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

RAE SCHIFF,

Plaintiff,

v.

DENNIS J. HURWITZ, M.D., ET AL.,

Defendants.

12cv0264
ELECTRONICALLY FILED

Memorandum Opinion re: Defendant's Motion To Dismiss (Doc. No. 24)

I. Introduction

Presently before this Court is the Motion to Dismiss filed by defendant Invasix. This is an action sounding in medical negligence, strict liability, and misrepresentation based upon a "BodyTite Procedure" that plaintiff underwent and was performed by co-defendant Dr. Dennis Hurwitz.[1] Invasix is the manufacturer of the medical device used in the "BodyTite Procedure" (hereinafter the "Invasix device"). In Count VI[2] of the Complaint, plaintiff alleges that Invasix was negligent in distributing the Invasix device. In Count VII of the Complaint, plaintiff alleges that Invasix is strictly liable. In Count VII [sic] (hereinafter Count VIII), plaintiff alleges that Invasix breached a warranty. In Count IX, plaintiff alleges that Invasix is liable for misrepresentation. After careful consideration of defendants' Motion to Dismiss (doc. no. 24) and Brief in Support (doc. no. 25), as well as plaintiff's Brief in Opposition (doc. no. 33), defendant's Motion to Dismiss will be GRANTED in PART and DENIED in PART.

[1] This Court has already denied Dr. Hurwitz's Motion to Dismiss. Doc. No. 18. Also, pending before this Court is a Motion to Dismiss filed by Essex Institutional Review Board. Doc. No. 29. The Court will issue an Opinion on that Motion upon the completion of briefing.

[2] All other Counts in the Complaint are against co-defendants and are not addressed in this Memorandum Opinion.

II. Factual Background

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, at this stage the Court accepts all of the factual allegations in the Complaint as true and all reasonable inferences are drawn in plaintiff's favor. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). Taking plaintiff's factual allegations as true solely for the purposes of this Memorandum Opinion, the facts of this case are as follows:

Invasix failed to properly label the Invasix device and failed to get proper approval as required by the Code of Federal Regulations (CFR). *See generally* doc. no. 1, ¶ 155. Invasix was aware that the device was unsafe but failed to notify plaintiff of this fact. *Id*.

On April 23, 2009, during an initial consultation with Schiff, Dr. Hurwitz planned surgery in two stages—stage one would include a "tummy tuck" and stage two would include a lower body lift. *Id.*, ¶ 72. On December 1, 2009, Schiff spoke with Dr. Hurwitz about dividing the operations into smaller procedures; however, Dr. Hurwitz allegedly never discussed nor documented the potential risk of the device used to perform these procedures, the Radio-Frequency Assisted Lipolysis ("RFAL"). *Id.*, ¶ 74.

On March 2, 2010, Schiff was given pre-operative markings, and according to Dr. Hurwitz's chart, RFAL was discussed with Schiff but not the specific risks of the procedure. *Id.*, ¶ 76. On March 3, 2010, Dr. Hurwitz performed a "BodyTite Procedure"[3] on Schiff using the Invasix Device. *Id.*, ¶¶ 78-79. Prior to the surgery, plaintiff signed a form in which Invasix agreed to pay her a sum of $175 and any treatment of injury arising out of the Invasix device. *Id*. ¶¶ 188-89.

[3] "BodyTite Procedure" refers to the numerous procedures Dr. Hurwitz performed on Schiff on March 3, 2010. See Doc. No. 1, ¶ 79(a) – (d).

During the procedure, Dr. Hurwitz was serving as an investigator for the Invasix Device in a clinical trial sponsored by Invasix and approved by Essex Institutional Research Board. *Id.*, ¶ 80. Schiff was allegendly unaware that Dr. Hurwitz was a paid investigator for the Invasix Device, that the Invasix Device was being used in a clinical trial sponsored by Invasix, and that the Food and Drug Administration ("FDA") neither was aware nor approved of the clinical trial of the Invasix Device. *Id.*, ¶¶ 86-87.

Prior to the "BodyTite Procedure" on March 3, 2010, Dr. Hurwitz allegedly failed to disclose to Schiff that: (1) she was not a candidate for the procedure due to the clinical study's protocol; (2) the clinical study's protocols limited the Invasix Device from being used on more than three areas of the body; and (3) Schiff could be paid for her participation as a subject of the investigation of the "BodyTite Procedure." *Id.*, ¶¶ 88-90.

On March 9, 2010, approximately six days after surgery, Schiff complained of increased pain, swelling, and fever during her first post-op visit to Dr. Hurwitz's office. *Id.*, ¶ 91. Over the course of several subsequent days, Schiff had increased pain on all areas of her body in which the procedure was performed and began taking medication prescribed by Dr. Hurwitz. *Id.*, ¶ 93.

By Mid-April 2010, Schiff's pain was allegedly uncontrollable even with prescribed medication. *Id.*, ¶ 94. The procedures performed by Dr. Hurwitz left Schiff with irregular scars and scar tissue, and in August of 2010, she was diagnosed with having developed a thermal mediated demyelination of the sensory and autonomic nerves in the thighs leading to a diffuse post RFAL dysesthesia of the thighs and lymphatic system compromise. *Id.*, ¶¶ 95, 97. Schiff avers that her injuries were the direct and proximate result of negligence of each defendant. *Id.*, ¶ 98.

III. Standard of Review

A. Rule 12(b)(5)

A plaintiff is required to effectuate service upon all defendants. Fed.R.Civ.P. 4. If the defendant files a Motion to Dismiss Pursuant to Fed.R.Civ.P. 12(b)(5) for failure to effectuate service, "[T]he party making the service has the burden of demonstrating its validity when an objection to service is made." *Reed v. Weeks Marine, Inc.*, 166 F.Supp.2d 1052, 1054 (E.D. Pa. 2001) (*citing Grand Entertainment Group, Ltd. v. Star Media Sales, Inc.*, 988 F.2d 476, 488-89 (3d Cir.1993)).

B. Rule 12(b)(6)

In considering a Motion to Dismiss brought pursuant to Fed.R.Civ.P. 12(b)(6), federal courts require notice pleading, as opposed to the heightened standard of fact pleading. Federal Rule of Civil Procedure 8(a)(2) requires only "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds on which it rests.'" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

Building upon the landmark United States Supreme Court decisions in *Twombly*, 550 U.S. 554 and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the United States Court of Appeals for the Third Circuit explained that a District Court must take three steps to determine the sufficiency of a complaint:

> First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." Third, "whe[n] there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." This means that our inquiry is normally broken into three parts: (1) identifying the elements of the claim, (2) reviewing the Complaint to strike conclusory allegations, and then (3) looking at the well-pleaded components of

> the Complaint and evaluating whether all of the elements identified in part one of the inquiry are sufficiently alleged.

Malleus v. George, 641 F.3d 560, 563 (3d Cir. 2011) (quoting *Iqbal*, 556 U.S. at 662).

The third step of the sequential evaluation requires this Court to consider the specific nature of the claims presented and to determine whether the facts pled to substantiate the claims are sufficient to show a "plausible claim for relief." "While legal conclusions can provide the framework of a Complaint, they must be supported by factual allegations." *Id.*; *See also Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009).

The Court may not dismiss a Complaint merely because it appears unlikely or improbable that Plaintiff can prove the facts alleged or will ultimately prevail on the merits. *Twombly*, 550 U.S. at 563 n.8. Instead, the Court must ask whether the facts alleged raise a reasonable expectation that discovery will reveal evidence of the necessary elements. *Id.* at 556. Generally speaking, a Complaint that provides adequate facts to establish "how, when, and where" will survive a Motion to Dismiss. *Fowler*, 578 F.3d at 212; *see also Guirguis v. Movers Specialty Services, Inc.*, 346 Fed. App'x. 774, 776 (3d Cir. 2009).

In short, the Motion to Dismiss should not be granted if a party alleges facts, which could, if established at trial, entitle him or her to relief. *Twombly*, 550 U.S. at 563 n.8.

IV. Discussion

A. Service Was Effectuated Under the Hague Convention[4]

The dispute on whether service was effectuated under the Hague Convention centers on Fed.R.Civ.P. 4(f)(1) and Article 10(a) of the Hague Convention, which states that, "Provided the

[4] This holding renders Doc. No. 34, Motion for Special Order of Service of Process, moot.

State of destination does not object, the present Convention shall not interfere with the freedom to send judicial documents, by postal channels, directly to persons abroad."[5] 20 U.S.T. 361. First, the Court recognizes that courts around the globe have interpreted Article 10(a) in different manners. Some courts have held that Article 10(a) allows process to be effectuated through registered mail while other courts have held that only process under Article 5[6] of the Hague Convention suffices.

Federal Courts in the United States are likewise split on whether service may be effectuated under Article 10(a) instead of Article 5.[7] Many courts, including the United States Courts of Appeals for the Second and Ninth Circuits and District Courts within this Circuit, have held that service may be effectuated under Article 10(a). *E.g. Brockmeyer v. May*, 383 F.3d 798, 802 (9th Cir. 2004); *Ackermann v. Levine*, 788 F.2d 830, 839 (2d Cir. 1986); *Knit With v. Knitting Fever, Inc.*, 2010 U.S. Dist. LEXIS 70412 (E.D. Pa. 2010); *Mitchell v. Theriault*, 516 F. Supp. 2d 450 (M.D. Pa. 2007); *EOI Corp. v. Medical Mktg. Ltd.*, 172 F.R.D. 133, 135 (D. N.J. 1997); *R. Griggs Group Ltd. v. Filanto Spa*, 920 F.Supp. 1100 (N.D. Ill 1996); *Sieger v. Zisman*, 106 F.R.D. 194 (N.D. Ill. 1985); *Weight v. Kawasaki Heavy Indus.*, 597 F.Supp. 1082, 1085-86 (E.D. Va. 1984); *Chrysler v. Gen. Motors*, 589 F.Supp. 1182, 1206 (D.D.C. 1984).[8] Other

[5] Neither Canada nor Israel has objected to Article 10(a). See www.hcch.net (the official website for the Hague Conference on Private International Law).

[6] Article 5 is the process where service is sent to the Central Authority in the foreign jurisdiction, who then serves the foreign individual in accordance with that nation's laws.

[7] The Court appreciates the candor of defense counsel in recognizing the sharp divide among both Courts of Appeals and District Courts on this issue.

[8] Many scholars have agreed with this approach. *E.g.* Patricia N. McCausland, *How May I Serve You? Service of Process by Mail under the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters,* 12 Pace L.Rev. 177 (1992); Craig R. Armstrong, *Permitting Service of Process By Mail on Japanese Defendants,* 13 Loy. L.A. Int'l

courts, including the United States Court of Appeals for the Fifth Circuit and District Courts in this Circuit, have held that service must be effectuated under Article 5. *E.g. Nuovo Pignone, SpA v. STORMAN ASIA M/V*, 310 F.3d 374, 384 (5th Cir. 2002); *Friedman v. Israel Labour Party*, 1997 U.S. Dist. LEXIS 9204, (E.D. Pa. 1997); *Gallagher v. Mazda Motor of America*, Inc., 781 F.Supp. 1079, 1082 (E.D. Pa. 1992); *Raffa v. Nissan Motor Co.*, 141 F.R.D. 45, 46 (E.D. Pa. 1991).

This Court will adopt the approach of the United States Courts of Appeals for the Second and Ninth Circuits, and hold that service may be effectuated under Article 10(a) of the Hague Convention, even when service under Article 5 is an option. The Court adopts the analysis of the extensive and well-reasoned opinions of the United States District Court for the Northern District of Illinois in *R. Griggs* and the United States District Court for the District of New Jersey in *EOI*. Furthermore, although the United States Court of Appeals for the Third Circuit has not ruled on this precise issue, this Court finds the *Umbenhauer v. Woog*, 969 F.2d 25 (3d Cir. 1992) case to be instructive. In that case, the United States Court of Appeals for the Third Circuit expressed an expansive view of the proper methods to effectuate service under the Hague Convention. Thus, service was effectuated under Fed.R.Civ.P. 4(h). Accordingly, the Court holds that plaintiff's service of Invasix was proper.

B. Claims are Not Preempted by the Medical Devices Act

Defendant next argues that all of the claims are preempted by the Medical Devices Act (MDA), 21 U.S.C. §360c *et seq*. The MDA preemption provision provides that:

& Comp. L.J. (1991); Franklin B. Mann, Jr., *Foreign Service of Process by Direct Mail under the Hague Convention and the Article 10(a) Controversy: Send v. Service*, 21 Cumb. L.Rev. 647 (1990/1991); Gary A. Magnarini, *Service of Process A broad Under the Hague Convention*, 71 Marq. L.Rev. 649 (1988).

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In *Riegel v. Medtronic Inc*., 552 U.S. 312, 321-23 (2008) the United States Supreme Court held that state law claims are preempted by the MDA if: (1) "specific requirements applicable to a particular device" have been established; and (2) the claims are based on "state requirements" related to safety and effectiveness that are "different from, or in addition to" the federal requirements. *See also Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010); *Gross v. Stryker Corp.*, -- F.Supp.2d --, 2012 WL 876719, at *11 (W.D. Pa. March 14, 2012) (Fischer, J). "State requirements" subject to federal preemption include common law causes of action, such as negligence, strict liability, and breach of implied warranty. *Riegel*, 552 U.S. at 324-25, 327-28; *see also Williams*, 388 F. App'x at 171 ; *Gross*, 2012 WL 876719 at *11.

The Invasix device at issue is a Class II medical device. E.g. doc. no. 25, 11. Class II devices can enter the market through premarket approval (PMA); however, defendant Invasix chose not to use PMA for the Invasix device. In this case, plaintiff avers that the defendant failed to comply with FDA requirements applicable to Class II devices. Doc. No. 1, ¶ 155. It is unclear from the pleadings if defendant filed a § 510(k) application.

Defendant relies upon *Meslar v. Johnson & Johnson Professional Inc.*, 1996 WL 162302 (E.D. Pa. April 4, 1996) (Rendell J.) for the proposition that 21 C.F.R. 801 *et seq*. constitutes "specific requirements." However, *Meslar* was decided twelve years prior to *Riegel*. The other cases upon which defendant relies all involved Class III devices. Defendant has not cited, and this Court

has not been able to discover, any case since *Riegel* in which a court held that state law claims were preempted by the MDA solely because of generic regulations.

Entering the market through the § 510(k) process does not impose device specific requirements within the meaning of 21 U.S.C. § 360k(a). *Riegel*, 552 U.S. at 322-23. Thus, a device manufacturer that has only gone through the § 510(k) process is not afforded federal preemption of state common law claims. *Id.*; *Gross*, 2012 WL 876719 at *12. Accordingly, since the Invasix device is not subject to specific requirements, whether it went through the § 510(k) process or not, the MDA's preemption provision does not apply in the case at bar.

C. The Negligence Claim is Based on More than Failure to Warn

Defendant next argues that plaintiff's claim for failure to warn should be dismissed because under Pennsylvania's learned intermediary doctrine a device manufacturer is only required to warn the prescribing physician, not the patient. Doc. No. 25, 13-14. However, Count VI of the Complaint is based upon more than a mere failure to warn. In particular, the Complaint alleges that defendant was negligent for failing to follow FDA regulations regarding investigative devices and failing to properly test the Invasix device. Thus, plaintiff has pled sufficient facts to maintain a claim of negligence and Count VI will not be dismissed.

D. Comment K Does Not Preclude Recovery for Strict Liability at this Stage

Next, defendant argues that comment k to Restatement of Torts (Second) Section 402A bars recovery for strict liability. The Pennsylvania Supreme Court adopted comment k in *Hahn v. Richter*, 673 A.2d 888, 890-91 (Pa. 1996). *Hahn* was extended to cover medical devices in *Creazzo v. Metronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. 2006). *See also Soufflas v. Zimmer, Inc.*, 474 F.Supp.2d 737 (E.D. Pa. 2007). Plaintiff argues that, because the strict liability claim is based on more than a failure to warn theory, the claim is permitted to go forward.

Plaintiff argues that the "risk of thermal injury rendered the device unsafe, defective and dangerous as well as Invasix' failure to consider the factors set forth in the FDA Guidance Document on RF medical devices" also permits for recovery for strict liability. At the Motion to Dismiss phase, this Court finds that plaintiff has adequately pled a claim for strict liability. Therefore, plaintiff has stated a claim for which relief can be granted with regards to Count VII of the Complaint.

E. Pennsylvania Law Does Not Recognize Breach of Implied Warranty Against Medical Device Manufacturers

Defendant argues that Pennsylvania law does not recognize breach of implied warranty claims against medical device manufacturers. Plaintiff counters that, because the Complaint avers that defendant violated FDA regulations, the claim for breach of implied warranty should not be dismissed. "[Breach of implied] warrant[y is] inapplicable to prescription medical devices in Pennsylvania. The very nature of prescription medical products which are considered unavoidably unsafe products precludes the imposition of a warranty of fitness for ordinary purposes." *Soufflas*, 474 F.Supp.2d at 752 (internal quotation marks omitted) (citation omitted). This Court agrees that, even if all FDA regulations were not followed, breach of implied warranty is barred by Pennsylvania law. Thus, Plaintiff has failed to state a claim for which relief can be granted with regards to the portion of Count VIII of the Complaint that alleges breach of implied warranty.

F. Plaintiff Has Not Stated a Claim for Breach of Express Warranty

Defendant next argues that plaintiff has failed to state a claim for breach of express warranty. "Absent a demonstration that a promise or affirmative statement was made, how or by whom the promise was made, or what was in fact promised, a claim for breach of express warranty is not sufficiently plead." *Gross*, 2012 WL 876719, at *27 (*citing Delaney v. Stryker Orthopaedics, et al*, 2009 WL 564243, at *9 (D. N.J. March 5, 2009)). "Moreover, a mere recitation of the elements of a cause of action, absent any factual support, specification of a particular promise that became the basis of the bargain, or a showing that the promise was directed at the consumer, is

insufficient to withstand dismissal." *Id*. (*citing Kester v. Zimmer Holdings, Inc.*, 2010 WL 2696467, at *10 (W.D. Pa. June 16, 2010) (McVerry, J)).

Plaintiff argues that defendant's representations were made because of certain CFR provisions. However, under Pennsylvania law this is not sufficient for a breach of express warranty. There are no facts alleged in the Complaint which claim that the necessary express promise was made by defendant. Furthermore, the arguments that co-defendant Dr. Hurwitz made such statements is also insufficient to plead breach of express warranty under these facts. Plaintiff did not know Dr. Hurwitz was operating as an agent for Invasix at the time the alleged statements were made. Thus, plaintiff has failed to state a claim for which relief can be granted with regards to the portion of Count VIII of the Complaint that alleges breach of express warranty. As both portions of the Count do not state a claim, Count VIII will be dismissed.

G. Plaintiff Has Stated a Claim for Misrepresentation

Count IX of the Complaint alleges intentional and negligent misrepresentation. In order to show intentional misrepresentation under Pennsylvania law, Plaintiff must show

> (1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and, (6) the resulting injury was proximately caused by the reliance.

Bortz v. Noon, 729 A.2d 555, 560 (Pa. 1999) (*citing Gibbs v. Ernst*, 647 A.2d 882, 889 (Pa. 1994)). Negligent misrepresentation has the same elements as intentional misrepresentation except for element three, which is "made under circumstances in which the misrepresenter ought to have known its falsity" for negligent misrepresentation. *Id*. at 561 (*citing Gibbs*, 647 A.2d at 890). Defendant argues that plaintiff does not meet the first element for either intentional or negligent misrepresentation.

In the case at bar, some of the alleged misrepresentations were made regarding the classification of the device. These alleged misrepresentations are not false by implication as defendant argues. These misrepresentations were actual representations made by Invasix. Thus, plaintiff has stated a claim for both negligent and intentional misrepresentation under Pennsylvania law.

H. Plaintiff Has Stated a Claim for Intentional Infliction of Emotional Distress and Punitive Damages

Count XIII of the Complaint alleges intentional infliction of emotional distress. In Pennsylvania, defendant's conduct must be "so outrageous in character and so extreme in degree as to go beyond all possible grounds of decency, and to be regarded as atrocious and utterly intolerable in a civilized society" in order to recover for intentional infliction of emotional distress. *Hoy v. Angelone*, 720 A.2d 745, 754 (Pa. 1988) (*quoting Buczek v. First National Bank of Mifflintown*, 531 A.2d 1122, 1125 (Pa. Super. 1987). "[It is not] enough that the defendant has acted with intent which is tortious or even criminal, or that he has intended to inflict emotional distress, or even that his conduct has been characterized by malice, or a degree of aggravation that would entitle the plaintiff to punitive damages for another tort." *Id*. (*citing Daughen v. Fox*, 539 A.2d 858, 861 (Pa. Super. 1988) (internal quotation marks omitted) (other citation omitted)).

Plaintiff cites *Brownstein v. Gieda*, 649 F.Supp.2d 368 (M.D. Pa. 2009) (Munley, J) to support her position. *Brownstein* held that conduct can be so egregious as to not require a special showing that the defendant knew his or her actions would cause emotional distress. *Id*. at 374. Plaintiff has pled facts which, although general in nature like in *Brownstein*, allege that the actions of Invasix were "atrocious" and "utterly intolerable." Thus, plaintiff has stated a claim for intentional infliction of emotional distress and punitive damages.

I. Plaintiff Has Stated a Claim for Breach of Contract

Page six of doc. no. 1-5 shows that Invasix allegedly entered into a contract with plaintiff. Invasix agreed to pay for treatment of any research-related injury and to pay plaintiff a sum of $175. Plaintiff's Complaint alleges that these obligations have not been fulfilled. Thus, plaintiff has stated a cause of action for breach of contract.

V. Conclusion

For the foregoing reasons, defendant's Motion to Dismiss will be GRANTED in PART and DENIED in PART. An appropriate Order follows.

s/Arthur J. Schwab
Arthur J. Schwab
United States District Judge

cc: All Registered ECF Counsel and Parties