REPORTED

IN THE COURT OF SPECIAL APPEALS

OF MARYLAND

No. 2623

September Term, 2006

REBECCA MARIE WALDT, *ET AL.*

v.

UNIVERSITY OF MARYLAND MEDICAL SYSTEM CORPORATION, *et al.*

Krauser, C.J.,
Eyler, Deborah S.,
* Murphy, Joseph F., Jr. (Specially Assigned),

JJ.

Opinion by Eyler, Deborah S., J.

Filed: September 5, 2008

* Joseph F. Murphy, Jr., Associate Judge of the Court of Appeals, participated in the hearing and conference of this case while an active member of this Court; he participated in the adoption of this opinion as a specially assigned member of this Court.

In the Circuit Court for Baltimore City, Rebecca Marie Waldt and her husband, Roy Waldt, sued Gregg Zoarski, M.D., and the University of Maryland Medical System ("UMMS") for medical malpractice. Using a device called the "Neuroform Microdelivery Stent System" ("neuroform stent"), Dr. Zoarski, the Chief of Interventional Radiology at UMMS, had performed a procedure to treat an aneurysm in a blood vessel in Mrs. Waldt's brain. During the procedure, an artery was perforated, which caused bleeding into the brain and a stroke. The stroke left Mrs. Waldt with significant physical and mental deficits.

In their complaint, the Waldts alleged two types of negligence: 1) ordinary medical negligence, *i.e.*, failure by Dr. Zoarski to adhere to the standard of care in the actual performance of the procedure; and 2) informed consent negligence, *i.e.*, failure by Dr. Zoarski to obtain the patient's informed consent to the procedure. The Waldts' sole claim against UMMS was for vicarious liability for the alleged malpractice of Dr. Zoarski.

The case went to trial beginning on November 30, 2006. Ultimately, at the close of the Waldts' case, on December 21, 2006, the court granted judgment in favor of UMMS and Dr. Zoarski on both counts.

The Waldts noted this appeal, raising seven questions for review, which we have reordered, consolidated, and reworded:

I. Did the trial court err in ruling that Gerard Debrun, M.D., the Waldts' expert witness, could not testify on the issue of whether Dr. Zoarski breached the standard of care in treating Mrs. Waldt?

II. Did the trial court err in ruling that Dr. Debrun could not testify as an expert witness on the medical issues that were part of the Waldts' informed consent claim?

III. Did the trial court err by granting judgment in favor of UMMS and Dr. Zoarski at the end of the Waldts' informed consent case?

IV. Did the trial court err by ruling inadmissible certain documentary evidence?

For the following reasons, we answer "Yes" to the first question and "No" to the second and third questions. Our disposition makes it unnecessary to address the fourth question. Accordingly, we shall affirm the judgment in favor of the appellees on the informed consent claim, reverse the judgment in favor of the appellees on the ordinary negligence claim, and remand the case to the circuit court for further proceedings on that claim.

FACTS AND PROCEEDINGS

In August 2002, Mrs. Waldt, then 52, went to see her primary care physician, Amy Jones, M.D., because for four months she had been experiencing headaches that were not improving with medication. Dr. Jones ordered an MRI of Mrs. Waldt's head, which revealed an unruptured intracranial "right paraopthalmic brain aneurysm." An aneurysm is a weak spot on a blood vessel that produces a bubble-like bulge, which can rupture. In Mrs. Waldt's case, the bubble had not yet burst. Mrs. Waldt had some knowledge of brain aneurysms because both her mother and aunt had died of them.

Dr. Jones referred Mrs. Waldt to Dennis Winters, M.D., a local neurosurgeon. Dr. Winters reviewed the MRI and arranged for a cerebral angiogram, a procedure that uses dye to mark the blood vessels in the brain so they can be seen and evaluated. The angiogram confirmed the presence of the aneurysm in Mrs. Waldt's middle cerebral artery ("MCA"), near its junction with the opthalmic artery. The area is deep inside the brain, at its base, on the right side, near the optic nerve and behind the eyes. The angiogram showed the aneurysm to be 8 millimeters in size with a wide "neck," that is, the point on the artery at which the bubble protrudes.

Due to the size and location of the aneurysm, Dr. Winters referred Mrs. Waldt to Francois Aldrich, M.D., a neurosurgeon at UMMS. Dr. Aldrich specializes in repairing damaged blood vessels in the brain by "open brain surgery," *i.e.*, surgery that involves the temporary removal of a section of the skull (a "craniotomy") to gain access to the damaged vessel in the brain. The aneurysm is repaired by the surgical placement of titanium "clips" across the weakened area of the vessel, closing it off. The procedure is called surgical "clipping."

On October 18, 2002, the Waldts met with Dr. Aldrich, at UMMS. He reviewed the various test results with them and discussed three treatment avenues. The first was to do nothing except to monitor the status of the aneurysm. The second was to perform open brain surgery with surgical clipping. The last avenue, which is the one that was taken, was a non-surgical procedure known as endovascular coiling ("coiling").

Coiling procedures are performed by interventional radiologists. The radiologist inserts a catheter in a large blood vessel in the patient's groin, into which he threads a "stent" and a guide wire through other blood vessels until they reach the aneurysm site. The stent is a hollow tube made of metal mesh, that serves as a scaffold. Using the guide wire, the radiologist moves the stent into place against the neck of the aneurysm. Then another catheter, containing tiny metal coils of various sizes, in the shape of pig tails, is inserted and deposited in the stented area. Again using the guide wire, the radiologist moves the metal coils, one by one, from inside the stent to inside the aneurysm sac. In doing so, he or she guides each coil through one of the mesh openings in the stent, into the sac. When the coils are in place in the sac, the catheter and guide wire are withdrawn. The stent remains, propping the artery open and covering the coil-filled sac. Blood coagulates around the coils, walling off the sac and thereby repairing the aneurysm.

On the same day as their consultation with Dr. Aldrich, the Waldts met with Dr. Zoarski, at Dr. Aldrich's suggestion. Dr. Zoarski agreed with Dr. Aldrich about the three treatment options. He and Dr. Aldrich strongly recommended against the "do nothing except monitor" approach, given Mrs. Waldt's family history. It is undisputed that the do nothing approach was not acceptable for Mrs. Waldt's condition.

During their October 18 meeting, Dr. Zoarski spent an hour discussing the coiling procedure with the Waldts. He explained how it is done and told the Waldts that, ordinarily, the stent that is used in the procedure is a cardiac stent, that is, one that is used in the blood vessels of the heart in heart surgery. He told the Waldts that a new stent, more supple than a cardiac stent, was in the process of being developed but was not yet available for use in the United States.

As a consequence of the meeting with Dr. Zoarski on October 18, Mrs. Waldt was scheduled to undergo the coiling procedure, with a cardiac stent, on November 20, 2002. Before that date, Dr. Zoarski learned that the new neuroform stent had become available for use in this country. He called the Waldts and informed them of that development. On November 13, 2002, when the Waldts came to UMMS for the pre-procedure preparation for the cardiac stent coiling procedure, they and Dr. Zoarski again met. Dr. Zoarski told the Waldts that although the neuroform stent was available for use, he would have to receive training from Boston Scientific, the manufacturer, before he could use it. Thus, if the Waldts wanted the coiling procedure to be performed using the neuroform stent, instead of the cardiac stent, the procedure date would have to be postponed. The Waldts decided in favor of that approach, and the procedure date was moved to December 19, 2002.

Dr. Zoarski in fact received training in the use of the neuroform stent at a Boston Scientific training session in Chicago on December 10, 2002.

The neuroform stent coiling procedure is essentially the same as the cardiac stent coiling procedure, except that the stent that is used is made of more flexible and less rigid metal mesh. Dr. Zoarski performed the neuroform stent coiling procedure on Mrs. Waldt as rescheduled, on December 19, 2002. He inserted a catheter into a large artery in Mrs. Waldt's groin and moved it through the other arteries into the artery in her brain in which the aneurysm was located. (Just as in the cardiac stent coiling, contrast material inside the catheter allowed Dr. Zoarski to use radiological studies to visualize inside the blood vessels and brain.)

Dr. Zoarski threaded the guide wire and the neuroform stent through the catheter; placed the neuroform stent in the artery in which the aneurysm was located; and fixed it in place so as to cover the neck of the aneurysm. When the neuroform stent was in place, he removed the guide wire and catheter. He then inserted a micro-catheter, containing the tiny metal coils, and threaded it and the guide wire through the arteries, to the location of the neuroform stent, next to the aneurysm. He began using the guide wire to move the coils, one by one, from inside the neuroform stent, through its wire mesh openings, into the aneurysm sac. He successfully moved two coils from inside the neuroform stent to inside the aneurysm sac.

The procedure went as planned until Dr. Zoarski was in the process of moving the third pigtail-shaped coil from inside the neuroform stent to inside the aneurysm sac. As he moved the third coil through the wire mesh, it became ensnared. For over two hours, Dr. Zoarski maneuvered the guide wire back and forth in an effort to free the tangled coil from the mesh. Ultimately, the coil broke. During that maneuvering period, the MCA was perforated, and blood and dye extravasated into the brain. Dr. Zoarski called for the assistance of a neurosurgeon. Dr. Aldrich responded, performed a craniotomy, and brought the bleeding under control. The bleeding inside the brain had

caused a stroke, however; and ultimately, and allegedly, the stroke caused injuries to Mrs. Waldt in the form of loss of use of her left hand, impaired cognition, loss of vision, confinement to a wheelchair, and severe depression.

Throughout the ensuing litigation, the Waldts' theory of the case was that the MCA was perforated at a location far beyond the site of the aneurysm, and the perforation was caused by Dr. Zoarski's repeatedly moving the guide wire back and forth ("fishing") through the catheter in an effort to unsnare the tangled coil. The Waldts' theory of the case was *not* that the neuroform stent failed, or was defective, or was itself the reason for the perforation. Dr. Zoarski's theory of defense was that the artery did not perforate at a site away from the aneurysm; rather, it perforated near the aneurysm, which is a known and usual risk of any coiling procedure. Alternatively, if the artery did perforate distant from the aneurysm site, it did not perforate due to a breach of the standard of care by him or by any other health care provider involved in Mrs. Waldt's treatment.

We shall include additional facts as pertinent to our discussion of the issues.

DISCUSSION

I.

Ordinary Medical Negligence Claim

In Maryland, the procedures in medical malpractice litigation are established by the Health Claims Arbitration Act, codified at Md. Code (1976, 2006 Repl. Vol., 2007 Supp.), section 3-2A-01 *et seq.* of the Courts and Judicial Proceedings Article ("CJ") ("the Act"). The Act requires that all malpractice claims against health care providers in which damages in excess of the jurisdictional limit of the District Court are sought be initiated by filing a statement of claim in the Health Claims

Alternative Dispute Resolution Office ("HCADRO"), formerly called the Health Claims Arbitration Office. *See* CJ § 3-2A-02(a); *McCready Memorial Hosp. v. Hauser*, 330 Md. 497, 512 (1993).

The Waldts filed their statement of claim in the HCADRO on August 1, 2005. It named UMMS as the sole health care provider. Pursuant to CJ section 3-2A-04(b)(1)(i), they also filed a certificate of qualified expert, signed by James Gerard Debrun, M.D., an interventional neuroradiologist. In the certificate, Dr. Debrun attested among other things that UMMS, through the actions and omissions of Dr. Zoarski, breached the standard of care in performing the coiling procedure on Mrs. Waldt, proximately causing her to suffer a stroke and consequent injuries.

On August 3, the Waldts unilaterally waived arbitration, as permitted by CJ section 3-2A-06B. Thereafter, on September 27, 2005, in the Circuit Court for Baltimore City, they filed their complaint. It too identified UMMS as the sole defendant. Three weeks before trial, the Waldts amended their complaint to name Dr. Zoarski as a defendant as well.

In count 1, the Waldts alleged that Dr. Zoarski (and in turn UMMS) failed to exercise reasonable care in their care and treatment of Mrs. Waldt. The gravamen of this ordinary medical negligence claim (in contrast to their informed consent negligence claim) was that Dr. Zoarski breached the standard of care in the way he performed the coiling procedure, thereby perforating Mrs. Waldt's MCA at a point distant from the site of the aneurysm and causing her injuries. Specifically, the Waldts alleged that Dr. Zoarski "negligently used extensive manipulation and excessive force to retrieve the stuck coil, causing a severe perforation of the artery resulting in a massive bleed in Mrs. Waldt's brain."

In the course of discovery, the Waldts identified Dr. Debrun as their expert witness. Dr. Debrun was educated in France and practiced interventional neuroradiology for 45 years before

retiring in July of 2001. He has held many positions in that field, including: Chief of Neuroradiology at the University Hospital of Paris, Director of Neuroradiology at the University of London in Canada, Chairman of the Department of Radiology at Massachusetts General Hospital, Visiting Professor at Harvard Medical School, and Director of Interventional Neuroradiology at The Johns Hopkins Hospital in Baltimore. Dr. Debrun has lectured extensively and written hundreds of articles on the subject of neuroradiology. He has in the past performed over 30 coiling procedures to treat wide-neck aneurysms. Between 10 and 15 of those aneurysms were similar in size to Mrs. Waldt's aneurysm. Because Dr. Debrun's retirement preceded the market release of the neuroform stent, he never performed a coiling procedure using that stent.

Dr. Debrun read Mrs. Waldt's medical records, including Dr. Zoarski's notes about the coiling procedure; reviewed the angiograms taken at various intervals during the procedure; and read literature about the neuroform stent system, published by its manufacturer, Boston Scientific. In a discovery deposition, Dr. Debrun opined that Dr. Zoarski breached the standard of care when he performed the coiling procedure by, *inter alia*, using the guide wire to "fish" for the stuck third coil, and in doing so perforating the MCA at a site away from the aneurysm. He explained that the perforation was caused by Dr. Zoarski's manipulation of the guide wire, and not by the stent itself, because (1) an angiogram taken during the procedure shows the stent and the coils perfectly deployed and in place, (2) the location of the bleed (as shown in an angiogram) was too distant from the aneurysm to have been caused by the stent, and (3) Dr. Zoarski's own notes, made at the time of the event, reflect his belief that the perforation occurred away from the site of aneurysm.

A.

Did the Trial Court Err By Excluding Dr. Debrun's Standard of Care

Testimony from Trial for Noncompliance with the "20 Percent Rule" ?

Under CJ section 3-2A-04(b), in a medical malpractice action other than one based solely on informed consent, each party must file a certificate of qualified expert (sometimes referred to as a certificate of merit). That subsection sets forth the proper and necessary elements for a valid certificate. In an ordinary medical negligence claim, the claimant/plaintiff's certifying expert must "attest[] to departure from standards of care, and that the departure from standards of care is the proximate cause of the alleged injury." CJ § 3-2A-04(b)(1)(i)1.[1]

For a certificate of qualified expert to pass muster under the Act, the certifying expert "may not devote annually more than 20 percent of the expert's professional activities to activities that directly involve testimony in personal injury claims." CJ § 3-2A-04(b)(4). This "20 Percent Rule," as it is commonly called, has been a requirement for a valid certificate of qualified expert ever since the certificates first became required, in 1986. 1986 Md. Laws Chap. 640 § 1.

More recently, effective January 11, 2005, the same 20 Percent Rule has been made a prerequisite for expert witness testimony offered in a medical malpractice hearing or trial. In a December 2004 Special Session of the General Assembly, a bill was enacted that amended CJ section 3-2A-04(b)(4) to provide:

> Unless the sole issue in the claim is lack of informed consent . . . : A health care provider who attests in a certificate of a qualified expert **or who testifies in relation to a proceeding before the arbitration panel or a court concerning compliance with or departure from standards of care** may not devote annually more than 20

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[1]Under the Act, when a case is pending in the HCADRO, the party filing a claim is called the "claimant" and the party against whom the claim is filed is called the "health care provider." CJ § 3-2A-01. In the circuit court, the ordinary plaintiff and defendant nomenclature is used. For ease of discussion, when we refer to party status in this case, we shall use "plaintiff" and "defendant."

> percent of the expert's professional activities to activities that directly involve testimony in personal injury claims.

(Emphasis added.) 2005 Md. Laws Spec. Sess. Chap. 5, § 1. During the same Special Session, the General Assembly enacted what is now CJ section 3-2A-02(c)(2):

> (c)*Establishing liability of health care provider; qualifications of persons testifying.*
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> * * * * *
>
> (2) (i) This paragraph applies to a claim or action filed on or after January 1, 2005.[2]
> (ii) 1. *In addition to any other qualifications, a health care provider who attests in a certificate of qualified expert or testifies in relation to a proceeding before a panel or court concerning a defendant's compliance with or departure from standards of care:*
> A. *Shall have had clinical experience, provided consultation relating to clinical practice, or taught medicine in the defendant's specialty or a related field of health care, or in the field of health care in which the defendant provided care or treatment to the plaintiff, within 5 years of the date of the alleged act or omission giving rise to the cause of action . . . .*

2005 Md. Laws Spec. Sess. Chap. 5, § 1 (emphasis added).[3]

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[2]As noted above, the Waldts' claim in the HCADRO and their action in the circuit court both were filed after January 1, 2005.

[3]The amendment goes on to provide, in addition:

> B. Except as provided in item 2 of this subparagraph, if the defendant is board certified in a specialty, shall be board certified in the same or a related specialty as the defendant.
> 2. Item (ii)1B of this subparagraph does not apply if: A. The defendant was providing care or treatment to the plaintiff unrelated to the area in which the defendant is board certified; or B. The health care provider taught medicine in the defendant's specialty or a related field of health care.

In the case at bar, both Drs. Zoarski and Debrun are board certified in radiology.

In the case at bar, Dr. Debrun attested in his certificate of qualified expert that he does *not* devote annually more than 20 percent of his professional activities to activities that directly involve testimony in personal injury claims. However, on December 1, 2006, the first day of trial testimony, Dr. Zoarski and UMMS moved to preclude Dr. Debrun from testifying on the ground that he *does* devote annually more than 20 percent of his professional activities to activities that directly involve testimony in personal injury claims. The Waldts opposed the motion. Outside of the presence of the jury, Dr. Debrun was examined by counsel, and by the court, about facts relevant to the 20 Percent Rule.

Dr. Debrun testified that he retired in July of 2001, and has not directly participated in patient care since then. He earns on average $30,000 per year from serving as an expert witness in medical malpractice cases. In most such cases, he is an expert witness for the plaintiff. Ordinarily, he participates as an expert witness in three or four medical malpractice cases a year. He estimates that he spends less than 50 hours per year in that endeavor. He participates in a given medical malpractice case by reviewing it and having his deposition taken. He rarely testifies in court (or before a panel) because most of the cases settle before trial. In the case at bar, Dr. Debrun had been paid $23,028. Dr. Debrun's only significant source of income other than the money he earns as an expert witness is his pension.

Dr. Debrun further testified that, in 2004 and 2005, he devoted an average of 559 hours per year to "professional activities" unrelated to his service as an expert witness in medical malpractice cases. These activities fall into five categories:

- Performing peer review of submitted articles for Surgical Neurology, a medical journal: 192 hours per year (16 hours per month);

- Reading the International Journal for Interventional Neuroradiology and Neurological Surgery Journal: 240 hours per year (20 hours per month);

- Observing colleagues performing various procedures: 96 hours per year (8 hours per month);

- Discussing ongoing patient medical cases with physicians: 16 hours per year (1.33 hours per month);

- Attending international conferences in the field of interventional radiology: 15 hours per year (approximately 1.33 hour per month).[4]

When pressed on cross-examination about the nature of these activities and how they relate, if at all, to his expert witness activities, Dr. Debrun testified as follows:

> Q. What is the last conference you attended, Doctor?
>
> A. Three years ago.
>
> . . .
>
> Q. Three years ago. What was it for?
>
> A. It was four or five years ago.
>
> Q. What was it on, what was it about? What was the subject of the conference?
>
> A. Whether there is any – it was an international meeting about everything in interventional neuroradiology.
>
> Q. So by interventional –
>
> A. Interventional treatment within one week.
>
> Q. Okay. And the information that you obtained from that conference will you be using that here in court to base any of your opinions on?
>
> A. Yes, I could.

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[4]Dr. Debrun actually estimated that he was spending between 10 and 15 hours a year on this endeavor, but we have used the 15 hour figure because when combined with the others it totals 559.

Q. Well, what else would you base your opinions on?

A. When I see what my colleagues are doing, I listen to their improvement in the technique and their – I keep that for me and when I testify in a case, I remember what I heard and what is done today so I think I can see what they are doing.

. . .

Q. Now, Dr. Debrun, when you read articles on neuroradiology, you may use that information you get to testify in court; is that correct?

A. Yes.

Q. And when you do peer review journals, some of the information in that peer review journal that you are reviewing you may use to testify in court; is that correct?

A. Yes.

Shortly thereafter, Dr. Debrun stated that he spent 30% of his time working on medical malpractice cases; he quickly corrected himself to say, "less than 20 percent." On re-direct, counsel for the Waldts attempted to clarify these answers:

Q. Why do you [Dr. Debrun] do these [activities like reading journals and observing procedures]?

A. Because I am interested to know what people are doing today.

. . .

Q. Are there times when, by coincidence, something that you read about or hear about or learn about with respect to your professional activities, the five things that we went through, are there sometimes when coincidentally something relates to a case that you may work on at some point?

. . .

A. Of course.

After his testimony on this point was completed, Dr. Debrun stepped outside the courtroom and counsel for the parties presented argument as to whether the doctor properly could testify under the 20 Percent Rule, *i.e.*, whether, at that time, Dr. Debrun was "devot[ing] annually more than 20 percent of [his] professional activities to activities that directly involve testimony in personal injury

claims." Thereafter, the trial judge, commenting that she had read and considered *Witte v. Azarian*, 369 Md. 518 (2002), granted the motion to exclude, ruling as follows:

> [T]he witness has indicated and has testified that he is retired. He has not seen any patients since July 2001. That he spends most of his time reading journals, writing journals, peer review, observing other colleagues performing other procedures and going to conferences and meetings.
>
> He is also indicating that the one meeting per year that he goes to does not have to do with his practice of medicine or with any patients. The journals that he reads do not have to do with his patients, however they do have to do with his previous practice of medicine.
>
> He has also indicated that approximately he earns about $30,000 per year from testifying in court albeit he has already earned, well, in this case alone, which he did not include in that $30,000, $23,028. He has also indicated he has read at least one journal or article in preparation for this case.
>
> He does not keep a calendar nor an electronic device with regards to his appointments or where he has to be or what he has to do.
>
> He says he knows where he has to be and he writes it down on a piece of paper, and he is aware of where he is supposed to be at the time he is supposed to be there.
>
> At these seminars or conferences, he has not presented any papers since – he said since retiring . . . .
>
> He has gone to these conferences on the interventional neuroradiological conferences. . . . But he doesn't use any of the information that he receives at these conference for testifying in court on behalf of plaintiffs. He doesn't use any of the information that he receives from reading the journals.
>
> He doesn't use any of the information or knowledge that he receives from his colleagues in Paris when he talks to them or tries to keep up on what is going on. He just does it just to be informed on what is going on in his field.
>
> The Court finds that to be absolutely amazing. And one of the questions that was asked of the witness, the Court can't recall at this moment the exact question, but the witness' response was, quote, when I was working or after I retired.

> The witness has no license to practice medicine in the United States. This is neither here nor there but he only has his license he says in Paris so he can write prescriptions for his family members.
>
> He has no patients, he has no privileges. He is not paid for any medical treatment he provides. He is not paid for any opinions that he gets from colleagues or gives to colleagues about what they do.
>
> At this time, the Court finds that the expert devotes more than 20 percent of his professional activities to the [sic] involving testimony or testifying in personal injury cases.

Accordingly, the court prohibited Dr. Debrun from giving standard of care testimony at trial.

On appeal, the Waldts challenge the trial court's exclusion of Dr. Debrun's standard of care testimony under the 20 Percent Rule. They argue that the court incorrectly interpreted the meaning of "professional activities," as used in CJ section 3-2A-04(b)(4). Specifically, it declined to count as "professional" the five non-litigation (as explained *infra* in *Witte*) activities that Dr. Debrun engages in (peer review commenting, reading medical journals, observing procedures performed by other physicians, consulting with colleagues, and attending conferences), upon an improper finding that they were not "professional" activities because the doctor was no longer practicing medicine or seeing patients in any capacity. In the trial judge's words, those activities "do[] not have to do with [Dr. Debrun's] practice of medicine or with any patients."

Dr. Zoarski and UMMS counter that the court's interpretation of the phrase "professional activities" as used in CJ section 3-2A-04(b)(4) was legally correct and in accordance with the analysis of the Court of Appeals in *Witte v. Azarian*, *supra*. They argue that the activities Dr. Debrun testified about "were not professional activities as they were not related to his practice of medicine or treatment of patients." They further complain that the activities he described in his testimony had

a "'clear and direct relationship to the testimony to be given by the doctor [in personal injury cases.]'" (Quoting *Witte, supra,* 369 Md. at 536.)

The primary question before the Court in *Witte v. Azarian* was what kind of activities "directly involve testimony in personal injury claims," within the meaning of CJ section 3-2A-04(b)(4), so as to constitute the numerator in the 20 Percent Rule. (The events in that case took place before the December 2004 Special Session, and therefore at a time when the 20 Percent Rule was relevant only to an expert's qualification to sign a certificate of merit, and not to his or her qualification to testify at a trial or hearing.) Mr. Azarian sued Dr. Witte, alleging that the doctor had committed malpractice when operating on his broken ankle. The Azarians filed a certificate of merit signed by Dr. Lawrence Honick, an orthopedist, in which he attested, *inter alia*, that "less than 20% of his professional activities were devoted annually to activities that directly involved testimony in personal injury claims." *Witte, supra*, 369 Md. at 521.

Dr. Honick had at one time performed surgery but had given up doing so. He still maintained a full-time office-based practice. Most of his time was devoted to performing medical examinations of plaintiffs in worker's compensation and personal injury tort cases, at the requests of lawyers. About 60% of his patients came from referrals from lawyers, and about 90% of his patients had "some sort of litigation involved in addition to their medical claims." *Id.* at 522 (quotation omitted). About half of the referred patients were seen by him for an evaluation, but not for treatment. Most of his patients' litigation did not result in trials, and therefore in any trial testimony on his part. During his 30 year career, he had attended between 300 and 400 depositions.

At trial, defense counsel moved to strike Dr. Honick's certificate of merit on the ground that the evidence about his practice did not support his attestation that he did not devote more than 20%

of his professional activities to activities directly involving testimony in personal injury claims. The trial court granted the motion, upon a finding that the 20 Percent Rule in CJ section 3-2A-04(b)(4) includes activities that lead to, or could lead to, testimony in personal injury claims, such as medical examinations performed on injured people in the course of litigation. The court then granted a renewed motion for summary judgment in favor of Dr. Witte.

This Court reversed. The Court of Appeals granted *certiorari* and affirmed our decision. *Id.* at 525. It reasoned that the operative statutory phrase at issue ("activities that directly involve testimony in personal injury claims"), was ambiguous, as its meaning could not be ascertained from its plain language, and that, in light of the legislative history of the Act as amended, including the amendments establishing the certificate of qualified expert requirement, that language had to be read narrowly, so as to avoid "creat[ing] an unreasonable impediment to the pursuit, or defense, of a common law right of action" for medical negligence. *Id.* at 533. From the legislative history, the Court determined:

> It seems abundantly clear to us that an activity cannot "directly involve testimony" unless there is, in fact testimony -- "[e]vidence that a competent witness under oath or affirmation gives at trial or in an affidavit or deposition." BLACK'S LAW DICTIONARY 1485 (7th ed. 1999). Even when the expert is called upon to testify, however, not everything that he or she does in the matter can be said to "directly involve" that testimony. We reject as factually unsupportable the notion that every medical examination conducted by a doctor upon referral by an attorney or insurance carrier directly involves testimony that may ultimately be given by the doctor. . . .
>
> *A more reasonable approach, we think, is to regard the statute as including only (1) the time the doctor spends in, or traveling to or from, court or deposition for the purpose of testifying, waiting to testify, or observing events in preparation for testifying, (2) the time spent assisting an attorney or other member of a litigation team in developing or responding to interrogatories and other forms of discovery, (3) the time spent in reviewing notes and other materials, preparing reports, and conferring with attorneys, insurance adjusters, other members of a litigation team, the patient, or others after being informed that the doctor will likely be called upon*

> *to sign an affidavit or otherwise testify, and (4) the time spent on any similar activity that has a clear and direct relationship to testimony to be given by the doctor or the doctor's preparation to give testimony.*

369 Md. at 535-36 (emphasis added). On that basis, the Court held that the trial court had erred in ruling that more than 20 percent of Dr. Honick's professional activities were devoted to activities "directly involv[ing] testimony in personal injury claims." *Id.* at 536.

Dr. Zoarski maintains, as he did below, that, given that Dr. Debrun is retired and therefore has no patients, the information he gains from the five professional activities he described (peer review commenting, reading medical journals, observing procedures performed by other physicians, consulting with colleagues, and attending conferences) necessarily becomes a part of his general knowledge in the field of interventional radiology, which in turn necessarily becomes the basis, in part, for the opinions he forms in his capacity as an expert witness in medical malpractice cases. For that reason, the activities "directly involve testimony in personal injury cases."

We disagree. The holding in *Witte* narrowly circumscribed those professional activities that "directly involve testimony in personal injury cases," and it is clear that the activities testified to by Dr. Debrun are not within the limited scope of that phrase. The activities are not any of those specifically enumerated in items (1) through (3) of the Court's analysis in *Witte*, nor do they fall within the Court's item (4), "time spent on any similar activity," *i.e.*, litigation-oriented activity *"that has a clear and direct relationship to testimony to be given by the doctor or the doctor's preparation to give testimony.*" *Id.* at 536 (emphasis added).

To the extent the trial court found that the five activities Dr. Debrun testified about in fact are activities that "directly involve testimony in personal injury cases," that finding was premised upon a legally incorrect reading of CJ section 3-2A-04(b)(4), and therefore was clearly erroneous.

The record does not make entirely clear, however, whether the court ruled on the basis of that finding or ruled that the five general activities described by Dr. Debrun are not "professional activities" at all, and therefore cannot be counted as part of the denominator for the 20 Percent Rule. If the latter was the court's ruling, it too was legally incorrect.

Again, for our purposes, the critical phrase in CJ section 3-2A-04(b)(4) is that the expert "may not devote annually more than 20 percent of *the expert's professional activities* to activities that directly involve testimony in personal injury claims." (Emphasis added.) The meaning of the words "the expert's professional activities" is a matter of statutory construction that we review *de novo*. *Maryland-National Capital Park and Planning Comm'n v. Anderson*, 395 Md. 172, 181 (2006); *Moore v. State*, 388 Md. 446, 452 (2005). Just as the *Witte* Court concluded that the plain meaning of the phrase "activities that directly involve testimony in personal injury claims," as used in CJ section 3-2A-04(b)(4), cannot be discerned from a simple reading of the statutory language, we conclude that the phrase "the expert's professional activities" in the same statute is likewise ambiguous. Neither that particular statute nor any definition section in the Act explains what "professional activities" are. Accordingly, we must turn to the principles of statutory construction to aid our analysis:

> If the true legislative intent cannot readily be determined from the statutory language alone . . . we may, and often must, resort to other recognized indicia -- among other things, the structure of the statute, including its title; how the statute relates to other laws; the legislative history, including the derivation of the statute, comments and explanations regarding it by authoritative sources during the legislative process, and amendments proposed or added to it; the general purpose behind the statute; and the relative rationality and legal effect of various competing constructions.

Witte, 369 Md. at 526 (citing *Beyer v. Morgan State Univ.*, 369 Md. 335, 349-50 (2002) and *Liverpool v. Baltimore Diamond Exchange, Inc.*, 369 Md. 304, 317-19 (2002)). *See also Ishola v. State*, 404 Md. 155, 160 (2008); *Stoddard v. State*, 395 Md. 653, 662 (2006).

The *Witte* Court discussed at length the medical malpractice insurance crisis of the 1970's that led to the enactment of the Health Claims Arbitration Act in 1976, and the reasons why the General Assembly thought that the changes in medical malpractice law brought about by the Act would help solve that crisis. In 1986, the legislature further amended the Act, to include a certificate of qualified expert requirement, in part based upon recommendations made by a 1985 task force convened to study whether the insurance crisis was continuing and, if so, what changes could be made to the Act to further ameliorate the crisis. As proposed, in Senate Bill 559, an expert only would be qualified to sign a certificate if he or she did not receive 50 percent or more income from testimony and other activities related to personal injury claims. That language was amended to become the 20 Percent Rule, that is, that to qualify, a certifying expert cannot devote more than 20 percent of his or her professional activities to activities directly involving testimony in personal injury claims.

As the *Witte* Court explained, the legislative history of the 1986 amendments to the Act suggests that the General Assembly was of two minds in imposing such eligibility requirements upon expert witnesses signing certificates. On the one hand, it wanted to exclude certain "professional witnesses" from "the pool of eligible experts" available to sign certificates of merit. On the other hand, it did not want to "shrink" the size of that pool so as to "deny the parties the ability to pursue and defend these [malpractice] claims." *Id.* at 534. The legislators achieved that balance in part by language changes keying the critical numerical measurement to time, instead of income, and

narrowing the activities originally described as "related to" personal injury claims to the more limited world of activities "directly involving testimony in personal injury claims." *Id.* at 535.

Beyond the legislative intent as gleaned by the Court in *Witte*, nothing in the legislative history of the Act, through the 1986 amendments, sheds light on the meaning of the phrase "professional activities" as the denominator for the 20 Percent Rule. Obviously, given that "activities directly involving testimony in personal injury claims" is the subset of activities addressed by the numerator in the 20 Percent Rule, those activities are included in the meaning of the phrase "professional activities." It is equally obvious, for the same reason, that "professional activities" encompass activities that are more far-reaching than those on which the certificate-signing (and now testifying) restriction is based.

A reference to "profession" in CJ section 3-2A-02, which establishes what must be proven to impose liability upon a health care provider, is more specifically described as "the same health care profession" as the health care provider/defendant who has been sued. CJ § 3-2A-02(c)(1) ("In any action for damages [for medical malpractice], the health care provider is not liable . . . unless it is established that the care given by the health care provider is not in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities at the time of the alleged act giving rise to the cause of action."). "Professional activities," as used in the 20 Percent Rule would seem to be a general term for those activities that relate to the health care profession of the expert witness who is signing a certificate of merit or testifying at a hearing or trial. This language does not distinguish the "professional activities" of a retired or non-practicing health care provider expert from those of one

who is not retired or non-practicing and does not qualify "professional activities" so that they must relate to patient care and treatment.

The December 2004 Special Session amendments to the Act addressed the issues of what kind and how much experience an expert witness must have to be qualified to sign a certificate of merit or to testify "in relation to a proceeding before a panel or court concerning a defendant's compliance with or departure from standards of care." CJ § 3-2A-02(c)(2)(ii). As relevant to our interpretation of the phrase "professional activities" in the 20 Percent Rule, the amendments require a certifying or testifying expert witness to

> *have had* clinical experience, provided consultation relating to clinical practice, or taught medicine in the defendant's specialty or a related field of health care, or in the field of heath care in which the defendant provided care or treatment to the plaintiff, *within 5 years of the date of the alleged act or omission giving rise to the cause of action . . . .*"

CJ § 3-2A-02(c)(2)(ii)1.A. (emphasis added).

A retired or non-practicing expert witness, *i.e.*, one without an existing clinical, teaching-based, or consulting practice, remains qualified to certify or testify about a negligent act alleged to have been committed or omitted not more than five years before he (or she) retired or ceased practicing. The 2004 Special Session amendments thus contemplated that some expert witnesses will be qualified to certify or testify based upon their experience in their field even though they no longer are in active practice in that field. As drafted and enacted, those amendments did not include language drawing a distinction between the "professional activities" of an actively practicing health care provider expert witness and the "professional activities" of a retired or non-practicing health care provider expert witness. Accordingly, this further confirms the legislature's intention that the

phrase "professional activities" should have the same meaning with reference to a qualified *practicing* expert witness as it has with reference to a qualified *retired/non-practicing* expert witness.

The trial court's ruling excluding Dr. Debrun from testifying under the 20 Percent Rule was premised upon a contrary principle: that an expert witness health care provider who is not in active practice does not engage in "professional activities" -- *i.e.*, that to engage in any professional activity in a health care field, an expert witness at least must be practicing in that field. Because Dr. Debrun had been in active practice within five years of the time of the allegedly negligent act or omission (December 2002), he was qualified, at least temporally, to testify as an expert witness for the Waldts. It did not matter that his "professional activities" did not include active treatment of patients.

The dictionary definition of "professional" is "of, relating to, or characteristic of a profession." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 991 (11th ed. 2003). The five areas of activities Dr. Debrun described in his testimony -- reading and peer editing of medical journals, consulting with colleagues about their ongoing cases, observing colleagues performing procedures, and attending medical conferences -- all were related to interventional radiology, his profession, and as we have explained were not activities directly involved in testimony in personal injury cases, as that phrase was interpreted in *Witte*. Also as we have explained, those activities did not become ones directly involving testimony in personal injury cases merely because Dr. Debrun was retired; such a construction would run contrary to the legislature's intention to allow certain retired or non-practicing medical professionals to testify in malpractice cases. (If that were the case, a retired or non-practicing health care provider always would be devoting more than 20 percent of his or her "professional activities" directly to testifying in personal injury cases.)

The evidence adduced before the court on the appellees' motion *in limine* showed that Dr. Debrun devoted no more than 50 hours per year to professional activities related to testifying in personal injury cases, and that he devoted 559 hours per year to other professional activities. Assuming that the court credited those first level facts, and we see nothing to suggest that it did not, then a legally correct application of the 20 Percent Rule should have led the court to conclude that Dr. Debrun was not disqualified from giving standard of care expert testimony.

B.

Did the Trial Court Err in its Pre-Trial Ruling Excluding Dr. Debrun's Standard of Care Opinion as Improper Evidence of "Negligence Per Se"?

In a civil case, a judgment will be reversed upon a finding of error by the trial court only if the error was prejudicial. *Flores v. Bell*, 398 Md. 27, 33 (2007); *Crane v. Dunn*, 382 Md. 83, 92 (2004). Given our decision on the 20 Percent Rule issue, this next issue now takes on importance in the context of prejudice. Before the trial court generally precluded Dr. Debrun's standard of care testimony under the 20 Percent Rule, it had granted a motion *in limine* precluding Dr. Debrun from testifying that a puncture of an artery during a coiling procedure always is a breach of the standard of care by the treating interventional radiologist. The court made plain that it was "exclud[ing] Dr. Debrun's opinion that if you perforate an artery it's *per se* negligence or *per se* in violation of the standard of care. That's what's excluded."[5] The Waldts contend this ruling was legally incorrect and

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[5]The trial court clearly stated its ruling several times:

> I'm excluding Dr. Debrun's opinion that if you perforate an artery its per se negligence or per se in violation of the standard of care. That's what [sic] excluded . . . . The Motion to Exclude Dr. Debrun's opinion that if an artery is punctured during this process, it's per se negligence or a violation of the standard of care.

therefore, the court's error in precluding Dr. Debrun from testifying under the 20 Percent Rule was prejudicial (*i.e.*, but for the error, Dr. Debrun would have been able to give admissible standard of care testimony to support the ordinary negligence claim).

Dr. Zoarski and UMMS respond that the trial court properly precluded Dr. Debrun from giving a "negligence *per se*" opinion. Therefore, even if the court's ruling on the 20 Percent Rule

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* * * *

> . . . Dr. Debrun will not be allowed to testify to the following, that a puncture of [sic] tear in the artery during this procedure or whatever it is, is per se negligent or per se a violation of the standard of care?

* * * *

> . . . Debrun will not be allowed to testify or give the opinion that a puncture of the artery during this procedure is per se negligent or a per se violation of the standard of care. Per se means that no matter what else happens in the world, if the puncture occurs, that's negligence.

As the court made its ruling, counsel for the Waldts proceeded to ask for clarification, and to argue about the ruling. That exchange ended as follows:

> [COUNSEL FOR THE WALDTS]: I believe I do [understand the ruling], Your Honor, and I believe that what you've said is that he can't testify, that it's per se negligence, but you have not precluded him from offering an opinion that it's his opinion in this case, in this particular case that Dr. Zoarski violated the standard of care. That's my understanding of the Court's ruling and that [sic] what I was trying to clarify.
>
> THE COURT: I thought I made it very clear and I'll try one final time. Dr. Debrun will not be allowed to testify that regardless of whatever else in the world happens, because there's a puncture, it equals negligence or equals a violation of the standard of care. . . .

issue was in error (which we have held it was), the error was not prejudicial, because Dr. Debrun's standard of care opinion still would not have been admissible in evidence, and the Waldts could not prove the standard of care element of their ordinary malpractice claim without expert opinion testimony. (Dr. Debrun was the only expert witness the Waldts had identified on that topic.)

The basis for the appellees' "negligence *per se*" motion *in limine* was the following deposition testimony of Dr. Debrun:

> Q: Is every complication that results in a rupture of a vessel a breach in the standard of care?
> . . .
> A. If there is no pathology on this vessel, if you are treating something else and it is a complication, what type of complication the patient has, clinical complication, it is a breach of standard of care. . . . It is below the standard of care to perforate a vessel when you are working with a guide wire into the branches of the brain. The vessel, there is no reason to perforate the vessel. If you perforate the vessel, if it happens to anyone, it is a breach of the standard of care, of course. It is not perforating the aneurysm. You can perforate the aneurysm with a wire with a coil because the aneurysm is a known fragile structure with a weak wall. . . . But outside the aneurysm, when you are advancing the guide wire into the intracerebral circulation, it is a breach of standard of care if you perforate a vessel during any of these maneuvers.
>
> Q. Has it ever happened to you?
>
> A. Yes
>
> Q. Did you breach the standard of care when it happened to you?
>
> A. Yes
>
> Q. How many times did you breach the standard of care?
>
> A. [Once]
> . . .
> Q. When that happened to you, were you acting carefully?
>
> A. I thought I was.

> Q. How is it, Doctor, that you could have perforated the vessel if you were acting carefully?
>
> A. Because things happen even if you are careful. An interventionalist is always careful with whatever he does.
>
> Q. Even if you are as careful as you can be, you can still perforate the vessel like you did?
>
> A. It could happen, but you have to realize your mistake and tell it.

Dr. Debrun went on to distinguish between the standard of care relative to perforating an *aneurysm* and the standard of care relative to perforating an *artery beyond the aneurysm*:

> And when [a doctor perforates the aneurysm itself causing it to rupture], it is a percentage associated with the procedure, with the disease. Even if you are very careful and very well experienced, this will occur to you one day or the other. It can happen to me. But in this scenario, I don't blame myself. I give you the tape . . . . [My analysis for the standard of care in perforating the artery away from the aneurysm] is different. You have, on one side, you have a normal artery with a normal wall with no pathology. On the other side, you have an aneurysm with a weak wall there is pathology. So these are not the same.

Dr. Debrun further testified that, when he was in practice, he would not inform his patients about to undergo coiling procedures of the risk of perforating the artery away from the aneurysm, because that risk is not a risk of the procedure itself:

> Q. Can [complications] happen in the absence of negligence?
>
> A. . . . I consider one hundred percent if I perforate a vessel which is not the artery where the aneurysm is which means that I have done a mistake by manipulating my wire and that I have perforated an artery. There is no reason to expect that I will perforate this vessel which is far away from the aneurysm, so I don't even mention this possibility to my patient, but, yes, I tell the patient there is a risk of rupture of the aneurysm and it is three or four percent risk.
>
> Q. Is it below the standard of care if [perforating an artery away from the aneurysm with a guide wire] happens to a reasonable endovascular surgeon?
> . . .

> A. [M]any endovascular surgeons perforate the vessel with a wire which is not near the aneurysm, away from the aneurysm, doing manipulation with the wire, it's below the standard of care for me. A reasonably well trained endovascular interventionalist cannot accept to perforate an artery while he is manipulating a wire away from an aneurysm. It's below standard of care.

The Waldts argue that, contrary to the court's ruling, Dr. Debrun had not opined, in deposition, that *any* artery perforation during a coiling procedure is *per se* negligence; rather, he had opined that any artery perforation distant from the aneurysm that occurs while the doctor is using a guidewire is, necessarily, a departure from the standard of care. As Dr. Debrun stated, "[a] reasonably well trained endovascular interventionalist cannot accept to perforate an artery while he is manipulating a wire away from an aneurysm. It's below standard of care."

The appellees maintain that the court's ruling correctly precluded Dr. Debrun from giving standard of care testimony that contradicts Maryland law. They characterize Dr. Debrun's opinion as expressed in his deposition as setting a "*per se* breach of the standard of care" standard for any perforation of an artery during a coiling procedure and assert that that opinion conflicts with established Maryland law that requires, in an ordinary negligence case, proof that a health care provider acted carelessly. Specifically, under Maryland law of medical malpractice, an unsuccessful result of a procedure is not, in and of itself, evidence of negligence. *Lane v. Calvert*, 215 Md. 457, 462-63 (1958). Debrun's proffered testimony would have contradicted that principle, thereby excusing the Waldts from having to prove that Dr. Zoarski acted carelessly, without the requisite skill, to prevail on their ordinary medical negligence claim.

The appellees rely upon *City of Frederick v. Shankle*, 367 Md. 5, 15-16 (2001), and *Franch v. Ankney*, 341 Md. 350, 363-65 (1996), for the proposition that "trial judges may strike expert opinions on the basis that such testimony 'was predicated upon a faulty interpretation of Maryland

law.'" (Quoting *Ankney*, *supra,* 341 Md. at 363.) In *Shankle*, a workers' compensation case, the Court of Appeals affirmed a trial court's decision to preclude the employer/defendant from putting on expert witness testimony that "stress from police work is never a factor in causing heart disease," because Maryland statutory law contains a presumption to the contrary, *i.e.*, that "being a policeman or fireman contributes to the development of coronary artery disease." 367 Md. at 8, 10 (quotation omitted). The Court explained that an expert witness "is not permitted . . . to deny or contradict the presumption altogether, simply because the expert does not agree with the basis for it." *Id*. at 15. Similarly, in *Ankney*, a legal malpractice case, the Court of Appeals affirmed a trial court's ruling striking the opinion testimony of two expert witness attorneys on the ground that their opinions about certain aspects of Maryland insurance law rested on a "faulty interpretation of Maryland law." 341 Md. at 363.

"It is the general rule that the admissibility of expert testimony is within the sound discretion of the trial judge and will not be disturbed on appeal unless clearly erroneous." *Wilson v. State,* 370 Md. 191, 200 (2002). The admission or exclusion of such testimony seldom constitutes ground for reversal. *Deese v. State*, 367 Md. 293, 302 (2001); *Buxton v. Buxton*, 363 Md. 634, 651 (2001). "Despite the broad discretion vested in a trial court, however, the 'decision to admit or reject [expert testimony] is reviewable on appeal and may be reversed if it is founded on an error of law or if the trial court clearly abused its discretion.'" *Bryant v. State*, 163 Md. App. 451, 473 (2005) (quoting *White v. State*, 142 Md. App. 535, 544 (2002)), *aff'd*, 393 Md. 196 (2006). As *Shankle* and *Ankney*

make clear, it would be an error of law, and therefore an abuse of discretion, for a trial court to permit an expert witness to give testimony that contradicts Maryland law.[6]

One element of an ordinary medical negligence claim is that the defendant health care provider " 'd[id] not use that degree of care and skill which a reasonably competent health care provider, engaged in a similar practice and acting in similar circumstances, would use.' " *Dingle v. Belin*, 358 Md. 354, 363 (2000) (quoting Maryland Civil Jury Pattern Instructions, 27:1); *see also* CJ § 3-2A-02(c)(i) of the Courts and Judicial Proceedings Article (plaintiff must prove "that the care given by the health care provider is not in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities at the time of the alleged act giving rise to the cause of action"). In most ordinary medical malpractice cases, the applicable standard of care, and whether it was breached, are matters outside the knowledge of lay people and generally call for expert testimony. *Rodriguez v. Clarke*, 400 Md. 39, 71 (2007); *Meda v. Brown*, 318 Md. 418, 428 (1990). The parties here do not dispute that expert witness testimony was needed to prove that Dr. Zoarski breached the standard of care in his performance of the coiling procedure on Mrs. Waldt.

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[6]The standard for admissibility of expert testimony is set forth in Rule 5-702. "Expert testimony is admissible if the court determines that the testimony will assist the trier of fact to understand the evidence or determine a fact in issue." *Buxton, supra*, 363 Md. at 650. In making that determination, the court evaluates "(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." *Id.* Rule 5-403 works in conjunction with Rule 5-702 and permits the exclusion of even relevant evidence if its probative value is substantially outweighed by the danger of unfair prejudice, confusion, or misleading the jury.

In *Kennelly v. Burgess*, 337 Md. 562 (1995), a medical malpractice case, the Court of Appeals held that a "mere happening" jury instruction, as given, was erroneous because it misstated Maryland law. The instruction had informed the jury that "an unsuccessful result following medical treatment is not evidence of negligence." *Id.* at 565 (emphasis omitted). The Court explained that its holding in *Lane v. Calvert*, *supra*, 215 Md. at 462-63, that "an unsuccessful result follow[ing] medical treatment is not of itself evidence of negligence," does not mean that an unsuccessful result following treatment cannot be evidence an expert witness can consider as a factor in developing an opinion as to whether there was a breach of the standard of care. "[A]n expert, as distinguished from a mere lay witness, may, in appropriate circumstances, rely on an unsuccessful result in concluding that a physician was negligent." *Kennelly, supra,* 337 Md. at 572 (citing *Meda, supra*, 318 Md. at 428). Thus, a proper statement of Maryland law is that "although an unsuccessful result does not create a presumption of negligence, it still may be considered as some evidence of negligence and [] an expert witness may consider it in formulating his or her opinion that there was negligence."[7] *Kennelly, supra*, 337 Md. at 575.

Returning to the case at bar, it is important at the outset to take into account that the trial court's *in limine* ruling did not track Dr. Debrun's proffered testimony. The ruling precluded Dr. Debrun from opining that any perforation of a vessel in the course of a coiling procedure is a breach of the standard of care. That was not Dr. Debrun's proffered testimony. Rather, he testified that it

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[7]The Court in *Kennelly* cautioned against the use of "mere happening" instructions, observing that "even in a professional malpractice action, [the instruction] elucidates the obvious and is generally redundant." 337 Md. at 576-77 (citation omitted). It also observed that the Maryland Civil Pattern Jury Instructions do not contain a "mere happening" instruction, "a further recognition of the undesirability of such an instruction." *Id*. at 577.

is a deviation from the standard of care for a doctor, in the course of a coiling procedure, to manipulate the guide wire so as to perforate a branch of an artery away from the aneurysm site. Dr. Debrun was not prepared to testify, and therefore would not have been offering an opinion, that any perforation of a vessel in the course of a coiling procedure is a breach of the standard of care. Indeed, he made plain that a doctor can perforate the vessel at the aneurysm site without departing from the standard of care. Whether, at trial, the court would have sustained an objection to the standard of care opinion Dr. Debrun actually gave in his deposition is impossible to know. What is knowable is that at trial, Dr. Debrun could have opined as he did in his deposition without violating the court's *in limine* ruling. For that reason alone, the court's error in precluding Dr. Debrun from testifying at all, based upon the 20 Percent Rule, was prejudicial.

In any event, Dr. Debrun's proffered standard of care testimony was not contrary to Maryland law so as to be subject to exclusion under the holdings of *Shankle* and *Ankney*. Dr. Debrun was not merely going to infer from the ultimate bad result in this case -- bleeding into the brain/brain injury -- that Dr. Zoarski necessarily breached the standard of care. His testimony, which was based upon a review of the records and studies made contemporaneously with the procedure, was going to be that, in the course of trying to free the snared coil, Dr. Zoarski manipulated the guide wire beyond the aneurysm site, into branches of the artery that were not nearby, and that his doing so was a violation of the standard of care; and in this case, that violation produced a perforation injury.

It did not matter that Dr. Debrun could not conjure up an example of a doctor doing such a thing and not breaching the standard of care. The testimony he was prepared to give as relevant to this case was that, on the facts as he interpreted them to be from the records and studies, Dr. Zoarski deviated from the standard of care by manipulating the guide wire into distant vessel branches, and

thereby puncturing a vessel and causing bleeding into the brain. This opinion does not rest upon a foundation that is contrary to Maryland law, specifically, the law that a health care provider will not be found liable for ordinary negligence in the absence of a breach of the standard of care.

Dr. Debrun's expert standard of care opinion, as proffered, should have been admitted into evidence at trial. Therefore, the court committed prejudicial error by ruling, based on the 20 Percent Rule, that Dr. Debrun could not be called to opine about the standard of care at all.

II.

Informed Consent Claim

As we have noted, in addition to their ordinary medical negligence claim, the Waldts advanced an informed consent claim. Before addressing their appellate contention about informed consent, we shall summarize the law in that area of medical malpractice litigation.

Maryland first recognized the informed consent type of medical malpractice claim in *Sard v. Hardy*, 281 Md. 432 (1977). "[T]he doctrine of informed consent imposes on a physician, before he subjects his patient to medical treatment, the duty to explain the procedure to the patient and to warn him of any material risks or dangers inherent in or collateral to the therapy, so as to enable the patient to make an intelligent and informed choice about whether or not to undergo such treatment." *Id*. at 439. The informed consent disclosure duty "is said to require a physician to reveal to his patient the nature of the ailment, the nature of the proposed treatment, the probability of success of the contemplated therapy and its alternatives, and the risk of unfortunate consequences associated with such treatment." *Id*. at 440. "[F]undamental fairness requires that the patient be allowed to know what risks a proposed therapy entails, alternatives thereto, and the relative probabilities of success." *Id*. at 443.

The Court in *Sard* held that "the scope of the physician's duty to inform is to be measured by the materiality of the information to the decision of the patient. 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. For that reason, the physician's duty to disclose, and the scope of that duty, are not subject to a professional standard of care; accordingly, in an informed consent claim, it is not necessary to introduce expert witness testimony on the issues of standard of care and breach of the standard of care. *Id.* at 447.

The *Sard* Court cautioned, however, that its holding was not to be understood to mean that "expert testimony can be dispensed with entirely in cases of informed consent." *Id.* at 447-48. "Such expert testimony would be required to establish the nature of the risks inherent in a particular treatment, the probabilities of therapeutic success, the frequency of 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. For a plaintiff in an informed consent case to prove proximate causation, he must show that "a reasonable person in the patient's position would have withheld consent to the surgery or therapy had all material risks been disclosed." *Id.* at 450.

> If disclosure of all material risks would not have changed the decision of a reasonable person in the position of the patient, there is no causal connection between nondisclosure and his damage. If, however, disclosure of all material risks would have caused a reasonable person in the position of the patient to refuse the surgery or therapy, a causal connection is shown. Under this rule, the patient's hindsight testimony as to what he would have hypothetically done, though relevant, is not determinative of the issue.

Id.

In the case at bar, the trial began and the Waldts called Dr. Debrun to testify as an expert about the material risks of the procedure Mrs. Waldt underwent. Counsel for the Waldts examined Dr. Debrun on *voir dire*, followed by counsel for the appellees. The court ruled that Dr. Debrun was not qualified to testify about the material risks of the procedure Mrs. Waldt underwent because he did not have a sufficient basis on which to give such testimony. The Waldts moved for reconsideration, which the court denied, explaining:

> The expert's training or experience need not be formal [for him to be qualified to testify as an expert witness]. There is no issue of that here.
>
> The witness has formal training and informal, that is, from his readings of journals and things of that nature.
>
> It must be that the witness' knowledge of the subject is significantly better than the average layperson so that the expert testimony would be of appreciable help to the jury.
>
> Any physician's testimony, I guess in this particular matter, would be helpful to the jury. The Court agrees the witness may qualify as an expert without actual experience.
>
> The Court agrees that, if the witness possessed sufficient special knowledge obtained from study or observation, the Court agrees with all of that.
>
> It is the last part. The trial judge exercises his or her discretion in determining whether the particular witness is sufficiently qualified that his or her opinion would be of assistance.
>
> The specific and appropriate grounds and basis has not been met for that to occur and that is the Court's ruling.

On appeal, the Waldts contend that the court erred in ruling that Dr. Debrun was not qualified to testify as an expert witness about the material risks of the procedure Mrs. Waldt underwent. The appellees respond that this issue is not preserved for review, as an adequate proffer of Dr. Debrun's testimony was not made, and that in any event the issue lacks merit because the court's decision was a matter of discretion and the preclusive ruling was not an abuse of that discretion.

Rule 5-103, entitled "**Rulings on evidence**" states, in relevant part:

> (a) **Effect of erroneous ruling**. Error may not be predicated upon a ruling that admits or excludes evidence unless the party is prejudiced by the ruling, and
> (1) Objection. In case the ruling is one admitting evidence, a timely objection or motion to strike appears of record, stating the specific ground of objection, if the specific ground was requested by the court or required by rule; or
> (2) *Offer of proof. In case the ruling is one excluding evidence, the substance of the evidence was made known to the court by offer on the record or was apparent from the context within which the evidence was offered. . . .*

(Emphasis added.) Here, because the ruling of the court was "one excluding evidence," to claim error on appeal, it was incumbent upon the Waldts to proffer the substance of the excluded evidence on the record. *See Merzbacher v. State,* 346 Md. 391, 416 (1997); *Muhammad v. State*, 177 Md. App. 188, 281 (2007), *cert. denied*, 403 Md. 614 (2008). In other words, the Waldts had to lay out on the record the testimony they would have elicited from Dr. Debrun had the court not excluded his testimony.

The purpose of the requirement, in Rule 5-103(a)(2), of a proffer on the record of evidence ruled not admissible by the trial court is to permit adequate review by the appellate court. Without specific information in the record about the evidence the trial court has ruled will not be admitted, an appellate court cannot determine whether the court erred or abused its discretion in ruling the evidence inadmissible and cannot determine whether any error or abuse of discretion was prejudicial to the offering party. *See Merzbacher*, *supra*, 346 Md. at 416 (objection to excluded evidence is not preserved when the reviewing court cannot discern the contents of what was excluded from the trial record).

We agree with the appellees that there was not an adequate proffer made of Dr. Debrun's testimony to preserve for review the issue of the propriety of the trial court's ruling. In their reply brief, in response to the appellees' preservation argument, the Waldts do not assert that a proffer of Dr. Debrun's expert testimony was made in the course of or soon after the court's ruling on the

defense motion to preclude Dr. Debrun from testifying as an informed consent expert witness. In fact, there was no proffer made during the argument on that motion or thereafter about the substance of Dr. Debrun's testimony about the material risks of the procedure that Mrs. Waldt actually underwent.

The Waldts maintain, however, that the substance of Dr. Debrun's testimony in that regard was made known or was apparent to the court from the following prior statements made by their counsel to the court.

> Yes, your Honor, very simply, this is an informed consent case. The point Dr. Debrun is going to testify to which is clearly set forth in his deposition is that Dr. Zoarski was given certain information by the manufacturer about what this device was for and not for. He represented to University of Maryland what he was going to use it for and not for. *And he did not tell Mrs. Waldt something that was material. He did not tell her that this device is, according to the manufacturer, not for use on aneurysms that are not amenable to clipping. And that's - it is an informed consent issue.*
>
> * * * *
>
> Now, after Dr. Debrun testified [in his deposition] that in his opinion to a reasonable degree of probability Mrs. Waldt should have been informed by Dr. Zoarski prior to the procedure that the stent was not approved for people like here [sic] . . . . And so Plaintiff's [sic] have properly set forth in this case and will properly set forth during trial, assuming you allow us to do so, the informed consent count, the testimony of Dr. Debrun that there were material risks that weren't disclosed for her, and that the nature of the procedure was not disclosed to her.
>
> * * * *
>
> [COUNSEL]: What Dr. Debrun 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.

> [COUNSEL]:His education, training, his experience, and the material that he reviewed in this case, including the 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 Dr. Debrun has garden variety infomed consent opinions . . . .
>
> * * * *
>
> THE COURT: Tell me what the plaintiffs plan to have revealed by Dr. Debrun with regards to the FDA.
>
> [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 amenable to clipping . . . .

(Emphasis added.)

To make out a *prima facie* case of informed consent negligence, the Waldts had to adduce expert testimony specifying the nature of the risks inherent in the procedure Mrs. Waldt actually underwent, *i.e.*, 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 Mrs. Waldt and which were not. *See Sard, supra*, 281 Md. at 448. Only with expert opinion testimony on those topics would a jury have the information it would need to determine whether the risk that materialized during Mrs. Waldt's neuroform stent coiling was material and whether a reasonable person in her situation would have consented to that procedure had that material risk been disclosed. *Compare Landon v. Zorn*, 389 Md.

206, 221 (2005) (plaintiff precluded from recovery on informed consent claim when plaintiff failed to elicit expert testimony describing "the risks associated with not submitting to a CAT scan") *with Mahler v. Johns Hopkins Hosp., Inc.*, 170 Md. App. 293, 320-21 (plaintiff's claim could proceed to jury because he put forth expert testimony that permanent numbness was a material risk of a particular surgical procedure that he had undergone), *cert. denied*, 396 Md. 13 (2006).

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

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

the Waldts' informed consent claim. Were they seeking to prove that the risk of bleeding in the brain was inherent in the neuroform stent coiling procedure and occurred with greater frequency in that coiling procedure as opposed to the cardiac stent coiling procedure, so that there was a more significant risk of bleeding in the brain with the neuroform stent coiling than with the cardiac stent coiling? Or were they seeking to prove that the risk of bleeding in the brain was inherent in the neuroform stent coiling procedure but not in the clipping procedure, or, if inherent in the clipping procedure, of a lower frequency than would be material to a reasonable person? As we can ascertain none of this from the proffer, we do not have before us the information we need to address whether exclusion of Dr. Debrun's testimony on the informed consent claim was prejudicial error. Accordingly, the issue is not properly before this Court for review.

We note, however, that to the extent the record reveals the basis for the court's exclusion ruling -- that Dr. Debrun did not have the necessary foundation to offer whatever informed consent opinions he was going to give -- the ruling was not error or an abuse of discretion.

The Waldts called Dr. Debrun as their first witness at trial. He testified about his background and experience in neuroradiology, as discussed above. He then stated that he had performed over 30 coiling procedures on paraopthalmic aneurysms similar to Mrs. Waldt's. Of the 30 coiling procedures Dr. Debrun had performed, 10 to 15 were on "small" aneurysms, which, like Mrs. Waldt's, were less than 10 millimeters at the "neck." In performing the coiling procedures for these "small" aneurysms, Dr. Debrun had used a balloon mechanism, not a stent, to protect the artery while inserting the coils. Also, of the 30 coiling procedures he performed, "four or five" were for "wide neck" aneurysms, like Mrs. Waldt's. On "two or three" occasions, in performing the coiling procedure on one of those aneurysms, he used a cardiac stent instead of the balloon mechanism. As noted above, the neuroform

stent was not approved for use in the United States until December of 2002, 18 months after Dr. Debrun stopped seeing patients in July of 2001.

On *voir dire* cross examination, counsel for the appellees questioned Dr. Debrun about his knowledge of the Neuroform stent. First, counsel asked Dr. Debrun about the balloon mechanism that he had used in place of a stent. The following colloquy ensued:

> Q. Neuroform stent is entirely different from [using the balloon] isn't it, yes or no?
>
> A. Yes, it is different from that.
>
> Q. All right . And a different set of risks that with the balloon, yes or no?
> . . .
> A. They are different.

Counsel for the Waldts questioned Dr. Debrun on *voir dire* re-direct:

> Q. Is the risk of injury different or the same [between using a balloon or the Neuroform stent]?
>
> A. For example, there is a 20 percent risk of thrombosis, of clotting formation inside the stent, either the earlier stent or the Neuroform stent, this will repeat with the balloon. So it is an example where the risks are totally different.

The Waldts then asked the court to accept Dr. Debrun as an expert witness qualified to testify as to the issue of informed consent in the Waldts' dealings with Dr. Zoarski. After hearing argument from the appellees, the judge indicated that she was inclined to exclude Dr. Debrun from testifying on the informed consent issue. The judge reasoned:

> [Dr. Debrun] actually said the risks are totally different. He has not given the Court any reason to indicate he is qualified to testify with regard to what, if any information should be given to patients who are about to have this procedure using this type of – using this type of procedure. He has not given the Court any basis to indicate he is qualified to do that.

The Waldts asked to be given another chance to elicit testimony from Dr. Debrun about the basis of his knowledge on the issue of informed consent for a Neuroform stent procedure. The Court granted the Waldts' request:

> Q. And are you [Dr. Debrun] familiar with the – not only the [Neuroform] procedure itself but the nature of risks and the consequences of that procedure?
> . . .
> A. Yes.
>
> Q. Have you reviewed the Boston Scientific material on this Neuroform device?
>
> A. Yes.
>
> Q. The Neuroform stent system?
>
> A. Yes.
>
> Q. And are you prepared to testify today regarding the nature of that procedure, that is the Neuroform stent system and the nature of the risks and consequences of that procedure? . . .
>
> A. Yes.

The Waldts again offered Dr. Debrun as an expert witness on informed consent issues and the appellees again objected, stating, through counsel:

> I don't think [Dr. Debrun] has met the threshold even with the additional testimony. Number one, he had a conclusory answer from the first. We are familiar with the risks. He didn't state the basis. There was nothing for you to evaluate there. And second, the only other basis he established was, he didn't read the book.

The following discussion ensued between the trial judge and counsel for the Waldts:

> THE COURT: [Dr. Debrun] has yet to satisfy how he knows. He has yet to say the basis of his knowledge. He has not given any of that. . . . He has not done it, you think he has?
>
> [COUNSEL FOR THE WALDTS]: I do, and the reason –
>
> THE COURT: What's the basis of his knowledge?

> [COUNSEL FOR THE WALDTS]: Practicing for 45 years treating with the aneurysms with coils and balloons, using these types of systems. This is – he knows what the risks are. He knows how the procedure is done, he knows what the risks are, he doesn't have to have to use the Neuroform stent.
>
> THE COURT: I didn't say he had to do that . . . . Under Maryland law. . . he is not qualified as an expert to testify with regards to informed consent in reference to this procedure or this device. The foundation has not been properly laid. It has not been established. So the defense objection at this point would be lodged for the witness being declared an expert [on informed consent.]

The Waldts argue that Dr. Debrun's experience in coiling procedures using balloons and cardiac stents combined with his review of the manufacturer's materials for the neuroform stent were adequate factual bases for him to express an opinion about the informed consent issues in this case, under Rule 5-702. They further argue that the trial judge erred by ruling, in effect, that because Dr. Debrun had never used the neuroform stent system to repair an aneurysm, he did not have a sufficient factual basis for an opinion about the informed consent issues in the case.

The appellees respond that "Dr. Debrun never explained how the risks were different or how he knew of the different risks." Further,

> at no time did Dr. Debrun testify that he read any literature on the subject of the Neuroform stent. . . . [and] he did not reference any of the materials set forth by the Waldts as the factual basis of his informed consent testimony. . . . There was no testimony, or proffer, as to what in the package insert materials would support his opinions.

They characterize Dr. Debrun's testimony as a "because I said so" opinion and therefore within the judge's discretion to exclude as in *Porter Hayden Co. v. Wyche*, 128 Md. App. 382, 391 (1999), *cert denied*, 357 Md. 234 (2000), and *Wood v. Toyota Motor Corp.*, 134 Md. App. 512, 523, *cert. denied*, 362 Md. 189 (2000). They point out that the trial judge's ruling was not based solely on the fact that Dr. Debrun had never used the neuroform stent system himself.

As already explained, the admissibility of expert witness opinion testimony, under Rule 5-702, turns on whether it "will assist the trier of fact to understand the evidence or to determine a fact in issue," which likewise turns on whether the witness is qualified, the expert testimony is appropriate on the particular subject, and there is a sufficient factual basis to support the expert testimony. As the trial court made clear in its ruling, it was not persuaded that Dr. Debrun had an adequate factual basis to give an expert opinion on the informed consent medical issues related to the use of the neuroform stent coiling system. The evidence before the court showed that Dr. Debrun's only knowledge of that system was based upon reading the manufacturer's literature. He had never used the device himself nor had he observed its use by others. Moreover, most of the coiling procedures he had performed on aneurysms similar to Mrs. Waldt's involved the use of a balloon mechanism instead of a stent, and the risks of the coiling with a stent and coiling with a balloon differ, according to Dr. Debrun's own testimony.

The Waldts are correct that, under *Radman v. Harold*, 279 Md. 167, 172-73 (1977), an expert witness need not have actually performed a particular procedure to be qualified to express an opinion about it. They are incorrect, however, that the trial judge based her ruling solely upon the fact that Dr. Debrun had no hands-on experience with the neuroform stent system. Indeed, the judge acknowledged the holding in *Radman* and explained that her ruling was not based upon Dr. Debrun's lack of experience with the neuroform stent system alone, although this was certainly a factor in the judge's analysis. Dr. Debrun's significant experience using a balloon technique to treat aneurysms was of little consequence to his expertise in performing a stent-based procedure since, by his own admission, the risks of the balloon procedure were "totally different" from those of using a stent. In using a cardiac stent, Dr. Debrun had treated only two to three "wide neck" aneurysms similar to that

of Mrs. Waldt, and even this experience had limited relevance to the factual foundation for his opinions, as the Waldts' theory of liability rested entirely on risks that were unique to the neuroform stent, not to a cardiac stent. (*I.e.*, Mrs. Waldt was required to prove that there was a risk specific to the neuroform stent that, if disclosed, would have caused a reasonable person in her position to opt for use of the cardiac stent or surgical clipping.) Thus, the trial court acted reasonably in thinking that Dr. Debrun's experience using the cardiac stent did not provide an adequate factual basis for opinion testimony about the material risks unique to the neuroform stent.

Nor did Dr. Debrun disclose any other factual or scientific foundation for his opinion on the material risks of using a neuroform stent. He cited to no scientific literature or studies that he had read in forming an opinion regarding the material risks associated with the neuroform stent. He stated only that he had reviewed "Boston Scientific material" on the device. There was no proffered description of the "Boston Scientific material" (at the time Dr. Debrun was offered as an expert) nor any description of what was within the "material" that would buttress his opinion about material risks of the neuroform stent procedure that were not disclosed to Mrs. Waldt.

In *Beatty v. Trailmaster Products, Inc.*, 330 Md. 726 (1993), the Court of Appeals affirmed the entry of summary judgment for the defendant when the plaintiff's only proffered expert disclosed neither evidence of a "developing [scientific] consensus nor sound data to buttress his opinion" that a device installed on the plaintiff's SUV was unsafe. *Id.* at 740. The Court emphasized that "because I say so" expert opinions are inadmissible to prove a defendant's liability: "Our cases hold that 'an expert's opinion is of no greater probative value than the soundness of his reasons given therefor will warrant.'" *Id.* at 741 (quoting *Surkovich v. Doub*, 258 Md. 263, 272 (1970)). *See also Wood, supra*, 134 Md. App. at 522-24 (affirming trial court's exclusion of an expert witness who was going to

testify that the size and location of vent holes in an airbag had caused the plaintiff's injuries during a crash; the expert's knowledge of the particular airbag in the plaintiff's car was limited, and the expert did not buttress his opinion with any evidence beyond curt and general observations on airbag safety issues).

Beatty and its progeny support the trial court's exercise of discretion to exclude Dr. Debrun from testifying as an expert on the informed consent claim. Given Dr. Debrun's limited experience with similar procedures and his failure to disclose any specific scientific or factual underpinnings for any knowledge about the material risks of the neuroform stent coiling procedure, the court did not err or abuse its discretion in excluding his testimony on this issue.

III.

After the trial court precluded Dr. Debrun from testifying about informed consent, so that he could not testify on any issue, the Waldts moved forward with their case by calling, adversely, Drs. Zoarski and Aldrich. At the close of the Waldts' case, the appellees moved for judgment on the informed consent claim on the ground that the Waldts had not adduced sufficient evidence to make out a *prima facie* informed consent negligence case. The court granted the motion, stating:

> As the law requires in deciding this motion, the Court must and shall consider all evidence and inferences in the light most favorable to the party against whom the motion is made and that would be in the light most favorable to the [Waldts].
>
> In reading these many cases over these many days, it is very clear to the Court that expert testimony is required in an informed consent case to established the nature of the risks inherent in a particular treatment, the probabilities of therapeutic success of that treatment, the frequency of occurrence of particular risks with regards to that treatment, the nature of available alternatives to that treatment, and whether or not disclosure would be detrimental to the patient.
>
> And the patient in this matter, Mrs. Waldt, is to be the objective reasonable person. That's how the Court is to view the plaintiff in this matter.
>
> Dr. Zoarski has testified in this case as the physician or interventional neuroradiologist of the plaintiff in this matter, and he was qualified as an expert in that field.

> Dr. Zoarski as an expert -- well, Dr. Aldrich testified as well, but I don't believe he was established as an expert in the field of informed consent.
>
> In any event, there has been no expert testimony with regards to the nature of the risks inherent in this particular treatment.
>
> There has been no testimony to indicate that the reasonable patient or the plaintiffs did not receive the required or -- or what was necessary to make an informed consent with regards to the material risks inherent in this treatment. There had been no expert testimony with regards to the probabilities of therapeutic success in this case.
>
> Therefore, there has been no testimony indicating that Dr. Zoarski did not provide the requisite required information to the patient with regards to the probability of therapeutic success.
>
> There has been no expert testimony given with regards to the frequence of occurrence of particular risks.
>
> Therefore, there has been no testimony to indicate or nothing for the jury to decide or the factfinder to decide or determine whether or not Dr. Zoarski's disclosure met that standard.
>
> There has been no expert testimony with regards to the nature of available alternatives to this treatment that should have been disclosed to the patient.
>
> Therefore, there is no determination for the jury to make with regards as to whether or not the information disclosed by Dr. Zoarski met that standard and that goes, as well, with nothing for the jury to decide whether or not -- no issue for the jury to decide with regards to whether or not the information disclosed by Dr. Zoarski meets the standard that any expert would have but did not disclose or testify to with regards to the nature of the risks as well as the probabilities of therapeutic success.
>
> Sard [*v. Hardy*, *supra*] is clear that such expert testimony is required in regards to informed consent. The motion presented by the defense is granted with regards to informed consent, Thus, it would also be granted with regards to Count 3, loss of consortium.

The Waldts contend the trial court committed legal error by granting the appellees' motion for judgment on the informed consent claim. They maintain that the evidence adduced in their case was legally sufficient to make the informed consent claim a jury question. The appellees argue that it was not.

On review of a motion for judgment in a civil negligence case, we ask whether on the evidence adduced, viewed in the light most favorable to the non-moving party, any reasonable trier of fact could find the elements of the tort by a preponderance of the evidence. *Lowery v. Smithsburg*

Emerging Medical Service, 173 Md. App. 662, 683 (2007); *Tate v. Bd. of Educ. of Prince George's County*, 155 Md. App. 536, 544 (2004). If there is even a slight amount of evidence that would support a finding by the trier of fact in favor of the plaintiff, the motion for judgment should be denied. *Lowery, supra*, 173 Md. App. at 683; *Tate, supra*, 155 Md. App. at 544.

We agree with the trial court that the evidence adduced by the Waldts in their case was not legally sufficient to make their informed consent claim a jury question. As we have explained in our discussion of Question II, in order to prove certain elements of an informed consent claim, expert witness testimony may be required. In particular, unless the information is within the common knowledge of laypeople, expert witness testimony is necessary to establish that there was a material risk inherent to the procedure actually performed that a reasonable person in the position of the patient would want to know and, if disclosed, would have caused that reasonable person to deny consent to the procedure. *See Landon, supra*, 389 Md. at 221; *Sard, supra*, 281 Md. at 448. In the case at bar, the average layperson would know nothing about the risks inherent in the procedure actually performed on Mrs. Waldt or other possible alternative procedures. Accordingly, expert witness testimony was needed for the Waldts to make out a *prima facie* case.

The Waldts called Drs. Zoarski and Aldrich adversely. Dr. Zoarski was accepted by the court as an expert in interventional radiology. He did not give any opinions that were favorable to the Waldts on the various informed consent medical issues, however. The Waldts did not elicit any testimony from Dr. Zoarski that the bleeding complication rate for the neuroform stent system was greater than the same complication rate for the cardiac stent procedure or the clipping procedure; nor did he testify that there were other risks inherent in the neuroform stent procedure that were not disclosed to Mrs. Waldt. In fact, Dr. Zoarski testified that the complication rate for all three

procedures -- based on his analysis of a recent European study of the neuroform stent and his prior knowledge of cardiac stents and surgical clipping -- was the same for treating Mrs. Waldt's type of aneurysm: a 1-5 percent risk of serious complications including bleeding. He further stated that, based on his experience using cardiac stents and the training he received to use the neuroform stent, the neuroform stent is an "excellent device" that provides a "good benefit" to people like Mrs. Waldt with difficult to treat aneurysms. Additionally, and contrary to the Waldts' characterization, Dr. Zoarski's testimony did not support the Waldts' theory that the neuroform device had not been intended for use on Mrs. Waldt's type of aneurysm. He testified that, although surgical clipping remained an option for Mrs. Waldt, a coiling procedure was the preferred treatment method, for reasons of safety and efficacy, and the neuroform stent "was made for that particular aneurysm like [that of] Mrs. Waldt" -- that is, an aneurysm of a sort that, historically, has been very difficult to treat with surgical clipping or using a cardiac stent.

Dr. Aldrich was never qualified as an expert for either party; he testified as a fact witness regarding his care of Mrs. Waldt. He did not testify about any risk of coiling with the neuroform stent that was not disclosed to Mrs. Waldt in making her choice of treatment. His testimony did not support the Waldts' informed consent claim.

Without expert witness opinion evidence of any quantifiable risk or alternative procedure that Mrs. Waldt was not informed about, the Waldts' informed consent claim could not be sustained. The trial court did not err in granting the appellees' motion for judgment on that claim.

IV.

In this last contention, the Waldts argue that the trial court erred both in admitting certain documentary evidence and in declining to admit certain other documentary evidence. The

documentary evidence not admitted was legally insufficient, standing alone, to satisfy the requirement that the Waldts prove the informed consent medical issues (such as existing of risk, frequency of risk, etc.) by expert testimony, nor does the record suggest that the opinions Dr. Zoarski and Dr. Aldrich gave would have been favorable to the Waldts if the documentary evidence had been admitted. Our disposition of this case has made it unnecessary to decide the evidentiary questions posed. Moreover, because the admissibility *vel non* of the documentary evidence in question may turn upon whether or not certain other evidence is admitted, this is not a circumstance in which guidance on remand is advisable.

JUDGMENT IN FAVOR OF THE APPELLEES ON INFORMED CONSENT CLAIM AFFIRMED. JUDGMENT IN FAVOR OF THE APPELLEES ON ORDINARY MEDICAL NEGLIGENCE CLAIM REVERSED. CASE REMANDED TO THE CIRCUIT COURT FOR BALTIMORE CITY FOR FURTHER PROCEEDINGS. COSTS TO BE PAID ONE-HALF BY THE APPELLANTS AND ONE-HALF BY THE APPELLEES.