REPORTED

IN THE COURT OF SPECIAL APPEALS

OF MARYLAND

No. 2819

September Term, 2010

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MAFALDA FUSCO, ET AL.

V.

KEVIN J. SHANNON, ET AL.

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Meredith,
Hotten,
Leasure, Gary G.,
(Specially Assigned),

JJ.

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Opinion by Hotten, J.

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Filed: March 20, 2013

Following the death of Anthony Fusco, Sr. ("Mr. Fusco"), appellants, Mafalda Fusco and the surviving children, filed a complaint in the Circuit Court for Prince George's County against appellees, Kevin Shannon, M.D. ("Dr. Shannon") and his practice, Hematology-Oncology Consultants, P.A. ("H.O. Consultants"). Appellants alleged that Dr. Shannon failed to obtain Mr. Fusco's informed consent regarding the risks associated with the administered drug, Amifostine. Appellants further contended that the direct and proximate result of appellees' failure caused Mr. Fusco to sustain injuries and ultimately his death. During discovery, appellants identified James Trovato, Pharm.D. ("Dr. Trovato"), a pharmacist, but not a medical doctor, as an expert witness to support their lack of informed consent claim.[1]

In addition to their motion for summary judgment, appellees filed a motion *in limine* to exclude Dr. Trovato's *de bene esse* deposition, alleging that appellants failed to present an expert witness who could testify that appellees breached their duty of obtaining Mr. Fusco's informed consent. In opposition, appellants argued that appellees failed to demonstrate that Dr. Trovato was not qualified to testify as an expert witness. Following a hearing on December 21, 2010, the trial court denied the motion for summary judgment, but granted the motion *in limine*. Pursuant to the court's order, appellants filed a proffer of Dr. Trovato's anticipated trial testimony.

During the hearing on January 7, 2011, the court disallowed Dr. Trovato's testimony

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[1] Appellants also designated Mohamed Al-Ibrahim, M.D. as an expert witness to explain why Amifostine caused Mr. Fusco's Toxic Epidermal Necrolysis Syndrome and his ultimate demise.

in its entirety. Appellees renewed their motion for summary judgment, but it was denied. Following the trial on January 10 through January 19, 2011, the jury returned a verdict for appellees. Appellants noted an appeal on February 15, 2011, and presented two questions for our review:

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

For the reasons that follow, we reverse the judgment of the circuit court.

## FACTUAL AND PROCEDURAL BACKGROUND

On June 26, 2001, Mr. Fusco, eighty-two years of age at the time, was diagnosed with prostate cancer. On December 27, 2002, Walid Mufarrij, M.D. ("Dr. Mufarrij"), a urologist, examined Mr. Fusco and determined that the cancer was "low-risk," so Mr. Fusco selected "watchful waiting" as his treatment plan. On February 21, 2003, Dr. Mufarrij and Mr. Fusco discussed additional options, to which Mr. Fusco elected a combination of radiotherapy and hormone treatment. Dr. Mufarrij conducted the hormone regimen, but referred Mr. Fusco to Lawrence Shombert, M.D. ("Dr. Shombert") for radiotherapy.

On March 6, 2003, Mr. Fusco consulted Dr. Shombert, who explained the nature of radiation, including the need for a commonly used radiation protectant, which would possibly eliminate inflammation of the urinary bladder and rectum. Dr. Shombert referred Mr. Fusco

to Dr. Shannon, and on March 12, 2003, they discussed a radiation protectant regimen. While testifying at trial, Dr. Shannon insisted that he discussed the following with Mr. Fusco:

> Very generally, with respect just to the [A]mifostine, we discussed the potential benefits which, again, is to, is a cytoprotective agent to reduce the risk of radiation induced injury to the organs of the, the bladder and the rectum. The potential side effects, the significant side effects, which, very briefly, can affect, [A]mifostine can affect blood pressure. It can affect the GI system in the way of causing nausea, and it can cause a local or slightly more extensive skin reaction and the alternatives, which, unfortunately, are none. We still don't have any alternatives to [A]mifostine, and, and I explain[ed] a little bit about how our office works. How the, the dose would be given which is to say subcutaneously, an injection in the arm, rather than an intravenous formation, and other general things to come well hydrated, that it would have to be given on a daily basis prior to radiation. So, the mechanics of administration I spoke of, and with respect to [A]mifostine, that, in general, was, was it.

Between April 15, 2003 and May 15, 2003, Mr. Fusco underwent approximately twenty-three injections of 500 milligrams of Amifostine. On May 16, 2003, Mr. Fusco was administered an Amifostine shot, and Dr. Shannon recorded that Mr. Fusco denied "headaches, visual disturbances, sores in the mouth, difficulty swallowing . . . . No nausea, vomiting, diarrhea and no dysuria. He has no known drug allergies . . . . No evidence of rash or inflammation."

The next day, on May 17, 2003, Mr. Fusco was hospitalized at Doctors Community Hospital in Lanham, Maryland for symptoms of acute onset of systemic rash and lip swelling. Dr. Shannon was notified, and theorized that Mr. Fusco had a reaction to the Amifostine.

The reaction resulted in Stevens-Johnson Syndrome.[2]

On May 20, 2003, Mr. Fusco was transferred to Johns Hopkins Burn Center in Baltimore, Maryland for further treatment. He was informed that his condition advanced to Toxic Epidermal Necrolysis Syndrome.[3] On August 5, 2003, Mr. Fusco was admitted into Magnolia Center Nursing Home in Lanham, Maryland for physical and occupational therapy and wound care. On October 6, 2003, he was re-admitted to Doctors Community Hospital due to an onset of acute pneumonia and fever. He was described as being at "a high risk for aspiration."[4] As a result, the hospital performed a tube insertion procedure. Unfortunately, the hospital's treatments proved to be unsuccessful, and Mr. Fusco died on December 4, 2003, from a stroke. No autopsy was performed, but the medical examiner listed arteriosclerotic cardiovascular disease with a contributing factor of Toxic Epidermal Necrolysis Syndrome as the cause of death.

On April 23, 2007, appellants filed wrongful death and survival actions against Dr.

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[2] Stevens-Johnson Syndrome, erythema multiforme, is an acute eruption of macules, papules, or subdermal vesicles presenting a multiform appearance, the characteristic lesion being the target or iris lesion over the dorsal aspect of the hands and forearms; its origin may be allergic, seasonal, or from drug sensitivity, and the eruption may be recurrent or may run a severe course with fatal termination. STEDMAN'S MEDICAL DICTIONARY 484 (24th ed. 1982).

[3] Toxic Epidermal Necrolysis Syndrome is a syndrome in which a large portion of the skin becomes intensely erythematous, relating to or marked by inflammatory redness, and peels off in the manner of a second-degree burn, often simultaneous with the formation of flaccid bullae. STEDMAN'S MEDICAL DICTIONARY 928 (24th ed. 1982).

[4] Aspiration is removal, by suction, of a gas or fluid from a body cavity, from unusual accumulations, or from a container. STEDMAN'S MEDICAL DICTIONARY 132 (24th ed. 1982).

Mufarrij, Dr. Shombert, Dr. Shannon, and H.O. Consultants. On December 21, 2010, the court granted motions for summary judgment relating to Drs. Mufarrij and Shombert, finding that "the duty to obtain informed consent only arose to the physician who provided the treatment." Hence, the claims against Drs. Mufarrij and Shombert were dismissed, and they are not parties to this appeal.

The event giving rise to this appeal occurred when appellees filed a joint motion *in limine* to preclude Dr. Trovato's *de bene esse* deposition. In pertinent part, Dr. Trovato opined that Amifostine was inappropriately used or should not have been used for Mr. Fusco, since he was undergoing radiation therapy for prostate cancer. Appellees argued that Dr. Trovato's testimony should have been excluded because (1) he was not a physician, and thereby not qualified to render opinions concerning a physician's advisement to obtain informed consent and (2) his testimony offered criticisms sounding in standard of care.

On December 16, 2010,[5] appellants filed a response to appellees' joint motion *in limine*, asserting that (1) case law did not require that Dr. Trovato be a medical doctor, and (2) his testimony regarding the use of Amifostine established the drug's risks, benefits, and alternatives. On December 21, 2010, the court granted appellees' motion *in limine*, finding that (1) Dr. Trovato did not testify regarding the standard of care for an expert in an informed consent case; (2) his testimony was more aligned with negligence than informed consent; (3) his testimony did not incorporate the *Sard v. Hardy* factors; and (4) he was a pharmacist,

[5] Before appellants filed a response, they filed a motion for postponement of trial due to their counsel's health, which was granted.

not a physician. After the ruling, the court offered appellants the opportunity to file a proffer of Dr. Trovato's anticipated trial testimony, which was submitted on December 27, 2010.

On January 7, 2011, during the second motions hearing, despite Dr. Trovato's extensive qualifications, the court ruled that he would not be permitted to testify because (1) he was a pharmacist and "[did] not have the ability to give the full demarcation of what [was] involved in informed consent[,]" and (2) his testimony would "confuse and disenchant the jury in their ability to determine what the doctrine of informed consent" denoted because the proffer did not give a completeness to the overall treatment plan. Appellees then renewed their motion for summary judgment, which was denied. On January 10 through January 19, 2011, following a jury trial, a verdict was returned in favor of appellees.[6] Appellants filed this timely appeal, to which appellees filed a cross-appeal that we need not resolve.

## STANDARD OF REVIEW

[6] According to the record before us, the issues at trial were (1) whether Dr. Shannon failed to obtain the decedent's informed consent concerning Amifostine therapy, and (2) "do you find by a preponderance of the evidence that a reasonable patient, having been informed of the material risks and complications associated with [A]mifostine therapy, would have refused to consent to its use?" After deliberations, the jury informed the court that, "[w]e have agreed on Question No. 2, but still no consensus on Question No. 1. How should we proceed? . . ." The trial judge instructed the jury to first deliberate regarding the second issue, and if it answered "yes," it was to continue to deliberate. However, if it answered "no," it was to inform the bailiff. The jury answered "no," and attempted to present the verdict sheet to the bailiff, but the trial judge decided to poll the jury. The jury reached an unanimous verdict concerning the second issue, that, by a preponderance of the evidence, a reasonable patient, having been informed of the material risks and complications associated with Amifostine therapy, would have consented to its use. However, it was not able to reach an unanimous verdict regarding whether Dr. Shannon failed to obtain the decedent's informed consent, and thus, the judge entered a judgment in favor of appellees.

Under Md. Rule 5-702, *supra*, "the admissibility of expert testimony is within the sound discretion of the trial judge and will not be disturbed on appeal unless clearly erroneous." *In re Adoption/Guardianship of Tatianna B.*, 417 Md. 259, 263 (2010) (citing *Blackwell v. Wyeth*, 408 Md. 575, 618 (2009)) (quoting *Wilson v. State*, 370 Md. 191, 200 (2002)). We therefore review a ruling to admit expert witnesses under the abuse of discretion standard. *Morton v. State*, 200 Md. App. 529, 545 (2011) (citing *Oken v. State*, 327 Md. 628, 659 (1992)).

Because admittance or exclusion of expert testimony is a matter substantially within the trial court's discretion, the court's ruling will seldom constitute a reason for reversal. *Gutierrez v. State*, 423 Md. 476, 486 (2011) (citing *Raithel v. State*, 280 Md. 291, 301 (1977)). Moreover, the court's exclusion of evidence will not be reversed in the absence of a clear abuse of discretion. *Thomas v. State*, 397 Md. 557, 579 (2007) (citing *Kelly v. State*, 392 Md. 511, 530 (2006); *Merzbacher v. State*, 346 Md. 391, 404-05 (1997)). "'An appellate court will only reverse upon finding that the trial judge's determination was both manifestly wrong and substantially injurious[,]'" *Wantz v. Afzal*, 197 Md. App. 675, 682, *cert. denied* 420 Md. 463 (2011) (citing *Brown v. Contemporary OB/GYN Assocs.*, 143 Md. App. 199, 252 (2002)) (additional citation omitted), or "may be reversed if founded on an error of law or some serious mistake, or if the trial court has clearly abused its discretion." *Gutierrez*, 423 Md. at 486 (citing *Raithel*, 280 Md. at 301).

**DISCUSSION**

"The doctrine of informed consent . . . imposes on a physician, before he or [she]

subjects his [or her] patient to medical treatment, the duty to explain the procedure to the patient and to warn 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." *Schwartz v. Johnson*, 206 Md. App. 458, 484 (2012) (quoting *Sard v. Hardy*, 281 Md. 432, 440 (1977)) [hereinafter "*Sard*"]. The duty to explain the procedure encompasses the following *Sard* factors:

> [T]he 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.

*Sard*, 281 Md. at 448 (citing *Getchell v. Mansfield*, 489 P.2d 953, 956 (Or. 1971); *Small v. Gifford Memorial Hosp.*, 349 A.2d 703, 705 (Vt. 1975)). "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." *Id.* at 444 (citing *Miller v. Kennedy*, 522 P.2d 852, 863 (Wash. Ct. App. 1974)) ("[W]hen a reasonable person in the patient's position probably would attach significance to the specific risk in deciding on treatment, the risk is material and must be disclosed."). *See also Getchell*, 489 P.2d at 956; *Wilkinson v. Vesey*, 295 A.2d 676, 689 (1972) (additional citation omitted).

Similar to a presumption of due care, there is a presumption of proper consent, which arises from "'the natural instinct of human beings to guard against danger . . . .'" *See Eagle-Pincher Indus. v. Balbos*, 326 Md. 179, 228 (1992) (quoting *Tucker v. State*, 89 Md. 471, 480

(1899)). 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. *See generally Schwartz*, 206 Md. App. at 484; *Sard*, 281 Md. at 444 (citing *Miller*, 522 P.2d at 863); *Goldberg, et al. v. Boone*, 396 Md. 94, 123 (2006) (citing *Sard*, 281 Md. at 448).

Complainants usually offer expert testimony to establish their *prima facie* case. An expert witness is required to ascertain the material risks and other significant factors concerning the medical therapy. *Univ. of Maryland Med. Sys. Corp. v. Waldt*, 411 Md. 207, 232 (2009) [hereinafter "*Waldt II*"]. Md. Rule 5-702 governs the admissibility of expert witness testimony. It provides:

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

Concerning the first factor, a trial court ought to contemplate whether the subject matter is within the expert's knowledge to which he or she could aid the trier of fact in ascertaining the evidence. *Wantz*, 197 Md. App. at 683 (citing *Radman v. Harold*, 279 Md. 167, 169 (1997); *Casualty Ins. Co. v. Messenger*, 181 Md. 295, 298 (1943)) (quotations omitted). "The trial court is free to consider any aspect of a witness's background in

determining whether the witness is sufficiently familiar with the subject to render an expert opinion, including the witness's formal education, professional training, personal observations, and actual experience." *Massie v. State*, 349 Md. 834, 851 (1998) (citations omitted).

As previously stated, appellees assert that the trial court properly exercised its discretion to preclude Dr. Trovato's testimony because he (1) was not a physician or clinician; (2) was not licensed to practice medicine; (3) did not prescribe or write prescriptions; and (4) had never obtained a patient's consent to treatment or had experience obtaining informed consent from patients. Appellants contend that Maryland's case law did not require Dr. Trovato to be a medical doctor who routinely provided the basis for informed consent. However, the more pressing issue was whether Dr. Trovato, as a pharmacist, was qualified to testify regarding Amifostine.

**I. Whether The Trial Court Abused Its Discretion In Ruling That Dr. Trovato Was Not Qualified To Testify Concerning The Material Risks of Amifostine In An Informed Consent Action.**

In an action alleging medical malpractice, a patient avers that a healthcare provider breached his or her duty of medical care and skill based on the medical community's standard of care. *McQuitty v. Spangler*, 410 Md. 1, 18 (2009) (citing *Dehn v. Edgecombe*, 384 Md. 606, 618 (2005)) ("Medical malpractice is predicated upon the failure to exercise requisite medical skill and, being tortious in nature, general rules of negligence usually apply in determining liability."). According to the Health Care Malpractice Act, "when a defendant health care provider is board certified in a specialty, an expert witness attesting that the

defendant deviated from (or complied with) the standard of care must be board certified in the same or a related specialty[ ] with certain exceptions." *Demuth, et al. v. Strong*, 205 Md. App. 521, 524 (2012) (internal quotations omitted).

However, regarding informed consent actions, this "qualification" restriction does not apply because a breach of informed consent action occurs when "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 of procedure." *McQuitty*, 410 Md. at 18-19 (citing *Sard*, 281 Md. at 444). The complainant ". . . is not required to establish either the scope or the breach of the physician's duty [of the standard of care] to disclose all material risks." *Mahler v. Johns Hopkins Hosp., Inc.*, 170 Md. App. 293, 319 (2006) (citing *Sard*, 281 Md. at 447).

For instance, in *Hinebaugh v. Garrett County Mem. Hosp. et al.*, 207 Md. App. 1, 16 (2012), our Court determined whether a dentist was board certified in a medical specialty. There, the plaintiff sustained injuries to his left cheek and jaw while incarcerated. *Id.* at 6. He was evaluated by three defendants–medical doctors, a family medicine physician and two radiologists. *Id.* The plaintiff filed a medical negligence claim against the defendants, alleging a breach of care when they failed to perform a maxillofacial CT scan. *Id.* at 7. To establish his *prima facie* case, the plaintiff identified a dentist, who specialized in oral and maxillofacial surgery (OMS), as his expert witness. *Id.* at 7-8.

The plaintiff was required to file a certificate of a qualified expert, in addition to his

qualifications, which attested to the defendants' breach of the standard of care.[7] *Id.* at 11. The defendants filed a joint motion to strike the dentist's certificate and to dismiss the complaint, arguing that he did not meet the same or related specialty board certifications. *Id.* at 12-13. The trial court dismissed the action, finding that:

> [A]lthough [the dentist] had taught OMS in OMS [sic] and dental departments and also in surgery departments of hospitals, the specialty of surgery was not related to the defendants' specialties; and, in any event, [the dentist] had not taught general surgery, because he [was] not a physician.

*Id.* at 16.

We affirmed the trial court's ruling, and analyzed as follows: (1) The dentist diagnosed and treated facial fractures, and taught OMS trainees, but this did not demonstrate that there was an overlap between OMS and family medicine/radiology; (2) In the dentist's certificate and his affidavit, he failed to establish his knowledge of the prevailing standard of care for family medical doctors in diagnosing patients, and for radiologists in examining x-rays; and (3) OMS dentists only specialized in limited areas concerning facial fractures. *Id.* at 26-29. We concluded that the dentist was not qualified as an expert because "the areas of knowledge and experience of board certified family medicine and radiology doctors [did] not overlap the areas of knowledge and experience of board certified OMS dentists." *Id.* at

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[7] In *Hinebaugh*, 207 Md. App. at 11, the plaintiff was required to file a certificate of a qualified expert pursuant to Md. Code (1974, 2006 Repl. Vol.), § 3-2A-04(b)(1)(i)1 of the Courts and Judicial Proceedings Article. However, as previously indicated, this is not a requirement for informed consent actions. *Id.* We surmise that the reasoning is because only a medical doctor can attest to whether the defendant-doctor breaches the duty to conform to the standard of care.

26.

As previously indicated, *Hinebaugh* is distinguishable because an informed consent action does not require that the complainant establish a breach of the physician's duty regarding the standard of care akin to a medical malpractice case. *See Mahler*, 170 Md. App. at 319 (citing *Sard*, 281 Md. at 447).

We have not found any Maryland cases concerning whether a pharmacist is qualified to testify regarding a prescription drug in an informed consent action. While this issue is one of first impression in Maryland, several jurisdictions have undertaken consideration of similar issues. Although not directly analogous to the instant case, our sister states have examined whether non-medical doctors, such as pharmacists and/or pharmacologists, are qualified as an expert to opine regarding properties, scientific effects, warning signs, and/or known material risks of prescribed drugs. We limit our focus to those specific aspects of these cases, along with the qualifications, because the aforementioned factors also impact informed consent claims.

In *Parker v. Harper*, 803 So.2d. 76, 79 (La. Ct. App. 2001), the Louisiana Court of Appeal, Third Circuit, ruled that the affidavit of a pharmacist could define the existence, nature, and the probability of a risks' occurrence. The plaintiffs filed a medical malpractice claim against the defendant–physician, alleging that he failed to inform them of the potential side effects and warning signs of the prescribed drug, Dilantin. *Id.* The injured plaintiff experienced daily seizures, so the physician increased the prescription to Dilantin 100 milligrams three times a day. *Id.* The plaintiff developed a rash on her face and was

hospitalized. *Id.* The plaintiff's diagnosis was a possible drug reaction, resulting in Stevens-Johnson Syndrome or a varicella virus infection. *Id.* at 79. She lost complete vision in one eye, partial vision in the other, and sustained permanent scarring on her body. *Id.*

The defendant filed a motion for summary judgment, which was granted. *Id.* at 80. In opposition, the plaintiffs offered a pharmacist's affidavit, who averred that Stevens-Johnson Syndrome was a possible side effect and known risk of taking Dilantin. *Id.* On appeal, the court ruled:

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

*Id.* at 84.

In *Sinkfield v. OH et al.*, 495 S.E.2d 94, 95 (Ga. Ct. App. 1997), the plaintiff experienced two previous miscarriages, and during her third pregnancy, she suffered from severe bleeding and excessive back pain. She was hospitalized, and the treating physician prescribed her Motrin 800. Subsequently, the plaintiff suffered her third miscarriage, and filed a complaint predicated on medical malpractice. *See id.* The defendants–physicians filed motions for summary judgment, arguing that the plaintiff failed to establish a causal connection between their conduct and the miscarriage. *Id.* In opposition, the plaintiff offered

testimony of a pharmacologist, who was also a toxicologist. He opined that:

> He [had] knowledge of the effects of dosages of Motrin on pregnant women and their fetuses at various states of pregnancy. [He] testified that it was his professional opinion that "'the Motrin-800 (ibuprofen, 800 milligrams) prescribed by [the treating physician] on December 24, 1992 was the predominate major contributing factor to the demise of the fetus of [the plaintiff].'"

*Id.*

The trial court excluded the pharmacologist's testimony, stating that he was unqualified because he was not a medical doctor. *Id.* On appeal, the Court of Appeals of Georgia reversed, and reasoned that the pharmacologist was not testifying to medical malpractice, but causation. *Id.* at 95-96. "If [he], as a toxicologist and pharmacologist, had been offered as an expert witness against the two medical doctors for purposes of [medical malpractice], [he] would not have been a competent witness" because it was traditionally held that an expert had to be qualified in the same or similar medical specialty. *Id.* at 96. However, because he was not opining to the standard of care, and because a pharmacologist was the individual who "ma[de] a study of the actions of drugs[,]'" the expert was qualified to testify regarding the scientific effect of the prescribed medicine. *Id.*

In *Tidwell v. Upjohn, Co.*, 626 So.2d 1297, 1299 (Ala. 1993), the decedent suffered from a sleeping disorder to which a physician prescribed him .25 milligram dosages of Halcion, and recommended him to a psychiatrist. The psychiatrist increased the dosage to .5 milligrams, and diagnosed him with severe depression. *Id.* The next day, the decedent expressed that he was "losing [his] mind," and subsequently committed suicide. *Id.* The

decedent's estate filed an action against the defendant–drug manufacturer, alleging that it failed to warn of the drug's effects. To establish its *prima facie* case, the estate submitted deposition testimony of a pharmacist. *Id.* The manufacturer moved for summary judgment, averring that the expert was not qualified because he was not a medical doctor. *Id.* The trial court granted the motion for summary judgment. *Id.*

On appeal, the Supreme Court of Alabama concluded that the trial court abused its discretion in excluding the expert testimony because the pharmacist's education, expertise, and training in pharmacology[8] rendered him qualified to opine regarding whether the drug contributed to the suicide. *Id.* at 1300.

In *Goodman et al. v. Lipman et al.*, 399 S.E.2d 255, 256 (Ga. Ct. App. 1990), the plaintiffs filed a medical malpractice complaint against the defendant–physician, asserting that he failed to exercise due care in treating the injured plaintiff's heart disease by prescribing Coumadin and Nembutal. To establish their case, the plaintiffs offered the testimony of a pharmacologist. *Id.* at 257. The defendant filed a motion to exclude the expert because he was not a medical doctor. *Id.* The trial court agreed, and granted the motion. *Id.* On appeal, the Court of Appeals for Georgia concluded that "'[t]he opinions of experts on any question of science, skill, trade, or like questions shall always be admissible

[8] The expert was "a pharmacist and pharmacologist with a Pharm.D. degree from the University of Michigan. He [was] the editor-in-chief of a professional pharmacy journal, ha[d] served as the assistant director of pharmacy at a Chicago hospital for 12 years, and ha[d] been an assistant professor of pharmacology at a Chicago medical school." *Tidwell*, 626 So.2d at 1300.

. . .[,]'" and that the evidence illustrated that the pharmacologist's testimony relating to the properties of the prescribed drugs was likely relevant to a finder of fact. *Id.* at 258.

In *Garvey v. O'Donoghue*, 530 A.2d 1141, 1142 (D.C. 1987), the plaintiffs filed a medical malpractice claim against the defendants–physicians for prescribing an antibiotic, which allegedly caused the injured plaintiff to contract tinnitus.[9] The plaintiffs identified a pharmacologist as their expert witness. *Id.* at 1146. The trial court limited the expert's testimony, and precluded him from testifying about the prescription's amount of dosage, and whether the prescription was properly prescribed. *Id.*

On appeal, the court stated:

> It seems clear, then, that to the extent physicians do rely on a body of pharmacological information, the expertise of a pharmacologist is virtually indistinguishable from that of the physician. Since physicians rely upon information that originates with or is provided by the practitioners in another field, here pharmacologists, this reliance opens the door for these non[-] physicians to testify as to that body of information. In effect, where a physician "borrows" a standard of care from the research and work of other professionals, members of that profession may testify about it.

*Id.* at 1147.

The District of Columbia ("D.C.") Court of Appeals concluded that the trial court erred in disallowing the pharmacologist to testify regarding the effects and proper dosage of the drug. *Id. See also Thompson v. Carter*, 518 So.2d 609, 615 (Miss. 1987) ("The instant

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[9] The case did not specify what type of tinnitus the injured plaintiff contracted, but tinnitus aurium is a sensation of sound in one or both ears associated with disease in the middle ear, the inner ear, or the central auditory apparatus. STEDMAN'S MEDICAL DICTIONARY 1455 (24th ed. 1982).

record reflect[ed] that [the pharmacologist], who taught medical students and advised and counseled physicians as to drug use and administration, through his skill, knowledge, training, and education, knew the standard of care to which physicians adhered when prescribing Bactrim," thereby, he was qualified as an expert witness.).

We also examine federal cases that have ruled on a similar issue. In *United States v. Smith*, 573 F.3d 639, 653 (8th Cir. 2009), the United States ("U.S.") Court of Appeals for the Eighth Circuit determined whether a pharmacist constituted an expert regarding a physician's standard of care. The defendant was convicted of several crimes[10] for prescribing medications over the internet without examining the patients or verifying their alleged illnesses and injuries. *Id.* at 643. On appeal, the defendant argued that the trial court erred because it permitted a pharmacist to testify as an expert. *Id.* at 646. The Eighth Circuit examined the pharmacist's expertise, and found that:

> [He was] . . . the executive director of the National Association of Boards of Pharmacy ("NABP") for twenty years . . . . [He] annually [gave] testimony before Congress, state legislatures, and state committees on Internet pharmacies and the relevant laws. Through his work with the NABP, [he] also helped institute a national accreditation program that developed standards of operation for legitimate Internet pharmacies . . . . [He had] twenty years of teaching at the Washington University Medical School, [which] qualifie[d]

[10] The defendant was convicted of "conspiracy to distribute and dispense controlled substances without an effective prescription in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(D), and 846; aiding and abetting the unlawful distribution of controlled substances in violation of 21 U.S.C. §§ 841(a)(1) and 841(b)(1)(D), and 18 U.S.C. §2; aiding and abetting the introduction of misbranded drugs into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 353(b)(1), and 18 U.S.C. §2; conspiracy to commit money laundering in violation of 18 U.S.C. § 1956(h); and continuing criminal enterprise in violation of 21 U.S.C. § 848(a) and (c)." *Smith*, 573 F.3d at 643.

> him as an expert entitled to express an opinion as to medical procedures in prescribing drugs . . . . [He] . . . also helped the Government identify over 1,500 "rogue pharmacies," or pharmacies that operate[d] in contravention of state and federal law and offer[ed] medications to patients or customers without legitimate or valid prescriptions.

*Id.* at 653-54. As a result, the Eighth Circuit concluded that the pharmacist was an expert with the necessary expertise to testify regarding the defendant's standard of care. *Id.* at 653.

In *United States v. Bek*, 493 F.3d 790, 795 (7th Cir. 2007), the defendant was "convicted of twenty-six counts of conspiring to distribute and distributing controlled substances, and committing health care fraud" for prescribing medications without examining his patient's medical records, performing MRIs, conducting x-rays, and failing to diagnose them. *Id.* at 796. During trial, the Government offered expert testimony from a pharmacist who opined that "[the defendant's] practices were dangerous and very unusual["] and that the defendant "should have conducted several diagnostic tests and reviewed patients' medical histories before prescribing drugs such as Vicodin." *Id.* at 796.

On appeal, the defendant did not contend whether the pharmacist was an expert, but instead averred that the Government's witness established a *prima facie* case for civil negligence, not criminal conduct. *Id.* at 798. The U.S. Court of Appeals for the Seventh Circuit concluded that the evidence was sufficient to fulfill the criminal standard. *Id.* at 799. *See also United States v. Jones*, 570 F.2d 765, 769 (8th Cir. 1978) (holding that "[a]lthough not a[ ] [medical doctor], [the pharmacist's] twenty years of teaching at the Washington University Medical School qualifie[d] him as an expert entitled to express an opinion as to medical procedures in prescribing drugs . . .").

Although we relate our ruling to the abovementioned cases, we observe that other jurisdictions and courts have ruled otherwise. In *Hollabaugh v. Arkansas State Med. Bd.*, 861 S.W.2d 317, 318 (Ark. Ct. App. 1993), the State Medical Board ("Board") found the defendant–physician grossly negligent for prescribing patients disproportionate amounts of harmful medications. A pharmacist, on behalf of the Board, testified about the kinds, quantities, and regularity of the medications that the physicians prescribed to the patients. *Id.* at 321. However, the pharmacist lacked experience in testifying whether the physician's treatment was a breach of ordinary care. *Id.* Because the expert could not ascertain whether the physician breached the medical community's standard of care, the Arkansas Court of Appeals reversed the trial court's ruling, and concluded that the expert was not qualified to testify. *Id.*

In *Chandler v. Koenig*, 417 S.E.2d 715 (Ga. Ct. App. 1992), the plaintiff alleged that two physicians breached the ordinary standard of care, resulting in medical malpractice. The plaintiff provided the court with an affidavit from a professor, who possessed a Ph.D in pharmacology and toxicology, to establish the defendants–physicians' negligence.[11] *Id.* The professor asserted that he was "familiar [with the] standard of care required and the properties and interactions of the drugs prescribed to [the plaintiff] by [the physicians] and with their recommended use" and was "competent to testify regarding the standards of care

[11] In his affidavit, the professor included his areas of expertise, the scientific and professional organizations to which he was a member, and contended that he trained medical students and postgraduates concerning the components of drugs. *Chandler*, 417 S.E.2d at 717.

and recommended use" of the drugs. *Id.* The Georgia Court of Appeals concluded that the professor's affidavit lacked evidence to illustrate that his "education, training, or experience *as a [pharmacologist]* would likewise demonstrate his *similar* expert qualifications as to [the prescribing of drugs by a medical doctor]," thereby, he did not qualify as an expert witness for the purposes of the defendants' alleged breach of the standard of care. *Id.* (emphasis in original).

In *Bell v. Hart*, 516 So.2d 562, 564 (Ala. 1987), the plaintiffs filed a medical malpractice action against the defendant–physician for prescribing the injured plaintiff a drug, which caused her to sustain injuries. The plaintiffs identified a psychologist and a pharmacist as their expert witnesses.[12] *Id.* The Alabama Supreme Court concluded that the trial court correctly excluded the expert witnesses' testimonies because:

> Although [the pharmacist and psychologist] [were] shown to be highly qualified experts in their fields of study, we [could] not permit them to testify whether a medical doctor followed the proper standard of care in prescribing the drug Elavil. Neither was shown to be authorized to prescribe the drug. While their knowledge of the drug and its effect on the human body may or may not be greater than that of a medical doctor authorized by law to prescribe the drug, we [could] not permit a non[-]physician, who [could] not legally prescribe a drug, to testify concerning the standard of care that should [have] be[en] exercise[d] in the prescription of the drug.

[12] The pharmacist testified that he was an assistant professor of a college's family medicine department. He was also the department chair in applied pharmacology. In that position, he was a consultant in drug therapy for medical students and community residents. He was also the chief of clinical pharmacokinectic services at a local hospital to which he consulted with physicians regarding the health issues the patients were experiencing as a result of the prescriptions. He also studied articles and treatises by experts and countless professionals. *Bell*, 516 So.2d at 564.

*Id.* at 570.

In *Rodriguez v. Jackson*, 574 P.2d 481, 482 (Ariz. Ct. App. 1977), the injured plaintiff brought a medical malpractice action against the defendants–physicians who prescribed an excessive amount of Streptomycin to address the plaintiff's tuberculosis diagnosis, resulting in permanent neural damage. Among other experts, the plaintiffs designated a pharmacologist to testify concerning the physician's breach of the standard of care.[13] *Id.* at 484. The Arizona Court of Appeals stated that:

> More than twenty-three hundred years ago Aristotle wrote, in his work on Politics, wrote [sic]: As a physician ought to be judged by the physician, so ought men to be judged by their peers. And for centuries the courts of this and other countries have, almost without exception, held that expert medical evidence is required to establish negligence respecting the service a physician or a surgeon renders his [or her] patient.

*Rodriguez*, 574 P.2d at 485 (quoting *Shea v. Phillips*, 98 S.E.2d 552, 555 (Ga. 1957)) (internal quotations omitted). Although the pharmacologist was qualified to testify regarding the effect of Streptomycin, the court held that she could not opine concerning whether the physicians were negligent. *Id.* at 485.

We surmise that the jurisdictions and cases that hold differently from our ruling conclude otherwise because they held that a pharmacist did not qualify to testify regarding a doctor's negligence, which differs from the case at bar. Our case is akin to *Parker*, *Sinkfield*, *Tidwell*, *Goodman*, and *Garvey*, which hold that the pharmacist was qualified to

[13] The pharmacologist was employed by the U.S. Food and Drug Administration and was involved in publications concerning tuberculosis. *Rodriguez*, 574 P.2d at 484.

testify about the drug's properties, possible side effects, and known material risks, which are factors in informed consent actions.

Appellees support their contentions with *Waldt II*, 411 Md. 207 (2009). There, the defendant–physician utilized a device, the "neuroform stent," to treat an aneurysm in the injured plaintiff's brain. *Id.* at 214. During the procedure, an artery was perforated, causing the injured plaintiff, Rebecca Waldt ("Ms. Waldt"), to sustain a stroke. *Id.* The plaintiffs filed a complaint, alleging that the defendants failed to properly obtain the injured plaintiff's informed consent before performing the procedure. *Id.* at 213. During trial, the plaintiffs called an expert witness, Gerard Debrun, M.D. ("Dr. Debrun"), to testify regarding the issue of informed consent. *Id.* The trial court excluded Dr. Debrun's testimony, finding that he lacked sufficient experience with the neuroform stent to be qualified as an expert. *Id.* The defendants moved for summary judgment, arguing that without expert testimony on the informed consent issue, there was no question for the jury. *Id.* The court agreed, and granted the defendants' motion. *Id.*

Our Court and the Court of Appeals affirmed the trial court's decision. *Id.* at 237. Dr. Debrun testified that he traditionally utilized a balloon procedure, and that he never used the neuroform stent because it was not approved for use until after he retired from active practice. *Id.* at 232. The Court held that the trial court evaluated Dr. Debrun's testimony and his qualifications, and correctly based its ruling on his inexperience with the neuroform stent. *Id.* at 232.

Appellants attempt to establish their assertions through *Wantz v. Afzal*, 197 Md. App.

675, 685, *cert. denied* 420 Md. 463 (2011), contending that *Waldt II* was inapposite, since it has long been established that a proposed medical expert "need not be a specialist in order to be competent to testify on medical matters." In *Wantz*, 197 Md. App. at 677, the plaintiff filed wrongful death and survival actions against the defendants-physicians for her mother's death, which was caused by a staph infection that developed during the spinal fusion surgery. The plaintiff designated a board-certified neurosurgeon as her expert witness,[14] who opined that immobilizing the decedent would have likely prevented the paralysis, and that without paralysis, the spinal fusion would have been successful. *Id.* at 680. The defendants moved to preclude the expert's *de bene esse* deposition, arguing that he had no experience in performing spinal fusion surgery nor in the postoperative regimen for patients who had undergone the surgery. *Id.* at 685.

The trial court granted the defendants' motion to strike, finding that the expert was not qualified to render such an opinion. *Id.* at 680-81. We reversed and indicated that "[t]he mere fact that [the expert] had never performed the actual vertebral fusion aspect of the surgery [did] not disqualify him from offering expert testimony." *Id.* at 689 (citing *Radman*, 279 Md. at 171). Because the expert had been involved with the neurological aspects and post-operative recovery, and had worked closely with and observed orthopedists perform the vertebral fusion of the surgery, the trial court erred in denying the expert's testimony. *Id.* at

[14] The plaintiff also designated a board-certified internist and a board-certified radiologist to testify. The defendants also moved to preclude these experts' testimonies. *Wantz*, 197 Md. App. at 680.

689-90.

We perceive that the case at bar is akin to *Wantz v. Afzal*, not *Waldt II* because similar to the expert witness in *Wantz*, Dr. Trovato possessed sufficient experience to opine about the material risks of Amifostine. In *Waldt II*, Dr. Debrun had no experience with the neuroform stent, but this is not a common factor regarding Dr. Trovato's knowledge of Amifostine therapy. As previously stated, the Health Care Malpractice Act requires that "when a defendant health care provider is board certified in a specialty, an expert witness attesting that the defendant deviated from (or complied with) the standard of care must be board certified in the same or a related specialty, with certain exceptions." *Demuth, et al.*, 205 Md. App. at 524 (internal quotations omitted). However, concerning a qualified expert witness in an informed consent case, the "qualification" restrictions that apply to a medical malpractice action do not pertain in an informed consent case because "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 of procedure." *McQuitty*, 410 Md. at 18-19 (citing *Sard*, 281 Md. at 444).

During trial, the court made the following statement:

> 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 Court[']s 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 . . . .

* * *

> Let me also say. [sic] 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 it[']s not because of his background or his ability or because I think he's not unbelievable [sic] or that his thing [sic]. It[']s because of what he's going to testify to in the nature of this case . . . .
>
> . . . I 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, [sic] is not in his field. And that's why I'm disqualifying him . . . .

As previously stated, the issue is not whether Dr. Trovato was qualified to opine about Dr. Shannon's advisement to obtain informed consent, but whether he, as a pharmacist, was qualified to testify regarding Amifostine. Maryland Pharmacy Act, codified at Md. Code (1981, 2009 Repl. Vol.), § 12-101 of the Heath Occupations Article defines "practice pharmacy." It reads:

> "Practice pharmacy" means to engage in any of the following activities: (i) Providing pharmaceutical care; (ii) Compounding, dispensing, or distributing prescription drugs or devices; (iii) Compounding or dispensing nonprescription drugs or devices; (iv) Monitoring prescriptions for prescription and nonprescription drugs or devices; (v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices; (vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices; (vii) Acting within the parameters of a therapy

> management contract . . .; (viii) Administering an influenza vaccination, . . ., or any vaccination that has been determined by the Board, . . ., to be in the best health interests of the community . . .; (ix) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approve pharmacy technician training program; (x) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approve pharmacy technician training program; or (xi) Providing drug therapy management . . . .

". . . [B]eing neither a [medical doctor] nor experienced in the day-to-day treatment of [informed consent] is not sufficient to block testimony by a pharmac[ist] about the drug itself. The border between what is peculiarly the province of medical doctors and that of pharmac[ists] or other professionals whose fields of expertise are closely related to the medical profession, has not, and we think cannot, be drawn with precision." *Garvey*, 530 A.2d at 1147 (footnote omitted).

As the trial court recognized, Dr. Trovato was well qualified in oncology pharmacy practice, as he received a Bachelor of Science in Pharmacy from Massachusetts College of Pharmacy, a Doctor of Pharmacy degree from Purdue University, and completed an oncology pharmacy residency training program at the University of Texas. He was an associate professor with the Department of Pharmacy Practice & Science at the University of Maryland School of Pharmacy and was the director the University's residency program. "[Dr. Trovato] provide[d] teaching and lectures to . . . pharmacy students in the areas of oncology therapeutics. [He] [was] also an oncology clinical specialist," and was involved in countless aspects of oncology medication at the University's cancer center.

Dr. Trovato testified that he had "counselled [sic] some patients on Amifostine. It was

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

**II. Whether The Trial Court Properly Denied Appellants' Evidence Relating To The Approved Uses Of Amifostine: The Federal Drug Administration ("FDA") Label and Package Insert.**

Although we constitute Dr. Trovato as a qualified expert regarding Amifostine, we still analyze the propriety of the trial court's denial of appellants' evidence relating to the approved uses of Amifostine. In *Waldt, et al. v. Univ. of Maryland Med. Sys. Corp.*, 181 Md. App. 217, 260 (2008) (hereinafter "*Waldt I*") (emphasis added in original), the following colloquy ensued:

> [PLAINTIFFS' COUNSEL]: What [the expert] is going to do with respect to informed consent in a garden variety informed consent count is testify based on his education, training, and experience what this patient should have been told, what in his opinion was a material risk and was a proper description of the procedure to be performed.
>
> THE COURT: That's not the question. The question is he is [sic] going to testify to that. What is the basis for that testimony. That's the question.
>
> [PLAINTIFFS' COUNSEL]: His education, training, his experience, and the material that he reviewed in this case, including medical records and also the documents from the manufacturer of the device that specifically say what the device can and can't be used for. This is not an issue of off-label use . . . . This is a device that was approved for specific uses and in this case, they used it by their own documents on an aneurysm that it wasn't supposed to be used

on and [the expert] has garden variety informed consent opinions . . . .

* * *

THE COURT: Tell me what the plaintiffs plan to have revealed by [the expert] with regards to the FDA.

[PLAINTIFFS' COUNSEL]: With regard to the FDA, that simply what the Boston Scientific material says on the issue of informed consent, that it is authorized by federal law for use on certain aneurysms that are not amendable to clipping . . . .

Our Court stated:

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

*Waldt I*, 181 Md. App. at 261. Furthermore, we ruled that the proffer was insufficient because it did not attest to the following *Sard* factors:

It [was] not a proffer of the substance of what [the expert] would testify were the inherent risks of the neuroform stent coiling procedure, the probability of success of that procedure, the frequency of the inherent risks materializing, the existence of alternative procedures (for instance, cardiac stent coiling or clipping), the risks inherent in those alternative procedures, and how the risks inherent in the neuroform stent coiling procedure compare by nature and frequency to the risk inherent in the alternative procedures.

*Id.* The Court of Appeals agreed with our conclusion that the plaintiff's proffer was insufficient, as the expert would have testified to the approved uses of the neuroform stent.

*Waldt II*, 411 Md. at 235. Hence, the Court never determined whether the FDA approval, or lack thereof, constituted a material risk, and ruled that the trial court did not abuse its discretion because the expert's testimony concerning approved uses failed to address the issue of informed consent, since it did not address the material risks of the procedure. *Id.* at 237.

Similar to the expert in *Waldt*, Dr. Trovato's *de bene esse* testimony centered on the inappropriate use of Amifostine. Dr. Trovato believed that his purpose in testifying was to explain the appropriate use of Amifostine and, that in his opinion, the use of Amifostine was not appropriate for Mr. Fusco. The following colloquy ensued over appellees' objections at the *de bene esse* deposition:

> [APPELLANTS' COUNSEL]: 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?
>
> * * *
>
> [DR. TROVATO]: 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.

Although portions of Dr. Trovato's testimony sounded in negligence, the other aspects of his testimony focused on the material risks associated with a regimen of Amifostine therapy in connection with radiation therapy, particularly for this patient, including that the use of this drug under these circumstances was not previously approved by the FDA.

In *Nolan v. Dillon et al.*, 261 Md. 516, 519 (1971), the defendant–physician administered two injections of Sparine to the plaintiff while she was delivering her baby.

The plaintiff was allergic to the dosage, and subsequently, her left hand suffered from gangrene. *Id.* As a result, her fingers required amputation. *Id.* The plaintiff filed a negligence action against the defendant–drug manufacturing company, as well as the physician. *Id.* During trial, the physician offered testimony from his expert that "the warnings given on the package insert provided reasonable directions as to dosage and concentration of [the drug] and represented the standard of care followed by physicians practicing in Montgomery County." *Id.* at 522. Despite this testimony, the jury returned a verdict against the physician, but in favor of the manufacturer. *Id.* at 520.

The physician appealed, and our Court affirmed. *Id.* The Court of Appeals determined "whether the warnings which [the manufacturer] gave regarding the use of [the drug] were adequate to warrant the granting of a directed verdict in its favor." *Id.* The Court concluded that the manufacturer's package insert completely released its duty to warn, and thereby the manufacturer was not negligent. *Id.* at 523. *See also Ragin v. Porter Hayden Co.*, 133 Md. App. 116, 144 (2000) (stating "[i]t is apparent . . . that a continuing duty to warn may emanate from either a negligence or a strict liability theory").

In *Southard v. Temple Univ. Hosp.*, 781 A.2d 101, 102 (Pa. 2001), the Pennsylvania Supreme Court determined whether the doctrine of informed consent required surgeons to advise their patients of the FDA regulatory status of a medical device. The court concluded that there was no such requirement. *Id.* at 102-03. The plaintiffs filed a complaint against the defendants, alleging that the defendants failed to obtain informed consent because they were not advised of the FDA regulatory status of the bone screws used in the surgery. *Id.* at

103. The jury returned a verdict in favor of the defendants, but the appellate court reversed. *Id.* at 105. On appeal, Pennsylvania's highest court concluded that:

> The category into which the FDA place[d] the device for marketing and labeling purposes simply [did] 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 [did] not constitute a material fact, risk, complication or alternative to a surgical procedure. It follow[ed] that a physician need not disclose a device's FDA classification to the patient in order to ensure that the patient has been fully informed regarding the procedure.

*Id.* at 107.

In *Garvey*, 530 A.2d at 1142, *infra*, the plaintiffs filed a medical malpractice action against the physicians for prescribing an antibiotic, which allegedly caused the injured plaintiff to contract tinnitus. The plaintiffs attempted to offer a package insert into evidence, but the trial court stated it constituted hearsay, and ruled that it was inadmissible evidence. *Id.* at 1144. On appeal, the D.C. Court of Appeals ruled that "[w]hen the package insert . . . [was] offered in conjunction with expert testimony . . ., that combination may be sufficient to establish the standard of care." *Id.* at 1146 (citing *Riffey v. Tonder*, 36 Md.App. 633, 652 (1977)).

In *Thompson v. Carter*, 518 So.2d at 610, the plaintiff was diagnosed with a kidney infection to which the defendant–physician prescribed Bactrim and penicillin for the plaintiff's subsequent influenza symptoms. The plaintiff's body became swollen with blisters, and she suffered from blurred vision. *Id.* at 610-11. The defendant then diagnosed her with Stevens-Johnson Syndrome. The plaintiff filed a medical malpractice action against

the defendant. *Id.* at 611. During trial, the plaintiff was not permitted to admit a package insert into evidence because the court deemed it hearsay. *See id.* at 611-12. On appeal, the Supreme Court of Mississippi ruled that the package was admissible pursuant to a hearsay exception, *id.* at 612, and that although it was not conclusive evidence, it could demonstrate that the physician deviated from the standard of care. *Id.* at 613.

In *Rodriguez*, 574 P.2d at 482, *infra*, the injured plaintiff sued the defendants–physicians regarding medical malpractice for prescribing an excessive amount of Streptomycin to cure the plaintiff's tuberculosis, which resulted in permanent neural damage. The plaintiffs' expert, a pharmacologist, indicated that a package insert recommended lower dosage amounts of the drug. *Id.* at 484. The Court of Appeals of Arizona stated that "[w]hile the package insert [was] admissible into evidence, it [did] not establish conclusive evidence of the standard or accepted practice in the use of the drug by physicians and surgeons, nor that a departure from such directions [constituted] negligence." *Id.* at 486 (citing *Salgo v. Leland-Stanford Jr. Univ. Bd. of Trustees*, 317 P.2d 170, 180 (1957)).

Our Courts have traditionally held that, "[e]xpert testimony is necessary to establish the material risks and other pertinent information regarding the treatment or procedure." *Id.* at 232. As stated previously, in *Waldt II*, the plaintiffs offered Dr. Debrun as their expert witness to opine regarding their informed consent claim. *Id.* at 213. However, in affirming the judgment of our Court and the ruling of the trial court, the Court of Appeals recognized the limits of Dr. Debrun's expertise ". . . 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 . . . ." *Id.* at 237. Writing for the majority, Judge Clayton Greene, Jr. observed that:

> The [plaintiffs] did not make a proffer of the substance of Dr. Debrun's anticipated testimony . . . . The only proffer that counsel for the [plaintiff's] had previously made regarding Dr. Debrun'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 [Ms.] Waldt's. There was no proffer as to the risks inherent to use of the neuroform stent on [Ms.] Waldt's aneurysm, such as: coiling with the neuroform stent; the probability of success of the coiling procedure with the neuroform stent; the frequency of the risks inherent in coiling with the neuroform stent; what procedures were available as alternatives to coiling with the neuroform stent; what were the risks inherent in those procedures; how did the risks inherent in those procedures compare both by nature and frequency to the risks inherent in coiling with the neuroform stent; and which risks of the neuroform stent coiling procedure were disclosed to [Ms.] Waldt and which were not.

*Id.* at 233-34 (citing *Waldt I*, 181 Md. App. at 260; *Sard*, 281 Md. at 448).

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

been tested on an elderly population."

As indicated, *Waldt II's* majority concluded that the plaintiffs did not submit a sufficient proffer regarding what Dr. Debrun's anticipated testimony was concerning informed consent. Unlike Dr. Debrun, in our case, there was a sufficient proffer of what Dr. Trovato would opine to as a pharmacist, including the material risks associated with Amifostine. As a result, appellants sought to further opine that Amifostine was not FDA approved for the proposed use, and that the package insert noted that it lacked testing on elderly patients, which were material risks.

During Dr. Shannon's deposition, the following colloquy ensued:

> [APPELLANTS' COUNSEL]: I understand. I understand that you have the ability to prescribe a drug off label based on your clinical experience and based on your education. My only question is, did you advise him that the Food and Drug Administration, I'm sorry. That the drug manufacturer recommended that it not be used because it hasn't been fully tested on elderly patients yet.
>
> [APPELLEES' COUNSEL]: Objection. Go ahead.
>
> [DR. SHANNON]: No, I didn't and there is additional reason why I don't. We are giving in terms of a dosage spectrum as we just spoke of we're really on the low end. Most of the concerns for side effects being hypotension, terrible nausea and vomiting dizziness. Need for hydration, parenteral IV hydration, occurs in these higher dosages where you're really pushing it. We're not pushing it. We're down here at this low end of the spectrum.
> So again, you know, you're dealing with what appeared to be a healthy walking, talking, feisty 80-year-old guy who wants treatment and this may help him prevent side effects from his determined therapy. I don't mention every should. I agree with you. You said you don't know what should means, I don't know what it means either.

Although "patients generally do not base their decision to purchase a prescription

medication on the instructions for its consumption or use or any information contained in the informational pamphlet accompanying the prescription drug."[15] *Rite Aid Corp. v. Levy-Gray*, 391 Md. 608, 640 (2006) (Harrell, J., dissenting), we disagree with our sister states, and perceive that this information could have been a material consideration regarding Mr. Fusco's decision whether to consent to the use of Amifostine. *See Waldt II*, 411 Md. at 241 (Adkins, J., dissenting) (stating, "[i]nformation about the lack of FDA approval is something that a patient could reasonably want to consider in deciding whether to place her confidence and trust in [his or] her physician about the treatment [he or] she is about to undertake.").

It is well settled in Maryland that our Courts will not reverse a trial judge's ruling if the error is harmless. *Barksdale v. Wilkowsky, et al.*, 419 Md. 649, 657 (2011) (citing *Flores v. Bell*, 398 Md. 27, 33 (2007)). *See also Greenbriar v. Brooks*, 387 Md. 683, 740 (2005); *Crane v. Dunn*, 382 Md. 83, 91 (2004)) (footnote omitted). The harmless error doctrine "'embod[ies] the principle that courts should exercise judgment in preference to the automatic reversal for 'error' and ignore errors that do not affect the essential fairness of the trial.'" *Barskdale*, 419 Md. at 657-58 (citing *Williams v. State*, 394 Md. 98, 120 (2006) (Raker, J., dissenting) (quoting *McDonough Power Equip., Inc. v. Greenwood*, 464 U.S. 548, 553 (1984)). In a civil case, the ruling will not be reversed unless the complainant demonstrates both error and prejudice. *Barksdale*, 419 Md. at 660.

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[15] In *Rite Aid Corp.*, 391 Md. at 634, the Court was reluctant to conclude that a pharmacy was liable under a breach of an expressed warranty when it provided a package insert.

As we previously stated, the trial court erred in excluding admissible portions of Dr. Trovato's *de bene esse* deposition and trial testimony because he was a qualified expert witness regarding the question of the material risks of Amifostine. According to the record before us, the jury reached an unanimous verdict that by a preponderance of the evidence, a reasonable patient, having been informed of the material risks and complications associated with Amifostine therapy would have consented to its use. However, as indicated above, the jury was not presented with Dr. Trovato's testimony regarding the FDA approval and package insert, which may have been material to the jury's determination. Without this, we can neither decide whether the jury's verdict would have remained the same nor can we determine whether the jury would have concluded that a reasonable patient would have refused. As a result, appellants were prejudiced by the exclusion of Dr. Trovato's testimony, and accordingly, we shall therefore reverse.

On remand, although Dr. Trovato indicated that he counseled and educated patients on the use of oncology medications, including Amifostine, informed consent encompasses more than the potential benefits and risks of Amifostine. There is an overall treatment plan, which the record indicated, including the patient's past medical, social, and family history, tobacco and alcohol intake, physical examinations, laboratory studies, anatomy demonstrations via diagrams and pictures, x-ray films, and lifestyle management, all of which are a part of a recommended course of treatment. Hence, we note that portions of Dr. Trovato's proffered testimony regarding informed consent were not admissible, as exceeding the scope of his expertise in an informed consent case. In that regard, Dr. Trovato's

testimony regarding the nature of the material risks associated with the particular regimen of treatment provided to Mr. Fusco, and any alternative treatment options, would exceed the extent of Dr. Trovato's expertise relative to informed consent.

**JUDGMENT OF THE CIRCUIT COURT FOR PRINCE GEORGE'S COUNTY IS REVERSED. CASE REMANDED FOR FURTHER PROCEEDINGS CONSISTENT WITH THIS OPINION. COSTS TO BE PAID BY APPELLEES.**