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

MOLLY GUINAN	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 08-0228
A.I. DUPONT HOSPITAL FOR CHILDREN, et al.	:	

SURRICK, J. **FEBRUARY 6 , 2009**

MEMORANDUM & ORDER

Presently before the Court is the Motion of Defendants Numed, Inc. and Allen J. Tower For Summary Judgment on the Complaint of Molly Guinan. (Doc. No. 25.) For the following reasons, the motion will be granted in part and denied in part.[1]

I. BACKGROUND

A. Procedural History

On October 15, 2004, Plaintiff, along with two other individuals, filed against Defendants on behalf of themselves and those similarly situated. The Complaint alleges six causes of action: negligence (Count I); Fraud and Intentional Misrepresentation (Count II); Assault and Battery (Count III); Strict Products Liability (Count IV); breach of express and implied warranty

[1] For purposes of this opinion, we refer to Molly Guinan as "Plaintiff"; A.I. duPont Hospital for Children, the Nemours Foundation, the Nemours Cardiac Center, and the Nemours Delaware Institutional Review Board as the "Institutional Defendants"; Doctors William Norwood and John Murphy as the "Medical Defendants"; Allen Tower and NuMed Inc. as "NuMed"; and all the Defendants together as "Defendants."

This Memorandum and Order follows a Memorandum and Order (hereinafter, "First Memorandum") which granted summary judgment in favor of the Medical Defendants and the Institutional Defendants as to all causes of action in the Complaint except Count VI (medical monitoring).

(Count V); and medical monitoring (Count VI). In February 2007, we granted the Medical Defendants' motion to dismiss certain theories of negligence under the Plaintiff's first cause of action; Plaintiff's third cause of action for assault and battery; Plaintiff's fourth cause of action for strict products liability; and Plaintiff's fifth cause of action for breach of express and implied warranty. (*See* No. 04-cv-4862, E.D. Pa., Doc. No. 50 (hereinafter, "February 14, 2007 Memorandum and Order").) After a scheduling conference in January 2008, it was agreed that the named plaintiffs' cases would be tried separately. (*See* Doc. No. 1.)

B. Plaintiff's Medical Treatment

Plaintiff was born on March 12, 2001, with Down Syndrome and a combination of heart defects. As part of her treatment for these heart defects, Plaintiff's doctors at the A.I. duPont Hospital for Children in Wilmington, Delaware, implanted a stent in her heart that was not approved by the Food and Drug Administration. The Medical Defendants used this stent, known as the Cheatham Platinum covered stent ("CP stent"), in the second step of a two-step process known as the Fontan procedure. The first step of the procedure, the Hemi-Fontan, was intended to redirect unoxygenated blood from the upper half of Plaintiff's body to her lungs for oxygenation, bypassing her non-functioning right ventricle. (Doc. No. 20, Ex. A ¶ 5 (hereinafter, "Norwood Decl.").) The second step of the procedure, the Fontan completion, was intended to redirect unoxygenated blood from the lower half of Plaintiff's body to her lungs. (*Id.* ¶ 7.) A traditional Fontan completion ("Surgical Completion") is an open heart surgery. (*Id.*) Some time prior to treating Plaintiff, the Medical Defendants determined that the Surgical Completion could be achieved through a less invasive catheterization procedure using the CP stent ("Catheterization Fontan").

On October 14, 2002, cardiologist Dr. Murphy implanted a CP stent in Plaintiff. After the procedure, Plaintiff developed protein losing enteropathy ("PLE") and plastic bronchitis, both rare and potentially life-threatening conditions. Plaintiff's parents were dissatisfied with the Medical Defendants' treatment in response to these conditions, and in May 2003, Plaintiff's parents decided to transfer Plaintiff to the care of Dr. Jack Rychik, Dr. Thomas Spray, and Dr. Jonathan Rome at the Children's Hospital of Philadelphia ("CHOP"). (Doc. No. 33, Ex. K at 150-52 (hereinafter, "J. Guinan Dep.").)

At CHOP, Plaintiff's doctors determined that fenestrating – i.e., putting a hole in – the CP stent was the best treatment for Plaintiff's plastic bronchitis, her PLE having dissipated on its own. (*See* Doc. No. 25, Ex. 21 at 22 (hereinafter, "Rome Dep.").) The doctors at CHOP believed that the Gore-Tex material that covered the stent might close back up if it were fenestrated. (Rome Dep. at 33-35; J. Guinan Dep. at 164, 292.) They conveyed this concern to Plaintiff's parents, who elected to proceed with the fenestration with that knowledge. (J. Guinan Dep. at 164; Doc. No. 33, Ex. L Vol. II at 108 (hereinafter, "K. Guinan Dep. Vol. II").) On December 17, 2004, Dr. Rychik used a catheter to fenestrate the CP stent in Plaintiff. (J. Guinan Dep. at 169.) In February, 2006, Drs. Rychik and Rome discovered that the fenestration in Plaintiff's CP stent was only allowing a "relatively small amount of blood" to pass through it. (Rome Dep. at 24.) Dr. Rychik suggested enlarging the fenestration in a procedure that would result in an extremely small stent sitting in the fenestration at a right angle to the CP stent. (*Id.* at 25.) Plaintiff's parents consented, and Dr. Rychik performed the procedure. (*See* K. Guinan Dep. Vol. II at 116-20; J. Guinan Dep. at 292-94.) Plaintiff continues to suffer from plastic bronchitis, which, combined with other physiological and developmental issues that accompany

Down Syndrome, necessitates ongoing medical supervision.

C. NuMed and the CP Stent

The CP stent was created by Dr. John Cheatham and NuMed's president, chief executive officer, and sole shareholder, Allen Tower. (*See generally* Doc. No. 33, Ex. G at 30-40 (hereinafter, "Cheatham Dep.").) The two began collaborating together in the mid-1990s to develop a stent specifically intended for treatment of cardiac problems in children. (*Id.* at 33-34.) In its original form, which took shape in 1997, the stent was bare and made out of platinum. By 2002, when the Medical Defendants implanted it in Plaintiff, the CP stent was made of platinum with gold welds and covered in Gore-Tex. (*See id.* at 52-53.)

It is uncontested that the CP stent is a Class III medical device under the Food, Drug & Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.* and the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360 *et seq.* *See* 21 U.S.C. § 360c(a)(1)(C). As a Class III device, the CP stent could not be sold or marketed by NuMed without obtaining premarket approval from the FDA. *See* 21 U.S.C. §§ 331, 351, 360e. In 1997, NuMed contacted the FDA to arrange to have the CP stent classified as a humanitarian use device ("HUD"), which is "a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year." *See* 21 C.F.R. § 814.3(n). A HUD classification allows a device manufacturer to obtain a humanitarian device exemption to the regular premarket approval requirements for Class III devices under the FDCA. *See* 21 U.S.C. § 360j(m). On May 10, 2000, NuMed obtained HUD approval for the first version of the CP stent from the FDA. (Doc. No. 25, Ex. 13 at 31-32 (hereinafter, "LaFlesh Dep.).)

Over the next year NuMed pursued an HDE so that it could market and sell the device.

The FDA refused NuMed's requests in July 2000 and January 2001. (*Id.* at 37-42.) NuMed withdrew its HDE application in March 2001 and indicated to the FDA that it intended to file for an investigational device exemption ("IDE"). *See* 21 U.S.C. §§ 360j(g), 360bbb(c); 21 C.F.R. §§ 812.1 *et seq.* During this time period, the CP stent was being tested in animals and modified. (LaFlesh Dep. at 62-63.) NuMed was also seeking approval to sell the device in Europe from the European Union. (*Id.* at 80-81.)

Over the course of the FDA approval process, NuMed was providing the CP stent to doctors under what NuMed believed to be the custom device exemption to the premarket approval requirements of the FDCA. (Doc. No. 25, Ex. 11 at 20 (hereinafter, "Tower Dep.").) The custom device exemption removes devices that, "in order to comply with the order of an individual physician[,] . . . necessarily deviate[] from an otherwise applicable performance standard or requirement prescribed by or under section [21 U.S.C. § 360e]" from the FDCA's premarket approval requirements if two conditions are met:

> (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and
>
> (2) such device –
>
> (A) (i) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or
>
> (ii) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and
>
> (B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).

21 U.S.C. § 360j(b). NuMed sent the CP stent used in Plaintiff's Catheterization Fontan to Dr. Murphy under what it believed was a custom device exemption to the FDCA. (LaFlesh Dep. at 138.)

The Medical Defendants first approached NuMed at a medical convention in Chicago in 2001 or 2002. (Tower Dep. at 5-6, 26-28.) They expressed interest in using the CP stent for doing transcatheter completions of the Fontan procedure. (*Id.* at 27.) At the time, Allen Tower believed that NuMed could provide the Medical Defendants with the CP stent if they wrote a prescription for a specific patient. (*Id.* at 20.) Tower believed that if the doctor wrote a prescription and NuMed shipped the paperwork that it had worked on with the FDA "to get the right wording," then what the Medical Defendants did with the CP stent was not "pertinent." (*See id.*) Tower, who is not a doctor, did not understand what the Fontan procedure was when he sent the CP stent to Dr. Murphy, and he did not think it was NuMed's place to tell doctors what they could or could not do with the CP stent. (*Id.* at 25.)

When Plaintiff developed PLE and plastic bronchitis after her Fontan was completed, her mother became dissatisfied with the treatment Plaintiff was receiving. That dissatisfaction led Plaintiff's mother to file several formal complaints with A.I. duPont Hospital and its Institutional Review Board. (*See* Doc. No. 33, Ex. JJ at 21 (hereinafter, "March 30, 2004 Letter").) Plaintiff's mother also contacted the FDA, which began an investigation into the use of the CP stent by the Medical Defendants. Over the course of several months, the FDA communicated with all Defendants to develop a series of remedial measures, which included, among other things, a recall of the CP stent, removing it from all institutions that had it on hand. (*See* Doc. No. 33, Ex. V at 2.)

The FDA's investigation culminated in the government bringing an information charging that NuMed and Tower violated 21 U.S.C. §§ 331(a) and 331(a)(1) by marketing an adulterated device (i.e., a device without premarket approval, *see* 21 U.S.C. § 351(f)(1)(B)). (*See* Doc. No. 33, Ex. EEE.) NuMed and Tower, in his individual capacity, pled guilty to two misdemeanor counts of introducing an adulterated device into interstate commerce in violation of 21 U.S.C. § 331(a). (*See* Doc. No. 33, Ex. UU (hereinafter, "Tower Plea Agreement" and "NuMed Plea Agreement").) As part of their plea agreements, NuMed and Tower agreed to pay a criminal fine of $2,293,451.00 and to perform a community service in the form of paying approximately $2 million to fund a clinical study of the CP stent for the indicated use of coarctation of the aorta administered by The Johns Hopkins University. (*See* Tower Plea Agreement at 2-3.) In addition to paying for the clinical study, Tower and NuMed agreed to supply CP stents for the study free of charge and, if FDA approves the CP stent, to supply it to health care providers who request it for treatment of coarctation of the aorta free of charge. (*Id.* at 3-4.)

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); *see also Fin. Software Sys., Inc., v. Lecocq*, No. 07-3034, 2008 U.S. Dist. LEXIS 41699, at *6 (E.D. Pa. May 27, 2008).

B. Choice of Law

Federal courts sitting in diversity must apply the law of the forum state. *See, e.g.*, *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.*, 203 A.2d 796, 805-06 (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 a court 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. Where there is no conflict, the court can refer interchangeably to the laws of the pertinent states in discussing the law applicable to the case. *On Air Entm't Corp. v. Nat'l Indem. Co.*, 210 F.3d 146, 149 (3d Cir. 2000) (*citing Lucker Mfg. v. Home Ins. Co.*, 23 F.3d 808, 813 (3d Cir. 1994)). If the court determines that a conflict does exist, it then must move 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." *Hanover*, 2007 U.S. Dist. LEXIS 92646, at *12.

The pertinent states in this case are: (a) Pennsylvania, the forum state; (b) Delaware, where the medical procedure occurred; (c) New Jersey, Plaintiff's residence; and (d) New York, NuMed's state of incorporation. Unless otherwise noted, we will apply Delaware law in this case because (1) both parties rely on Delaware law in their memoranda; (2) to the extent that there is no conflict of laws, the laws of the states whose law would be potentially applicable can be applied interchangeably; and, (3) most importantly, to the extent that a conflict exists, the parties have agreed that, under Pennsylvania's choice of law analysis, Delaware has the greatest interest. *See Smith v. Cont'l Cas. Co.*, No. 07-1214, 2008 U.S. Dist. LEXIS 76818, at *22-23 (M.D. Pa. Sep. 30, 2008) ("The parties to this action have not explicitly addressed the choice of law question, but they have relied on Pennsylvania law in their submissions and seem to agree that Pennsylvania law governs the insurance contract at issue. Accordingly, to the extent that the law

of a state other than Pennsylvania could control the resolution of the present motion, the issue has been waived by the parties."); *see also Mellon Bank, N.A., v. Aetna Bus. Credit Inc.*, 619 F.2d 1001, 1005 n.1 (3d Cir. 1980) (finding that the parties had waived any objection to the application of Pennsylvania law where the parties "proceeded at the trial and appellate level as if Pennsylvania law applied . . . [and] [n]o objection was raised below or on appeal . . ."); *Sofia v. McWilliams*, No. 01-5394, 2003 U.S. Dist. LEXIS 5622, at *50-51 (E.D. Pa. Mar. 31, 2003) (applying New Jersey law because the parties implicitly agreed that New Jersey law applied when they based their arguments exclusively on New Jersey law; the parties did not brief the issue; the choice of law would not impact the result; and there was no perceivable reason to apply another state's law); *Textile Biocides v. Avecia Inc.*, 52 Pa. D. & C.4th 244, 260 & n.10 (Pa. Ct. Com. Pl. 2001) (allowing the parties to agree on choice of law "as long as the state whose law is chosen bears a reasonable relationship to the transaction and the chosen law does not affect the court's subject matter jurisdiction or violate public policy"). NuMed argues that "if there is any conflict in the laws of Pennsylvania, New Jersey, New York and Delaware, the Court should apply Delaware law . . . ." (Doc. No. 25 at 16-17.) Similarly, Plaintiff states that "Delaware has the greatest interest in this case, given that the medical treatment giving rise to these claims was rendered in Delaware." (Doc. No. 33 at 32.) We agree with the parties that Delaware's interests in this matter are stronger than the interests of the other states and that Delaware law should apply where conflicts exist.[2] Delaware has the greater interest because the complained-of conduct occurred in Delaware, including the purported misrepresentations, and Delaware has a

[2] Indeed, we have determined on several occasions that Delaware law applies to the nexus of facts and legal claims that form the basis of this case. (*See* First Memorandum at 10-16; *see also* No. 04-cv-4862, E.D. Pa., Doc. Nos. 50, 151.)

demonstrable interest in regulating health care practice and policies within its borders.

We will not, however, apply Delaware law to the "piercing the corporate veil" issue, which must be considered in light of Plaintiff's claims against Allen Tower as an individual. Pennsylvania courts apply the internal affairs doctrine, which "holds that courts look to the law of the state of incorporation to resolve issues involving the internal affairs of a corporation." *See Banjo Buddies, Inc. v. Renosky*, 399 F.3d 168, 179 n.10 (3d Cir. 2005) (*citing*, inter alia, *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 89-93 (1987)). "Pennsylvania has adopted the 'internal affairs' doctrine by statute." *Banjo Buddies*, 399 F.3d at 179 n.10 (*citing* 15 Pa. Cons. Stat. § 4145(a); *In re Estate of Hall*, 731 A.2d 617, 622 (Pa. Super. Ct. 1999)); *see also United States v. Funds Held ex rel. Wetterer*, 210 F.3d 96, 106 (2d Cir. 2000) (finding that "[q]uestions relating to the internal affairs of corporations . . . are generally decided in accordance with the law of the place of incorporation"); *McDermott Inc. v. Lewis*, 531 A.2d 206, 215 (Del. 1987) (holding that Delaware recognizes the internal affairs doctrine). NuMed is incorporated in the state of New York. Accordingly, we will apply the law of New York to the issue of piercing the corporate veil.

III. LEGAL ANALYSIS

A. Negligence (Count I)

Plaintiff's negligence claims against NuMed include failure to test, failure to warn, and negligence per se based on violation of the FDCA. (*See* Doc. No. 33 at 42-65.) In the First Memorandum, we determined that Plaintiff's medical negligence and informed consent claims against the Medical Defendants and the Institutional Defendants failed because Plaintiff had not met her burden of producing expert testimony on the essential element of causation. *See* 18 Del.

C. § 6853(e); *see also O'Donald v. McConnell*, 858 A.2d 960, 960 (Del. 2004) (granting defendant's summary judgment motion because plaintiff had not produced medical expert testimony regarding causation); *Burkhart v. Davies*, 602 A.2d 56, 59 (Del. 1991), *cert. denied*, 504 U.S. 912 (1992) (holding medical expert testimony on the defendant's deviation from the standard of care and the causal connection between that deviation and plaintiff's alleged injury are essential elements of medical negligence claims). In the First Memorandum, we analyzed Plaintiff's negligence claims against the Medical Defendants and the Institutional Defendants under the framework of Delaware's Health Care Malpractice Insurance and Litigation Act (the "Health Care Act"), 18 Del. C. §§ 6801 *et seq.* Plaintiff's negligence claims against NuMed are not governed by the Health Care Act because NuMed is not a health care provider under the Act's terms. *See* 18 Del. C. § 6801(5) ("'Health care provider' means a person, corporation, facility or institution licensed by this State pursuant to Title 24, excluding Chapter 11 thereof, or Title 16 to provide health care or professional services or any officers, employees or agents thereof acting within the scope of their employment . . . ."). Nevertheless, Plaintiff's negligence claim against NuMed cannot survive summary judgment.

The prescriptions of the Health Care Act notwithstanding, in order to withstand summary judgment, all tort plaintiffs in Delaware must produce medical expert testimony regarding causation when their claims are for bodily injury. *Rayfield v. Power*, 840 A.2d 642, 642 (Del. 2003) ("With a claim for bodily injury, the causal connection between the defendant's alleged negligent conduct and the plaintiff's alleged injury must be proven by the direct testimony of a competent medical expert.") (footnote omitted); *Money v. Manville Corp. Asbestos Disease Comp. Trust Fund*, 596 A.2d 1372, 1377 (Del. 1991) ("The plaintiff always has the burden of

proving by competent evidence that there was a reasonable probability of a causal connection between each defendant's negligence and the plaintiff's injury. When the issue of causation is presented in a context which is not a matter of common knowledge, such a reasonable probability can only be proven by the testimony of a competent expert witness."); *Cann v. Dunner*, No. 07C-02-15, 2008 Del. Super. LEXIS 424, at *7 (Del. Super. Ct. Nov. 13, 2008) (holding that plaintiff had failed to establish a prima facie case of negligence, entitling defendant to summary judgment, where plaintiff had not produced expert testimony connecting the automobile accident allegedly caused by defendant to plaintiff's claimed soft tissue injuries). Plaintiff has not produced expert testimony linking any of NuMed's alleged deviations from the standard of care to the cognizable legal injuries that she claims.

Plaintiff contends that she has satisfied her burden regarding causation. (Doc. No 33 at 33-42.) She asserts that there is ample evidence to find causation and cites to two paragraphs in the report of her expert, pediatric cardiologist Dr. Paul Grossfeld:

> As far as [Plaintiff's] future is concerned, given the fact that the CP stent implanted in her on October 14, 2002, was not safe for use in humans[3] [sic] that the Cheatham platinum stent has never been shown to be safe or effective for use of stent based Fontan completion, and there was no original plan for long term care and follow up of this implanted device, I find that Molly's future is truly unknown.
>
> There is nothing in the deposition of Allen Tower or Dr. Cheatham that would indicate that they have any knowledge as to what the safety and effectiveness of the [CP] stent will be in the future. [Plaintiff] has already had two additional procedures to fenestrate the stent – which was never meant to be fenestrated – in order to deal with her protein losing enteropathy and plastic bronchitis. Clearly, her future is unknown and relies upon the physicians at [CHOP] to continue in their attempts to manage this unknown and unapproved device implanted in [Plaintiff's] heart.

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[3] At his deposition, Dr. Grossfeld revised the statement in his report that the CP stent was "not safe for use in humans." He testified that the statement should have been that the safety of the stent was unknown. (*See* Doc. No. 25, Ex. 6 at 286-89 (hereinafter, "Grossfeld Dep.").)

(Doc. No. 33 at 34, 40 (*quoting* Doc. No. 33, Ex. WW (hereinafter, "Grossfeld Report")).) However, it is clear from the text of Dr. Grossfeld's report that he offers no opinion regarding the causal connection between the catheterization procedure or the CP stent and Plaintiff's claimed injuries. Without adequate medical expert testimony on causation, Plaintiff's negligence claims fail. NuMed is entitled to summary judgment. *See Rayfield*, 840 A.2d at 642; *Money*, 596 A.2d at 1377.

B. Fraud and Intentional Misrepresentation (Count II)

In Count II of her Complaint, Plaintiff alleges that "Defendants committed common law fraud in intentionally misrepresenting the risks of undergoing the stent implantation and the complete truth behind the history of the NuMED Stent." (Compl. ¶ 102.) Plaintiff requests compensatory and punitive damages on this claim. NuMed moves for summary judgment on Plaintiff's fraud and intentional misrepresentation claim, arguing that NuMed did not make any factual misrepresentation or conceal any material fact and that NuMed did not engage in intentionally deceptive conduct toward Plaintiff. (Doc. No. 25 at 34-37.) Furthermore, NuMed argues that there is no evidence to support Plaintiff's demand for punitive damages. (*Id*. at 37-38.)

> Intentional misrepresentation, or common-law fraud, requires that
>
> > (1) the defendant falsely represented or omitted facts that the defendant had a duty to disclose; (2) the defendant knew or believed that the representation was false or made the representation with a reckless indifference for the truth; (3) the defendant intended to induce the plaintiff to act or refrain from acting; (4) the plaintiff acted in justifiable reliance on the representation; and (5) the plaintiff was injured by its reliance.

ABRY Partners V, L.P., v. F&W Acquisition LLC, 891 A.2d 1032, 1050 (Del. Ch. 2006). "In addition to overt representations, fraud may also occur through deliberate concealment of

material facts, or by silence in the face of a duty to speak." *H-M Wexford LLC v. Encorp., Inc.*, 832 A.2d 129, 144 (Del. Ch. 2003).

NuMed asserts that Plaintiff cannot establish the first element of a common-law fraud claim, that is, that NuMed falsely represented or omitted facts that it had a duty to disclose. (Doc. No. 25 at 35.) First, NuMed argues that under the "learned intermediary" doctrine, it was only required to warn Plaintiff's physicians about the regulatory status of the CP stent or any risks associated with the stent. (*Id*. (*citing Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)).) Second, NuMed argues that since no NuMed representative spoke with Plaintiff's family until one year after the procedure, NuMed clearly cannot be said to have affirmatively misrepresented any fact. (*Id.* at 36 (*citing* J. Guinan Dep. at 231-32, 298-303; K. Guinan Dep. Vol I. at 246-51, Vol. II. at 122-27).) Finally, NuMed argues that "[t]o the extent that Guinan's fraud and intentional misrepresentation claim is based on the NuMED consent form, that form clearly states that the CP Stent is not FDA-approved." (*Id*. at 36 n.23.) Plaintiff responds that NuMed deliberately concealed a material fact and that NuMed's silence in the face of its duty to speak shows that NuMed is culpable of fraud. (Doc. No. 33 at 66.) Furthermore, Plaintiff argues that "[t]he 'learned intermediary' rule is inapplicable here, because, as an exception to the Rule, the manufacturer, Numed, has failed to follow Federal regulations, namely, facts material to the use, and the substance of the information given to the doctors." (*Id.* at 55.)

"The learned intermediary doctrine provides for an exception to the general rule that the manufacturer of a drug [or medical device] owes a duty to warn the consumer directly concerning risks associated with the drug [or medical device]." *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399 (Del. Sup. Ct. 1989) (brackets in original). The doctrine provides that

> in circumstances where (1) ethical drugs or medical devices that can be prescribed or installed only by a physician are involved and (2) a physician prescribes the drug or installs the medical device after having evaluated the patient, the manufacturer of the drug or device owes the patient only the duty to warn the physician and to provide the physician with adequate product instructions.

Talley v. Danket Med., Inc., 179 F.3d 154, 163 (4th Cir. 1999); *see also, e.g., Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 740 (N.D. Tex. 2000) (applying "the learned intermediary doctrine, under which manufacturers need only warn the ultimate user's physician"); *Minisan v. Danek Med., Inc.*, 79 F. Supp. 2d 970, 978 (N.D. Ind. 1999) ("[U]nder the Learned Intermediary Doctrine, manufacturers of prescription medical products have a duty only to warn phsycians, rather than patients, of the risks associated with the use of the product."). Courts reason that

> [f]or physician-prescribed drugs and medical devices, the physician is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment.
>
> The manufacturer, on the other hand, generally has no ability to assess the suitability of its product for a particular patient in a particular situation. Manufacturers of ethical drugs (i.e., drugs administrable only by a doctor's prescription) and medical devices make products which, while generally beneficial when used properly in the right circumstances, are often inherently dangerous when used improperly or in improper circumstances. The manufacturer lacks precisely the patient-specific information the physician possesses and uses to determine if, when, and how an ethical drug or device should be used.
>
> In addition, practical realities support the learned intermediary doctrine because it is virtually impossible in many cases for a manufacturer to directly warn each patient. While a manufacturer can enclose warnings with the product, when the product is applied directly by the physician . . . there is no practical way that the manufacturer could ensure that the patient receives the written warnings.

Talley, 179 F.3d at 163 (internal quotes, citations omitted). This reasoning certainly makes sense in the context of this case, where Plaintiff could not have obtained independent access to the CP stent, where the Medical Defendants had to order the CP stent from NuMed by prescription, and where the Medical Defendants inserted the CP stent into Plaintiff during a medical procedure.

See, e.g., Lacy, 567 A.2d at 401 ("The rationale supporting the learned intermediary doctrine is even stronger when applied to the IUD, as opposed to an oral contraceptive, because not only must the physician order the IUD for his patient, but the physician must also fit the IUD in place. Thus, the patient is required to rely on her physician's expertise whenever an IUD is used.").

Plaintiff argues that the learned intermediary rule should not apply here because there was no warning insert or physician guidance provided by NuMed, and therefore a question of fact exists. (Doc. No. 33 at 59.) Plaintiff supports her position by devoting three full pages of her brief to a block quote from a Delaware Superior Court case. (*See* Doc. No. 33 at 56-59 (*quoting O'Brien-Hastings v. Howmedica Corp.*, 1996 Del. Super. LEXIS 211, at *4-7 (Del. Super. Ct. May 15, 1996)).) This extended quotation serves as Plaintiff's legal analysis of the learned intermediary doctrine. The *O'Brien* court refused to apply the learned intermediary doctrine because there existed a question of fact as to "whether the actual content of the warning [provided by the medical device manufacturer to the doctor] was sufficient in light of the degree of harm that a patient could suffer . . . ." *O'Brien*, 1996 Del. Super. LEXIS 211, at *8. NuMed argues that Plaintiff has not pointed to any "evidence that NuMED failed to provide adequate training and instructions to Dr. Murphy, to the extent that any such training or instructions were necessary." (Doc. No. 25 at 26.)

Plaintiff responds that "there is ample evidence that defendants actively concealed a material fact – the CP stent was purely experimental and not approved for anything . . . ." (Doc. No. 33 at 69.) Plaintiff states that although NuMed knew that doctors were using the CP stent for Fontan completion (*Id.* at 67 (*citing* Tower Dep. at 16)), NuMed "did not provide *any* information with regard to using the CP stent for fontan completion." (Doc. No. 33 at 69

(emphasis in original).) In support of this assertion, Plaintiff quotes from Allen Tower's deposition:

> Q: What information did you know that Dr. Murphy had that said using this stent, your Cheatham platinum, the CP covered stent in a Fontan completion context was safe to use?
>
> A: He got nothing from NuMED on that and in my mind he learned about this from Cheatham and from other doctors that were doing Fontan completions throughout the world.

(Tower Dep. at 65 (*cited in* Doc. No. 33 at 69).) Tower's response did not indicate that NuMed "did not provide *any* information with regard to using the CP stent for fontan completion." (Doc. No. 33 at 69 (emphasis in original).) Rather, Tower's answer indicates that NuMed did not assure the doctors that the CP stent was safe to use in the Fontan completion. Tower's deposition does not provide a basis upon which to conclude that NuMed misrepresented or failed to disclose the status and risks of the CP stent.

Plaintiff also argues that "Defendants' silence in the face of his duty to speak, yes a Duty to Warn, . . . shows that defendants are culpable of fraud, who by this omission fail to reveal that which it was their duty to disclose, in order to prevent statements actually made by Drs. Murphy and Gidding from being misleading." (Doc. No. 33 at 66.) It is difficult to determine exactly what Plaintiff is trying to communicate here. If Plaintiff is arguing that NuMed's fraud occurred when NuMed failed to disclose to the Medical Defendants that the CP stent was not FDA-approved, and that this omission caused the doctors to make misleading statements to Plaintiff's parents, Plaintiff has presented no evidence to support the proposition that NuMed concealed either the regulatory status or risks of the CP stent from the doctors, or that it failed to disclose that information. In fact, the record reflects that it was NuMed's practice to include a NuMed

consent form with the CP stent when it was mailed to doctors upon receiving a prescription order. (*See, e.g.*, LaFlesh Dep. at 50 ("With each CP stent that was shipped out was an informed consent form . . . . [e]xplaining the device.").) The NuMed consent form, titled "Use of the Investigational NuMED Cheatham Platinum (CP) Stent Adult/Parent Consent Form," states in pertinent part:

> The NuMED Cheatham Platinum (CP) stent has been developed over the past two years and remains in the investigational stage. NuMED, Hopkinton, New York, has helped with the development and manufacturing of the stent and has agreed to allow its use in you or your child. Because the CP stent has not been approved by the United Stated [sic] Food and Drug Administration (FDA), we would like to maintain appropriate records regarding the clinical effectiveness and safety of the stent.

(Doc. No. 25, Ex. 4.) The form describes the composition of the CP stent and the catheterization procedure. (*Id*.) The form then lists potential risks, discomforts and complications that could result from the catheterization, the balloon valvuloplasty or angioplasty, or the use of a stent. (*Id*.) There is a factual dispute regarding whether or not Plaintiff's parents saw or signed the NuMed consent form. NuMed says that Plaintiff's father signed the form and submits a signed form as evidence. (Doc. No. 25 at 6 n.3; *id.*, Ex. 4.) Plaintiff's father insists that he did not see or sign the form. (K. Guinan Dep. Vol. I at 87-88, 113, 117, 228; *see also* J. Guinan Dep. 173, 283-85.) In any event, Plaintiff points to no evidence suggesting either that the doctors did not see this consent form, which states explicitly that the device was not FDA-approved, or that the doctors did not receive additional information about the device. Plaintiff cannot create a genuine issue of material fact with a conclusory assertion that there was no warning insert and no physician guidance. She must point to facts in the record. Despite Plaintiff's statement that there is "ample evidence" to show that NuMed concealed the fact that the CP stent was not FDA-approved, Plaintiff has failed to locate this evidence is in the record for the Court. After our own

review of the record, it is apparent that, as the record stands, Plaintiff cannot establish the first element of the intentional misrepresentation claim.

The second element of a common law fraud claim requires Plaintiff to show that NuMed acted with a reckless indifference for the truth. *ABRY Partners*, 891 A.2d at 1050. Plaintiff does not offer any additional evidence on this element. Moreover, the fact that NuMed, as a practice, sent doctors a copy of the NuMed consent form along with the CP stent is inconsistent with the allegation that NuMed acted with an intent to deceive.

Finally, as discussed above and in the First Memorandum, Plaintiff has produced no evidence that NuMed's actions caused Plaintiff's injuries. Even if we determine that Plaintiff had established that NuMed made false representations or failed to disclose material facts to the Medical Defendants and Plaintiff's parents, NuMed would still be entitled to summary judgment on this claim because Plaintiff has not established that she suffered injuries as a result of her reliance on NuMed's misrepresentations.

For these same reasons Plaintiff's negligent misrepresentation claims suffer the same fate. A negligent misrepresentation, or equitable fraud, claim must "satisfy all the elements of common-law fraud with the exception that plaintiff need not demonstrate that the misstatement or omission was made knowingly or recklessly." *H-M Wexford*, 832 A.2d at 144. As discussed, Plaintiff has not met her burden with regard to the first and last elements of an intentional misrepresentation claim. These same elements must be established to survive summary judgment on a negligent misrepresentation claim. Accordingly, we will grant Defendant's Summary Judgment Motion as to Plaintiff's negligent misrepresentation claim.

Finally, Plaintiff cannot establish a claim for punitive damages. There must be

compensatory damages in order for there to be punitive damages. *See, e.g., Pipher v. Burr*, 1998 Del. Super. LEXIS 26, at *14 (Del. Super. Jan. 29, 1998) ("[W]here compensatory damages are not available, punitive damages are also not available."); *Franklin Inv. Co. v. Smith*, 383 A.2d 355, 358 (D.C. 1978) ("[P]unitive damages may not be awarded where there is no basis for an award of compensatory damages.").

C. Assault and Battery (Count III)

Count III of Plaintiff's Complaint states a claim of assault and battery. (Compl. ¶¶ 106-07.) Plaintiff alleges that "Defendants failed to inform [Plaintiff] . . . of the risks and alternatives to of [sic] all treatment, care, therapy and procedures performed so as to afford [Plaintiff] . . . the opportunity to make an informed decision . . . ." (*Id.* ¶ 107.)

In Delaware, informed consent claims sound in negligence, not battery. *See, e.g., 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.") Under the Health Care Act, informed consent is defined as

> the 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) (emphasis added). 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.

Id. § 6852(a) (emphasis added). Clearly, the Health Care Act places the burden of obtaining informed consent on health care providers, not manufacturers. *See id*. NuMed is not a health care provider. *See id*. § 6801(5). Therefore NuMed had no duty to obtain informed consent from Plaintiff.

Plaintiff argues, however, that NuMed inserted itself into and participated in the informed consent process and therefore is not entitled to summary judgement on the assault and battery claims. (Doc. No. 33 at 80.) Plaintiff appears to argue that by enclosing an informed consent form with the CP stent, NuMed has created a voluntary duty to obtain informed consent directly from Plaintiff. Plaintiff does not support this argument with citation to legal authority. However, to the extent that Plaintiff is arguing that NuMed has the same duty as the Medical Defendants to obtain informed consent, our analysis in the First Memorandum explains why NuMed is entitled to summary judgment. NuMed's summary judgment motion on the assault and battery claim must be granted.

D. Strict Products Liability (Count IV)

Count IV of the Complaint is a claim based on a theory of strict products liability. NuMed seeks summary judgment on the claim. In support thereof, NuMed advances three arguments. First, NuMed contends that under Delaware law, Article 2 of the Uniform Commercial Code preempts strict products liability claims and, consequently, "Delaware does not recognize a cause of action in strict products liability." (Doc. No. 25 at 43.) Second, NuMed contends that under Delaware law, strict liability principles do not apply to prescription medical

devices like the CP stent. (*Id.*) Finally, NuMed contends that even if Delaware recognized Plaintiff's strict products liability claim as a cause of action, Plaintiff has not shown that the CP stent was defective in design or manufacture and has not shown that NuMed failed to warn. Thus, NuMed contends that Plaintiff has not shown the necessary elements of a strict liability claim. (*Id.* at 44.)

In response to NuMed's contention that Article 2 of the UCC preempts strict products liability claims under Delaware law, Plaintiff argues that NuMed relied on several cases that did not involve a Class III medical device like the CP stent. (Doc. No. 33 at 81.) The cases involved a shower door, a peanut jar, and an air compressor. *See Miley v. Harmony Mill Ltd.*, 803 F. Supp. 965, 967 (D. Del. 1992) (shower door); *DiIenno v. Libbey Glass Div., Owens-Illinois, Inc.*, 668 F. Supp. 373, 376 (D. Del. 1987) (peanut jar); *Amoroso v. Joy Mfg. Co.*, 531 A.2d 619, 621 (Del. Super. Ct. 1987) (air compressor). Plaintiff argues that unlike a shower door, peanut jar, or air compressor, the CP stent is an "abnormally dangerous product" such that "Delaware would apply strict liability." (Doc. No. 33 at 81.)[4] In response to NuMed's contention that strict liability principles do not apply to prescription medical devices, Plaintiff again argues that the CP stent is an "abnormally dangerous product" and, "as such, Delaware would apply strict liability." (*Id.* at 82.) Finally, in response to NuMed's contention that Plaintiff has not shown the necessary elements of a strict liability claim even if Delaware recognized such a claim, Plaintiff argues that "there is ample evidence of defective design / manufacture" and "NuMed has not been able to

[4] Plaintiff did not mention the other cases on which NuMed relied for the same proposition. *See Matter of L.B. Trucking, Inc.*, 163 B.R. 709, 718 (Bankr. D. Del. 1994) (damaging herbicidal chemicals); *Cline v. Prowler Indus. of Md., Inc.*, 418 A.2d 968, 980 (Del. 1980) (exploding propane heater).

provide sufficient evidence that the CP stent was safe for use in humans to obtain any sort of FDA approval." (*Id.* at 82, 89.) Plaintiff also argues that there is evidence that NuMed failed to warn. (*Id.* at 89.)

With respect to the issue of whether Delaware recognizes strict products liability claims, we conclude that it does not. The Delaware Supreme Court recognized nearly thirty years ago that the doctrine of strict liability in tort is not applicable in Delaware in cases involving sales of allegedly defective goods. *See Cline v. Prowler Indus. of Md., Inc.*, 418 A.2d 968, 980 (Del. 1980) (*en banc*). In *Cline*, the plaintiff sued the manufacturer and installer of a propane heater after the heater exploded, causing injury. *Id.* at 970. The plaintiff's complaint contained counts based on the doctrine of strict tort liability, breach of warranty under the Uniform Commercial Code, and negligence. *Id.* The trial court refused to instruct the jury on strict tort liability, and the jury found in favor of the defendants on the remaining breach of warranty and negligence claims. *Id.* at 970. On appeal, the Delaware Supreme Court affirmed the trial court's refusal to instruct the jury on strict liability, concluding that "by the [adoption of the UCC,] the General Assembly preempted the field of the law of products liability . . . as to sales." *Id.* at 979. The court reasoned that while other state courts have held that the adoption of the UCC does not preempt the application of the strict liability doctrine, those courts have so held because those states have made and preserved a distinction between the contractual nature of a UCC claim and the tort nature of a strict liability claim. *Id.* The court distinguished Delaware because Delaware law has melded the two claims together through its adoption of the UCC. *Id.* Under Delaware's adoption of the UCC, a plaintiff's recovery can be affected by manufacturer's notice of the defect, the existence of disclaimers, and the applicable statute of limitations. *Id.* at 974. The

court reasoned that the creation of a parallel cause of action in strict liability tort would be tantamount to a judicial repeal of those UCC provisions:

> The General Assembly's choice to make the Code nearly coextensive with the coverage under [Restatement (Second) of Torts] § 402A, at least with respect to privity and the scope of injury, suggests clearly, we think, that it intended that products liability remedies in sales cases be treated within the confines of sales warranty law and that there be no remedy therefor outside the Code.

Id. at 979. The court therefore concluded that the application of strict tort liability to sales transactions would constitute impermissible judicial legislation. *Id.* at 971.

Since *Cline*, Delaware state and federal courts applying Delaware law have consistently declined to recognize causes of action grounded on strict products liability. *See, e.g.*, *Johnson v. Hockessin Tractor, Inc.*, 420 A.2d 154, 156 (Del. 1980) (noting that "the doctrine of strict tort liability has been preempted in this State in sales cases by the General Assembly's adoption of the Uniform Commercial Code"); *LeJeune v. Bliss-Salem, Inc.*, 85 F.3d 1069, 1072 (3d Cir. 1996) ("Applying Delaware law, we can immediately dispose of Appellants' product liability claim. Appellants' claim fails because Delaware does not recognize strict products liability."); *Baylis v. Red Lion Group, Inc.*, 214 Fed. App'x 193, 196 n.6 (3d Cir. 2007) (unpublished opinion) (noting that under Delaware law, the UCC preempts common law strict liability in cases of sales of goods); *Nationwide Mut. Fire Ins. Co. v. Sears Roebuck & Co.*, No. 07-0153, 2008 WL 613145, at *2 (D. Del. Mar. 5, 2008) (dismissing strict liability claim "[b]ecause Delaware does not recognize a claim for strict liability"); *DiIenno*, 668 F. Supp. at 376 (rejecting strict liability claim and noting that "[i]f [the plaintiff] is to recover in this action it can only be under the UCC breach of warranty theory she alleges . . . in her complaint"); *Sellon v. Gen. Motors Corp.*, 571 F. Supp. 1094, 1102 (D. Del. 1983) ("In cases decided after *Cline*, Delaware state and

federal decisions have unanimously declined to recognize a cause of action in strict tort liability in cases involving sales transactions."); *Middlesex Mut. Assur. Co. v. Del. Elec. Signal Co.*, No. 07C-12-005, 2008 WL 4216145, at *5 (Del. Super. Ct. Sept. 11, 2008) (noting same); *Gunzl v. CJ Pony Parts*, No. 07C-10-169, 2008 WL 755272, at *2 n.10 (Del. Super. Ct. Mar. 20, 2008) ("Under Delaware law, a claim of strict liability based on sales is governed by the [UCC] and not by tort law. Thus, [the plaintiff] can only recover damages for a breach of an implied or express warranty where there is privity between the parties, notice is established, and the applicable statute of limitations has not run."); *Thompson v. Reinco, Inc.*, No. 01C-04-076, 2004 WL 1426971, at *1 n.1 (Del. Super. Ct. Jun. 15, 2004) (noting that "the doctrine of strict liability is preempted in Delaware by the [UCC] in sales cases"); *Smith v. DaimlerChrysler Corp.*, No. 94C-12-002, 2002 WL 31814534, at *2 (Del. Super. Ct. Nov. 20, 2002) ("In Delaware, the doctrine of strict liability has been preempted by the UCC in sales cases, which Plaintiff concedes."); *Evans v. FMC Corp.*, No. 89C-AU27, 1991 WL 165901, at *1 (Del. Super. Ct. 1991) (noting that "the theory of strict products liability is not available in Delaware as a basis for recovery when the sale is governed by the UCC").

Plaintiff contends that *Cline* and its progeny do not apply to bar strict liability claims where the allegedly defective product is "abnormally dangerous" and presents "a high degree of harm."[5] (Doc. No. 33 at 81.) In support of this argument, Plaintiff relies on *Bell v. Celotex*

[5] Plaintiff also states that she is "confused as to [D]efendants' citations to stand for [sic], 'Furthermore, Delaware like many other states refused to apply strict liability principles to any product claims concerning a prescription medical device.'" (Doc. No. 33 at 80-81.) Plaintiff's confusion is evident. The issue is whether Delaware recognizes strict products liability claims like the one at issue. NuMed relies on a line of legal authority for the proposition that Delaware does not recognize such claims. Plaintiff appears to be confused by NuMed's inference that since Delaware generally does not recognize strict liability claims outside of the UCC, Delaware

Corporation, No. 79C-DE-125. 1988 WL 7623, at *2 (Del. Super. Ct. Jan. 19, 1988) (unpublished opinion). In *Bell*, the plaintiffs alleged that they were exposed to asbestos in the course of their work. *Id.* The plaintiffs brought a strict liability claim against their employer, alleging that Delaware should apply strict liability considerations to a tort claim involving asbestos as an abnormally dangerous product. *Id.* The court rejected the plaintiffs' argument that the abnormally dangerous nature of the product removed the case from the purview of *Cline* and its progeny. In doing so, the court attached in an appendix an opinion issued in another case, *In re Asbestos Litigation*, No. 79C-DE-125 (Sep. 30, 1985), for the proposition that "the sale of a product containing an inherently dangerous substance d[oes] not remove that sale from the line of cases which have found strict liability to be inapplicable to sales." *Id.* at *3 (citations omitted). In the attached case, the court noted its concern that the plaintiffs relied on cases decided before *Cline*, observing that:

> It is indeed baffling why plaintiffs argue such cases in light of recent Delaware decisions, which plaintiffs either misread or chose to ignore, holding that the legislative enactment of the Uniform Commercial Code . . . prevents "the extension of the doctrine of strict tort liability to the law of sales."

Id. at *6 (citations omitted). The court elaborated that *Cline* definitively stated that the doctrine of strict liability does not apply to the sale of abnormally dangerous products:

> It is deserving of special mention that in [previous cases], the plaintiffs, like the plaintiffs in the instant case, asserted that despite *Cline*, strict liability applies to the sale of "inherently dangerous products." The plaintiffs argued that the inherently dangerous propensities of a product remove it from the purview of *Cline*. However, the Court definitively stated [that the UCC] applies to sales transactions in goods,

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does not recognize strict liability claims in this context. Plaintiff therefore draws factual distinctions between the CP stent and the products involved in the legal authorities that NuMed cited. We fail to see how the factual distinctions that Plaintiff makes affect the Delaware Supreme Court's reasoning in *Cline*.

> making no distinction as to type of goods, i.e., inherently hazardous, or non-hazardous. Even if this Court took judicial notice that "Drain Snake," which contains almost 90% sulfuric acid, is hazardous . . . the nature of the transaction, i.e., sale of a product, does not change. In view of the holding in *Cline*, the doctrine of strict tort liability does not apply to the sale of an inherently dangerous product.

Id. at *7; *see also Franchetti v. Intercole Automation, Inc.*, 523 F. Supp. 454, 457 (D. Del. 1981) ("Although the precise holding of *Cline* does not apply to this case, it is clear that the Court's rationale was considerably broader than its holding."). The court in *In re Asbestos Litigation* was "compelled," *sua sponte*, to sanction the plaintiffs reasoning that "as a result of the position taken by counsel for the plaintiffs regarding an action in tort for strict liability, measured against the backdrop of well-settled Delaware law, counsel have swelled the record and caused unnecessary expense." *Id.* The court therefore ordered the plaintiffs' counsel to pay "all reasonable costs to include reasonable attorneys fees . . . to any and all defense counsel of record who incurred actual expenses and/or billable time in this regard." *Id.*

Here, Plaintiff relies on *Bell* – and its attached case, *In re Asbestos Litigation* – for the very proposition that the Delaware courts rejected twenty years ago. Indeed, the court was "baffled" by the plaintiff's argument in light of well-settled case law. *Id.* at *6. We are similarly baffled. Plaintiff's reliance on *Bell* is even more troubling in light of Plaintiff's contradictory position at an earlier, consolidated stage of this litigation. In responding to the medical providers' motion to dismiss Plaintiff's strict liability claim, Plaintiff maintained that "Delaware is one of only a handful of states that has not adopted Section 402A of the Restatement. Instead, Delaware recognizes strict products liability for design defects under Article 2 of the [UCC]." (No. 04-4862, Doc. No. 34 at 17-18.) For that proposition, Plaintiff cited *Beattie v. Beattie*, a case that recognizes and applies the rule from *Cline* that "the [UCC] preempt[s] strict liability in

'sale of goods' transactions." 786 A.2d 549, 554 (Del. Super. Ct. 2001). Thus, Plaintiff has long recognized that the UCC – and not the Restatement – provides the applicable rule of law. Plaintiff's counsel certainly should have been aware – based on her own legal arguments, if nothing else – that in Delaware the UCC preempts strict liability in sale of goods transactions.[6] *See Beattie*, 786 A.2d at 554.

We agree with NuMed that under Delaware law, it is well-settled that the doctrine of strict liability is preempted by the UCC in sales cases. *See Nationwide Mut.*, 2008 WL 613145, at *2; *DiIenno*, 668 F. Supp. at 376; *Sellon*, 571 F. Supp. at 1102; *Middlesex*, 2008 WL 4216145, at *5; *Gunzl*, 2008 WL 755272, at *2 n.10; *Thompson*, 2004 WL 1426971, at *1 n.1; *Evans*, 1991 WL 165901, at *1. Plaintiff's attempt to distinguish the instant case based on the alleged "abnormally dangerous" nature of the CP stent is inconsistent with the reasoning that the Delaware Supreme Court set forth in *Cline*. *See* 418 A.2d at 980. Delaware courts have repeatedly rejected distinctions like the one that Plaintiff now makes. *See, e.g.*, *Bell*, 1988 WL 7623, at *2; *In re Asbestos Litig.*, No. 90C-10-72, 1993 WL 603386, at *2 (Del. Super. Ct. 1993) ("The law in Delaware is well-settled on this issue: the doctrine of strict liability in tort has no application to the sale of a product. This is true even where it is alleged that the product is inherently dangerous.") (citations omitted); *Hammond v. Colt Indus. Operating Corp.*, 565 A.2d 558, 562 (Del Super. Ct. 1989) (noting that, since *Cline*, "Delaware courts have refused to extend strict liability to cases involving the sale of a product even where it is alleged that the product is

[6] It is appropriate to remind counsel of their obligations to the Court. *See* Fed. R. Civ. P. 11(b)(2) (providing that "[b]y presenting to the court a pleading, written motion, or other paper, . . . an attorney . . . certifies that . . . the . . . legal contentions are warranted by existing law or by a non-frivolous argument for extending, modifying, or reversing existing law or for establishing new law").

inherently dangerous"). We are satisfied that the "abnormally dangerous" nature of a product does not remove it from the rule set forth in *Cline*, and the doctrine of strict liability does not apply in this case.[7] Summary judgment in favor of NuMed on Count IV will be granted.[8]

E. Breach of Express and Implied Warranty (Count V)

Count V of the Complaint alleges breach of express and implied warranties. The Delaware UCC provides for three types of warranties arising from the sale of goods: (1) express warranties, *see* 6 Del. C. § 2-313 (2009); (2) implied warranties of merchantability, *see* 6 Del. C. § 2-314 (2009); and (3) implied warranties for a particular purpose, *see* 6 Del. C. § 2-315 (2009). NuMed contends that it is entitled to summary judgment on Plaintiff's express warranty claim since "Plaintiff has not identified any express warranty about the stent made by NuMed." (Doc. No. 25 at 53.) NuMed contends that it is entitled to summary judgment on Plaintiff's implied warranty of merchantability claim since "Plaintiff has presented no evidence that the CP stent implanted in her was defective in any way[, n]or has she offered any expert testimony showing that the stent was defective or demonstrating that the stent caused any injury to Plaintiff." (*Id.* at 54.) Finally, NuMed contends that it is entitled to summary judgment on Plaintiff's implied

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[7] Although Count IV of the Complaint cites the Restatement (Second) of Torts Section 402A, we agree with the parties that Section 402A does not apply to Plaintiff's claim against NuMed. (*See* Doc. No. 25 at 43; No. 04-4862, Doc. No. 35 at 17-18.) Instead, Article 2 of the UCC provides the governing framework. (*Id.*) *See Franchetti*, 523 F. Supp. at 457 (noting that the UCC provides "a right of recovery [that is] nearly as coextensive as strict tort liability" and that "[t]he scope of that recovery reflects the legislature's understanding that there would be no remedy beyond negligence in products liability cases involving sales transactions outside of the [UCC]"). Even if Section 402A applied, we are satisfied that, for the reasons mentioned *infra*, Plaintiff has failed to present evidence that the CP stent was defective to subject NuMed to liability.

[8] We note that NuMed elected not to file a motion to dismiss Count IV under Federal Rule of Civil Procedure 12(b)(6).

warranty for a particular purpose claim since "[t]here is no evidence that the CP stent was unfit or unsafe for the purposes for which it was manufactured, nor that it was defective or unreasonably dangerous." (*Id.*)

Plaintiff attempts to survive summary judgment on all three claims. Plaintiff responds that there is sufficient evidence to support a claim for breach of an express warranty, since:

> NuMed has described the CP stent as "custom," when there is no indicia [sic] of a "custom device," a product that could be obtained for use in an approved manner, and [Plaintiff] relied upon that bargain. What [Plaintiff] received, [sic] was an unapproved experimental device that noone [sic] is using for fontan [sic] completion.

(Doc. No. 33 at 94.) Plaintiff argues that there is sufficient evidence to support a claim of breach of the implied warranty of merchantability, since "NuMed sold the CP stents, which were "defective" and "not merchantable" for Fontan completion. (*Id.* at 96.) Finally, Plaintiff argues that there is sufficient evidence to support a claim of breach of the implied warranty for a particular purpose, since "Numed and Allen Tower had reason to know that this CP stent . . . would be used by Defendants Murphy and Norwood, and for what purpose [i.e., a Fontan completion]." (*Id.* at 97.) Thus, Plaintiff argues that "there is an implied warranty that the CP stent was fit for that purpose." (*Id.* at 98.) Plaintiff alleges that NuMed breached this warranty because "the stent is not used for fontan [sic] completion in the United States, or Canada" and "NuMed was never able to prove to the FDA that the CP stent was safe and effective for use." (*Id.*)

1. Breach of Express Warranty

Plaintiff's express warranty claim is governed by Delaware statute. *See* 6 Del.C.

§ 2-313.[9] The statute provides that "a seller creates an express warranty by making (1) an affirmation of fact or promise; (2) to the buyer; (3) which relates to the goods; and (4) becomes part of the basis of the bargain." *Harris v. Dependable Used Cars, Inc.*, No. 96C-10-023, 1997 WL 358302, at *4 (Del. Super. Ct. Mar. 20, 1997). The statute is "identical to Section 2-313(1) and (2) of the Uniform Commercial Code." *Bell Sports, Inc. v. Yarusso*, 759 A.2d 582, 592 (Del. 2000). The Delaware Supreme Court has noted that "[t]he official commentary to that section under the UCC indicates that the drafters intended its warranty provisions to be construed and applied liberally in favor of a buyer of goods." *Id.* (*citing* UCC § 2-313 cmt. 1 (1977) ("Express warranties rest on 'dickered' aspects of the individual bargain, and go so clearly to the essence of that bargain that words of a disclaimer in a form are repugnant to the basic dickered terms."); UCC § 2-313 cmt. 3 ("In actual practice affirmations of fact made by a seller about the goods

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[9] The statute, 6 Del. C. § 2-313, provides that:

(1) Express warranties by the seller are created as follows:

(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
(c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

(2) It is not necessary to the creation of an express warranty that the seller use formal words such as "warrant" or "guarantee" or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

See 6 Del.C. § 2-313.

during a bargain are regarded as part of the description of those goods; hence no particular reliance on such statements need be shown in order to weave them into the fabric of the agreement."); UCC § 2-313 cmt. 4 ("[A] contract is normally a contract for a sale of something describable and described. A clause generally disclaiming 'all warranties, express or implied' cannot reduce the seller's obligation with respect to such description. . . ."). "Formal wording is not necessary to create a warranty and a seller does not have to express any specific intention to create one." *Id.* (*citing Pack & Process, Inc. v. Celotex Corp.*, 503 A.2d 646, 658-59 (Del. Super. Ct. 1985)); *see also* 6 Del.C. § 2-313(2) ("It is not necessary to the creation of an express warranty that the seller use formal words such as 'warrant' or 'guarantee. . . .'").

Delaware does not require privity of contract between the buyer and the seller of the good in order for the express warranty to apply. *See Cline*, 418 A.2d at 976 ("In Delaware, privity has largely been abolished."). Under Delaware law, "[a] seller's warranty whether express or implied extends to any natural person who may reasonably be expected to use, consume or be affected by the goods and who is injured by breach of the warranty." 6 Del. C. § 2-318 (2009); *see also Coun. of Unit Owners of Sea Colony E. v. Carl M. Freeman Assoc., Inc.*, No. 86-AU-49, 1989 WL 48568, at *5 (Del. Super. Ct. Apr. 28, 1989) ("Clearly, this statute removes the absolute bar to recovery where privity is lacking in an action upon the sale of goods.").[10] The law further

[10] The comment which appears as an annotation to 6 Del. C. § 2-318 provides, in pertinent part:

> The case law in most of the larger commercial states has resulted in large measure in the abolition of the privity requirement and the adoption of a rule which is substantially in accord with the version of § 2-318 adopted by Delaware. The Delaware Uniform Commercial Code Committee is of the opinion that the recommended amendment is reasonable, is in accord with modern commentaries, and will bring the Delaware law in substantial conformity with the law of a number of

provides that "[a] seller may not exclude or limit the operation of this section." *Id.*

NuMed relies on *DiIenno*, 668 F. Supp. at 376, for the proposition that "[a]n action on an express warranty may not be maintained in Delaware without proof of reliance on the warranty." (Doc. No. 25 at 53.) In *DiIenno*, the plaintiff injured her right hand when an allegedly defective jar shattered as she attempted to replace its lid. 668 F. Supp. at 375. The plaintiff brought a negligence action against the jar's manufacturer, distributor, and seller. *Id.* The plaintiff alleged that the manufacturer and distributor breached an expressed warranty that the jar would perform as illustrated in the manufacturer's catalog: that it would open and close properly. *Id.* at 376. However, there was "no evidence in the record to suggest that [the plaintiff] ever saw the [manufacturer's] catalog let alone relied on it when she purchased the jar." *Id.* The court granted summary judgment in favor of the defendants on the plaintiff's express warranty claim, reasoning that "[i]t is clear that a successful action for breach of an expressed warranty may not be maintained in Delaware absent *some* reliance by the buyer on the warranty." *Id.* (emphasis added) (*citing* 6 Del. C. § 2-313).

The issue of whether Plaintiff must show reliance on NuMed's alleged statement or representation is not as clear as NuMed would have it. Delaware law recognizes express warranties that are "part of the basis of the bargain." 6 Del. C. § 2-313 ("Any affirmation of fact or promise . . . which . . . becomes part of the basis of the bargain creates an express warranty . . . ."); *see also Pack & Process, Inc.*, 503 A.2d at 656 (recognizing that an express warranty "must have been part of the basis of the bargain"). The Delaware Supreme Court has not addressed the issue of whether a buyer must show reliance in order for an express warranty to be

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states (including the larger commercial states) which have adopted the Code.

Franchetti, 523 F. Supp. at 456 n.4 (citing annotation).

considered part of the "basis of the bargain." *DiIenno,* the case on which NuMed relies, stands more for the general proposition that the express warranty must have been part of the basis of the bargain, not that a buyer must show reliance on the representation. *See* 668 F. Supp. at 375. The plaintiff in *DiIenno* was not aware of the catalog that contained the alleged express warranty. *See id.* at 376. Thus, the court observed that an action for breach of an expressed warranty may not be maintained "absent *some* reliance by the buyer." *Id. DiIenno* simply applies the statutory requirement that the warranty constitute part of the basis of the bargain. Since the plaintiff in *DiIenno* did not know about the representation – much less rely on it – the representation could not have formed an express warranty.

The Fifth Circuit recently observed that "[t]here is a clear split of authority among the jurisdictions as to whether a buyer must show reliance on a statement or representation for it to be considered part of the 'basis of the bargain.'" *Cole v. Gen. Motors Corp.,* 484 F.3d 717, 726 (5th Cir. 2007) (multiple citations omitted). "In jurisdictions that require actual reliance as an element of a claim for breach of an express warranty under the UCC, this means that only a seller's affirmations of fact and promises relating to goods that are actually relied upon become part of the basis of the bargain and thus an express warranty." *In re Gen. Motors Dex-Cool Prods. Liab. Litig.*, 241 F.R.D. 305, 322 (S.D. Ill. 2007).

We do not need to predict how the Delaware Supreme Court would decide this issue since Plaintiff was not aware of any representations made by NuMed about the stent. Plaintiff contends – without citation to the record – that she relied on NuMed's description of the CP stent as "custom," when "[w]hat [Plaintiff] received, [sic] was an unapproved experimental device that noone [sic] is using for fontan [sic] completion." (Doc. No. 33 at 94.) However, Plaintiff does

not proffer evidence that NuMed or any physicians who purchased the stent from NuMed made representations to her about the nature of the stent.[11] Judith Guinan testified that Dr. Murphy told her nothing about the stent before the procedure at issue:

> Q: Did you have a discussion with Dr. Murphy about the procedure?
> A: We spoke to him briefly that morning.
> . . .
> Q: Do you remember what he said to you in that five or ten minutes?
> A: That Molly was going to have the completion in the catheterization lab; that it shouldn't take very long; that she would recover very quickly; and she probably wasn't going to need to go to the CICU; that she would go from stepdown right back into her room.
> Q: Did he say anything to you about the covered stent that was to be used to complete the Fontan completion?
> A: No.
> Q: Nothing at all?
> A: No.

(J. Guinan Dep. at 284-85.) Judith Guinan also testified that she did not understand what a covered stent was and "did not have very much knowledge":

> Q: [W]ere you curious about the procedure at all?
> A: No.
> Q: Were you curious about the covered stent that was going to be used in the procedure?
> A: No. I don't think at that point I even understand [sic] what a covered stent was as supposed [sic] to an uncovered stent.
> Q: Did you know what an uncovered stent was at that time?
> A: No. I just knew the term stent.
> Q: What kind of understanding did you have of the term stent at that time?
> A: Basically it was a tube that was going to connect one part to the other. It was going to complete the Fontan. I didn't have very much knowledge.

(*Id.* at 285.) Similarly, Kevin Guinan testified that he did not know any details about the stent prior to the procedure and had never heard the word stent:

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[11] Plaintiff need not have purchased the stent directly from NuMed in order to state a claim against NuMed for breach of an express warranty. *See* 6 Del. C. § 2-318.

Q: Can you tell us everything you can recall discussing with Dr. Murphy at the time you signed the hospital consent form in October of 2002?
A: It was just, "We're going to finish it up." There wasn't really much detail about it at all that I remember. At that point we had no – I don't think I asked any questions because I didn't have any questions to ask.
Q: Prior to that time had you discussed with any other patients at duPont having the Fontan completion by stent?
A: No. I don't know that before that time I had ever heard the word stent. Maybe the completion – the cath – going in by the catheter we had heard. That's what they told us. I didn't know what a stent was.

(K. Guinan Dep. Vol. I at 106.) Thus, the evidence in the record shows that Judith Guinan and Kevin Guinan knew little, if anything, about the stent. Kevin Guinan "didn't know what a stent was." (*Id.*)

Plaintiff here is therefore similar to the plaintiff in *DiIenno* who did not know about, much less rely on, the manufacturer's representation about the defective jar in a catalog. *See* 668 F. Supp. at 375. The court granted summary judgment in favor the manufacturer, reasoning that a representation of which the plaintiff was unaware could not constitute an express warranty. Here, we will grant summary judgment in favor of NuMed for the same reason: Plaintiff has not proffered evidence that the nature of the stent was "part of the basis of the bargain" to constitute an express warranty. *See* 6 Del. C. § 2-313. To the extent that NuMed made any representations about the stent prior to the sale of the stent, Plaintiff was not aware of them. *Cf. Pack & Process, Inc.*, 503 A.2d at 659 (denying summary judgment on express warranty claim where "[t]he defendant gave assurances and made statements to the plaintiff regarding the condition of the roof and the quality of the repairs"). Plaintiff's argument that she relied on NuMed's description of the stent as "custom" is without merit.

2. Breach of the Implied Warranty of Merchantability

Plaintiff's implied warranty of merchantability claim is likewise governed by Delaware

statute. *See* 6 Del. C. § 2-314.[12] "[T]o be successful on a breach of warranty of merchantability claim, a plaintiff must prove: (1) that a merchant sold the goods; (2) which were defective at the time of sale; (3) causing injury to the ultimate consumer; (4) the proximate cause of which was the defective nature of the goods; and (5) that the seller received notice of the injury." *Reybold Group, Inc. v. Chemprobe Tech., Inc.*, 721 A.2d 1267, 1269 (Del. 1998) (citations omitted). "[P]roof of a defect is an essential element of a claim for breach of warranty of merchantability." *Id.* "It is clear [that] 'some evidence of the existence of a defect at the time of delivery is an essential element of a cause of action." *Brink v. Ethicon, Inc.*, No. 02C-01-030, 2003 WL 23277272, at *2 (Del. Super. Ct. Dec. 9, 2003) (citations omitted). "A defect may take the form of a design defect, where an entire product line is designed improperly, or a manufacturing defect, where a product line is properly designed but a particular item was manufactured

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[12] The statute, 6 Del. C. § 2-314, provides that:

> (1) Unless excluded or modified (Section 2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. . . .
>
> (2) Goods to be merchantable must be at least such as
>
> (a) pass without objection in the trade under the contract description; and
> (b) in the case of fungible goods, are of fair average quality within the description; and
> (c) are fit for the ordinary purposes for which such goods are used; and
> (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
> (e) are adequately contained, packaged, and labeled as the agreement may require; and
> (f) conform to the promises or affirmations of fact made on the container or label if any.
>
> (3) Unless excluded or modified (Section 2-316) other implied warranties may arise from course of dealing or usage of trade.

See 6 Del.C. § 2-314.

incorrectly." *DiIenno*, 668 F. Supp. at 377 (citations omoitted).

To satisfy her burden of showing that the stent was defective, Plaintiff offers the testimony of William Damaska as "an expert in FDA regulations especially as they pertain to medical devices." (Doc. No. 33 at 84.) Damaska opined that "[t]he CP stent implanted in [Plaintiff] was not safe for use in humans." (*Id.*) Damaska explained this opinion at his deposition:

> Q: Now, you also say that – in this opinion in the last sentence, the CP stent implanted in [Plaintiff] was not safe for use in humans. How do you know that?
> A: Well, it certainly had never been shown to be safe.
> Q: Had it been shown to be unsafe?
> A: Not at that point. Nobody knew whether it was safe or unsafe. [. . .]
> Q: Did FDA ever say it was unsafe?
> A: No, but in the export they said it was – they couldn't determine that it was not contrary to public health and safety.

(Damaska Dep. at 145-46.) Plaintiff also cites the testimony of Lee Benson, a defense expert, who had "adverse outcomes" using the stent. (Benson Dep. at 12.) However, Benson explained that the adverse outcomes had nothing to do with the CP stent itself and instead related to the surgical setup:

> [T]he surgical setup wasn't perfect in our institution and there had to be some modifications in the way the surgeons did their component of it and then the catheter Fontan side of things, the stent itself wasn't perfect the way we had set up the surgical implantation. You could set it up surgically so the CP stent would be perfect, but that's not the way we wanted to pursue the surgical setup, so the CP stent turned out not to be a perfect implant for us.

(*Id.*) Benson elaborated that the problem was not with "the stent itself," but with the surgical setup:

> We started the project in 2004 and after the first seven [procedures] were done we stopped because of the problems with the surgical setup and the stent, not the stent itself, but the way we had set the surgical setup, that stent didn't allow us to have

> a secure, to secure the ends. That was still the problem is the security of the ends, so it depends on how you set it up.

(*Id.* at 14.)

The expert testimony on which Plaintiff relies fails to support an inference that the stent was defective. Damaska testified that while the stent was not "shown to be safe," neither was the stent "shown to be unsafe." (Damaska Dep. at 145.) Plaintiff maintains that Damaska's testimony that the stent was not "shown to be unsafe" supports an inference that the stent was unsafe or defective. Plaintiff therefore relies on an absence of evidence of defect as support for the proposition that a defect exists. Plaintiff commits the logical fallacy of *argumentum ad ignorantiam*, that is, an argument from ignorance. "An argument from ignorance is 'the mistake that is committed whenever it is argued that a proposition is true simply on the basis that it has not been proved false, or that it is false because it has not been proved true.'" *Ala. Tombigbee Rivers Coalition v. Kempthorne*, 477 F.3d 1250, 1257 (11th Cir. 2007) (*citing* Irving M. Copi & Carl Cohen, Introduction to Logic 93 (8th ed. 1990)). Plaintiff mistakenly assumes that an absence of evidence to support its proposition establishes the proposition. However, an absence of evidence that the stent was defective does not establish defectiveness. Plaintiff's logical fallacy underscores her failure to carry her burden of proffering evidence that allows an inference of defect. *See DiIenno*, 668 F. Supp. at 378 ("But it is not incumbent upon the defendants to prove the lack of a manufacturing defect. [The plaintiff] bears the burden of producing some evidence that the jar had a manufacturing defect at the time of sale."). Plaintiff's reliance on Benson's testimony also fails to carry her burden. Benson testified that the problem was not with "the stent itself," but rather with the surgical setup that Benson used. (Benson Dep. at 14.) Indeed, the stent "would be perfect" with a proper surgical setup. (*Id.*) For all of these reasons,

Plaintiff fails to show evidence that would allow an inference that the stent was defective at the time it was manufactured.

Plaintiff also argues that the stent was not merchantable since it was "not fit for Fontan completion." (Doc. No. 33 at 96.) Implicit in Plaintiff's argument is the proposition that Fontan completion is an "ordinary purpose" for which the stent is used. *See* 6 Del. C. § 2-314. Plaintiff therefore relies on the stent's lack of FDA approval as evidence of its defective design or manufacture. A lack of FDA approval is not a *per se* defect of design or manufacture under Delaware law. *See, e.g.*, *Baker v. Smith & Nephew Richards, Inc.*, No. 97-1233, 1999 WL 1129650, at *6 (N.D. Ga. Sept. 30, 1999) (applying Georgia law). The plaintiffs in *Baker* brought an action under the Georgia UCC claiming that the defendants breached the implied warranty of merchantability by manufacturing and designing allegedly defective bone screws. *Id.* Like the Delaware UCC, the Georgia UCC requires that the plaintiff show evidence of a manufacturing or design defect. *See* Ga. Code Ann. § 51-1-11(b) (2009).[13] The court noted that the plaintiffs "identif[ied] issues regarding FDA approval and the effectiveness of [bone] screws generally," but did not "point to evidence of the existence of a manufacturing or design defect." *Baker*, 1999 WL 1129650, at *6. The court granted summary judgment in favor of the

[13] The Georgia statute provides that:

> The manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

Ga. Code Ann. § 51-1-11(b) (2009).

defendants, reasoning that "[f]ailure to seek FDA approval does not constitute a defect under [the Georgia UCC]." *Id.*; *see also In re Ortho. Bone Screw Litig.*, No. 94-0002, 1996 WL 107556, at *3 (E.D. Pa. Mar. 8, 1996) ("The FDA labels given to a medical device do not speak directly to the medical issues surrounding a particular surgery."); *Uribe v. Sofamor, S.N.C.*, No. 95-0464, 1999 WL 1129703, at *15 n.9 (D. Neb. Aug. 16, 1999) (noting that the plaintiff "may also be alleging that the [medical device's] 'defect' is that it allegedly was marketed before approval by the FDA. If that is [the plaintiff's] claim, the court specifically finds that the status of FDA approval does not constitute a 'defect' in the product. . . ."); *Kirkman v. Sofamor, S.N.C.*, No. 98-0100, 1998 WL 666706, *4 (W.D.N.C. Jul. 21, 1998) ("Plaintiff's contention that the [medical device's] defect was the fact that it was marketed prior to FDA approval is without merit."). *Cf. Reeves v. AcroMed Corp.*, 44 F.3d 300, 308 (5th Cir. 1995) (holding that FDA rejection of medical device created jury issue that device was "unreasonably dangerous" *per se* because of "several potential health hazards" relating to the spine, together with evidence that the plaintiff suffered spine injury from the device).

As in *Baker*, the lack of FDA approval of the stent here does not constitute a defect under the applicable UCC provision. *See id.* Plaintiff has identified issues regarding FDA approval and the effectiveness of the stent in Fontan completion generally, but Plaintiff has not pointed to evidence of a manufacturing or design defect in the stent itself. Moreover, unlike *Reeves*, there is no evidence here that the FDA rejected the stent because of potential health hazards. *See* 44 F.3d at 308. The lack of FDA approval, without more, is not enough to create an inference of a

manufacturing or design defect.[14] *See Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 257 (E.D.N.Y. 1999) ("The fact that a medical device has not been approved by the FDA for a particular use does not, however, mean that the device is unsafe, much less that the device is defective."); *Minisan v. Danek Med., Inc.*, 79 F. Supp. 2d 970, 977 (N.D. Ind. 1999) (holding same); *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 828 (N.D. Ind. 1999) (holding same).

3. Breach of the Implied Warranty of Fitness for a Particular Purpose

Plaintiff's final warranty claim, breach of the implied warranty of fitness for a particular purpose, similarly arises under Delaware statute. *See* 6 Del. C. § 2-315 (2009).[15] "Warranty of fitness for a particular purpose arises when: (1) a buyer has a special purpose for certain goods; (2) the seller knew or had reason to know of that purpose; (3) the seller knew or had reason to know that the buyer was relying on the seller's superior skill to select goods that fulfilled that purpose; and (4) the buyer in fact relied on the seller's superior skill." *DiIenno*, 668 F. Supp. at 376 (citation omitted).

Plaintiff argues that NuMed "had reason to know" that the stent was going to be used for Fontan completion. Plaintiff relies on deposition testimony of Allen Tower for this proposition.

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[14] The FDCA bolsters our conclusion. *See* 21 U.S.C. § 337(a). The FDCA provides that except for certain enforcement actions concerning food brought by state governments in their own name, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a) (2009). The statute therefore indicates that Congress did not intend for violations of the Act to serve as a basis for private tort claims. *See* James M. Beck & John A. Valentine, Challenging the Viability of FDCA-Based Causes of Action in the Tort Context: The Orthopedic Bone Screw Experience, 55 Food & Drug L.J. 389, 401-02 (2000) (observing same).

[15] The statute provides that "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." 6 Del. C. § 2-315.

Tower testified that Dr. Murphy "was using [the stent] for Fontan." (Tower Dep. at 16.) Tower also testified, however, that he "didn't understand the [Fontan] procedure," so there was "nothing that [NuMed] could do in that." (*Id.* at 25.) Tower explained that "the only thing that [NuMed had] control over [wa]s the strength of the stent, the diameter it expands to, the length of it after it's expanded." (*Id.* at 24.) When Tower was asked why NuMed sold the stent to Dr. Murphy if he "didn't even understand the procedure that it was being used for," Tower answered:

> Well, when we make any of our products the doctors will buy them and we cannot follow up on everything that they do with them. They're the doctors and, you know, if I needed to know what every one was used for then I would be practicing medicine and then I would have to say no, I can't, because you're doing a Fontan you cannot use this stent, and I don't think that that's NuMed's place.

(*Id.* at 25.)

There is no evidence that NuMed knew or had reason to know that Dr. Murphy was relying on NuMed's "superior skill" to select a stent that fulfilled the purpose of a Fontan completion. On the contrary, the undisputed evidence shows that NuMed "didn't understand the [Fontan] procedure" and had control only over "the strength of the stent" and "the diameter it expands to." (Tower Dep. at 25.) Dr. Murphy did not rely on NuMed's "superior skill" in selecting a stent for a Fontan procedure, because it was not "NuMed's place" to "practic[e] medicine" or decide for the doctor whether to use a particular stent. (*Id.*) Plaintiff proffers no evidence that Dr. Murphy – or anyone else – relied on NuMed's representations about the stent in deciding whether to use the stent for Fontan completion. *See* 6 Del. C. § 2-315. Summary judgment in favor of NuMed is therefore appropriate on Plaintiff's claim of breach of the implied warranty of fitness for a particular purpose.

F. Medical Monitoring (Count VI)

Count VI of the Complaint states a claim for medical monitoring. Delaware has not expressly adopted a medical monitoring claim. However, for the same reasons we discussed at length in the First Memorandum, we predict that if presented with the facts of this case, the Delaware Supreme Court would adopt a claim for medical monitoring. We based this prediction in large part on the fact that in this case, the FDA, NuMed, and the Institutional Defendants have advised that medical monitoring is necessary because, inter alia, the safety of the CP stent is unknown. Accordingly, the NuMed's motion for summary judgment as to Count VI of the Complaint will be denied.[16]

G. Piercing the Corporate Veil

Plaintiff's Complaint asserts claims both against NuMed, Inc., and against Allen Tower as an individual. NuMed also moves for summary judgment on all claims against Tower, arguing that (1) Plaintiff's allegations relate to actions taken by NuMed as a corporation, not Tower individually, (2) Plaintiff has no evidence of any wrongdoing by Tower, (3) Plaintiff has not alleged that NuMed's corporate veil should be pierced, and (4) Plaintiff has failed to make factual averments suggesting that the corporate veil be pierced. (Doc. No. 25 at 57-58.) Plaintiff responds that Tower (1) has been an integral part of supplying the CP stent and is personally involved, (2) pled guilty to selling the CP stents without premarket approval from the FDA, and (3) directed, participated in, and controlled the manufacture and sale of the CP stents. (Doc. No. at 106-07.)

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[16] As a technical matter, medical monitoring is a legal action for Seventh Amendment purposes. *See Barnes v. Am. Tobacco Co.*, 989 F. Supp. 661, 668 (E.D. Pa. 1997) (Barnes I) (holding that medical monitoring is a legal action for purposes of the Seventh Amendment, entitling defendants to a jury trial). The parties here are entitled to a jury trial on this issue.

Under New York law,

> [t]he concept of piercing the corporate veil is a limitation on the accepted principles that a corporation exists independently of its owners, as a separate legal entity, that the owners are normally not liable for the debts of the corporation, and that it is perfectly legal to incorporate for the express purpose of limiting the liability of the corporate owners.

Matter of Morris v. N.Y. State Dept., 623 N.E.2d 1157, 1160 (N.Y. 1993) (citations omitted). To convince a court to pierce the corporate veil, a plaintiff must establish that "(1) the owners exercised complete domination of the corporation in respect to the transaction attacked; and (2) that such domination was used to commit a fraud or wrong against the plaintiff which resulted in plaintiff's injury." *Id*. at 1160-61 (citations omitted); *see also Mars Elecs. v. U.S.A. Direct*, 28 F. Supp. 2d 91, 97 (E.D.N.Y. 1998) ("[U]nder New York law a plaintiff seeking to pierce the corporate veil must prove both complete domination and that the domination was used to commit a fraud with respect to the transaction at issue."). Factors to consider when determining whether complete domination exists include:

> (1) disregard of corporate formalities; (2) inadequate capitalization; (3) intermingling of funds; (4) overlap in ownership, officers, directors, and personnel; (5) common office space, address and telephone numbers of corporate entities; (6) the degree of discretion shown by the allegedly dominated corporation; (7) whether the dealings between the entities are at arms length; (8) whether the corporations are treated as independent profit centers; (9) payment or guarantee of the corporation's debts by the dominating entity, and (10) intermingling of property between the entities.

Freeman v. Complex Computing Co., 119 F.3d 1044, 1053 (2d Cir. 1997). However, a mere showing of complete corporate domination is not sufficient. *Morris*, 623 N.E.2d at 1161; *see also Freeman*, 119 F.3d at 1053 ("[T]he element of domination and control never was considered to be sufficient of itself to justify the piercing of corporate veil."). Rather, "[t]hose seeking to pierce a corporate veil . . . bear a heavy burden of showing that the corporation was dominated as

to the transaction attacked and that such domination was the instrument of fraud or otherwise resulted in wrongful or inequitable consequences." *TNS Holdings, Inc. v. MKI Sec. Corp.*, 703 N.E.2d 749, 751 (N.Y. 1998) (citations omitted); *see also MAG Portfolio Consult, GmbH v. Merlin Biomed Group LLC*, 268 F.3d 58, 64 (2d Cir. 2001) ("Without a finding that the domination occurred for the purpose of committing a wrong, the second element of a veil-piercing analysis has not been met."); *Freeman*, 119 F.3d at 1053 ("Unless the control is utilized to perpetrate a fraud or other wrong, limited liability will prevail."); *Morris*, 623 N.E.2d at 1161 ("While complete domination of the corporation is the key to piercing the corporate veil, especially when the owners use the corporation as a mere device to further their personal rather than the corporate business, such domination, standing alone, is not enough; some showing of a wrongful or unjust act toward plaintiff is required." (citations omitted)).

Plaintiff has not offered any evidence that relates in any way to the "complete domination" factors, nor has Plaintiff argued that any of the factors considered in finding domination favor her. Moreover, Plaintiff has not offered any evidence to show, or even suggest, that Tower misused the corporate form in order to commit a wrong or fraud that injured Plaintiff. Plaintiff points only to Tower's guilty plea agreement, in which Tower and NuMed admitted to introducing adulterated devices into the stream of commerce and in which it was stated that Tower "directed, participated in, and controlled the manufacture and sale of the medical devices NuMED manufactured and sold." (Doc. No. 33 at 106 (*quoting* Doc. No. 33, Ex. UU (Tower plea agreements); EEE (NuMed Indictment)).) There is no question that Tower is the president and sole owner of NuMed, and therefore exerts substantial control over the company. Evidence of control, however, in the absence of other relevant evidence, is not sufficient to raise a question

of fact as to whether Tower exercised "complete domination" for purposes of piercing the corporate veil. *See Island Seafood Co. v. Golub Corp.*, 759 N.Y.S.2d 768, 770-71 (N.Y. App. Div. 2003) ("While [the defendant] may be the sole stockholder, director and officer of both corporations and seems to exhibit disregard of corporate formalities, this, in and of itself, constitutes insufficient proof of complete domination and control which permit a corporate veil to be pierced. Significantly, the record is devoid of evidence of [the defendant's] personal use of corporate funds or that [the corporation] was undercapitalized." (citations omitted)); *see also Thrift Drug v. Universal Prescription Adm'rs*, 131 F.3d 95, 97-98 (2d Cir. 1997) (finding that complete domination of the corporation by the defendant, who was the sole director and stockholder, was established where evidence showed that the corporation never held formal shareholders' meetings, maintained no records of directors' meetings, was inadequately capitalized, issued loans to the defendant without any identified corporate purpose, and issued loans to properties owned by the defendant). Therefore, Plaintiff cannot establish the first prong of New York's veil-piercing framework. Furthermore, even if Plaintiff had adduced evidence to suggest complete domination, the guilty plea admissions do not raise the inference that the domination was the instrument of fraud or otherwise resulted in wrongful or inequitable consequences. *See Morris*, 623 N.E.2d at 1161 (finding that, even if plaintiffs could establish domination, plaintiffs "fell far short of meeting their burden on the second critical point: that [the defendant], through his domination, misused the corporate form for his personal ends so as to commit a wrong or injustice . . ."). *Cf. FDIC v. Finkielstain*, No. 91-8020, 1993 U.S. Dist. LEXIS 12141, at *8-9 (S.D.N.Y. Sep. 2, 1993) (finding that "defendant's admissions in the above-quoted [guilty plea hearing] allocution establish that he used his control over [the

corporation] to perpetrate a fraud; having used the corporation for this purpose he is not now entitled to shield himself from liability . . .”). Accordingly, we will grant NuMed’s Motion for Summary Judgment as to the claims against Allen Tower.

IV. CONCLUSION

For the foregoing reasons, NuMed’s Motion for Summary Judgment will be granted in part and denied in part.

An appropriate Order follows.

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

MOLLY GUINAN	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 08-0228
A.I. DUPONT HOSPITAL FOR CHILDREN, et al.	:	

ORDER

AND NOW, this 6th day of February, 2009, upon consideration of the Motion of Defendants Numed, Inc. and Allen J. Tower For Summary Judgment on the Complaint of Molly Guinan, (Doc. No. 25.), and all papers submitted in support thereof and in opposition thereto, it is ORDERED as follows:

1. The Motion of Defendants Numed, Inc. and Allen J. Tower For Summary Judgment on the Complaint of Molly Guinan is GRANTED as to Counts I (Negligence), Count II (Fraud and Intentional Misrepresentation), Count III (Assault and Battery), Count IV (Strict Products Liability), and Count V (Breach of Express and Implied Warranty); and

2. The Motion of Defendants Numed, Inc. and Allen J. Tower For Summary Judgment on the Complaint of Molly Guinan is DENIED as to Count VI (Medical Monitoring).

IT IS SO ORDERED.

BY THE COURT:

/s/ *R. Barclay Surrick*
U.S. District Court Judge