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

TEAGUE CONWAY	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 04-4862
A.I. DUPONT HOSPITAL FOR CHILDREN, et al.	:	

SURRICK, J. **JANUARY 6, 2009**

MEMORANDUM & ORDER

Presently before the Court are the Motion of Defendant William I. Norwood, M.D., Ph.D., for Summary Judgment Pursuant to Rule 56 of the Federal Rules of Civil Procedure (Doc. No. 116), the Institutional Defendants' Motion for Partial Summary Judgment (Doc. No. 117), the Motion for Partial Summary Judgment to Dismiss the First Cause of Action (Doc. No. 118), and the Motion for Partial Summary Judgment to Dismiss Count II of the Complaint Alleging Fraud and Intentional Misrepresentation and Punitive Damages Claim (Doc. No. 119). For the following reasons, Defendants' Motions will be granted.

I. BACKGROUND[1]

[1] The Complaint names several "institutional" defendants, including the A.I. duPont Hospital for Children, the Nemours Foundation, the Nemours Cardiac Center, and the Nemours Delaware Institutional Review Board. (*See* Doc. No. 1.) Counsel for these defendants informs us that, of the group, the Nemours Foundation is the only legal entity. (*See* Doc. No. 119 at 1 n.1.) Plaintiff does not contest this. However, neither party has moved to correct the record. *See generally* Fed. R. Civ. Pro. 17(b)(3) (setting standard for capacity to sue or be sued). For purposes of this opinion, we refer to this group of defendants as the Institutional Defendants. The Complaint also names Doctors William Norwood, John Murphy, and Kenneth Murdison. (*See* Doc. No. 1.) We refer to these defendants collectively as the Medical Defendants.

This case arises out of the medical treatment received by Teague[2] Conway ("Plaintiff") at the A.I. Dupont Hospital in Wilmington, Delaware. Plaintiff was born on January 16, 2001, with Hypoplastic Left Heart Syndrome ("HLHS"), "[a] congenital heart disorder marked by underdevelopment of the left ventricle (lower chamber of heart), deformity of the aorta, narrowing of the aortic valve, and narrowing of the mitral valve." Matthew Bender & Co., 3-H Attorneys' Dictionary of Medicine 5914 (2005). Babies born with HLHS inevitably die shortly after birth unless they receive medical attention. (*See* Doc. No. 119, Ex. A ¶ 1.) The standard treatment for HLHS involves three separate open-heart surgical procedures that restructure the aorta so that the right side of the heart does the work of the underdeveloped left side. (*Id.* ¶ 2.) The first procedure, called the "Norwood Procedure," allows oxygenated blood to be pumped from the right side of the heart to the body. (*Id.* ¶ 3.) The second and third procedures achieve the goal of allowing unoxygenated blood from the upper and lower body to go directly to the lungs for oxygenation, bypassing the heart. (*Id.*) These are called, respectively, the "Hemi-Fontan" and "Fontan Completion" procedures. (*Id.* ¶ 4.) The first procedure was performed on Plaintiff on January 17, 2001. (*Id.* ¶ 11.) The second procedure was performed on Plaintiff on June 19, 2001. (*Id.*)

Sometime in 2002, Defendants Murphy and Norwood determined that the Fontan Completion procedure could be achieved via catheterization[3] of a device known as the Cheatham

---

[2] The parties refer to Plaintiff's first name variously as "Teagh" or "Teague." The name "Teague Conway" appears in the case caption, and the Complaint refers to Plaintiff as "Teague" (*see* Doc. No. 1 at 2). We will use the spelling used in Plaintiff's Complaint.

[3] Cardiac catheterization entails "[t]he passage of a small catheter into the heart through the venous system." Matthew Bender & Co., 1-C Attorneys' Dictionary of Medicine 1556 (2005).

Platinum covered stent ("CP stent").[4] (*See generally* Doc. No. 117, Ex. D at 1-5 (hereinafter the "March 30, 2004, Letter").)[5] The use of the stent would avoid the necessity of the third open-heart surgery required by the Fontan Completion procedure. (Doc. No. 119, Ex. A ¶ 6.) The doctors believed that the CP stent procedure would "accomplish the same physiological and anatomical outcome" as the surgery, with the difference being that instead of a pediatric heart surgeon opening an infant's chest and connecting veins and arteries with a Gore-tex patch, an interventional cardiologist would implant the CP stent using a less invasive catheterization process. (*Id.* ¶¶ 7-9.)

In April 2002, Dr. Murphy began implanting the CP stent in his patients. (March 30, 2004, Letter at 8.) He obtained the CP stents from NuMed, Inc., a New York-based medical device manufacturer.[6] The CP stent had not been approved by the FDA; however, NuMed was in the process of seeking FDA approval. (*Id.* at 3, 6-7.) During the period spanning April 2002 to May 2003, Dr. Murphy implanted the CP stent in sixteen patients. (*Id.* at 8-12.) On June 26, 2003, Dr. Murphy received a letter from NuMed informing him that it was recalling the CP stent, that the stent was not to be used except on an emergency or compassionate use basis, and that Dr.

---

[4] Drs. Murphy and Norwood appear to have adopted the idea of using a stent catheterization to replace the surgical Fontan Procedure from European researchers who had successfully used the catheterization procedure and published the results. (*See* Doc. No. 134, Ex. 1 at 52-24 (hereinafter the "Weber Deposition"); Doc. No. 135, Ex. 4.)

[5] On March 30, 2004, Dr. David J. Bailey, Vice President of Patient Operations and Chief Operating Officer of the Hospital, and Dr. Carlos Rosé, Chair of the Hospital's Institutional Review Board, sent a letter to Consumer Safety Officer Doreen Kezer of the Food and Drug Administration detailing an investigation done by the Institutional Review Board into the use of the CP stent at the Hospital.

[6] NuMed and its employee, Allen J. Tower, were named Defendants in this suit. They settled with Plaintiff in August 2008. (*See* Doc. No. 114.)

Murphy should provide NuMed with background information on each CP stent he implanted, including consent forms and follow-up data. (*Id.* at 13.)

Shortly thereafter, Dr. Murphy sought NuMed's assistance with obtaining FDA approval for compassionate use of the CP stent in twenty patients. (*Id.*) Dr. Murphy notified the Hospital's Institutional Review Board ("IRB") of his pending requests on July 11, 2003. (*Id.* at 17.) The March 30, 2004, Letter states that this was the Hospital's first notification about use of CP stent and that, up to that time, it did not know that Dr. Murphy had already implanted the CP stent into patients.[7] (*Id.* at 17-18.)

On October 30, 2003, Dr. Murphy sent a compassionate use application for use of the CP stent in Plaintiff to the Regulatory Affairs department of NuMed, which forwarded it to the FDA. (*See* Doc. No. 119, Ex. D.) The application contained two consent forms signed by Plaintiff's parents, Chris and Kristen Conway. It also included an IRB memorandum addressed to Dr. Murphy informing him of the IRB's procedures surrounding an application for compassionate use, and a letter from Dr. Norwood expressing his belief that use of the CP stent was the "safest and most effective way of saving this boy's life." (*Id.*) On November 10, 2003, the FDA granted the compassionate use application. (March 30, 2004, Letter at 20; Doc. No. 118, Ex. K.) On December 4, 2003, Plaintiff underwent a transcatheter completion of the Fontan procedure. (March 30, 2004, Letter at 20.) He was discharged from the hospital in early January 2004. (*Id.*

[7] The March 30, 2004, Letter claims that the Hospital did not become aware that Dr. Murphy had already implanted the CP stent into patients until October 2003, when the parents of one of the patients who had already received a CP stent complained to the Hospital. (*Id.* at 17-18.) The Letter further claims that the Hospital did not learn that the CP stent was unapproved until late November 2003 when one of its administrators noticed the language on the NuMed Consent form stating that the CP stent was not FDA approved. (*Id.* at 18.) It was shortly after this discovery that the IRB began its preliminary investigation into the use of the CP stent. (*Id.*)

at 21.)

After the final CP stent procedures performed by Dr. Murphy, the IRB and the Hospital conducted an investigation that resulted in the March 30, 2004, Letter. At about that time, Plaintiff's parents contacted Dr. Jack Rychik, a pediatric cardiologist at the Children's Hospital of Philadelphia ("CHOP") who is now Plaintiff's doctor. Plaintiff was experiencing pleural effusions and a significant amount of fluid build-up in his abdomen and Plaintiff's parents wanted "an additional opinion and . . . some additional thoughts" on how to treat Plaintiff for effusions that he was experiencing. (Doc. No. 146 at 9 (hereinafter the "Rychik Deposition")) Plaintiff was transferred to CHOP under the care of Dr. Rychik. At his deposition, Dr. Rychik testified that "[e]ffusions are collections of fluid in potential spaces that exist between tissue planes within the body. One can see effusions around the lung or around the heart or sometimes in the abdomen, and that's referred to as ascites." (*Id.* at 9-10.) When Dr. Rychik examined Plaintiff, he determined that Plaintiff had pleural effusions (fluid build-up around the lungs) and "a significant amount of ascites." (*Id.* at 10.) Dr. Rychik testified that he had experience treating pleural effusions and ascites following Fontan Completion procedures. He noted that "the presence of effusions can be a common phenomenon" after a Fontan Completion, stating "[i]t's not a rare or unusual phenomenon at all." (*Id.* at 12.)

Dr. Rychik determined that the best treatment for Plaintiff would be to conduct what is known as a "take-down" of the Fontan. (*Id.* at 13.) Dr. Rychik explained the procedure as follows:

> In order to define [a take-down of the Fontan], one perhaps has to explain what the Fontan is and the step that one takes to achieving the Fontan operation. In the Fontan, the veins that drain blood from the lower part of the body are connected to the pulmonary arteries in some fashion. And there are a number of different

> modifications for this. The step prior to the Fontan operation is one in which the veins from the top part of the body connect to the pulmonary arteries, the superior vena cava.
>
> And in a take-down from a Fontan to a previous step, one goes back to reestablishing connection between the inferior vena cava and the heart, turning that blood back away from the lung to the heart itself.

(*Id.* at 13-14.) Dr. Thomas Spray, a cardiothorasic surgeon at the CHOP, performed the take-down of the Fontan on Plaintiff. After the take-down, Plaintiff had a "relatively rapid" recovery, including abatement of the pleural effusions and, eventually, of the ascites. (*Id.*) Plaintiff went on to have a Fontan Completion procedure, in which Dr. Spray surgically implanted a Gore-tex patch in Plaintiff's chest. (*Id.* at 21.) As of September 2008, Plaintiff, who was then 6 years old, was "doing very well" and there were no future surgeries planned. (*Id* at 27.)

Plaintiff has filed the instant law suit alleging, inter alia, medical negligence, lack of informed consent, and fraud against the Defendants.

II. LEGAL STANDARD

A. Summary Judgment

Summary judgment is appropriate when "the pleadings, the discovery, and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); s*ee also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); *Fed. Home Loan Mortgage Corp. v. Scottsdale Ins. Co.*, 316 F.3d 431, 443 (3d Cir. 2003). Only facts that might affect the outcome of a case are "material." *Anderson*, 477 U.S. at 248. The moving party bears the burden of identifying the absence of a genuine issue of material fact, which it may satisfy by "showing" the court that there is an absence of evidence supporting the non-moving party's case. *Celotex Corp.*

v. Catrett, 477 U.S. 317, 322, 325 (1986); *UPMC Health Sys. v. Metro. Life Ins. Co.*, 391 F.3d 497, 502 (3d Cir. 2004). All reasonable inferences from the record are drawn in favor of the non-movant. *Knabe v. Boury Corp.*, 114 F.3d 407, 410 n.4 (3d Cir. 1997).

Although the movant has the initial burden of demonstrating the absence of genuine issues of material fact, the non-movant must then establish the existence of each element on which it bears the burden of proof. *See Watson v. Eastman Kodak Co.*, 235 F.3d 851, 857-58 (3d Cir. 2000). Plaintiffs cannot avert summary judgment with speculation or by resting on the allegations in the pleadings, but rather must present competent evidence from which a jury could reasonably find in their favor. *Ridgewood Bd. of Educ. v. N.E. for M.E.*, 172 F.3d 238, 252 (3d Cir. 1999); *Woods v. Bentsen*, 889 F. Supp. 179, 184 (E.D. Pa. 1995).

B. Choice of Law

Federal courts sitting in diversity must apply the law of the forum state. *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)). "This general rule embraces the application of choice of law principles." *First State Underwriters Agency of New England Reinsurance Corp. v. Travelers Ins. Co.*, 803 F.2d 1308, 1316 (3d Cir. 1986) (*citing Klaxon Co. v. Stentor Electric Mfg. Co.*, 313 U.S. 487 (1941)). Thus, we apply Pennsylvania's choice of law rules.

Pennsylvania uses an interest analysis to determine choice of law. *See Griffith v. United Airlines Inc.*, 65 A.2d 796 (Pa. 1964); *see also Hanover Ins. Co. v. Ryan*, No. 06-2650, 2007 U.S. Dist. LEXIS 92646, at *9-12 (E.D. Pa. Dec. 17, 2007) (explaining *Griffith*). *Griffith* requires courts to engage in a two-step inquiry. *See Cipolla v. Shaposka*, 267 A.2d 854 (Pa. 1970);

Hanover, 2007 U.S. Dist. LEXIS 92646 at *11. First, a court must examine whether a conflict exists between the laws of the competing states. *Hanover*, 2007 U.S. Dist. LEXIS 92646 at *11. If the court determines that a conflict exists, it then must move on to the second step of "weigh[ing] the interests of each state in the resolution of the dispute, and determin[ing] which state has greater contacts with the dispute." *Id.* at *12.

There are substantial conflicts between the law of Delaware and the law of Pennsylvania with regard to Plaintiff's medical malpractice and fraud claims. In several areas, Delaware law, including the Health Care Malpractice Insurance and Litigation Act (the "Health Care Act"), 18 Del. C. § 6801 *et seq.*, imposes different burdens on plaintiffs than does Pennsylvania law. For instance, Pennsylvania requires expert testimony that a defendant's conduct was a "substantial factor" in causing the harm suffered. *See Winschel v. Jain*, 925 A.2d 782, 789 (Pa. Super. Ct. 2007). Delaware, however, requires expert testimony that the defendant's conduct was the "but for" cause of the harm suffered, a more rigorous standard. *See Spicer v. Osunkoya*, No. 04-218, 2008 Del. Super. LEXIS 257, at *3 (Del. Super. Ct. 2008). In addition, Delaware informed consent claims sound in negligence. In Pennsylvania, informed consent claims sound in battery. *Compare Brzoska v. Olson*, 668 A.2d 1355, 1366 (Del. 1995) ("If a health care provider violates his . . . duty of care in obtaining the consent of the patient by failing to disclose all relevant information (risks) that a reasonable person would deem significant in making a decision to have the procedure, the action should be pleaded in negligence – not battery.") *with Fitzpatrick v. Natter*, No. 1-2007, 2008 Pa. LEXIS 2266, at *32 n.13 (Pa. Dec. 17, 2008) ("An informed consent action . . . sounds in battery rather than in negligence."). Plaintiff's fraud claim is also subsumed by Delaware's Health Care Act, rendering it, in essence, a negligence claim.

Regardless of whether the essential elements of fraud are the same in Pennsylvania and Delaware, the Health Care Act creates a conflict between the two in the context of medical malpractice actions.

The existence of a difference between Delaware and Pennsylvania laws requires us to engage in the second step of the *Griffith* analysis, which is straightforward in this case. There is no doubt that Delaware's interests in this matter are stronger than Pennsylvania's and that Delaware law should apply to Plaintiff's negligence theories. The reasons for this have been discussed by the several federal courts and Pennsylvania courts that have applied Delaware negligence law to the malpractice claims of Pennsylvania residents when those residents, as Plaintiff did here, intentionally traveled to Delaware for the allegedly negligent medical care. *See, e.g., Blakesley v. Wolford*, 789 F.2d 236, 243 (3d Cir. 1986) ("[I]t is only fair that the law of the state to which the patient has voluntarily travelled, and in which the doctor has chosen to conduct the operation, be applied to adjudicate the respective rights duties, and obligations between the parties.").

Delaware has the greater interest because the complained-of conduct occurred in Delaware, including the purported misrepresentations, and Delaware has a demonstrable interest in regulating health care practice and policies within its borders. *See Svindland v. A.I. Dupont Hosp. for Children of the Nemours Found.*, No. 05-0417, 2006 U.S. Dist. LEXIS 80601, at *6 (E.D. Pa. Nov. 3, 2006) (looking to where medical treatment occurred as one factor in *Griffith* analysis). Delaware also has an interest maintaining the predictability of its regulations so that health care professionals practicing within its borders know what standards govern their conduct. Finally, Delaware has an interest in that Defendants are its citizens. By contrast, Pennsylvania

has an interest as the forum state and an interest in that Plaintiff is its citizen. Clearly, Delaware law applies here.[8]

III. LEGAL ANALYSIS

Delaware's Health Care Act governs the outcome of this case. *See* 18 Del. C. § 6801, *et seq.* "Chapter 68 of Title 18 was enacted with the purpose of providing an atmosphere in which the number of suits and claims of malpractice, as well as the size of judgments and settlements, would be reduced thereby reducing the cost and/or maintaining the availability of medical malpractice insurance for health care providers." *Miller v. Spicer*, 822 F. Supp. 158, 172 (D. Del. 1993).[9] The Health Care Act creates a statutory scheme that imposes rigid requirements on

[8] We reached a similar conclusion in our Memorandum and Order dated February 14, 2007. *See Conway v. A.I. Dupont Hosp. for Children*, No. 04-4862, 2007 U.S. Dist. LEXIS 10563, at *10 n.3 (E.D. Pa. Feb. 14, 2007). Moreover, the parties appear to agree that Delaware law applies. (*See* Doc. No. 117 at 6-7; Doc. No. 125 at 4.)

[9] The Delaware General Assembly stated the purpose of the Health Care Act in the Act's preamble:

> WHEREAS, the number of suits and claims for damages both in Delaware and throughout the Nation as well as the necessary costs of defense and the size of judgments and settlements thereon, arising from professional patient care have increased tremendously in the past several years; and
>
> WHEREAS, there has been a tremendous increase in the cost of liability insurance coverage for health care providers in Delaware, and in some instances the withdrawal of liability insurance companies from the business of insuring health care providers in Delaware, endangering the ability of the citizens of Delaware to continue to receive quality health care as well as adequate and just compensation for negligent injuries; and
>
> WHEREAS, the General Assembly determines it is necessary to make certain major modifications to its current legal system as it relates to health care malpractice claims if the citizens of Delaware are to continue to receive a high quality of health care while still assuring that any person who has sustained bodily injury or death as a result of a tort or breach of contract on the part of a health care provider resulting from professional services rendered, or which should have been rendered, can obtain

plaintiffs seeking to bring tort claims arising from the provision of medical services. Specifically, as it pertains to this matter, the Health Care Act defines the terms "medical negligence" and "informed consent," and it sets out evidentiary standards with which plaintiffs must comply. These definitions and requirements limit the theories of recovery that are available to plaintiffs.

Medical negligence is defined in the Health Care Act as:

> [A]ny tort or breach of contract based on health care or professional services rendered, or which should have been rendered, by a health care provider to a patient. The standard of skill and care required of every health care provider in rendering professional services or health care to a patient shall be that degree of skill and care ordinarily employed in the same or similar field of medicine as defendant, and the use of reasonable care and diligence.

18 Del. C. § 6801(7). In order to establish a claim for medical negligence, a plaintiff must present "expert medical testimony . . . as to the alleged deviation from the applicable standard of care in the specific circumstances of the case and as to the causation of the alleged personal injury or death . . . ."[10] 18 Del. C. § 6853(e). This requirement is an essential element of a medical negligence claim. *See Burkhart v. Davies*, 602 A.2d 56, 59 (Del. 1991), *cert. denied*, 504 U.S. 912 (1992) ("As a result of the [section 6853] statutory mandate, the production of

---

> a prompt determination of adjudication of that claim and receive fair and reasonable compensation from financially responsible health care providers who are able to insure their liability, under a strictly construed fault principle as now, at a cost which is not prohibitive and does not lead to the problems and practices described above, while still maintaining Delaware's overall legal system as to health care malpractice claims except as modified by this legislation.

Miller, 822 F. Supp. at 172-73 (*quoting* 60 Del. Laws 373 (1975)).

[10] There are certain exceptions to this requirement that are not present here. *See* 18 Del. C. § 6853(e).

expert medical testimony is an essential element of a plaintiff's medical malpractice case . . . .").

Informed consent is a subset of medical negligence that the Health Care Act defines as:

> [T]he consent of a patient to the performance of health care services by a health care provider given after the health care provider has informed the patient, to an extent reasonably comprehensible to general lay understanding, of the nature of the proposed procedure or treatment and of the risks and alternatives to treatment or diagnosis which a reasonable patient would consider material to the decision whether or not to undergo the treatment or diagnosis.

18 Del. C. § 6801(6); *see also Patten v. Freedman*, No. 61, 1989 Del. Super. LEXIS 222, at *7-8 (Del. Super. Ct. May 18, 1989) ("An action based on lack of informed consent is an action for malpractice, and malpractice is defined by a negligence standard. The conclusion follows that an action for malpractice based on lack of informed consent is a negligence action."). Plaintiffs bringing an informed consent claim must establish the following:

> (1) The injury alleged involved a nonemergency treatment, procedure or surgery; and (2) 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.

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. *See Valentine v. Mark*, No. 12-244, 2004 Del. Super. LEXIS 352, at *8 (Del. Super. Ct. Oct. 20, 2004) (reasoning that because the Informed Consent Statute can be found under the Medical Negligence chapter of the Delaware Insurance Code, other requirements under the chapter applied to informed consent claims); *Patten*, 1989 Del. Super. LEXIS 222, at *7-8 (applying the Health Care Act's requirements to an informed consent claim).

The Health Care Act requires that Plaintiff provide an expert who satisfies two

requirements. *See* 18 Del. C. § 6853-54. First, the Health Care Act requires that the expert be competent to offer an opinion on the medical issues presented by the case. *See* 18 Del. C. § 6854. Second, the Health Care Act requires that Plaintiff produce expert medical testimony on the defendant's alleged deviation from the standard of care and on causation. *See* 18 Del. C. § 6853(e). This requirement applies to each claim as applied to each defendant. Our analysis of the testimony of each of Plaintiff's experts provides a clear basis for granting Defendants' motions for summary judgment.

Defendants have moved for summary judgment on Plaintiff's negligence claims in Count I, and on Plaintiff's fraud and intentional misrepresentation claim in Count II.

A. Expert Reports

Plaintiff has retained two expert witnesses, Dr. Howard S. Weber (Doc. No. 118, Ex. I, the "Weber Report"), and Dr. Sheldon Zink[11] (*id.*, Ex. J, the "Zink Report").

Dr. Weber is a board-certified pediatric cardiologist and professor of pediatrics at Penn State University College of Medicine. The portion of Dr. Weber's written report that contains his opinion reads as follows:

> After careful review of the above documents, it is my opinion that [Plaintiff] underwent transcatheter completion of the Fontan procedure using a non FDA approved [CP stent] manufactured by Numed corporation. It is evident that the patient developed severe ascites with symptoms of protein losing enteropathy secondary to obstruction as a direct result of thrombus[12] formation within the covered stent and inferior vena cava as described by Dr. Spray at the time of surgical

[11] Dr. Zink has earned a Ph.D. She is not a medical doctor.

[12] A thrombus is "[a] crust or plug of clotted blood formed in a blood vessel (artery or vein) or in one of the chambers of the heart. It remains attached to the inner surface of the blood vessel or the heart, and may be envisioned as a barnacle attached to an underwater structure." Matthew Bender & Co., 6-T Attorneys' Dictionary of Medicine 949 (2005).

> removal. As a consequence of this obstruction, [Plaintiff] had to undergo surgical removal of the conduit with cardiopulmonary bypass while in a fragile state. It was below the standard of care at the time for the physicians and staff at A.I. Dupont hospital to not have informed the [Plaintiff's parents] that the covered stent had not been previously utilized in the United States in this particular situation, was not currently being evaluated in any FDA approved clinical protocols for this particular situation and, in fact, was to be only utilized on a compassionate (emergent) basis in select patients with coarctation of the aorta. In addition, the Numed consent form describes the use of a non-covered CP stent for compassionate use which was not utilized in this particular situation. The consent process was below the standard of care with respect to informing the parents of the alternatives to the stent procedure since surgical Fontan completion has been the standard of care for many years with excellent early (<30 day) and late (10-20 years) results. The patient in question here was not considered high risk for surgical "elective" Fontan completion based on the hemodynamic data obtained via echocardiography and at catheterization immediately prior to stent implantation. Therefore, there was not true indication for compassionate use of the covered stent which might require surgical intervention. The consent process was below the standard of care with respect to [i]nforming the parents of possible "future" unknown complications related to the stent which might require surgical intervention. These deficiencies are corroborated during the depositions of [Plaintiff's parents] from 7/2/07. It is also inappropriate and below the standard of care to proceed with such an investigational type of procedure using a non FDA approved device without appropriate IRB oversight and approval. I hold these opinions to a reasonable degree of medical certainty.

(Weber Report at 3-4.) In the portion of his report summarizing the factual basis for his opinion, Dr. Weber notes that the operative report of Dr. Spray, the surgeon who performed the take-down of the Fontan, describe "a thrombus inside the covered stent which was partially adherent to the right atrium and also partially occluded the atrial septal communication." (*Id.* at 4.) The operative report also notes that "[t]here was a peel of tissue extending from the inferior vena caval-right atrial connection site." (*Id.*)

Defendants' counsel questioned Dr. Weber about the issue of causation at his deposition. Dr. Weber explained that Plaintiff experienced symptoms – protein losing enteropathy[13] ("PLE")

[13] Protein losing enteropathy is "[a]n abnormal condition marked by an increased loss of serum protein (protein present in the blood) through the feces (stool). It occurs when the lining of

and ascites – that necessitated a take-down of the Fontan, which in turn necessitated a surgical Fontan Completion. (*See* Weber Deposition at 120.) In response to questioning about the cause of Plaintiff's symptoms, Dr. Weber testified:

> A: What I believe is that he had an obstruction within the conduit at some level and that caused a high central venous pressure in his inferior vena cava, acutely, and that led to basically the ascites, which is an extravasation of fluid into his abdomen, because of the high hydrostatic pressure in his venous system and then obviously that's low cardiac output and the fact that they had to drain the fluid – to drain abdominal fluid must mean you have a lot of abdominal fluid.
>
> Q: What caused the obstruction in the first place?
>
> A: Obstruction within the stent, the covered stent.
>
> Q: What caused that?
>
> A: What [caused[14]] the thrombus in the stent?
>
> Q: Yeah.
>
> A: That is the $60,000 question. I don't know.

(*Id.* at 121.)

With regard to the consent process, Dr. Weber opined that "[t]he consent process was below the standard of care with respect to informing the parents of the alternatives to the stent procedure since surgical Fontan completion has been the standard of care for many years with excellent . . . results." (Weber Report at 4.)

---

the intestine is ulcerated, in the adult form of celiac disease (which see), and in obstruction of the lymphatic system of the intestine." Matthew Bender & Co., 5-PR Attorneys' Dictionary of Medicine 1769 (2005).

[14] The court reporter transcribed the word as "covered." Obviously, Dr. Weber was simply repeating the question, which used the word "caused" – not "covered," which Dr. Weber had used in his previous answer.

Dr. Zink is a medical anthropologist who has taught at the University of Pennsylvania Medical School in the Department of Medical Ethics.[15] (Zink Report at 1.) Her report comments on a number of events, facts, and considerations that led to Plaintiff's procedure. She concludes that the Medical Defendants engaged in "ethical misconduct." (*Id.*) She opines that the Medical Defendants, individually and as a group, failed to inform properly Plaintiff's parents of the factual circumstances surrounding the CP stent catheterization. For example, her report sets out eleven reasons why one of the consent forms signed by Plaintiff's parents was "grossly inadequate and misleading." (*Id.*) One such reason was that, in Dr. Zink's opinion, over the course of the consent process, the information presented to Plaintiff's parents tended to "normalize" the procedure and downplay the appeal of the surgical Fontan Completion, which had known risks and benefits. (*Id.* at 6-7.) She also opines that the Institutional Defendants, specifically the hospital's IRB, failed to oversee the Medical Defendants, thereby breaching ethical duties owed to Plaintiff and his parents. (*Id.* at 4-5.)

At her deposition, Dr. Zink testified that she was "not versed" in the clinical processes surrounding the treatment of HLHS. (*See* Doc. No. 133, Ex. C at 109 (hereinafter the "Zink Deposition").) She also testified: "I'm not a clinician and I do not understand the delicate

---

[15] Section 6854 of the Health Care Act states that "[n]o person shall be competent to give expert medical testimony as to applicable standards of skill and care unless such person is familiar with the degree of skill ordinarily employed in the field of medicine on which he or she will testify." 18 Del. C. § 6854; *see also Miville v. Abington Mem'l Hosp.*, 377 F. Supp. 2d 488, 492 (E.D. Pa. 2005) ("[Federal Rule of Evidence] 601 specifically applies state rules of witness competency to federal diversity cases."). Defendants have challenged Plaintiffs experts in two motions in limine that are currently pending before us. (*See* Doc. Nos. 133, 134.) Clearly, Dr. Zink, by her own admission, is not competent to testify as to any element of Plaintiff's malpractice-based medical negligence claim. Dr. Zink testified that she has no medical training and that she does not understand the "delicate nuances of the clinical and surgical process." (Zink Depo. at 109-10.)

nuances of the clinical and surgical processes . . . . Nor would I ever pretend to." (*Id.* at 109-10.)

B. Malpractice-Based Medical Negligence

Plaintiff's allegations regarding negligence fall into two categories. Plaintiff alleges that Defendants were negligent because they performed the catheterization procedure and implanted the CP stent and they did not perform a surgical Fontan Completion, or, in the case of the Institutional Defendants, because they did not adequately oversee the provision of Plaintiff's care and ensure that Plaintiff received a surgical Fontan Completion.[16] In addition, Plaintiff alleges that Defendants failed to obtain Plaintiff's parents' informed consent before performing the stent

[16] The parties have framed Plaintiff's general theory of negligence against the Institutional Defendants as a claim of corporate negligence (Doc. No. 117 at 8; Doc. No. 125 at 8), a cause of action against hospitals recognized in many states. *See, e.g.*, *Thompson v. Nason*, 591 A.2d 703, 708 (Pa. 1991) ("Corporate negligence is a doctrine under which the hospital is liable if it fails to uphold the proper standard of care owed the patient, which is to ensure the patient's safety and well-being while at the hospital."); *Pedroza v. Bryant*, 677 P.2d 166, 169 (Wash. 1984) (collecting non-exclusive list of jurisdictions that apply corporate negligence doctrine). Under Delaware law, regardless of what a theory of liability against a hospital is called, if it is premised on medical negligence, the Health Care Act provides the framework for analyzing it. The Health Care Act's definition of medical negligence refers to "health care provider[s]." *See* 18 Del. C. § 6801(7). Health care providers are:

> [Any] person, corporation, facility or institution licensed by [Delaware] . . . to provide health care or professional services or any officers, employees or agents thereof acting within the scope of their employment; provided, however, that the term "health care provider" shall not mean or include any nursing service or nursing facility conducted by or for those who rely upon treatment solely by spiritual means in accordance with the creed or tenets of any generally recognized church or religious denomination.

18 Del. C. § 6801(5). This definition includes hospitals. *See Harris v. Penserga*, No. 88-7, 1990 Del. Super. LEXIS 21, at *8 n.2 (Del. Super. Ct. Jan. 10, 1990); *see also Dougherty v. Horizon House, Inc.*, No. 05-250, 2008 Del. Super. LEXIS 278, at *12 (Del. Super. Ct. June 16, 2008) (determining that plaintiff's case against a nursing home for its failure to adequately watch over plaintiff, a disabled adult, fell "under the broad statutory definition of 'healthcare medical negligence' lawsuit"). All of the Health Care Act's requirements, including those of section 6853, apply to claims of medical negligence against hospitals.

procedure.

With regard to the Medical Defendants, Plaintiff argues that they knew (1) that the CP stent was not approved by the FDA and (2) that there was a commonly accepted, "standard" approach to treating Plaintiff, namely the surgical Fontan Completion. (*See* Doc. No. 127 at 1-2.) Plaintiff contends that the use of an unproven, novel procedure was a deviation from the standard of care and "the stent that [Defendants] placed in Teagh Conway caused him to suffer pleural effusions, became [sic] clotted and had to be removed to save [Plaintiff's] life." (*Id.* at 2-3.)

As noted above, Delaware law requires a plaintiff to present expert testimony regarding the defendant's deviation from that standard of care and the causal connection between the deviation and the plaintiff's injury. *See* 18 Del. C. § 6853(e); *see also O'Donald v. McConnell*, 858 A.2d 960, 960 (Del. 2004); *Burkhart v. Davies*, 602 A.2d 56, 59 (Del. 1991), *cert. denied*, 504 U.S. 912 (1992); *Davis v. St. Francis Hosp.*, No. 06-045, 2002 Del. Super. LEXIS 272, at *6-8 (Del. Super. Ct. July 26, 2002). The expert testimony is itself an essential element of a health care negligence action. *See Burkhart*, 602 A.2d at 59 ("As a result of the [section 6853] statutory mandate, the production of expert medical testimony is an essential element of a plaintiff's medical malpractice case . . . ."). The failure of a plaintiff to provide appropriate expert testimony in a medical negligence case is a proper basis for granting summary judgment. *See id.* (holding plaintiff bears the burden of proof with regard to the expert testimony); *see also O'Donald*, 858 A.2d at 960 (granting defendant's summary judgment motion where plaintiff did not satisfy section 6853's expert testimony requirement); *Svindland*, 2006 U.S. Dist. LEXIS 80601, at *16-19 (same).

With regard to causation, the medical expert must opine that the defendant's conduct that

allegedly breached the standard of care was the "but for" cause of the plaintiff's injury. *Davis*, 2002 Del. Super. LEXIS 272, at *7-8. An opinion that merely posits that the complained of conduct was a "substantial factor" in causing the injury is insufficient. *See Osunkoya*, 2008 Del. Super. LEXIS 257, at *3 ("It is well settled that stating that any breach of the applicable standard of care was a 'substantial contributing factor' of Plaintiff's injuries is insufficient . . . [A]n expert witness [must be] 'prepared to meet Delaware's more rigorous 'but for' proximate cause standard.'" (*quoting Ellet v. Ramzy*, No. 03-201, 2004 Del. Super. LEXIS 332, at *3-4 (Del. Super. Ct. Sept. 29, 2004)). The "but for" cause of harm is the direct cause without which the harm would not have occurred. *See Culver v. Bennet*, 588 A.2d 1094, 1097 (Del. 1991). "Section 6853 does not require medical experts to couch their opinions in legal terms or to articulate the standard of care with a high degree of legal precision or with 'magic words.'" *Green v. Weiner*, 766 A.2d 492, 495 (Del. 1999).

Defendants argue that Plaintiff's expert testimony on causation is insufficient. (*See, e.g.*, Doc. No. 118 at 25-26.) We agree.[17]

In response to Defendants' argument that Dr. Weber's report does not address causation, Plaintiff argues that the second and third sentences of Dr. Weber's report satisfy the requirement. (*See* Doc. No. 127 at 9.) Those sentences read:

> It is evident that the patient developed severe ascites with symptoms of [PLE] secondary to obstruction as a direct result of thrombus formation within the covered stent and inferior vena cava as described by Dr. Spray at the time of surgical removal. As a consequence of this obstruction, [Plaintiff] had to undergo surgical removal of

[17] Summary judgment is appropriate because Plaintiff has failed to establish a genuine issue of material fact as to causation, an essential element of his claim. Accordingly, we need not discuss whether Plaintiff has established an issue of material fact regarding the standard of care and Defendants' deviation from the standard of care.

the conduit with cardiopulmonary bypass while in a fragile state.

(Weber Report at 4.) Notwithstanding the Delaware Supreme Court's admonition in *Green* that legal precision and magic words are not necessary to establish but for causation, *see* 766 A.2d at 495, the sentences cited by Plaintiff simply do not establish causation. The first sentence essentially states that a clot of blood at the site of the stent caused ascites and PLE. The second sentence states that the clot necessitated a take-down of the Fontan. Neither sentence – and, for that matter, no statement in Dr. Weber's Report – concludes or conveys an expert's opinion that the CP stent caused the clot. Without this necessary conclusion, Dr. Weber's report offers no opinion that there is a causal link between the Defendants' deviation from the standard of care and Plaintiff's complained of harm. Dr. Weber acknowledged as much at his deposition when he stated that the cause of the clot was the "$60,000 question" and that he did not know what caused the clot. (*See* Weber Depo. at 121.)

Finding a causal link between the CP stent and the clot may at first blush seem appealing given that Plaintiff underwent additional procedures. However, the fact that the clot was found at the site of the complained of procedure does not, as Plaintiff argues, necessarily mean that the complained of procedure caused the clot. To automatically conclude that that is the case would be to succumb to the logical fallacy of *cum hoc ergo propter hoc* (i.e., using correlation to establish causation). *See Ortzian v. McNeilus Truck & Mfg.*, No. 07-0646, 2008 U.S. Dist. LEXIS 98151, at *12 (D.N.J. Dec. 4, 2008) (designated not for publication) ("In the absence of evidence regarding causation, the attempts to propose . . . various contingencies reveal the classic *cum hoc ergo propter hoc* ('with this, and therefore because of this') fallacy . . . .").

Another significant problem with the testimony of Plaintiff's experts is that there appear

to be other potential medical explanations for the cause of the clot. *See McCusker v. Surgical Monitoring Assocs.*, No.01-891, 2005 U.S. Dist. LEXIS 7298, at*11-12 (D. Del. Feb. 7, 2005) ("[W]here two possible causes may explain an injury, one of which can be said to be defendant's fault while the other is not, the plaintiff cannot recover without demonstrating that the fault-based cause was more likely the source of the injury . . . . [which] must be supported at each step by expert medical testimony."). At his deposition, Plaintiff's current cardiologist, Dr. Rychik, testified that "the presence of effusions can be a common phenomenon" after a Fontan Completion and that the presence of effusions is "not a rare or unusual phenomenon at all." (Rychik Depo. at 12.) These side-effects can result from a "derangement or dysfunction of the . . . Fontan setup" or from "an inherent way in which the body accommodates the Fontan." (*Id.* at 18-19.) He further testified that clot formation during the course of the surgical Fontan Completion procedure is a known risk of that procedure. (*Id.* at 22.) Moreover, the cover of the CP stent implanted in Plaintiff was Gore-tex, the same material used in the surgical Fontan Completion procedure. (Weber Depo. at 84.) In fact, Dr. Rychik testified that Plaintiff experienced post-operative pleural effusions and a thrombus after the Fontan Completion performed by Dr. Spray. (Rychik Depo. at 24-26.) These side-effects, which are not uncommon, dissipated on their own in this instance, and no further surgery was necessary. (*See id.* at 24-26.)

Dr. Rychik's testimony brings into focus the issue of the finder of fact having no basis upon which to evaluate whether it was indeed the CP stent that caused the clot or whether the clot was caused by something else and the CP stent just happened to be where the clot lodged. Without guidance from a medical expert, the finder of fact cannot make this determination.

As an alternative to arguing that Dr. Weber's report discusses causation, Plaintiff seeks to

defend the absence of testimony regarding causation in Dr. Weber's report by reasoning that:

> [I]t is not surprising that a cardiologist would not know the precise cause of a clot forming in a stent that has never been subjected to animal testing or clinical trials. The same would be true if the stent broke or became dislodged . . . . An expert opinion that a clot formed in a stent that never should have been used, and that the clot caused an obstruction significant to cause [Plaintiff] to undergo [a take-down of his Fontan] is sufficient to assist a jury in assessing the harm that Defendants' negligent conduct cause.

(Doc. No. 140 at 8.) However, when finders of fact do not have the guidance of a qualified expert, they are legally incapable of making a determination regarding the essential element of causation in medical malpractice actions, no matter how appealing such a determination may be. *See O'Donald*, 858 A.2d at 960 ("[T]he purpose of expert medical testimony, as recognized by the General Assembly, . . . is that, subject to the exceptions listed in the statute, the proximate cause of injuries that are claimed to be attributable to medical negligence are not within the common knowledge of a layperson."). We do not require legal precision or magic words. However, an expert must be able to state an opinion. Not knowing the "precise cause of a clot" did not, as Plaintiff argues, prevent Dr. Weber from giving his informed opinion on whether the clot was caused by the stent or whether it was simply a common occurrence when performing surgery of this type on an HLHS patient. Dr. Weber does not offer an opinion regarding the relationship between the clot to the stent in either his report or his deposition testimony. Adopting Plaintiff's explanation and argument regarding Dr. Weber's inability to identify the CP stent as the cause of the clot would vitiate the expert testimony requirement in informed consent cases.

Moreover, we cannot ignore the causation requirement merely because it appears tempting to identify a causal link between the procedure and Plaintiff's harm. *See O'Donald*,

858 A.2d at 960 (dismissing medical negligence claim, despite plaintiff's assertion that his injury "obviously resulted from the breach of the standard of care," because plaintiff had not provided expert testimony on the element of causation); *Duryea v. Perrotta*, No. 08-005, 1999 Del. Super. LEXIS 557, at *6 (Del. Super. Ct. Oct. 27 1999) ("Unusual or upsetting results alone are not sufficient evidence of malpractice or negligence."). We understand that the additional procedures experienced by the very young Plaintiff were difficult and upsetting, however, the Health Care Act and interpreting case law have made it abundantly clear that results-oriented arguments, standing alone, are insufficient to withstand summary judgment. *See Burkhart*, 602 A.2d at 60; *O'Donald*, 858 A.2d at 960; *Duryea*,1999 Del. Super. LEXIS 557, at *6. An expert must testify regarding causation, and there cannot be the sort of break in the causal chain that is present in Dr. Weber's report.[18]

Dr. Zink's report does not opine as to the but for cause of Plaintiff's injuries. Moreover, as we noted above, Dr. Zink is not competent to testify as to causation on the medical issues. (*See* Zink Depo. at 109-10.) By her own admission, she does not have the training or knowledge to offer such an opinion.

The same reasoning holds true regarding the Institutional Defendants, who also argue that neither of Plaintiff's experts opine that the conduct of the Institutional Defendants that was

---

[18] Plaintiff is not entitled to a res ipsa loquiter-type inference (i.e., the clot appearing in or around the CP stent speaks for itself). Section 6853 precludes such an inference. *See Williams v. Dyer*, No. 11-010, 1992 Del. Super. LEXIS 381, at *3-4 (Del. Super. Ct. Aug. 12, 1992) (rejecting "outright" the applicability of the doctrine of res ipsa loquiter to medical malpractice claims that do not fall into one of the three enumerated exception of section 6853); *Lacy v. G.D. Searle & Co.*, 484 A.2d 527, 530 (Del. Super. Ct. 1984) ("[T]he last sentence of § 6853, which bars drawing an inference or presumption of negligence on the part of a health care provider based upon facts which do not satisfy § 6853, makes res ipsa loquitur no longer applicable to cases involving health care providers if the facts do not fall within § 6853.").

allegedly below the standard of care was the but for cause of Plaintiff's injuries. (*See* Doc. No. 117 at 14.) Plaintiff responds that summary judgment is not appropriate because there is "substantial evidence" that would allow a jury to find negligence on behalf of the Institutional Defendants and that, in any event, Plaintiff's experts do opine that the Institutional Defendants' conduct was the but for cause of Plaintiff's injuries.

Dr. Weber's report, however, states no opinion whatsoever regarding the conduct of the Institutional Defendants. There is no mention of the standard of care required of hospitals or IRBs. There is no discussion of deviation from that standard of care. And there is no mention of causation. Clearly, the Weber Report does not satisfy the requirements of section 6853 with regard to the Institutional Defendants. Similarly, the Zink Report does not opine as to causation.

Since Plaintiff has not produced expert testimony on the issue of causation, as required by section 6853, Defendants' motions must be granted on Plaintiff's malpractice-based medical negligence claims.

C. Informed Consent

Plaintiff makes a number allegations regarding the Medical Defendants' deviation from the standard of care in the context of obtaining informed consent from Plaintiff's parents. Plaintiff contends that Defendants:

1. did not disclose the risks, including clotting, stent fractures and death (Doc. No. 127 at 3);

2. did not disclose the results of CP stent catheterization Fontan Completions in other children (*id.*);

3. induced Plaintiff's parents into believing that the CP stent procedure was as safe as, or safer than, surgical Fontan Completion (*id.*);

4. did not inform Plaintiff's parents of the correct details of the CP stent's regulatory

status (*id.* at 6);

5. did not discuss the advantages of a procedure that had known risks and benefits (*id.* at 15);

6. provided Plaintiff's parents with consent forms that were contradictory (*id.*);

7. and, provided consultations, through Dr. Baffa, that contradicted the information contained in the consent forms (*id.* at 16).

Section 6853 of the Health Care Act applies to informed consent claims as well as standard malpractice claims based upon a deviation from the standard of care. *See Valentine*, 2004 Del. Super. LEXIS 352, at *8 (applying section 6853's causation requirement to an informed consent claim); *Patten*, 1989 Del. Super. LEXIS 222, at *7-8 (same). In *Valentine*, the court expressed its view that informed consent claims "cannot . . . be used as a backdoor around the requirement that causation in medical negligence cases be supported by expert testimony." 2004 Del. Super. LEXIS 352, at *8. Plaintiff's case highlights exactly why this should be so. The Health Care Act represents a determination by the Delaware General Assembly that harm experienced by patients can only be linked to the conduct of health care providers with the guidance of expert medical testimony. There is no difference in the harm that Plaintiff claims that he suffered as a result of his malpractice-based medical negligence claim and the harm suffered as a result of his informed consent claim. Applying the expert testimony requirement of section 6853 to one and not the other would lead to a result that defeats the purpose of the Health Care Act.[19]

[19] We note that the result might be different if informed consent claims in Delaware sounded in battery. *Cf. Brzoska*, 668 A.2d at 1366. The focus of an inquiry into the tort of battery is whether an unconsented-to touching occurred. In Pennsylvania, there is a cause of action arising from a surgical procedure performed without informed consent, simply by virtue of

Since the causation analysis for Plaintiff's informed consent claim is the same as the causation analysis for his medical negligence claim, Plaintiff has not established causation, and his informed consent claim must fail.

D. Fraud

Plaintiff articulates several theories of fraud and intentional misrepresentation. Plaintiff alleges that the Medical Defendants knowingly supplied Plaintiff's parents with misleading consent forms on which Plaintiff's parents relied to Plaintiff's detriment. Plaintiff alleges that Dr. Baffa, who is not a defendant in this action, made misrepresentations about the catheterization procedure to Plaintiff's parents, which Plaintiff's parents relied on to Plaintiff's detriment. In addition, Plaintiff alleges that Drs. Norwood and Murphy lied to the FDA in order to obtain approval to implant the CP stent in Plaintiff. Finally, Plaintiff alleges that the Medical Defendants misled the hospital to avoid appropriate oversight in deciding to implant the stent.

Plaintiff's parents signed three consent forms regarding the implantation of the CP stent.[20] Two of the forms were pre-procedure consent forms and one was a post-procedure authorization to disclose protected health information. On October 23, 2003, Plaintiff's parents signed the pre-procedure consent forms, the Numed Consent Form and the Nemours Consent Form. On the day

---

the unlawful touching. *See, e.g.*, *Montgomery v. Bazaz-Sehgal*, 798 A.2d 742, 749-50 (Pa. 2002) ("A lack of informed consent [claim that sounds in battery] is actionable even if the subject of the surgery was properly performed and the overall result is beneficial . . . . It has long been the law that damages for emotional injuries are compensable . . . where there is some evidence of physical contact or injury, even if the physical contact or injury is trivial in nature.").

[20] All three forms signed by Plaintiff's parents are included as Exhibit E to Defendants' Motion for Summary Judgment on Count II of the Complaint. (Doc. No. 119). We identify these documents by the following names: "Numed Consent Form," "Nemours Consent Form," and "Health Information Disclosure Form."

of the procedure, Plaintiff's parents initialed and dated the same forms again.

The Numed Consent Form is entitled "Use of the Investigational NuMED Cheatham Platinum (CP) Stent Adult/Parent Consent Form." It informed Plaintiff's parents that the CP stent "is being made available to you or your child on a compassionate use basis in accordance with [FDA] guidelines. The CP Stent is not approved by the FDA. Therefore, the safety and effectiveness of the stent are unknown at this time." The Numed Consent Form contains a one-paragraph explanation of the procedure and lists potential risks associated with catheterization and stents, including death, partial blockage of surrounding vessels, fracture of the stent, infection of the stent, subsequent surgeries necessitated by dislodgment or partial expansion of the stent, and stent thrombosis. Just above the signature line, the Numed Consent Form also contains a Voluntary Participation Clause informing Plaintiff's parents that their choice to implant the CP stent was voluntary and that they had read and understood the information contained in the form.

The Nemours Consent Form contains less detail than the Numed Consent Form. It lists the procedures in check-boxes, one box labeled "Cardiac Catheterization and Angiography" and another labeled as "Other," with "Completion of Fontan using NuMed covered stent" type-written in the empty space following the box. The form goes on to state: "The Physician . . . has explained to me in detail the diagnosis and the reason for this special test or procedure. I understand that I am encouraged to speak with the attending physician or the specialist performing this test or procedure if I have any questions or concerns." (Doc. No. 119, Ex. E.)

The Health Information Disclosure Form authorized the disclosure of all Plaintiff's protected health information to the FDA and a third-party auditor. It contains an

acknowledgment that disclosure of the information was not mandatory and a guarantee that Plaintiff's parents could request an accounting of the uses and disclosures of the information.

Plaintiff claims that conversations regarding Plaintiff's treatment options between Plaintiff's parents and Dr. Baffa were also misleading. Dr. Baffa is a non-invasive cardiologist with whom Plaintiff's parents had most, if not all, of their consultations regarding Plaintiff's treatment. The exact parameters of these discussions are unclear, but Plaintiff alleges that Dr. Baffa told Plaintiff's parents that Plaintiff was a perfect candidate for the catheterization procedure, while failing to adequately discuss the surgical Fontan Completion option. (Doc. No. 126 at 25.) Plaintiff further alleges that Dr. Baffa did not inform Plaintiff's parents that the catheterization approach was experimental and that the information that Dr. Baffa did convey contradicted the Numed Consent Form. (*Id.* at 15-16.) Plaintiff does not refer to any affidavits or evidence – in the form of testimony from Plaintiff's parents, Dr. Baffa, or otherwise – that corroborates these allegations. Nor does Plaintiff clarify the connection between Dr. Baffa and the Medical Defendants. It is apparent that Dr. Baffa had been in charge of interacting with Plaintiff's parents and she certainly had some connection to the Medical Defendants, but exactly what that connection was is not clear.

Defendants have attached portions of Plaintiff's parents' depositions as exhibits to their moving papers, parts of which relate to Plaintiff's parents' interactions with Dr. Baffa. (*See* Doc. No. 119, Exs. F and G.) Plaintiff's mother testified that all of her questions and her husband's questions were answered by Dr. Baffa. (*See id.*, Ex. F at 36, 45.) She went on to state that she and her husband "always talked about wishing this didn't have to be a three-stage open heart [procedure]. And then at some point during one of our visits [with Dr. Baffa], and I don't

remember when, there started to be talk of a stent." (*Id.*, Ex. F at 51.) During the meetings, Dr. Baffa would often refer to her opinions and Dr. Norwood's opinions regarding the stent. (*Id.*, Ex. F at 52.) When asked about specific statements made by Dr. Baffa, Plaintiff's mother stated that she could not remember "any specifics other than that it [the CP stent] was a great thing, that you don't have to do open heart surgery." (*Id.*, Ex. F at 54.) Plaintiff's father testified that Dr. Baffa told him that the Hospital was the only institution where the CP stent was in use, that the CP stent had been implanted in a "handful of children," and that "it was working fine" in those children. (*See id.*, Ex. G at 107-08.)

Plaintiff also believes that Drs. Norwood and Murphy mislead the FDA in order to obtain a compassionate use exception allowing them to implant the CP stent in Plaintiff. (*Id.* at 16-23.) As the Numed Consent Form expressly states, the CP stent was not an FDA-approved device at the time the Medical Defendants implanted it in Plaintiff. The Medical Defendants filed an application for compassionate use (*see* Doc. No. 119, Ex. D) that Plaintiff contends was misleading in two significant respects. First, Plaintiff claims that the application failed to adequately discuss the availability of the alternative surgical Fontan Completion procedure. Second, Plaintiff contends that compassionate use applications require the endorsement of an "uninvolved" specialist and that Dr. Norwood made a material misrepresentation to the FDA by sending a letter of endorsement that did not adequately disclose his connection to the patient or his bias in favor of a catheter completion of the Fontan procedure.

Plaintiff's theory that the Medical Defendants misled the Hospital and the IRB appears to be that the Medical Defendants relied on an informal and misleading conversation with the vice-chair of the IRB, Dr. Locke, as justification for not obtaining IRB oversight. (Doc. No. 126 at

24.) This misleading conversation, in turn, resulted in IRB ignorance of the Medical Defendants' actions and the absence of oversight. In addition to the specific, allegedly misleading conversation, Plaintiff contends that the Medical Defendants misled the Hospital and IRB by the same course of conduct that Medical Defendants engaged in to mislead the FDA. (*Id.* at 25.) However, the IRB did submit a memorandum in support of the Medical Defendants' compassionate use application that appears to support the statements made by Drs. Murphy and Norwood. (*See* Doc. No. 119, Ex. D.) Plaintiff does not allege that the IRB's memorandum in support of the compassionate use was obtained by fraud or deceit.

Unlike a typical fraud claim, Plaintiff's fraud claim is governed by the Health Care Act, which defines medical negligence as "any tort or breach of contract based on health care or professional services rendered, or which should have been rendered, by a health care provider to a patient." 18 Del. C. § 6801(7). We have found no case that directly addresses the issue of the scope of section 6801(7) with regard to torts. However, the plain language of the section leads us to conclude that Plaintiff's fraud claim is, by virtue of legislative mandate, a medical negligence claim. *Cf. Miller*, 822 F. Supp. at 171-74 (dismissing breach of contract action against physician and hospital because plaintiff failed to meet section 6853's expert testimony requirement). We take the phrase "'Medical Negligence' means any tort . . ." to mean exactly what it says. The General Assembly could have used the terms "negligence," "unintentional tort," or "breach of duty," but it chose "any tort," which includes intentional torts such as fraud.[21] By choosing the

[21] The leading treatise on the law of torts, after a long discussion on the difficulty of defining the term tort, offers the following as one attempt at a definition:

> Included under the head of torts are miscellaneous civil wrongs, ranging from simple, direct interference with the person, such as assault, battery and false imprisonment,

term "any tort," the General Assembly explicitly elected to subject all torts arising out of the provision of medical services, including fraud, to the framework of the Health Care Act. This includes subjecting all tort theories to the expert testimony requirements of section 6853.[22] *See* 18 Del. C. § 6853(e); *see also Miller*, 822 F. Supp. at 173 (subjecting contract claim to section 6853's requirements).[23]

Plaintiff's fraud theory is "based on health care or professional services rendered, or which should have been rendered, by a health care provider to a patient." *See* 18 Del. C. § 6801(7); *cf. Patten*, 1989 Del. Super. LEXIS 222, at *1 (granting summary judgment against plaintiff who alleged, inter alia, that the physician-defendant "failed to disclose fully the alternatives available to surgery, depriving the plaintiffs the opportunity to exercise informed

---

> or with property, as in the case of trespass or conversion, up through various forms of negligence, to disturbances of intangible interests, such as those in good reputation or commercial or social advantage.

Prosser and Keeton on the Law of Torts § 1 (W. Page Keeton et al. eds., 1984).

[22] The fact that section 6855 of the Act establishes punitive damages for certain types of medical negligence further supports our reading of the statute. *See* 18 Del. C. § 6855. Normally, "mere negligence itself is not a basis for awarding punitive damages." *Premcor Ref. Group, Inc., v. Matrix Serv. Indus. Contractors, Inc.*, No. 01-095, 2008 Del. Super. LEXIS 195, at *27 (Del. Super. Ct. May 7, 2008). Section 6855's incorporation of punitive damages for malicious or wilful and wanton conduct, *see* 18 Del. C. § 6855, supports a broad reading of the statute's scope that includes intentional torts.

[23] Section 6853(e) says "[n]o liability shall be based upon asserted *negligence*," and not "medical negligence," the term used in section 6801. *See* 18 Del. C. §§ 6801, 6853. This does not alter our analysis. It is clear that the Health Care Act uses the terms interchangeably. *See Lougheed v. Med. Ctr. of Del.*, No. 05-141,1994 Del. Super. LEXIS 537, at *11 (Del. Super. Ct. Oct. 31, 1994) (noting that the Health Care Act used the term medical malpractice in section 6801(7) – which was changed to medical negligence in 1998 – interchangeably with the term negligence). No authority indicates that the court's analysis in *Lougheed* was altered in any way by the substitution of the term "medical negligence" for the term "medical malpractice" in section 6801(7).

consent," because plaintiff produced no expert testimony as required by section 6853). The substance of Plaintiff's allegations is that the Defendants mislead Plaintiff's parents with regard to the best available treatment for Plaintiff's HLHS, that Plaintiff's parents relied on Defendants' misrepresentations, and that Plaintiff was harmed as a result. However, the harm Plaintiff experienced is the same regardless of the legal theory used to redress it and the question regarding the cause of the harm does not change. Either the implantation of the stent was the but for cause of Plaintiff's harm or it was not. In order for a jury to determine that it was, it must have the guidance of a qualified medical expert.[24]

---

[24] To suggest that fraud claims of the sort that Plaintiff asserts here do not fall within the scope of the Health Care Act would raise a significant problem. Plaintiff's theory would create the potential for liability for fraud in all informed consent cases where a physician did not disclose information the injured party deemed important. Such a result would defeat the purpose of the Health Care Act.

It is interesting to note that the courts of New York and New Jersey have determined that plaintiffs cannot state claims for fraud arising out of the provision of medical services unless (1) the alleged fraud occurs "separately from and subsequent to the malpractice," and (2) the damages are "separate and distinct from those flowing from the malpractice." *Spinosa v. Weinstein*, 571 N.Y.S.2d 747, 753 (N.Y. App. Div. 1991) (*quoting Coopersmith v. Gold*, 568 N.Y.S.2d 250, 252 (N.Y. App. Div. 1991)); *Howard v. Univ. of Med. and Dentistry of N.J.*, 800 A.2d 73, 81-82 (N.J. 2002) (disallowing cause of action for fraud where it "would circumvent the requirements for proof of both causation and damages imposed in a traditional informed consent setting"). For example, in *Detwiler v. Bristol-Myers Squibb Co.*, 884 F. Supp. 117, 119 (S.D.N.Y. 1995), the plaintiff asserted a fraud claim against a doctor who allegedly failed to warn her of the risks associated with a procedure involving silicone injections. Specifically, the plaintiff alleged that the doctor failed to warn her that "silicone could cause autoimmune diseases; that her body could reject the silicone; that physical scarring, infection, and pigmentation changes could occur; that the silicone could migrate within her body or shift position; and that silicone had not been approved by the FDA for injection into the human body." *Id.* She also claimed that the doctor represented the silicone was safe, when it was in reality unsafe. *Id.* In dismissing the fraud claim, the court reasoned that "[t]he allegedly fraudulent actions – inaccurate assurances of safety and failure to inform of the risks – are the same as those which form the basis for the malpractice claim for lack of informed consent." *Id.* at 120. Although section 6801(7) accomplishes the same goal through legislative means, the effect is very similar, if not the same.

The *Patten* case is instructive. In *Patten*, the plaintiff's claim arose out of treatment she received for carpel tunnel syndrome. *Patten*, 1989 Del. Super. LEXIS 222, at *2. Her doctor, the defendant, recommended surgery, which relieved the symptoms of the carpel tunnel syndrome, but which left the plaintiff with an arthritic joint. *Id.* Plaintiff brought a medical malpractice premised on the following alleged deviations from the standard of care:

> 1) [defendant] failed to advise the plaintiffs that he was inexperienced or unskilled in the performance of the surgery and that [plaintiff] could be referred to other specialists; 2) [defendant] failed to disclose fully the alternatives available to surgery, depriving the plaintiffs the opportunity to exercise informed consent; 3) [defendant] failed to refer [plainitff] to a more experienced surgeon and performed surgery for which he had inadequate training and experience; 4) [defendant] failed to use a proper technique in performing the surgery.

Id. at *1-2 (italics removed). The court granted the defendant's summary judgment motion because the plaintiff had adduced no expert testimony satisfying section 6853's requirements. *Id.* at *7-8.

Here, Plaintiff's claim that the Medical Defendants misled Plaintiff's parents by not disclosing enough information to them is similar to the plaintiff's claim in *Patten*. The main difference, however, is that here Plaintiff has alleged both fraud and lack of informed consent whereas in *Patten* the plaintiff only alleged lack of informed consent. To permit plaintiffs to plead around the Health Care Act's requirements by alleging fraud in addition to or instead of an informed consent claim would be to permit a result inconsistent with the outcome in *Patten* and inconsistent with the Health Care Act's requirements. The fact that Plaintiff alleges that the Medical Defendants "deliberately misled the FDA, Dupont Hospital, and the Conway parents so that [they] could perform this procedure . . ." (Doc. No. 126 at 6) does not change our analysis. Certainly, if the Medical Defendants had committed fraud, that would support an argument that

they had deviated from the standard of care, and such a deviation could expose the Medical Defendants to liability for punitive damages. *See* 18 Del. C. § 6855 (providing for punitive damages in medical negligence cases where a plaintiff injury was "maliciously intended or was the result of wilful or wanton misconduct by the health care provider").

We have determined, however, that Plaintiff has failed to provide expert testimony on the issue of causation as required by section 6853. Given that determination, we need not speculate about the Medical Defendants' state of mind and Plainitff's right to punitive damages.[25] Plaintiffs' fraud claim must be dismissed.

E. Counts Three, Four, and Five of the Complaint

The Institutional Defendants also seek dismissal of Plaintiff's Assault and Battery Claim (Count III), Strict Liability Claim (Count IV), and Breach of Express and Implied Warranties Claim (Count V). (*See* Doc. No. 117 at 12.) The Institutional Defendants base their request on our February 14, 2007, Memorandum and Order dismissing those claims against Drs. Murphy and Norwood. *See Conway v. A.I. Dupont Hosp. for Children*, No. 04-4862, 2007 U.S. Dist. LEXIS 10563 (E.D. Pa. Feb. 14, 2007). Plaintiff does not contest the Institutional Defendants' request in his opposition papers. We will dismiss Counts Three, Four, and Five as to the Institutional Defendants for the reasons stated in the Memorandum and Order dated February 14, 2007.

IV. CONCLUSION

For the foregoing reasons, Defendants' motions for summary judgment will be granted.

An appropriate Order follows.

---

[25] In Delaware, there must be compensatory damages in order for there to be punitive damages. *See, e.g., Franklin Inv. Co. v. Smith*, 383 A.2d 355, 358 ("[P]unitive damages may not be awarded where there is no basis for an award of compensatory damages." (*citing Wardman-Justice Motors, Inc. v. Petrie*, 39 F.2d 512, 516 (D.C. Cir. 1930)).

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

TEAGUE CONWAY	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 04-4862
A.I. DUPONT HOSPITAL FOR CHILDREN, et al.	:	

ORDER

AND NOW, this 6th day of January, 2009, upon consideration of the Motion of Defendant William I. Norwood, M.D., Ph.D., for Summary Judgment (Doc. No. 116), the Institutional Defendants' Motion for Partial Summary Judgment (Doc. No. 117), the Motion for Partial Summary Judgment to Dismiss the First Cause of Action (Doc. No. 118), and the Motion for Partial Summary Judgment to Dismiss Count II of the Complaint Alleging Fraud and Intentional Misrepresentation and Punitive Damages Claim (Doc. No. 119), and all papers submitted in support thereof and in opposition thereto, it is ORDERED as follows:

1. Motion of Defendant William I. Norwood, M.D., Ph.D., for Summary Judgment is GRANTED;

2. The Institutional Defendants' Motion for Partial Summary Judgment is GRANTED;

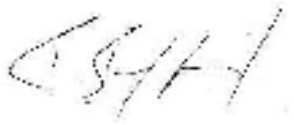
3. The Defendants' Motion for Partial Summary Judgment to Dismiss the First Cause of Action is GRANTED;

4. The Defendants' Motion for Partial Summary Judgment to Dismiss Count II of

the Complaint Alleging Fraud and Intentional Misrepresentation and Punitive Damages Claim is GRANTED.

IT IS SO ORDERED.

BY THE COURT:



_____

R. Barclay Surrick, Judge