J-A05027-14

NON-PRECEDENTIAL DECISION - SEE SUPERIOR COURT I.O.P. 65.37

BEVERLY H. SCHEER, AS ADMININSTRATOR AND PERSONAL REPRESENTATIVE OF THE ESTATE OF R. SCOTT SCHEER Appellant v. JAMES F. BURKE, M.D., MICHAEL J. DUZY, D.O., JOSEPH T. CONROY, D.O., AND MAIN LINE HOSPITALS, INC., D/B/A LANKENAU HOSPITAL Appellees	IN THE SUPERIOR COURT OF PENNSYLVANIA No. 1901 EDA 2013

Appeal from the Judgment Entered June 18, 2013
in the Court of Common Pleas of Montgomery County Civil Division
at No(s): 2003-22057

BEFORE: ALLEN, JENKINS, AND FITZGERALD, JJ.*

MEMORANDUM BY FITZGERALD, J.: **FILED MARCH 26, 2015**

Appellant, Beverly H. Scheer, individually and as administrator and personal representative of the estate of R. Scott Scheer, M.D. ("decedent"), appeals from the entry of a pretrial stipulated judgment in favor of Appellees, James F. Burke, M.D. ("Dr. Burke"), Michael J. Duzy, D.O. ("Dr. Duzy"), Joseph T. Conroy ("Dr. Conroy"), and Main Line Hospitals, Inc., d/b/a Lankenau Hospital ("Lankenau"). Appellant claims the trial court erred in granting Appellees' motions *in limine* to exclude or limit testimony from

* Former Justice specially assigned to the Superior Court.

three of her proposed experts and precluding her from referencing statements made to and by a federal agency. We vacate the judgment and remand for further proceedings.

The decedent, Appellant's husband, died while participating in the "Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial" ("ALLHAT"). Appellee Lankenau maintained a facility at which an ALLHAT regional trial was conducted. Appellee Dr. Burke was the principal ALLHAT investigator at the Lankenau facility and board-certified in internal medicine and cardiology. Appellee Dr. Duzy was an ALLHAT co-investigator and board-certified in internal medicine and cardiovascular diseases. Appellee Dr. Conroy was board-certified in internal medicine and, at the times relevant to Appellant's action, was either a resident, or a cardiology fellow, in Dr. Burke's group practice.

ALLHAT was a "practice-based, randomized, clinical trial of antihypertensive pharmacologic treatment." ALLHAT Protocol, 3/13/95, at 2. ALLHAT consisted of an antihypertension component and a cholesterol-lowering component. A participant in the antihypertension component was randomly assigned one of four "first-line" medications, chlorthalidone, amlodipine, lisinopril, or doxazosin. ***Id.*** The first-line medications were "blinded." ***Id.*** at 26.

ALLHAT protocols permitted an investigator-physician to add "second-line" medication—*i.e.*, reserpine, clonidine, or atenolol—and a "third-line"

medication—*i.e.*, hydralazine—if the participant-patient was "unable to attain satisfactory blood pressure control on the maximum available first-line drug that they [could] tolerate." ***Id.*** at 26. The second- and third-line medications would be provided in "open-label form." ***Id.***

The decedent was a practicing physician specializing in radiology and, according to Appellant, suffered mildly high blood pressure, for which he was taking medications. In March 1997, he saw an advertisement for ALLHAT and contacted the clinical research coordinator at Lankenau. He signed informed consent forms and stopped taking his previous antihypertension medications. He was assigned the blinded, first-line medication amlodipine, and beginning in April 1997, he was given medications through ALLHAT.[1]

In October of 1998, Dr. Duzy added the third-line antihypertensive medication hydralazine to the decedent's ALLHAT medications. The decedent continued on the first and third-line antihypertension medications, and the cholesterol-lowering medication, for nearly three years. On July 15, 2001, the decedent was found unresponsive on the floor next to his bed and was declared dead at the scene. He was sixty-two years old at the time of his death.

Following the decedent's death, his daughter wrote to the U.S. Department of Health and Human Services' Office of the Human Research

[1] Appellant was also enrolled in ALLHAT's cholesterol-lowering component and was given pravastatin.

Protection ("OHRP"). Letter from Kirsten Scheer Bauer to OHRP Director Greg Kosk & OHRP Chief Enforcement Officer Michael Carone, 8/18/01. The OHRP, in subsequent correspondence with Lankenau Institute of Medical Research (LIMR),[2] summarized the allegations against Appellees and identified possible problems in Appellees' conduct of ALLHAT. Letter from OHRP Compliance Oversight Coordinator Patrick J. McNeily to Lankenau Acting President Barry S. Rabner ("Rabner"), 10/24/01; Letter from OHRP Compliance Oversight Coordinator Kristina C. Borror ("Borror") to Rabner, 8/5/02. The OHRP requested additional information, and LIMR responded. Letter from Lankenau Institutional Official Vincent J. Cristofalo ("Cristofalo") to Borror, 10/11/02. The OHRP, on November 14, 2002, expressed its ongoing concerns and listed corrective and required actions to address its concerns. Letter from Borror to Cristofalo, 11/14/02. The OHRP, on December 20, 2002, closed its investigation after finding that Lankenau's corrective actions addressed its concerns adequately. Letter from Borror to Cristofalo, 12/20/02.[3]

Appellant filed a complaint in the Philadelphia County Court of Common Pleas on July 8, 2003. Her action was transferred to the Montgomery County Court of Common Pleas, where she filed an amended

[2] As discussed in note 4, ***infra***, Appellant withdrew her claims against LIMR.

[3] We refer to the letter from the decedent's daughter and the correspondence between the OHRP and Lankenau collectively as "the OHRP communications."

complaint on January 28, 2004. After the entry of pretrial judgment, Appellant's claims consisted of: (1) negligence, lack of informed consent, fraud and misrepresentation, and breach of fiduciary duty against Drs. Burke and Duzy; (2) negligence and breach of fiduciary duty against Dr. Conroy; and (3) negligence, lack of informed consent, and fraud and misrepresentation against Lankenau.[4]

Appellant alleged, in relevant part, hydralazine "causes edema, increases the risk of toxicity and can cause kidney damage or drug-induced lupus if taken over 12 months." Appellant's Pre-Trial Statement, 5/25/12, at 4-5. She claimed the decedent "died from a pulmonary embolism, a consequence of drug induced lupus and end stage rapidly progressing glomerulonephritis brought on by the continued ingestion of hydralazine." ***Id.*** at 6. According to Appellant, Appellees failed to (1) comply with ALLHAT protocols by prescribing hydralazine before using a second-line medication;

[4] Appellant agreed to dismiss her claims against, *inter alia*, LIMR and the Main Line Hospitals Institutional Review Board ("IRB") and George Reichard, Jr., Ph.D. Stipulation of Dismissal of Defendants George A. Reichard, Jr., Ph.D., Lankenau Institute of Medical Research and Main Line Institutional Review Board, approved by Order, 2/6/13. As part of a further stipulation with Appellees, Appellant agreed that Appellees Drs. Burke, Duzy, and Conroy could offer evidence about the IRB's role in ALLHAT, including approval of the written consent form signed by the decedent. Addendum to the Stipulation of Dismissal of Defendants George A. Reichard, Jr., Ph.D., Lankenau Institute of Medical Research and Main Line Institutional Review Board, approved by Order, 2/6/13. Appellee Lankenau "acknowledge[d] it [was] responsible for any negligence of the IRB as it relate[d] to [the decedent]." ***Id.***

(2) determine whether hydralazine was appropriate; (3) conduct laboratory testing before prescribing hydralazine; (4) monitor and test the decedent for side effects while he was taking hydralazine; and (5) address the decedent's symptoms during in-person visits in December of 1998, March of 2000, and March of 2001. Appellant's Pre-Trial Statement, 5/25/12, at 5. Additionally, Appellant asserted the informed consent form signed by decedent was defective and misleading, because it (1) failed to apprise him of the risks associated with participation in ALLHAT; (2) failed to inform him that the third-line drug was hydralazine; (3) misrepresented that hydralazine was a "standard medication[ ] commonly used by doctors[;]" and (4) overstated the benefits of participation in ALLHAT. ***Id.*** at 3-4.

In support of her claims regarding causation and negligence, Appellant intended to present expert evidence from Dr. Mary Crow ("Dr. Crow"), Dr. John J. Schrogie, ("Dr. Schrogie"), Vernette Molloy ("Nurse Molloy"), and Dr. John J. Laragh ("Dr. Laragh"). ***Id.*** at 8-9. A brief summary of these experts' opinions follows.

Dr. Crow, Appellant's proposed expert in rheumatology, authored a report stating:

> The most likely mechanism that accounts for hydralazine's lupus-related toxicity involves demethylation of DNA. This action is likely due to the capacity of the drug to decrease the activation of a cellular protein kinase and secondarily decrease expression of an important methyltransferase enzyme (DNA methyltransferase 1).

Report of Dr. Crow, 3/25/08, at 1. Dr. Crow opined,

> [T]here [was] a high likelihood that [the decedent's] death might have been avoided if 1) an ANA [antinuclear antibody] test had been ordered prior to starting hydralazine and regularly during the course of his treatment; 2) if [the decedent] had had more frequent evaluation, including appropriate blood and urine analyses to assess renal function and development of autoimmunity; and 3) if hydralazine had been withdrawn at the first sign of positive ANA, anemia, impaired renal function (elevated BUN and/or creatinine), proteinuria or active urine sediment.

Id. at 2.

Dr. Schrogie was offered as an expert in internal medicine and clinical pharmacology. Appellant's Pre-Trial Statement, 5/25/12, at 4-5. He was a professor at, and director of, the Clinical Research Center at LIMR. ***See*** Ex. A to Appellant's Omnibus Mem. in Opp'n to the Appellees' Mot. to Preclude and/or Limit the Expert Test., 5/29/13. Dr. Schrogie would have discussed "the risks and effects of hydralazine" and concluded that the decedent's "death was caused by and consistent with the effects of hydralazine." Appellant's Brief at 16. Moreover, Appellant offered Dr. Schrogie to address "the standard of care incumbent upon those prescribing the pharmaceutical hydralazine, including disclosing the significant risks associated with that drug and conducting the testing required by the product's label." Appellant's Brief at 15-16. In his supplemental report, Dr. Schrogie stated he agreed with Dr. Crow's expert report with no further discussion. Supp. Report of Dr. Schrogie, 9/22/10, at 3.

Nurse Molloy, according to Appellant, was a "senior good clinical practices auditor" and "conducted and managed national and international audits of clinical trials involving drugs and devices for over seventy companies." Appellant's Brief at 18. Nurse Molloy would have testified that there were "breaches in [Food and Drug Administration ("FDA")] requirements regarding the conduct of clinical trials" and good clinical practices. ***Id.*** Appellant intended to present Nurse Molloy's opinions that Appellees failed to follow ALLHAT's protocols and manual of operation when adding and monitoring hydralazine. ***Id.***

Dr. Laragh was board-certified in internal medicine and specialized in hypertension. Dep. of Dr. Laragh, 9/27/11, at 21. According to Appellant, Dr. Laragh "is one of the world's leading experts on the diagnosis and management of hypertension." Appellant's Brief at 17. Dr. Laragh prepared an expert report for Appellant and was deposed on videotape for the purposes of trial. Dr. Laragh testified (1) the addition of hydralazine to the decedent's ALLHAT treatment was unnecessary; (2) hydralazine was known to cause "lupus erythematosus;" and (3) hydralazine caused the decedent to suffer drug-induced lupus. Dep. of Dr. Laragh, at 35-36, 45, 49-50, 61-62, 67-68. In his report, Dr. Laragh also concluded the fatal disease could have been avoided if "appropriate ANA tests were performed before and during hydralazine therapy." Report of Dr. Laragh, 2/25/08, at 6.

On May 16, 2013, Lankenau filed motions *in limine* to exclude (1) Nurse Molloy's opinions that the ALLHAT written consent form given to the decedent was inadequate and did not meet FDA requirements; and (2) correspondence between Lankenau and the OHRP. Drs. Burke and Conroy filed motions *in limine* to exclude Dr. Laragh's videotaped deposition and Nurse Molloy's report and testimony. Appellee Dr. Duzy filed a motion in *limine* seeking to exclude Dr. Schrogie's expert opinions. Appellees also filed motions joining each others' motions *in limine*.

The trial court, on June 7, 2013, and June 18, 2013, entered separate underlying orders granting Appellees' motions *in limine* regarding Dr. Schrogie, Nurse Molloy, Dr. Laragh, and the OHRP communications. As to Dr. Schrogie, the court ruled (1) the doctor was "not qualified to offer standard of care opinions regarding internal medicine and cardiovascular disease and his opinions shall be limited to pharmacology[;]" (2) he was "not qualified to offer causation testimony under Pennsylvania law[;]" and (3) "repeating the opinions of [Appellant's] other expert, [Dr. Crow], is precluded." Order (Dr. Schrogie), 6/7/13, at ¶¶ 1-3. As to Nurse Molloy, the court ruled, "At trial of this matter, [Appellant] will not be permitted to introduce or otherwise rely upon Ms. Molloy's report and testimony." Order (Nurse Molloy), 6/7/13. As to Dr. Laragh, the court ruled, "At trial of this matter, [Appellant] will not be permitted to introduce or otherwise rely upon Dr. Laragh's video trial deposition or a transcript thereof." Order (Doctor

Laragh), 6/7/13. As to the OHRP communications, the court ruled "no evidence or argument related to these OHRP investigation documents, correspondence or findings may be admitted or referenced at trial." Order 6/16/13.

On June 18, 2013, the court entered the underlying judgment in favor of Appellees based on a stipulation among the parties. Stipulated Order of Final J., 6/18/13. Appellant timely filed a notice of appeal from the entry of the stipulated judgment and complied with the trial court's order to file a Pa.R.A.P. 1925(b) statement.

The trial court filed a Pa.R.A.P. 1925(a) opinion explaining its rulings. The court opined Dr. Schrogie was not competent under the MCARE Act[5] to discuss the standards of care owed by Drs. Burke, Duzy, and Conroy, who were cardiology or internal medicine specialists.[6] Trial Ct. Op., 8/26/13, at 7-8 (citing 40 P.S. § 1303.512(c)). The court also determined Dr. Schrogie improperly restated Dr. Crow's opinions without offering an independent expert opinion. ***Id.*** at 8. As to Nurse Molloy, the court found that she was not engaged in active clinical practice as required by the MCARE Act and further held that she was not competent to testify against Appellees because

[5] The Medical Care Availability and Reduction of Error Act ("MCARE Act"), 40 P.S. §§ 1303.101-1303.910. Section 512 of the MCARE Act is entitled "Expert Qualifications."

[6] As discussed below the trial court did not explain its ruling that Dr. Schrogie was not competent to discuss causation.

she was not a physician. ***Id.*** at 5-6 (citing 40 P.S. § 1303.512(b)). As to Dr. Laragh, the court concluded that Appellant's counsel impermissibly led the doctor in the videotaped deposition and he failed to state any factual basis for his conclusions. ***Id.*** Lastly, the court concluded the OHRP communications were privileged under the Peer Review Protection Act ("PRPA"), 63 P.S. § 425.1 to .4. ***Id.*** at 9.

Appellant presents the following questions on appeal.

> DID THE TRIAL COURT COMMIT REVERSIBLE ERROR BY SUBSTANTIALLY LIMITING THE EXPERT TESTIMONY OF JOHN J. SCHROGIE, M.D.?
>
> DID THE TRIAL COURT COMMIT REVERSIBLE ERROR BY PRECLUDING THE EXPERT TESTIMONY OF VERNETTE MOLLOY, MBA, RN?
>
> DID THE TRIAL COURT ABUSE ITS DISCRETION WHEN IT PRECLUDED THE TESTIMONY OF JOHN LARAGH, M.D.?
>
> DID THE TRIAL COURT COMMIT REVERSIBLE ERROR BY PRECLUDING EVIDENCE RELATED TO THE OHRP'S INVESTIGATION OF THIS MATTER?
>
> SHOULD THE ORDER OF DISMISSAL BE REVERSED, IN LIGHT OF THE RULINGS IMPROPERLY EXCLUDING EVIDENCE AND IMPERMISSIBLY BARRING THE APPELLANT FROM PRESENTING PROOF OF CAUSATION?

Appellant's Brief at 7.

We summarize Appellant claims and arguments, which we have reordered for the purposes of this disposition. First, Appellant claims Dr. Schrogie's education and experience in pharmacology met the MCARE Act's requirements for an expert offering causation opinion. ***Id.*** at 34. Second,

Appellant claims Dr. Schrogie qualified for an exception to the MCARE Act's requirements for standard-of-care testimony. ***Id.*** at 34, 39. Third, Appellant argues Nurse Molloy's opinions regarding the consent forms signed by the decedent, ALLHAT protocols, and "good clinical practices" were not governed by the MCARE Act or subject to an exception. ***Id.*** at 38. Fourth, Appellant claims the court erred in precluding Dr. Schrogie from referencing Dr. Crow's opinion regarding causation under the rule barring hearsay evidence. ***Id.*** at 34-35. Fifth, Appellant asserts the court erred in excluding Dr. Laragh's opinions due to her counsel's use of leading questions during Dr. Laragh's videotaped deposition. ***Id.*** at 47-49. Sixth, Appellant claims the court erred in finding the OHRP communications were privileged under the PRPA. ***Id.*** at 52-53. In sum, Appellant asserts the stipulated judgment against her should be vacated and her case be remanded for further proceedings. For the reasons that follow, we vacate the judgment without prejudice to the parties to litigate the issues on a more developed record.

The entry of the pretrial stipulated judgment giving rise to this appeal is akin to entry of summary judgment following the determination of a motion *in limine*. ***See Catlin v. Hamburg***, 56 A.3d 914, 919-20 (Pa. Super. 2012) (citation omitted), *appeal denied*, 74 A.3d 124 (Pa. 2013). "The ultimate inquiry in deciding a motion for summary judgment is whether the **admissible** evidence in the record, considered in the light most favorable to

the respondent to the motion, fails to establish a *prima facie* case."[7] ***Johnson v. Harris***, 615 A.2d 771, 775 (Pa. Super. 1992) (citation omitted) (emphasis added). "Summary judgment may be entered only in cases that are clear and free from doubt." ***Id.*** (citation omitted). When reviewing the trial court's ruling on a motion *in limine*, "we apply the scope of review appropriate to the particular evidentiary matter." ***Rachlin v. Edmison***, 813 A.2d 862, 869 (Pa. Super. 2002) (citations and punctuation omitted).

Appellant's first three claims focus on Dr. Schrogie's and Nurse Molloy's qualifications as expert witnesses under the MCARE Act. Our standards for reviewing such claims are well settled.

> [T]he admission of expert scientific testimony is an evidentiary matter for the trial court's discretion and should not be disturbed on appeal unless the trial court abuses its discretion. An abuse of discretion may not be found merely because an appellate court might have reached a different conclusion, but requires a result of

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[7] To sustain a *prima facie* case of medical malpractice,

> a plaintiff must establish a duty owed by the physician to the patient, a breach of that duty by the physician, that the breach was the proximate cause of the harm suffered, and the damages suffered were a direct result of the harm. Because the negligence of a physician encompasses matters not within the ordinary knowledge and experience of laypersons a medical malpractice plaintiff must present expert testimony to establish the applicable standard of care, the deviation from that standard, causation and the extent of the injury.

Toogood v. Owen J. Rogal, D.D.S., P.C., 824 A.2d 1140, 1145 (Pa. 2003) (citations and punctuation omitted).

> manifest unreasonableness, or partiality, prejudice, bias, or ill-will, or such lack of support so as to be clearly erroneous.

Grady v. Frito-Lay, Inc., 839 A.2d 1038, 1046 (Pa. 2003) (citations omitted).

Appellant's claims regarding the MCARE Act raise questions of statutory interpretation. ***See Smith v. Paoli Mem'l Hosp.***, 885 A.2d 1012, 1016 (Pa. Super. 2005). Because statutory interpretation is a question of law, our standard of review of the court's interpretation and application of the MCARE Act is *de novo* and our scope of review is plenary. ***Renna v. Schadt***, 64 A.3d 658, 664 (Pa. Super. 2013).

The relevant provisions of the MCARE Act are as follows:

> **(a) General rule.—**No person shall be competent to offer an expert medical opinion in a medical professional liability action against a physician unless that person possesses sufficient education, training, knowledge and experience to provide credible, competent testimony and fulfills the additional qualifications set forth in this section as applicable.
>
> **(b) Medical testimony.—**An expert testifying on a medical matter, including the standard of care, risks and alternatives, causation and the nature and extent of the injury, must meet the following qualifications:
>
> (1) Possess an unrestricted physician's license to practice medicine in any state or the District of Columbia.
>
> (2) Be engaged in or retired within the previous five years from active clinical practice or teaching.
>
> Provided, however, the court may waive the requirements of this subsection for an expert on a matter other than the

> standard of care if the court determines that the expert is otherwise competent to testify about medical or scientific issues by virtue of education, training or experience.
>
> **(c) Standard of care.—**In addition to the requirements set forth in subsections (a) and (b), an expert testifying as to a physician's standard of care also must meet the following qualifications:
>
> (1) Be substantially familiar with the applicable standard of care for the specific care at issue as of the time of the alleged breach of the standard of care.
>
> (2) Practice in the same subspecialty as the defendant physician or in a subspecialty which has a substantially similar standard of care for the specific care at issue, except as provided in subsection . . . (e).
>
> (3) In the event the defendant physician is certified by an approved board, be board certified by the same or a similar approved board, except as provided in subsection (e).
>
> * * *
>
> **(e) Otherwise adequate training, experience and knowledge.—**A court may waive the same specialty and board certification requirements for an expert testifying as to a standard of care if the court determines that the expert possesses sufficient training, experience and knowledge to provide the testimony as a result of active involvement in or full-time teaching of medicine in the applicable subspecialty or a related field of medicine within the previous five-year time period.

40 P.S. § 1303.512(a)-(c), (e).

"With passage of the MCARE Act, the General Assembly created a more stringent standard for admissibility of medical expert testimony in a medical malpractice action by the imposition of specific additional requirements not present in the common law standard." ***Vicari v. Spiegel***,

989 A.2d 1277, 1280 (Pa. 2010). Those "additional requirements" have been summarized as follows:

> pursuant to Section 512, to testify on a medical matter in a medical malpractice action against a defendant physician, an expert witness must be a **licensed and active**, or a recently retired, **physician**. In addition, in order to render an opinion as to the applicable standard of care, the expert witness must be **substantially familiar** with the **standard of care for the specific care in question**. Furthermore, the expert witness must practice in the **same subspecialty** as the defendant physician, **or** in a subspecialty with a **substantially similar standard of care for the specific care at issue** ("same specialty requirement"). Finally, if the defendant physician is board certified, the expert witness must be **board certified by the same or a similar board** ("same board certification requirement"). Importantly, the expert witness must meet **all** of these statutory requirements in order to be competent to testify. However, there is an **exception** to the same specialty and same board-certification requirements: if a court finds that an expert witness has sufficient **training, experience, and knowledge** to testify as to the applicable standard of care, as a result of **active involvement** in the defendant physician's subspecialty or in a related field of medicine, then the court may waive the same specialty and same board certification requirements.

Id. at 1281 (emphasis in original). The proponent of an expert witness bears the burden of establishing an expert's qualifications under the MCARE Act. ***Weiner v. Fisher***, 871 A.2d 1283, 1290 (Pa. Super. 2005).

Procedurally, Pennsylvania courts have expressed a preference for litigating an expert's qualification under the MCARE Act in motions *in limine*. ***See Anderson v. McAfoos***, 57 A.3d 1141, 1152 (Pa. 2012). That preference comports with the purposes of motions *in limine*, judicial

economy, and fairness to the parties. ***See id.*** at 1149-1152; ***see also id.*** at 1153 (Baer, J., concurring) (discussing policy considerations of defense objections to expert's qualifications under MCARE Act at trial). However, neither the Civil Procedural Rules Committee nor the governing case law have adopted a settled pretrial procedure for objecting or responding to objections to an expert's qualifications under the MCARE Act. ***See id.*** at 1151 (noting a defendant-physician "cannot be faulted for proceeding in accordance with the traditional procedure of testing an expert's qualifications through the *voir dire* process"); ***Vicari***, 989 A.2d at 1284 (noting qualifications of plaintiff's expert regarding related fields of medicine "is likely to require a supporting evidentiary record and questioning of the proffered expert during *voir dire*").

Appellant first claims that Dr. Schrogie possessed sufficient qualifications to testify on causation and opine that "the decedent's death from a pulmonary embolism was related to drug-induced Lupus and kidney failure from Hydralazine." Appellant's Brief at 34. We conclude the trial court's review of the record and its reasoning did not support its ruling to preclude Appellant from offering this evidence.

Section 512(b)(1) requires that a plaintiff's expert "[p]ossess an unrestricted physician's license to practice medicine in any state or the District of Columbia." 40 P.S. § 1303.512(b)(1). The expert must also be "engaged in or retired within the previous five years from active clinical

practice **or** teaching." 40 P.S. § 1303.512(b)(2) (emphasis added). "Teaching," under Section 512(b)(2) need not be a full-time responsibility. ***Weiner*** 871 A.2d at 1289-90. However, "the level of teaching must be sufficient to establish the general requirement of the statute that the witness possesses sufficient education, training, knowledge and experience to provide credible, competent testimony." ***Id.*** at 1290 (citation and punctuation omitted).[8]

Section 512(b) also permits the trial court to "waive" the requirements of Subsection (b)(1) and (b)(2). 40 P.S. § 1303.512(b). Under this exception, the court may permit an expert to testify "on a matter other than the standard of care," if it "determines that the expert is otherwise competent to testify about medical or scientific issues by virtue of education, training or experience." 40 P.S. § 1303.512(b).

[8] We note the MCARE Act does not define the phrase "active clinical practice." ***Cf.*** 40 P.S. § 991.2120 (defining active clinical practice as "[t]he practice of clinical medicine by a health care provider for an average of not less than twenty (20) hours per week"). Moreover, there is a dearth of case law discussing the meaning of the phrase. Our decisions hold that an offer that a physician who sees and treats patients in a hospital setting is sufficient to show he is engaged in "active clinical practice." However, neither this Court nor the Pennsylvania Supreme Court has yet to hold that such activities are necessary conditions to meet the active clinical practice factor. ***But see Amato v. Centre Med. & Surgical Assoc., P.C.***, 2004 WL 1987427, *5 (C.P. Centre Aug. 10, 2004) (ruling that physician's "participation as a mentor, in an informal, 'committee-style' meeting with students for a several hours on two days a week fails to meet the more stringent requirement of an active clinical practice").

Instantly, Dr. Schrogie was a licensed physician and met the first requirement under Section 512(b)(1). ***See*** 40 P.S. § 1303.512(b)(1); ***Vicari***, 989 A.2d at 1281. As to the second requirement under Section 512(b), *i.e.*, "active clinical practice or teaching" within five years of trial, we are constrained to observe that the trial court's rulings and reasoning are inconsistent. The court precluded Dr. Schrogie from testifying regarding causation. Order (Schrogie), at ¶ 2. Yet, the court ruled that his testimony "shall be limited to pharmacology," ***id.*** at ¶ 1, and "determined Dr. Schrogie **practices** as a pharmacologist." Trial Ct. Op. at 8 (emphasis added). To the extent the court regarded Dr. Schrogie as a qualified expert in pharmacology and as a "practicing" and licensed physician, it should have deemed Dr. Schrogie competent to testify against Drs. Burke, Duzy, and Conroy on causation. ***See Vicari***, 989 A.2d at 1281. Furthermore, if the court determined Dr. Schrogie was otherwise competent to render opinions regarding pharmacology, it should have considered whether the exception set forth in Section 512(b) was applicable. Accordingly, the ruling to exclude Dr. Schrogie's opinions regarding causation cannot stand and we vacate that portion of the order without prejudice to parties to litigate this issue on a more developed record.

Appellant's second claim focuses on the trial court's ruling that excluded Dr. Schrogie from testifying regarding the standard of care. We conclude this issue has been waived for the purposes of this appeal.

At the outset, we reiterate that the requirements in Sections 512(a), (b), and (c) are cumulative. ***See Vicari***, 989 A.2d at 1281. To qualify an expert to opine on the standard of care, a plaintiff must establish a record that the expert meets the requirements of Sections 512(a) and (b). ***Id.*** Additionally, a standard-of-care expert must meet the substantial familiarity, same speciality, and same board certification requirements of Section 512(c), or meet the exception set forth in Section 1303.512(e). ***Id.***

Under Section 512(e), the plaintiff bears a burden of establishing that her "expert possesses sufficient, training and knowledge . . . as a result of active involvement in or full-time teaching of medicine in the applicable subspecialty or a related field within the previous five-year time period." 40 P.S. § 1303.512(a)-(c), (e). In ***Vicari***, the Pennsylvania Supreme Court observed

> the "relatedness" of one field of medicine to another for purposes of subsection 512(e) cannot be established in a broad and general sense that will henceforth be applicable to all situations and all claims. Rather, the "relatedness" of one field of medicine to another, under subsection 512(e), can only be assessed with regard to the specific care at issue. Two fields of medicine may be "related" with respect to certain specific issues of care, but unrelated with respect to other specific issues of care. Determining whether one field of medicine is "related" to another with respect to a specific issue of care is likely to require a supporting evidentiary record and questioning of the proffered expert during *voir dire*. This interpretation of "related field of medicine" is most compatible with the text of subsection 512(e) as a whole, which sets forth an exception to the formal same specialty and same board certification rules for experts otherwise qualified to testify.

Vicari, 989 A.2d at 1284. A claim that the trial court erred in refusing to apply the exception in Subsection (e) may be waived by the plaintiff's failure to raise the issue in the trial court or develop a record establishing her right to relief. ***Anderson***, 57 A.3d at 1149. Moreover, "the appealing party bears the burden of establishing that the trial court's decision is erroneous." ***The York Group, Inc. v. Yorktowne Caskets, Inc.***, 924 A.2d 1234, 1246 (Pa. Super. 2007).

Instantly, Appellant preserved her claim she was entitled to the statutory exception. Appellant's Omnibus Mem. in Opp'n to the Appellees' Mot. to Preclude and/or Limit the Expert Test. at 16. In support, she asserted the specific care at issue concerned "individuals conducting clinical research who prescribe a disfavored drug without adequately disclosing its risks, and then fail[ing] to conduct critical testing required by the product's labeling." ***Id.*** However, Appellant merely recited Dr. Schrogie was the Director of the Clinical Research Center at LIMR and argued "it is absurd to claim . . . that the person who presently directs clinical research at Lankenau cannot testify as to the standard of care incumbent upon individuals he presently oversees." ***Id.***

An overlap between Dr. Schrogie's field—pharmacology—and the specific care at issue—the use of hydralazine—may exist. However, the mere reference to Dr. Schrogie's title as a director or teacher at LIMR did not establish he was "active" either "in medicine" or "full-time teaching of

medicine" in "a related field" as required by Section 512(e). Thus, Appellant has not developed a record for this Court to find error in the trial court's ruling. ***See Weiner***, 871 A.2d at 1290 (noting "appellant must provide more than vague pronouncements" to qualify an expert under the MCARE Act, but remanding for further proceedings). Therefore, we decline to disturb this portion of the court's order, but, in light of the procedural uncertainties surrounding the pretrial litigation of an expert's qualification, we do so without prejudice to the parties to develop the record following remand. ***See id.; accord Vicari***, 989 A.2d at 1284.

Appellant's third claim focuses on the ruling precluding her from "introduc[ing] or otherwise rely[ing] upon [Nurse] Molloy's report and testimony." Order (Nurse Molloy). Although we agree with the trial court that Nurse Molloy lacked adequate credentials to testify regarding the standard of care owed by board certified internists and/or cardiologists, we conclude its ruling was overly broad in light of the claims raised by Appellant.

The MCARE Act does not expressly define the phrase "medical matter" used in Section 512(b). ***See*** 40 P.S. § 1303.512(b) ("An expert testifying on a medical matter, including the standard of care, risks and alternatives, causation and the nature and extent of the injury, must meet the following qualifications . . ."). However, the MCARE Act's definitions provide guidance on the meaning of the phrase:

> "Medical professional liability action." Any proceeding in which a medical professional liability claim is asserted, including an action in a court of law or an arbitration proceeding.
>
> "Medical professional liability claim." Any claim seeking the recovery of damages or loss from a health care provider arising out of any tort or breach of contract causing injury or death **resulting from the furnishing of health care services which were or should have been provided**.

40 P.S. § 1303.103 (emphasis added). A "patient," moreover, is defined as "a natural person who receives or should have received health care from a health care provider." ***Id.*** Thus, the phrase "medical matter" relates to the "furnishing of health care services," ***see id.***, which comports with general understandings of the term "medical." See Webster's Ninth Collegiate Dictionary 737 (1987) (defining "medical" as "**1:** of, relating to, or concerned with physicians or the practice of medicine **2:** requiring or devoted to medical treatment.").

Instantly, it is undisputed that Nurse Molloy was not a physician and therefore lacked an unrestricted physician's license as required by Section 512(b)(1). Accordingly, under the MCARE Act, she was not qualified to testify regarding any "medical matter." Thus, we have no basis to disturb the trial court's conclusion that Nurse Molloy could not testify regarding the standards of care owed by physicians to a patient when rendering health care services such as the use of hydralazine.

However, we agree with Appellant that Nurse Molloy offered testimony that did **not** relate to the furnishing of health care services or the practice of medicine. For example, Appellant's claims of informed consent and fraud and misrepresentation have not been dismissed. Moreover, Nurse Molloy intended to testify on the following:

> Failure of the Principal Investigator (PI), Dr. Burke, to provide a satisfactory informed consent document (ICD), as required by 21 CFR Part 50.25. The Investigator is responsible for creating the document and the IRB is responsible for approving it. **The IC was deficient for the following reasons**:
>
> -it failed to adequately disclose side effect of study drugs, specifically hydralazine.
>
> -it failed to describe what is meant by "medical tests."
>
> -it failed to designate Dr. Burke as the Investigator of the study; rather it referred to Dr. Burke as "your doctor" which is misleading to the study candidates.
>
> -it failed to state the names and side effects of other drugs that may be used in the study.
>
> -it failed to identify what "other blood tests" are.
>
> -it failed to identify who will provide for the cost of medical care in the case of study-drug related injury.
>
> -it failed to define National Heart, Lung and Blood Institute as a government agency, rather than a commercial study sponsor.
>
> -it stated that treatment will be "the same as it would be without your being in the study." The word "treatment" cannot be used in a clinical trial ICD. In addition, the assertion that the care would be the same as it would be if the subject were not in the study is speculative and also should not be included in an ICD.

Report of Nurse Molloy, 9/29/10, at 2 (emphasis added).

In our view, the alleged defects in the informed consent document did not pertain to the practice of medicine or the treatment of a patient. Therefore, we vacate the order to the extent it prevented her from testifying about non-medical matters.

Appellant next claims that the trial court erred when it precluded Dr. Schrogie from "repeating the opinions of [Appellant's] other expert, [Dr. Crow.]" Order (Dr. Schrogie), at ¶ 3. We agree with the general principle that an expert witness may not repeat the opinions of another expert. However, we conclude the trial court's determination that Dr. Schrogie could not assert an independent opinion was premature.

The evidentiary principles underlying this claim are well settled.

> [A]n expert may not act as a mere conduit or transmitter of the content of an extrajudicial source.
>
> > An expert should not be permitted simply to repeat another's opinion or data without bringing to bear on it his own expertise and judgment. Obviously, in such a situation, the non-testifying expert is not on the witness stand and truly is unavailable for cross-examination. The applicability of the rule permitting experts to express opinions relying on extrajudicial data depends on the circumstances of the particular case and demands the exercise, like the admission of all expert testimony, of the sound discretion of the trial court. Where the expert uses several sources to arrive at his or her opinion, and has noted the reasonable and ordinary reliance on similar sources by experts in the field, and has coupled this reliance with personal observation, knowledge and

> experience, we conclude that the expert's testimony should be permitted.

Woodard v. Chatterjee, 827 A.2d 433, 444 (Pa. Super. 2003) (citation and punctuation omitted).

In light of these principles, the trial court properly determined that Dr. Schrogie could not testify that he simply agreed with Dr. Crow's description of the "biochemical method by which hydralazine produces this lupus effect." Report of Dr. Schrogie, 9/22/10, at 3. However, the record remains unclear as to whether an expert in clinical pharmacology would ordinarily rely on such opinions as offered by Dr. Crow, a rheumatologist, and whether Dr. Schrogie was able to apply his own knowledge and experience to reach an independent conclusion regarding the alleged role of hydralazine in the decedent's death. Therefore, we decline to disturb this order as it is written, but conclude that the precise scope of the order will require further development of the record regarding Dr. Schrogie's ability to opine independently upon the alleged causal relationships related to hydralazine, Appellee's acts and omissions, and the decedent's death.

Appellant directs her fifth challenge to the trial court's ruling that Dr. Laragh's videotaped deposition was inadmissible due to leading questions posed by Appellant's counsel. We affirm the trial court's order excluding Dr. Laragh's videotaped deposition.

"At the trial, any part or all of a deposition, so far as admissible under the rules of evidence, may be used against any party who was present or

represented at the taking of the deposition or who had notice thereof if required[.]" Pa.R.C.P. 4020(a). "[A] video deposition of a medical witness or any witness called as an expert, other than a party, may be used at trial for any purpose whether or not the witness is available to testify." Pa.R.C.P. 4017.1(g).

It is well settled that "[t]he allowance of leading questions lies within the discretion of the trial court and a court's tolerance or intolerance of leading questions will not be reversed absent an abuse of discretion." ***Katz v. St. Mary Hosp.***, 816 A.2d 1125, 1128 (Pa. Super. 2003). Pennsylvania Rule of Evidence 611 currently states:

> Leading questions should not be used on direct or redirect examination except as necessary to develop the witness's testimony. Ordinarily, the court should allow leading questions:
>
> (1) on cross-examination; and
>
> (2) when a party calls a hostile witness, an adverse party, or a witness identified with an adverse party. A witness so examined should usually be interrogated by all other parties as to whom the witness is not hostile or adverse as if under redirect examination.

Pa.R.E. 611(c) (as amended by orders of Jan. 17, 2013 and Sept. 18, 2014).[9] A leading question is one where the question suggests the answer

[9] The former version of Rule 611(c) is substantially similar:

> Leading questions should not be used on the direct or redirect examination of a witness except as may be necessary to develop the witness' testimony. Ordinarily,

to the witness, such that the "answers are not those of the witness, but of the one who examined him . . . ." ***Buckman v. Phila. & R. Ry. Co.***, 75 A. 1069, 1070 (Pa. 1910); ***accord Commonwealth v. Chambers***, 599 A.2d 630, 640 (Pa. 1991) ("A leading question is one which puts the desired answer in the mouth of the witness.").[10]

A review of the transcript of Dr. Laragh's videotaped deposition reveals that Appellant's counsel presented long, narrative form questions. Although they did not suggest the specific answer to the question ultimately asked, the form of the question "put words in the mouth of the witness." Rather than testifying based on his report, Dr. Laragh was read the pertinent parts of his report by counsel. For example,

> [Appellant's counsel:] Now you say, "It's my assertion that the lowest dose of the original blinded drug would have continued to produce a reasonably—corrected BP in thiš healthy nonsmoking physician. It was worthy goal, after all. The ALLHAT protocols state the therapeutic goal is to achieve blood pressure control on the lowest possible

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> leading questions should be permitted on cross-examination. When a party calls a hostile witness, an adverse party or a witness identified with an adverse party, interrogation may be by leading questions; a witness so examined should usually be interrogated by all other parties as to whom the witness is not hostile or adverse as if under redirect examination.

Pa.R.E. 611(c) (subsequently amended by orders of Jan. 17, 2013 and Sept. 18, 2014).

[10] The parties agreed at the deposition that objections were reserved for trial, and Appellees raised their objection to the leading nature of Appellant's counsel's questions in their motions *in limine*"

dosage of the first-line drug. In first adding the hydralazine to the triple dose of the blinded drug and then doubling the hydralazine dosage, with the investigator's goal of getting the patient's systolic to 85, Dr. Duzy needlessly and incorrectly put his and Dr. Burke's own research goals before the safety of the patient."

So it's your opinion, I take it, Doctor, that this patient never should have been given the hydralazine in the first place, given his blood pressure results?

[Dr. Laragh:] He didn't qualify, according to ALLHAT's guidelines. They had—they skipped a whole drug, because he—the drug—the next drug he was going to get was a beta blocker, and he was afraid he would get impotent. That's what I was told, and it's hearsay. So they skipped the usual routine. You don't have the option, in the ALLHAT trial, to use hydralazine unless you have tried the—usually unless you have tried the beta blocker.

[Appellant's counsel:] You write, "It's also my opinion that Dr. Duzy and Dr. Burke, as principal investigator, violated the ALLHAT protocol by skipping the intended three-step care treatment plan as is described in both the protocol and manual of operations. Hydralazine was an option after the maximum titrated dose of the second-line drug has been tried. Material does not describe altering the steps. The protocol gives the investigator the discretion to choose a second-line drug. Any of the step 2 would have been safer choices, considering hydralazine's—

[Dr. Laragh:] Yeah, that's what I just said.

[Appellant's counsel:] —"intrinsic risks."

[Dr. Laragh:] That's right.

[Appellant's counsel:] "But still, the best clinical choice would have been to reduce the blinded drug by half, considering that this might have corrected the ankle edema."

> So it's your opinion that not only should the hydralazine not have been given, but they overprescribed that level I drug?
>
> [Dr. Laragh:] Yes, they did.
>
> [Appellant's counsel:] And that could have been reduced in half?
>
> [Dr. Laragh:] Sure. Easily. Most people would have done it.

Dep. of Dr. Laragh at 63-65.

Although the above sample represents a small excerpt from the deposition of Dr. Laragh, our review reveals that counsel and Dr. Laragh continually engaged in similar exchanges in which counsel read Dr. Laragh's report into the record. Accordingly, we discern no reversible abuse of discretion in the ruling of the trial court to exclude Dr. Laragh's videotaped deposition.

Appellant's final argument focuses on the ruling of the court to exclude any "evidence or argument" related to the OHRP communications under the PRPA. We agree with Appellant that the trial court did not properly apply the PRPA.

The PRPA provides:

> The proceedings and records of a review committee shall be held in confidence and shall not be subject to discovery or introduction into evidence in any civil action against a professional health care provider arising out of the matters which are the subject of evaluation and review by such committee and no person who was in attendance at a meeting of such committee shall be permitted or required to testify in any such civil action as to any

> evidence or other matters produced or presented during the proceedings of such committee or as to any findings, recommendations, evaluations, opinions or other actions of such committee or any members thereof: Provided, however, That information, documents or records otherwise available from original sources are not to be construed as immune from discovery or use in any such civil action merely because they were presented during proceedings of such committee, nor should any person who testifies before such committee or who is a member of such committee be prevented from testifying as to matters within his knowledge, but the said witness cannot be asked about his testimony before such a committee or opinions formed by him as a result of said committee hearings

63 P.S. § 425.4. The following terms are defined by the statute:

> **"Peer review"** means the procedure for evaluation by professional health care providers of the quality and efficiency of services ordered or performed by other professional health care providers, including practice analysis, inpatient hospital and extended care facility utilization review, medical audit, ambulatory care review, claims review, and the compliance of a hospital, nursing home or convalescent home or other health care facility operated by a professional health care provider with the standards set by an association of health care providers and with applicable laws, rules and regulations.
>
> **"Professional health care provider"** means:
>
> > (1) individuals or organizations who are approved, licensed or otherwise regulated to practice or operate in the health care field under the laws of the Commonwealth . . .
>
> **"Review organization"** means any committee engaging in peer review, including a hospital utilization review committee, a hospital tissue committee, a health insurance review committee, a hospital plan corporation review committee, a professional health service plan review committee, a dental review committee, a physicians' advisory committee, a veterinary review committee, a nursing advisory committee, any committee established

> pursuant to the medical assistance program, and any committee established by one or more State or local professional societies, to gather and review information relating to the care and treatment of patients for the purposes of (i) evaluating and improving the quality of health care rendered; (ii) reducing morbidity or mortality; or (iii) establishing and enforcing guidelines designed to keep within reasonable bounds the cost of health care. It shall also mean any hospital board, committee or individual reviewing the professional qualifications or activities of its medical staff or applicants for admission thereto. It shall also mean a committee of an association of professional health care providers reviewing the operation of hospitals, nursing homes, convalescent homes or other health care facilities.

63 P.S. § 425.2.

This Court has observed

> [t]he PRPA, 63 P.S. § 425.1 et seq., was promulgated to ensure the protection of patients and the general public by maintaining high professional standards in the practice of medicine. In order to foster the free and frank discussions by review organizations, however, the legislature built into the PRPA particular immunity and confidentiality provisions. The official comments to section 425.1 of the PRPA provides that the PRPA is "[a]n Act providing for the increased use of peer review groups by giving protection to individuals and data who report to any review group."

McClennan v. Health Maint. Org., 660 A.2d 97, 100 (Pa. Super. 1995) (citations omitted). The PRPA reflects the policy that "because of the expertise and level of skill required in the practice of medicine, the medical profession itself is in the best position to police its own activities." ***Troescher v. Grody***, 869 A.2d 1014, 1018 (Pa. Super. 2005) (citation omitted). As with any claim of confidentiality or privilege, the party claiming nondisclosure bears the initial burden of demonstrating that a privilege has

been properly invoked. ***T.M. v. Elwyn, Inc.***, 950 A.2d 1050, 1062 (Pa. Super. 2008).

Instantly, we agree with the trial court that the OHRP communications appear to contain the types of information the PRPA intended to hold confidential. However, neither the parties nor the court considered whether the entities involved in the OHRP communications, namely, the decedent's daughter, the OHRP, and LIMR constitute a "review organization" or "peer review" under PRPA.

As to the communication between the decedent's daughter and the OHRP, we discern no basis in the record to conclude that this communication was part of the "the proceedings and records of a peer review committee." and, in any event, were made available through original sources, *i.e.*, the decedent's daughter. With respect to the OHRP's correspondence to LIMR, Appellees failed to adduce any information that the OHRP conducts "peer-review" or is a "review organization" whose findings and determinations were confidential and could not be used at trial.

Lastly, as to LIMR's correspondence to the OHRP, our review reveals that Appellees assert only that LIMR itself was a "review organization" that conducted "peer-review." Lankenau's Brief at 30 ("LIMR is a wholly owned subsidiary of Main Line Hospitals, Inc., and reviews the conduct and procedures of research studies undertaken at The Lankenau Hospital."). Appellant respond that LIMR itself is not a review committee and that the

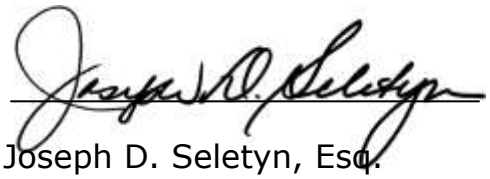
trial court failed to assess whether a committee to conduct "peer review" existed. Appellant's Brief at 52. We agree that the allegation that LIMR is itself a review organization is too vague and broad to sustain the trial court's ruling as it pertains to LIMR's communications. ***See Piroli v. Lodico***, 909 A.2d 846, 850-853 (Pa. Super. 2006). We note, however, that the LIMR correspondence to the OHRP discussed the creation of an "Allegations Committee" to investigate conduct of ALLHAT at LIMR. However, that fact was not developed by the parties, nor addressed by the trial court. Therefore, we vacate the order excluding the OHRP communications based on the PRPA without prejudice to the parties to develop a record on this issue.

In sum, we: (1) vacate that portion of the order that held Dr. Schrogie was unqualified to offer causation testimony; (2) affirm that portion of the order finding Appellant did not establish Dr. Schrogie's qualifications to offer standard-of-care testimony; (3) vacate the order excluding Nurse Molloy's report and testimony; (4) affirm, on a limited basis, the order prohibiting Dr. Schrogie from "repeating the opinions" of another expert; (5) affirm the order excluding Dr. Laragh's videotaped deposition; and (6) vacate the exclusion of the OHRP correspondence based on the PRPA. We emphasize that, we have reviewed the trial court's orders and its specific reasoning in support of its evidentiary rulings. We have not considered the alternative objections raised by Appellees. Our memorandum shall not preclude the

parties from raising their objections or offers of proof on a more complete evidentiary record.

Judgment vacated. Case remanded. Jurisdiction relinquished.

Judgment Entered.



Joseph D. Seletyn, Esq.
Prothonotary

Date: 3/26/2015