Fourth Court of Appeals
San Antonio, Texas

OPINION

No. 04-15-00029-CV

DIAGNOSTIC RESEARCH GROUP and John R. Holcomb, M.D.,
Appellants

v.

Sushma **VORA**,
Appellee

From the 407th Judicial District Court, Bexar County, Texas
Trial Court No. 2013-CI-00357
Honorable Larry Noll, Judge Presiding

Opinion by: Jason Pulliam, Justice
Concurring and Dissenting Opinion by: Patricia O. Alvarez, Justice

Sitting: Karen Angelini, Justice
Patricia O. Alvarez, Justice
Jason Pulliam, Justice

Delivered and Filed: August 19, 2015

AFFIRMED IN PART; REVERSED AND REMANDED IN PART

This is an interlocutory appeal of the trial court's denial of a motion to dismiss filed by Appellants Diagnostic Research Group (DRG) and Dr. John Holcomb. DRG and Dr. Holcomb contend the trial court abused its discretion in denying the motion to dismiss, finding the causes of action asserted against DRG are not health care liability claims under the Texas Medical Liability Act (TMLA). Further, DRG and Dr. Holcomb contend the trial court abused its discretion by denying their challenges to the expert report of Plaintiff Sushma Vora's (Vora) expert, Dr. Amy Mulroy.

Based upon the particular record in this case, we affirm in part and reverse in part the trial court's order denying DRG and Dr. Holcomb's motion to dismiss. We remand for further proceedings consistent with this opinion.

BACKGROUND

This case arises from Vora's participation in the pre-market study of a drug, linaclotide, anticipated to treat irritable bowel syndrome. The drug study was conducted by DRG, with Dr. Holcomb serving as the Principal Investigator. It is undisputed that during her participation in the study, Vora experienced three severe adverse events, each resulting in hospitalization. After the third event, Vora was removed from the pre-market drug study. Vora later suffered seizures and strokes, which she alleges severely disabled her.

Vora filed suit against DRG and Dr. Holcomb asserting causes of action of negligence and gross negligence. In her petition, Vora asserts DRG and Dr. Holcomb departed from accepted standards of medical care "by conducting a study of a dangerous medication and allowing Ms. Vora to receive linaclotide which had serious side effects …." Vora asserts this conduct caused preventable, permanent and debilitating injury.

Although Vora maintains her negligence claims do not fall within the ambit of the TMLA, in the interest of caution, she timely served upon all defendants the expert report and curriculum vitae of Dr. Amy Mulroy, as required by Section 74.351 of the TMLA. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(a)(West Supp. 2014). DRG and Dr. Holcomb timely objected to Dr. Mulroy's report based upon her lack of qualifications to serve as an expert on causation. DRG and Dr. Holcomb also timely filed a motion to dismiss Vora's negligence claims asserting the causes of action are health care liability claims, and as such, Vora was required to timely serve an expert report. Because Vora's expert report did not meet the statutory requirements, DRG and Dr. Holcomb contended the suit should be dismissed.

Following a hearing on the motion to dismiss, the trial court overruled the objections to Dr. Mulroy's expert report and denied DRG and Dr. Holcomb's motion to dismiss. In its denial of their motion to dismiss, the trial court found Vora's suit against Dr. Holcomb asserts health care liability claims; however, Vora's suit against DRG does not assert health care liability claims. Also, the trial court found Dr. Mulroy's expert report was "adequate as to Dr. Holcomb as it puts him on notice of the claims asserted by Plaintiff." DRG and Dr. Holcomb then perfected this interlocutory appeal.

ANALYSIS

Issue One: ***Whether Vora's causes of action asserted against DRG are "Health Care Liability Claims"***

DRG and Dr. Holcomb first contend Vora's negligence causes of action asserted against DRG are health care liability claims pursuant to the TMLA because DRG is a health care provider, and the nature of her claims concern the care and treatment rendered to Vora during her participation in the drug study. DRG and Dr. Holcomb assert DRG satisfies the statutory definition of "health care provider" because DRG is an affiliate of a physician, Dr. Holcomb.

Standard of Review

Ordinarily, an appellate court reviews a trial court's determination of a motion to dismiss for failure to comply with Section 74.351 of the TMLA under an abuse of discretion standard. *San Antonio Extended Med. Care, Inc. v. Vasquez*, 327 S.W.3d 193, 196-97 (Tex. App.—San Antonio 2010, no pet.). However, determination whether a petition asserts a health care liability claim under the TMLA is a question of law, to which we apply a *de novo* standard of review. *Id.*; *Inst. for Women's Health, P.L.L.C. v. Imad*, No. 04–05–00555–CV, 2006 WL 334013, *1 (Tex. App.—San Antonio 2006, no pet.) (mem. op.). "[W]hen making that determination courts should consider the entire court record, including the pleadings, motions and responses, and relevant evidence

properly admitted." *Loaisiga v. Cerda*, 379 S.W.3d 248, 258 (Tex. 2012). In construing a statute, an appellate court must give it the effect the Legislature intended as found in the plain meaning of the statute's text. *Bioderm Skin Care, LLC v. Sok*, 426 S.W.3d 753, 757-58 (Tex. 2014); *Lopez v. Osuna*, 453 S.W.3d 60, 64 (Tex. App.—San Antonio 2014, no pet.).

Applicable Law

A "health care liability claim" is defined as:

> [A] cause of action against a health care provider or physician for treatment, lack of treatment, or other claimed departure from accepted standards of medical care, or health care, or safety or professional or administrative services directly related to health care, which proximately results in injury to or death of a claimant, whether the claimant's claim or cause of action sounds in tort or contract.

TEX. CIV. PRAC. & REM. CODE ANN. § 74.001(a)(13) (West Supp. 2014). Following this statutory definition, a health care liability claim under the TMLA has three elements: (1) the defendant is a health care provider or physician; (2) the essence of the nature of the underlying claim concerns treatment, lack of treatment or other departure from accepted standards of medical care, or health care, or safety or professional or administrative services directly related to health care; and (3) the defendant's alleged act or omission was a proximate cause of the claimant's alleged injury.[1] *Loaisiga*, 379 S.W.3d at 255. The party asserting application of the TMLA carries the burden to show the causes of action asserted are health care liability claims. *Bioderm Skin Care*, 426 S.W.3d at 758; *Brown v. Villegas*, 202 S.W.3d 803, 806 (Tex. App.—San Antonio 2006, no pet.).

With regard to the first definitional element, a health care provider is "any person, partnership, professional association, corporation, facility, or institution duly licensed, certified, registered, or chartered by the State of Texas to provide health care." TEX. CIV. PRAC. & REM.

[1] The parties' dispute in the trial court and on appeal focuses on the first two definitional elements. The parties do not dispute the third element: causation. Therefore, the third element is not discussed.

CODE ANN. § 74.001(a)(12)(A) (West Supp. 2014). The term includes an officer, director, shareholder, member, partner, manager, owner, or affiliate of a health care provider or physician. *See id*. at § 74.001(a)(12)(B)(i).

Following the statutory definition, the crux of classification as a "health care provider" is the initial requirement that the party be licensed or certified to provide health care. *See id*. at § 74.001(a)(12)(A). As the party asserting application of the TMLA, DRG had the burden to present evidence to establish this licensure or certification. *See Bioderm Skin Care*, 426 S.W.3d at 758; *Brown v. Villegas*, 202 S.W.3d at 806. DRG failed to provide any such evidence, however, as the record is silent as to any licensure or certification to provide health care. Without this evidence of licensure or certification, generally, a court cannot determine whether DRG satisfies the statutory definition of "health care provider." *See e.g. Shiloh Treatment Ctr., Inc. v. Ward*, No. 01-14-00626-CV, 2015 WL 1825757, at *4 (Tex. App.—Houston [1st Dist.] 2015, no pet.); *Doctors Data, Inc. v. Stemp*, No. 03-12-00079-CV, 2014 WL 3809742, at *3 (Tex. App.—Austin 2014, pet. denied) (mem. op.); *Brown v. Villegas*, 202 S.W.3d at 806. However, in this factual situation, the analysis need not end with this omission of important evidence because the statutory definition of health care provider goes on to encompass any affiliate of a physician. *See Bioderm Skin Care*, 426 S.W.3d at 758.

The TMLA defines a health care provider to include, *inter alia*, an affiliate of a physician. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 74.001(a)(12)(B)(i); *Bioderm Skin Care*, 426 S.W.3d at 758. The TMLA then defines "affiliate" as "a person who, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with a specified person, including any direct or indirect parent or subsidiary." TEX. CIV. PRAC. & REM. CODE ANN. § 74.001(a)(1). Further, the statute defines "control" as "the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of the person, whether

through ownership of equity or securities, by contract, or otherwise." *Id*. at § 74.001(a)(3). Therefore, if DRG is an affiliate of Dr. Holcomb, then it is a health care provider under the first element of the three-prong test to determine whether the claim against it is a health care liability claim. *Id.* at §§ 74.001(a)(1), 74.001(a)(12)(B)(i); *see Bioderm Skin Care*, 426 S.W.3d at 758-59; *Doctors Data, Inc.*, 2014 WL 3809742, at *3.

DRG attached no evidence to its motion to dismiss and presented no evidence during the hearing on the motion to dismiss.[2] Due to this sparse record, the only facts upon which this court may rely to make any determination regarding whether DRG is an affiliate of Dr. Holcomb are the undisputed facts derived from Vora's petition and the appellate briefs. As stated, no party disputes that Dr. Holcomb is a physician duly licensed in Texas to practice medical care and is employed by DRG. The trial court found Dr. Holcomb to be a physician and found Vora's negligence claims against Dr. Holcomb to be health care liability claims as defined by the TMLA. This holding is not challenged on appeal, and therefore, will be accepted as a given fact. It is also undisputed that Dr. Holcomb, as DRG's employee, was the Principal Investigator of the subject drug study in which Vora participated. Vora's petition states DRG is a Texas Limited Liability Corporation and may be served with process through its registered agent, Charles Andrews.

This limited record contains no evidence that Dr. Holcomb held any ownership of DRG or exercised any control over DRG's management and policies. The limited record contains no evidence of Dr. Holcomb's scope of employment or job description. The undisputed facts provide no basis from which this court could determine whether DRG satisfies the statutory definition of

[2] Although DRG and Dr. Holcomb attach evidence to their appellate brief, this evidence was not presented to the trial court in its determination of the motion to dismiss and objections to Vora's expert report. For this reason this court may not consider the evidence. *See e.g. Crutcher v. Dallas Indep. Sch. Dist.*, 410 S.W.3d 487, 492 (Tex. App.—Dallas 2013, no pet.); *Hendee v. Dewhurst*, 228 S.W.3d 354, 376 (Tex. App.—Austin 2007, pet. denied) (citing *Cincinnati Life Ins. Co. v. Cates*, 927 S.W.2d 623, 626 (Tex. 1996)) (in summary judgment context).

"affiliate" or "control" to determine whether DRG is an affiliate of Dr. Holcomb. TEX. CIV. PRAC. & REM. CODE ANN. § 74.001(a)(3); *but see Bioderm Skin Care*, 426 S.W.3d at 758-59 (record contained evidence Dr. Nguyen was the sole owner of the clinic, possessed power to direct its management and policies and was responsible for its operations.).

Given the sparse record evidence, DRG has failed to show it "was duly licensed, certified, registered, or chartered by the State of Texas to provide health care." *See Shiloh Treatment Ctr., Inc.*, 2015 WL 1825757, at *4; TEX. CIV. PRAC. & REM. CODE ANN. § 74.001(a)(12)(A). Further, given the sparse record evidence, DRG has failed to show that DRG is an affiliate of a physician to otherwise meet the statutory definition of health care provider. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 74.001(a)(12)(B)(i); *Bioderm Skin Care*, 426 S.W.3d at 758. Because there is no evidence, based upon the limited undisputed facts before this court, this court cannot conclude DRG is a health care provider as defined by the TMLA. Because DRG failed to show it is a health care provider, it also cannot show Vora's claims against it are health care liability claims. *See Loaisiga*, 379 S.W.3d at 255. [3]

Based upon this particular record, DRG's first issue is overruled, and we affirm the trial court's order concluding Vora's causes of action asserted against DRG are not health care liability claims under the TMLA.

Issue Two: Dr. Mulroy's Qualifications to Opine on the Issue of Causation

DRG and Dr. Holcomb[4] assert the trial court abused its discretion by denying their motion to dismiss because Dr. Mulroy is not qualified to opine on causation. Without expert opinion on

[3] Because we make this determination, the court will not reach the second prong of the analysis whether Vora's asserted causes of action are health care liability claims: the essence of the nature of the asserted claims.

[4] DRG makes these assertions assuming this court concluded the claims asserted against it are health care liability claims, and therefore, the suit against it falls within the purview of the TMLA. Because we do not conclude the claims asserted against DRG are health care liability claims under the facts and evidence before the court, we address this issue only as it applies to Dr. Holcomb.

causation, Dr. Holcomb contends Vora fails to meet the requirements of the TMLA, and therefore, her claims against him should be dismissed. Specifically, Dr. Holcomb argues Dr. Moyer's report fails to establish she is qualified to testify on the issue of the causal relationship between Dr. Holcomb's decision to prescribe linaclotide and the claimed side effects. Dr. Holcomb argues Dr. Mulroy's report does not "state that she has any experience or training regarding linaclotide or gastrointestinal conditions" and fails to indicate whether Dr. Mulroy has any specific knowledge or experience in assessing the causal relationship between the prolonged use of linaclotide and the alleged side effects and injuries.

Standard of Review

We review a trial court's determination with regard to an expert's qualifications to assert an opinion pursuant to Section 74.351 for an abuse of discretion. *See Am. Transitional Care Ctrs. of Tex., Inc. v. Palacios*, 46 S.W.3d 873, 875 (Tex. 2001). A trial court abuses its discretion if its decision is arbitrary, unreasonable, and without reference to any guiding principles and rules. *Bowie Mem'l Hosp. v. Wright*, 79 S.W.3d 48, 52 (Tex. 2002) (per curiam). Under this standard, when reviewing factual matters committed to a trial court's discretion, an appellate court may not substitute its own judgment for the trial court's judgment. *Gray v. CHCA Bayshore L.P.*, 189 S.W.3d 855, 858 (Tex. App.—Houston [1st Dist.] 2006, no pet.). Merely because a trial court may decide a matter within its discretion in a different manner than an appellate court would in a similar circumstance does not demonstrate that an abuse of discretion has occurred. *Davisson v. Nicholson*, 310 S.W.3d 543, 548 (Tex. App.—Fort Worth 2010, no pet.). A trial court does not abuse its discretion if it commits a mere error in judgment. *See E.I. du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, 558 (Tex. 1995).

Applicable Law

In determining whether the report constitutes a good faith effort to comply with the statutory requirements, the trial court's inquiry is limited to "the four corners" of the report. *Palacios*, 46 S.W.3d at 878; *Mem'l Hermann Healthcare Sys. v. Burrell*, 230 S.W.3d 755, 758 (Tex. App.—Houston [14th Dist.] 2007, no pet.); *Gray*, 189 S.W.3d at 859. Thus, an expert's qualifications cannot be inferred, but must be present in the expert report and the curriculum vitae. *See Olveda v. Supulveda*, 141 S.W.3d 679, 683 (Tex. App.—San Antonio 2004, pet. denied). Should a plaintiff fail to establish the purported expert's qualifications to submit the report, it is deficient and does not comply with Section 74.351. *Collini v. Pustejovsky*, 280 S.W.3d 456, 464-66 (Tex. App.—Fort Worth 2009, no pet.); *see* TEX. CIV. PRAC. & REM. CODE ANN. §§ 74.351(l), (r)(5)-(6) (West Supp. 2014).

A person is qualified to give opinion testimony concerning the causal relationship between the alleged injury and the alleged departure from the applicable standard of care only if the person is a physician and is otherwise qualified to render opinions on that causal relationship under the Texas Rules of Evidence. *See* TEX. CIV. PRAC. & REM. CODE ANN. §§ 74.351(r)(5)(C) (West Supp. 2014), 74.403(a) (West 2011). To be so qualified under the Texas Rules of Evidence, an expert must have "knowledge, skill, experience, training, or education" regarding the specific issue before the court. TEX. R. EVID. 702 (West 2014); *Broders v. Heise*, 924 S.W.2d 148, 153 (Tex. 1996). Sections 74.351 and 74.403(a) do not require that the physician serving as an expert be a practitioner in the same medical specialty as the defendant. Accordingly, the proper inquiry concerning whether a doctor is qualified to testify regarding causation is not the doctor's area of practice or expertise, but rather the doctor's familiarity with the issues involved in the factual claim before the court. *Roberts v. Williamson*, 111 S.W.3d 113, 121 (Tex. 2003); *Collini*, 280 S.W.3d at 464; *Blan v. Ali*, 7 S.W.3d 741, 745 (Tex. App.—Houston [14th Dist.] 1999, no pet.). "A

physician who is not of the same school of medicine may be competent [to testify as to causation] if he has practical knowledge of what is usually and customarily done by a practitioner under circumstances similar to those confronting the defendant." *Estorque v. Schafer*, 302 S.W.3d 19, 26 (Tex. App.—Fort Worth 2009, no pet.); *see also Ehrlich v. Miles*, 144 S.W.3d 620, 625 (Tex. App.—Fort Worth 2004, pet. denied).

Analysis

Following these guidelines, to establish Dr. Mulroy's qualifications to opine on causation, Vora was required to demonstrate Dr. Mulroy's knowledge, skill, experience, training, or education that would qualify her to opine regarding the *specific issues* raised in Vora's petition. *See Roberts*, 111 S.W.3d at 120-21; *Ehrlich*, 144 S.W.3d at 625. Vora's original petition states Dr. Holcomb was "negligent in conducting a study of a dangerous medication and allowing Ms. Vora to receive Linaclotide which had serious side effects including, but not limited to, bowel obstructions, seizure and stroke." Vora contends Dr. Holcomb's acts and omissions caused her asserted injuries.

Thus, the issues involved in the factual claim before the court are Dr. Holcomb's conduct in facilitating a drug study and Dr. Holcomb's continued prescription of linaclotide to Vora after she exhibited side-effect symptoms while participating in the study. Based upon the allegation in the petition, the specialized branches of internal medicine or gastroenterology are not implicated by Dr. Holcomb's alleged negligence in conducting the drug study or continuing to prescribe linaclotide, nor is experience with linaclotide or knowledge of its side effects implicated. Rather, the factual issues raised in Vora's petition pertain to a doctor's standard of care in conducting a study of an experimental drug and in continuing a person in a drug study after exhibition of potential side effects. Thus, Vora must demonstrate Dr. Mulroy's knowledge, skill, experience,

training, or education in the field of conducting a drug study of an experimental drug and in treatment of a participant should potential side-effect symptoms arise.[5]

Dr. Mulroy's curriculum vitae shows she has been a licensed physician in the State of Texas since 1994 and has been board certified in psychiatry and neurology since 1998. Dr. Mulroy is a practicing adult psychiatrist, and outside of her private practice, Dr. Mulroy served as a Principle Investigator for at least 45 pre-market drug studies from 2003 to 2012. These pre-market studies included "open label studies", as in this case, as well as "double blind studies." The majority of these drug studies in which Dr. Mulroy served as the Principal Investigator involved medication used primarily in the practice of psychiatry; however, many involved medication relevant to other medical fields. Through this experience as a Principal Investigator, Dr. Mulroy states she has an understanding of, and is qualified to testify to, the responsibilities and standards required of a physician conducting a study of an experimental drug. Dr. Mulroy states these responsibilities and standards in conducting a drug study are the same regardless of the condition and/or symptoms the experimental medication is used to treat.

Based upon independent review of Dr. Mulroy's curriculum vitae and expert report, we conclude the trial court did not abuse its discretion in finding Dr. Mulroy's credentials and experience provide adequate qualifications to express an expert opinion on causation under these facts. The relevant inquiry under these facts is whether Dr. Mulroy's experience in conducting pre-market drug studies provides sufficient familiarity with the presented issues whether Dr. Holcomb acted pursuant to the standard of care in conducting the subject drug study and whether

[5] Although Dr. Holcomb asserts the factual issues before the court are "the causal relationship between the prolonged use of linaclotide and the alleged side effects and injuries", this is a mischaracterization of the allegations in the original petition against Dr. Holcomb. This characterization pertains to the strict product liability claim asserted against the drug manufacturer. Dr. Holcomb also argues Dr. Mulroy's report does not "state that she has any experience or training regarding linaclotide or gastrointestinal conditions" and fails to indicate whether Dr. Mulroy has any specific knowledge or experience in assessing the causal relationship between the prolonged use of linaclotide and the alleged side effects and injuries; however, this is a mischaracterization of the required specialization.

Vora's continuation in the study after her hospitalizations caused her alleged injuries. Dr. Mulroy exhibits extensive experience as a Principal Investigator in these numerous studies of experimental medication, the same position held by Dr. Holcomb. Dr. Mulroy's practice as a Principal Investigator in a drug study provides sufficient knowledge, experience and training for the trial court to conclude she possesses sufficient qualifications to opine on the causal link between Vora's alleged injuries and Dr. Holcomb's alleged acts or omissions in allowing Vora to continue participating in the drug study following two hospitalizations. Based upon this review of Dr. Mulroys curriculum vitae and report, the trial court's conclusion is not arbitrary, unreasonable, and without reference to any guiding principles and rules.

For this reason, we conclude the trial court did not abuse its discretion in finding Dr. Mulroy qualified to opine on causation, and thus, overruling Dr. Holcomb's objections to Dr. Mulroy's expert report. Dr. Holcomb's second issue is overruled, and the trial court's order is affirmed in part in this respect.

Issue Three: Sufficiency of Dr. Mulroy's Expert Report on Causation

Dr. Holcomb argues the trial court abused its discretion in denying his motion to dismiss because Dr. Mulroy's expert report is merely conclusory on the issue of causation, and therefore, does not constitute a good faith effort to comply with the statutory expert report requirement of Section 74.351. Dr. Holcomb contends Dr. Mulroy's report contains only a series of repetitious, conclusory statements regarding causation and does not provide the necessary medical detail and explanation of the causal relationship between Dr. Holcomb's prescription of linaclotide and Vora's alleged injury.

Standard of Review

Again, we review a trial court's denial of a motion to dismiss pertaining to an expert's report served pursuant to Section 74.351 for an abuse of discretion. *See Palacios*, 46 S.W.3d at

875. A trial court abuses its discretion if its decision is arbitrary, unreasonable, and without reference to any guiding principles and rules. *Bowie Mem'l Hosp.*, 79 S.W.3d at 52.

Applicable Law

Pursuant to Section 74.351, a plaintiff who brings a health care liability claim must serve on the defendant an expert report that addresses standard of care, liability and causation no later than the 120th day after the claim is filed. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(r)(6) (West Supp. 2014); *HEB Grocery Co., L.L.P. v. Farenik,* 243 S.W.3d 171, 173 (Tex. App.—San Antonio 2007, no pet.). If an expert report has not been served on a defendant within the 120–day period, then on the motion of the affected defendant, the trial court must dismiss the claim with prejudice and award the defendant reasonable attorney's fees and costs. TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(b); *Barber*, 303 S.W.3d at 790-91. A report has not been served under the statute if it is found to be deficient. *Lewis v. Funderburk,* 253 S.W.3d 204, 207-08 (Tex. 2008); *Barber*, 303 S.W.3d at 790-91. In such instance, the trial court has discretion to grant one thirty-day extension to allow the plaintiff the opportunity to cure the deficiency. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(c); *Barber*, 303 S.W.3d at 790-91. If the deficiency is not cured or cannot be cured, the case must be dismissed. *Id.* § 74.351(b)(2).

A report is deficient if it does not represent an objective good faith effort to comply with the definition of an expert report. TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(l); *Barber*, 303 S.W.3d at 791. To qualify as a good faith effort, the report must "discuss the standard of care, breach, and causation with sufficient specificity to inform the defendant of the conduct the plaintiff has called into question and to provide a basis for the trial court to conclude that the claims have merit." TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(r)(6); *Palacios*, 46 S.W.3d at 878; *Barber*, 303 S.W.3d at 791. A report does not fulfill this requirement if it merely states the expert's

conclusions or if it omits any of the statutory requirements. *Palacios*, 46 S.W.3d at 879; *Barber*, 303 S.W.3d at 790-91.

When reviewing the adequacy of a report, the only information relevant to the inquiry is the information contained within the four corners of the document alone. *Palacios*, 46 S.W.3d at 878; *Barber*, 303 S.W.3d at 790-91. This requirement precludes a court from filling gaps in a report by drawing inferences or guessing as to what the expert likely meant or intended. *Barber*, 303 S.W.3d at 790-91; *see Austin Heart, P.A. v. Webb*, 228 S.W.3d 276, 279 (Tex. App.—Austin 2007, no pet.) (citing *Bowie Mem'l Hosp.*, 79 S.W.3d at 53).

Although the report need not marshal all of a plaintiff's proof, it must do more than merely state conclusions; rather, it must explain the basis for the expert's causation opinions by linking the expert's conclusions to the relevant facts. *Palacios*, 46 S.W.3d at 878-79; *Bogar v. Esparza*, 257 S.W.3d 354, 364 (Tex. App.—Austin 2008, no pet.). Thus, to satisfy the statutory purpose with regard to causation, an expert report must provide a fair summary of the expert's opinions on the causal relationship between a breach in the standard of care and the alleged harm with enough specificity to allow the trial court to conclude the plaintiff's claims have merit. *Palacios*, 46 S.W.3d at 878-79; TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(r)(6). The report must explain how any breach in the standard of care caused the alleged injury. *Jones v. King*, 255 S.W.3d 156, 160 (Tex. App.—San Antonio 2008, no pet.).

Application

Dr. Mulroy states in her report that Dr. Holcomb "breached the standard of care and that as a result of this breach Ms. Vora was hospitalized for a third time while participating in the study. Ms. Vora's third hospitalization and the pain and suffering related thereto would have been wholly prevented if Dr. Holcomb … had withdrawn Ms. Vora from the study after her first two hospitalizations …." To reach this conclusion, Dr. Mulroy began by explaining the standard of

care of a Principal Investigator of a drug study. The first responsibility is to monitor a participant for "severe adverse events." If one occurs, the second responsibility is to re-assess the safety of the participant, the appropriateness of the participant's continued involvement in the study and the integrity of the study. Dr. Mulroy explained that upon the occurrence of more than one severe adverse event, such as hospitalization, the Principal Investigator must "highly question the appropriateness of that patient in the study" and "hospitalization for a potential side effect … is enough to warrant a decision to remove the patient from the study." Finally, Dr. Mulroy opines that after the first hospitalization, Dr. Holcomb had a duty to closely monitor and communicate with Vora; however, Dr. Holcomb failed to do so, and therefore, was not aware of Vora's second hospitalization. Dr. Mulroy opines, then, under the standard of care of a doctor conducting a drug study, discovery of the second hospitalization would have required Dr. Holcomb to remove Vora from the study. Because Dr. Holcomb did not discover the second hospitalization, and therefore, did not remove Vora from the study, Dr. Mulroy opines Vora continued to ingest a drug that presented dangerous side effects to her. Dr. Mulroy concludes that if Dr. Holcomb had removed Vora from the study, she would not have continued this use of linaclotide. Based upon this premise, Dr. Mulroy concluded "the proximate cause of the third hospitalization was the continued use of linaclotide. The third hospitalization was for a distended abdomen and vomiting, which was a known risk of the drug. Therefore, it was foreseeable that the continued use of the drug could cause distended abdomen and vomiting. Ms. Vora had already been hospitalized twice for similar injuries while taking the drug, making it foreseeable that continued use of the drug would result in distended abdomen and vomiting."

Upon review of Dr. Mulroy's expert report, we conclude the report is conclusory with regard to causation. Dr. Mulroy adequately explained the standard of care of a Principal Investigator of an experimental drug study, explained how Dr. Holcomb breached the standard of

care and explained how Dr. Holcomb should have acted under these facts. However, Dr. Mulroy failed to provide sufficient facts to support her opinion that Dr. Holcomb's failure to comply with the standard of care, i.e. failing to monitor Vora closely after the first hospitalization and failing to remove Vora from participation in the study following the second hospitalization, caused Vora's third hospitalization and other alleged resulting injuries. The report fails to set forth a specific link between Dr. Holcomb's alleged omissions with Vora's alleged injuries and fails to discuss the factual basis of her opinion that Vora's continued ingestion of linaclotide caused Vora's third hospitalization. Particularly, Dr. Mulroy fails to state she reviewed Vora's medical records pertaining to her hospitalizations. Dr. Mulroy's report does not provide a fair summary of her opinions on the causal relationship between the asserted breach in the standard of care and the alleged harm with enough specificity to allow the trial court to conclude Vora's claims have merit and to adequately inform Dr. Holcomb of the specific conduct that Vora calls into question. For these reasons, Dr. Mulroy's expert report is deficient.

Accordingly, we conclude the trial court abused its discretion by denying Dr. Holcomb's motion to dismiss based upon insufficiency of Dr. Mulroy's expert report on the element of causation. Dr. Holcomb's third issue is sustained.

Although Dr. Holcomb contends the proper resolution is to render a judgment dismissing Vora's claims against him, the Texas Supreme Court has held that should a court of appeals conclude an expert report is deficient in a manner that can be cured, Section 74.351 permits one thirty-day extension to cure the specified deficiency. *Leland v. Brandal*, 257 S.W.3d 204, 207 (Tex. 2008); *Collini*, 280 S.W.3d at 468. Accordingly, the trial court should have an opportunity to consider granting Vora an extension to cure the deficiencies detailed in this opinion.

CONCLUSION

Based upon the foregoing reasons and based upon the limited appellate record, we affirm in part and reverse in part the trial court's order denying DRG and Dr. Holcomb's motion to dismiss. We remand for further proceedings consistent with this opinion.

Jason Pulliam, Justice