

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 09-3760

ROBERT DADDIO, As Parent and Natural Guardian and Administrator of the Estate of
Michael Daddio, a Minor, Deceased; ROBERT DADDIO; TRACIE DADDIO,
Individually and in their own right,

Appellants,

v.

THE NEMOURS FOUNDATION; WILLIAM I. NORWOOD, M.D., PH.D.; JOHN
MURPHY, M.D.

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civ. No. 05-00441)
District Judge: Honorable Mary A. McLaughlin

Submitted Under Third Circuit L.A.R. 34.1(a)
on October 4, 2010

Before: SCIRICA, FUENTES, and JORDAN, Circuit Judges.

(Opinion Filed: November 02, 2010)

OPINION OF THE COURT

FUENTES, Circuit Judge:

This action arises from the death of the two-year-old son, Michael, of Appellants Robert and Tracie Daddio (hereinafter the “Daddios”) as a result of lung and heart failure. The Daddios claim that their son’s death was caused by negligence during the second of three surgical procedures performed by Appellee Dr. William Norwood in order to alter the flow of blood through the child’s heart and thereby correct for one of multiple congenital heart defects. After concluding that the testimony of the Daddios’ sole expert witnesses was unreliable and inadmissible, the District Court granted the summary judgment motion of both Dr. Norwood and Appellee Nemours Foundation, the owner of the cardiac center where the procedures were performed. The District Court found that in the absence of expert witness testimony on the element of causation, the Daddios’ negligence and informed consent claims failed as a matter of law. We conclude that the District Court did not abuse its discretion in so ruling and will affirm.¹

I.

Because we write for the parties, we discuss the facts only to the extent necessary for resolution of the issues raised on appeal. On June 5, 2001, the Daddios’ son, Michael, was born with multiple heart defects, including a condition called Hypoplastic Left Heart Syndrome (“HLHS”). To address those defects, doctors determined to alter the flow of blood through his heart by means of three staged surgical procedures, known respectively as the “Norwood,” the “hemi-Fontan,” and the “Fontan” or “Fontan completion”

procedures. The Norwood procedure was successfully performed by Dr. Norwood on June 7, 2001. To conduct the November 9, 2001 hemi-Fontan procedure, Dr. Norwood used a technique known as “deep hypothermic circulatory arrest” (“DHCA”), in which the body is cooled to a point that reduces the amount of oxygen that is needed by the body’s organs, and then blood is removed from and stored outside the body. This permits the surgeon to operate in a bloodless field on a heart that is not beating. At some point after the hemi-Fontan procedure was performed, Michael developed a liquid buildup surrounding his lungs known as “persistent pleural effusions.” About twenty months after the hemi-Fontan procedure, on July 23, 2003, Michael died from serious lung disease and heart dysfunction.

The Daddios filed suit in the United States District Court for the Eastern District of Pennsylvania, alleging that Dr. Norwood’s cooling technique as well as the manner in which he used DHCA were negligent.² They also alleged that Dr. Norwood had failed to obtain their informed consent for the use of a modified version of the hemi-Fontan procedure, which they contend led to Michael’s death. The Daddios’ expert, Dr. Hannan, opined that Dr. Norwood had made unnecessary and experimental modifications to the hemi-Fontan procedure, including a 59-minute period of circulatory arrest and aortic cross-clamping, which he contended led to “increased pleural effusions.” Dr. Hannan also opined that Dr. Norwood was negligent because he cooled Michael’s body too

¹ The District Court had jurisdiction pursuant to 28 U.S.C. § 1332, and we exercise jurisdiction pursuant to 28 U.S.C. § 1291.

rapidly to protect the myocardium, failed to ligate Michael's azygous vein, and failed to timely address Michael's pulmonary artery stenosis, the combination of which eventually led to right ventricular failure.

Dr. Norwood filed a motion under Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993), and Federal Rule of Evidence 702 to preclude evidence and testimony offered by Dr. Hannan. In their opposition, the Daddios contended that their theory of negligence rested on the length of circulatory arrest, rather than the rate at which Michael's body was cooled, and that Doctor Hannan would testify to a causal relationship between the length of circulatory arrest and the pleural effusions. After multiple hearings, additional briefing, and the Daddios' repeated revision of their theory of causation, on August 21, 2009 the District Court concluded that Dr. Hannan's testimony was unreliable under the standards imposed by Daubert and Federal Rule of Evidence 702 and entered summary judgment in Appellees' favor.

II.

The principal issue raised on appeal is whether the District Court abused its discretion in excluding the testimony of the Daddios' expert witness, Dr. Hannan, as to the issue of causation. See United States v. Schiff, 602 F.3d 152, 161 (3d Cir. 2010) (trial court's decision to exclude expert witness testimony is reviewed for abuse of discretion). For the following reasons, as well as the reasons set forth in the District

² The remaining claims and parties listed in the Complaint were dismissed by stipulation or by orders of the District Court that have not been appealed.

Court's thorough memorandum and order, we conclude that the District Court did not abuse its discretion in excluding the testimony of Dr. Hannan.

The introduction of expert opinion testimony is governed by Federal Rule of Evidence 702, under which the admissibility of expert testimony turns on (1) the qualifications of the expert, (2) the sufficiency of the data underlying the expert's testimony, (3) the reliability of the expert's methodology and (4) the expert's application of that methodology to the facts of the case. See Fed. R. Evid. 702. "While [t]he focus, of course, must be solely on principles and methodology, not on the conclusions that they generate, . . . a district court must examine the expert's conclusions in order to determine whether they could reliably follow from the facts known to the expert and the methodology used." Heller v. Shaw Industries, Inc., 167 F.3d 146, 153 (3d Cir. 1999) (quoting Daubert, 509 U.S. at 595) (alteration in original) (internal quotation marks omitted). Further, because the District Court had jurisdiction based on the diversity of the parties, the Daddios' expert must meet state law requirements for the certainty of expert opinion as well. Id. at 153 n.4. Under Delaware law, which the parties agree applies here, medical expert testimony must be stated with a "reasonable medical probability." Money v. Manville Corp. Asbestos Disease Compensation Trust Fund, 596 A.2d 1372 (Del. 1991) (internal citations omitted).

To prove negligence under Delaware law, a plaintiff must demonstrate that the negligent act or omission was the "but for" cause of his injury. "Most simply stated, proximate cause is [defined in Delaware as] that direct cause without which the accident

would not have occurred.” Culver v. Bennett, 588 A.2d 1094, 1097 (Del. 1991) (quoting Chudnofsky v. Edwards, 208 A.2d 516, 518 (Del. 1965)) (alteration in original). Similarly, because under Delaware law an informed consent action sounds in negligence, it too requires the plaintiff to establish that the negligent failure to obtain consent was the “but for” cause of his injury. See 18 Del. C. § 6852 (setting forth the requirements of and defenses to a claim for lack of informed consent) ; Valentine v. Mark, 2004 WL 2419131, *3 (Del. Super. 2004) (“[A]n informed consent action still requires expert testimony as to causation” and thus “Section 6852 cannot . . . be used as a backdoor around the requirement that causation in medical negligence cases be supported by expert testimony.”); Moore v. Fan, 2004 WL 2914318, *4 (Del. Super. 2004) (“In order to prevail on her [informed consent] claim, the Plaintiff must still prove that she has suffered injury as a proximate result of the Defendant’s negligence.”)

The Daddios’ expert witness, Dr. Hannan, sought to testify that the length of Michael’s circulatory arrest during the hemi-Fontan procedure either caused his persistent pleural effusions or made his organs unable to overcome them. The District Court found that neither Dr. Hannan’s professional experience nor the literature he presented demonstrated that his testimony was reliable to support that opinion. Because the studies cited by the Dr. Hannan did not assert or imply that a circulatory arrest period of 59 minutes is unsafe or will lead to pleural effusions, the District Court was within its discretion to reject them as a basis for Dr. Hannan’s opinion. Similarly, in light of Dr. Hannan’s own admitted uncertainty about the causes of pleural effusions and the fact that

pleural effusions occur in HLHS patients even in the absence of negligence, the District Court did not abuse its discretion in concluding that Dr. Hannan's own experience as a practitioner did not provide him with a sufficient basis to opine that the length of circulatory arrest caused Michael's pleural effusions. Nor did it abuse its discretion in finding that Dr. Hannan's testimony that weakened organs may have prevented Michael's body from withstanding the effusions was speculative and unsupported by any evidence in the record.

The District Court also rejected Dr. Hannan's opinion that Dr. Norwood failed to timely address Michael's azygous vein and pulmonary artery stenosis, thereby increasing his postoperative pressure and resulting in pleural effusions. First, the District Court noted that Dr. Hannan failed to specify the "people" within the medical field who "believe" that arterial and venous pressures are linked to pleural effusions. Second, Dr. Hannan admitted that the azygous vein and pulmonary artery stenosis issues may not have had a material effect on those pressures. Finally, and most importantly, the District Court emphasized the lack of any evidence that Michael's arterial or venous pressures were ever elevated. (App. at R8, R329-R30). For these reasons, its conclusion was not an abuse of discretion.

The District Court also denied Dr. Hannan the opportunity to opine that Dr. Norwood should have ligated Michael's thoracic duct. Despite many opportunities to raise the thoracic duct issue, Dr. Hannan did not do so until the July 7, 2009 pretrial telephone hearing. (App. at 110-11). The District Court's finding that allowing Dr.

Hannan to raise the issue on the eve of trial would have prejudiced the Appellees was also not an abuse of discretion.

Finally, the Daddios argue that even if Dr. Hannan's testimony was properly excluded, they may nevertheless be able to make out an informed consent claim "merely by showing that had they known the information that Dr. Norwood failed to provide them they would have looked elsewhere and would not have consented to the surgery in question." (Appellant's Br. at 45.) However, as the District Court explained, Tracie Daddio submitted an affidavit stating that she and her husband wanted and intended for Michael to undergo the standard hemi-Fontan procedure, and that they had not consented only to the alleged modifications to that procedure. See (App. at R28-R31). Therefore, in order to prove that Dr. Norwood's failure to obtain consent was the cause of Michael's death, the Daddios would have had to establish that it was these unconsented-to modifications to the hemi-Fontan procedure rather than the hemi-Fontan procedure generally that was the cause of his death. The District Court was correct to conclude that without the benefit of an expert witness to testify that these modifications were the "but for" cause of Michael's death, the Daddios could not establish the element of causation for their informed consent claim.³

³ Appellants also contend that the District Court erred by excluding evidence as to Dr. Norwood's general practices about informed consent, whether Michael's surgery was "experimental," and whether Dr. Norwood's alleged plan to use a "Cheatham stent" during the third stage of the heart surgery would have been in conflict with the practices of the Nemours Institutional Review Board and the FDA. However, because of the lack of admissible expert testimony as to the element of causation, it is unnecessary to address these remaining evidentiary rulings.

Having concluded that the District Court did not abuse its discretion in excluding the testimony of Dr. Hannan, we agree with the District Court that the Daddios could not satisfy the element of causation as to either of their claims. Accordingly, the Appellees were entitled to summary judgment.

III.

For the foregoing reasons, we will affirm the District Court's order.⁴

⁴ Included in the Appendix submitted on appeal are five pages of Dr. Norwood's deposition testimony from a different case, as well as the February 2, 2010 transcript of a pre-trial conference in a third case. (App. at R43-R47, R60-R113). Because only pages R43-R44 of Dr. Norwood's deposition testimony were considered by the District Court as an exhibit to Appellants' summary judgment opposition, we hereby grant Appellees' Motion to Strike the remainder of these pages of the Appendix. See Fed. R. App. P. 10(a) (providing that the record on appeal shall include the transcript of proceedings, a certified copy of the docket entries, and "the original papers and exhibits filed in the district court[.]").