Opinion issued November 19, 2020

In The

Court of Appeals

For The

First District of Texas

NO. 01-20-00146-CV

TEXAS CHILDREN'S HOSPITAL, Appellant

V.

AVIV BARR AND ELA BARR, INDIVIDALLY AND AS NEXT FRIENDS OF M.B., A MINOR CHILD, Appellees

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On Appeal from the 189th District Court
Harris County, Texas
Trial Court Case No. 2019-12365

MEMORANDUM OPINION

Appellees, Aviv Barr and Ela Barr, individually and as next friends of M.B., a minor child, sued Texas Children's Hospital (TCH) and others for negligence in

connection with a brain surgery performed on M.B.[1] After several objections and subsequent amendments to the Barrs' expert report, TCH moved to dismiss the Barrs' claims, arguing that their amended expert report was insufficient as to causation. The trial court denied the motion to dismiss. In its sole issue, TCH argues that the trial court abused its discretion in denying TCH's objections to the amended expert report and motion to dismiss. Because we conclude that the expert affidavit was sufficient, we affirm.

Background

The Barrs' minor daughter, M.B., underwent a minimally-invasive brain surgery to treat her epilepsy at TCH in Houston.[2] On July 20, 2018, Dr. Daniel Curry performed the surgery at TCH using the NeuroBlate system, which is an MRI-guided[3] laser ablation device that had been subject to a recall by the Food and Drug Administration (FDA), prior to M.B.'s surgery, in October 2017. M.B. was discharged from TCH on July 22, 2018, but she later experienced symptoms such as

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1 The Barrs also sued Dr. Daniel Curry, the surgeon, and Monteris, the manufacturer of the ablation laser that allegedly malfunctioned, but they are not parties to this appeal.

2 We accept the facts included in Dr. Avellino's report for the limited purpose of this appeal. *See Marino v. Wilkins*, 393 S.W.3d 318, 320 n.1 (Tex. App.—Houston [1st Dist.] 2012, pet. denied); *see also Bowie Mem'l Hosp. v. Wright*, 79 S.W.3d 48, 53 (Tex. 2002) (review of Chapter 74 report is limited to four corners of report).

3 The NeuroBlate system used Magnetic Resonance Imaging to guide the surgeon's use of the laser probe.

dizziness, vomiting, and loss of consciousness and was admitted to St. Mary's Medical Center in Florida for further treatment. Doctors at St. Mary's concluded that M.B. had a ruptured pseudoaneurysm and treated her with additional surgery, and M.B. was then moved to a hospital in Tel Aviv, Israel for further rehabilitation. The Barrs allege that M.B. has suffered permanent brain damage.

The Barrs filed suit against TCH, Dr. Curry, and Monteris, the manufacturer of the NeuroBlate system. The Barrs alleged product-liability claims against Monteris, and they alleged that Dr. Curry was negligent in several ways, including that he failed to disclose to the Barrs that the NeuroBlate system had been recalled by the FDA when he obtained their consent for the surgery and that he failed to order vascular studies after M.B. first experienced a brain bleed during her surgery in July 2018 that would have identified the pseudoaneurysm before its rupture. Finally, the Barrs alleged that TCH was negligent in permitting Dr. Curry to use its recalled NeuroBlate laser probe to perform M.B.'s surgery. The Barrs supported their pleadings with the expert report of Dr. Anthony Avellino, a pediatric and adult neurosurgeon.[4]

Dr. Avellino's report, as amended to address deficiencies pointed out by TCH, provided details regarding the FDA's recall of the NeuroBlate laser probe. Dr.

[4] The Barrs also provided an additional expert report from an engineer regarding the malfunctioning of the laser probe, but that report is not relevant to this appeal.

Avellino stated in his report that this recall was due to "unexpected heating and probe damage, which 'could cause unanticipated heating of surrounding brain tissue, or damage the tip of the probe, and allow the CO2 cooling gas inside the probe to leak into the brain.'" He stated that, on October 5, 2017, the device was the subject of a Class I recall by the FDA, which recommended that health care providers "should strongly consider treating patients using alternative procedures if available." He also indicated that a Class I recall meant "by definition [the malfunctioning device] can cause death or serious injury." Monteris likewise sent notices to healthcare providers between October and December 2017 about the unintentional heating and advised doctors to "take certain precautionary steps to mitigate the risk to patients, including limiting MRI scans while the probe is in the patient." However, on March 22, 2018, the FDA subsequently provided a "Safety Alert," informing health care providers that the steps recommended by Monteris were "not sufficient to mitigate the risk of unintended laser probe heating."

On April 24, 2018, the FDA warned health care providers "that the MR thermometry, which is used to monitor the changes in temperature at the laser ablation site, was potentially inaccurate and may not account for continued spread of energy to the surrounding brain tissue." Dr. Avellino further stated that the FDA stated in its notice that several adverse events were associated with use of the NeuroBlate system: "neurological deficits, increased intracerebral edema or

pressure, intracranial bleeding, and/or visual changes." Monteris continued to work on designing a new laser probe for the NeuroBlate system that replaced the metal thermocouple with a new, non-metallic fiber optic sensor, "thus eliminating any risk of unintended probe heating." This design was submitted to the FDA on July 30, 2018, ten days after M.B.'s surgery. On November 8, 2018, the FDA notified healthcare providers that Monteris had received FDA clearance for the new probe and stated that the safety risks associated with the old probe remained.

Regarding M.B.'s surgery specifically, Dr. Avellino reviewed M.B.'s medical records from TCH and noted that "[p]ostoperative head CT imaging on 7/21/2018 revealed a small amount of acute hemorrhage at the lesion site, intraventricular hemorrhage, and subarachnoid hemorrhage in the ambient cistern with an abnormal irregular rounded shaped focal lesion lateral to the ambient cistern suspicious for an aneurysm." He noted that, despite this head CT, "the cranial vasculature was not evaluated with a head CT angiogram to rule out an aneurysm and no explanation was given for the hemorrhages outside the lesion bed." Rather, Dr. Curry relied on imaging that showed the bleeding appeared to be resolving, and M.B. was discharged. She later sought further treatment at St. Mary's Medical Center after she "became comatose."

When M.B. was admitted to St. Mary's on August 7, 2018, "head CT imaging showed a large acute right temporal intracerebral hematoma with diffuse

intraventricular hemorrhage, acute hydrocephalus, and uncal herniation." She underwent emergency surgery to reduce the swelling in her brain, and further imaging revealed that she had a pseudoaneurysm, which was treated at St. Mary's. M.B. was then released for "further rehabilitation" to a hospital in Tel Aviv "with permanent neurologic sequelae."

Regarding the standard of care and breach with regard to TCH, Dr. Avellino stated in his report that a hospital like TCH "requires formulation and enforcement of adequate policies regarding the use of recalled medical devices in surgical procedures performed at its facility." He stated the TCH breached the standard of care by permitting Dr. Curry to use the NeuroBlate system because "the device is subject to a Class I recall (which by definition can cause death or serious injury)" against FDA warnings and advice that "health care providers strongly consider treating patients with alternative procedures if available." Dr. Avellino stated that alternative procedures were available at the hospital.

Regarding the causal connection between the outlined breaches and M.B.'s injuries and damages, Dr. Avellino opined: "The NeuroBlate laser probe used in [M.B.'s] surgery can cause unintended heating to surrounding brain tissue, damaging blood vessels in the brain and creating pseudoaneurysms. A pseudoaneurysm occurs when a blood vessel wall is injured, and the leaking blood collects in the surrounding tissue." He recounted the above-listed facts regarding the

FDA's recall of the NeuroBlate laser probe as facts relevant to the "General Causation" of M.B.'s injuries.

He further stated, "The NeuroBlate laser probe used in [M.B.'s] surgery caused unintended heating to surrounding brain tissue, damaging a blood vessel in her brain and creating a pseudoaneurysm" that eventually ruptured. In addition to the information from the FDA that the NeuroBlate probe was recalled because it was prone to overheating and the FDA notices that such overheating had been associated with brain bleeds in other patients, Dr. Avellino specifically identified Dr. Curry's operative report. This report noted that during surgery, "there was an element of abnormal MR thermography at this point, which scanning revealed to be a small intraventricular and cisternal hemorrhage." Dr. Avellino stated, "Therefore, according to his operative report, Dr. Curry noticed an abnormal heating pattern during [M.B.'s] surgery and discovered a bleed in her brain. Therefore, the recalled laser probe caused unintended overheating and blood vessel damage, resulting in a bleed during the surgery." Dr. Avellino's expert report further observed that "sixteen days after her discharge, [M.B.] suffered a massive right temporal bleed, the same region of the brain as her intraoperative bleed." He stated, "Based on the defective nature of the recalled laser probe and the location of the second bleed, the ruptured pseudoaneurysm was caused by the unintended overheating of the laser probe during the laser ablation surgery."

Finally, Dr. Avellino opined,

> If [TCH] had prevented Dr. Curry from using the recalled NeuroBlate laser probe at its facility during [M.B.'s] surgery, her resulting injuries and damages would not have occurred. As previously discussed, the recalled NeuroBlate laser probe used in [M.B.'s] surgery caused unintended heating to surrounding brain tissue, damaging a blood vessel in the brain and creating a pseudoaneurysm that eventually ruptured. Thus, had [TCH] properly prevented Dr. Curry from using the NeuroBlate laser probe, [M.B.] would not have suffered her resulting injuries. It was foreseeable that permitting a physician to utilize a medical device subject to a Class I Recall would cause injury to patients, including [M.B.] Moreover, [M.B.'s] injury was foreseeable to [TCH], as the NeuroBlate laser probe had been recalled months earlier for unintended overheating of surrounding brain tissue, which could (and did) result in intracranial hemorrhage.

TCH objected to Dr. Avellino's amended expert report on the basis that it did not provide an adequate opinion as to causation, and it moved to dismiss the Barrs' suit against it for failure to provide an adequate expert report. The trial court denied the motion to dismiss, and this appeal followed.

Expert Report

In its sole issue, TCH argues that the trial court erred in overruling its objection to Dr. Avellino's expert report as to causation and denying its motion to dismiss.

A. Standard of Review and Relevant Law

Section 74.351 of the Texas Medical Liability Act (TMLA) provides that no medical negligence cause of action may proceed until the plaintiff has made a good-faith effort to demonstrate that a qualified medical expert believes that a defendant's

conduct breached the applicable standard of care and caused the claimed injury. *See* TEX. CIV. PRAC. & REM. CODE § 74.351(*l*), (r)(6). "[T]he purpose of the expert report requirement is to weed out frivolous malpractice claims in the early stages of litigation, not to dispose of potentially meritorious claims." *Abshire v. Christus Health Se. Tex.*, 563 S.W.3d 219, 223 (Tex. 2018) (per curiam).

An expert report is sufficient under the TMLA if it "provides a fair summary of the expert's opinions . . . regarding applicable standards of care, the manner in which the care rendered . . . failed to meet the standards, and the causal relationship between the failure and the injury." TEX. CIV. PRAC. & REM. CODE § 74.351(r)(6); *Abshire*, 563 S.W.3d at 223. "Importantly, the trial court need only find that the report constitutes a 'good faith effort' to comply with the statutory requirements." *Abshire*, 563 S.W.3d at 223 (citing TEX. CIV. PRAC. & REM. CODE § 74.351(*l*)); *see also Am. Transitional Care Ctrs. of Tex., Inc. v. Palacios*, 46 S.W.3d 873, 878 (Tex. 2001) (holding that courts look to report itself to determine whether it "represents a good-faith effort to comply with the statutory definition of an expert report"). An expert report demonstrates a "good faith effort" when it "(1) inform[s] the defendant of the specific conduct called into question and (2) provid[es] a basis for the trial court to conclude the claims have merit." *Abshire*, 563 S.W.3d at 223 (citing *Baty v. Futrell*, 543 S.W.3d 689, 693–94 (Tex. 2018)). A report "need not marshal all the claimant's proof," but "a report that merely states the expert's conclusions about the

standard of care, breach, and causation" is insufficient. *Id.* (quoting *Palacios*, 46 S.W.3d at 878–79); *see also Miller v. JSC Lake Highlands Operations, LP*, 536 S.W.3d 510, 517 (Tex. 2017) (per curiam) (holding that expert report does not have to meet same requirements as evidence in summary judgment proceeding or at trial). The expert must explain the basis for his statements and link his conclusions to the facts. *Bowie Mem'l Hosp. v. Wright*, 79 S.W.3d 48, 52 (Tex. 2002).

"We review a trial court's decision to grant or deny a motion to dismiss based on the adequacy of an expert report for an abuse of discretion." *Abshire*, 563 S.W.3d at 223. "A trial court abuses its discretion if it acts in an arbitrary or unreasonable manner without reference to any guiding rules or principles." *Wright*, 79 S.W.3d at 52. As a court reviewing matters committed to the trial court's discretion, we may not substitute our own judgment for that of the trial court merely because we would have ruled differently. *Id.*; *see also Larson v. Downing*, 197 S.W.3d 303, 304 (Tex. 2006) (per curiam) (holding that, when reviewing decisions that fall within trial court's discretion, "[c]lose calls must go to the trial court"). In analyzing a report's sufficiency under this standard, we consider only the information contained within the four corners of the report. *Wright*, 79 S.W.3d at 52. We are also mindful that expert-report challenges are made at an early, pre-discovery stage in the litigation. *See Baty*, 543 S.W.3d at 697 & n.10 (rejecting argument that expert report was inadequate, concluding that expert report sufficed "particularly in light of the

purposes the report is intended to serve" at early stage in litigation, and stating "additional detail is simply not required at this stage of the proceeding").

TCH argues that Dr. Avellino's expert report is insufficient as to causation. An expert report must set out "the causal relationship between the failure and the injury." TEX. CIV. PRAC. & REM. CODE § 74.351(r)(6); *Abshire*, 563 S.W.3d at 223. "A causal relationship is established by proof that the negligent act or omission constituted a substantial factor in bringing about the harm and that, absent the act or omission, the harm would not have occurred." *Kline v. Leonard*, No. 01-19-00323-CV, 2019 WL 6904720, at *9 (Tex. App.—Houston [1st Dist.] Dec. 19, 2019, pet. denied) (mem. op.); *Costello v. Christus Santa Rosa Health Care Corp.*, 141 S.W.3d 245, 249 (Tex. App.—San Antonio 2004, no pet.).

For causation, the expert report must explain "how and why" the physician's or healthcare provider's breach proximately caused the plaintiff's injury. *Columbia Valley Healthcare Sys., L.P. v. Zamarripa*, 526 S.W.3d 453, 459–60 (Tex. 2017); *Jelinek v. Casas*, 328 S.W.3d 526, 536 (Tex. 2010) ("It is not enough for an expert simply to opine that the defendant's negligence caused the plaintiff's injury. The expert must also, to a reasonable degree of medical probability, explain how and why the negligence caused the injury."). "In satisfying this 'how and why' requirement, the expert need not prove the entire case or account for every known fact; the report is sufficient if it makes 'a good-faith effort to explain, factually, how

proximate cause is going to be proven.'" *Abshire*, 563 S.W.3d at 224 (quoting *Zamarripa*, 526 S.W.3d at 460).

Proximate cause has two components: (1) foreseeability and (2) cause-in-fact. *Zamarripa*, 526 S.W.3d at 460; *Kelly v. Ford*, 543 S.W.3d 383, 390 (Tex. App.—Houston [14th Dist.] 2018, pet. denied). A causation opinion must explain both foreseeability and cause-in-fact and provide a "straightforward link" between the alleged breach of the standard of care and the claimed injury. *See Abshire*, 563 S.W.3d at 225; *Miller*, 536 S.W.3d at 515; *Zamarripa*, 526 S.W.3d at 460. The court's role is to determine whether the expert has explained how the negligent conduct caused the injury. *Abshire*, 563 S.W.3d at 226.

B. Analysis

Dr. Avellino's expert report states that TCH was negligent in permitting Dr. Curry to use the recalled laser probe during M.B.'s laser ablation surgery. Dr. Avellino opined that the laser probe—which the FDA had indicated was prone to overheating and damaging tissue in the area around the probe—overheated during M.B.'s surgery. To support this opinion, Dr. Avellino cited Dr. Curry's operative report that "there was an element of abnormal MR thermography" during the surgery, and he generally cited the FDA's warning that "the MR thermometry which is used to monitor the changes in temperature at the laser ablation site, was potentially inaccurate and may not account for continued spread of energy to the

surrounding brain tissue." He opined that the overheated probe damaged a nearby blood vessel, causing bleeding during surgery, as the FDA noted had happened in other cases when the probe overheated. This damage caused a pseudoaneurysm—a type of weakness in a blood vessel's wall that "occurs when a blood vessel wall is injured, and the leaking blood collects in the surrounding tissue."

Dr. Avellino further opined that, although M.B.'s initial brain imagining after surgery was "suspicious for an aneurysm," Dr. Curry relied on follow up scans that showed that the hemorrhages were resolving before he discharged M.B. Dr. Curry did not evaluate the vessels with a "head CT angiogram" to rule out an aneurysm and "no explanation was given for the hemorrhages outside the lesion bed." Thus, the pseudoaneurysm went undetected until it ruptured—which Dr. Avellino noted was a "vascular emergency"—and M.B. suffered neurological damage.

Dr. Avellino's expert report sets out a chain of events that links TCH's alleged negligence in allowing Dr. Curry to use the recalled NeuroBlate laser probe with damage that occurred during her surgery, which subsequently caused further damage when the pseudoaneurysm ruptured. *See Abshire*, 563 S.W.3d at 225. The expert report indicates that the injury to M.B. was foreseeable to TCH. *See Zamarripa*, 526 S.W.3d at 460. The FDA had recalled the NeuroBlate laser probe because it was prone to overheating and causing brain bleeds, and this was precisely the injury sustained by M.B. Dr. Avellino also set out facts necessary to establish the cause-in-

fact element of proximate cause by asserting that, but for TCH's negligence in permitting Dr. Curry to use the recalled laser probe, it could not have overheated during M.B.'s surgery, damaging her blood vessels and causing the development of the pseudoaneurysm that later ruptured. *See id.*

The trial court could reasonably have concluded that the report sets out "to a reasonable degree of medical probability . . . how and why" TCH's alleged negligence in allowing Dr. Curry to use the recalled device to perform surgery caused an injury to the vessel in M.B.'s brain, which in turn caused the remainder of her injuries. *See Jelinek*, 328 S.W.3d at 536; *Kline*, 2019 WL 6904720, at *9 (providing that causal relationship is established by proof that alleged negligence was substantial factor in bringing about harm).

TCH asserts that Dr. Avellino's expert report is conclusory and merely states his unsupported opinion, and it argues that his conclusions are impermissibly vague. Specifically, it argues that Dr. Avellino's opinion fails to link his conclusion that the probe overheated to the underlying facts and fails to explain how the overheating caused the bleed. TCH argues that Dr. Avellino "improperly extrapolates" from Dr. Curry's operative report—noting abnormal MR thermography and an area of bleeding—to support the conclusion that the NeuroBlate laser probe overheated and damaged surrounding brain tissue. TCH asserts, "Dr. Curry's operative report does not say that the probe overheated; nor does it say that the abnormal MR

thermography is evidence that the probe overheated." TCH argues that Dr. Curry's report stated that the abnormal temperature reading was caused by the brain bleed, which was "a known complication of laser ablation surgery, irrespective of any overheating of the medical device."

This argument, however, misconstrues the requirements for expert reports. Dr. Avellino's expert report was required to make "'a good-faith effort to explain, factually, how proximate cause is going to be proven.'" *Abshire*, 563 S.W.3d at 224 (quoting *Zamarripa*, 526 S.W.3d at 460). He did that by stating that abnormal thermography indicated that the laser probe overheated, damaging surrounding brain tissue, which eventually caused the remainder of M.B.'s injuries. The fact that Dr. Curry's operative report does not expressly state that the laser probe overheated does not render Dr. Avellino's conclusions insufficient. Nor does the fact that Dr. Curry attributed the abnormal thermography to a different cause render Dr. Avellino's report conclusory. "An expert report need not marshal all of the plaintiff's proof necessary to establish causation at trial, and it need not anticipate or rebut all possible defensive theories that may ultimately be presented to the trial court." *Kline*, 2019 WL 6904720, at *9; *see Wright*, 79 S.W.3d at 52; *Cornejo v. Hilgers*, 446 S.W.3d 113, 123 (Tex. App.—Houston [1st Dist.] 2014, pet. denied).

TCH further argues that Dr. Avellino's report does not explain why the abnormal thermography is an indication that the probe overheated or how this fact

supports his conclusion that the overheated probe caused the interoperative bleed. But Dr. Avellino's expert report states that the probe was recalled because it had been known to overheat, and the FDA had specifically warned healthcare providers that the MR thermography was potentially unreliable because it "may not account for continued spread of energy to the surrounding brain tissue." He opined that thermography during M.B.'s surgery showed "an abnormal heating pattern" in the region where the laser probe was being used, leading Dr. Curry to discover a bleed in M.B.'s brain. Rather than ruling out the possibility of a pseudoaneurysm, which is caused when blood vessels are injured, Dr. Curry discharged M.B., and the pseudoaneurysm subsequently ruptured. These facts from the expert report allowed the trial court to determine that Dr. Avellino had explained how TCH's negligent conduct caused M.B.'s injury. *See Abshire*, 563 S.W.3d at 226.

TCH further argues that Dr. Avellino's expert report fails to explain how M.B.'s brain bleed caused a ruptured pseudoaneurysm eighteen days after surgery, asserting that he bases his opinion solely on the fact that the pseudoaneurysm was located in the same region of M.B.'s brain as the intraoperative bleed, which "is pure *ipse dixit*." Contrary to this assertion, however, Dr. Avellino's report provides not only that the pseudoaneurysm was located in the same region of M.B.'s brain as the intraoperative bleed, but also that pseudoaneurysms are caused by injury to blood

vessel walls. He then explained that the laser probe overheated, damaged the surrounding blood vessels, causing a bleed.

Dr. Avellino's expert report was required to provide some basis for proving that TCH's act or omission proximately caused M.B.'s injury. *See Wright*, 79 S.W.3d at 53; *Scoresby v. Santillan*, 346 S.W.3d 546, 556 (Tex. 2011) ("No particular words or formality are required [in the expert report], but bare conclusions will not suffice."). With respect to causation, our role "is to determine whether the expert has explained how the negligent conduct caused the injury. Whether this explanation is believable should be litigated at a later stage of the proceedings." *Abshire*, 563 S.W.3d at 226; *see also Miller*, 536 S.W.3d at 516–17 (stating that "whether [an expert's opinion of applicable] standards appear reasonable is not relevant to the analysis of whether the expert's opinion constitutes a good-faith effort" and that adequate expert reports need not "meet the same requirements as the evidence offered at summary judgment or trial).

Because Dr. Avellino explained how the alleged negligent conduct—TCH's providing a recalled device with which it allowed Dr. Curry to perform M.B.'s surgery—caused the damage to the blood vessel in M.B.'s brain that resulted in the remainder of her injuries, we cannot conclude that the trial court abused its discretion in determining that the expert report satisfied the TMLA's requirement to provide

"the causal relationship between the failure and the injury." *See* TEX. CIV. PRAC. & REM. CODE § 74.351(r)(6); *Abshire*, 563 S.W.3d at 223.

We overrule TCH's sole issue.

Conclusion

We affirm the trial court's order denying TCH's motion to dismiss.

Richard Hightower
Justice

Panel consists of Chief Justice Radack and Justices Hightower and Adams.