IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ROBERT DADDIO, et al.	:	CIVIL ACTION
	:	
v.	:	
	:	
THE A.I. DUPONT HOSPITAL FOR CHILDREN OF THE NEMOURS FOUNDATION, et al.	:	NO. 05-441

MEMORANDUM

McLaughlin, J. August 21, 2009

Robert and Tracie Daddio bring this medical negligence action under Delaware law seeking damages for the death of their son, Michael Daddio. Michael died approximately twenty months after undergoing pediatric cardiac surgery to correct his congenital heart defects at the A.I. duPont Hospital for Children (the "duPont Hospital") in Wilmington, Delaware. The defendants are the Nemours Foundation, which owns and operates the Nemours Cardiac Center at the duPont Hospital, and Dr. William I. Norwood, the pediatric heart surgeon who operated on Michael. The plaintiffs state two claims against the defendants. First, they claim that Michael received negligent care and treatment from the defendants, which resulted in his death. Second, they claim that they did not give their informed consent to a procedure Michael underwent.[1]

[1] The remaining parties and claims asserted in the complaint have been dismissed by stipulation of the parties or by orders of the Court.

This case came to this Court in September 2008, following an appeal in a related case, Svindland, et al. v. The Nemours Foundation, et al., Civ. A. No. 05-417. After that appeal, both the Svindland case and this case were transferred to the undersigned. The Court held a status conference with the parties in September 2008, at which time the parties informed the Court that the case was all but ready for trial, and that a limited number of issues remained to be decided, including the admissibility of testimony from the plaintiffs' expert witness, Dr. Robert L. Hannan. Following the September 2008 conference, the defendants filed a motion to preclude certain testimony by Dr. Hannan under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), and Rule 702 of the Federal Rules of Evidence.

The Court held a hearing on this motion and other evidentiary motions on March 11, 2009. At that hearing, at which the plaintiffs did not offer testimony from Dr. Hannan, plaintiffs' counsel explained that they were uncertain as to Dr. Hannan's theory of causation. Rather than decide the motion, the Court allowed the plaintiffs the opportunity to attempt to clarify their position at a later date.

Following the March 11, 2009, hearing, the plaintiffs filed various additional submissions with the Court, including an affidavit from Dr. Hannan, attempting to clarify their theory of

the case. Throughout the period following the hearing, and up until the pretrial conference on June 24, 2009, at which new counsel for the plaintiffs appeared, the Court understood the plaintiffs' theory of causation to be something other than what they now argue it to be.

At the final pretrial conference, the Court continued to express concern about the reliability of Dr. Hannan's testimony. Accordingly, the Court allowed the plaintiffs yet another opportunity to present testimony from Dr. Hannan at a special hearing on July 7, 2009. Following a hearing with Dr. Hannan on that date, the parties agreed to postpone trial so that the plaintiffs might have a final opportunity to clarify their position on the scope and content of Dr. Hannan's expert testimony, and so that the defendants might have the opportunity to respond.

The defendants continue to argue that Dr. Hannan's testimony is not reliable under Daubert and Rule 702 - both the theories that they originally moved to preclude and the theories since argued by new counsel for the plaintiffs. They have also since filed a motion for summary judgment on the basis that the plaintiffs have not provided any other evidence of causation to support their medical negligence or informed consent claims.

Upon consideration of the various filings submitted to the Court since September 2008, and having heard from Dr. Hannan

himself, the Court concludes that Dr. Hannan's proposed testimony, as it has been presented to the Court, is not supported by reliable scientific data and methods. The Court will grant the defendants' Daubert motion and will preclude Dr. Hannan from presenting testimony that any of the defendants' alleged acts of negligence caused Michael Daddio's injuries. The Court will also grant the defendants' motion for summary judgment, and will enter judgment for the defendants on the plaintiffs' medical negligence and informed consent claims.

I. Factual Background and Procedural History

Michael Daddio was born on June 5, 2001, with multiple congenital heart defects, including a condition known as Hypoplastic Left Heart Syndrome ("HLHS"). To survive, Michael needed three surgical procedures to alter the flow of blood through his heart. The first of these surgeries is commonly referred to as the "Norwood procedure." The second is commonly referred to as the "hemi-Fontan" procedure. The third is known as the "Fontan" or "Fontan completion" procedure.

On June 7, 2001, Dr. Norwood performed the first of three scheduled surgeries to correct Michael's heart defects. A second surgery was performed on November 9, 2001. At some point after the second surgery, Michael developed persistent pleural

effusions, which are liquid buildups surrounding the lungs. Michael died approximately twenty months later, on July 23, 2003.

Prior to both of Michael's surgeries, Dr. Norwood utilized a technique known as "deep hypothermic circulatory arrest" ("DHCA"), in which the body is cooled to a certain temperature, blood is removed and stored, and the surgeon operates in a bloodless field on a heart that does not beat. Cooling serves the purpose of reducing the amount of oxygen required by the body's organs in the absence of blood flow. In their operative complaint, the plaintiffs asserted that Dr. Norwood's cooling technique was negligent, as was the manner in which he used circulatory arrest. See Am. Compl. ¶ 32. They did not identify any other ways in which Dr. Norwood's conduct was negligent.

This case was originally assigned to the Honorable Berle M. Schiller of the United States District Court for the Eastern District of Pennsylvania.[2] Judge Schiller was also the trial judge assigned to another case brought against Dr. Norwood and the Nemours Foundation, Svindland, et al. v. The Nemours Foundation, et al., Civ. A. No. 05-417.

[2] Unless otherwise noted, the Court will refer to all filings by their case name and docket number (e.g., "Daddio Docket No. __"). The Court will also refer to the defendants' Daubert motion (Daddio Docket No. 129) as "Defs.' Daubert Mot." and their motion for summary judgment (Daddio Docket No. 201) as "Defs.' Mot. Summ. J."

Upon agreement of the parties, these two cases were consolidated for the purposes of discovery with other cases filed against the defendants. Pursuant to a stipulation filed by the parties, Judge Schiller would decide discovery issues that were common to all cases; other disputes would be decided by whichever judge was sitting as the trial judge. See Svindland Docket No. 20; Daddio Docket No. 21.

A. Dr. Hannan's Report and Deposition

By letter dated September 28, 2006, Dr. Hannan expressed his criticisms of Dr. Norwood's treatment of Michael Daddio. See Defs.' Daubert Mot. Ex. B. In this letter, he opined that Dr. Norwood made unnecessary and experimental modifications to Michael's hemi-Fontan procedure, thus leading to a 59-minute period of circulatory arrest and aortic cross-clamping, which, according to Dr Hannan, led to "increased pleural effusions." He also concluded that Dr. Norwood was negligent because he cooled Michael Daddio "rapid[ly]." Dr. Hannan further concluded that there was insufficient "protection of the myocardium which was a cause of the right ventricular failure and poor functioning of Michael's heart." Id. at 2, 6.

Dr. Hannan also explained that he believed that Dr. Norwood was negligent in failing to ligate Michael's "azygous vein" and in failing to timely address Michael's "pulmonary

artery stenosis." According to Dr. Hannan, "[a]ny increase in pressure to the venous pathways will cause and increase pleural effusions." Dr. Hannan explained that "[t]here was a known RPA stenosis prior to the surgery," and the conditions of both the RPA and the azygous vein "raise[d] the venous pressures, which was the major cause of the chronic pleural effusions." He also stated that in this case, "[t]he LPA stenosis caused an increase in pressure in the SVC and the PA which caused the effusions, and caused desaturations by shunting blood through the azygous [vein]." Dr. Hannan concluded that Michael's heart could not tolerate these conditions and Michael eventually suffered right ventricular failure "due to a combination of all of these factors." Id. at 3-4, 6.

Dr. Hannan's deposition in the Daddio case took place on October 23, 2006. See Daddio Docket No. 136 Ex. C. At his deposition, Dr. Hannan was questioned about his experience with performing hemi-Fontan procedures. Dr. Hannan explained that he does not perform the hemi-Fontan procedure, but rather, that he performs a procedure called the "Bidirectional Glenn." He also explained that there are ways in which a stage two operation can be done without utilizing circulatory arrest. See id. at 9-10.

Dr. Hannan was also questioned about the incidence of pleural effusions as a side effect of procedures to correct HLHS. Dr. Hannan acknowledged that there is a range of effusions that

is generally accepted among pediatric cardiothoracic surgeons. He explained that pleural effusions, generally, can result from the third-stage Fontan procedure. He also acknowledged, however, that it would be fair to say that there is a reported rate of effusions following a stage two procedure. Dr. Hannan further acknowledged that pleural effusions can occur in a stage two or a stage three procedure absent negligence, and that he has had patients develop pleural effusions after a stage two procedure. See id. at 16-18, 21.

Dr. Hannan was further questioned about the cause or causes of postoperative pleural effusions. Dr. Hannan stated that the "prolonged" period of circulatory arrest Michael underwent failed to sufficiently protect his myocardium. He stated that there is a "well-documented relationship" in the literature between prolonged aortic cross-clamping or circulatory arrest and postoperative pleural effusions. Id. at 34.[3] He also stated that "[e]levated pulmonary artery pressures can lead to the effusions," and that "people believe" that "elevated SVC or pulmonary artery pressures" and "elevated venous pressures,"

[3] The plaintiffs have equated "cross-clamp time" with the duration of circulatory arrest and also with DHCA time. See Daddio Docket No. 142 at 3 ("For our purposes, cross-clamp time and circulatory arrest time are synonymous."). The defendants have objected that these terms and times are not interchangeable. See Daddio Docket No. 144 at 7-8 & n.6.

cause pleural effusions. He admitted, however, that "people don't completely understand why effusions form." Id. at 49-50.

Dr. Hannan also criticized Dr. Norwood's handling of Michael's azygous vein and pulmonary artery stenosis. According to Dr. Hannan, Michael should have had pulmonary artery angioplasty and occlusion of his azygous vein "much sooner." The purpose of occluding the azygous vein is to prevent the vein from decompressing the pulmonary arteries and reducing effective pulmonary artery blood flow. In this case, Dr. Hannan stated that he "suspected" that failing to address Michael's azygous vein made him "bluer" and "increased the volume in the inferior vena cava." According to Dr. Hannan, closing the vein may not "materially change" SVC pressures, "but one of the treatments of recurrent effusions is taking collaterals out . . . of the picture." See id. at 35, 37, 39, 50.

With respect to pulmonary artery angioplasty, Dr. Hannan stated that, although Michael received that procedure six months after his surgery, he should have had it "weeks after surgery . . . based on his pleural effusions." According to Dr. Hannan, Dr. Norwood's failure to perform the procedure sooner had an impact on Michael's pulmonary artery pressures, and "[e]levated pulmonary artery pressures can lead to the effusions." Dr. Hannan also stated, however, that postoperative

pressures are "immaterial" in the setting of "recurrent" pleural effusions. Id. at 41, 47, 49, 50, 52.

When asked whether there was an improvement when the azygous vein was excluded and a stent was placed in the left pulmonary artery, Dr. Hannan responded, "I don't know. I'd have to look at the cath sheet. Again, the [postoperative] pressures are relatively immaterial in this situation." Id. at 52.

B. The Svindland Trial and Appeal

In May 2007, the Svindland case proceeded to trial. At trial, the Svindlands concentrated on two issues. They claimed that Dr. Norwood only cooled Ian Svindland for six minutes, which was not long enough to protect Ian's organs, and ultimately caused his death. They also claimed that the information given to them in order to constitute informed consent did not acquaint them with the mortality risks for Ian's operation.

Following a jury verdict for the defendants, the plaintiffs appealed. The Daddio case was stayed pending that appeal. In August 2008, the United States Court of Appeals for the Third Circuit vacated the jury verdict in Svindland, in part, because it could not discern the rationale for some of the Court's evidentiary rulings. See Svindland v. The Nemours Foundation, 287 F. App'x 193, 195 (3d Cir. 2008). The Court of Appeals did not reach the merits of the legal issues presented on

appeal, and instead remanded the case for decision on these issues and for a new trial. After the Court of Appeals vacated the jury verdict in Svindland, both the Svindland case and the Daddio case were reassigned to the undersigned.

D. Proceedings in Svindland and Daddio After the Svindland Appeal

The Court held an on-the-record status conference on September 16, 2008, to isolate the issues for decision in both cases in light of the Svindland appeal and to discuss schedules for the retrial of the Svindland case and for the trial of the Daddio case. See Svindland Docket No. 145; Daddio Docket No. 127. At the conference, counsel agreed that the only motion that had not been addressed by the Svindland appeal and which had not been decided by Judge Schiller in the Daddio case was a prior version of the defendants' Daubert motion to preclude Dr. Hannan from testifying that Michael's pleural effusions were caused by the length of time for which he was cooled or for which he underwent circulatory arrest. See Daddio Docket No. 77. See generally Daddio Docket No. 127 at 23-40.[4]

[4] Judge Schiller had previously denied the defendants' motion without prejudice because the cooling issue was already on appeal to the United States Court of Appeals for the Third Circuit in another related case, Reger v. A.I. duPont Hosp. for Children of the Nemours Foundation, Civ. A. No. 05-661. In Reger, Judge Schiller granted the defendants' motion to preclude expert testimony that Nicholas Reger's effusions were caused by the cooling and cardiopulmonary bypass techniques used during his

In describing the Daddio case to the Court, counsel for the plaintiff explained that "Daddio is a cooling case," and that the plaintiffs' theory of causation was that "cooling damaged parts of [Michael's] body . . . through lack of oxygen, during the cooling process." See id. at 12. Counsel further explained that, with respect to cooling, "there's not a definite relationship, . . . but because it's oxygen deprivation, the organs of the baby sort of choose which needs it most, and so there may be varying kinds of organ damage." Id. at 13.

Shortly after the conference, the parties filed various evidentiary motions in both cases. Both sides filed motions related to certain subpoenas that the plaintiffs served on the Children's Hospital of Philadelphia ("CHOP") and Dr. James Goin, a statistician at CHOP, to obtain the raw data that served as the basis for publications of two studies done at CHOP (the "CHOP data"). The defendants moved for a protective order over the

---

surgery. See Reger Docket No. 71. Judge Schiller concluded that Dr. Hannan presented no evidence to support his opinion that the defendants' cooling practices caused Nicholas's pleural effusions. At best, the literature submitted established that DHCA "may in some cases lead to organ failure." This fact alone was not sufficient to support the conclusion that DHCA, as it was administered, caused Nicholas's effusions. See id. at 1 n.1. The Court of Appeals affirmed Judge Schiller's decision in a non-precedential opinion on January 9, 2008. See Reger v. A.I. duPont Hosp. for Children of the Nemours Foundation, 259 F. App'x 499, 500 (3d Cir. 2008). In affirming, the panel noted that Dr. Hannan did not support his opinion about the cause of Nicholas's effusions by citation or reference to any scientific data or text. Id. at 3.

CHOP data. The plaintiffs responded by moving to compel CHOP and Dr. Goin to produce the data. These data, according to the plaintiffs, constituted the only available set of data in existence from which the relationship of cooling duration to postoperative outcomes could be analyzed. See Daddio Docket No. 127 at 26-27; see also Daddio Docket No. 143 at 110.

The defendants also filed a motion in the Daddio case under Daubert v. Merrell Dow Pharmaceuticals and Federal Rule of Evidence 702 to preclude certain evidence and certain testimony by Dr. Hannan. See Daddio Docket No. 129. In their motion, the defendants asked the Court to preclude the plaintiffs from offering expert testimony or other evidence that pleural effusions are caused by, or related to, the duration of cooling or circulatory arrest during open-heart surgery.

In their opposition to the defendants' Daubert motion, the plaintiffs disavowed that their theory of negligence was based on the amount of time that Michael Daddio was cooled prior to his November 9, 2001, surgery. Instead, they stated that Dr. Norwood was negligent because he improperly modified Michael's hemi-Fontan procedure, thus leading to a longer period of circulatory arrest than was necessary. See Daddio Docket No. 136 at 4. Dr. Hannan, according to the plaintiffs, would testify not to a relationship between cooling time and pleural effusions, but rather, to a causal link between the length of circulatory arrest

- or rather, "aortic cross-clamping" - and pleural effusions. Id. at 4. In their opposition to the defendants' Daubert motion, the plaintiffs further stated that increased "cross-clamp" time "leads to" pleural effusions and that the medical literature identifies it as "a significant contributing factor." Id. at 2 & n.2.

E. March 11, 2009, Hearing and Post-Hearing Briefing

On March 11, 2009, the Court held a conference with the parties for the purpose of hearing oral argument on all pending evidentiary motions, including the defendants' Daubert motion in the Daddio case.[5] At the hearing, the plaintiffs reaffirmed the position taken in their opposition to the defendants' Daubert motion - that Dr. Hannan would not testify to a link between cooling duration and pleural effusions, but rather, that he would draw a connection between the duration of circulatory arrest and pleural effusions. See id. at 138, 146-49.

Although the plaintiffs admitted that Dr. Hannan would not testify that cooling caused Michael Daddio's pleural effusions, at the same time, however, counsel for the plaintiffs

[5] The defendants filed their motion on September 22, 2008. The plaintiffs filed, and the Court granted, four requests to extend the plaintiffs' time to respond to the motion. The plaintiffs ultimately filed their response on February 20, 2009, approximately five months after the defendants filed their Daubert motion.

stated that cooling was not completely out of the case, in that cooling "made a contribution" to the outcome. Id. at 163. Counsel further stated, however: "I'm not clear . . . in my own mind in terms of the scientific part of how [Dr. Hannan is] saying that the rapid cooling . . . also . . . may have had an effect." Id. at 165. Counsel further attempted to explain that "inadequate" or "bad cooling" may lead to organ damage, "and the fact that pleural effusions have occurred . . . could be an indication that the kidneys or the heart has been affected." Id. at 166-67 (emphasis added).

The plaintiffs did not present any witnesses at the March 11 hearing. Instead, they asked the Court to refrain from ruling on the pleural effusions motion until they had the opportunity to submit an additional affidavit from Dr. Hannan. The Court stated that the plaintiffs could file an additional opposition to the defendants' Daubert motion, after they had more time to clarify for themselves their theory of causation.

After the hearing, the plaintiffs filed an additional opposition to the defendants' Daubert motion, in which they further attempted to explain Dr. Hannan's theories of negligence and causation. They explained that "rapid cooling remains an issue in this case, although we are not contending that rapid cooling caused the onset of the pleural effusions that ultimately led to Michael Daddio's death. . . . In the present case the

issue is not the method used for cooling but the cross-clamp time, and Plaintiff [sic] has provided the court with medical literature that supports the fact that prolonged circulatory arrest causes pleural effusions." Daddio Docket No. 142 at 1. The plaintiffs attached various articles to this filing, two of which they had not produced prior to the March 11 hearing.

The defendants filed a reply brief in support of their Daubert motion on March 26, 2009. See Daddio Docket No. 145. In response, the plaintiffs submitted an additional affidavit from Dr. Hannan. See Daddio Docket No. 146.[6] In this affidavit, Dr. Hannan explained that "[b]ypass, crossclamping and DHCA procedures all increase the risk of end organ damage and are intrinsically related," and that "[c]onsequently, studies showing that the longer these procedures last the more likely they are to cause organ damage and pleural effusions are applicable to each." He also explained that

> every authoritative medical reference recommends limiting the duration of DHCA to the shortest time necessary to perform the necessary surgery; there is, however, no magic period of time (e.g. 60 minutes) in which there is no injury from DHCA.

[6] The Court did not grant leave for the plaintiffs to file an additional affidavit from Dr. Hannan. Indeed, at the March 11 hearing, plaintiffs' counsel asked whether he might file another report from Dr. Hannan. The Court stated that the plaintiffs might submit a filing clarifying their position, but not a report from Dr. Hannan. See Daddio Docket No. 143 at 178-79. Nevertheless, as this affidavit is relevant to understanding the nature of Dr. Hannan's opinions, the Court will consider it.

Id. In his affidavit, Dr. Hannan did not comment on any specific aspect of Michael Daddio's hemi-Fontan operation. Nor did he identify or purport to rely on any data from Michael's medical records identifying any documented organ damage.

F. Plaintiffs' Motions for Consolidation and Recusal

On April 21, 2009, plaintiffs' counsel filed a motion to consolidate the Svindland and Daddio cases with each other and with six other cases pending in this district. See Svindland Docket No. 172. The basis for the motion was that, in each and every surgery in these cases, "the Defendants' method of cooling violated the applicable standards of care, thereby, resulting in harm" to the patients whose surgeries were at issue. Id. at 5. According to the plaintiffs, the cases contained a common issue of law and fact - whether Dr. Norwood engaged in negligent conduct by cooling the children too rapidly. Deciding this issue as to each case, the plaintiffs argued, would save the Court and the parties considerable time and expense.

The Court denied the motion to consolidate on May 7, 2009. See Svindland Docket No. 179. The Court concluded that consolidation of the cases would not serve the interests of convenience or economy of administration, and that consolidation presented the potential to confuse a jury and to prejudice the defendants. On May 11, 2009, the plaintiffs asked the Court to

reconsider that decision, arguing that the Court did not understand the purpose of the plaintiffs' motion for consolidation. The plaintiffs again explained that "[e]ach of the cases proposed for consolidation has the common claim that Defendant William Norwood was negligent in employing a rapid cooling method and failing to observe safe circulatory arrest guidelines related to the cooling." See Svindland Docket No. 182 at 4 (footnote omitted). The Court denied the motion for reconsideration on May 13, 2009. See Svindland Docket No. 184.

On May 19, 2009, the Court issued a memorandum opinion ruling on various evidentiary motions filed in the Svindland and Daddio cases, including the parties' motions regarding the CHOP data. The Court granted the defendants' motion for a protective order and denied the plaintiffs' motion to compel in a memorandum opinion filed on May 19, 2009. See Daddio Docket Nos. 185-86. The Court did not, at that time, decide the defendants' Daubert motion in the Daddio case.

On June 1, 2009, one week before the Svindland trial was set to begin, the Svindland plaintiffs filed a motion for the undersigned to recuse from sitting as trial judge in the Svindland and Daddio cases. On June 5, 2009, the Daddios filed an identical motion. The basis for these motions was that the Court represented CHOP in an antitrust action filed in 1993. The plaintiffs argued that the Court's prior representation of CHOP

presented the appearance of impropriety, and that, as a result of the Court's May 19, 2009, opinion, they were deprived access to data that they had previously argued to be the only existing data from which the effects of cooling time could be analyzed. On June 5, 2009, in a telephone conference with counsel, the parties were informed that the undersigned would not recuse. The Court also told the parties a written decision would issue later so as not to delay trial of the Svindland case.

The plaintiffs filed an emergency appeal of the denial of their motion for recusal on June 5, 2009. They also filed an emergency motion to stay the proceedings. The Court held a telephone conference with the parties on the afternoon of June 5, 2009. At that time, the Court informed the parties that it would grant the motion to stay the cases pending the outcome of the Svindlands' appeal. It filed an order to that effect later that afternoon. See Svindland Docket No. 205. The United States Court of Appeals for the Third Circuit denied the plaintiffs' motion on June 8, 2009. Retrial of the Svindland case began on June 9, 2009, and concluded on June 18, 2009, with a jury verdict for the Svindlands.

G. Final Pretrial Matters

Prior to the retrial of the Svindland case, the Court learned that counsel who had been representing the plaintiffs

would be turning over control of the Daddio case to new counsel. See Daddio Docket No. 156. Out of a courtesy to new counsel, the Court elected to refrain from deciding the defendants' Daubert motion until new counsel had an opportunity to be heard on it. The parties also agreed that resolution of outstanding pretrial issues in Daddio, including the defendants' Daubert motion, would occur subsequent to the completion of the Svindland trial.

On June 24, 2009, the Court held a final pretrial conference in the Daddio case. At that time, the Court asked new counsel for the plaintiffs to describe Dr. Hannan's theories of negligence and causation as specifically as possible. Counsel stated several theories. First, they explained that Dr. Norwood performed a surgery in a manner that was untested, unknown in terms of risk, and involved experimental approaches, which, in itself, was negligent. Second, Dr. Norwood's unnecessary modifications to Michael's hemi-Fontan procedure increased the length of cardiopulmonary bypass and circulatory arrest, thus creating a "greater" risk to Michael. Third, Dr. Norwood failed to address Michael's pulmonary artery stenosis during surgery, and this condition worsened after surgery, which is also "causally significant" to the development of pleural effusions because there is scientific literature linking prolonged elevated pressures from stenosis to pleural effusions. Fourth, Dr. Norwood did not attend to Michael's pulmonary artery stenosis in

a timely fashion after the operation. Fifth, Dr. Norwood failed to ligate Michael's azygous vein during surgery, which was a "contributing factor" to the pleural effusions and their "intractable nature." See Daddio Docket No. 196 at 6-7, 16-20.

At the final pretrial conference, the Court asked plaintiffs' counsel whether there would be any attempt to say that the cooling period was below the standard of care. Counsel replied, "No, Your Honor." Id. at 11. Counsel further stated: "[W]e're not proceeding with that as a theory." Id. at 12. As to the remainder of Dr. Hannan's theories, the Court explained to counsel that it was hesitant to preclude Dr. Hannan's testimony on those issues without having first heard from Dr. Hannan.[7]

In view of the pendency of the defendants' Daubert motion, on which the Court had not yet ruled, the Court asked the parties whether they would prefer to have a short postponement of the trial. Despite the Court's own concerns regarding Dr. Hannan's testimony, the parties both agreed that the case should proceed as scheduled. Daddio Docket No. 196 at 33-34, 104.

The Court issued an Order ruling upon the various issues discussed at the conference on June 26, 2009. With respect to the defendants' Daubert motion, the Court ruled that

[7] The plaintiffs did not call Dr. Hannan as a witness at the Court's March 11, 2009, hearing, or at the final pretrial conference. At no earlier time did the plaintiffs attempt to offer live testimony from Dr. Hannan.

the defendants' motion was granted with the consent of the plaintiffs, to the extent that the plaintiffs would not pursue a theory of negligence based on the duration of cooling used during Michael's surgery. The Court further ruled that it would address the defendants' objections to the plaintiffs' other theories of negligence at a later date. See Daddio Docket No. 179 at 1.

On June 29, 2009, the plaintiffs sent a letter to the Court again attempting to clarify their position on the defendants' Daubert motion. In this letter, plaintiffs' counsel stated that the issue before the Court is whether Dr. Hannan can testify that the 59-minute circulatory arrest period is causally related to Michael Daddio's developing "intractable effusions." Letter from Aaron J. Freiwald to Hon. Mary A. McLaughlin 1 (June 29, 2009). Counsel also reiterated Dr. Hannan's position that Dr. Norwood failed to ligate the azygous vein or to address Michael's right pulmonary artery stenosis, which leads to elevated venous pressures, which then lead to pleural effusions. Id. at 2-3. Plaintiffs' counsel also reasserted Dr. Hannan's position that Dr. Norwood failed to treat Michael's pleural effusions in an appropriately aggressive and timely way. Id. at 3. Finally, counsel argued that because the body's responses and reactions to different events are not easily distinguished from one another, "it is difficult to find an article in the literature that addresses precisely and specifically the question

as Defendants have framed it." Id. at 2. The defendants filed a response to plaintiff's counsel's letter on July 1, 2009. See Daddio Docket No. 184.

On July 1, 2009, the Court issued an order setting a time for a special pretrial hearing, at which Dr. Hannan was required to appear so that he might clarify and explain the basis for his theories. See Daddio Docket No. 186. Due to scheduling conflicts, the Court scheduled this conference for July 6, 2009. On July 2, 2009, counsel for the plaintiffs informed the Court that Dr. Hannan would not be available at the time ordered by the Court, but that he would be available on the morning of July 7, 2009. Upon agreement of the parties, the Court permitted the extension and held the conference on the morning of July 7, 2009, at 7:00 a.m., in order to accommodate Dr. Hannan's schedule.

On July 6, 2009, after again having deposed Dr. Norwood in another case, plaintiffs' counsel filed a supplemental brief with the Court containing testimony from that deposition. See Daddio Docket No. 193. In this deposition, plaintiffs' counsel asked Dr. Norwood whether, at some point, the protective effects of cooling are "diminished" by the length of circulatory arrest. Dr. Norwood answered that cooling can be protective "for circulatory periods within a certain range." He stated that the protective effects of cooling would not be sufficient "to allow circulatory arrest periods of half a day or a day." See id. Ex.

A at 69-70. Dr. Norwood also acknowledged that thirty minutes "would fall within a safe period" of time for circulatory arrest given adequate cooling. Id. at 3. This testimony, according to the plaintiffs, added further support for denial of the defendants' Daubert motion.

H. July 7, 2009, Hearing and Postponement of Trial

On July 7, 2009, the Court held an early morning hearing, at which Dr. Hannan testified over the telephone. At this hearing, counsel for the plaintiff asked Dr. Hannan to state his theories of negligence and causation. Dr. Hannan began by summing up his theory of the case as follows:

> My criticisms of the actual surgery itself were that the modifications to the hemi-Fontan procedure resulted in a prolonged operation and resulted in modifications, and that increased the risk of the surgery, and that the modifications increased the risk of the surgery; and but for those changes, the boy would have survived.

See Daddio Docket No. 198 at 4. Upon further questioning by plaintiffs' counsel, Dr. Hannan stated that Michael Daddio's "period of circulatory arrest was clearly prolonged over the standard hemi-Fontan operation." Id. According to Dr. Hannan, this prolonged period caused Michael Daddio's injuries. The basis for this opinion, according to Dr. Hannan, was "[his] experience as a pediatric cardiac surgeon for the past eighteen

years, . . . [his] review of the literature; and [his] knowledge of pediatric cardiac surgery in general." Id. at 5.

In explaining the mechanism by which prolonged periods of circulatory arrest can lead to death from pleural effusions, Dr. Hannan stated that

> circulatory arrest deprives the baby's vital organs of oxygen; . . . the longer you deprive the baby's vital organs of oxygen, the more organ damage there is; and the organ damage can be manifested in many ways, including the inability of lungs to handle the effusions.

Id. at 6. Dr. Hannan also criticized the manner in which Dr. Norwood addressed Michael's pulmonary artery stenosis:

> [Y]ou know, ideally, you address it at the time of surgery, but if for one reason or another you don't recognize it or don't address it at the time of the surgery, when you have pleural effusions that last longer than a week or so, you need to address them very expeditiously. So, should he have addressed them at the time of surgery? Yes. But certainly, letting them linger was below the standard of care.

Id. at 8. With respect to how Dr. Norwood was negligent in his postoperative care, Dr. Hannan stated that Dr. Norwood should

have ligated Michael's "thoracic duct." Id. at 15.[8] Dr. Hannan did not state any critique with respect to the azygous vein.

On cross-examination, Dr. Hannan admitted that he had not, at any time prior to 2001 when Dr. Norwood operated on Michael Daddio, performed a hemi-Fontan procedure. Id. at 18.[9] Dr. Hannan also admitted that Michael's postoperative venous pressures were normal, as were his pressures three weeks later. Id. at 27-28. He also admitted that he does not know how long it normally took Dr. Norwood to do a hemi-Fontan procedure, and that he has not undertaken any review of Dr. Norwood's operative notes generally. Id. at 29-30. He also stated that he is aware that there have been many ways that Dr. Norwood has performed the hemi-Fontan operation over the years. Id. at 30.

After cross-examination by defense counsel, the defendants argued that Dr. Hannan's testimony amounted to an allegation that Dr. Norwood's allegedly negligent acts "increased the risk" to Michael Daddio. Such an allegation, they argued,

---

[8] Dr. Hannan admitted that he had not previously raised the criticism that Dr. Norwood should have ligated the thoracic duct. He stated, however that he had previously said that Dr. Norwood did not appropriately or expediently treat Michael postoperatively. He went on: "And I included, I guess in my mind, that lack of ligation in the inappropriate treatment and the delayed treatment." See Daddio Docket No. 198 at 18. According to defense counsel, the defendants had not prepared an expert on ligation of the thoracic duct. Id. at 20.

[9] Dr. Hannan stated that he believes that the hemi-Fontan procedure is an "archaic operation with unnecessary risks." Daddio Docket No. 198 at 18.

would not be sufficient to meet the plaintiffs' burden of proof under Delaware law. They also submitted an additional brief to this effect.[10]

Following the conclusion of Dr. Hannan's testimony, the Court met in chambers with counsel for both sides to discuss how to proceed with the case. The Court informed the parties that it was inclined to grant the defendants' motion, and that it had been so inclined since the March 11 hearing. The Court explained that a decision was not issued earlier in order to give new counsel for the plaintiffs an opportunity to make any additional arguments on the Daubert issue. The Court further explained that it would not rule on the Daubert motion until the plaintiffs had an opportunity to be heard on the issue of increased risk.

At that time, the defendants also stated that they intended to file a motion for summary judgment because a ruling precluding Dr. Hannan's testimony would leave the plaintiffs with no testimony on causation. The Court stated that the defendants could file such a motion. In light of the outstanding issues, the parties agreed that it would be best to dismiss the jury, and further agreed upon a briefing schedule for the remaining issues.

---

[10] In an additional brief submitted on July 14, 2009, counsel for the plaintiff complained that the defendants never filed this brief. See Daddio Docket No. 200 at 3 n.1. In a brief filed on July 31, 2009, defense counsel explained that they opted not to file the brief, and instead decided to incorporate the relevant portions into the July 31 brief. See Daddio Docket No. 202 at 9.

See Daddio Docket No. 198 at 46-47. The parties have since submitted additional briefs.

II. Analysis

According to the defendants, none of Dr. Hannan's theories of causation - with respect to circulatory arrest or otherwise - withstands scrutiny under Daubert and Federal Rule of Evidence 702. They argue that there is no scientifically reliable basis to conclude that any of Dr. Norwood's allegedly negligent acts caused Michael Daddio's pleural effusions or that they somehow made Michael unable to recover from the effusions. They further argue that, in the absence of Dr. Hannan's testimony on causation, the plaintiffs' medical negligence and informed consent claims fails as a matter of law.

The plaintiffs, for their part, argue that the defendants have waived objection to any issue aside from whether an extended circulatory arrest period causes pleural effusions. They further argue that, in any event, Dr. Hannan's testimony is reliable, and that the defendants have misconstrued both the requirements of Daubert and of Delaware medical negligence law.[11]

[11] Federal courts sitting in diversity must apply the law of the forum state, including the application of choice of law principles. Thabault v. Chait, 541 F.3d 512, 521 (3d Cir. 2008) (citing Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938); Pennsylvania v. Brown, 373 F.2d 771, 777 (3d Cir. 1967)); First State Underwriters Agency of New Eng. Reins. Corp. v. Travelers Ins. Co., 803 F.2d 1308, 1316 (3d Cir. 1986) (citing Klaxon Co.

The Court concludes that the defendants have not waived their ability to challenge the entirety of Dr. Hannan's testimony. It also concludes that Dr. Hannan's testimony on causation is not reliable under the standards imposed by Daubert and Federal Rule 702. Finally, it concludes that, in the absence of Dr. Hannan's testimony on causation, the plaintiffs' medical negligence and informed consent claims fail as a matter of law. The Court will grant the defendants' motions.

A. Waiver

The plaintiffs argue that the defendants have waived any challenge to any of Dr. Hannan's testimony other than his testimony regarding circulatory arrest because such challenges did not appear in their Daubert motion as originally filed. The Court will consider all of the defendants' challenges for a variety of reasons.

As an initial matter, the plaintiffs object that any additional Daubert challenges raised by the defendants have been raised after the date for submitting pretrial motions. This date, however, was set by the Court, and the Court has the discretion to change this date as part of its inherent authority to manage trials. See Luce v. United States, 469 U.S. 38, 41 n.4

---

v. Stentor Elec. Mfg. Co., 313 U.S. 487 (1941)). The parties agree that Delaware law governs the plaintiffs' medical negligence and informed consent claims.

(1984). Even so, to the extent that the plaintiffs complain that the deadline for pretrial motions was May 1, 2009, the plaintiffs themselves continued to file motions after that date.

Next, the Court, as the "gatekeeper" for expert testimony, has a duty to screen expert opinion testimony for relevance and reliability. See Daubert, 509 U.S. at 589. The gatekeeping function of the trial court is "a flexible one" that depends upon the particular circumstances of the particular case at issue. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999). An expert must have an adequate basis for his testimony, and it is within the trial court's discretion to decide whether such a basis has been shown. See id. at 141-42, 152.

Throughout the course of the proceedings on this motion, it has become clear that Dr. Hannan will offer testimony beyond that which the defendants - and the Court - were led to believe based on the plaintiffs' representations to the Court at earlier stages of this litigation. As the plaintiffs have further clarified their positions on the testimony that Dr. Hannan will give at trial, the scope of the issues arising out of that testimony has evolved.

Under Daubert and Kumho Tire, the Court has the discretion to address those issues as necessary to ensure that the jury receives reliable testimony. In addition, given that trial has been postponed at the request of the parties so that

the Court can determine the reliability of Dr. Hannan's testimony, the Court finds it prudent to exercise its discretion and consider all objections to the reliability of Dr. Hannan's proposed testimony.

B. Daubert Standard

The party offering an expert witness must establish by a preponderance of the evidence the qualifications of the expert and the expert opinion's compliance with Federal Rule of Evidence 702. See Daubert, 509 U.S. at 592-93 & n.10 (citing Fed. R. Evid. 104(a)). Rule 702 permits parties to introduce at trial scientific opinions from witnesses who are qualified as experts by knowledge, skill, experience, training, or education. Such opinions, however, must be based on sufficient facts or data and must be the product of reliable principles and methods. An expert's opinion must also be based on a reliable application of the principles and methods to the facts of the case. Federal law thus establishes three restrictions on expert testimony: "qualification, reliability, and fit." Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003).

Qualification requires the witness to possess specialized expertise. Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008). Although the United States Court of Appeals for the Third Circuit interprets this requirement "liberally,"

allowing for a "broad range of knowledge, skills, and training," the party offering the expert must nonetheless demonstrate that the expert in fact has the necessary expertise. Id.; Keller v. Feasterville Family Health Care Ctr., 557 F. Supp. 2d 671, 675 (E.D. Pa. 2008).

To establish reliability, the expert must have "good grounds" for his on her belief. Schneider, 320 F.3d at 404. Accordingly, the Court must examine the expert's conclusions to determine whether they reliably follow from the facts known to the expert and the methodology used. Heller v. Shaw Indus., Inc., 167 F.3d 146, 153 (3d Cir. 1999). An expert's opinion must be "based on the methods and procedures of science rather than on subjective belief or unsupported speculation." Schneider, 320 F.3d at 404 (internal quotation marks omitted).

Although trained experts commonly extrapolate from existing data, nothing in either Daubert or the Federal Rules of Evidence requires a court to admit opinion evidence that is "connected to existing data only by the ipse dixit of the expert." General Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997); Oddi v. Ford Motor Co., 234 F.3d 136, 158 (3d Cir. 2000). A court may determine that an expert's opinion is unreliable if it concludes that there is "too great an analytical gap" between the data and the opinion proffered. Id.

In determining the reliability of expert testimony, the Court must be certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. The Court has "considerable leeway" in deciding how to test an expert's reliability and in deciding whether or not the expert's relevant testimony is reliable. It thus has the same kind of latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides whether or not that expert's relevant testimony is reliable. The Court also has the discretionary authority needed both to avoid unnecessary proceedings in ordinary cases where reliability is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert's reliability arises. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152-53 (1999).

In addition to the requirements of the Federal Rules of Evidence, in a diversity case such as this, state rules on the degree of certainty required of an expert's opinion apply. Heller, 167 F.3d at 153 n.4. In Delaware, expert medical testimony in support of a medical negligence claim must be stated with a reasonable degree of medical certainty. See Money v.

Manville Corp. Asbestos Disease Comp. Trust Fund, 596 A.2d 1372, 1377 (Del. 1991); Laskowski v. Wallis, 58 Del. 98, 101, 205 A.2d 825 (Del. 1964) (quoting Henne v. Balick, 146 A.2d 394 (Del. 1958)).

C. Delaware Law on Medical Negligence

To prevail on a claim for medical negligence under the Delaware Health Care Malpractice Insurance and Litigation Act, a plaintiff must produce expert medical testimony that specifies (1) the applicable standard of care, (2) the alleged deviation from that standard, and (3) the causal link between the deviation and the alleged injury. 18 Del. C. § 6853(e); O'Donald v. McConnell, 858 A.2d 960, 960 (Del. 2004); Green v. Weiner, 766 A.2d 492, 494-95 (Del. 2001).

To provide competent expert medical testimony as to applicable standards of skill and care, an individual must be familiar with the degree of skill ordinarily employed in the field of medicine on which he or she will testify. Id. § 6854. To establish causation, on the other hand, the plaintiff must provide expert testimony to show, to a reasonable degree of medical certainty, that a defendant's conduct was the "but for" cause of a plaintiff's injury. Culver v. Bennett, 588 A.2d 1094, 1097 (Del. 1991); Davis v. St. Francis Hosp., No. 00C-06-045-JRJ, 2002 WL 31357894, at *3 (Del. Super. Ct. July 26, 2002). The

"but for" cause of harm is the direct cause without which the harm would not have occurred. Culver, 588 A.2d at 1097. An opinion that the conduct complained of was a "substantial" or "contributing" factor in causing the injury is insufficient. See id.; Spicer v. Osunkoya, No. 08C-04-218, 2008 WL 2955544, at *1 (Del. Super. Ct. July 25, 2008).[12]

The defendants also argue that, to the extent that a plaintiff complains that a negligent act by a defendant "increased the risk" of harm, the Delaware Supreme Court has not recognized increased risk as a theory of causation. Although Dr. Hannan's testimony, on several occasions, has been couched in such terms of increased risk, the plaintiffs have stated that they "do not claim that increased risk of harm is the basis for causation here." See Daddio Docket No. 200 at 6 n.1. Accordingly, even to the extent that increased risk may be a valid theory of causation under Delaware law, the plaintiffs have

[12] According to Dr. Hannan, "but for" Dr. Norwood's modifications, Michael would have survived. Dr. Hannan later stated that these opinions were expressed to a "reasonable degree of medical certainty." See Docket No. 198 at 4, 17. Although Dr. Hannan's opinion is couched in terms of the standards imposed by Delaware law, the Court is not required to accept Dr. Hannan's conclusory use of such language. See Oddi, 234 F.3d at 152; cf. Barriocanal v. Gibbs, 697 A.2d 1169, 1172-73 (Del. 1997).

disavowed such a theory of causation, and the Court need not consider it.[13]

D. Causation

The plaintiffs have presented, over the course of this litigation, several acts of negligence on the part of Dr. Norwood that Dr. Hannan believes caused Michael Daddio's injuries: (1) an improper "cooling strategy"; (2) an "extended" or "prolonged" 59-minute period of circulatory arrest, resulting from the addition of unnecessary, "experimental" surgical steps; (3) the failure to ligate Michael's azygous vein at the appropriate time; (4) the failure to treat Michael's pulmonary artery stenosis during surgery or postoperatively; and (5) the failure to properly treat Michael postoperatively, including the failure to ligate Michael's thoracic duct.

On June 26, 2009, with the consent of the plaintiffs, the Court granted the defendants' motion to preclude evidence that pleural effusions are caused by, or related to, the duration of cooling used in Michael's surgery. See Daddio Docket No. 179 ¶ 1. Neither side has asked the Court to revisit that decision.

[13] The Court notes, however, that the Delaware Supreme Court has considered, and rejected, the notion that increased risk - or, as other jurisdictions have referred to it, "loss of chance" - alters the meaning of causation. United States v. Anderson, 669 A.2d 73, 78-79 (Del. 1995). It has not decided, however, whether there is a cause of action for increased risk under Delaware law. See id. at 76-79.

As to the remainder of Dr. Hannan's theories, the plaintiffs have not carried their burden of proving that Dr. Hannan can reliably testify, to the degree of certainty required by federal and Delaware law, that Dr. Norwood's other allegedly negligent acts caused Michael's injuries.

1. Circulatory Arrest Time

The Court has seen no basis to support an opinion, with the requisite level of certainty, that the additional time taken to complete Michael's second-stage surgery caused Michael's pleural effusions, or, as the plaintiffs argue, that it caused organ damage that made Michael unable to combat his pleural effusions. Neither Dr. Hannan's own experience nor the articles presented by the plaintiffs convince the Court that Dr. Hannan can reliably present such opinions. Nor have the plaintiffs stated that there is medical evidence in this case to support those opinions.

As a preliminary matter, neither Dr. Hannan nor counsel for the plaintiffs has stated by how long Dr. Norwood's actions prolonged Michael's surgery. The Court is thus without sufficient information to conclude whether Dr. Norwood's allegedly experimental acts took thirty seconds or thirty minutes, and whether or to what extent any such prolongation of circulatory arrest appreciably increased the severity of

Michael's pleural effusions or otherwise exacerbated his condition.

Although the plaintiffs insist that an "abundance of medical literature" reveals a causal link between the length of circulatory arrest and pleural effusions," the Court is not persuaded that the articles provided by the plaintiffs constitute an adequate basis for the opinions which Dr. Hannan has stated. That is, none of these articles provides a basis to conclude that circulatory arrest, regardless of whether or not it is extended beyond "standard" limits, is the cause of pleural effusions.

The Court has read and re-read the articles that have been provided by the plaintiffs in opposition to the defendants' motion. The Court fails to see how these articles support the conclusion that Dr. Hannan would draw from these articles, and the plaintiffs have not explained, other than in a conclusory fashion, how these articles support such a conclusion. The plaintiffs point to one article, which states that in the practice of the authors, the average duration of hypothermic circulatory arrest for a hemi-Fontan procedure is 30 minutes, which is a "very safe interval" for circulatory arrest. See Marshall L. Jacobs & Kamal K. Pourmoghadam, The Hemi-Fontan Operation, 6 Pediatric Cardiac Surgery Annual of the Seminars in Thoracic and Cardiovascular Surgery 90, 94 (2003), attached to Docket No. 136. This article does not establish, however, that

any time over thirty minutes is necessarily unsafe or that such time will lead to pleural effusions.

Only one of the articles provided suggests that there is an "association" between longer periods of "cardiopulmonary bypass" ("CPB") and "increased volume of pleural drainage," and that prolonged cardiopulmonary bypass times constitute a "significant" risk factor in that respect. See Anuja Gupta, et al., Risk Factors for Persistent Pleural Effusions After the Extracardiac Fontan Procedure, 127 Journal of Thoracic and Cardiovascular Surgery 1664 (2004), attached to Docket No. 136.[14] The article acknowledges that "persistent pleural effusions" are a "significant source of morbidity in the postoperative period," and that "previous studies have demonstrated this problem to occur in 13% to 39% of patients after surgical intervention."

[14] The authors of this study examined, among other things, the relationship between prolonged cardiopulmonary bypass times and "persistent" pleural effusions. Persistent pleural effusions were defined as two categories of effusions: (1) pleural effusions lasting more than two weeks after the operation or (2) effusions that lead to chest-tube drainage of more than a certain average volume per day. It found that increased CPB time was associated with the latter category of persistent effusions, i.e., the category involving the volume and rate of drainage. On the other hand, the article did not find a relationship between increased CPB time and the former category of persistent pleural effusions, i.e., the category involving effusions lasting more than two weeks. In this case, the "persistence" of Michael's effusions have not been explained as increased volume of chest tube drainage. The plaintiffs have only focused on his long-term effusions. The study did not find a significant association between CPB time and the duration of the effusions, but rather, merely increased volume of chest tube drainage.

Id. at 1665. The article also states that HLHS itself "remains a risk factor for persistent pleural effusions." Id. at 1668.

Even to the extent that CPB and circulatory arrest are "intrinsically related," as Dr. Hannan has suggested, this article does not provide a basis to conclude that either technique causes pleural effusions or "persistent" pleural effusions.[15] To the contrary, the article itself states that "the causal association of these risk factors could not be adequately established because of the retrospective design of the study. Also, because the study was focused on early postoperative outcome alone, the correlation of these risk factors to intermediate and long-term outcomes remains to be established." Id. At best, this article supports the proposition that longer CPB times may increase the risk of having a greater volume of pleural effusions.

Nor does Dr. Hannan's own experience suggest to the Court that there is a basis for concluding that circulatory arrest - prolonged or not - is a cause of pleural effusions. To the contrary, Dr. Hannan has stated that the cause of pleural effusions is not precisely known, although "people believe" that elevated pulmonary artery or venous pressures are potential

[15] The evidence presented demonstrates that circulatory arrest and cardiopulmonary bypass are not interchangeable terms; among other things, cardiopulmonary bypass may be performed without the use of circulatory arrest.

causes. This is not a basis to conclude that circulatory arrest causes pleural effusions. He has further acknowledged that there is a reported rate of pleural effusions for non-negligent performance of surgery to correct HLHS, and that he himself has had patients develop pleural effusions for second-stage procedures. Significantly, Dr. Hannan does not perform hemi-Fontan procedures; nor did he perform such procedures during the relevant time period.[16]

The plaintiffs have also asserted an additional theory of causation related to Michael's circulatory arrest period: that circulatory arrest caused organ damage that made Michael's effusions "intractable," in that the damage to Michael's organs made him unable to recover from his pleural effusions. To this end, the plaintiffs have submitted an article stating that DHCA can be "detrimental" for the body's organ systems, and that it can cause "significant side-effects." See Axel Haverich & Christian Hagl, Organ Protection During Hypothermic Circulatory Arrest, 125 Journal of Thoracic and Cardiovascular Surgery, 460, 460 (2003). In addition, Dr. Hannan has stated that

> Damage to end organs may be caused by the technique and length of cardiopulmonary bypass, aortic crossclamping and the precise

[16] Dr. Hannan has also stated that second-stage procedures can be done without the use of circulatory arrest. Whether or not the use of circulatory arrest in and of itself is negligent, however, is not at issue in this case.

> techniques of circulatory arrest, including length of cooling, temperature cooled to, and duration of arrest. End organ damage is associated with all mechanical support, and with cessation of circulation and oxygen delivery as in circulatory arrest. End organ damage may be unrecoverable and lead to morbidity and mortality.

See Daddio Docket No. 146.

Even accepting that unnecessarily prolonged periods of circulatory arrest can lead to organ damage generally, the plaintiffs have not stated that Dr. Hannan can or will identify any of Michael's organs that were damaged. Nor have they suggested that there is evidence that Michael succumbed to pleural effusions because of weakened organs. Although counsel for the plaintiffs speculated that there might be such a link at the March 11, 2009, hearing, the plaintiffs have not stated that there is any objective, documented evidence to support a conclusion that such damage occurred in this case. Nor have they suggested that such evidence exists. It would not be proper to permit Dr. Hannan to testify that unspecified, undocumented organ damage caused Michael Daddio to be unable to combat pleural effusions. Such guesswork is not based on the methods and procedures of science, and cannot serve as the basis for expert testimony.[17]

[17] Although Dr. Hannan has stated that Michael suffered right ventricular failure, that failure was "due to a combination of all of [the] factors" he has identified. Although Delaware

2. Other Theories

The plaintiffs object that the defendants' motion, as originally filed, only involved Daubert challenges to Dr. Hannan's cooling and circulatory arrest theories. They argue that they have consistently taken the position that Dr. Hannan will testify to a causal link between circulatory arrest and pleural effusions.[18] The plaintiffs also argue that the defendants, by virtue of Dr. Hannan's report and deposition, may not be heard at this stage to assert additional objections to Dr. Hannan's other theories regarding Michael's azygous vein, pulmonary artery stenosis, and postoperative care.

Regardless of whether or not the defendants raised objections to Dr. Hannan's other theories of negligence in September 2008, the Court is not obliged to permit unreliable

---

law does recognize that there may be multiple proximate causes of an injury, the Court is not persuaded that Dr. Hannan has a reliable basis for this conclusion. Nor is such an assertion sufficient to sustain a medical negligence claim under Delaware law. See infra n.24.

[18] Contrary to plaintiffs' counsel's characterization of the litigation, the defendants have not "injected" cooling into this case. The very first thing that the Court was told about this case is that "Daddio is a cooling case." As late as May 2009, the plaintiffs moved to consolidate this case with seven other cases on the basis of a common issue related to Dr. Norwood's cooling technique. In addition, in June 2009, approximately four weeks before trial of this matter was set to occur, the Daddios asked the undersigned to recuse herself after issuing a ruling denying plaintiffs access to what the Court was told would constitute the only set of data from which a retrospective study of cooling could be conducted.

expert testimony to be presented to the jury. The plaintiffs bear the burden of showing that Dr. Hannan has good grounds for his belief, and the Court must be certain that Dr. Hannan, as an expert, will employ in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. The Court also has the discretionary authority needed both to avoid unnecessary proceedings and to require additional appropriate proceedings in more complex cases where cause for questioning the expert's reliability arises. Kumho Tire, 526 U.S. at 152-53. Having reviewed Dr. Hannan's report and deposition multiple times, having heard from Dr. Hannan himself, and having read through multiple briefs on these issues, the Court concludes that there is a basis to question the reliability of Dr. Hannan's opinions. The Court will address these opinions at this time.

Although the plaintiffs argue that a decision on the entirety of Dr. Hannan's causation testimony at this late stage unduly prejudices them, the Court disagrees. As an initial matter, the Court has asked the plaintiffs on numerous occasions to clarify and to state their theories of negligence with specificity. Prior to June 24, 2009, the date of the pretrial conference, plaintiffs' counsel had not stated that they intended to move forward at trial with any theory of negligence other than their theories regarding cooling, circulatory arrest, and organ

failure. See, e.g., Daddio Docket No. 143 at 178.[19] Nor was any other theory mentioned in the plaintiffs' pretrial memorandum. Thus, as late as June 24, 2009, the Court did not know that the plaintiffs intended to move forward with any other theories of causation at trial. The defendants, for their part, did not ask the Court to preclude any additional theories of causation until the plaintiffs articulated them.

The Court has never denied the plaintiffs the opportunity to file a brief or to grant them an extension for the purpose of allowing them to attempt to explain their theories of

---

[19] At oral argument on March 11, 2009, the Court specifically asked plaintiffs' counsel about the scope of Dr. Hannan's testimony:

> The Court: So I'm just struggling with what Dr. Hannan would be saying. I mean, his expert report, he said what he said, and the only issue is not that he wasn't clear, I guess, but what's the support for what he's saying, and I thought in your opposition -- see, I thought in your opposition, you seemed to concede that yes, indeed, you do need medical literature and we have it on the only issue he's going to testify about, which is circulatory arrest. That's what I thought you were saying.
>
> Counsel: Yes, Your Honor, and the only issue that's giving me pause is that when I re-read the report today and focused on the language with respect to the cooling, I wanted to be sure that I properly presented to the Court what his medical theory is . . . on that issue, and not with respect to adding [to] the literature . . . but just clarification.

See Daddio Docket No. 143 at 178 (emphasis added).

negligence and causation. In fact, the Court offered a special hearing on July 7, 2009, to permit Dr. Hannan to justify the reliability of his opinions.[20] Given the history of the litigation of this case, the Court does not find that a ruling on the reliability of the entirety of Dr. Hannan's testimony is unduly prejudicial to the plaintiffs. The Court will, accordingly, address these other theories.

a. Azygous Vein and Pulmonary Artery Stenosis

According to Dr. Hannan, Michael's azygous vein and pulmonary artery stenosis should have been addressed earlier than they ultimately were. Standard of care issues aside, the Court is not satisfied that the plaintiffs have shown a basis for Dr. Hannan's opinions that either or of both of these factors caused Michael's pleural effusions.

[20] Plaintiffs' counsel's complaint that this hearing was held "only minutes to go before opening speeches" is not well taken. The Court asked Dr. Hannan to appear on July 6, 2009. The time and date of Dr. Hannan's appearance was the plaintiffs' choosing. To the extent that the plaintiffs felt they might have been prejudiced, they did not ask the Court to postpone trial, despite the Court having expressed its amenability to do so on several occasions. Nevertheless, at no time prior to July 7, 2009, did the plaintiffs attempt to offer testimony from Dr. Hannan in opposition to the defendants' Daubert motion. The hearing on July 7, 2009, was offered for the benefit of the plaintiffs, so that Dr. Hannan could state to the Court, in his own words, the causal link between any of Dr. Norwood's alleged acts of negligence and Michael Daddio's pleural effusions.

Dr. Hannan's report states that an increase in Michael's venous pressures "was the major cause of the chronic pleural effusions." See Defs.' Daubert Mot. Ex. C at 3. In his deposition, Dr. Hannan also opined that elevated pulmonary artery pressures "can lead to the effusions." He further explained that "people believe" that elevated SVC, pulmonary artery, or venous pressures cause pleural effusions. He admitted, however, that "people don't completely understand why effusions form." Hannan Dep. at 49-50.

Despite Dr. Hannan's own averment to the contrary, the Court is not persuaded that Dr. Hannan's opinions are reliable to the extent required under federal and Delaware law, which requires opinions to be stated "to a reasonable degree of medical certainty." Although Dr. Hannan has opined that "people believe" that arterial or venous pressures are linked to pleural effusions, he has not stated which "people" hold such a belief. Dr. Hannan himself admits that the scientific community does not completely understand why pleural effusions form. Even to the extent that other doctors may believe that elevated arterial and/or venous pressures can cause pleural effusions, the plaintiffs have provided no objective evidence to that effect.

In addition, even assuming that elevated arterial or venous pressures do cause pleural effusions, Dr. Hannan has not testified, and the plaintiffs have not produced evidence to show,

that elevated pressures caused Michael Daddio's pleural effusions. Dr. Hannan has not stated that Michael's pressures were documented as abnormal at any stage of his care or treatment. The only pressures that have been presented to the Court are those immediately following Michael's surgery, which, Dr. Hannan has admitted, were normal. In any event, Dr. Hannan has also opined that postoperative pressures are "immaterial" in the setting of recurrent pleural effusions.

Subjective belief and unsupported speculation are not enough to sustain an expert opinion. Dr. Hannan refers to no specific scientific articles, textbooks, or studies to support his conclusions. The plaintiffs have not shown that there is medical evidence to corroborate Dr. Hannan's opinions. Accordingly, even to the extent that Dr. Hannan's theory of causation is reliable, the Court is not persuaded that such a theory fits the facts of this case. Accordingly, Dr. Hannan may not present such an opinion.

b. Thoracic Duct and Postoperative Care

As a preliminary matter, Dr. Hannan may not opine that Dr. Norwood should have ligated Michael's thoracic duct. That theory does not appear in the operative complaint, in Dr. Hannan's report or deposition, or anywhere else in the record. The thoracic duct was not mentioned until the morning of July 7,

2009. Allowing Dr. Hannan to testify to that effect would be unduly prejudicial to the defendants.[21]

As to Michael's postoperative care generally, Dr. Hannan did not, prior to the July 7, 2009, hearing, state any way in which Dr. Norwood's postoperative treatment of Michael caused injury, other than that he failed to treat Michael's effusions "aggressively."[22] The only basis that the Court has seen for this conclusion, however, is Dr. Hannan's opinion that Dr. Norwood should have "addressed" Michael's azygous vein and pulmonary artery stenosis at an earlier time. As the Court has explained, however, the Court is not persuaded that Dr. Hannan can reliably opine that Dr. Norwood's failure to address these conditions at an earlier time caused either Michael's pleural

---

[21] At the July 7, 2009, hearing, when cross-examined by defense counsel as to why he had not previously criticized Dr. Norwood's failure to ligate the thoracic duct, Dr. Hannan stated: "I said [that Dr. Norwood provided] inappropriate treatment and delayed treatment. And I included, I guess in my mind, that lack of ligation in the inappropriate treatment and the delayed treatment." See Docket No. 198 at 18. What Dr. Hannan may have included in his mind, however, is not sufficient to have given the defendants notice of the opinion he intended to give on the ligation of the thoracic duct.

[22] The Court here expresses no opinion as to whether Dr. Hannan's critiques of Michael's postoperative care are in fact critiques of Dr. Norwood, or whether they are in fact critiques of other doctors, including the cardiologists and anesthesiologists who cared for Michael after his surgery. To the extent that they are critiques of other doctors, those doctors are no longer defendants in this lawsuit. However, even to the extent that Dr. Norwood were to owe Michael a duty for the eighteen months following his surgery, the plaintiffs have not adduced sufficient evidence to establish that Dr. Hannan's testimony is reliable.

effusions or an "inability to combat" the pleural effusions. Nor will the Court infer that Dr. Norwood's postoperative care must be what caused Michael's injuries simply because Michael did not recover. The Court will preclude this testimony.

E. Standard of Care

Although the defendants concede that their Daubert motion, as originally filed, pertained to the issue of causation, as the parties have discussed the content of Dr. Hannan's proposed testimony, issues concerning the reliability of some of his standard of care testimony has also indirectly arisen. In particular, they argue that there is no evidence to support the conclusion that Michael's circulatory arrest period was "too long," that the azygous vein or pulmonary artery should have been addressed earlier, and that the thoracic duct should have been ligated postoperatively.

In view of its decision with respect to Dr. Hannan's testimony on causation, the Court need not decide whether Dr. Hannan's proposed standard of care testimony is reliable. Nevertheless, it does have various additional concerns about whether, on this record, the plaintiffs have shown an adequate basis for Dr. Hannan's conclusions. For example, the Court does not read any of the articles presented by the plaintiffs as establishing that 59 minutes of circulatory arrest, in and of

itself, is not safe, or that it is necessarily dangerous or in violation of the relevant standard of care. Moreover, Dr. Hannan has admitted that he does not perform hemi-Fontan procedures, or that, at least, he was not performing such surgeries at or around the period during which Michael Daddio's second-stage surgery took place. Dr. Hannan has further admitted that he has not conducted an investigation into the length of circulatory arrest in a "standard" hemi-Fontan operation, and that he does not know how long it took Dr. Norwood to perform hemi-Fontan procedures.

In addition, as to the plaintiffs' argument that Dr. Norwood's own testimony in other cases further supports Dr. Hannan's opinions, the Court disagrees. Dr. Hannan has stated that Michael Daddio's period of circulatory arrest was "prolonged." Dr. Norwood has stated that "[b]eyond a certain period of time," hypothermia cannot protect against the effects of circulatory arrest. Although Dr. Norwood agreed that 30 minutes was "certainly" a safe period of time, and that hypothermia can be protective for circulatory arrest periods that fall "within a certain range," the only time periods Dr. Norwood identified as being harmful in and of themselves, even given adequate cooling, are "half a day or a day." The Court does not view Dr. Norwood's testimony as establishing that 59 minutes is

too long, or that a long period of circulatory arrest causes pleural effusions.[23]

Finally, with respect to the plaintiffs' allegations regarding Michael's postoperative care, the Court is concerned that the plaintiffs are charging Dr. Norwood with periods of Michael's care in which he may not have been involved or in which he may have had not duty to be involved. Although the Court expresses no opinion as to whether Dr. Norwood did or did not owe Michael Daddio a duty of care in the postoperative period, or, if so, for how long that duty would last, the Court cannot ignore the fact that Michael Daddio died nearly two years after his second-stage surgery, and that during those two years, Michael was cared for by a primary cardiologist, who the plaintiffs voluntarily dismissed as a defendant from this lawsuit.

F. Summary Judgment

The defendants argue that, to the extent the Court precludes Dr. Hannan's testimony, the plaintiffs' medical negligence and informed consent claims fail as a matter of law.

[23] Rather than Dr. Norwood's logic supporting Dr. Hannan's position that 59 minutes was unnecessarily long, Dr. Hannan's April 13, 2009 affidavit appears to support Dr. Norwood's position that there is no "magic line" with respect to circulatory arrest periods. In that affidavit, Dr. Hannan states that there is "no magic period of time (e.g. 60 minutes) in which there is no injury from DHCA." See Daddio Docket No. 146.

Absent Dr. Hannan's testimony, they argue, the plaintiffs cannot establish the causation element of either claim.

1. Medical Negligence

The production of expert medical testimony is an "essential element" of a plaintiff's medical negligence case and is an element on which he or she bears the burden of proof. Froio v. Du Pont Hosp. for Children, 816 A.2d 784, 786 (Del. 2003). The plaintiffs have not presented reliable expert testimony on the issue of causation. At best, they have presented testimony that certain factors increased the risk of or contributed to Michael's injuries.[24] This testimony does not satisfy the plaintiffs' burden of providing expert testimony on but for causation. Accordingly, summary judgment on the plaintiffs' medical negligence claim is appropriate at this time.

[24] Dr. Hannan has alleged that the combination of these factors produced Michael's injury. Delaware law recognizes the possibility of multiple proximate causes. Culver, 588 A.2d at 1097. It is not sufficient simply to identify numerous allegedly negligent acts and, without scientific texts or data to support a conclusion that any act does more than contribute to or increase the risk of injury, to assert that all of these acts proximately caused the injury or injuries at issue. Delaware law requires an expert to state, to a reasonable degree of medical certainty, that but for a particular course of conduct, an injury would not have occurred.

2. Informed Consent

The defendants raise various objections to the defendants' informed consent claim. However, the Court granted the defendants leave to file a motion for summary judgment on this claim only to the extent that the absence of Dr. Hannan's testimony on causation necessarily causes the plaintiffs' informed consent claim to fail as a matter of law. The defendants have already filed, and lost, a motion for summary judgment on the plaintiffs' informed consent claim on other bases. See Daddio Docket Nos. 55, 93 at 2 n.2. The Court will not address any basis for summary judgment that does not pertain to the sufficiency of the expert testimony offered by the plaintiffs.

Informed consent under Delaware law is statutorily defined and requires the patient to demonstrate that a health care provider failed to supply information concerning the treatment or procedure "customarily given" by other licensed health care providers with similar training and/or experience in the relevant medical community. 18 Del. C. § 6852(a)(2). An informed consent claim in Delaware does not sound in battery, but rather, in negligence. Brzoska v. Olson, 668 A.2d 1355, 1365-66 (Del. 1995).

To succeed on a cause of action for informed consent, a plaintiff must establish the following: (1) that the injury

alleged involved a non-emergency treatment, procedure or surgery; and (2) that the health care provider did not supply information regarding such treatment, procedure, or surgery to the extent customarily given to patients, or other persons authorized to give consent for patients by other licensed health care providers in the same or similar field of medicine as the defendant. See 18 Del. C. § 6852(a).

Because informed consent claims in Delaware sound in negligence, not battery, the requirements imposed by section 6852(a) are in addition to the Health Care Act's other requirements regarding medical negligence claims, including that the plaintiff must provide expert testimony on causation. See Valentine v. Mark, No. 02C-12-244PLA, 2004 WL 2419131, at *3 (Del. Super. Ct. Oct. 20, 2004). In Valentine, the Superior Court explained that informed consent claims cannot "be used as a backdoor around the requirement that causation in medical negligence cases be supported by expert testimony." See Valentine, 2004 WL 2419131, at *3. A plaintiff must therefore present expert testimony that a negligent act by the defendant caused the injury in question. See Moore v. Fan, No. 02C09027WLW, 2004 WL 2914318, at *4 (Del. Super. Ct. Dec. 3, 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.").

Although the parties agree that a plaintiff suing on informed consent must establish "causation," they differ in their interpretations of the nature of the causal link that must be shown. The plaintiffs read Delaware law as requiring the plaintiff merely to show that an individual suffered harm as a proximate result of the procedure, in that but for the defendant's performance of a procedure without informed consent, no injury could have occurred. The defendants, on the other hand, argue that the causation analysis for an informed consent claim is identical to the causation analysis for a medical negligence claim, in that the Court must determine whether the underlying medical negligence proximately caused injury to the plaintiff. See Defs.' Mot. Summ. J. at 22-23 (citing Conway v. A.I. duPont Hosp. for Children, No. 04-4862, 2009 WL 57016, (E.D. Pa. Jan. 6, 2009)).

For a plaintiff to prevail on an informed consent claim, ultimately, the plaintiffs must present expert medical testimony that the medical professional's failure to disclose information customarily given to patients was a proximate or "but for" cause of an injury, and thus, that it had an effect on the outcome of the case. See Valentine, 2004 WL 2419131, at *2-3. Here, the plaintiffs do not allege that but for Dr. Norwood's failure to inform them of the modifications to the hemi-Fontan surgery, Michael would not have had a second-stage procedure -

whether an "unmodified" hemi-Fontan procedure, or even a Bidirectional Glenn procedure. To the contrary, they intended for Michael to have an "unmodified" hemi-Fontan procedure, and believed that they consented to such a procedure.

The plaintiffs have not stated, and cannot state, that if Michael had received a proper second-stage procedure, he would not have developed pleural effusions, or that such effusions would not have been "persistent" or "recurring." Indeed, the medical literature provided by the plaintiffs suggests that HLHS itself remains a significant risk factor for the development of persistent pleural effusions. The plaintiffs thus have not shown that but for Dr. Norwood's failure to obtain informed consent, Michael would not have developed pleural effusions or that he would not have died. The plaintiffs have not established causation under Delaware law, and the Court will enter judgment for the defendants on this claim.

An appropriate Order shall issue separately.