# Fourth Court of Appeals
## San Antonio, Texas

## CONCURRING AND DISSENTING 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

I agree with the majority's opinion that Dr. Amy Mulroy is qualified. I also concur in the majority's conclusion that Appellee Sushma Vora's negligence causes of action asserted against Appellants Diagnostic Research Group are not health care liability claims pursuant to the TMLA.

The majority also concludes DRG failed to show it was duly licensed, certified, registered, or chartered by the State of Texas to provide health care. I agree. I do not agree, however, with the majority's blanket conclusion that because DRG (1) failed to show it was "duly licensed, certified, registered, or chartered by the State of Texas to provide health care," and (2) failed to show that it was an affiliate of a physician who otherwise met the statutory definition of health

care provider, it cannot prove Ms. Vora's claims are health care liability claims under the TMLA. I believe there is more to this analysis than the majority's opinion suggests. *See, e.g., The Fredericksburg Care Co. v. Perez*, 461 S.W.3d 513, 522 (Tex. 2015) (making it "abundantly clear that the TMLA and its predecessor were enacted for the purpose of making health care more affordable in Texas" by "reducing the cost of health care liability claims.").

Finally, I respectfully disagree with the majority opinion's determination on the sufficiency of Dr. Mulroy's report with regard to Dr. John Holcomb, the study's principal investigator. I would affirm the trial court's denial of the motion to dismiss pursuant to section 74.351 of the Texas Civil Practices and Remedies Code. TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(r)(6). Accordingly, I dissent as follows to the majority's conclusion that Dr. Mulroy's report does not meet the statutory requirements on causation.

## SUFFICIENCY OF EXPERT REPORT

I disagree with the majority's conclusion that 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.

### A. Section 74.351 Expert Report Requirement

An expert report under section 74.351 "must provide a fair summary of the expert's opinions as of the date of the report regarding the applicable standards of care, how the health care provider failed to meet the standards, and the causal relationship between that failure and the injury, harm, or damages claimed." *Legend Oaks-South San Antonio, LLC v. Molina ex rel. Rocamontes*, No. 04-14-00289-CV, 2015 WL 693225, at *5 (Tex. App.—San Antonio Feb. 18, 2015, no pet.) (mem. op., not designated for publication) (citing TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(r)(6)). Conclusory opinions on causation are not sufficient. *Jelinek v. Casas*, 328

S.W.3d 526, 539 (Tex. 2010). "However, because one of the purposes of the expert report requirement is to provide a basis for the trial court to conclude the claims have merit, the expert report needs to meet the statutory requirements only as to one liability theory." *Legend Oaks-South San Antonio*, 2015 WL 693225, at *5 (citing *Certified EMS, Inc. v. Potts*, 392 S.W.3d 625, 630–31 (Tex. 2013)). "If the expert [report] shows that at least one of the alleged theories of liability has expert support, the claim is not frivolous and the entire case should move forward." *Id.* (citing *Nexion Health at Duncanville, Inc. v. Ross*, 374 S.W.3d 619, 626 (Tex. App.—Dallas 2012, pet. denied) (holding report need not be sufficient as to, or even address, each specific act of negligence pleaded in order to satisfy expert report requirement)). "The claimant is not required to present evidence in the report as if he were actually litigating the merits." *Id.* (citing *Am. Transitional Care Ctrs. of Tex., Inc. v. Palacios*, 46 S.W.3d 873, 879 (Tex. 2001)). "And the report may be informal in that the information in the report does not need to meet the same requirements as the evidence offered in a summary judgment proceeding or trial." *Id.* (citing *Palacios*, 46 S.W.3d at 879). "If the report satisfies these requirements as to any one theory of liability, the claimant is entitled to proceed with the suit against the health care provider and the motion to dismiss should be denied." *Id.* (citing *Certified EMS*, 392 S.W.3d at 630).

**B. Dr. Amy Mulroy's Report**

Because I join with the majority holding that Ms. Vora's causes of action are not health care claims under the TMLA, my discussion of Dr. Mulroy's report is limited to (1) the standard of care owed by Dr. Holcomb, (2) Dr. Holcomb's breach of that standard of care, and (3) the causal relationship between Ms. Vora's injuries and Dr. Holcomb's breach.[1]

[1] Because I also agree with the majority's conclusion the trial court did not abuse its discretion in finding Dr. Mulroy was qualified to opine on the causal link between Ms. Vora's injuries and Dr. Holcomb's alleged breach of the standard of care, I do not address Dr. Mulroy's qualifications.

*1. Standard of Care*

According to Dr. Mulroy, "[t]he standards required of a physician conducting studies of experimental medications are the same regardless of what condition and/or symptoms the drug is being used to treat." She continues "[o]ne of the primary duties of a principal investigator, a study sponsor and studying facility is to monitor the participant for 'severe adverse events.'" Severe adverse events, or SAEs, include significant medical problems or outcomes occurring during the study, including hospitalizations. "If a patient reports an SAE, the standard of care requires the principal investigator to assess the symptoms, severity, and outcome to the patient as well as if the patient continues to meet requirements that make him or her an appropriate candidate for research." The investigator assesses the safety of the patient and integrity of the study protocol.

If the investigator ultimately determines a patient may be retained in the study, "it is paramount [for the investigator] to closely monitor the patient for the reason the SAE occurred and for any other reason that suggest that the patient I not an appropriate candidate for a research study." Ultimately, the investigator must (1) assess the patient to determine whether the patient should be removed from the study and/or (2) very closely monitor the patient thereafter. If, at any time during the study, "the investigator determines that a patient cannot meet the requirements of the protocol or is no longer an appropriate candidate for a research study then it is his/her duty to remove that patient from the study." Dr. Mulroy warns that when a patient suffers more than one SAE during any given study, "it is paramount for the investigator to highly question the appropriateness of that patient to the study."

*2. Breach of Duty*

According to Dr. Mulroy, the documentation reveals that on February 23, 2011, Ms. Vora reported being hospitalized in January of 2011. This hospitalization qualified as an SAE. The

initial doctor notations indicated Ms. Vora was hospitalized for pneumonia, however Dr. Holcomb changed the diagnosis to ileus, "a bowel condition related to the side effects of linaclotide." The study's sponsor reviewed Dr. Holcomb's report and "blessed the decision for Ms. Vora to continue in the study."

Dr. Mulroy opines this was a breach of the standard of care. Because ileus is a potential side effect of the study medication, and Ms. Vora was hospitalized for this side effect, she should have been removed from the study. She was not; and instead, Ms. Vora was ultimately hospitalized two more times for the very side effects being studied.[2] Additionally, when the determination was made to allow Ms. Vora to remain in the study, the "investigator had a duty to very closely monitor Ms. Vora." Clearly this did not happen. Ms. Vora was hospitalized again in March of 2011—a second SAE. This SAE apparently went undetected by the investigator. It was not until May 23, 2011, when Ms. Vora suffered her third SAE that Dr. Holcomb knew of her continued problems. Dr. Holcomb's failure to sufficiently monitor Ms. Vora allowed a two-month time period to pass between the second SAE and the team's knowledge of such.

*3. Proximate Cause*

Dr. Mulroy opines that had Ms. Vora been closely monitored after her first SAE, the investigator would have learned of her second SAE, "which would have required him, the study sponsor and the studying facility to remove [Ms. Vora] from the study following the second related SAE." Dr. Holcomb's failure to closely monitor Ms. Vora fell below the standard of care owed to Ms. Vora and the "third hospitalization and the pain and suffering related thereto would have been wholly prevented." Dr. Mulroy contends that "the third SAE was wholly preventable and should

[2] I acknowledge that Ms. Vora's failure to notify Dr. Holcomb of her second hospitalization may be an issue of contributory negligence at trial, but it is not a question for review on the sufficiency of the expert report under section 74.351. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(r)(6).

never have happened. Ms. Vora should have been removed from the study no later than March 2011 when the second SAE occurred. If this had been done, then the May 2011 SAE would have been prevented."

Dr. Mulroy avers that Dr. Holcomb, as principal investigator for the open label study of the drug linoclotide,

> breached the standard of care by allowing Ms. Vora to continue in the study of linaclotide after not one but two severe adverse events—the January and March 2011 hospitalizations. If Dr. Holcomb had timely removed her from the study, the third severe adverse event—the May 2011 hospitalization for which Ms. Vora was removed from the study would not have occurred.

Finally, Dr. Mulroy concludes the proximate cause of Ms. Vora's third hospitalization was the continued use of linaclotide, and it was foreseeable the continued use of the drug would cause the second and third SAE. But for Dr. Holcomb's failure to monitor Ms. Vora and discontinue the linaclotide following the second SAE, "in reasonable medical probability, Ms. Vora would not have suffered the [symptoms], or the associated hospitalization and pain and suffering."

**C. Conclusion**

Dr. Mulroy's report ties the standard of care to the linaclotide study. The report indicates Ms. Vora had three SAEs. After failing to remove Ms. Vora from the study following the first SAE, and then subsequently failing to closely monitor and observe her, Dr. Holcomb breached the standard of care owed to Ms. Vora. This breach resulted in Ms. Vora being hospitalized for a third time while participating in the study.

Contrary to the majority's conclusion, I believe Dr. Mulroy's opinion represents a good faith effort to provide a fair summary of her opinions regarding the applicable standards of care, the manner in which Dr. Holcomb failed to meet those standards, and the causal relationship

between the failure and the harm claimed. TEX. CIV. PRAC. & REM. CODE ANN. § 74.351 (1), (r)(6); *see Bowie Mem'l Hosp. v. Wright*, 79 S.W.3d 48, 51–52 (Tex. 2002) (per curiam). Dr. Mulroy's report constitutes a good faith effort to link the breach of duty to the third SAE and provides enough detail to inform Dr. Holcomb of the specific conduct being questioned, i.e. fair notice of the complaints being raised and sufficient detail upon which the trial court may conclude the claim has merit. *See Jelinek*, 328 S.W.3d at 539; *see also Palacios*, 46 S.W.3d at 879.

Chapter 74 does not require Dr. Mulroy's report to present evidence sufficient for litigation purposes. *See Palacios*, 46 S.W.3d at 879. The trial court could have reasonably concluded that Dr. Mulroy's report satisfied the expert report requirements on Dr. Holcomb's determination to allow Ms. Vora to continue in the study and, following that determination, his failure to closely monitor Ms. Vora and discontinue the linaclotide following the second SAE, resulted in Ms. Vora's third SAE, the hospitalization, and the pain and suffering.

For these reasons, I believe the trial court did not abuse its discretion and I would affirm its denial of Dr. Holcomb's motion to dismiss the complaint under the TMLA.

Patricia O. Alvarez, Justice