HEADNOTE:

MEDICAL MALPRACTICE — STANDARD OF CARE — EXPERT WITNESS — INFORMED CONSENT — OFFER OF PROOF — An expert witness was properly prevented from testifying about the standard of care in a medical malpractice case under § 3-2A-04(b)(4) of the Courts & Judicial Proceedings Article when the expert devoted annually more than 20 percent of his professional activities to activities that directly involved testimony in personal injury claims. Activities are "professional activities" when the activity contributes to or advances the profession to which the individual belongs or involves the individual's active participation in that profession. Professional activities include time devoted to testifying and engaging in peer review of journal articles, but do not include time devoted to reading journal articles, observing procedures, discussing patients with other professionals, and attending conferences when those activities are undertaken for personal or leisurely reasons. The question of whether the expert was sufficiently qualified to testify regarding informed consent was not preserved for appellate review because the plaintiff did not make a sufficient proffer on the trial record of what the substance of the expert's testimony would have been. In addition, the trial judge did not err or abuse her discretion when she evaluated the expert's testimony and qualifications and concluded that the expert did not have a sufficient factual basis on which to render an expert opinion on informed consent.

IN THE COURT OF APPEALS OF MARYLAND

No. 130
September Term, 2008

UNIVERSITY OF MARYLAND MEDICAL SYSTEM CORPORATION, ET AL.

v.

REBECCA MARIE WALDT, ET AL.

Bell, C.J.
Harrell
Battaglia
Greene
Adkins
Eldridge, John C. (Retired, Specially Assigned)
Raker, Irma S. (Retired, Specially Assigned),

JJ.

Opinion by Greene, J.
Adkins, Eldridge, and Raker, JJ., Dissent.

Filed: November 10, 2009

This case arises from a medical malpractice claim filed by Respondents, Rebecca Marie Waldt and her husband, Roy Waldt ("Waldts"), in the Circuit Court for Baltimore City. In December of 2002, Mrs. Waldt underwent a procedure to treat an aneurysm in her brain. The procedure caused bleeding in Mrs. Waldt's brain, resulting in a stroke and extensive physical and mental impairment. The Waldts argue that Petitioners, Dr. Gregg Zoarski and the University of Maryland Medical System's ("UMMS"), care and treatment of Mrs. Waldt did not conform to the proper standard of care and the medical providers did not properly obtain Mrs. Waldt's informed consent before performing the procedure.

At trial, the Waldts called Dr. Gerard Debrun as an expert witness, offering his expert testimony as to the standard of care and on the issue of informed consent. The trial judge excluded Dr. Debrun's testimony as to the standard of care on the grounds that Dr. Debrun did not meet the minimum requirements for an expert witness as set forth by Md. Code (1974, 2006 Repl. Vol.), § 3-2A-04(b)(4) of the Courts & Judicial Proceedings Article ("the 20 Percent Rule").[1] Dr. Debrun was also prevented from giving expert testimony on the informed consent claim because the trial court determined that the witness did not have sufficient experience with the specific procedure to be qualified as an expert. At the

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[1]Md. Code (1974, 2006 Repl. Vol.), § 3-2A-04(b)(4) of the Courts & Judicial Proceedings Article states:

> A health care provider who attests in a certificate of a qualified expert or who testifies in relation to a proceeding before an arbitration panel or a court concerning compliance with or departure from standards of care may not devote annually more than 20 percent of the expert's professional activities to activities that directly involve testimony in personal injury claims.

conclusion of the Waldts' case in chief, UMMS and Dr. Zoarski moved for summary judgment on both counts. The Waldts conceded that no evidence of negligence was presented and the court granted judgment in favor of UMMS and Dr. Zoarski. After hearing arguments concerning the informed consent claim, the court ruled that, without expert testimony on the informed consent claim, there was no question for the jury, and thus granted judgment for UMMS and Dr. Zoarski.

The Waldts appealed to the Court of Special Appeals, which overturned the trial court's ruling as to the medical negligence claim and upheld the trial court on the informed consent claim. *Waldt v. UMMS*, 181 Md. App. 217, 254, 267-68, 956 A.2d 223, 244-45, 252 (2008). The intermediate appellate court held that Dr. Debrun did not dedicate more than 20 percent of his professional activities to activities directly involving testimony, and he was therefore qualified to testify as to the standard of care pursuant to the 20 Percent Rule. The Court of Special Appeals stated: "[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." *Waldt*, 181 Md. App. at 245, 956 A.2d at 239. We granted *certiorari* to determine whether the Court of Special Appeals properly interpreted the 20 Percent Rule and whether the court properly affirmed the trial court's ruling to exclude Dr. Debrun as an expert on informed consent. We reverse the judgment of the Court of Special Appeals in regard to its interpretation of the 20 Percent Rule and affirm with respect to the informed consent determination.

FACTS AND PROCEDURE

We adopt, in part, the facts as set forth by the Court of Special Appeals in *Waldt*:

> 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.
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> In their complaint, the Waldts alleged two types of negligence: 1) ordinary 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.
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> * * * *
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> In the course of discovery, the Waldts identified Dr. [James Gerard] 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 procedures; 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 [middle cerebral artery] 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 the aneurysm.

Waldt, 181 Md. App. at 223, 229-30, 956 A.2d at 226, 230.

Section 3-2A-04(b)(4) of the Courts & Judicial Proceedings Article establishes a minimum requirement for an expert witness to testify to the standard of care in a medical malpractice case: the expert must not devote annually more than 20 percent of his or her professional activities to activities directly involving testimony in personal injury cases. Dr. Debrun attested that he satisfied the 20 percent requirement. At trial, however, Dr. Zoarski and UMMS moved to preclude Dr. Debrun as a witness, arguing that he devoted more than 20 percent of his professional activities to testifying in personal injury cases. Dr. Debrun was extensively questioned about his professional activities by counsel for both parties and the trial judge. The Court of Special Appeals summarized his testimony as follows:

> 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.
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> 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:
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> - 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[s] per month).

Waldt, 181 Md. App. at 233-34, 956 A.2d at 232.

After considering Dr. Debrun's testimony about his activities, the trial judge granted the motion to exclude his testimony with respect to the standard of care:

> [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 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 also indicates that the last meeting he has gone to, the . . . [i]nterventional neuroradiology conference, the last one was about three years ago.

He also stated that he has not practiced since 2001.

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 conferences 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 question 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 actually 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 anywhere. He is not paid for any medical treatment that 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.

Dr. Debrun was thus not permitted to give expert testimony on the standard of care.

The trial court also granted a motion by UMMS and Dr. Zoarski to prevent Dr. Debrun from testifying about the informed consent claim. The trial judge ruled that Dr. Debrun was not an expert on the use of the neuroform stent. Dr. Debrun had never performed or observed a procedure utilizing the neuroform stent as it was not approved for use in the United States until after Dr. Debrun retired from active practice. The trial judge ruled that Dr. Debrun's expertise in the field of interventional neuroradiology was not sufficient for him to be qualified as an expert in this particular case.

On appeal to the Court of Special Appeals, the Waldts argued that the trial judge erred in excluding all of Dr. Debrun's testimony. They argued that the trial judge: (1) improperly interpreted the meaning of "professional activities" in calculating what percentage of his professional time Dr. Debrun devotes to testifying, and thus should not have excluded his testimony regarding the standard of care; and (2) erred in preventing Dr. Debrun from testifying concerning the informed consent claim.

The intermediate appellate court held that Dr. Debrun should have been allowed to testify to the standard of care. The court opined:

> 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 . . . . [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.

Waldt, 181 Md. App. at 245, 956 A.2d at 239. Ultimately, the intermediate appellate court reversed the judgment entered on the ordinary negligence claim and remanded the case to the Circuit Court for further proceedings.

The Court of Special Appeals affirmed the trial court's judgment on the informed consent claim. Citing Maryland Rule 5-103,[2] the court ruled that the issue had not been properly preserved for appeal because the Waldts failed to make a sufficient proffer of the substance of Dr. Debrun's informed consent testimony. The intermediate appellate court reasoned:

> 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. . . .
>
> 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.

Waldt, 181 Md. App. at 258, 956 A.2d at 247. After stating that the issue was not properly before the court, the court went on to explain that "to the extent the record reveals the basis

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[2]Maryland Rule 5-103 states in 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 . . . (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.

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." *Waldt*, 181 Md. App. at 262, 956 A.2d at 249.

Dr. Zoarski and UMMS filed a petition for writ of certiorari for this Court to review the intermediate appellate court's decision concerning Dr. Debrun's qualification as an expert on the standard of care.[3] The Waldts filed a cross-petition for review of the Court of Special Appeals' decision on Dr. Debrun's exclusion as an expert on the informed consent claim.[4]

DISCUSSION

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[3]Dr. Zoarski and UMMS presented the following questions in their petition for writ of certiorari:

> 1. Did the Maryland Legislature intend to exclude professional witnesses from testifying in medical malpractice cases where 100% of their professional activities directly involve testimony in personal injury claims?
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> 2. Whether the trial court correctly interpreted the statute to advance the stated public policy by finding, as a matter of fact, that a professional witness devoted more than 20% of his professional time to activities that directly involve testimony in personal injury claims.

[4]In their cross-petition for certiorari, the Waldts presented the following questions:

> 1. Did the Court of Special Appeals commit reversible error when it concluded that a sufficient proffer of Dr. Debrun's testimony was not made, and/or the substance of Dr. Debrun's testimony was not apparent to the trial court from the context within which he was offered as an expert?
>
> 2. Did the Court of Special Appeals commit reversible error when it concluded that the trial court properly excluded Dr. Debrun as an expert witness on the issue of informed consent for failing to have a sufficient factual basis for his testimony?

I. Twenty Percent Rule

Petitioners argue that the Court of Special Appeals erred in overturning the trial court's ruling regarding the 20 Percent Rule. They argue that Dr. Debrun's activities — conducting peer review, reading journals, observing procedures, discussing patients with former colleagues, and attending conferences — were not "professional activities" in the sense of relating to the profession of medicine. According to Petitioners, Dr. Debrun is retired, all of his professional activities are for the purpose of testifying in medical malpractice cases, and therefore 100 percent of his time is dedicated to activities directly related to giving testimony. Allowing him to qualify as an expert witness, Petitioners contend, eliminates the purpose of the requirement, allowing professional witnesses to criticize practicing doctors without themselves being members of the profession.

The Waldts counter, reasoning that Dr. Debrun's activities were "professional activities," but did not directly relate to giving testimony in medical malpractice cases. The Waldts contend that because all the activities Dr. Debrun engaged in concern the field of interventional neuroradiology, and involve his former profession of medicine, they count as "professional activities."

The meaning of statutory text is an issue we review as a matter of law. *Park and Planning v. Anderson*, 395 Md. 172, 181, 909 A.2d 694, 699 (2006); *Moore v. State*, 388 Md. 446, 452, 879 A.2d 1111, 1114 (2005). The relevant portion of § 3-2A-04(b)(4) of the Courts & Judicial Proceedings Article states that an 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." The plain language of the section suggests that to discern whether an expert is qualified to testify under this requirement, we must perform a mathematical equation: we must identify those activities that "directly involve testimony in personal injury claims" (the numerator) and then divide it by those activities that comprise the body of "professional activities" in general (the denominator). *See Waldt*, 181 Md. App. at 243, 956 A.2d at 238 (identifying activities that "directly involve testimony" as the numerator and "professional activities" as the denominator in the 20 Percent Rule).

In *Witte v. Azarian*, 369 Md. 518, 801 A.2d 160 (2002), this Court addressed the numerator and set a clear standard for identifying those activities that "directly involve testimony."[5]

> 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.

[5]At the time *Witte v. Azarian*, 369 Md. 518, 801 A.2d 160 (2002), was before this Court, the 20 Percent Rule only applied to experts who were hired to sign a certificate of merit to initiate a medical malpractice suit. In 2004, the General Assembly met in a Special Session and expanded § 3-2A-04(b)(4) of the Courts & Judicial Proceedings Article to apply to experts giving testimony as well. *Waldt v. UMMS*, 181 Md. App. 217, 238, 956 A.2d 223, 235 (2008).

Witte, 369 Md. at 535-36, 801 A.2d at 171. This set of activities counts as the numerator in the 20 percent calculation.

This Court did not address in *Witte* which activities qualify as "professional activities" for purposes of calculating the denominator. We have yet to rule on the meaning of the phrase "professional activities" as it is used in the 20 Percent Rule. In statutory interpretation cases, "[t]he cardinal rule . . . is to ascertain and effectuate the intent of the Legislature." *Chow v. State*, 393 Md. 431, 443, 903 A.2d 388, 395 (2006); *Oakland v. Mountain Lake*, 392 Md. 301, 316, 896 A.2d 1036, 1045 (2006). If the statute is clear and unambiguous based on the plain language, then our inquiry will end there. *Bowen v. Annapolis*, 402 Md. 587, 613-14, 937 A.2d 242, 257-58 (2007); *Walzer v. Osborne*, 395 Md. 563, 571-72, 911 A.2d 427, 431-32 (2006); *Kushell v. DNR*, 385 Md. 563, 576-78, 870 A.2d 186, 193-94 (2005).

A statute is "ambiguous," however, when there exist two or more reasonable interpretations of the words used. *Walzer*, 395 Md. at 572-73, 911 A.2d at 432. The 20 Percent Rule itself does not state the set of activities that qualify as "professional," and no other provision in the code provides a definition. The Waldts agree with the Court of Special Appeals that "professional activities" includes anything related to the profession of medicine, whether the individual is actively practicing medicine or not; Dr. Zoarski and UMMS argue that professional activities are limited to those things that relate to active practice or are in furtherance of the medical profession. Both parties' interpretations are reasonable. When the plain language of the statute is ambiguous, we must look to other indicia of the intended meaning. In *Witte*, we explained that we look to:

> 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.

369 Md. at 525-26, 801 A.2d at 165 (citing *Beyer v. Morgan State*, 369 Md. 335, 349-50, 800 A.2d 707, 715 (2002); *Liverpool v. Baltimore Diamond*, 369 Md. 304, 317-19, 799 A.2d 1264, 1272 (2002)).

In the proceedings below, the Court of Special Appeals reviewed the legislative history of the 20 Percent Rule. The intermediate appellate court concluded:

> 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.
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> 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." 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."
>
> 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.

Waldt, 181 Md. App. at 242-43, 956 A.2d at 237-38 (internal citations omitted).

Following its review of the available legislative history, the intermediate appellate court in this case turned to the dictionary definition of professional: "of, relating to, or characteristic of a profession." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 991 (11th ed. 2003). Under this definition, the court ruled that all of Dr. Debrun's listed activities — reading and peer editing of medical journals, consulting with colleagues about their ongoing cases, observing colleagues performing procedures, and attending medical conferences — related to his profession of interventional radiology, and thus qualified as professional activities. The total number of hours devoted to these activities was 559. The court also ruled that the only time Dr. Debrun dedicated to activities directly involving testimony was the 50 hours he originally indicated as such in his testimony. Therefore, pursuant to the Court of Special Appeals' calculation, Dr. Debrun only devoted 8 percent of his professional time to activities directly involving testimony.

We disagree with the Court of Special Appeals' definition of "professional activities." A profession carries with it the concept of a business or vocation, and an individual who engages in a profession has some responsibility and obligation or purpose within his or her

field. Activities are "pursuit[s] in which a person is active," and to be "active" is to be "characterized by action rather than by contemplation or speculation." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 13. We hold that, for an individual's activities to qualify as "professional activity," the activity must contribute to or advance the profession to which the individual belongs or involve the individual's active participation in that profession. In classifying "professional activities," a distinction must be drawn between the hours spent furthering one's profession versus the hours spent on personal or leisurely pursuits. *See Estate of Gawel v. Schatten*, 109 F. Supp. 2d 719, 723 (E.D. Mich. 2000) ("[A]n expert devotes 'a majority of his or her professional time' and is qualified under the statute where he or she spends the bulk of their *professional* time, as opposed to *recreational* or other *personal* time, engaged in either the active practice of medicine or teaching.") (interpreting a Michigan statute that requires expert witnesses to spend a majority of their professional time in active clinical practice or teaching).

Our interpretation of "professional activities" is in line with other states that have restrictions on how expert witnesses must spend their professional time. Kansas, for example, requires expert witnesses to devote at least 50 percent of their professional time to active clinical practice for the two-year period preceding the incident giving rise to the action in which the witness is testifying. KAN. STAT. ANN. § 60-3412 (2005). In calculating the percentage of time a doctor devoted to active clinical practice, the Kansas Supreme Court considered all of the following activities to be included in "professional time": direct patient care, group therapy, time spent on-call in the emergency room, governmental consulting,

writing, editing, directorships of academic programs, involvement with professional organizations and committees, and teaching. *Dawson v. Prager*, 76 P.3d 1036, 1041 (Kan. 2003). Though the court never explicitly stated a definition of "professional activities," all of these activities involve some contribution to or advancement in the profession of medicine or involve the doctor's active participation in the profession. Similar decisions have been made under Ohio and North Carolina law. *See, e.g., Cornett v. Watauga Surgical Group, P.A.*, 669 S.E.2d 805, 808 (N.C. Ct. App. 2008) (listing clinical practice, leading rounds, assisting residents, performing administrative functions, attending conferences, and participating in committee meetings as a doctor's professional activities); *Goldstein v. Kean*, 461 N.E.2d 1350, 1353 (Ohio Ct. App. 1983) (counting scholarly research and writing, medical/legal consulting, direct patient care, and evaluating worker's compensation claims as professional time for purposes of calculating the percentage of professional time spent on clinical treatment).

As the decisions of other state courts demonstrate, requiring "professional time" to advance or contribute to the profession or involve active participation in the profession in some way does not mean "professional time" is limited to active clinical practice. Indeed, the text of the 20 Percent Rule necessarily requires time spent testifying to be included as professional activity. "[G]iven 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.'" *Waldt*, 181 Md. App. at 243, 956 A.2d at 238. Time spent testifying in and preparing for testifying in

medical malpractice cases is not active practice of medicine, but it still contributes something to the profession by providing the necessary expertise for the resolution of malpractice claims. In addition, § 3-2A-02(c)(2)(ii)(A) of the Courts & Judicial Proceedings Article requires expert witnesses in medical malpractice cases 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 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 . . . . (Emphasis added.)

This Five Year Rule demonstrates that *current* clinical or education work is not required — the witness merely must have had such experience within five years of the incident in question. As the Court of Special Appeals stated below:

> 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 after 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.

Waldt, 181 Md. App. at 244, 956 A.2d at 238-39.

Though active clinical practice is not required, the doctor must still engage in professional activities other than testifying in court. Such a doctor is still required to satisfy the 20 Percent Rule. This allows a qualified doctor to continue to utilize his or her expertise, but prevents him or her from launching a second career as purely an expert witness. The primary professional activities (at least 80 percent) must still be in the medical profession that he or she is professing.

In the present case, Dr. Debrun testified that he spends only 50 hours per year on activities directly related to giving testimony in medical malpractice cases. We agree with the Court of Special Appeals that, under *Witte*, these 50 hours are the extent of Dr. Debrun's activities that are directly related to giving testimony and therefore count as the numerator in the 20 percent calculation. Dr. Debrun testified that he is compensated for all his work that directly relates to preparing for giving testimony and the remainder of his time does not fall into any of the four categories established by *Witte*.

Under our construction of professional activities, Dr. Debrun's professional activities are limited to testifying in medical malpractice cases and assisting with peer review of medical journals. We examine each of these two activities in turn:

Testifying. As previously discussed, activities related to giving testimony must be a part of the greater category of professional activities. The numerator is necessarily included in the denominator.

Peer review. Dr. Debrun testified to the work involved in peer review of medical journals as follows:

> Dr. Ausman [editor of *Surgical Neurology*] . . . sends me approximately three or four articles every month that I am to read. And I spend three or four hours in reading each article. Then on my computer, I write my comments about the article.
>
> If the article can be published as it is or if the article has to be improved or if things are missing in the article and depending on my answer, he sends the article back to the author who will send it back again with all the revision [sic], and, finally, I will be asked if I consider that the article is ready for publication.

Peer review of scholarly work is a vital step in the scientific research process, guaranteeing the legitimacy of methods and analysis of results. *See* Peter Cummings and Frederick P. Rivara, *Reviewing Manuscripts for Archives of Pediatrics and Adolescent Medicine*, 156 ARCHIVES OF PEDIATRICS AND ADOLESCENT MEDICINE 11 (2002) ("Peer review is a critical element in the editorial process . . . . The goals are to provide expert advice to the authors regarding their work, a check on the scientific validity of the data and methods, and information to the editors for use in their decision about the suitability of the paper for publication . . . ."); *see also* Journal of the American Medical Association, Information for Authors and Reviewers, http://jama.ama-assn.org/misc/aboutjama.dtl (last visited Oct. 19, 2009). Dr. Debrun's work on these articles qualifies as "professional," even though he is not paid for his time, because he is contributing to the profession. He is utilizing his knowledge gained through years of experience and is advancing the field.

Dr. Debrun's other activities, however, despite being related to the field of interventional neuroradiology, do not actively contribute to the development or advancement of the field or involve Dr. Debrun's active participation in the field and are therefore not professional activities. We address each activity in turn:

Reading journals. Dr. Debrun himself testified that he does not read journals for any particular purpose other than the fact that he is "interested to know what people are doing today." Apart from the occasional situation where something he read coincidentally related to a case he testified in, Dr. Debrun stated that he does not use the knowledge gained through

reading journals. This time would be better classified as "personal" or "leisurely" as it is for his own personal edification.

Observing procedures. As with reading journals, Dr. Debrun stated that his observation of procedures is purely for his own personal knowledge and the information gained is not used for any advancement of the field, nor does it involve his own active participation in the field. He engages in this activity "[t]o know what people are doing and to know the field of interventional neuroradiology. To be informed on what is going on in the field."

Discussing patients with former colleagues. Dr. Debrun testified that the occasional phone call he has with colleagues is for the purpose of "asking them what they are doing." There was no testimony that he uses this knowledge for anything other than to satisfy his personal curiosity. His being told what other doctors are doing does not contribute anything to the "field" or involve his active participation in the field.

Attending conferences. Dr. Debrun testified that the last conference he attended was four or five years before his testimony. This cannot reasonably be included in the calculation of his current annual activities. Even if the attendance had been more recent, he has not presented at a conference or written a paper for a conference since retiring. Therefore, he has not contributed anything to the profession of medicine or actively participated in the profession through this activity and it is not a "professional activity."

Under this classification, Dr. Debrun devotes 50 hours annually to activities directly involving testimony and 242 hours total to professional activities annually (50 hours on

testimony and 192 hours on peer review). This results in Dr. Debrun devoting 20.66% of his professional time to activities directly involving testimony. Dr. Debrun therefore does not satisfy the 20 Percent Rule and was properly prevented from giving testimony regarding the standard of care. Accordingly, we reverse the judgment of the Court of Special Appeals and affirm the trial court's ruling on this issue.

II. Informed Consent Claim

The intermediate appellate court held that the issue of the trial judge's exclusion of Dr. Debrun's testimony on the issue of informed consent was not properly preserved for appeal. The court reasoned that the Waldts failed to proffer sufficiently the substance of the excluded evidence in accordance with Maryland Rule 5-103, which states that "[e]rror may not be predicated upon a ruling that admits or excludes evidence unless the party is prejudiced by the ruling, and . . . the substance of the evidence was made known to the court by offer on the record or was apparent from the context . . . ." Additionally, the intermediate appellate court held that the trial judge did not abuse her discretion in ruling that Dr. Debrun did not have the necessary foundation to offer an opinion on informed consent. We affirm the Court of Special Appeals' conclusion and uphold the trial judge's ruling excluding Dr. Debrun's informed consent testimony.

In an informed consent case, "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 . . . ." *Sard v. Hardy*, 281 Md. 432, 444, 379 A.2d 1014, 1022 (1977). Expert testimony is necessary to establish the material risks and other pertinent information regarding the treatment or procedure. The Waldts offered Dr. Debrun as their expert witness for the informed consent claim.

The trial judge heard testimony regarding Dr. Debrun's qualifications, including his education and experience in the field of interventional neuroradiology. Dr. Debrun testified that throughout his career he had operated on about 30 aneurysms like Mrs. Waldt's, 10-15 of which were similar in size to Mrs. Waldt's, and four or five of which were "wide neck" aneurysms. He also testified that he traditionally used a balloon procedure that is different from a stent and that he had never used the neuroform stent because it was not approved for use in the United States until after he retired from active practice.

Maryland Rule 5-702 makes it the responsibility of the trial judge to determine whether an individual qualifies as an expert witness.[6] After Dr. Debrun's *voir dire*, the trial judge ruled that Dr. Debrun was not qualified to testify regarding informed consent, stating:

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[6] Maryland Rule 5-702, "Testimony by Experts," states:

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

> 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 possesses 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.

The Waldts did not make a proffer of the substance of Dr. Debrun's anticipated testimony at that time. The only proffer that counsel for the Waldts had previously made regarding Dr. Debrun's testimony was that he would have testified about the approved uses of the neuroform stent and that it was not approved for use on an aneurysm like Mrs. Waldt's. *Waldt*, 181 Md. App. at 261, 956 A.2d at 248. There was no proffer as to the risks inherent to use of the neuroform stent on Mrs. Waldt's aneurysm, such as:

> coiling with the neuroform stent; the probability of success of the coiling procedure with the neuroform stent; the frequency of the risks inherent in coiling with the neuroform stent; what procedures were available as alternatives to coiling with the neuroform stent; what were the risks inherent

> in those procedures; how did the risks inherent in those procedures compare both by nature and frequency to the risks inherent in coiling with the neuroform stent; and which risks of the neuroform stent coiling procedure were disclosed to Mrs. Waldt and which were not.

Waldt, 181 Md. App. at 260, 956 A.2d at 249 (citing *Sard*, 281 Md. at 448, 379 A.2d at 1024).

The Waldts appealed the trial judge's ruling to the Court of Special Appeals. The intermediate appellate court held that the Waldts failed to preserve the issue for appeal by not making a sufficient proffer on the trial record of what the substance of Dr. Debrun's testimony would have been, had he been allowed to testify. *Waldt*, 181 Md. App. at 258, 956 A.2d at 247. The court held that Dr. Debrun's intended testimony concerning the approved uses of the neuroform stent did not address the issue of informed consent because it was not testimony concerning the material risks of the procedure. *Waldt*, 181 Md. App. at 261, 956 A.2d at 248. Without a proffer of testimony that would establish the elements of an informed consent claim, the Court of Special Appeals "[did] not have before [it] the information [needed] to address whether exclusion of Dr. Debrun's testimony on the informed consent claim was prejudicial error." *Waldt*, 181 Md. App. at 262, 956 A.2d at 249.

In addition, the Court of Special Appeals stated that the trial judge's ruling excluding Dr. Debrun was not an error or an abuse of discretion. *Waldt*, 181 Md. App. at 262, 956 A.2d at 249. Acknowledging that, under *Radman v. Harold*, 279 Md. 167, 172-73, 367 A.2d 472 (1977), an expert need not necessarily have actually performed a procedure to qualify as an expert witness, the court then went on to hold that the trial judge had sufficient grounds

for excluding Dr. Debrun. "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." *Waldt*, 181 Md. App. at 267-68, 956 A.2d at 252.

In their petition to this Court, the Waldts argue that the Court of Special Appeals erred in holding that a sufficient proffer was not made to preserve the issue for appeal and that the trial judge erred in refusing to qualify Dr. Debrun as an expert. On the preservation issue, the Waldts contend that a sufficient proffer was made when counsel for the Waldts made it clear that Dr. Debrun intended to testify that the neuroform stent was not approved for use on an aneurysm like Mrs. Waldt's. According to the Waldts, this is information that would be material to a patient in making an informed decision concerning the surgery. In *Sard*, this Court acknowledged the doctrine of informed consent, identifying general categories of information that must be communicated to the patient: (1) the nature of the ailment, (2) the nature and the risks of a treatment, (3) the probability of success, (4) the frequency of occurrence of risks, and (5) available alternatives to the treatment. 281 Md. at 438-40, 379 A.2d at 1019-20. The Waldts acknowledge that testimony about approved uses of the stent would not have fit neatly into one of these five categories. Notwithstanding, they rely on this Court's decision in *Goldberg v. Boone*, 396 Md. 94, 912 A.2d 698 (2006), holding that certain other considerations may also need to be discussed and resolved on a case by case basis. The Waldts argue that the approved uses of the neuroform stent and the fact that it was

only approved for aneurysms that were not amenable to surgery (of which Mrs. Waldt's was not one) would have been a material factor in Mrs. Waldt's decision concerning the surgery.

The purpose of Rule 5-103(a)(2) is to allow adequate review by the appellate courts. Without a proffer, it is impossible for appellate courts to determine whether there was prejudicial error or not. *See Merzbacher v. State*, 346 Md. 391, 416, 697 A.2d 432, 444 (1997). We agree with the Court of Special Appeals that a sufficient proffer was not made as to the substance of Dr. Debrun's testimony. The Waldts' proffer was that Dr. Debrun would testify about the approved uses of the neuroform stent. The intermediate appellate court explained,

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

Waldt, 181 Md. App. at 261-62, 956 A.2d at 248, 249. We agree with the intermediate court that no testimony was proffered concerning the material risks of the procedure that would make out a *prima facie* case for informed consent.

In addition, it is within the discretion of the trial judge to qualify witnesses as experts. As this Court has previously held, "[i]t 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. In this regard, the trial judge has wide latitude in determining whether expert testimony is sufficiently reliable to be admissible." *Wilson v. State*, 370 Md. 191, 200, 803 A.2d 1034, 1039 (2002). The trial judge evaluated Dr. Debrun's testimony and qualifications and concluded that he did not have a sufficient factual basis on which to render an expert opinion on informed consent. The Waldts were allowed more time for *voir dire* and were not able to present sufficient testimony to convince the trial judge that Dr. Debrun should be allowed to testify. We agree with the Court of Special Appeals that "[g]iven Dr. Debrun's limited experience with similar procedures and his failure to disclose any specific scientific or factual underpinnings for any knowledge about the material risks of the neuroform stent coiling procedure, the court did not err or abuse its discretion in excluding

his testimony on this issue." *Waldt*, 181 Md. App. at 267-68, 956 A.2d at 252. We therefore affirm the judgment of the Court of Special Appeals and uphold the ruling of the trial judge.

JUDGMENT OF THE COURT OF SPECIAL APPEALS REVERSED IN PART AND AFFIRMED IN PART. RESPONDENTS TO PAY THE COSTS.

In the Circuit Court for Baltimore City
Civil No. 24-C-05-008653

IN THE COURT OF APPEALS

OF MARYLAND

No. 130

September Term, 2008

UNIVERSITY OF MARYLAND MEDICAL SYSTEM CORPORATION, ET AL.

v.

REBECCA MARIE WALDT, ET AL.

Bell, C.J.
Harrell
Battaglia
Greene
Adkins
Eldridge, John C.
(Retired, Specially Assigned)
Raker, Irma S.
(Retired, Specially Assigned),

JJ.

Dissenting Opinion by Adkins, J.

Filed: November 10, 2009

Adkins, J., dissenting:

I.

I join the majority opinion with respect to the first issue.

II.

I respectfully dissent from the majority opinion with regard to the Waldts's informed consent claim. In my estimation, it was error for the trial court to find that Dr. Debrun was "not qualified as an expert to testify with regards to informed consent in reference to this procedure or this device."[1] As a result of this ruling, the trial court granted judgment against the Waldts for failure to prove a lack of informed consent, on the grounds that the Waldts had no expert to testify "with regards to the nature of the risks inherent in this particular treatment [or] the probabilities of therapeutic success." The Waldts proffered that Dr. Debrun would testify about Dr. Zoarski's failure to inform Ms. Waldt that the Neuroform stent had only been approved by the FDA in the limited instance when the patient's aneurysm is *not* amenable to surgical clipping, an alternative procedure. I believe that in this instance, knowledge concerning the limited extent of FDA approval of the Neuroform stent could be material to Ms. Waldt's consent. Materiality of this information was a fact to be determined by the jury.

The majority clothes its decision rejecting the Waldts's informed consent claim in a procedural wrap, i.e., as a non-preservation issue. Yet, in holding that "a sufficient proffer was not made as to the substance of Dr. Debrun's testimony," the majority actually makes a substantive ruling, one that could have a widespread impact on informed consent claims. Majority Opinion, *supra*, at 27. The majority maintains that the proffer falls short because it did not include testimony about the actual risks of using the Neuroform stent or the probabilities of therapeutic success. In doing so, it implicitly rejects as insufficient the Waldts's proffer that Dr. Debrun would testify "that the neuroform stent device was not approved for use on Mrs. Waldt's type of aneurysm." *Waldt v. Univ. of Md. Med. Sys. Corp.*, 181 Md. App. 217,

[1]In addressing the Waldts's proffer of Dr. Debrun's testimony on the informed consent issue, I have not considered whether Dr. Debrun would be disqualified under the 20% rule from giving testimony on the informed consent claim. *See McQuitty v. Spangler*, 410 Md. 1, 28, 976 A.2d 1020, 1036 (2009) (holding that a informed consent claim sounds in negligence). That issue was not raised in this Court.

261, 956 A.2d 223, 248 (2008). This implicit rejection constitutes a holding that expert testimony about FDA approvals is immaterial unless it expressly identifies the risks that would cause the FDA to withhold approval.

But this holding undermines our decision in *Goldberg v. Boone*, 396 Md. 94, 912 A.2d 698 (2006), in which we held that obtaining a patient's informed consent may require a broader range of disclosures than those merely addressing risks. *See Goldberg*, 396 Md. at 125, 912 A.2d at 716 (*quoting Dingle v. Belin*, 358 Md. 354, 370, 749 A.2d 157, 165 (2000)) (holding that although "'[r]isks . . . must be disclosed routinely,' we also have made clear that 'other considerations . . . may also need to be discussed and resolved.'"). In *Goldberg*, the information withheld by the doctor was that he had performed the unusually complicated surgical procedure only once in the previous three years, and there were more experienced doctors in the region. We held that information could be found by the jury to be material, and was part of the doctor's disclosure obligation.

In *Goldberg* we held that "there is no bright-line test [for] items that must be disclosed by a physician in order to procure an informed consent from a patient." 396 Md. at 125, 912 A.2d at 716. Rather, a physician is obligated to disclose any information that "would be material to a reasonable person in the position of the patient having to decide whether to submit to the medical treatment in issue . . . ." *Id.* The focus of the informed consent inquiry is therefore a patient's perspective, and not the judgment of a treating physician. *See Sard v. Hardy*, 281 Md. 432, 442, 379 A.2d 1014, 1021 (1977) ("[T]he appropriate test is not what the physician . . . thinks a patient should know[;] . . . rather, the focus is on what data the patient requires in order to make an intelligent decision.").

The facts of this case fit easily within the *Goldberg* rationale. Evidence was introduced that even though Ms. Waldt's aneurysm could have been treated with surgical clipping, she was advised that the Neuroform stent was a safe and successful treatment, widely used in Europe, and that it had the best chance of success among the treatment options available to her. The absence of FDA approval for use when other surgery was available could at least indicate to Ms. Waldt that the Neuroform stent had not undergone the full rigorous testing process that ordinarily accompanies an FDA approval. Although a patient might place her faith in her doctor despite that information, she has the right to knowingly make that choice. In a risky procedure, a patient's knowledge that a device has not been tested by the FDA or approved for that particular use could tip the balance against going forward with the operation when alternatives are available.

I do not advance the proposition that every nuance of a surgical procedure need be disclosed to a patient in order to obtain informed consent – some information is so commonplace that it could not reasonably be expected to affect a

patient's course of treatment. For example, no reasonable patient would base a decision to pursue surgery on the type of scalpel or forceps that would be used in the procedure. Other examples abound. But the disclosure at issue here is a far cry from a commonplace surgical component.

To be sure, lack of FDA approval does not necessarily mean that a treatment is high-risk. Other courts have found this disconnect sufficient reason to hold that information about FDA approvals is not generally material to a patient's informed decision. *See, e.g.*, *Southard v. Temple Univ. Hosp.*, 566 Pa. 335, 781 A.2d 101 (2001) (holding that because FDA approval does not constitute a "material fact, risk, complication, or alternative [to treatment,]" a physician need not disclose associated information on FDA status). I do not agree with these courts, and consider their views inconsistent with Maryland's law of informed consent.

Contrary to the trial court's ruling, neither our holding in *Goldberg* nor our holding in *Sard* limits a doctor's disclosure obligation to information precisely demonstrating increased risk to the patient.[2] The purpose of the patient-centered standard of care established in *Sard* is to preserve "the patient's fundamental right of physical self-determination – the very cornerstone of the informed consent doctrine[.]" 281 Md. at 442, 379 A.2d at 1021. When a patient elects to pursue a particular course of treatment on a physician's advice, that patient is making a decision to place her trust in her physician. In order for that decision to be meaningful, the patient must possess all material facts.

Information about the lack of FDA approval is something that a patient could reasonably want to consider in deciding whether to place her confidence and trust in her physician about the treatment she is about to undertake. The

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[2] The trial court noted that:

> 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 . . . what was necessary to make an informed consent with regards to the material risks inherent in this treatment. There has been no expert testimony with regards to the probabilities of therapeutic success in this case. . . . There has been no expert testimony given with regards to the frequency of occurrence of particular risks. . . . 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. . . . *Sard* is clear that such expert testimony is required in regards to informed consent.

presence of such approval is some indication of safety, although not determinative. While the absence of FDA approval does not establish a higher risk, it does mean that the device has not undergone, or not passed, normal FDA testing procedures. A person facing surgery may reasonably assume that a device critical to that surgery has received FDA approval. A physician carries the responsibility of educating her patient if that assumption is false. Petitioner's proffer that Dr. Debrun would testify about the lack of FDA approval for use of the Neuroform stent for Waldt's type of aneurysm was sufficient. Dr. Debrun's testimony would "assist the trier of fact to understand the evidence or to determine a fact in issue." Md. Rule 5-702. To exclude Dr. Debrun's testimony and then grant judgment was error. To hold otherwise strays from the careful path that we have laid out in *Sard*, *Goldberg*, and our most recent case, *McQuitty v. Spangler*, 410 Md. 1, 976 A.2d 1020 (2009). Accordingly, I would vacate the judgment entered on the informed consent issue, and remand for further proceedings.

IN THE COURT OF APPEALS
OF MARYLAND

No. 130

September Term, 2008

UNIVERSITY OF MARYLAND MEDICAL SYSTEM CORPORATION, *ET AL.*

v.

REBECCA MARIE WALDT, *ET AL.*

Bell, C.J.
Harrell
Battaglia
Greene
Adkins
Eldridge, John C.
(Retired, Specially Assigned)
Raker, Irma S.
(Retired, Specially Assigned),
JJ.

Dissenting Opinion by Raker, J.,
which Eldridge, J., Joins.

Filed: November 10, 2009

Raker, J. dissenting, joined Eldridge, J.:

I respectfully dissent. Few people favor a "professional expert witness." I certainly do not. In my view, however, Dr. Debrun is not a professional expert witness and does not fall into the category of witnesses precluded from testifying in medical malpractice cases by the Maryland 20 percent rule. I agree with the well-reasoned opinion of the Court of Special Appeals in which the court held that the activities testified to by Dr. Debrun are not "professional activities that 'directly involve testimony in personal injury cases,'" and therefore, he was not precluded from testifying as an expert witnesses under Md. Code (1976, 2006 Repl. Vol., 2008 Supp.), Courts and Judicial Proceedings Article, § 3-2A-04(b)(4). *See Waldt v. UMMS*, 181 Md. App. 217, 254, 956 A.2d 223, 244-45 (2008). I disagree, however, with the Court of Special Appeals' and the majority's holding with regard to the informed consent issue.

I.

The critical phrase in C.J. § 3-2A-04(b)(4) is that an 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." Both the Court of Special Appeals and the majority opinion agree that the term "the expert's professional activities" is ambiguous. *See Waldt*, 181 Md. App. at 241, 956 A.2d at 237. The majority defines the phrase as an activity which "must contribute to or advance the profession to which the individual belongs or involve the individual's active participation in that profession," drawing a distinction between "the hours spent furthering one's profession versus the hours spent on personal or leisurely pursuits." Maj. op. at 15.

The Court of Special Appeals interprets "professional activities" under § 3-2A-04(b)(4) as simply a "general term for those activities that relate to the health care profession of the expert witness." *Waldt*, 181 Md. App. at 243, 956 A.2d at 238. The Court of Special Appeals followed the command set out in *Witte v. Azarian*, 369 Md. 518, 801 A.2d 160 (2002), in which this Court stated that the statutory language limiting expert witnesses had to be read narrowly, so as to avoid creating an unreasonable impediment to the pursuit, or defense of a common law right of action for medical negligence. *Id.* at 533-34, 801 A.2d at 169-70. *Witte* set out the following factors to be considered in making the 20 percent rule determination:

> "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 adjustors, 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, 801 A.2d at 171. The Court of Special Appeals held that Dr. Debrun's activities did not fall within the *Witte* proscribed activities and that "[b]ecause 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." *Waldt*, 181 Md. App. at 245, 956 A.2d at 239.

According to the majority, Dr. Debrun did not satisfy the 20 percent rule because most of his activities did not qualify as "professional activities" and, of those that did, more than 20 percent were directly related to his work as an expert witness. Maj. op. at 20. The majority's interpretation of "professional activities" is not supported by ordinary principles of statutory construction nor by case law in other jurisdictions that have considered similar issues. The majority's construction is a bald interpretation, with no support whatsoever.

The majority's definition of professional activities confuses, rather than clarifies, the meaning of "professional activities." No guidelines are provided to establish what qualifies as "contributing to or advancing" a profession and, by itself, the phrase is impossible to understand. Many professionals do not seem to contribute to or advance the profession to which they belong. For example, tax professionals routinely concentrate on applying settled principles of taxation and family physicians apply settled principles of medicine to diagnose a common cold. Under the majority's theory, does the application of settled principles "advance" a profession or maintain the status quo? The majority's definition also does not explain at what point in time courts should assess whether a professional activity has "contributed to or advanced" a profession. Since this phrase is inherently results oriented, determining whether an activity contributes to or advances a profession can often only be made after enough time has passed to assess the impact of the activity. If an activity, originally characterized by a court of law as not contributing to or advancing a profession, is later found to do so, would the court be required to review its initial determination? Lower courts are left in the dark after reading the majority's opinion.

The second part of the majority's definition of professional activities—activities which involve a professional's "active participation"—does nothing to clear up the ambiguity. The majority explains that "active participation" is characterized by "action rather than by contemplation or speculation." Maj. op. at 15. A whole range of professions, however, from designers and architects to philosophers, mathematicians and medical practitioners, spend time contemplating or speculating on various methodologies, problem solving techniques or available resources to achieve professional objectives. Not all of this time spent on such contemplation leads to a contribution or advancement in the professional's respective field. Yet, no one would dispute that such time is necessary to achieve professional objectives. Would the majority have us exclude these activities from consideration under the 20 percent rule? The standard set forth by the majority today leaves the lower courts on their own to craft an articulate standard to apply to the meaning of "professional activities."

Factually, no more than 20 percent of Dr. Debrun's professional activities "directly involved testimony in personal injury claims." "Professional activities" are not expressly defined in § 3-2A-04(b)(4) or in any definition section in the Act. As this Court noted in *Witte*, the Legislature chose only to limit the extent of professional activities "directly involving testimony in personal injury claims" but did not interfere with or otherwise limit the scope of other categories of professional activities. *Witte*, 369 Md. at 535, 801 A.2d at 170. Webster's Third New International Dictionary defines "professional" as "of, relating to, or characteristic of a profession or calling." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (1961). Based on the statute's legislative history and the plain meaning of

"professional," professional activities are those activities that arise out of one's vocation or calling.

In determining that "professional activities" must contribute to or advance the profession to which an individual belongs or involve the individual's active participation in the profession, the majority does not reference the legislative intent of § 3-2A-04(b)(4) or its legislative history, nor does it rely on any Maryland case law that defines "professional activities." Furthermore, the three cases referred to by the majority from other states in support of its construction of "professional activities" are not concerned with the definition of this phrase.[1] Our sister states which have considered similar issues have emphasized that "professional activities" encompass a wide range of activities. For example, in *Quintana v. United Blood Servs., Div. of Blood Sys., Inc.*, 811 P.2d 424, 430 (Colo. Ct. App. 1991), the

[1] All three of the cases referenced by the majority consider only very specific uses of an expert witness's "professional time." In *Dawson v. Prager*, 76 P.3d 1036, 1038 (Kan. 2003), the statute at issue, Kansas Statute § 60-3412, required an expert witness in a medical malpractice action to devote at least 50% of his "*professional time* within the two-year period preceding the incident giving rise to the action . . . to actual clinical practice in the same profession in which the defendant is licensed." Similarly, the statute in *Cornett v. Watauga Surgical Group, P.A.*, 669 S.E.2d 805, 807-08 (N.C. Ct. App. 2008), makes no mention of "professional activities," instead requiring that an expert witness offering testimony in a medical malpractice case must have devoted a majority of his or her "*professional time*" to "[t]he active clinical practice of the same health profession in which the party against whom or on whose behalf the testimony is offered," or to "[t]he instruction of students in an accredited health professional school or accredited residency or clinical research program in the same health profession in which the party against whom or on whose behalf the testimony is offered." Finally, in *Goldstein v. Kean*, 461 N.E.2d 1350, 1352 (Ohio Ct. App. 1983), the statute at issue required an expert witness testifying in a medical malpractice suit to devote "three-fourths of his *professional time* to the active clinical practice in his field of licensure, or to its instruction in an accredited university."

Colorado Court of Appeals considered the nature of "professional activities." The court noted as follows:

> "It is generally accepted that professions possess a number of defining characteristics in common, the first and foremost of which is individual autonomy and responsibility. Professionals are usually granted the right to determine the details of how their work will be performed. Moreover, they rely on peers to judge the quality of their work and behavior as professionals. Closely related, and a reflection of the profession's right to determine its own conduct, is that professions generally compose and practice under codes of ethics which define rules of proper behavior.
>
> Other characteristics of a profession include long formal training, undertaken in formalized institutions which are established to transmit the specialized knowledge of the profession and formal recognition of expertise through licensure and certification.
>
> It is precisely these characteristics of professional activity which have long led the courts to grant the medical profession and other professions a 'preferred position' in which the accepted or customary practices of similarly trained and situated professionals are generally taken as conclusive evidence of the professional standard of care."

Id. (internal citations omitted). In *Harad v. Aetna Cas. & Sur. Co.*, 839 F.2d 979, 984 (3d Cir. 1988), the United States Court of Appeals for the Third Circuit defined a professional act as "one arising out of a vocation, calling, occupation, or employment involving specialized knowledge, labor, or skill . . . ."

At trial, Dr. Debrun testified that he engaged in the following activities: testifying as an expert witness, peer review of medical journals, reading journals, observing procedures during grand rounds, discussing patients with former colleagues, and attending medical educational conferences. The majority's contention that these are not "professional activities" because they "do not actively contribute to the development or advancement of

the field or involve Dr. Debrun's active participation in the field," Maj. op. at 20, fails the test of common sense and leads to an absurd result. Dr. Debrun's activities demonstrate active participation in the field of interventional neuroradiology and were not undertaken for personal gratification or as a leisurely pursuit, as the majority contends. Under the majority's theory, are activities that arise out of one's own vocation but do not satisfy the high threshold of "contributing to the development of the field or involving the individual's active participation in the profession" considered "non-professional?" That appears to be the conclusion the majority would have us reach. The standard embraced by the majority would appear to exclude any physician who has retired from the clinical practice of medicine and does not teach medicine. Dr. Debrun's participation in peer review, clinical rounds and physician consultations satisfy the definition of "professional activities." Peer review of medical journals, reading journals, observing medical procedures, discussing patients with former colleagues, and attending conferences do not directly involve testimony in personal injury claims.

Applying this Court's holding in *Witte* to this case, Judge Deborah Eyler, writing for the panel, stated as follows:

> "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.*' [*Witte*, 369 Md. at 536, 801 A.2d at 171] (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.

* * *

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."

Waldt, 181 Md. App. at 240-41, 244-46, 956 A.2d at 236-39.

I would hold that the application of the 20 percent rule by the Court of Special Appeals was correct.

II.

I disagree also with the majority's holding with respect to the issue of informed consent. I disagree with the majority's holding that "no testimony was proffered concerning the material risks of the procedure that would make our a *prima facie* case for informed consent." Maj. op. at 28.

In my view, the Waldts sufficiently proffered that their expert would testify that Dr. Zoarski failed to inform Ms. Waldt that the Neuroform stent had only been approved by the FDA in limited circumstances when the patient's aneurysm is not amenable to surgical clipping. This knowledge concerning the limited extent of FDA approval of this stent is material to the issue of Ms. Waldt's informed consent, and an issue which should have been presented to the jury. In this regard, I agree with the reasoning in Judge Adkins's substantive discussion on the issue in Part II of her dissent.

Accordingly, I would reverse the judgment of the Court of Special Appeals, remand the case to that court with directions to reverse the judgment of the Circuit Court and to order a new trial on all issues.

Judge Eldridge joins this dissenting opinion.