthermore, the package insert had a warning for use in **elderly** patients; the drug had not undergone significant clinical testing for use in the **elderly** population. (E. 341, E. 268). It is the Appellants' contention that Mr. Fusco was provided with woefully inadequate information to make an informed decision as to whether or not to utilize this medication. However, as discussed in detail below, the majority of these crucial pieces of information, which were withheld from Mr. Fusco, were deemed inadmissible at trial.

ARGUMENT

I. THE TESTIMONY OF JAMES TROVATO, PHARM.D. WAS ERRONEOUSLY EXCLUDED AS DR. TROVATO IS QUALIFIED TO TESTIFY TO THE FIVE FACTORS OF INFORMED CONSENT AS REQUIRED BY MARYLAND LAW.

In an informed consent case, the measurement of the physician's duty to inform the patient is determined by the materiality of the information to the ultimate decision of the patient. *Sard v. Hardy*, 281 Md. 432, 444, 379 A.2d 1014, 1022 (1977). A "material risk" has been defined in Maryland as a risk that is "one which a physician knows or ought to know would be significant to a reasonable person in the patient's position..." *Id.* A party bringing an informed consent suit is **not** required to provide expert medical ***9** testimony as to the **standard of care, and subsequent breach of that standard, as the duty is to be determined by reference to a general standard of reasonable conduct in the eyes of the patient.** *Id.* at 447, 379 A.2d at 1024. Instead, expert testimony is required in an informed consent case solely for the purpose of establishing the nature of the risks inherent in a particular treatment, the probabilities of therapeutic success, the frequency of the occurrence of particular risks, the nature of available alternatives to treatment and whether or not disclosure would be detrimental to a patient. *Id.* at 448, 379 A.2d at 1024.

In evaluating the sufficiency of an expert, it is the responsibility of the trial judge to determine whether an individual is qualified to serve as an expert witness in the specified area. Md. Rules, Rule 5-702. In Maryland, the discretion of the trial judge regarding

the admissibility of expert testimony will not be disturbed on appeal unless it was clearly erroneous. *Wilson v. State*, 370 Md. 191, 200, 803 A.2d 1034, 1039 (2002).

In the instant case, the Appellants offered James Trovato, Pharm.D. to testify about the material risks associated with the drug Amifostine. (E. 85). Dr. Trovato is an associate professor with the Department of Pharmacy Practice & Science at the University of Maryland School of Pharmacy and is the director of the University's residency program. Dr. Trovato is also board certified in oncology pharmacy practice. (E. 486).

Prior to trial, the trial court was provided with the opportunity to assess the de bene esse deposition of Dr. Trovato during its review of the Appellees' Renewed Motion ***10** for Summary Judgment. During the December motions hearing, it was proffered by the Appellants that Dr. Trovato would testify, based on his extensive knowledge in the field of pharmacology and of the use of Amifostine in oncology, to the material risks and benefits of Amifostine treatment. The vast majority of Dr. Trovato's opinions had nothing to do with the standard of care. Despite this fact, the trial court repeatedly misconstrued Dr. Trovato's testimony regarding the material risks and benefits of Amifostine treatment as testimony regarding a deviation in the standard of care. The trial court seemingly misinterpreted the standards for an informed consent case versus a medical malpractice case. The following conversation regarding Dr. Trovato's qualifications occurred at the first motions hearing:
MR BELSKY: ...Dr. Trovato is eminently qualified. He is a pharmacologist. He is a doctor of pharmacy. He's the most appropriate type of expert in this case. He's not a standard of care expert. He's never been posited as a standard of care expert.

THE COURT: **Well that's what this case is about, a standard of care. It's about an informed consent.**

MR. BELSKY: **Its not about standard of care. Its about informed consent.**

THE COURT: **Right. But the problem is Dr. Trovato has never done an informed consent. He's never weighed the risk, never related to the risk.**

MR. BELSKY: He doesn't have to under Maryland law. And in fact, Maryland law discourages that. I mean the bottom line is that this is not a standard of care case. The question here isn't –

THE COURT: But that's what he testifies. I read his deposition last night on my kitchen table, I read it.

MR. BELSKY: And I'm going to concede one point. There's one question that was asked of Dr. Trovato, which I agree should be stricken. And that is, was it a violation of the standard of care. Because that's not the issue here. Maryland case law –

***11** THE COURT: Okay but where else in there does he say it?

MR. BELSKY: What he talks about –

THE COURT: What you said, just said it shouldn't be administered. That's his opinion. He's not a medical doctor.

MR. BELSKY: Correct. I agree with you. I'm agreeing with you. But nobody need testify that it should or should not be administered. That's the difference between this and a medical malpractice case. In a medical malpractice case, Maryland law has always held you must have a physician, board certified in the same speciality [sic] to come in and testify that there was a breech [sic] or a violation in the standard of care. In Maryland the law from Sard on down has held. [sic] That the Defendant or the physician is free to introduce evidence of his compliance with the standard of care. But that proof is not dispositive or conclusive in any way. It is for the jury to determine whether the patient as deprived of his right to self determination...[t]he only place where expert testimony could become material in an informed consent case, as opposed to a medical negligence or a medical malpractice case, is in talking about what the side effects or complications of medication or treatment are. And what we have here is exactly that. Dr. Trovato is the best person to testify to that. He need not and cannot, as a matter of law, testify

there was or was not a deviation in the standard of care. The only issue here, the simple issue in any informed consent case, is not the typical medical malpractice case. It's not was there or was there not a breach. (E. 515-17).

The court continued to misinterpret the nature and purpose behind Dr. Trovato's testimony in later discussions during the hearing:
MR. BELSKY: Well the risk is different then [sic] the question, is it appropriate or inappropriate for this drug to have been administered. That question is not relevant in an informed consent case.

THE COURT: But that's all your guy was saying in his deposition.

MR. BELSKY: No. Your Honor, he went on for pages and pages talking about the risks and side effects and complications of amifostine. He went through the handout and in the standard of care. So says Sard, so says Mahler, so says Spangler.

***12** THE COURT: But Trovato is not talking about informed consent. He's talking about the drug itself.

MR. BELSKY: Correct.

THE COURT: Isn't that a negligence question?

MR. BELSKY: No, he's talking about the risks of the drug. Which is what we need – what the jury needs to hear. And what the jury is entitled to hear under Sard and McQuity [sic] and Mahler, is that this is the drug that was administered, these are the risks of that drug. That's it. That's all they need to be given. (E. 518-19).

Despite multiple attempts by the Appellants to clarify the evident confusion regarding the purpose behind Dr. Trovato's testimony, and the overall rationale behind an informed consent case, the court granted the Motion in Limine to exclude Dr. Trovato's de bene esse testimony. (E. 558). Following the granting of the motion, the court requested that the Appellants submit a proffer of Dr. Trovato's live testimony at trial to determine whether he would be completely excluded as an expert. (E. 564).

In response to the trial court's ruling, the Appellants submitted a full and extensive proffer of the testimony of Dr. Trovato. (E. 486). In their proffer, the Appellants reiterated Dr. Trovato's extensive credentials in the area of pharmacology and his experience regarding the appropriate or safe use of medication in oncology patients, specifically, the education and advice he provides regarding the use and risks of Amifostine, stating:
Dr. Trovato is an associate professor with the Department of Pharmacy Practice & Science at the University of Maryland School of Pharmacy and is the Director of the University's Residency program. Dr. Trovato is board certified in oncology pharmacy practice...[i]n addition to his teaching responsibilities, Dr. Travato [sic] has a clinical practice which focuses on “insur(ing) appropriate or safe use of medication in ***13** oncology patients”...[a]s a part of his teaching and clinical responsibilities, Dr. Trovato educates and advises patients on the appropriate and safe use of oncology medications, including the use of Amifostine. Dr. Trovato plays a pivotal role in educating patients and physicians about the risks and side effects of particular modes of treatment as well as the potential benefits of treatment and, ultimately, in selecting said treatment...Dr. Trovato makes recommendations to the physicians and patients as to what drug therapy is best for each patient, and plays a direct role in obtaining informed consent from a patient... (E. 486-87).

The Appellants went on to outline in their proffer:

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

> testify that the most common risks of Amifostine are hypotension, nausea, vomiting and skin changes...Dr. Trovato will explain the properties of Amifostine as a cytoprotective agent and how it is used to protect certain normal tissue from damage either form [sic] chemotherapy or from radiation therapy. Dr. Trovato will testify that Amifostine has been proven to provide this type of benefit to normal tissues in patients **only with head and neck cancer and kidney cancer**Dr. Trovato will testify that it is unknown whether or not Amifostine protects the normal cells of a patient with prostate cancer... Dr. Trovato will explain that there have only been phase I and phase II clinical trials relative to the administration of Amifostine in patients with prostate cancer. Therefore, he will testify that there is no medical literature or clinical trials that demonstrate the efficacy of Amifostine for treatment in prostate cancer, only its toxicity...Dr. Trovato will testify that the package insert of Amifostine gives a precaution as to the administration of the drug to an **elderly** patient, like Plaintiff, because the toxic effects of the drug have not been tested on an **elderly** population...**Dr. Trovato will testify that the alternative to the administration of Amifostine is to refrain from its administration and treat solely with radiation therapy.** He will further testify, based upon his experience in making treatment recommendations and engaging in the informed ***14** consent process with patients, that there is no detriment to advising the patient fully about the risks associated with this medication. (E. 487-88).

Despite this extensive and specific proffer of Dr. Trovato's testimony, the trial court excluded the testimony of Dr. Trovato. In support of its ruling the trial court stated:

> There is an entirety to the informed consent and that is not just the medications, but the entire treatment. And as such, a pharmacist does not, in the Courts opinion, have the ability to give the full demarcation of what is involved in informed consent. **Quite frankly, he's never given informed consent. He's not trained in informed consent.** And he, quite frankly, he is very limited in what he does with patients... [l]et me say. I think Dr. Trovato, based on what I read, is an expert in the field of pharmacology. And he's well qualified in that area. But this is a different area. And I don't want to put any lack of shine to his credentials. This is not a thing where I have said that he's disqualified because of his background. It's because of the background and the case. For that I want to reinstate and say I have disqualified him in this case but its [sic] not because of his background or his ability or because I think he's not unbelievable or that his thing. Its [sic] because of what he's going to testify to in the nature of this case...1 do think he's well respected in a field, in pharmacology, and based on what I read, in a pharmacology case, a right case, he's qualified, more than qualified. **In this case, an informed consent case, is not in his field. And that's why I'm disqualifying him.** (E. 576, 579-80).

Such a ruling not only blurs the lines between what is required in an informed consent case, as opposed to a medical malpractice action, but, more importantly, goes against the clear and concise requirements of a prima facie informed consent case, as described in *Sard v. Hardy.*

In *Sard*, the court outlined five factors to be established by expert testimony in an informed consent case, including the "nature of risk inherent in particular treatment, ***15** probabilities of therapeutic success, frequency of occurrence of particular risk, the nature of available alternatives to treatment and whether or not disclosure would be detrimental to patient." *Sard*, 281 Md. at 447-48, 279 A.2d at 1024. The court further stated that expert testimony was not, and should not, be required to establish the scope and breach of the physician's duty, as Maryland has adopted a patient centered standard in informed consent cases. *Id.* at 447, 279 A.2d at 1024. Fostering a patient-centric approach, the ultimate determination regarding whether a patient was adequately informed was to be left to the jury. *Id.* **Nowhere in Sard, nor its progeny, did the court mandate that the expert testifying as to the five factors be certified in the same medical field or even be a medical doctor who routinely provides the basis for informed consent. In fact Maryland statutory law explicitly provides, in accordance with Sard, that, in an informed consent case, the requirements of a certificate of qualified expert are disposed of.** *See* Md. Code, Cts. & Jud.

Proc., §3-2A-04(b) (stating explicitly that a certificate of qualified expert must be filed "[u]nless the sole issue in the claim is lack of informed consent.").

In furtherance of their arguments, the Appellees consistently relied on *University of Maryland Medical System v. Waldt* to establish that Dr. Trovato was not qualified to testify as to the five required elements of an informed consent case. *Univ. of Maryland Med. Sys. Corp. v. Waldt,* 411 Md. 207, 983 A.2d 112 (2009). In Waldt, a patient and her husband brought a medical malpractice action against a doctor and his employer alleging negligence in the use of a neuroform stent to treat the patient's aneurysm and the failure ***16** of the doctor to obtain adequate informed consent for such treatment. *Id.* at 212-13, 983 A.2d at 115. In support of their case, the Waldts called a retired interventional neuroradiologist to testify as to the nature and use of a neuroform stent. Id. at 213, 983 A.2d at 116. The expert had very limited experience with the particular procedure, and testified during his voir dire that he typically used an alternative procedure because the neuroform stent was not approved for use in the United States until after he retired. *Id.* at 232-33, 983 A.2d at 126-27. The single proffer that was made regarding the expert's testimony by the plaintiffs was that he would testify that the neuroform stent was not approved for use on a person such as the plaintiff. *Id.* at 233, 983 A.2d at 127-28. No proffer was made as to the risks inherent in the use of the neuroform stent, the probability of success, the frequency of the risks, or available alternatives. *Id.*

Ultimately, the *Waldt* Court held that, considering the expert's lack of experience with the neuroform stent, his failure to disclose any specific scientific or factual underpinnings for any knowledge about the neuroform stent, as well as the skeletal nature of the proffer, the trial court did not **abuse** its discretion by finding that the expert's testimony was not "sufficiently reliable" to be admitted as to the Waldts' informed consent claim. *Id.* at 236-37, 983 A.2d at 129-30. As the Court of Appeals concluded, quoting and adopting this honorable Court's reasoning,

> Indeed, what little information was imparted to the court about the substance of Dr. Debrun's anticipated testimony was so sketchy that, on review, we are unable to determine even the theory of Waldts' informed consent claim. *Id.* at 236.

On every level, this case stands in direct contrast to *Waldt.*

***17** Contrasting the limited, and arguably non-existent, proffer made by the plaintiffs in Waldt regarding their expert's qualifications, the Appellants in the instant case extensively outlined Dr. Trovato's lengthy qualifications in their proffer. (E. 486). As previously articulated, Dr. Trovato is an associate professor with the Department of Pharmacy Practice & Science at the University of Maryland School of Pharmacy and is the director of the University's residency program. Dr. Trovato is also board certified in oncology pharmacy practice. (E. 486). Further, Dr. Trovato maintains a clinical practice that focuses on insuring the appropriate and/or safe use of medication in oncology patients. As a part of his responsibilities in teaching and clinical studies, Dr. Trovato routinely educates and advises patients on the appropriate and recommended uses of oncology medications, including the use of Amifostine treatment. (E. 486-87). Further, in advising the patients, Dr. Trovato also makes recommendations to the physicians and patients as to what drug therapy is the most suitable for each patient, thereby playing a direct role in the informed consent process. **In total contrast to the expert in Waldt, who was clearly lacking in knowledge and experience with the type of treatment at issue, Dr. Trovato was (and is) exceptionally qualified and knowledgeable about Amifostine.**

Of significance, the trial court in the instant case conceded that Dr. Trovato was an experienced, qualified expert in the field of pharmacology. As the court indicated, amongst a myriad of other accolades, "(he) is an expert in the field of pharmacology. And he's well qualified in that area." (E. 579). The court's basis for excluding him was his purported lack of experience - not with Amifostine - but with giving informed consent. ***18** As the court ruled, "He's not trained in informed consent." (E. 576). This flawed analysis is precisely the type of result that Sard sought to avoid when it held that expert testimony is required in informed consent cases for the purpose of discussing the material risks, not for the purpose of discussing deviations in the standard of care. In point of fact, a pharmacologist is the most appropriate type of expert in this case. The court's error relative to Dr. Trovato's qualifications was born out of a fundamental misapplication of the law.

It must be pointed out that, irrespective of the trial court's analysis, the uncontroverted evidence in this case was that Dr. Trovato had a tremendous amount of experience in acquiring informed consent. While it is the Appellants' position that this experience is utterly immaterial to an appropriate analysis of *Sard*, Appellant also does not want Dr. Trovato's proffer or experience to be distorted. As the proffer indicated:

> As part of his teaching and clinical responsibilities, Dr. Trovato educates and advises patients on the appropriate and safe use of oncology medications, including the use of Amifostine. Dr. Trovato plays a pivotal role in educating patients and physicians about the risks and side effect of particular modes of treatment as well as the potential benefits of the treatment and, ultimately, in selecting said treatment (*See* Discovery Deposition, Trovato, pp. 5-18). Dr. Trovato makes recommendations to the physicians and patients as to what drug therapy is best for each patient, and plays a direct role in obtaining informed consent from a patient (*See* Discovery Deposition, Trovato, pp. 36-40, 76-90, and Deposition generally). (E. 487).

This averment was not contradicted by a single fact in the record.

***19** Standing in even starker contrast to the "sketchy" and "arguably non-existent" proffer made by the Appellant in *Waldt*, the actual substance of Dr. Trovato's proffer diligently addressed each of the five elements necessary to establish informed consent case. It must be stated again that Dr. Trovato's testimony, both in his de bene esse and in the Appellants' proffer, was strictly limited to the use and risks associated with Amifostine treatment and the approved uses of the drug relative to the type of cancer that Mr. Fusco was diagnosed with and his age. As outlined in the proffer, and quoted directly on page 13 *infra.*, he was expected to testify to the following:

- the nature and frequency of the risks of Amifostine treatment, including hypotension, nausea, vomiting and skin changes;

- the probability of therapeutic success;

- the fact that Amifostine was not approved for use in the treatment of prostate cancer, and, more specifically, the reasons for the lack of approval;

- the results of clinical trials, which document the known and unknown successes of the drug, including the lack of testing in **elderly** patients and the lack of testing for use in the treatment of prostate cancer;

- the warning on the package insert cautioning against the use of Amifostine in **elderly** patients;

- the availability of other treatments, including the option to refrain from the use of Amifostine and proceed solely with radiation therapy; and

- the lack of any detriment to advising the patient fully about the risks associated with this medication.

Overall, the proposed testimony and proffer of Dr. Trovato was exponentially more substantial than that of the *Waldt* expert.

***20** Several months ago, the Court of Special Appeals distinguished the Waldt case, providing direct support and clarification for the issues in this appeal. *See Wantz v. Afzal*, 197 Md. Ct. Spec. App. 675, 14 A.3d 1244 (2011). In *Wantz*, the daughter of a deceased patient brought an action alleging negligence in the treatment of a staph infection that her mother developed at the site of a spinal fusion surgery. *Id.* at 677-78, 14 A.3d at 1245-46. At a hearing prior to trial, the court granted the defendants' motion challenging the admissibility of the expert testimony of three doctors and, subsequently, granted the defendants' motion for judgment. *Id.* The plaintiff had provided a de bene esse deposition of one of the experts and discovery depositions of the other two experts, in addition to the curriculum vitae of the experts, and additional materials supporting their credibility. *Id.* at 678,

14 A.3d at 1246. The Court of Special Appeals analyzed the qualifications of each expert, including the expert neurosurgeon, who gave opinions regarding the method of the procedure and whether alternative treatment would have prevented the staph infection. *Id.* at 680-81, 14 A.3d at 1247. Despite having not performed a spinal fusion, the expert neurosurgeon had over fifty years' experience in neurosurgery and spinal conditions, had been actively involved with the neurological aspects of the surgery and post-operative recovery from the surgery, and had worked closely with and observed orthopedists performing the same surgery. *Id.* at 689-91, 14 A.3d at 1252-53. The intermediate appellate court held that the *Waldt* situation was inapposite to the one at hand, due to the fact that the neurosurgeon, despite never having actually completed such a procedure, had extensive and credible experience, enough so to testify as to the nature of the procedure. *Id.* at 689-90, 14 A.3d at 1253.

***21** In point of fact, Dr. Trovato was, and is, more qualified than a hematologist oncologist to testify as to known risks and benefits of Amifostine treatment in an **elderly** patient with prostate cancer. Based on these qualifications, and his experience with Amifostine, Dr. Trovato was, and is, the best expert possible to inform the jury about the nature of Amifostine in oncology treatment. *See Reed v. State*, 283 Md. 374, 379-80, 391 A.2d 364, 367 (1978) (a main consideration regarding the admissibility of expert testimony is whether a jury can receive considerable and appreciable help from the expert, which is dependent on the circumstances of each case).

The Appellants conceded at all motions hearings conducted prior to trial, that Dr. Trovato was not qualified to testify as to the quality of the information specifically given to Mr. Fusco. Nor was Dr. Trovato qualified to testify as to whether that information was sufficient in Mr. Fusco's case. To allow Dr. Trovato to do so would have improperly taken the matter out of the jury's hands and would deviate from the established patient-centric standard in informed consent cases. Dr. Trovato's testimony, instead, was to be limited strictly to his expertise, namely, the general risks and information available on the drug Amifostine, for the sole purpose of informing **the jury** about the nature of the drug in order for the jury to make a determination regarding the quality of information that Mr. Fusco was given by the Appellee. As such, it is not required, as the trial court erroneously mandated, that Dr. Trovato be a medical doctor or provide informed consent on a daily basis. It is simply required that expert testimony be provided to establish the ***22** five categories of information outlined in *Sard*, which Dr. Trovato was more than prepared to impart.

The trial court confused the requirements for expert testimony in this case - a strict informed consent case - with those required in a negligence, standard of care case. As a result, the trial court obliterated the purpose underlying the doctrine of informed consent, namely, the perspective and impression of the patient when consenting to a treatment or procedure.

II. THE TRIAL COURT'S REPEATED MISINTERPRETATION OF MARYLAND CASE LAW LED TO THE CONSISTENT, ERRONEOUS DENIAL OF THE ADMISSION OF APPELLANTS' RELEVANT EVIDENCE

In the instant case, a pattern of **abuses** of discretion and errors on the part of the trial court resulted in a slippery slope of flawed evidentiary rulings, severely hindering the jury's ability to make a fair determination in this case. The errors foundationally centered on the misinterpretation of *Waldts* breadth. In essence the trial court took the narrow holding of *Waldt* and blanketly applied it to evidence never remotely anticipated or envisioned by the *Waldt* court. The result of these errors is that the jury was denied evidence of all of the following: (1) the warnings on the package insert about the use of this drug in **elderly** patients; (2) the fact that this drug had not undergone significant clinical testing in **elderly** patients; (3) the fact that this drug was not approved for use in the treatment of prostate cancer; or (4) that this drug had not undergone significant clinical testing for use in the treatment of prostate cancer.

***23** The general standard of review for a trial court's ruling on the admissibility of evidence is that, unless there is a showing that the court **abused** its discretion, or that the denial was based on an error of law, the ruling will not be disturbed on appeal. See Md. Rules, Rule 5-403 (stating that, when a trial judge's evidentiary ruling involves a weighing of both the probative value of a particular item of evidence, and the danger of unfair prejudice that would result from the admission of that evidence, the courts apply an **abuse** of discretion standard); *see also Franceschina v. Hope*, 267 Md. 632, 298 A.2d 400 (1973) (holding that a party challenging the ruling of a lower court regarding the admissibility of expert testimony holds the burden of demonstrating the

abuse of discretion). Thus, the lower court's evidentiary ruling will not be disturbed absent a showing of manifest or obvious **abuse** in discretion, resulting in a significant injustice to one party. Hance v. State Rds. Comm., 221 Md. 164, 176, 156 A.2d 644, 650-51 (1959). Such is the case here, on repeated occasions.

As outlined above, the *Waldt* case, first and foremost, focused on whether the issue of the trial judge's exclusion of the plaintiffs' expert on the issue of informed consent was properly preserved for appeal. The Court affirmed the holding of the Court of Special Appeals that the issue had not been adequately preserved. *Id.* at 231-32, 983 A.2d at 126-27. The Court went on to state that, even if the plaintiffs had adequately preserved the issue of the expert's exclusion, the **sole** basis for the expert's testimony on informed consent was the proffer that the treatment was not approved for use **in this specific medical case.** *Id.* at 232, 983 A.2d at 127. Further, the plaintiffs in *Waldt* proffered no basis for such expert testimony other than the treatment's approved use and, ***24** as a result, the court held that the testimony about the approved uses of the treatment, alone, was not a sufficient basis for the expert's qualification. *Id.* at 236-27, 983 A.2d at 129-30.

The Appellees, in the instant case, utilized this narrow and fact-specific holding regarding the disqualification of an expert to support their argument that FDA approval was never relevant in an informed consent case, and therefore, the Appellants should be barred from introducing **any** evidence of the approved uses of Amifostine at the time of Mr. Fusco's treatment. According to the Appellee, FDA approval was not relevant to any of the five categories of information outlined in *Sard.*

In response, the Appellants consistently argued at trial, and further argue in this appeal, that the evidence would not **solely** be that the drug was not FDA approved, but, rather, that the evidence would consist of the factual and scientific evidence, or lack thereof, behind the non-approved uses. Such evidence would consist of the lack of clinical trials conducted both in **elderly** patients and patients with prostate cancer. The Appellants did not simply wish to introduce evidence that Amifostine was not approved for use in prostate cancer. Rather, the Appellants wished to elicit testimony concerning the clinical trials, or lack thereof, which serve as the sole basis for evaluating the associated risks of a drug and any therapeutic success the drug may produce. Evidence concerning the clinical trials is obviously relevant for a jury to determine whether Mr. Fusco was provided informed consent regarding Amifostine.

Despite the multiple valid arguments raised by the Appellants, the trial court consistently adopted its unique flawed interpretation of *Waldt,* promoted by the ***25** Appellees. At every turn, the phrases “FDA” and “approved use” were met with a flurry of sustained objections and extreme, unwarranted sensitivity on the part of the court. (E. 596, E. 603, E. 610, E. 626). These objections and reactions transcended simple mentions of FDA approval and bled into any discussion about the lack of clinical trials conducted on **elderly** patients or patients with prostate cancer or the warning on the package insert. As a result, the Appellants were severely handcuffed in their presentation of evidence during their case in chief.

Upon even a cursory review of the Waldt case it is clear that the Court of Appeals did not mean for it to be a sweeping restriction on the overall use of any FDA-related evidence at trial. In fact, the main focus of the court in analyzing FDA approval was not on its relevancy, but was on FDA approval as the sole basis for the introduction of the testimony of an otherwise unqualified expert. *See id.* at 232-33, 983 A.2d at 127-28. Specifically, the court stated that

> [t]he only proffer that counsel for the Waldts had previously made regarding [the expert's] testimony was that he would have testified about the approved uses of the neuroform stent and that it was not approved for use on an aneurysm like Mrs. Waldt's. There was no proffer as to the risks inherent to the use of the neuroform stent on Mrs. Waldt's aneurysm... *Id.* at 233, 983 A.2d at 127-28.

The Court went on to state, “[w]e agree with the intermediate court that no testimony was proffered concerning the material risks of the procedure that would make out a *prima facie* case for informed consent. *Id.* at 236, 983 A.2d at 129. Nowhere in the body of the *Waldt* opinion does the court state that the approved uses of a treatment are **never** considered to be relevant in **any** informed consent case. ***26** *Waldt,* 411 Md. 207, 983 A.2d 112. Instead, the analysis narrowly focused on the use of FDA approval **alone** as the **sole** foundation for the qualification of an expert's testimony **in that specific scenario.** *Id.*

As stated above, due to the misinterpretation and misapplication of Waldt, the Appellants were denied the opportunity to present highly relevant and important evidence in their case in chief for informed consent. Further, due to the court's harsh reaction to **any** reference of FDA approval of Amifostine, the Appellants were continually denied the opportunity to refute the Appellees' misleading interpretation of Maryland case law. The overall result was that the jury was not given satisfactory evidence and facts upon which to render a proper verdict. The following are examples of the trial court's misinterpretation and unreasonable expansion of *Waldt.*

A. Motion in Limine

Prior to opening statements, counsel for Appellants informed the Appellees and the Court that it would like to reference the information contained in the manufacturer's package insert for Amifositne in opening statements. The package insert specifically stated that Amifostine was for use in "head and neck cancer, and ovarian and rectal cancer," not prostate cancer. This disclosure prompted Appellee's counsel to make a Motion in Limine regarding the "package insert, for Amifostine, which includes information that sets forth the approved uses of Amifostine." (E. 596- 97). Appellees' counsel went on the articulate the basis of their motion and stated, "Specifically, with regard to FDA approval, to the extent that counsel intends to articulate what the approved FDA uses were for Amifostine, we would argue and ask they be excluded in opening statements as irrelevant." (E. 597). In granting the Appellees' Motion in Limine the court ***27** ruled, "But in opening statements, Plaintiffs are not to mention or to show that exhibit to the jury." (E. 602). Appellants did not mention the FDA approved uses of Amifostine or show the exhibit in opening statements.

B. Opening Statements

Appellant abided by the court's ruling with respect to opening statement. In opening statement counsel for Appellants did, however, argue the following:
Now, he was never advised, and everybody agrees that he was never advised, that this medication has not been properly tested for use in **elderly** patients, shouldn't use it in **elderly** patients. Never told that. And so, he never had that material information in making his decision about whether or not to use the Amifostine. Never had it. Nobody disputes that fact. And that's, at the end of the day, the case right there. We need go no further. But we will go further. We will.

MR. FARLEY: Your Honor, may we approach? (E. 603-04).

Thereafter a bench conference ensued wherein the trial court admonished Appellant's counsel for "pushing the envelope." (E. 605). The trial court extended its earlier ruling to now preclude Appellants from even suggesting that Amifostine had not been tested for use in **elderly** patients or that the package insert contained a warning for use in **elderly** patients. This ruling stretched the holding of *Waldt* to an illogical and utterly unreasonable end.

C. Dr. Shannon's Deposition Excerpts

In a further effort to ameliorate the previous erroneous rulings, the Appellants attempted to read portions of Dr. Shannon's deposition into the record, in order to substantiate their claims that Mr. Fusco was not adequately informed of the risks associated with Amifostine. The Appellants intended to read into the record Dr. ***28** Shannon's testimony concerning the fact that Amifostine's label included a warning for use with **elderly** patients. (E. 268, E. 611). Additionally, the Appellants sought to introduce Dr. Shannon's testimony concerning the lack of clinical trials on patients with prostate cancer and his statement that Amifostine was not approved for use with prostate cancer patients. (E. 268, E. 611). Because the testimony mentioned Amifostine's approved uses, however, the attempt was met with an immediate objection by the Appellee, who referred back

to the court's prior ruling on the "FDA issue" with the package insert. Yet again, the trial court went through a faulty analysis of *Waldt:*

THE COURT: We're going to get to this at some point. I mean, you know, the problem I'm having with this is, if you look at the Judge Adkins' decision in the Wald [sic] case...there is no definitive - I mean, can you point to me in the Wald [sic] decision, is there anywhere it says that FDA is not relevant?

MR. FARLEY: It's not relevant.

THE COURT: Or, it's relevant. I mean, read what, actually, Judge Adkins says. That's Mallard [sic]. Hold on a second. I've been through these opinions so much lately, folks, that maybe I'm at a point of saturation. I mean, I don't see where the majority talks about the FDA approval, but she seems to speak about it a great deal...I'm sorry. Material is the world I'm looking for, Mr. Farley. And she goes on to say, and she cites a Pennsylvania case, she says to be sure, lack of FDA approval does not necessarily mean that a treatment is high risk. Other courts have found this disconnect sufficient reason to hold that the information about FDA approvals is not generally material to patient's informed consent...[a]nd I think that's really what you're saying, right?

MR. FARLEY: That's precisely what I'm saying.

THE COURT: You're saying that it's not material.

***29** MR. FARLEY: Well, it's not material. And beyond that, there's not any, there will be no expert testimony by the Plaintiff to speak to the issue. So, on the first level of analysis, it's not material, it's not relevant. On the second level of analysis, even assuming, hypothetically it was, and I'm not suggesting there's any basis for that, you still need an expert to say why it is and what the FDA says is material.

THE COURT: That's the difficulty I'm having in this, Mr. Belsky, is - and I recognize that this is a split - not really a split decision because the majority never really speaks to the FDA approval. (E. 611-13).

The discussion was continued in further attempts by the Appellants to read portions of Dr. Shannon's deposition transcript into the record, as follows:

> THE COURT: And I understand where you're at. Hold on a second. Let me think this through a little bit. You know, and I'm slow. And I'll admit that. I admit that on the record. You all have had this case far longer than I have. And this is a difficult issue because of the way it's presented to me and reading Wald [sic] and it's difficult because it's a split decision. It's a split decision of the Court of Appeals. And while I do find that Judge Adkins' rationale is perhaps correct, in my view, it's not the law of the State at this present time. Mr. Belsky, you agree with that, right?...Then I'll go with what the law of the State is. I'll sustain - and I'm going to reconsider and sustain [the Appellee's] objection based on Wald [sic], okay? So I'm clear. I have, while I - I am troubled by this decision and I am troubled with the way it would, was brought out, I am a trial judge. I am not an appellate judge. I will never be an appellate judge...My duty right now and forever more will be a trial judge. And I will go with Wald [sic]. And what's written in Wald [sic] in the Court of Special Appeals and what's written in the Court of Appeals. And I'll live with what the letter of the law is right now. And I must adopt that as the law of the state, and I follow that law. So we're clear. All right [sic]? I recognize where you're at, counsel. You know where I'm at personally and where I look at. I like Judge Adkins' analysis. However, it is not the law of the state right now. (E. 622-23).

***30** The evidence at issue was not only was highly relevant to the jury's ultimate determination, but also created a material dispute of fact as to what Mr. Fusco was informed of during his consult with Dr. Shannon. [2]

Accordingly, when Appellee testified in trial, Appellee gave his “version” of his discussion with Mr. Fusco about the use and material risks of Amifostine. (E. 629-30). In light of the trial court's ruling, Appellee utterly omitted the discussion which he had previously admitted having had with Mr. Fusco, at his deposition, regarding the lack of approval of this drug for treatment in prostate cancer patients. (E. 268).

The trial court's rulings yielded the following illogical net result. All along, Dr. Shannon had indicated that the lack of FDA approval for prostate cancer was part of his informed consent discussion with Mr. Fusco (E. 268). The trial court ruled that FDA approval, or lack thereof, is per se irrelevant in an informed consent case. Accordingly, Appellants were not permitted to read excerpts of Dr. Shannon's own deposition and/or cross-examine Dr. Shannon on the actual informed consent conversation he claims he had with Mr. Fusco. This net result is illogical and leaves the jury with an utterly flawed version of the truth. If it is the sworn testimony of Dr. Shannon, Appellee, that he included FDA non-approval in his discussion with Mr. Fusco, then it was an absolute **abuse** of discretion for the trial court to exclude that part of the informed consent conversation.

Throughout the course of this trial the Appellants were prohibited from putting ***31** before the jury crucial pieces of evidence relative to its determination. Amifostine was a medication with little known benefit in a situation like Mr. Fusco's. However, it was a medication with potentially fatal toxicities. The bulk of the evidence supporting these uncontroverted facts were never made a part of this trial.

CONCLUSION

For the foregoing reasons, the Appellants request that this Honorable Court reverse and remand the case to the Circuit Court of Prince George's County with appropriate remedial instructions.

Footnotes

1 Defendants Mufarrij and Shombert have been dismissed for the purposes of this appeal. For the purpose of the statement of facts and statement of case, Doctors Mufarrij, Shombert and Shannon and Hematology Oncology Asociates will collectively be referred to as the “Defendants.”

2 Michael Fusco's trial testimony regarding what his father was told during his meeting with Dr. Shannon differed from Dr. Shannon's testimony in that Michael Fusco contended that the approved uses of Amifostine for **elderly** patients and/or patients with prostate cancer was never mentioned during his father's consult with Dr. Shannon.

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