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

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

SURRICK, J. **FEBRUARY 14 , 2007**

MEMORANDUM & ORDER

Presently before the court is the Motion Of Defendants John Murphy, M.D., And William I. Norwood, Jr., M.D. Ph.D., To Dismiss For Failure To State A Claim For Relief And To Strike Pursuant To Rules 12(b) And (f) Of The Federal Rules of Civil Procedure (Doc. No. 19). For the following reasons, the Motion will be granted in part and denied in part.

I. BACKGROUND

Plaintiffs' Complaint raises issues concerning the use, design, manufacture, and marketing of the Cheatham Platinum Stent manufactured by Defendant NuMED, Inc. ("NuMED CP Stent"). The lawsuit was filed on behalf of three infants with congenital heart defects. Plaintiff Molly Guinan, through her parents and natural guardians, alleges that during surgical procedures to correct her congenital heart defect, Dr. Norwood inserted a collar in her heart in preparation for receiving the NuMED CP Stent. (Doc. No. 1 ¶ 52.) Guinan alleges that on October 14, 2002, the NuMED CP Stent was implanted. (*Id.* at ¶ 53.) Over the course of the next six months, she developed Protein Losing Enteropathy and plastic bronchitis, which she alleges were a direct result of the stent placement and its resulting physiologic effects on her body. (*Id.* ¶¶ 54, 57.) Guinan further claims that the Guinan family had not given their

informed consent for the stent procedure. (*Id.* ¶¶ 58-59.)

Plaintiff Teague Conway, through his parents and natural guardians, asserts that Drs. Norwood and Murphy implanted the NuMED CP Stent in him on December 4, 2003. (*Id.* ¶ 62.; Doc. No. 34 at 4.) After the stent was inserted, it clotted and required emergent cardiac surgery to remove the stent. (Doc. No. 1 ¶ 65.) Conway further alleges that additional cardiac surgery will be required because of the clotting. (*Id.*) Conway's parents state that they were misled about the need for the stent and possible risks associated with it. (*Id.* ¶ 63.)

Plaintiff Mark Aaron Hess, Jr., through his parents and natural guardians, states that two NuMED CP Stents were implanted in him on January 12, 2003. (*Id.* ¶ 67.) After the surgery, he had breathing problems and was admitted to the hospital on two different occasions for management of cardiac complications. (*Id.* ¶¶ 68-69.) He states that he will need ongoing care for these complications for the rest of his life. (*Id.* ¶ 70.) Hess alleges that his family had not been informed of the nature and risks of the stent. (*Id.* ¶ 71.)

On October 15, 2004, Plaintiffs Teague Conway, Molly Guinan, and Mark Aaron Hess filed this Class Action Complaint against a number of defendants, including Drs. Norwood and Murphy and the manufacturer NuMED.[1] In the Complaint, Plaintiffs assert six separate causes of action arising from the implantation of the NuMED CP Stent device in each of the Plaintiffs. Defendants Drs. Murphy and Norwood ("Movants") have moved to dismiss certain of Plaintiffs' claims as they pertain to Movants, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

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[1] The other Defendants are A.I. DuPont Hospital for Children, Nemours Foundation, Nemours Cardiac Center, Allan J. Tower, John P. Cheatham, M.D., Kenneth A. Murdison, M.D. and Nemours De Institutional Review Board.

II. LEGAL STANDARD

When considering a motion to dismiss a complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court must "accept as true all of the allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party." *Rocks v. City of Phila.*, 868 F.2d 644, 645 (3d Cir. 1989). The court may dismiss a complaint only if "'it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.'" *H. J. Inc. v. Nw. Bell Tel. Co.*, 492 U.S. 229, 249 (1989) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)). When considering a motion to dismiss, we need not credit a plaintiff's "bald assertions" or "legal conclusions." *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1429-30 (3d Cir. 1997)).

III. DISCUSSION

A. Motion to Strike

As an initial matter, Movants move to strike the exhibits attached to Plaintiffs' Complaint pursuant to Federal Rule of Civil Procedure 12(f), arguing that "they provide no basis for legal recovery to Plaintiffs" and violate Federal Rule of Civil Procedure 8. (Doc. No. 19 at 25.) On a motion to strike, "the court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). A plaintiff may attach exhibits to a complaint provided they do not constitute "redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Motions under Rule 12(f) are disfavored and should not be granted in the absence of a demonstration that the allegations

attacked have no possible relation to the controversy and may prejudice the other party. *Wright v. Phila. Gas Works*, Civ. No. 01-2655, 2001 U.S. Dist. LEXIS 15852, at *6 (E.D. Pa. Sept. 28, 2001). "A district court has broad discretion in deciding Rule 12(f) motions." *Korman v. Trusthouse Forte PLC*, Civ. A. No. 89-8734, 1991 WL 3481, at *1 (E.D. Pa. Jan. 11, 1991).

Here, Plaintiffs have attached a warning letter issued by the Food and Drug Administration to Defendant Dr. Cheatham. Plaintiffs allege that the letter concerned Cheatham's use of the NuMED CP Stent without FDA approval. (Doc. No. 1 at Ex. A.) Plaintiffs also attached a copy of a complaint filed in Delaware state court by Movants regarding the termination of their employment by co-Defendant Nemours Foundation. (*Id.* at Ex. B.) Movants argue that the documents "are irrelevant to the pleading requirements set forth in Rule 8," (Doc. No. 19 at 25), but do not explain why, nor do they explain how they are prejudiced by these documents. It is apparent that the documents relate to several of the allegations made in the Complaint and may provide documentary support for some of Plaintiffs' claims. Accordingly, Movant's Motion to Strike the exhibits will be denied.

B. Motion to Dismiss

Plaintiffs' Complaint asserts the following causes of action against all defendants: negligence, fraud and intentional misrepresentation, assault and battery, strict products liability, breach of warranty, and medical monitoring. Movants concede that the Complaint sets forth a cognizable claim of negligence for breach of the duty to obtain informed consent. (Doc. No. 19

at 12.) Movants contend that with respect to the other causes of action, the Complaint fails to state viable claims against them.[2]

1. First Cause of Action: Negligence

[2] In addressing the other claims or causes of action asserted by Plaintiffs, we specifically note the following paragraphs in the Complaint:

> ¶2 Defendant, NuMed, Inc. (NuMED), designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or used the NuMED Cheatham Platinum Stent (hereinafter NuMED CP Stent) for the treatment of cardiovascular conditions in children.
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> ¶3 Defendants designed, researched, created, tests (sic), advertised, marketed, sold and/or promoted the implantation procedure for implantation of the NuMED CP Stent in children (hereinafter implantation procedure).
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> ¶20 Defendant, William S. Norwood, M.D., PhD., is a cardiac surgeon who at all times pertinent hereto, was the Director of the Nemours Cardiac Center and acted in concert with the co-defendants to perform the improper and wrongful conduct regarding the NuMED CP Stent as more fully described herein.
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> ¶21 Defendant, John D. Murphy, M.D., is a pediatric cardiologist who, at all times pertinent hereto, was an employee, agent, and/or servant of the co-defendants, and was intimately involved in the improper activities and wrongful conduct regarding the NuMED CP Stent as more fully described herein.
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> ¶89 Defendant, NuMED, is the designer, manufacturer, seller, and/or supplier of the NuMED CP Stent.
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> ¶90 All Defendants are the creators, researchers and/or users of the implantation procedure.

Plaintiffs' Complaint sets forth several different theories of negligence. These theories include providing substandard medical care, the failure to obtain informed consent, failure to warn, failure to perform adequate testing, negligent marketing, negligent design, negligent misrepresentation, and failure to abide by certain federal regulations, healthcare reports, international codes and declarations. (Doc. No. 1 ¶¶ 88-100.) Under Delaware law,[3] "[t]o state a claim for negligence one must allege that defendant owed plaintiff a duty of care; defendant breached that duty; and defendant's breach was the proximate cause of plaintiff's injury." *New Haverford P'ship v. Stroot*, 772 A.2d 792, 798 (Del. Super. Ct. 2001). We will examine each of Plaintiffs' negligence theories in turn.

a. Failure to Warn

Movants request that paragraphs 91, 93, 95, 95(a), (d)(e)(i) and (h), and 99 be stricken. Movants argue that these paragraphs do not state a cognizable claim against them for failure to obtain informed consent but rather set forth product liability claims for failure to warn.[4]

Plaintiffs' Complaint alleges that Defendants, including Movants, "had a duty to exercise reasonable care in the development, promotion, and use of a procedure to implant the NuMED CP Stent." (Doc. No. 1 ¶ 94.) The Complaint further states that Defendants were negligent "in the design, testing, manufacturing, advertising, marketing, promoting, labeling, warnings given,

[3] In a diversity case, a district court must determine which state's substantive law will govern. To make this determination, we apply the conflict of law rules of the forum state. *Kirschbaum v. WRGSB Assocs*., 243 F.3d 145, 150 (3d Cir. 2001). Pennsylvania's choice of law analysis incorporates elements of both the "government interest" and "significant relationship" tests. *Id.* at 151. The parties have applied Delaware law for the purpose of addressing the Motion to Dismiss. We agree that Delaware law governs.

[4] Paragraphs 93 and 95(i) do not appear to allege failure to warn.

and safety measures of the stent in that they: failed to accompany the stent with proper warnings "regarding all possible adverse risks associated with its use" (*id*. ¶ 95(a)); failed to warn Plaintiffs prior to actually encouraging the use of the stent about the risk of follow-up medical treatment and the extent of possible injuries (*id.* ¶ 95(d)); failed to warn that "the risks associated with the stent could exceed the risks of the comparable forms of treatment available" (*id.* ¶ 95(e)); and failed to comply with their duty to warn which arose when they knew or should have known "that their devices were being used without warning of the true risks involved" (*id.* ¶ 95(h)). Plaintiffs aver that these failures to warn by Defendants caused Plaintiffs to use the stent and suffer injuries as a result. (*Id.* ¶ 99.) The injuries allegedly suffered by Plaintiffs include medical expenses, costs of counseling to alleviate emotional distress, and additional medical monitoring expenses above and beyond what was needed prior to the implantation of the NuMED CP Stent. (*Id.* ¶ 5(a)-(c); Doc. No. 34 at 8-9.)

Movants argue that their duty to warn a patient is based solely on the doctrine of informed consent and not on a product liability concept of negligent failure to warn, and that product liability claims of negligent failure to warn should be dismissed. (Doc. No. 19 at 14.) A claim based on the absence of informed consent is "a logical corollary" to a duty to warn. *See Wagner v. Olmedo*, 365 A.2d 643, 645 (Del. 1976). "In the malpractice context, informed consent is statutorily defined and requires the patient to demonstrate the health care provider failed to supply information concerning the treatment or procedure 'customarily given' by other 'licensed health care providers with similar training and/or experience' in the community." *Brzoska v. Olson*, 668 A.2d 1355, 1365-66 (Del. 1995) (quoting Del. Code. Ann. 18 § 6852(a)(2)). Delaware courts have made no distinction between claims based on a duty to warn and claims

derived from a lack of informed consent. Rather, the courts have focused on the scope of a physician's duty to warn patients. In *DiFilippo v. Preston*, 173 A.2d 333, 339 (Del. 1961), the Supreme Court of Delaware stated:

> Whether or not a physician or surgeon is under a duty to warn a patient of the possibility of a specific adverse result of a proposed treatment depends upon the circumstances of the particular case, and of the general practice with respect to such cases followed by the medical profession in the locality. The custom of the medical profession to warn must be established by expert medical testimony.

Id. (internal citations omitted); *see Coleman v. Garrison*, 327 A.2d 757, 762-63 (Del. Super. Ct. 1974) (same). Moreover, § 6801 of Title 18 of the Delaware Code defines "informed consent" 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.

Del. Code. Ann. 18 § 6801(6). In order for a plaintiff to recover damages based on a failure to warn or a lack of informed consent, the plaintiff must produce evidence of the standard of care required and whether the physician has met that standard. *See Barriocanal v. Gibbs*, 697 A.2d 1169, 1172 (Del. 1997) (citing Del. Code. Ann. 18 § 6852). We are aware of no authority, and Plaintiffs have provided none, that would require a surgeon to provide his patient with the same warnings prior to surgery that would be required of the manufacturer of a product. Although it remains to be seen whether Plaintiffs will be able to establish that Norwood and Murphy breached their duty to warn as required under Delaware's informed consent law, to the extent that

paragraphs 91, 95, 95(a), 95(d), 95(e), 95(h) and 99 assert claims of negligence with respect to a duty to warn in the context of an informed consent claim, the request to strike is denied.

b. Failure To Perform Adequate Testing

Movants request that paragraphs 92 and 95(b) which assert a claim for failure to test be stricken. Essentially, they argue that as doctors, they had no duty to test medical devices before using them.

Plaintiffs allege that Defendants, including Movants, "failed to perform adequate testing concerning the safety of the NuMED CP Stent because adequate testing would have shown that the stent procedure posed a serious risk and would have permitted the defendant [sic] to provide adequate and appropriate warnings to plaintiffs" (Doc. No. 1 ¶ 92) and "failed to conduct adequate testing and surveillance to determine the safety of the stent." (*Id.* ¶ 95(b)). However, these claims appear to be directed towards Defendant NuMED, whom Plaintiffs list as the manufacturer of the stent. (Doc. No. 1 ¶ 89.) In this context we note that courts have concluded that a "failure to test" is encompassed by claims for design defect and failure to warn. *See, e.g.*, *Adams v. G.D. Searle & Co., Inc.*, 576 So. 2d 728, 730-31 (Fla. Dist. Ct. App. 1991) ("The duty to test . . . is a subpart of a manufacturer's duty to design a product with reasonable care, and thus is subsumed in the plaintiffs' claims for defective design and failure to warn." (citing *Kociemba v. G.D. Searle & Co., Inc*., 707 F. Supp. 1517 (D. Minn. 1989)). Delaware courts do not appear to recognize a separate cause of action based on a duty to test. In *Joseph v. Jamesway Corp*., Civ. No. 93C-12-182-JO, 1997 WL 524126, at *6 (Del. Super. Ct. July 9, 1997), the Superior Court of Delaware held that, in an action against a bicycle manufacturer for a product defect, "there is no separate cause of action for failure to test." The *Joseph* court cited *Kociemba* which

stated: "If the manufacturer designs the product safely, manufactures the product safely, and provides an adequate warning of dangers inherent in the use of the product, then a failure to test the product cannot, standing alone, cause any injury." *Joseph*, 1997 WL 524126, at *6 (quoting *Kociemba*, 707 F. Supp. at 1527.)

In any event, we have found no authority, and Plaintiffs have provided none, recognizing a claim against a physician for failure to test a medical device that the physician surgically implants in a patient. While Plaintiffs' Complaint broadly alleges that all Defendants are "the creators, researchers, and/or users of the Implantation Procedure," (Doc. No. 1 ¶ 90), this allegation does not impose an obligation on the Movant doctors to conduct tests on the stent manufactured and designed by NuMED before performing the implantation procedure. Accordingly, paragraphs 92 and 95(b) will be stricken as they relate to Movants.

c. Negligent Marketing and Design

Movants request that paragraphs 95(e) and (f) be stricken because as physicians they were not involved in the marketing or design of the stent.

The Complaint sets forth claims of negligent marketing by the Defendants, including Movants, alleging that Defendants "[f]ailed to provide adequate training and instructions to medical care providers for appropriate use of the stent" (Doc. No. 1 ¶ 95(c)); and "[n]egligently marketed and over-marketed the stent despite the fact that the risks associated with its use were so high that no reasonable medical device company, exercising due care, would have done so." (*Id.* ¶ 96(f).) We are aware of no authority, and Plaintiffs have provided none, recognizing a claim against a physician for negligent marketing of a medical device that they have implanted in a patient and that was manufactured by someone else. Moreover, as Movants point out,

paragraph 95(f) is directed at a "medical device company" and the Complaint contains no factual assertions that Movants had any involvement in the marketing of the stent device. (Doc. No. 1 ¶ 95(f).) Similarly, paragraph 95(c) asserts that Defendants failed to provide adequate training and instructions to "medical care providers" for appropriate use of the stent, but the Complaint provides no basis for asserting that Movants as the "creators, researchers and/or users of the Implantation Procedure" were required to be involved in the instruction and training of other medical care providers regarding the NuMED CP Stent. Paragraphs 95(c) and (f) fail to state a claim for negligent marketing as it relates to the Movants.

To the extent that paragraph 95 of the Complaint alleges a claim for negligent design of the stent device against Movants, that claim will also be dismissed. The Complaint specifically states that "Defendant, NuMED, is the designer, manufacturer, seller and/or supplier of the NuMED CP Stent." (*Id.* ¶ 89.) The Complaint indicates that Movants are the designers of the Implantation Procedure. Plaintiffs do not specifically allege that Movants played any part in the design of the device. The broad statements that Norwood "acted in concert with the co-defendants to perform the improper activities and wrongful conduct" (*id.* ¶ 20) and that Murphy was an employee of the co-defendants who "was intimately involved in the improper activities and wrongful conduct" (*id.* ¶ 21) are not sufficient to establish that Movants are legally responsible for the design of the stent.

d. Negligent Misrepresentation

Movants contend that paragraphs 95, 95(g), 97, and 98 of the Complaint fail to state a claim for negligent misrepresentation within the Delaware legal standard. Paragraphs 95 and 95(g), when read in conjunction, state:

> Defendants are negligent in the design, testing, manufacturing, advertising, marketing, promoting, labeling, warnings given, and safety measures of the stent in that they . . . [r]emained silent, despite their knowledge of the growing public acceptance of the information and misrepresentations regarding the safety of the stent, and did so because the prospect for huge profits outweighed health and safety issues, all to the significant detriment of plaintiffs and Plaintiff Class.

(Doc. No. 1 ¶ 95.) The Complaint further states that "Defendants' actions constitute knowing omission, suppression and/or concealment of material facts, made with the intent that others rely upon such omissions, suppression and/or concealment in connection with the use of the stent." (*Id.* ¶ 97.) Finally, the Complaint alleges:

> The conduct of defendants demonstrates that defendants acted unlawfully and negligently, used or employed unconscionable commercial and business practices, engaged in deception, fraud, false pretense, false promises or misrepresentation, and/or perpetrated knowing concealment, suppression or omission of material facts, with the intent that individuals such as plaintiffs and the Class rely upon such concealment, suppression and/or omission in connection with the promotion, marketing and use of the NuMED CP Stent.

(*Id.* ¶ 98.)

Under Delaware law, in a claim for negligent misrepresentation the plaintiff must prove: "(1) a particular duty to provide accurate information, based on the plaintiffs [sic] pecuniary interest in that information; (2) the supplying of false information; (3) failure to exercise reasonable care in obtaining or communicating information; and (4) a pecuniary loss caused by justifiable reliance on the false information." *H-M Wexford LLC v. Encorp, Inc.*, 832 A.2d 129, 147 n.44 (Del. Ch. 2003) (internal citations omitted). Movants argue that paragraphs 95 and 95(g) of the Complaint are claims of negligence directed at the manufacturer, and not the physicians. (Doc. No. 19 at 17.) However, there is nothing in these paragraphs that appears to limit the scope of the claim to the manufacturer. Plaintiffs have alleged elsewhere in the

Complaint that all named Defendants, including Movants, "knew that there was a potential danger in the stent implantation procedure, that it had not been done before, and the consequences were unknown, yet misled the families into a false sense of security that the proposed, experimental procedure was safer and less risky than the standard surgical approach." (*Id.* ¶ 30.) Plaintiffs further alleged that the informed consent form that they signed "minimized the risks of this experimental stent, and did not describe, as required, the true nature of the history, knowledge and significant risks of complications, requirements of the revision surgery, and made it sound as if the stent procedure was much less risky and safer than the third surgical approach." (*Id.* ¶ 35.) In addition, Plaintiffs' Complaint states that Defendants had knowledge of the stent's risks and long-term consequences, and failed to disclose the true risks of the stent. (*Id.* ¶ 36.) The Complaint avers that Plaintiff Guinan "was told by the defendants and their agents, servants and/or employees . . . prior to the stent implantation procedure that the stent was something that was done 'all the time' and was much safer than the standard surgical approach." (*Id.* ¶ 53.) Finally, Plaintiffs have alleged the types of injuries suffered as a result of Movants' negligence, including medical expenses and counseling costs. (*Id.* ¶ 5.) Taken together, these averments satisfy the elements of negligent misrepresentation.

Movants contend that the claims in paragraphs of 97 and 98 fail to state a claim of negligent misrepresentation because in both paragraphs, the alleged negligence is premised on an omission of material fact. (Doc. No. 19 at 17.)[5] In Delaware, "liability for the tort of negligent

[5] Movants also argue that paragraph 98 should be stricken to the extent that it can be read to assert a claim against Movants for deceptive business practices. (Doc. No. 19 and 20.) As Movants have noted, such a claim is based on Delaware statutory law. *See* Del. Code Ann. 6 § 2533. The Delaware courts have limited standing for such claims to businesses, not consumers.

misrepresentation is premised on a defendant's supplying 'false information,' and not on the omission of material information." *Brug v. Enstar Group, Inc.*, 755 F. Supp. 1247, 1259 (D. Del. 1991); *see also George v. Kuschwa*, 1986 WL 6588, at *4 (Del. Super. Ct. May 21, 1986) ("The Court finds no authority for the proposition that silence or non-action states a claim for negligent misrepresentation."). To the extent that paragraph 97 and 98 allege the omission, suppression and concealment of material facts they cannot be used to support a claim of negligent misrepresentation.[6]

e. Use of International, Federal, and State Laws in Negligence Claims

In Paragraphs 95(j) through 95(m), Plaintiffs allege that Defendants, including Movants, have failed to comply with certain international treaties, such as the Nuremberg Code and the Declaration of Helsinki, as well as certain provisions of the Code of Federal Regulations, and standards set forth in the Belmont Report and by the Joint Commission on Accreditation of Healthcare Organizations. (Doc. No. 1 ¶ 95.) Movants contend that Plaintiffs "seek several private causes of action based on a 'right to dignity' for violations" of these codes, reports, regulations and declarations. (Doc. No. 19 at 18.) Plaintiffs respond that these paragraphs do not purport to allege private causes of action under international treaties and federal laws. (Doc. No. 34 at 17; Doc. No. 35 at 8-9.) Rather, Plaintiffs argue, that these treaties, laws, and reports set

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See Crosse v. BCBSD, Inc., 836 A.2d 492, 497 (Del. 2003) (consumer plaintiff with no business interest in the alleged unlawful conduct does not have standing to bring a deceptive trade practice claim). To the extent that paragraph 98 alleges a claim for deceptive business practices, this claim will be dismissed as to Movants.

[6] We note that evidence of the omission, suppression or concealment of information may have some relevance to Plaintiffs' claim of negligence based upon a lack of informed consent. *See Barriocanal*, 697 A.2d at 1172, (citing Del. Code Ann. 18 § 6852).

forth a standard of care that applies to Movants and that Movants have breached. (Doc. No. 35 at 8-9.)

Courts have held that there is no private right of action for violations of these declarations, codes, reports, or regulations. *See, e.g.*, *Ammend v. BioPort, Inc.*, 322 F. Supp. 2d 848, 872-73 (W.D. Mich. 2004) (no private right of action for alleged violation of international law under the Declaration of Helsinki and the Nuremberg Code); *Wright v. Fred Hutchinson Cancer Research Ctr.*, 269 F. Supp. 2d 1286, 1289 (W.D. Wash. 2002) (no private right of action under provisions of Code of Federal Regulations regarding human research subjects). Nevertheless, these paragraphs, when read in conjunction with the Plaintiffs' claims of professional negligence, may provide an indication of the appropriate standard of care. Since these provisions provide no private right of action, we have no claim to evaluate. Whether these codes, regulations, reports, or declarations establish a standard of care for Movants is an issue for another day.

2. Second Cause of Action: Fraud and Intentional Misrepresentation

Under Delaware law, to prove a claim of common law fraud the plaintiff must show: (1) the existence of a false representation, usually one of fact, made by the defendant; (2) the defendant had knowledge or belief that the representation was false, or made the representation with requisite indifference to the truth; (3) the defendant had the intent to induce the plaintiff to act or refrain from acting; (4) the plaintiff acted or did not act in justifiable reliance on the representation; and (5) the plaintiff suffered damages as a result of such reliance. *H-M Wexford*, 832 A.2d at 144. 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. *Id.* Plaintiffs'

Complaint meets this five-part test. Plaintiffs have established the existence of a factual misrepresentation in stating that Movants misrepresented the risks and history of the NuMED CP Stent. (Doc. No. 1 ¶ 102.) Specifically, the Complaint states that Defendants, including Movants, had knowledge of the stent's risks and long-term consequences but failed to disclose these risks and failed to inform Plaintiffs' families that the FDA had failed to approve the stent for five years. (*Id.* ¶ 36.) In addition, the Complaint states that Defendants represented to Plaintiff Guinan's family that the stent implantation procedure was done "all the time," (*id.* ¶ 53); that Plaintiff Conway's parents were misled "as to their child's actual condition, need for the stent, and the true experimental and unknown nature and future risks of the experimental NuMED stent" (*id.* ¶ 63); and that Plaintiff Hess's family was not informed of the true nature of the stent and its attendant risks (*id.* ¶ 71.) Plaintiffs also allege that Movants did not disclose that the stent was experimental (*id.* ¶ 64), and that Movants did not disclose the attendant risks of the stent (*id.* ¶ 71). These allegations satisfy the first element of an action for fraud.

Plaintiffs further allege that Defendants made these representations "with the knowledge that they were false when made." (*Id.* ¶ 103.) This allegation satisfies the second element of an action for fraud. Paragraph 97, incorporated into this cause of action by reference, satisfies the third element in stating that Movants' actions were "made with the intent that others rely upon such omissions, suppression and/or concealment in connection with the use of the stent." (*Id.* ¶ 97.) Paragraph 104 alleges that "Plaintiffs and the members of the Class justifiably relied upon the above-stated misrepresentations in making the decisions to participate and continue in the Trial." (*Id.* ¶ 104.) This satisfies the fourth element of fraud. Finally, the Complaint asserts that "[a]s a direct and proximate result of defendants' intentional and material misrepresentations,"

Plaintiffs were "induced to receive the stent." (*Id.* ¶ 105.) The Complaint states in several places that Plaintiffs suffered injury as a result of the implantation of the stent. (*Id.* ¶¶ 4, 5, 99, 100.) Since the Complaint alleges all of the elements of an action for fraud against Movants, Movants' Motion to Dismiss this cause of action will be denied.

3. Third Cause of Action: Assault and Battery

> The Complaint states that Defendants, including Movants, failed to inform Plaintiffs
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> of the risks and alternatives to [] all treatment, care, therapy and procedures performed so as to afford the plaintiffs, plaintiffs' decedent and the members of the Class the opportunity to make an informed decision as to the performance of said procedures in violation of the minimal standard and the federal requirements as outlined herein; thus, the therapy plaintiffs and other members of the Class received constituted a battery.

(Doc. No. 1 ¶ 107.) Delaware courts have refused to recognize a cause of action for battery based on lack of informed consent. In *Brzoska*, the Supreme Court of Delaware noted that "the tort of battery is properly limited in the medical/dental setting to those circumstances in which a health care provider performs a procedure to which the patient has not consented." *Brzoska*, 668 A.2d at 1366. Thus, "[a] physician may be held liable for battery when he or she obtains the consent of the patient to perform one procedure and the physician instead performs a substantially different procedure for which consent was not obtained." *Id.* "If a health care provider violates his or her 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." *Id.* While Plaintiffs argue that they were not fully informed of all relevant information regarding the stent procedure, Plaintiffs do not allege that the procedures performed were

substantially different than the procedures to which their families consented. Plaintiffs have not set forth a claim cognizable under Delaware law for assault and battery. Accordingly, that claim will be dismissed.

4. Fourth Cause of Action: Strict Products Liability

Plaintiffs' Complaint alleges that Defendants, including Movants, are liable on a theory of strict products liability as provided in §402A of the Restatement (Second) of Torts. (Doc. No. 1 ¶ 110.) Movants argue that as medical professionals they are not suppliers of the stent and are not subject to §402A liability. In an interesting twist, in their Answer to Movants' Motion to Dismiss, Plaintiffs take issue with Movants for analyzing Defendants' obligations under § 402A. They argue that Delaware has not adopted § 402A of the Restatement Second and that Delaware applies Article 2 of the Uniform Commercial Code (UCC) instead. (Doc. No. 35 at 17-18.) We note, however, that the strict liability claim in Plaintiffs' Complaint specifically alleges § 402A liability and does not mention the UCC. (Doc. No. 1 ¶¶ 108-11.)

In any event, Delaware courts recognize a distinction between products and services in applying the doctrine of strict liability. *Golt v. Sports Complex, Inc.*, 644 A.2d 989, 993 (Del. Super. Ct. 1994) (citing *Castaldo v. Pittsburgh-Des Moines Steel Co., Inc.*, 376 A.2d 88, 91 (Del. 1977); *Cropper v. Rego Distrib. Ctr., Inc.*, 542 F. Supp. 1142, 1148 (D. Del. 1982)). Delaware imposes no liability on those who provide professional services, absent a showing of negligence. *Id.* This service/product distinction has been extended in Delaware to the rendering of a service with a product incidentally involved. *Id.* The Superior Court of Delaware provided the rationale for the service/product distinction as follows:

> Professional services do not ordinarily lend themselves to [strict liability] because they lack the elements which gave rise to the doctrine. There is no mass production of goods or a large body of distant consumers whom it would be unfair to require to trace the article they used along the channels of trade to the original manufacturer and there to pin-point an act of negligence remote from their knowledge and even from their ability to inquire.

Id. (quoting *LaRossa v. Scientific Design Co.*, 402 F.2d 937, 942 (3d Cir. 1968)). Accordingly, in their capacity as providers of medical services, Movants cannot be held liable on the theory of strict liability.

Furthermore, Plaintiffs have provided no basis for including Movants as a producer or designer of the NuMED CP Stent. The Complaint clearly states that NuMED is the designer, manufacturer, seller and/or supplier of the NuMED CP Stent. (Doc. No. 1 ¶ 89.) This allegation is incorporated by reference into the cause of action for strict products liability. (*Id.* ¶ 108). Nowhere in the Complaint are Movants described as the suppliers, sellers or manufacturers of the stent. As discussed above, allegations that Murphy was "intimately involved in the improper activities and wrongful conduct regarding the NuMED CP Stent" and that Norwood "acted in concert with the co-defendants to perform the improper activities and wrongful conduct regarding the NuMED CP Stent" are not sufficient to establish that Movants are sellers, suppliers, designers or manufacturers of the stent. In his Brief in Opposition to Movants' Motion, Plaintiff Conway argues that "[o]n information and belief, moving defendants were involved in the design, modification, marketing and promotion of the NuMED CP Stent." (Doc. No. 34 at 22.) The Complaint does not support this assertion.

5. Fifth Cause of Action: Express and Implied Warranties

The Complaint states that "[i]n manufacturing, producing, promoting, and distributing the NuMED CP Stent, defendants expressly and impliedly warranted that the aforementioned product was merchantable, fit and safe for the ordinary and particular purposes for which it was sold, and that it was free from all defects and dangers" and that Defendants, including Movants, breached these warranties "by producing, promoting and distributing the NuMED CP Stent in an unsafe, defective and unfit condition." (Doc. No. 1 ¶¶ 113-15.) As discussed above, only NuMED has been identified in the Complaint as the designer, manufacturer, seller and supplier of the stent. There is no basis for a claim for breach of warranty against Movants. Furthermore, even if this claim for breach of warranty somehow applied to Movants, it is clear under Delaware law that "[i]n the absence of a special agreement a surgeon does not warrant or guarantee a good result by his patient or that he will effect a cure." *Coleman v. Garrison*, 349 A.2d 8, 11 (Del. 1975), *rev'd on other grounds, Garrison v. Med. Ctr. of Del. Inc.*, 571 A.2d 786 (Del. 1989) (Table); *see also Wagner v. Olmedo*, 365 A.2d 643, 645 (Del. 1976) (surgeon not liable to plaintiffs on a breach of warranty basis). We are aware of no special agreement in this case. The Complaint avers that Defendants, including Movants, "advertised the stent as being safe and effective when it was not." (Doc. No. 1 ¶ 114.) We are aware of no authority which recognizes the creation of an express warranty based upon a physician's communication with his patient regarding a medical device that he did not design, manufacture, or sell. Plaintiffs' Complaint fails to state a cognizable claim against the moving Defendants for breach of warranty.

6. Sixth Cause of Action: Medical Monitoring

Plaintiffs claim that medical monitoring is appropriate here because "[a]s a direct result of defendants' acts, omissions and conduct, plaintiffs and members of the proposed Classes who

have received NuMED CP Stent have been exposed to a hazardous procedure and product, and suffered a significantly increased risk of the side effects caused by this device." (Doc. No. 1 ¶ 117.) According to Plaintiffs, this increased risk "makes periodic diagnostic and medical examinations reasonable and necessary." (*Id.*) Plaintiffs contend that "[i]ncreased susceptibility to injuries and irreparable threat to the health of plaintiffs" due to the implantation of the NuMED CP Stent can be mitigated or addressed by the creation of a medical monitoring program that does the following:

> (a) Notifies individuals who have received the NuMED CP Stent of the potential harm from the stent;
>
> (b) Aids individuals who received the NuMED CP Stent in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring;
>
> (c) Provides individuals who received NuMED CP Stent in Class I with state of the art medical testing;
>
> (d) Provides for the accumulation and analysis of relevant medical and demographic information from Class members;
>
> (e) Provides for the creation, maintenance and operation of a "Registry" in which relevant demographic and medical information concerning all Class members can be gathered, maintained and analyzed;
>
> (f) Provides for medical research concerning the incident, prevalence, natural course and history, diagnosis and treatment of NuMED CP Stent-induced injuries; and
>
> (g) Allows for publication and dissemination of all such information to members of Class I and their physicians.

(*Id.* ¶ 123.)

Traditionally, medical monitoring has been awarded only in toxic tort cases. *See Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795, 824 (Cal. 1993); *Bourgeois v. A. P. Green Indus., Inc*., 716 So. 2d 355, 359-60 (La. 1998); *Ayers v. Twp. of Jackson*, 525 A.2d 287, 298 (N.J.

1987); *Redland Soccer Club, Inc. v. Dep't of the Army*, 696 A.2d 137, 145-46 (Pa. 1997); *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 975-78 (Utah 1993); *Bower v. Westinghouse*, 522 S.E.2d 424, 430 (W.Va. 1999). More recently "tort plaintiffs have increasingly sought, and have regularly been awarded, medical monitoring costs in both toxic tort and product liability cases." *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 571 (6th Cir. 2005). There are varying views, however, regarding whether medical monitoring is permissible in a products liability action. In *In re Orthopedic Bone Screw Products Liability Litigation*, Civ. A. 93-7074, 1995 WL 273597 (E.D. Pa. Feb. 22, 1995), the plaintiffs brought a products liability action for damages and equitable relief, including medical monitoring, for injuries allegedly suffered by plaintiffs as a result of the surgical implantation of spinal fixation devices into their spines. *Id.* at *1. The plaintiffs sought, among other damages, equitable relief in the form of a court-supervised medical monitoring program. *Id.* at *4. On the plaintiffs' motion for class certification, the district court, analyzing the medical monitoring claim under Pennsylvania law, concluded that the plaintiffs had failed to demonstrate "that medical testing procedures exist which can detect warning signs of future problems which may result from spinal implantation surgery." *Id.* at *9. The court distinguished toxic tort cases from products liability cases as follows:

> Medical monitoring is a suitable form of relief in toxic substance exposure types of cases because doctors can often diagnose warning signs of diseases and other medical problems associated with toxic substance exposure through medical monitoring. The same argument, however, cannot be made for medical monitoring relief in products liability cases, where diseases caused by exposure to toxic substances are not the type of injury at issue.

Id. (internal citations omitted).

In *Sutton*, the plaintiff brought a suit on behalf of a proposed class of individuals who had undergone cardiac bypass surgery using a certain bypass medical device. *Sutton*, 419 F.3d at 569. Alleging that the device was defective and had led to economic losses, large medical expenses, and a risk of physical injuries, the plaintiff sought the imposition of a medical monitoring fund. *Id.* The fund would provide notice to persons implanted with the device, medical examinations to determine the extent of harm to the patient, education for physicians about diagnosing and treating any scarring that might result from using the device, and medical treatment to remove the device from all individuals exhibiting injury as a result of using the device. *Id.* at 569-70. The Sixth Circuit, in holding that the plaintiff had standing to seek such a remedy, noted that "[a] medical monitoring award aids presently healthy plaintiffs who have been exposed to an increased risk of future harm to detect and treat any resultant harm at any early stage." *Id.* at 572;*see also Friends for All Children, Inc. v. Lockheed Aircraft Corp.* , 746 F.2d 816 (D.C. Cir. 1984) (D.C. tort law recognizes a cause of action for diagnostic examinations even where there is no proof of actual injury).

The Third Circuit has set forth the elements necessary to make out a medical monitoring claim under Pennsylvania law. A plaintiff must show that: (1) plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant; (2) as a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease; (3) that increased risk makes periodic diagnostic medical examinations reasonably necessary; and (4) monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial, and such monitoring regime is different than the one that would have been prescribed in the absence of the exposure at issue. *In*

re Paoli R. R. Yard PCB Litig., 35 F.3d 717, 787-88 (3d Cir. 1994). This is substantially the same test that is used in other jurisdictions as well. *See Bourgeois*, 716 So. 2d at 360-61; *Ayers*, 525 A.2d at 311-12; *Hansen*, 858 P.2d at 979; *Bower*, 522 S.E.2d at 431.[7]

Plaintiffs' Complaint alleges that Plaintiffs "have been exposed to a hazardous procedure and product" (Doc. No. 1 ¶ 117) and that this "exposure to the hazardous product and procedure was proximately caused by defendants' tortious conduct." (*Id.* ¶ 118(b).) The Complaint also asserts that "[a]s a direct result of defendants' acts, omissions and conduct, plaintiffs and members of the proposed Classes . . . [have] suffered a significantly increased risk of the side effects caused by this device." (*Id.* ¶ 117.) Paragraph 118 states that medical monitoring will "detect injuries from the NuMED CP Stent and its implantation" and "assist in preventing further injuries from or as a consequence of implantation of the NuMED CP Stent". (*Id.* ¶ 118(c), (e).) Plaintiffs allege that "[e]ffective monitoring and testing procedures exist which make early detection and treatment of these injuries possible and beneficial." (*Id.* ¶ 120.) In addition, they allege that "[t]his monitoring will be different from what normally is recommended to individuals who did not receive a NuMED CP Stent." (*Id.* ¶ 118(d).) Construing these allegations in a light most favorable to Plaintiffs, we conclude that the claim for medical monitoring under these circumstances is appropriate. As the Court observed in *Sutton*, "[a] defective medical device embedded in an individual's body can pose just as serious a threat as an exposure to toxic substances. Indeed, such devices may be more dangerous given the fact that an

[7] We note that the Sixth Circuit has observed that medical monitoring "is more properly considered one of a number of possible remedies to an underlying tort, rather than a separately actionable tort." *Sutton*, 419 F.3d at 572 (disagreeing with *Paoli* description of medical monitoring as a "non-traditional" tort that has developed in the common law).

individual with such an implant will continuously be exposed to its increased risks." Accordingly, we conclude that at this stage of the proceedings, Plaintiffs' Complaint states a viable claim for medical monitoring.

An appropriate Order follows.

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

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

ORDER

AND NOW, this 14th day of February, 2007, upon consideration of the Motion Of Defendants John Murphy, M.D., And William I. Norwood, Jr., M.D. Ph.D., To Dismiss For Failure To State A Claim For Relief And To Strike Pursuant To Rules 12(b) And (f) Of The Federal Rules Of Civil Procedure (Doc. No. 19), it is ORDERED as follows:

1. The First Cause of Action in Plaintiffs' Complaint is DISMISSED with respect to Defendants Murphy and Norwood to the extent that it alleges negligence for failure to perform adequate testing, negligent marketing and design, and deceptive trade practices.

2. The Third, Fourth, and Fifth Causes of Action in Plaintiffs' Complaint are DISMISSED with respect to Defendants Murphy and Norwood.

IT IS SO ORDERED.

BY THE COURT:

R. Barclay Surrick, Judge