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

DONALD GROSS Plaintiff, v. STRYKER CORPORATION t/a/d/b/a STRYKER HOWMEDICA OSTEONICS; STRYKER ORTHOPPEDICS, A DIVISION OF HOWMEDICA OSTEONICS CORPORATION; AND STRYKER ORTHOPEDICS, A DIVISION OF HOWMEDICA OSTEONICS CORPORATION Defendants.	)	Civil No. 11-1229 Judge Nora Barry Fischer

MEMORANDUM OPINION

I. INTRODUCTION

In this action, Plaintiff Donald Gross ("Plaintiff") brings multiple medical device liability claims against Defendants Stryker Corporation t/a/d/b/a Stryker Howmedica Osteonics ("Stryker"); Stryker Orthoppedics [sic], a division of Howmedica Osteonics Corporation; and Stryker Orthopedics, a division of Howmedica Osteonics Corporation,[1] whereby he seeks to recover damages, including punitive damages, arising from the surgical implantation of an artificial hip prosthesis known as the Trident System. (*See* Docket No. 1-3). Plaintiff alleges that due to a defect present in a component of the Trident System prosthesis he received, he suffered an infection at the operation site, experienced severe left hip pain, and required a

[1] Two Defendants, Stryker Orthoppedics [sic], a division of Howmedica Osteonics Corporation, and Stryker Orthopedics, a division of Howmedica Osteonics Corporation, were never properly served with the Complaint. (*See* Docket No. 13). Plaintiff failed to respond to the Court's Amended Order to Show Cause as to why service was not effectuated on these Defendants within 120 days of the filing of the Complaint. (*See* Docket No. 14). Accordingly, Stryker Orthoppedics [sic] and Stryker Orthopedics are dismissed, without prejudice, pursuant to FED. R. CIV. P. 4(m) for failure of Plaintiff to make service. (*See id*).

revision procedure to replace the defective device. (*See id.* at ¶¶ 4-8, ¶ 23). He brings claims sounding in strict liability based on manufacturing defect and marketing defect theories (Count I), negligence and *res ipsa loquitur* (Count II), as well as breach of express and implied warranties (Count III). (*See id.* at 13-18). Stryker moves to dismiss the Complaint under Rule 12(b)(6) on the grounds that it is not a proper party to this litigation[2] and Plaintiff's claims are all expressly preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k, to the Federal Food, Drug and Cosmetics Act ("FDCA"). (*See* Docket No. 8). Alternatively, Stryker argues that Plaintiff failed to adequately plead cognizable parallel claims and that Plaintiff's purported strict liability and breach of express warranty claims fail to state claims upon which relief can be granted. (*See id.*). Upon consideration of all the parties' submissions and for the reasons outlined herein, Stryker's Motion to Dismiss under Rule 12(b)(6) is granted and all of Plaintiff's claims against Stryker are dismissed, with prejudice.

II. BACKGROUND

A. Factual Background[3]

On October 20, 2007, Plaintiff underwent a left hip arthroplasty[4] performed by Dr. Ari Pressman, M.D., at Mercy Hospital in Pittsburgh, PA. (Docket No. 1-3 at ¶ 3). Plaintiff's left hip was replaced with an artificial hip prosthesis called the Trident System, which Stryker allegedly designed, manufactured, and marketed. (*Id.*). The Trident System is comprised of a

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[2] For further discussion of this issue, *see* section IV(A).

[3] In evaluating a Motion to Dismiss, this Court must accept the Plaintiff's allegations as true and construe them in favor of the Plaintiff. *Phillips v. County of Allegheny*, 515 F.3d 224 (3d Cir. 2008). Generally, this Court should consider "only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim." *Lum v. Bank of Am.*, 361 F.3d 217, 222 n.3 (3d Cir. 2004).

[4] Arthoplasty is the "[c]reation of an artificial joint to correct advanced degenerative arthritis." STEDMAN'S MEDICAL DICTIONARY 161 (28th ed. 2000). It "restore[s] as far as possible the integrity and functional power of a joint." *Id.*

ceramic-on-ceramic acetabular[5] bearing couple. (*Id.* at ¶ 11). This ceramic-on-ceramic acetabular bearing couple is itself made up of (1) an alumina ceramic insert (alternatively, "socket liner") and (2) an alumina ceramic femoral head (alternatively, "ball"). (*Id.*). The Trident System is used with a metal acetabular shell (alternatively, "metal acetabular cup" or "socket") and a metal femoral stem (alternatively, "hip stem"). (*Id.*). Plaintiff's suit focuses on the allegedly defective metal acetabular cup component of the Trident System. (*Id.* at ¶¶ 6-7, ¶ 23).

After his hip replacement surgery, Plaintiff claims that he experienced an infection at the operation site and needed antibiotic intervention. (*Id.* at ¶ 4). Plaintiff suffered left hip pain for approximately one year after surgery, which he contends "incrementally increas[ed]" until about October 2008, when an X-ray revealed a dislocation of Plaintiff's left hip and a failure of the hip prosthesis. (*Id.* at ¶¶ 5-6). Dr. Pressman informed Plaintiff that his severe left hip pain had been caused by the failure of at least the Trident acetabular insert and shell. (*Id.* at ¶ 6). Consequently, Plaintiff underwent revision hip replacement surgery in October 2008. (*Id.* at ¶ 7). During the surgery, it was found that the Trident acetabular insert had fractured and required removal and replacement. (*Id.*).

Plaintiff claims that Stryker obtained approval from the United States Food and Drug Administration ("FDA") to market the Trident System consisting of the ceramic-on-ceramic acetabular bearing couple under the premarket approval ("PMA") process[6] on approximately February 3, 2003. (*Id.* at ¶ 12). Prior to receiving approval through the PMA process for the entire prosthesis, individual components of the Trident System were approved by the FDA

[5] Acetabular refers to the acetabulum, which is "[a] cup-shaped depression on the external surface of the hip bone, with which the head of the femur articulates." STEDMAN'S MEDICAL DICTIONARY 11 (28th ed. 2000).

[6] The premarket approval process is described in section (IV)(C)(1).

pursuant to either the PMA or the § 510(k) processes.[7] (*Id.* at ¶¶ 12-15). Notably, earlier generations of the Trident acetabular shell received FDA approval pursuant to the § 510(k) process on December 11, 1998, August 4, 2000, and December 5, 2001. (*Id.* at ¶ 13).

On November 28, 2007, the FDA issued a warning letter to Stryker after inspecting its Mahwah, New Jersey facilities in June and July of 2007. (*Id.* at ¶ 19, 25-30). According to the warning letter that Plaintiff attached to his Complaint, the FDA investigation revealed that the Trident System devices were "adulterated," meaning "that the methods used in, or the facilities or controls used for their manufacture, packing, storage, or installation [were] not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of General Regulations (C.F.R.), Part 820."[8] (*Id.* at 25). Prior to receiving this warning letter, Stryker received a Form FDA 483,[9] List of Inspectional Observations, identifying problems related to the production of the Trident System. (*Id*. at ¶ 19).

On June 12, 2008, Stryker allegedly recalled certain Trident metal acetabular shells that were manufactured at its Mahwah, New Jersey facilities between January 2000 and December 2007. (*Id.* at ¶ 20). Plaintiff claims that his hip prosthesis bearing the serial numbers of 508-11-

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[7] Approval of medical devices through the § 510(k) process is described in section (IV)(C)(1).

[8] Title 21, C.F.R., Part 820 contains the Current Good Manufacturing Practice ("CGMP") requirements for Quality System regulation. These requirements:

> govern the methods used in, and the facilities and controls used for, the design manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged.

21 C.F.R. 820.1(a)(1).

[9] According to the FDA's official website, an FDA Form 483 is "issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgement [sic] may constitute violations of the Food Drug and Cosmetic Act and related Acts." FDA, *Inspections, Compliance, Enforcement, and Criminal Investigations: FDA Form 483 Frequently Asked Questions*, http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm (last visited Jan. 6, 2011). A Form FDA 483 is not "a final Agency determination of whether any condition is in violation of the [Food Drug & Cosmetic Act] or any of its relevant regulations." *Id.*

64G and 690-10-28H[10] was included in this recall. (*Id.* at ¶ 23). The recall occurred after an investigation revealed the presence of excessive bioburden and viable microorganisms in the devices' final rinse tank, thereby contaminating the devices and leaving behind impermissible, excessive manufacturing residuals. (*Id.* at ¶ 20).

In describing these residues, Plaintiff states that they are not an acceptable part of the manufacturing process for any hip device and are ostensibly direct evidence of an adulterated device. (*Id.*). Plaintiff notes in his Complaint that he has not yet determined[11] whether the residues on the hip prosthesis were foreign bodies or native material from the manufacturing process. (*Id.*). Despite this uncertainty, Plaintiff alleges that orthopedic surgeons have expressed the opinion that when such residues remain on the back of the acetabular cup, "boney ingrowth" is inhibited and the cup is not held securely into the socket. (*Id.* at ¶ 23).[12] Plaintiff further avers that when his own hip prosthesis was removed, the back of his Trident metal acetabular cup had fractured, which caused the cup to loosen thereby necessitating the revision surgery. (*Id.*).

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[10] Plaintiff cites to "Exhibit B" (Docket No. 1-3 at 31-33) in support of the contention that his own Trident System prosthesis was included in the June 18, 2008 recall. Exhibit B is an exhaustive list of serial numbers for various Trident System components. (*See id.*). At the bottom of Exhibit B is the Internet address, http://www.fda.gov/Safety/Recalls/EnforcementReports/2008/ucm120511.htm, which links to a page on the FDA's official website, entitled "Enforcement Report for June 18, 2008." Plaintiff did not highlight or circle the serial numbers of his own Trident System prosthesis on this list. (*See* Docket No. 1-3 at 31-33). Upon the Court's review of Exhibit B, the pertinent serial numbers, 508-11-64G and 690-10-28H, could not be found. (*See id.*).

[11] "An attorney must conduct a reasonable inquiry before filing a lawsuit, and cannot pursue the action unless he or she reasonably believes that facts exist to support the allegations." *Haniotakis v. Nassan*, 727 F. Supp. 2d 388, 411 (W.D. Pa. 2010) (citing FED. R. CIV. P. 11(b)(3)); *see also Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, 2010 U.S. Dist. LEXIS 59869, at *22-23 (W.D. Pa. June 16, 2010). Plaintiff underwent the revision arthroplasty procedure in October 2008. (*See* Docket No. 1-3 at ¶ 7). Almost two years later, on September 28, 2010, Plaintiff's counsel filed the Praecipe for Writ of Summons in the Court of Common Pleas of Allegheny County. (*See* Docket No. 1-1 at ¶ 1). During this approximately two-year time period, Plaintiff's attorney had a duty to investigate whether the residues on Plaintiff's initial hip prosthesis were foreign bodies or native material from the manufacturing process. *See* FED. R. CIV. P. 11(b)(3). Moreover, he could have pursued pre-complaint discovery in the Court of Common Pleas of Allegheny County. For further discussion of pre-complaint discovery, *see* section IV(E).

[12] Plaintiff has not submitted any medical records or reports in support of this allegation.

Plaintiff also claims that by recalling the Trident acetabular devices, Stryker admitted the cup was manufactured in a way that violated certain federal regulations and requirements. (*Id.*).[13]

B. Procedural History

Plaintiff, a resident of Allegheny County, Pennsylvania, initially filed a Praecipe for Writ of Summons on September 28, 2010 in the Court of Common Pleas of Allegheny County, Pennsylvania against Defendants, Stryker Corporation t/a/d/b/a Stryker Howmedica Osteonics, Stryker Orthoppedics [sic], and Stryker Orthopedics.[14] (*See* Docket No. 1 at ¶ 1). Stryker Corporation appeared. (*See id.*). Stryker Corporation is a Michigan corporation with a principal place of business in Kalamazoo, Michigan. (Docket No. 1-3 at ¶ 2; Docket No. 8-1 at ¶ 1). As the Court has noted, Plaintiff undertook no discovery in aid of filing the Complaint. Instead, on July 26, 2011, Stryker served a Praecipe of Rule to File Complaint on Plaintiff, and on August 27, 2011, Stryker was served with the Complaint. (*See* Docket No. 1-2.). Stryker has admitted that Howmedica Osteonics Corporation is a wholly-owned subsidiary of Stryker Corporation.

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[13] The Supreme Court described in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319-20 (2008), that "[t]he FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under conditions in its labeling." *See also* 21 U.S.C. § 360e(e)(1) (describing withdrawal of premarket approval). Additionally, pursuant to 21 U.S.C. § 360h(e)(1), the FDA can mandate the recall of a medical device if "there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death." As this Court explains, *infra*, in section IV(C)(2)(a), the Trident System is a medical device that received premarket approval. Plaintiff does not plead that the FDA ever withdrew its premarket approval or mandated the recall of any Trident System devices. (*See* Docket No. 1-3). Instead, Plaintiff avers that *Stryker* initiated the June 12, 2008 recall. (*See id.* at ¶ 20). A voluntary recall "takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective." 21 C.F.R. § 7.40. Furthermore, a manufacturer may initiate a recall "because it *believes* the product to be violative." 21 C.F.R. § 7.46 (emphasis added). Therefore, it is incorrect that "[b]y recalling the Trident System devices, Stryker admitted the [Trident System metal acetabular] cup was manufactured in violation of federal regulations and requirements." (Docket No. 1-3 at ¶ 23). A voluntary recall is effectively a preventative action taken by a medical device manufacturer and can occur for various reasons. *See* 21 C.F.R. §§ 7.40, 7.46. Accordingly, a voluntary recall cannot be properly regarded as a conclusive admission that Stryker "violated certain federal regulations and requirements." (Docket No. 1-3 at ¶ 23).

[14] In its Notice of Removal, Defendant Stryker indicates that it was named twice in the Caption, albeit with different spellings. (Docket No. 1 at ¶ 1 n.1).

(Docket No. 1 at ¶ 4 n.2). Yet, Stryker maintains Howmedica Osteonics Corporation was never served with a copy of the Complaint.[15] (Docket No. 1 at ¶ 4 n.2; Docket No. 8 at 15 n.3).

Plaintiff asserts claims sounding in strict liability for manufacturing and marketing defects (Count I), negligence and *res ipsa loquitur* (Count II), as well as breach of express and implied warranties (Count III). (Docket No. 1-3 at 13-18). Plaintiff also seeks punitive damages due to Stryker's alleged gross negligence or, alternatively, Stryker's "fraud, oppression, and malice." (*Id.* at 19-22).

On September 26, 2011, Stryker filed a petition for removal from state court, premised on diversity jurisdiction. (*See* Docket No. 1 at 1, ¶¶ 4-7). A week later, Stryker filed a Motion to Dismiss for failure to state a claim under Rule 12(b)(6) and an accompanying brief in support. (*See* Docket Nos. 7-8). At Exhibit A to Stryker's brief in support, Stryker filed a Certification by Erica Visokey,[16] in which she states, "Stryker Corporation does not design, manufacture, assemble, equip, test, inspect, service, maintain, repair, advertise, market or sell the Trident™ Ceramic on Ceramic Acetabular System or any of its components." (*See* Docket No. 8-1 at ¶ 3). Plaintiff filed a Response (Docket No. 10), and Stryker replied to said Response (Docket No. 11). Plaintiff did not file a surreply nor seek to do so by way of a motion for leave, despite Stryker's preliminary statement that Plaintiff did not address all of Stryker's arguments. (*See* Docket No. 11 at 5). Nor has either party requested argument on this Motion.[17]

On February 27, 2012, the Court requested additional briefing from Plaintiff and Stryker in light of the recent decision in *Bass v. Stryker Corp.*, 2012 WL 266985, 2012 U.S. App. LEXIS

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[15] Plaintiff failed to effectuate service on Defendants Stryker Orthoppedics [sic], a division of Howmedica Osteonics Corporation, and Stryker Orthopedics, a division of Howmedica Osteonics Corporation, within 120 days of filing his Complaint. (*See* Docket Nos. 13-14). As discussed in more detail, *supra*, at n.1, these parties are dismissed, without prejudice.

[16] Erica Visokey identifies herself as Counsel for Stryker Legal. (*See* Docket No. 8-1 at ¶ 1).

[17] *See Practices and Procedures of Judge Nora Barry Fischer,* § II.A, *available at:* http://www.pawd.uscourts.gov/Documents/Judge/fischer_pp.pdf (effective March 23, 2010).

1789 (5th Cir. Jan. 31, 2012).[18] (Docket No. 15). Both Plaintiff and Stryker filed said supplemental briefs on March 9, 2012. (Docket Nos. 16, 17).

Thus, Stryker's Motion is now fully briefed and ripe for disposition.

III. STANDARD OF REVIEW

A motion to dismiss pursuant to FED. R. CIV. P. 12(b)(6) challenges the legal sufficiency of a complaint.[19] The United States Supreme Court has held that "[a] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286, (1986)) (alterations in original).

The Court must accept as true all well-pleaded facts and allegations and must draw all reasonable inferences therefrom in favor of the plaintiff. As the Supreme Court made clear in *Twombly*, however, the "factual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. The Supreme Court has subsequently broadened the scope of this requirement, stating that "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1950 (2009) (emphasis added).

Thus, after *Iqbal*, a district court must conduct a two-part analysis when presented with a motion to dismiss for failure to state a claim. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210

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[18] Counsel have a duty of candor to the Court pursuant to Rule 3.3 of the Pennsylvania Rules of Professional Conduct. PA. RULES OF PROF'L CONDUCT R. 3.3 (2012). This duty of candor requires counsel to "recognize the existence of pertinent legal authorities," which includes advising the Court of changes in law. *See id.* at cmt. 4.

[19] "[O]nce a case has been removed to federal court, it is settled that federal rather than state law governs the future course of proceedings, notwithstanding state court orders issued prior to removal." *Granny Goose Foods, Inc. v. Brotherhood of Teamsters & Auto Truck Drivers*, 415 U.S. 423, 427 (1974). "The Federal Rules of Civil Procedure, like other provisions of federal law, govern the mode of proceedings in federal court after removal." *Id.* at 438; *see also* FED. R. CIV. P. 81(c)(1) ("[The Federal Rules of Civil Procedure] apply to a civil action after it is removed from a state court").

(3d Cir. 2009). First, the Court must separate the factual and legal elements of the claim. *Id*. Although the Court "must accept all of the complaint's well-pleaded facts as true, [it] may disregard any legal conclusions." *Id*. at 210–211. Second, the Court "must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.' In other words, a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." *Id*. at 211 (citing *Iqbal*, 129 S. Ct. at 1949). The determination for "plausibility" will be "'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 129 S. Ct. at 1950).

As a result, "pleading standards have seemingly shifted from simple notice pleading to a more heightened form of pleading, requiring a plaintiff to plead more than the possibility of relief to survive a motion to dismiss." *Fowler*, 578 F.3d at 211. That is, "all civil complaints must now set out 'sufficient factual matter' to show that the claim is facially plausible. This then 'allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Id*. at 210 (quoting *Iqbal*, 129 S. Ct. at 1948).

However, nothing in *Twombly* or *Iqbal* changed the other pleading standards for a motion to dismiss pursuant to FED. R. CIV. P. 12(b)(6), and the requirements of FED. R. CIV. P. 8 must still be met. *See Phillips v. Co. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (internal citations omitted). FED. R. CIV. P. 8 requires a showing, rather than a blanket assertion, of entitlement to relief, and "contemplates the statement of circumstances, occurrences, and events in support of the claim presented and does not authorize a pleader's bare averment that he wants relief and is entitled to it." *Twombly*, 550 U.S. at 555 n.3 (internal citations and quotations omitted). Additionally, the Supreme Court did not abolish the FED. R. CIV. P. 12(b)(6) requirement that

"the facts must be taken as true and a complaint may not be dismissed merely because it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on those merits." *Phillips*, 515 F.3d at 231 (citing *Twombly*, 550 U.S. at 553).

The parties' attorneys must also be cognizant of Rule 11 of the Federal Rules of Civil Procedure, which establishes the standards that counsel and unrepresented parties must follow when making written representations to the court. *See* FED. R. CIV. P. 11. Rule 11(b) provides, in pertinent part:

> By presenting to the court a pleading, written motion, or other paper--whether by signing, filing, submitting, or later advocating it--an attorney or unrepresented party certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances:
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> . . .
>
> (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery[.]

FED. R. CIV. P. 11(b)(3). Generally, Rule 11 "'imposes on counsel a duty to look before leaping and may be seen as a litigation version of the familiar railroad crossing admonition to 'stop, look, and listen.'" *Oswell v. Morgan Stanley Dean Witter & Co.*, 507 F. Supp. 2d 484, 488 (D.N.J. 2007) (quoting *Lieb v. Topstone Indus.*, 788 F.2d 151, 157 (3d Cir. 1986)).

Furthermore, in deciding a Rule 12(b)(6) motion to dismiss, the Court may consider "only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim." *Lum v. Bank of Am.*, 361 F.3d 217, 222 n.3 (3d Cir. 2004). A document forms the basis of a claim if it is "*integral to or explicitly relied upon* in the complaint." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999) (emphasis in original; internal citations and quotations omitted).

IV. DISCUSSION

Stryker advances several arguments in support of its Motion to Dismiss Plaintiff's claims. (*See* Docket No. 8). Specifically, Stryker maintains that: (1) it is not a proper party to this litigation; (2) all claims against the Trident System, a Class III PMA medical device, are expressly preempted pursuant to the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); (3) Plaintiff has not alleged parallel claims to avoid express preemption; (4) Plaintiff fails to state claims for strict liability and breach of express warranty; and (5) Plaintiff's claim for punitive damages must be dismissed. (*See* Docket No. 8). Due to the overlapping nature of these arguments, the Court will first address whether Stryker is a proper party and then will address Stryker's challenges to each of Plaintiff's claims in the order that the claims are presented in the Complaint. (*See* Docket No. 1-3). Therefore, this Court will discuss the strict liability claims at Count I, followed by the claims for negligence, *res ipsa loquitur*, breach of implied warranty at Counts II and III, and then the claim for breach of express warranty at Count III.[20] Next, this Court will address Plaintiff's request for punitive damages. Finally, the Court will determine whether this Court should convert the pending motion to one for summary judgment and with said conversion permit discovery.

A. "Proper Party" Argument

The Court first turns to Stryker's argument that it is an improper party to this litigation. (*See* Docket No. 8 at 14-15). Plaintiff alleges in his Complaint that "Defendants were in the business of designing, manufacturing, marketing and selling hip prostheses including the Trident System shell and liners implanted in Plaintiff on October, 2007." (Docket No. 1-3 at ¶ 9). Stryker claims that this allegation is erroneous as Howmedica Osteonics Corporation, another

[20] Plaintiff's breach of express warranty and breach of implied warranty claims at Count III will be discussed separately because of the vastly different manner in which each claim is pled. (*See* Docket No. 1-3 at 17-18).

named defendant and a wholly-owned subsidiary of Stryker Corporation, is the entity which should be the defendant in the instant suit.[21] (Docket No. 1 at ¶ 4 n.1; Docket No. 8 at 15 n.3). Defendant Howmedica Osteonics Corporation was never served with a copy of the Complaint and has been dismissed from the lawsuit. (*See* Docket Nos. 13-14; *see also* Docket No. 1 at ¶ 4 n.2; Docket No. 8 at 15 n.3). Plaintiff did not respond to Stryker's argument that it is an improper party. (*See* Docket No. 10).

To illustrate that it is an improper party to this litigation, Stryker explains that it "does not design, manufacture, assemble, equip, test, inspect, service, maintain, repair, advertise, market, or sell the Trident System, any of its component parts, or medical devices of this type." (*Id.* at 14). In making this statement, Stryker quotes the sworn affidavit of Erica Visokey, Counsel for Stryker Legal, that it attached as Exhibit A to its brief in support of the Motion to Dismiss. (*See* Docket No. 8-1).

For the Court to consider the affidavit of Erica Visokey at this stage in the litigation, the Court would first have to convert Stryker's Motion to Dismiss to a motion for summary judgment.[22] *See* FED. R. CIV. P. 12(d). In adjudicating Rule 12(b)(6) motions, the court may consider "only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim." *Lum*, 361 F.3d at 222 n.3. There is

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[21] Many plaintiffs with medical device liability claims arising from the installation of the Trident System hip prosthesis have named Stryker Corporation as the defendant. *See e.g. Rhynes v. Stryker Corp.*, No. 10-5619 SC, 2011 WL 5117168, 2011 U.S. Dist. LEXIS 58286 (N.D. Cal. Oct. 27, 2011); *Cornwell v. Stryker Corp.*, No. 1:10-cv-00066-EJL, 2010 WL 4641112, 2010 U.S. Dist. LEXIS 116824 (D. Idaho Nov. 1, 2010); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648 (S.D. Tex. 2010). Likewise claims regarding the Trident System have also been brought against Howmedica Osteonics Corporation. *See e.g. Desabio v. Howmedica Osteonics Corp.*, No. 09-CV-287S, --- F. Supp. 2d ---, 2011 WL 4074391, 2011 U.S. Dist. LEXIS 103288 (W.D.N.Y. Sept. 13, 2011); *Wilhite v. Howmedica Osteonics Corp.*, No. 5:10-cv-2471, 2011 WL 2530984, 2011 U.S. Dist. LEXIS 64843 (N.D. Ohio June 20, 2011); *Hayes v. Howmedica Osteonics Corp.*, No. 08-cv-6104, 2009 WL 6841859 (D.N.J. Dec. 15, 2009).

[22] Stryker maintains in its latest brief that Plaintiff did not respond to the facts set forth by Ms. Visokey. (Docket No. 17 at 5). However, in his Response brief, Plaintiff requests the Court to convert Stryker's Motion to Dismiss into a motion for summary judgment. (Docket No. 10 at 14-16). Plaintiff argues that Stryker "request[s] the court to consider matters outside the pleadings," which is impermissible at the motion to dismiss stage. (*Id.* at 14). No "matters outside the pleadings" will be considered in resolving this Motion, except for matters that the Court may take judicial notice of at this stage. *See Lum v. Bank of Am.*, 361 F.3d 217, 222 n.3 (3d Cir. 2004).

an exception to this general rule in which a court may also "consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993). Otherwise, a plaintiff with a legally insufficient claim could survive a motion to dismiss "simply by failing to attach a dispositive document on which it relied." *Id.* Only "narrowly defined types of material" fit this exception, such as a "document *integral to or explicitly relied upon* in the complaint." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d at 287 (emphasis in original; internal citations and quotations omitted).

The Court declines to convert Stryker's Motion to Dismiss to a motion for summary judgment so that this affidavit may be considered. Although the affidavit is sworn (*see* Docket No. 8-1), it is not a document that is integral to or explicitly relied upon in Plaintiff's Complaint (*see* Docket No. 1-3). Moreover, even though Plaintiff has not directly questioned the authenticity of this document in his reply to Stryker's Motion to Dismiss (*see* Docket No. 10), the affidavit does not fall within the definition of an "undisputedly authentic document" that may be considered by the Court at the motion to dismiss stage. *See Pension Ben. Guar. Corp*, 998 F.2d at 1196. Plaintiff avers in his Complaint and in his reply to Stryker's Motion to Dismiss that "Defendant Stryker designed, manufactured and marketed an artificial hip replacement system that was implanted in Plaintiff," which contradicts the content of the affidavit by Erica Visokey. (Docket No. 10 at 2; *see also* Docket No. 1-3 at ¶ 11).

Consequently, the Court will regard this affidavit as a document that is outside of the pleadings and will exclude it from consideration. *See* FED. R. CIV. P. 12(d). The Court will take all of Plaintiff's allegations contained in its Complaint, including that Stryker designed, manufactured, and marketed the Trident System, to be true in accordance with the proper

procedure for adjudicating Rule 12(b)(6) motions. (*See* Docket No. 1-3 at ¶ 3). *See Fowler*, 578 F.3d at 210-11. In addition, the Court believes that the substitution of Howmedica Osteonics Corporation as the proper party would not modify the Court's rulings that all of Plaintiff's claims must be dismissed, with prejudice. *See e.g. Loh v. Richardson-Browne*, No. 10-0054, 2010 WL 5055787, 2010 U.S. Dist. LEXIS 128016, at *1 n.1 (D.N.J. Dec. 2, 2010) (finding that even though defendants were improper parties to the suit, the court would proceed with its analysis because it would not alter the court's decision as to the underlying claims). Thus, the Court finds it appropriate to continue its analysis of the parties' remaining arguments.

B. Strict Liability (Count I)

Stryker next argues that Plaintiff's strict liability claim should be dismissed for its failure to state a claim under Pennsylvania law.[23] (Docket No. 8 at 31, 33). Stryker contends that, pursuant to comment k of Section 402A of the RESTATEMENT (SECOND) OF TORTS, the strict liability theory of recovery does not apply to "unreasonably dangerous" products, which include prescription medical devices like the Trident System. (*Id.* at 31). Plaintiff does not address this argument in his brief in response. (*See* Docket No. 10).

Pennsylvania has adopted RESTATEMENT (SECOND) OF TORTS § 402A, which provides that a manufacturer is strictly liable for physical harm to the "ultimate user or consumer, or to his property" that may result from the sale of "any product in a defective condition unreasonably dangerous."[24] *See Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966). Pennsylvania courts have also

[23] Stryker alternatively argues that Plaintiff's strict liability claims are subject to dismissal based on express preemption grounds under 21 U.S.C. § 360k of the Medical Device Amendments of 1976. (*See* Docket No. 8 at 20-21). Because these claims can be dismissed by virtue of their inability to survive under Pennsylvania law, the Court declines to undertake the alternative analysis of this claim.

[24] For § 402A to apply, the seller must be " [(a)] engaged in the business of selling such a product, and (b) [the product] is expected to and does reach the user or consumer without substantial change in the condition in which it is sold." RESTATEMENT (SECOND) OF TORTS § 402A(1). This rule applies even though "(a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller." *Id.* at § 402A(2).

adopted comment k to RESTATEMENT (SECOND) OF TORTS § 402A, which creates an exception to this rule and exempts "unavoidably unsafe products" from strict liability:

> k. *Unavoidably unsafe products*. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

REST. (SECOND) OF TORTS § 402A cmt. k. Although comment k mentions prescription medical drugs, it does not refer directly to medical devices. *See id.*

In *Riley v. Medtronic, Inc.*, a decision addressing the viability of a strict liability claim under Pennsylvania law against the manufacturer of a cardiac pacer machine, this Court summarized the applicable law as follows:

> In *Hahn v. Richter*, the Pennsylvania Supreme Court adopted comment k, concluding that strict liability could not be applied to prescription drugs where adequate warnings of the drug's potential risks had been provided. *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888, 890-91 (Pa. 1996). The Pennsylvania Superior Court concluded that comment k applied to medical devices, finding "no reason why the same rationale applicable to prescription drugs may not be applied to medical devices." *Creazzo v. Medtronic, Inc.,* 2006 PA Super 152, 903 A.2d 24, 31 (Pa. Super. 2006). In addition, several federal district courts have extended comment k to prescription medical devices. The United States District Court for

> the Eastern District of Pennsylvania noted "that the reasoning behind comment k, and the Pennsylvania Supreme Court's reasoning in *Hahn*, supports [comment k's] application to prescription medical devices." *Soufflas v. Zimmer*, 474 F.Supp.2d 737, 750 (E.D. Pa. 2007) (citing *Taylor v. Danek Medical, Inc.*, No. 95-7232, 1998 U.S. Dist. LEXIS 20265, 1998 WL 962062,*7 (E.D. Pa. 1998)). Applying the same reasoning as *Taylor*, several federal courts have determined that prescription medical devices are not covered by Section 402A and have denied plaintiffs' strict liability claims based on prescription medical devices. *See Burton v. Danek Medical, Inc., et al.*, No. 95-5565, 1999 U.S. Dist. LEXIS 2619, 1999 WL 118020 (E.D. Pa. 1999); *Murray v. Synthes*, No. 95-7796, 1999 U.S. Dist. LEXIS 13436, 1999 WL 672937 (E.D. Pa. 1999); *Davenport v. Medtronic, Inc.*, 302 F.Supp.2d 419 (E.D. Pa. 2004); *Parkinson v. Guidant Corp.*, 315 F.Supp.2d 741 (W.D. Pa. 2004); *Kester v. Zimmer Holdings, Inc.*, 2010 U.S. Dist. LEXIS 59869, 2010 WL 2696467 (W.D. Pa. 2010).

Riley v. Medtronic, Inc., 2011 WL 3444190, 2011 U.S. Dist. LEXIS 87368, at *29-30 (W.D. Pa. Aug. 8, 2011). Subsequent to this Court's decision in *Riley*, no change in the law has occurred, and district courts have continued to apply comment k to medical devices. *See Horsmon v. Zimmer Holdings, Inc.*, No. 11-1050, 2011 WL 5509420, 2011 U.S. Dist. LEXIS 130415, at *3-6 (W.D. Pa. Nov. 10, 2011); *Esposito v. I-Flow Corp.*, No. 10-cv-3883, 2011 WL 5041374, 2011 U.S. Dist. LEXIS 122570, at *13-14 (E.D. Pa. Oct. 24, 2011).

Although the aforementioned legal principles described in *Riley* apply to the instant case, the outcome in *Riley* does not dictate the same result here as the facts are distinguishable. The defendant in *Riley* filed a motion to dismiss the plaintiffs' strict liability claim, alleging that it failed to state a claim under Pennsylvania law. *Riley*, 2011 U.S. Dist. LEXIS 87368, at *1. Despite the fact that the plaintiffs' complaint did not specifically identify the cardiac pacer machine as a prescription medical device, the defendant argued that such an inference could readily be made by the Court. *Id.* at *31. The parties' briefs illustrated the existence of a question of fact concerning whether the pacer box was a prescription medical device. *Id.* By construing the plaintiffs' allegations in their favor, the Court held that the plaintiffs' allegations were sufficient for the case to continue through the discovery stage during which the precise

nature of the cardiac pacer machine could be determined. *Id.* at *31-32. Accordingly, the defendant's motion to dismiss the strict liability claim was denied. *Id.* at *32.

Even though the motion to dismiss was denied in *Riley*, the facts in the instant matter do not support a similar conclusion here. Unlike the pacer box at issue in *Riley*, the Trident System is a Class III medical device which received FDA approval pursuant to the PMA process.[25] *See* FDA, *Summary of Safety and Effectiveness Data*, *available at* http://www.accessdata.fda.gov/cdrh_docs/pdf/P000013b.pdf (last visited Feb. 26, 2012).[26] Further, it is a matter of public record that the Trident System is a hip prosthesis "indicated for patients requiring primary total hip arthroplasty due to painful disabling joint disease resulting from non-inflammatory degenerative arthritis." *Id.* Moreover, the inherently rigorous nature of the premarket approval process and the contraindications, warnings, and precautions described in the Trident System's Summary of Safety and Security Data all suggest that the Trident System is an "unavoidably unsafe" product to which strict liability does not apply. *Id.* Most importantly, courts within the Third Circuit have barred strict liability claims against Stryker and other analogous medical device manufacturers by applying comment k to § 402A. *See e.g. Horsmon*, 2011 U.S. Dist. LEXIS 130415, at *6 (W.D. Pa. Nov. 10, 2011) (holding that a strict liability claim against medical device manufacturer was barred by Pennsylvania law); *Esposito*, 2011 U.S. Dist. LEXIS 122570, at *14 (same); *Geesey v. Stryker Corp.*, No. 09-2988, 2010 WL 3069630, 2010 U.S. Dist. LEXIS 78677, at *13-14 (E.D. Pa. Aug. 4, 2010) (same); *Delaney v.*

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[25] Further discussion of the FDA approval process can be found in section IV(C)(2)(a).

[26] A matter of public record may be considered by the court when adjudicating a motion to dismiss. *See Lum v. Bank of Am.*, 361 F.3d 217, 222 n.3 (3d Cir. 2004). Plaintiff summarizes and quotes the Summary of Safety and Effectiveness Data in his Complaint. (*See* Docket No. 1-3 at ¶¶ 15-16). This Summary provides information about all aspects of the Trident System, including a description of the device, warnings and precautions for its use, a summary of adverse effects, and a summary of the FDA approval process. *See* FDA, *Summary of Safety and Effectiveness Data*, *available at* http://www.accessdata.fda.gov/cdrh_docs/pdf/P000013b.pdf (last visited Feb. 26, 2012). This Summary is a matter of public record, and this Court takes judicial notice of the entirety of this document. *See White v. Stryker Corp.*, No. 3:09-CV-544-H, --- F. Supp. 2d ---, 2011 WL 1131496, 2011 U.S. Dist. LEXIS 32568, at *6 n.2, 9-10 (W.D. Ky. Mar. 25, 2011) (considering the Summary at the motion to dismiss stage).

Stryker Orthopaedics, No. 08-03210, 2009 WL 564243, 2009 U.S. Dist. LEXIS 16865, at *18-19 (D.N.J. Mar. 5, 2005) (same).

As a result, the Trident System can be considered a prescription medical device that falls within the scope of comment k to § 402A. *See Riley*, 2011 U.S. Dist. LEXIS 87368, at *29-30. Plaintiff does not provide the Court with any reason that would prevent application of comment k to § 402A to his claim for product liability under a manufacturing defect theory. (*See* Docket No. 10). In fact, Plaintiff fails to address this argument entirely. (*See id.*).

Therefore, this Court holds that Plaintiff's strict liability claims (Count I) are not viable under Pennsylvania law. Accordingly, Stryker's Motion to Dismiss as to Count I for failure to state a claim is granted, and said claim is dismissed, with prejudice.

C. Negligence and *Res Ipsa Loquitur* (Count II) and Breach of Implied Warranty (Count III)

Stryker also contends that Plaintiff's claims in Counts I, II, and III of the Complaint are subject to the express preemption provision of the MDA, 21 U.S.C. § 360k.[27] (*See* Docket No. 8 at 9). For a claim against the manufacturer of a medical device to be expressly preempted under this provision, the medical device must have been subject to specific federal requirements related to its safety and effectiveness and the claim must be premised on state law that imposes requirements that are different or additional to the specific federal requirements. *See Riegel*, 552 U.S. at 321-23. State common law claims challenging the safety and effectiveness of a Class III medical device receiving approval under the FDA's PMA process are precisely the type of claims that are subject to express preemption. *See id.* at 324-25. Because the Trident System is subject to specific federal requirements and Plaintiff's claim for breach of implied warranty

[27] Even though Stryker raises the argument that all of Plaintiff's claims are expressly preempted, analysis of Plaintiff's claims for strict liability (Count 1) and breach of express warranty (Count III) within this context is unnecessary. This Court has already disposed of Plaintiff's strict liability claims in section IV(B) and will, in turn, dispose of the breach of express warranty claim in section IV(D).

(Count III) is premised on state common law that imposes different or additional requirements on Stryker, this claim is expressly preempted by 21 U.S.C. § 360k. *See Riegel*, 552 U.S. at 321-25.

Although many courts have held that negligence claims are expressly preempted as well, further analysis of Plaintiff's claims of *res ipsa loquitur* and negligence (Count II) as purported parallel claims is necessary because Plaintiff attempts to premise these claims on alleged violations of federal regulations. *See id.* at 330. The Court finds that the references to federal regulations in his negligence and *res ipsa loquitur* claims are too vague and general to establish what standard of care Stryker allegedly breached. *See, inter alia*, *In re Medtronic Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010) ("*In re Medtronic"*); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011). Moreover, in Plaintiff's supplemental brief submitted to this Court, he concedes that the *res ipsa loquitur* claim lacks merit. (Docket No. 16 at 6). As Plaintiff fails to allege sufficient parallel claims sounding in negligence and based on *res ipsa loquitur*, they are preempted. Plaintiff's claims for negligence and *res ipsa loquitur* (Count II), as well as Plaintiff's claim for breach of implied warranty (Count III) are thus dismissed, with prejudice. The Court's analysis follows.

1. Federal Regulation of Medical Devices

The MDA, 21 U.S.C. § 360c et seq., established a federal regulatory regime for medical devices. More specifically, the MDA created three classes of medical devices, which categorize the devices "depending on the risks they present." *Riegel*, 552 U.S. at 316; *see also* 21 U.S.C. § 360c (enumerating the three classes of medical devices and describing their characteristics). Of the three classes, Class III devices have the most stringent level of federal oversight. *Riegel*, 552 U.S. at 317; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001)

(identifying Class III devices as "incur[ring] the FDA's strictest regulation"). Class III devices are intended "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or . . . presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(I)-(II).

Before a Class III medical device enters the market, the device's manufacturer must obtain FDA approval. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The FDA's premarket approval process entails a "rigorous" evaluation in which manufacturers submit detailed, voluminous applications to the FDA. *Id*. Then, the FDA reviews these applications, spending "an average of 1,200 hours on each submission." *Id.* The FDA grants PMA if it receives "'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(d)). After obtaining premarket approval, the manufacturer may not "make, without FDA permission, changes . . . that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

Prior to making any modifications to a medical device that has already received premarket approval, manufacturers must submit an application for supplemental premarket approval. *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)). Additionally, manufacturers must adhere to post-PMA reporting requirements in which newly-reported information could potentially result in the FDA's withdrawal of its premarket approval. *Riegel*, 552 U.S. at 319-20 (citing 21 U.S.C. § 360i; 21 U.S.C. § 360e(e)(1); 21 U.S.C. § 360h(e)).

The majority of Class III devices do not undergo this intensive PMA review. *Riegel*, 552 U.S. at 315. Medical devices that are "substantially equivalent" to existing devices submit to a more limited form of evaluation called § 510(k) premarket notification, which refers to the

original section of the MDA describing this review process. *Lohr*, 518 U.S. at 478. If the FDA determines that the device in question is "substantially equivalent" to one that is already in existence, then the device satisfies the § 510(k) approval requirements and may be marketed without additional assessment. *Id.* The FDA completes § 510(k) review "in an average of only 20 hours." *Id.* at 479.

2. Express Preemption of State Law Claims

In addition to separating medical devices into three categories, the MDA contains an express preemption provision with two elements that must be satisfied in order for preemption to apply. The provision states:

> Except as provided in subsection (b) of this section, 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 or 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*, 552 U.S. at 321-23, the Supreme Court held that state laws are preempted by the MDA if: (1) the Federal Government has established "specific requirements applicable to a particular device"; and (2) the plaintiff's 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) (applying the two-part test for federal preemption pursuant to *Riegel*). The Supreme Court reasoned that a state law demanding a manufacturer's devices "to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme." *Riegel,* 552 U.S. at 325. Included in the meaning of "state requirements" subject to federal preemption are

common law causes of action, such as negligence, strict liability, and breach of implied warranty. *Id.* at 324-25, 327-28; *see also Williams*, 388 F. App'x at 171 (holding that appellants' allegations of strict products liability based on manufacturing defect and breach of warranty, which are "[g]eneralized common law theories of liability," are preempted by the MDA).

a. Element 1: Whether Specific Federal Requirements Apply

The § 510(k) approval process does not impose specific federal requirements within the meaning of 21 U.S.C. § 360k(a) that would allow state common law claims to be preempted. *See Riegel*, 552 U.S. at 322-23. Rather, medical devices entering the market through this procedure are subject to a review that compares them to products already in the marketplace, thus reflecting "entirely generic concerns about device regulation generally." *Id.* at 322 (quoting *Lohr*, 518 U.S. at 501). The § 510(k) review procedure "'focus[es] on *equivalence*, not safety,'" and devices approved through this process have "'never been formally reviewed under the MDA for safety or efficacy.'" *Riegel*, 552 U.S. at 323 (quoting *Lohr*, 518 U.S. at 493) (emphasis in original)). Despite the device-specific nature of § 510(k) review, state law claims brought against manufacturers of medical devices that have been approved through this procedure are not subject to the MDA express preemption provision. *Riegel*, 552 U.S. at 322.

State common law claims against manufacturers of medical devices that are approved through PMA, on the other hand, are subject to federal preemption. *See id.* at 322-25. As was previously explained, the Supreme Court determined in *Riegel* that the MDA's express preemption clause "bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the [FDA]." *Riegel*, 552 U.S. at 315. Unlike devices that receive § 510(k) approval, PMA devices are subject to "requirements" that are "specific to individual devices." *Id.* at 322-23. Furthermore, PMA inherently "*is* [a] federal

safety review" in which "'the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness.'" *Id.* at 323 (quoting 21 U.S.C. § 360e(d) (emphasis in original)). Consequently, state law claims premised on tort duties regarding safety or effectiveness are in fact "requirements" that are preempted by the PMA process. *Riegel*, 552 U.S. at 325.

It is undisputed that the Trident System hip prosthesis is a Class III medical device. (*See* Docket No. 1-3 at ¶ 12; Docket No. 8 at 17, 20; Docket No. 10 at 3, 8). The parties disagree, however, on whether the metal acetabular cup, which is the allegedly defective component at issue in the present case, can be regarded as a medical device that is separate from the other portions of the Trident System. Although the entire Trident System hip replacement prosthesis received premarket approval by the FDA, the metal acetabular cup received prior § 510(k) approval in its own right. (*See* Docket No. 1-3 at ¶¶ 12-13; Docket No. 10 at 8, 11). Plaintiff contends that this Court should regard the metal acetabular cup as a separate medical device that is not subject to express preemption by the MDA as interpreted by the Supreme Court in *Riegel* "merely by virtue of [its] coupling with [a] PMA devic[e]." (Docket No. 10 at 8). In response, Stryker argues that the entire Trident System, including the metal acetabular cup, received premarket approval, and thus Plaintiff's claims are preempted and should be dismissed. (*See* Docket No. 8 at 17-21; Docket No. 11 at 6-11). Resolving the issue of whether the Trident System hip prosthesis should be regarded as a PMA device or, alternatively, a § 510(k) device that has been approved for use with a PMA device, is essential in determining whether express preemption pursuant to *Riegel* applies.

In support of his position that the metal acetabular cup is not a PMA medical device, Plaintiff directs the Court's attention to the Summary of Safety and Effectiveness Data that the

FDA released when it granted premarket approval of the Trident System. (*See* Docket No. 1-3 at ¶¶ 15-16; Docket No. 10 at 4). The Summary describes the Trident System as a medical device that is "indicated for patients requiring total hip arthroplasty." *Id.* In addition, it provides that the Trident System features a "ceramic-on-ceramic acetabular bearing couple" with a ceramic acetabular insert that "features a pre-assembled titanium alloy sleeve on the back of the insert which mates with the metal acetabular shell *component.*" *Id.* (emphasis added). The Summary also states that the insert is to be "used in conjunction with the commercially available" Trident acetabular shell. *Id.*

Plaintiff interprets this Summary to mean that only the ceramic-on-ceramic bearing couple, made up of the ceramic liner and ceramic femoral head, received premarket approval. (Docket No. 10 at 4). Although Plaintiff is correct that the Summary does address adverse events relating to the liner and femoral head, the Summary also includes warnings, precautions, testing, and conclusions related to the acetabular shell as a component of the Trident System. *See* FDA, *Summary of Safety and Effectiveness Data*; *see also White v. Stryker Corp.*, No. 3:09-CV-544-H, --- F. Supp. 2d ---, 2011 WL 1131496, 2011 U.S. Dist. LEXIS 32568, at *9-10 (W.D. Ky. Mar. 25, 2011) (describing the Summary's content when discussing the Trident System's PMA process); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 655 (S.D. Tex. 2010) (same). Plaintiff even quotes one of these specific warnings in his Complaint:

> Replace both the ceramic insert and the *metal acetabular shell* if the insert is chipped, cracked, or otherwise damaged during the implant procedure or postoperative time frame. This is because the acetabular shell taper, once it has been deformed through assembly to its mating ceramic insert, cannot be reassembled to another ceramic insert.

(Docket No. 1-3 at ¶ 16 (emphasis added)). This warning focuses on the insert, which is part of the ceramic-on-ceramic bearing couple, and the metal acetabular shell in a way that implies that

they are both component parts of the entire Trident System hip prosthesis. (*See id.*). Also, as previously noted, the Summary plainly refers to the shell as a "component." (*See id.*). As such, the Summary illustrates that the Trident System, made up of such parts as the metal acetabular shell, underwent thorough FDA evaluation in its entirety and subsequently received premarket approval. (*See id.*); *see also Lewkut*, 724 F. Supp. 2d at 655 (stating, "[t]hat the acetabular cup is described as a 'component' of the approved system is, to this Court, of considerable significance").

Plaintiff further maintains that testimony by Stryker's agents before an FDA panel supports a finding that the metal acetabular cup is a medical device independent of the ceramic-on-ceramic bearing couple. (*See* Docket No. 10 at 12). Plaintiff, however, does not raise these allegations in his Complaint; instead, he discusses them for the first time in his responding brief.[28] (*See id.*). Additionally, Plaintiff does not provide a citation to the source of this alleged testimony before an FDA panel at an unidentified date and time.[29] (*See id.*). Plaintiff also offers no context for this testimony and does not provide the Court with a record or transcript of this hearing, merely noting that it occurred "before the PMA panel conducting the hearing for the Trident System." (*Id.*). By providing the Court with isolated statements allegedly made by Stryker's agents during this FDA panel hearing without also providing the context in which these statements were made, it is difficult to comprehend their true meaning. (*See id.*). To that end, the Court is unable to construe these quoted statements as providing support to Plaintiff's argument here. Moreover, this information, even if supported, constitutes matters outside of the

[28] This Court must judge the Complaint based on allegations in same and not on new allegations that are alleged in a party's brief or at oral argument. *See Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994) (stating, "In determining whether a claim should be dismissed under Rule 12(b)(6), a court looks only to the facts alleged in the complaint and its attachments without reference to other parts of the record").

[29] Without additional details provided by the Plaintiff, it is unclear whether this testimony is a matter of public record. (*See* Docket No. 10 at 12).

pleadings which this Court may not consider on a motion to dismiss. *See Lum*, 361 F.3d at 222 n.3.

Plaintiff also argues that "[i]t is extremely telling that Defendants' [sic] have not attached the original PMA application for the Trident System that was submitted to the FDA." (Docket No. 10 at 12). Plaintiff states that this PMA application, which it has not had the opportunity to review, would have identified the components of the Trident System that actually received premarket approval.[30] (*Id.*). Again, this argument is misguided. The application submitted to the FDA does not facilitate this Court's determination of what the FDA actually approved during the PMA process. *See Lewkut*, 724 F. Supp. 2d at 655 (noting, "In determining the legal scope of the FDA approval of the Trident System, this Court is tasked only with determining what was ultimately approved via the PMA process. What was submitted in the FDA application has little bearing on this court's assessment of what was ultimately approved"). Instead, the focus remains on the approved device and whether Plaintiff's claims challenge the effectiveness of the approved device. *See id.*

Furthermore, Plaintiff argues that "no case has ever specifically held that medical devices approved through the § 510(k) process are cloaked with preemption when coupled with a PMA device." (Docket No. 10 at 8). Stryker, however, identifies several courts that have rejected the argument that a specific defective component receiving prior § 501(k) approval can be separated from the PMA-device as a whole. (*See* Docket No. 8 at 18-20; Docket No. 11 at 7). For instance, the court in *Bentzley v. Medtronic, Inc.*, No. 10-3827, --- F. Supp. 2d ---, 2011 WL 5942128, 2011 U.S. Dist. LEXIS 136570, at *18 (E.D. Pa. Nov. 29, 2011) stated, "Plaintiff's contention that, in considering a preemption issue, the Court must break a medical device into its

[30] Plaintiff could have made a Freedom of Information Act ("FOIA") request to obtain this information from the FDA. For further discussion of the FOIA, *see* section IV(E).

component parts, is without legal support." In *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009), the court summarized the illogical nature of this argument, explaining, "[i]t makes no sense – indeed, it would probably be impossible – to pick apart the components of a medical device and apply different preemption analyses to different components." The Court agrees with Stryker, as well as the courts in *Bentzley* and *Riley*, that a device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption.

Significantly, several district courts in other circuits have held that the acetabular cup, or shell, of the Trident System, the precise component at issue in the instant matter, should be considered as approved pursuant to PMA as a part of the entire Trident System medical device. The *Lewkut* court explained:

> [T]his Court cannot see the logic in holding that the ceramic components of the Trident System were PMA-approved for use with the acetabular shell, but that that acetabular shell itself was not PMA approved. *An acetabular shell being used in conjunction with the identified ceramic components is precisely the device that was approved via PMA.* To require that a distinction be drawn between the approval process of the individual components of the system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers.

724 F. Supp. 2d at 656 (emphasis added). Similarly, in *Cornwell v. Stryker Corp.*, No. 1:10-cv-00066-EJL, 2010 WL 4641112, 2010 U.S. Dist. LEXIS 116824, at *8-9 (D. Idaho Nov. 1, 2010):

> The Court finds the record in this case supports that the Trident System, including its component parts, received PMA approval under the PMA process. *Plaintiff argues the Trident acetabular cup was initially approved via the § 510(k) process and even though it was later approved for use with the ceramic-on-ceramic Trident System which received PMA approval, claims regarding the acetabular cup are exempt based on its original approval under § 510(k). This argument has been rejected by every other court determining whether the acetabular cup received approval via the PMA process. . . .* Having found the medical device at issue in this case was approved via the PMA process, the Court finds Plaintiff's product liability claims are preempted by the MDA and must be dismissed.

(emphasis added). *See also Bass v. Stryker Corp.*, No. 4:09-cv-632-Y, 2010 WL 3431637, 2010 U.S. Dist. LEXIS 90226, at *8-12 (N.D. Tex. Aug. 31, 2010), *rev'd on other grounds,* --- F.3d ---, 2012 WL 266985, 2012 U.S. App. LEXIS 1789 (5th Cir. Jan. 31, 2012) (determining that the metal acetabular cup is a part of the Trident System, which received premarket approval in its entirety).

This Court is persuaded by this authority and finds that the Trident System, in its entirety, received premarket approval. *See, inter alia*, *Cornwell*, 2010 U.S. Dist. LEXIS 116824, at *8-9; *Bass*, 2010 U.S. Dist. LEXIS 90226, at *8-12; *Lewkut*, 724 F. Supp. 2d at 656. Despite the prior § 501(k) approval of the metal acetabular cup and its commercial availability at the time of the Trident System's premarket approval, the metal acetabular cup still underwent the PMA process as a component of the Trident System. *See, inter alia*, *Cornwell*, 2010 U.S. Dist. LEXIS 116824, at *8-9; *Bass*, 2010 U.S. Dist. LEXIS 90226, at *8-12; *Lewkut*, 724 F. Supp. 2d at 656. Therefore, the federal government has imposed device-specific "requirements" on the entire Trident System hip prosthesis, and the first prong of the two-part test of express preemption under 21 U.S.C. § 360(k) has been fulfilled. *See Riegel*, 552 U.S. at 322-23

b. Element 2: Whether State Requirements are Different From, or in Addition, to the Federal Requirements

This Court must next determine whether Plaintiff's claims based on negligence and *res ipsa loquitur* (Count II) and his breach of implied warranty claim (Count III) are expressly preempted by the MDA. (*See* Docket No. 15-18). As was previously discussed, the second prong of express preemption under 21 U.S.C. § 360(k) requires the court to evaluate whether the state requirements underlying the plaintiff's claims relate to the device's safety and effectiveness and are "different from or in addition to" the federal requirements. *See Riegel*, 552 U.S. at 321-22. In *Riegel*, the Supreme Court equated state common law duties with state requirements. *Id.*

at 323-24, 327-28. The Supreme Court determined that claims for breach of implied warranty and negligence regarding Class III PMA medical devices suggest that "a device was designed, labeled or manufactured in an unsafe or ineffective manner." *Id.* at 328. Allowing these claims to go forward would result in the imposition of different or additional requirements related to the safety or effectiveness of a device. *Id.* at 327-28; *see also Walker v. Medtronic, Inc.*, No. 10-2219, --- F.3d ---, 2012 WL 208036, 2012 U.S. App. LEXIS 1334, at *22-23 (4th Cir. Jan. 25, 2012) (2-1 decision) (stating that *Riegel* "provides a rigorous, comprehensive, and exclusive framework that precludes state law tort claims that seek to impose different or higher standards upon federally approved devices"). "Generalized common law theories of liability . . . are precisely the types of claims the MDA sought to preempt." *Williams*, 388 F. App'x at 171 (citing *Riegel*, 552 U.S. at 325; *Horn v. Thoratec Corp.*, 376 F.3d 163, 173 (3d Cir. 2004)).

Many courts have evaluated state common law claims regarding the very product at issue in this litigation, the Trident System and its component parts, and have deemed them expressly preempted. *See e.g. Rhynes v. Stryker Corp.*, No. 10-5619 SC, 2011 WL 5117168, 2011 U.S. Dist. LEXIS 58286 (N.D. Cal. Oct. 27, 2011) (dismissing negligence and strict liability claims as expressly preempted under the MDA per the Supreme Court's reasoning in *Riegel*); *Cornwell*, 2010 U.S. Dist. LEXIS 116824 (dismissing product liability claims); *Lewkut*, 724 F. Supp. 2d 648 (dismissing claims for, *inter alia*, strict liability and negligence premised on alleged manufacturing, marketing, and design defects); *Anthony v. Stryker Corp*., No. 1:09-cv-2343, 2010 WL 1387790, 2010 U.S. Dist. LEXIS 31031 (N.D. Ohio Mar. 31, 2010) (dismissing claims for strict liability, negligence, breach of implied warranty, breach of express warranty, and misrepresentation); *Yost v. Stryker Corp*., No. 2:09-cv-28-FtM-29DNF, 2010 WL 1141586, 2010 U.S. Dist. LEXIS 27079 (M.D. Fla. Mar. 23, 2010) (dismissing claims for strict product liability,

negligence/wantonness, breach of express warranty, and breach of implied warranties of merchantability and fitness for a particular purpose); *Lemelle v. Stryker Orthopaedics*, 698 F. Supp. 2d 668 (W.D. La. 2010) (dismissing product liability claims); *Funk v. Stryker Corp*., 673 F. Supp. 2d 522 (S.D. Tex. 2009) (dismissing claims for, *inter alia*, strict liability and negligence), *aff'd*, 631 F.3d 777 (5th Cir. 2011); *Covert v. Stryker Corp*., No. 1:08CV447, 2009 WL 2424559, 2009 U.S. Dist. LEXIS 68962 (M.D.N.C. Aug. 5, 2009) (dismissing claims for failure to warn, defective manufacturing, defective design, negligence and recklessness, and breach implied warranties); *Delaney*, 2009 U.S. Dist. LEXIS 16865 (dismissing claims for failure to warn, strict liability, negligence and recklessness, and breach of implied warranties as preempted by MDA); *Horowitz v. Stryker Corp.,* 613 F. Supp. 2d 271 (E.D.N.Y. 2009) (dismissing claims for strict liability, negligence and recklessness, and breach of express and implied warranties); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298 (D. Colo. 2008) (dismissing claims for failure to warn, manufacturing defect, design defect, breach of express and implied warranties, breach of implied warranty of fitness, breach of implied warranty of merchantability, and negligence and recklessness).[31] Upon consideration, the Court finds these decisions to be very persuasive.

As was previously explained, Plaintiff asserts that express preemption pursuant to § 360k is entirely inapplicable to the metal acetabular cup due to its approval via the § 510(k) process. (*See* Docket No. 10 at 11-13). This Court has already rejected this argument[32] in section IV(C)(2)(a) after determining that the Trident System, including the metal acetabular cup

[31] Stryker also provides the Court with citations to two bench opinions and attaches copies of these opinions to its moving brief. (*See* Docket No. 8 at 18; Docket No. 8-2; Docket No. 8-3). They are: *Van Dyke v. Howmedica Osteonics Corp.*, No. 09-cv-78-BU-SHE (D. Mont. Apr. 23, 2010) (Haddon, J.) (Docket No. 8-2); *Hayes v. Howmedica Ostenoics Corp.*, No. 08-cv-6104 (D.N.J. Dec. 15, 2009) (Hayden, J.) (Docket No. 8-3). The *Hayes* opinion is also available at 2009 WL 6841869 (D.N.J. Dec. 15, 2009).

[32] *See* section IV(C)(2)(a) *infra.*

component, received approval through the PMA process. In his responsive brief and latest brief, Plaintiff does not address this second prong of the *Riegel* two-part test directly and instead argues that all of his claims assert violations of federal law which "'parallel' rather than add to, federal regulations." (*Id.* at 13 (quoting *Riegel*, 552 U.S. at 330); Docket No. 16 at 7 (quoting same)). As such, Plaintiff maintains that his claims are all parallel claims that are premised on violations of specific federal requirements, not different or additional state requirements. (*See* Docket No. 10 at 13-14; Docket No. 16 at 7-8).

The Court agrees with Stryker's argument, however, that Plaintiff's breach of implied warranty claim is a state law claim that imposes requirements that are different, or in addition to, specific federal requirements imposed by the FDA.[33] (*See* Docket No. 8 at 20-21). This Court finds no indication in the Complaint that Plaintiff's claim of breach of implied warranty (Count III) alleges violations of federal regulations. (*See* Docket No. 1-3 at 13-18). Rather, Plaintiff sets forth a general common law claim. (*See id.*). *See also Williams*, 388 F. App'x at 171. To find that, despite complying with all FDA regulations, the Trident System violated state requirements, this Court would be imposing different or additional requirements on the Trident System relating to its safety and effectiveness. *See Riegel*, 552 U.S. at 321-23.

Although not labeled as such, Plaintiff's breach of implied warranty claim sets forth allegations of a breach of the implied warranty of merchantability. (*See* Docket No. 1-3 at 17-18). Pennsylvania has adopted the Uniform Commercial Code formulations of the implied warranty of merchantability. 13 Pa. Cons. Stat. § 2314; *see also Gavula v. Ara Servs., Inc.*, 756 A.2d 17, 21 (Pa. Super. Ct. 2000). Under Pennsylvania law, the implied warranty of merchantability "serve[s] to protect buyers from loss where goods purchased are below

[33] Stryker asserts that all of Plaintiff's claims are expressly preempted by the MDA. (*See* Docket No. 8 at 20-21). This Court limits her discussion in this section to Plaintiff's claims for negligence and res ipsa loquitur (Count II) and breach of implied warranty (Count III).

commercial standards." *Turney Media Fuel, Inc. v. Toll Bros.*, 725 A.2d 836, 840 (Pa. Super. Ct. 1999) (citing *Borden, Inc. v. Advent Ink Co.*, 701 A.2d 255, 258 (Pa. Super. Ct. 1997)).

Therefore, it is evident that Pennsylvania state law imposes its own standards on the merchantability of goods. *See Turney Media Fuel, Inc.,* 725 A.2d at 840. By virtue of its premarket approval, the Trident System is subject to federal regulations regarding its merchantability. *See Riegel*, 552 U.S. at 322-25. These federal regulations are in conflict with the Pennsylvania standards for merchantability. *See Bentzley*, 2011 U.S. Dist. LEXIS 5942128, at *25-26; *Davenport v. Medtronic*, 302 F. Supp. 2d 419, 434 (E.D. Pa. 2004) (stating, "[A] judgment for breach of implied warranty would rest on allegations relating to standards 'different from or in addition to' federal requirements set forth in the PMA. Specifically, the accepted standards of design and manufacture for products in the state of Pennsylvania would be 'different from or in addition to' the requirements set through the PMA process"). Because Plaintiff's implied warranty claim is premised on requirements that are different from, or in addition to, the federal requirements imposed by the FDA, Plaintiff's implied warranty claim is preempted by the MDA. *See Williams*, 388 F. App'x at 171 (holding that breach of warranty claims are expressly preempted); *Bentzley*, 2011 U.S. Dist. LEXIS 5942128, at *26 (same); *Anthony*, 2010 U.S. Dist. LEXIS 31031, at *13 (same).[34]

[34] Alternatively, Plaintiff's breach of implied warranty claim can be dismissed because Pennsylvania law does not recognize these claims for medical devices. *See Horsmon v. Zimmer Holdings, Inc.*, No. 11-1050, 2011 WL 5509420, 2011 U.S. Dist. LEXIS 130415, at *6-9 (W.D. Pa. Nov. 10, 2011); *Esposito v. I-Flow Corp.*, No. 10-cv-3883, 2011 WL 5041374, 2011 U.S. Dist. LEXIS 122570, at *14 (E.D. Pa. Oct. 24, 2011). In *Makripodis v. Merrell-Dow Pharms., Inc.*, 523 A.2d 374, 376 (Pa. Super. Ct. 1987), the Pennsylvania Superior Court held that Pennsylvania law precludes breach of implied warranty of merchantability claims for prescription drugs. Several courts have held that the reasoning in *Makripodis* applies to claims against medical device manufacturers as well. *See e.g. Kester v. Zimmer Holdings, Inc.*, 2010 WL 2696467, 2010 U.S. Dist. LEXIS 59869, at *32-33 (W.D. Pa. June 16, 2010); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 751-52 (E.D. Pa. 2007); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 752-53 (W.D. Pa. 2004). This Court agrees with these other courts and finds that Plaintiff's breach of implied warranty claim against Stryker is precluded under Pennsylvania law.

This Court also recognizes that a sizable number of courts have held that negligence claims against the manufacturer of the Trident System are expressly preempted by the MDA. *See e.g.*, *inter alia*, *Rhynes*, 2011 U.S. Dist. LEXIS 58286; *Lewkut*, 724 F. Supp. 2d 648; *Anthony*, 2010 U.S. Dist. LEXIS 31031. In *Riegel*, 552 U.S. 324-25, 327-28, the Supreme Court held that a common law claim for negligence against the manufacturer of a defective medical device was subject to express preemption. To the extent that Plaintiff's claims rely on general, common law negligence standards, said claims are expressly preempted.[35]

Plaintiff's negligence and *res ipsa loquitur* claims can only survive if he pleads specific violations of federal law that establish a parallel state duty, rather than a duty that is different, or in addition to, those imposed by federal regulations. One subparagraph of Plaintiff's negligence claim in Count II alleges a "violation of the FDA requirements and standards as set forth and describe[d] above in the Statement of Facts and Count One." (Docket No. 1-3 at 16). A generous reading of the Complaint reveals that the "requirements and standards" to which Plaintiff refers are violations of federal regulations related to the manufacturing of the metal acetabular cup component of the Trident System in such a way that it left behind residues on the Trident System prosthesis. (Docket No. 1-3 at 13). In his Complaint, Plaintiff alleges that

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[35] The other subparagraphs to paragraph 2 in Plaintiff's claim for negligence assert breaches of Plaintiff's alleged duty to Stryker but do not reference violations of federal regulations. (*See* Docket No. 1-3 at 16). Plaintiff claims that Stryker was negligent in:

> (b) placing the Trident acetabular cup into the stream of commerce when it contained unsafe manufacturing residuals and/or bacteria;
> (c) placing a hip prosthesis into the stream of commerce that was not sterile;
> (d) manufacturing a hip prosthesis that was not sterile;
> (e) failing to warn consumers in general, and Plaintiff or her [sic] physicians specifically, of the risk that the hip prostheses could become loose because it contained manufacturing residuals that impeded boney ingrowth.

(*Id.*). These claims are premised on common law negligence standards, which are expressly preempted by the MDA. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-25, 327-28 (2008); *Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010).

Stryker violated three FDA Current Good Manufacturing Practice requirements ("CGMPs")[36] applicable to the manufacture of the Trident System. (*Id.* at ¶ 18; 13-14). By reference, Plaintiff also premises his claim on the November 28, 2007 FDA warning letter issued to Stryker and the June 18, 2008 voluntary recall of certain Trident System shells. (*See* Docket No. 1-3 at ¶¶ 19-20, ¶ 23). The allusions to these alleged violations of federal regulations demonstrate Plaintiff's attempt to come within a narrow exception to avoid preemption. *See Riegel*, 552 U.S. at 330.

To that end, the Court will evaluate Plaintiff's claim for negligence and *res ipsa loquitur* (Count II) as purported parallel claims. The Court acknowledges that unlike the breach of implied warranty claim that is based on Pennsylvania state law, the negligence and *res ipsa loquitur* claims include a reference to Stryker's alleged violations of federal regulations. (*See* Docket No. 1-3 at 15-16). Plaintiff has conceded, however, that his *res ipsa loquitur* claim fails as a purported parallel claim. (Docket No. 16 at 6)

3. Parallel Claims Based on Federal Requirements

In *Riegel*, the Supreme Court found that "[21 U.S.C.] § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" because the state duties would "'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (citing *Lohr*, 518 U.S. at 495, 513). "To properly allege parallel claims, the complaint must set forth facts showing 'action or inaction in [defendants'] efforts to take part in the PMA process or implement its results.'" *Parker*, 584 F. Supp. 2d at 1301 (quoting *Heisner ex rel. Heisner v. Genzyme Corp.*, No. 08-C-593, 2008 WL 2940811, 2008 U.S. Dist. LEXIS 60569, at *12-13 (N.D. Ill. July 25, 2008)); *accord Williams*, 654 F. Supp. 2d 301, 306 (E.D. Pa.

[36] As previously explained, CGMP regulations "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1). They exist "to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." *Id.*

2009), *aff'd*, 388 F. App'x 169 (3d Cir. 2010) (finding, "To avoid federal preemption, a plaintiff must make a showing that the medical device was not manufactured in accordance with FDA standards").

Even if a plaintiff does properly plead facts demonstrating the defendant's failure to satisfy federal regulations, there is no private cause of action against a device manufacturer under the FDCA. *See Buckman Co.*, 531 U.S. at 349 n.4. Only the federal government may file suits against manufacturers that do not comply with federal regulations. *See* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"). Although the Supreme Court acknowledged in *Riegel* that parallel claims based on violations of federal regulations would escape *express* preemption under § 360k, § 337(a) has been held to *impliedly* preempt private claims against device manufacturers for failure to comply with federal regulations. *See In re Medtronic*, 592 F. Supp. 2d at 1160-61 & n.17. As a result, "*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Riley*, 625 F. Supp. 2d at 777.

The United States District Court for the District of Minnesota articulated two exceptions to implied preemption in which a plaintiff could assert a viable parallel claim. *See In re Medtronic*, 592 F. Supp. 2d at 1161 n.17. First, "an adequately pleaded claim that a specific device was not manufactured in accordance with its PMA specifications can survive preemption." *Id.* (citing *Rollins v. St. Jude Medical, Daig Division, Inc.*, 583 F. Supp. 2d 790 (W.D. La. 2008)). To be an adequately pleaded parallel claim, "Plaintiffs cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption." *In re Medtronic*, 592 F. Supp. 2d at 1158; *accord Wolicki-Gables*, 634 F.3d at 1301 (stating, "Parallel

claims must be specifically stated in the initial pleadings"). The second exception to implied preemption recognized in *In re Medtronic* is for claims brought under a state statute "providing a remedy for a violation of the FDCA." *In re Medtronic*, 592 F. Supp. 2d at 1161 n.17 (citing *Bausch v. Stryker Corp.*, 2008 WL 5157940, 2008 U.S. Dist. LEXIS 99118, at *12-13 (N.D. Ill. Dec. 9, 2008), *rev'd,* 630 F.3d 546 (7th Cir. 2010)). Neither of these exceptions is applicable in the instant matter because: (1) Plaintiff fails to adequately plead a sufficient, specific basis for his purported parallel claims, and (2) Plaintiff's claims arise from generalized common theories of liability and not state statutes that provide a private cause of action for FDCA violations.

In support of his purported parallel claims of negligence and *res ipsa loquitur*, Plaintiff alleges violations of certain CGMPs and asserts the existence of an FDA warning letter and a voluntary recall notice. (*See* Docket No. 1-3 at ¶¶ 18-23, 13, 16). Plaintiff identifies these CGMPs as follows:

1. failing to ensure the quality policy is understood, implemented and maintained at all levels of the organization, 21 C.F.R. § 820.20(a);
2. failing to provide adequate resources, including trained personnel for management, performance of work and assessment activities, including internal quality audits necessary to comply with the federal regulations as required by 21 C.F.R. § 820.20(b)(2); and
3. failing to establish and maintain procedures to prevent [contamination] [sic] of equipment or product by substances that could reasonably be anticipated to have an adverse effect on product quality as required by 21 C.F.R. § 820.70(e).

(*Id.* at 13-14). Plaintiff relies upon these CGMPs, as well as the November 28, 2007 FDA warning letter issued to Stryker and the June 18, 2008 voluntary recall of certain Trident System shells, as establishing Stryker's duty to Plaintiff in his cause of action for negligence. (*See id.* at ¶¶ 18-23, 13-16). Plaintiff also avers that Stryker must "comply with the FDA standards and requirements established and approved through the PMA process for . . . the Trident System." (*Id.* at ¶ 17).

It is hornbook law in Pennsylvania that "[t]here are four elements to a cause of action for negligence: a duty of care, a breach of that duty, a causal connection between the defendant's conduct and the resulting injury, and damages." *Zeidman v. Fisher*, 980 A.2d 637, 639-40 (Pa. Super. Ct. 2009) (citing *Morena v. S. Hills Health Sys.*, 462 A.2d 680, 684 n.5 (1983)). "The primary element in any negligence cause of action is that the defendant owes a duty of care to the plaintiff." *Althaus v. Cohen*, 756 A.2d 1166, 1168 (Pa. 2000). Additionally, "[n]egligence is the absence of ordinary care that a reasonably prudent person would exercise in the same or similar circumstances." *Martin v. Evans*, 711 A.2d 458, 461 (Pa. 1998) (citing *Lanni v. Pa. R.R.. Co.*, 88 A.2d 887 (Pa. 1952)).

The Court recognizes that no courts within the Third Circuit have directly ruled on the requisite specificity with which a plaintiff must plead parallel claims. According to the pleading standards set forth in *Iqbal* and *Twombly*, however, Plaintiff's broad references to federal regulations are insufficient to establish the duty element of a negligence state law claim which would parallel a violation of federal law. *See In re Medtronic,* 592 F. Supp. 2d at 1157-1158; *Wolicki-Gables*, 584 F.3d at 1301; *Ilarraza v. Medtronic, Inc.*, 677 F Supp. 2d 582, 588 (E.D.N.Y. 2009); *Horowitz*, 613 F. Supp. 2d at 280; *Parker*, 584 F. Supp. 2d at 1301. To state a plausible cause of action that avoids MDA preemption, a plaintiff must allege "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Moreover, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 129 S. Ct. at 1949 (internal citations omitted). Courts within the Third Circuit closely adhere to the pleading standards set forth in *Iqbal* and *Twombly*. *See Warren v.*

Gen. Hosp. v. Amgen Inc., 643 F.3d 77, 84 (3d Cir. 2011) (quoting *Fowler*, 578 F.3d at 210). As the United States District Court for the Western District of Kentucky remarked in *White v. Stryker Corp.*, 2011 U.S. Dist. LEXIS 32568, at *12, "In the context of MDA preemption, *Twombly* and *Iqbal* make a plaintiff's job more difficult than it would be in a typical product liability case."

The FDA acknowledges that the CGMPs "are intended to serve only as 'an umbrella quality system,' providing 'general objectives' medical-device manufacturers must seek to achieve." *In re Medtronic*, 592 F. Supp. 2d at 1157 (quoting FDA Device Advice, Good Manufacturing Practices (CGMP)/Quality System (QS) Regulation, available at http://www.fda.gov/cdrh/devadvice/32.html#flexibility (last visited Jan. 2, 2009))[37]; *see also Ilarraza*, 677 F. Supp. 2d at 588 (noting that CGMPs are "intentionally vague and open-ended"). CGMPs do not address the specific aspects of a particular medical device's design, production, and marketing requirements. *Ilarraza*, 677 F. Supp. 2d at 588. Because the CGMPs "do not provide such a fine level of detail concerning the manufacture [of a medical device]," the manufacturer must establish its own specific quality control system for the medical devices it produces to ensure that they are safe and effective. *In re Medtronic*, 592 F. Supp. 2d at 1158; *accord Horowitz*, 613 F. Supp. 2d at 279 (concluding, "The CGMP requirements, therefore, leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective"). To the extent that a plaintiff fails to plead a manufacturer's noncompliance with a particular condition of premarket approval, a parallel claim will fail. *Walker*, 2012 U.S. App. LEXIS 1334, at *22-23 (holding that the plaintiff failed to assert a parallel claim because she did not plead the device manufacturer's

[37] This Internet address redirects to FDA, *Device Advice: Comprehensive Regulatory Assistance*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm (last visited Feb. 26, 2012).

failure to conform to a formal performance standard, which is a condition of a device's premarket approval).

As this area of law continues to develop, some courts have found that references to particular CGMPs can serve as a basis for a parallel claim. *See Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 437, 440-41 (6th Cir. 2010); *Bausch v. Stryker Corp.*, 630 F.3d 546, 555-56 (7th Cir. 2010); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 159 (S.D.N.Y. 2011). In a recent decision, *Bass v. Stryker Corp.*, the United States Court of Appeals for the Fifth Circuit held that the plaintiff had pled parallel claims when the same CGMPs that Plaintiff references in the instant matter, 21 C.F.R. §§ 820.20(a), 820.20(b)(2), and 820.70(e), were cited in the plaintiff's amended complaint. *Bass*, 2012 U.S. App. LEXIS 1789, at *14, *20. As an initial matter, the court acknowledged that "the circuits are not in complete agreement as to what constitutes a sufficient pleading with regard to a CGMP." *Id*. at *20. The court then went on to explain that "reliance on CGMPs" is not critical to successfully pleading a parallel claim. *Id.* at *20. Rather, the essential elements to a parallel claim are "the existence of a manufacturing defect caused by a violation of federal regulations *and* allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury."[38] *Id.* The court reasoned that a CGMP could not be deemed "too vague to be enforced by a jury, because by the time the case is tried, the jury will have before it the PMA application that was approved by the FDA." *Id.* at *22. Therefore, because the plaintiff "will have to prove violations of the more specific, FDA-approved PMA

[38] The Court also notes that the plaintiff in *Bass* pled his injury with more precision than the Plaintiff in the instant matter. In *Bass*, the plaintiff alleged, "On or about July 29, 2009, due to continued severe left him pain, Plaintiff underwent a revision of his left total hip replacement. During the procedure, the surgeon confirmed that the acetabular component had failed in that it was grossly loose. Plaintiff's failed Stryker Trident PSL Shell was revised." (*Bass First Amended Complaint* at No. 09-cv-00632-Y, Docket No. 13 at ¶ 26). In the instant matter, however, the Plaintiff avers, "On October, 2008, the Plaintiff underwent a subsequent operation for revision surgery where it was discovered that the liner had fractured and needed to be removed and changed." (Docket No. 1-3 at ¶ 8). To the extent the *Bass* court held that the plaintiff pled "allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury," the instant matter is distinguishable. *See Bass v. Stryker Corp*,. --- F.3d ---, 2012 WL 266985, 2012 U.S. App. LEXIS 1789 (5th Cir. Jan. 31, 2012).

process for this device" at trial, a manufacturer's noncompliance with non-specific CGMPs may be pled as the basis of a parallel claim. *Id.* at *24.

The Court declines to follow the reasoning set forth in *Bass*. In *Riegel*, the Supreme Court stated that parallel claims arise out of "violations of FDA regulations" because the state duties would "'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (citing *Lohr*, 518 U.S. at 495, 513). Under the premarket approval process, the FDA imposes federal "requirements" that are "specific to individual devices." *Riegel*, 552 U.S. at 322-23. Allowing a plaintiff to plead non-specific regulations as a basis for a parallel claim is inconsistent with the Supreme Court's reasoning in *Riegel*, as well as the pleading requirements articulated in *Twombly*, *Iqbal*, and *Fowler*. *See Riegel*, 552 U.S. at 322-23, 330; *Twombly*, 550 U.S. at 555, 570; *Iqbal*, 129 S. Ct. 1949; *Fowler*, 578 F. 3d at 210-11. This Court requires a greater level of specificity in pleading a parallel claim, rather than allowing claims premised on violations of general regulations to go forward merely because plaintiffs will supplement their pleadings at trial. *See Bass*, 2012 U.S. App. LEXIS 1789, at *22-24.

In *Howard*, an unpublished opinion, the United States Court of Appeals for the Sixth Circuit held that a citation to a CGMP addressing manufacturing material, 21 C.F.R. § 820.70(h), was a sufficient foundation on which to base a parallel claim. *See Howard*, 382 F. App'x at 440-41. The court read this CGMP to require actual removal of manufacturing material when it "'adversely affect[s] the device's quality.'" *Id.* at 440 (quoting 21 C.F.R. § 820.70(h)). This CGMP is distinguishable from the general regulations Plaintiff claims were violated in this case. (*See* Docket No. 1-3 at 13-14). The CGMPs allegedly violated by Stryker do not similarly prescribe a specific course of action that a manufacturer must take and impose liability when the manufacturer fails to do so. (*See id.*).

The United States Court of Appeals for the Seventh Circuit adopted a comparable approach in *Bausch*, 630 F.3d at 555-56. Although the plaintiff in *Bausch* did not allege any violations of CGMPs in her complaint, the court held that such violations could serve as a basis for a parallel claim. *Id.* (*See also Bausch Complaint* at No. 08-04248, Docket No. 1). The court went a step further than the *Howard* court, though, and declined to differentiate between "general requirements and 'concrete, device-specific' requirements," as violations of both could feasibly survive preemption. *Bausch*, 630 F.3d at 555. The court expressed its underlying motivation for this liberal pleading standard, stating, "Defendants' proposed distinction between concrete, product-specific requirements and more general requirements would also leave injured patients without a remedy for a wide range of harmful violations of federal law." *Id.*

This Court finds the *Bausch* court's rationale to be unpersuasive and declines to follow its holding. First, in *Riegel*, 552 U.S. at 318, the Supreme Court acknowledged that the PMA process does not certify the absolute safety of medical devices; rather, the process entails the balancing of risks and benefits by the FDA throughout the approval process. *See also Banner v. Cyberonics, Inc.*, No. 08–0741, 2010 WL 455286, 2010 U.S. Dist. LEXIS 9393, at *10 (D.N.J. Feb. 4, 2010) (stating, "Thus, if the FDA approves a manufacturing process and the defendant-manufacturer conforms with it, a device thereby produced that nevertheless does not function as intended does not give rise to liability"). Second, pursuant to the premarket approval process, medical device manufacturers must adhere to device-specific requirements. *See Riegel*, 552 U.S. at 322-23. As such, violations of same, and not merely any requirement, properly serve as the basis of a parallel claim. *See id.* at 322-23, 330. Third, as stated previously, such a liberal pleading standard is in conflict with *Twombly* and *Iqbal*, as well as Third Circuit precedent

interpreting same, including *Fowler*. *See Twombly*, 550 U.S. at 555, 570; *Iqbal*, 129 S. Ct. 1949; *Fowler*, 578 F. 3d at 210-11.

In the instant case, the CGMPs cited by Plaintiff direct Stryker to have a "quality policy" in place, "adequate resources" to meet this quality policy, and "procedures to prevent [contamination] [sic]" of the devices that it manufactures. (*See* Docket No. 1-3 at 13-14). These regulations are not only general; they apply to *all* Class III PMA medical devices. *See In re Medtronic*, 592 F. Supp. 2d at 1157-58; *Horowitz*, 613 F. Supp. 2d at 278-79. Furthermore, because these regulations do not address the manufacturing of the specific device at issue, the Trident System hip prosthesis, they cannot establish the requisite standard of care that a particular manufacturer must meet. *See Ilarraza*, 677 F. Supp. 2d at 588. The regulations delegate the maintenance of device-specific quality control to the manufacturer. Yet, Plaintiff does not plead that Stryker violated its own policies regarding product safety. Plaintiff, instead, alleges that Stryker violated very broad CGMPs that are not device-specific to the Trident System. *See Horowitz*, 613 F. Supp. 2d at 278-79. As a result, Plaintiff does not plead sufficient facts to support a claim that Stryker did not comply with these CGMPs to adequately assure the safety of its manufacturing procedures when these CGMPs merely dictate that Stryker develop and enforce individualized quality control policies. (*See* Docket No. 1-3).

Similarly, Plaintiff's references to a warning letter and a voluntary recall notice do not establish an applicable standard of care to support a well-pled negligence claim. *See Horowitz*, 613 F. Supp. 2d at 280; *Parker*, 584 F. Supp. 2d at 1302. Plaintiff states that the November 28, 2007 warning letter establishes that Stryker violated CGMPs in its Mahwah, New Jersey facilities between June 1, 2007 and July 12, 2007. (*See* Docket No. 1-3 at ¶ 19, 25-30). Additionally, Plaintiff claims that Stryker initiated a June 12, 2008 recall of some of its hip

devices, allegedly including Plaintiff's own device. (*See id.* at ¶ 20). Plaintiff appears to assert that these facts establish that Stryker manufactured the Trident System in a negligent manner thus causing the failure of his hip prosthesis, his pain, and the necessary revision surgery. (*See id.* at ¶¶ 19-20).

The warning letter and voluntary recall notice do not, however, establish any duty that Stryker had to Plaintiff in manufacturing the Trident System. Nor do they indicate that Stryker breached any alleged duty by failing to comply with the PMA process. *See Parker*, 584 F. Supp. 2d at 1301. Instead, the warning letter and voluntary recall evidence that the FDA purportedly acknowledged some deviation from the CGMPs, and subsequently, Stryker recalled Trident System devices. (*See* Docket No. 1-3 at ¶¶ 19-20, 25-30). It is also unclear in the Complaint how an alleged voluntary recall conducted by Stryker, and not mandated by the FDA, supports a finding that Stryker failed to comply with the PMA process. (*See id.* at ¶ 22).

Absent an illustration of Stryker's precise duty to Plaintiff, Plaintiff cannot plead a cause of action for negligence under Pennsylvania law. *See Althaus*, 756 A.2d at 1168; *Zeidman*, 980 A.2d at 639-40. Plaintiff's purported parallel claim for negligence falls short of being "specifically stated in the initial pleadings." *Wolicki-Gables*, 634 F.3d at 1301. Although Plaintiff acknowledges that Stryker must comply with the specific regulations that apply to the Trident System as a PMA device, he does not outline what these regulations are or how Stryker allegedly violated same. (*See* Docket No. 1-3 at ¶ 18). Because Plaintiff pled his negligence claim in a very general manner, he has failed to state a claim for negligence that survives preemption. *See Twombly*, 550 U.S. at 555, 570; *Iqbal*, 129 S. Ct. 1949; *Fowler*, 578 F. 3d at 210-11.

To the extent that Plaintiff relies on the same violations of federal regulations to establish *res ipsa loquitur*, it logically follows that Plaintiff's claim based on *res ipsa loquitur* similarly fails as a parallel claim. (*See* Docket No. 1-3 at 16-17). Notably, Plaintiff has conceded that this claim "perhaps may not [survive as a parallel claim]." (Docket No. 16 at 6).

"*Res ipsa loquitur*, meaning literally 'the thing speaks for itself,' is 'a shorthand expression for circumstantial proof of negligence – a rule of evidence.'" *Quinby v. Plumsteadville Family Practice, Inc.*, 907 A.2d 1061, 1071 (Pa. 2006) (quoting *Gilbert v. Korvette, Inc.*, 327 A.2d 94, 99 (Pa. 1974)). It "allows juries to infer negligence from the circumstances surrounding the injury." *Quinby*, 907 A.2d at 1071. Pennsylvania has adopted the doctrine of *res ipsa loquitur* set forth in RESTATEMENT (SECOND) OF TORTS § 328D:

> (1) It may be inferred that harm suffered by the plaintiff is caused by negligence of the defendant when
>
> > (a) the event is of a kind which ordinarily does not occur in the absence of negligence;
> > (b) other responsible causes, including the conduct of the plaintiff and third persons, are sufficiently eliminated by the evidence; and
> > (c) the indicated negligence is within the scope of the defendant's duty to the plaintiff.

REST. (SECOND) OF TORTS § 328D; *see also Gilbert*, 327 A.2d at 100.[39]

This Court has already determined that Plaintiff is unable to maintain a claim for negligence. As such, this Court declines to *infer* the existence of such negligence in accordance with the doctrine of *res ipsa loquitur* under Pennsylvania law. *See Quinby*, 907 A.2d at 1071. Finding *res ipsa loquitur* here would require the Court to rely on even fewer facts than Plaintiff

[39] Because *res ipsa loquitur* is a rule of evidence, "'[i]t does not have to be pleaded in the complaint or noticed by specific designation to the adverse party as a pre-trial or at a trial, since it is neither a cause of action nor a ground for recovery, nor an issue.'" *Hollywood Shop, Inc. v. Pa. Gas & Water Co.*, 411 A.2d 509, 513 (Pa. Super. Ct. 1979) (quoting *Fassbinder v. Pa. R.R. Company*, 322 F.2d 859, 861 (3d. Cir. 1963)). A party may still "include[e] a reference to res ipsa loquitur in a claim of negligence." *Banks v. Ashland Oil Co.*, 127 F. Supp. 2d 679, 682 (E.D. Pa. 2001); *see also Napolitano v. Haven Homes Inc.*, Civ. Action No. 10-1712 (FLW), 2012 WL 253175, 2012 U.S. Dist. LEXIS 9383, at *33-34 (D.N.J. Jan. 26, 2012) (finding, "[W]hile a plaintiff need not include *res ipsa loquitur* in his complaint, nothing in the Court's liberal pleading standards actually prevents him from doing so").

pled in support of his negligence claim by inferring the existence of negligence from an event that "is of a kind which ordinarily does not occur in the absence of negligence." REST. (SECOND) OF TORTS § 328D.

Plaintiff also fails to rule out "other responsible causes, including the conduct of the plaintiff and third persons" as potential causes of his alleged injuries. REST. (SECOND) OF TORTS § 328D(1)(b); *see also* REST. (SECOND) OF TORTS § 328D cmt. f (stating, "It is never enough for the plaintiff to prove that he was injured by the negligence of some person unidentified. It is still necessary to make the negligence point to the defendant"). "[T]he critical inquiry as to whether this subsection of § 328D is satisfied is whether a particular defendant is the responsible cause of the injury." *Quinby*, 907 A.2d at 1072-73 (citing *Jones v. Harrisburg Polyclinic Hosp.*, 437 A.2d 1134, 1139 (Pa. 1981); *Gilbert*, 327 A.2d at 101).

In his Complaint, Plaintiff claims that he "immediately suffered an infection ath [sic] operation site which required intensive anti biotic [sic] intervention." (Docket No. 1-3 at ¶ 4). Furthermore, after experiencing left hip pain for the year following his hip replacement surgery, Plaintiff avers, "Dr. Pressman informed Plaintiff that his severe left hip has been caused by the failure of at least the Stryker Trident PSL acetabular shell and insert in that it is loose and recommended he undergo a revision surgery." (*Id.* at ¶ 6). However, Plaintiff does not plead sufficient facts to rule out other possible causes of the aforementioned infection,[40] nor does he rule out the possibility of surgical error on behalf of his own doctor. Plaintiff also does not

[40] The Summary of Safety and Effectiveness Data for the Trident System warns of the possibility of infection as an adverse effect of Trident System implantation. *See* FDA, *Summary of Safety and Effectiveness Data*, *available at* http://www.accessdata.fda.gov/cdrh_docs/pdf/P000013b.pdf (last visited Feb. 26, 2012). Moreover, the Summary lists infection as a contraindication, *id.*, meaning "a specific situation in which a drug, procedure, or surgery should NOT be used, because it may be harmful to the patient," MedlinePlus, *Contraindications*, *available at* http://www.nlm.nih.gov/medlineplus/ency/article/002314.htm (last visited Feb. 26, 2012).

negate the possibility of his own contributory negligence[41] due to improperly caring for his incision following the initial arthroplasty or adhering to a prescribed rehabilitation regimen.[42]

Furthermore, as this Court explained previously, the PMA process under which the Trident System was approved does not guarantee that a medical device will be free of risks. *See Riegel*, 552 U.S. at 318; *Banner*, 2010 U.S. Dist. LEXIS 9393, at *10. Medical devices, even Class III medical devices receiving rigorous premarket approval, inherently carry risks and the potential for harm to consumers, and negligence on behalf of the manufacturer is not necessarily the source of this harm. *See Funk*, 673 F. Supp. 2d at 531-32 (holding that a medical device "could have failed for a variety of reasons and therefore its failure did not 'speak for itself' and establish the defendants' negligence").

In support of his argument that all claims alleged in the Complaint are parallel claims, Plaintiff provides citations to authority from outside of the Third Circuit, as no courts within the Third Circuit have directly ruled on this point. (*See* Docket No. 10 at 7-8, 13-14). One such case, *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009), has received a varied treatment by other courts. *See e.g. Lewkut*, 724 F. Supp. 2d at 658 n.3 (stating, "Because the reasoning in *Hofts* has been discredited by several other courts, this Court declines to adopt

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[41] Under Pennsylvania law:

> Contributory negligence is conduct on the part of a plaintiff which falls below the standard [of care] to which he should conform for his own protection and which is a legally contributing cause, cooperating with the negligence of the defendant, in bringing about the plaintiff's harm. Contributory fault may stem either from a plaintiff's careless exposure of himself to danger or from his failure to exercise reasonable diligence for his own protection.

Angelo v. Diamontoni, 871 A.2d 1276, 1280-81 (Pa. Super. Ct. 2005) (citing *Columbia Med. Group, Inc. v. Herring & Roll, P.C.*, 829 A.2d 1184, 1192 (Pa. Super. Ct. 2003)).

[42] In his responding brief to Stryker's Motion to Dismiss, Plaintiff states, "Despite following all of his surgeon's instructions after his surgery including rehabilitative programs, Plaintiff began to experience a site infection in the left him at the site of the operation which required hospitalization." (Docket No. 10 at 4). Plaintiff did not plead these facts in his Complaint and mentions them for the first time in his responding brief. (*See* Docket No. 1-3; Docket No. 10 at 4). Again, this Court must judge the Complaint based on allegations in same and not on new allegations that are alleged in a party's brief or at oral argument. *See Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994) (stating, "In determining whether a claim should be dismissed under Rule 12(b)(6), a court looks only to the facts alleged in the complaint and its attachments without reference to other parts of the record").

the analysis of this case"); *Ilarraza*, 677 F. Supp. 2d at 589 (stating, "The court declines to follow that court's analysis [in *Hofts*], and instead follows the larger number of courts that have rejected the sufficiency of pleading nothing more than the violation of CGMP's in support of a parallel claim"); *Covert*, 2009 U.S. Dist LEXIS 68962, at *39 (stating, "In this Court's view, *Twombly* requires more from a plaintiff pleading a case such as that attempted by Plaintiff Covert than the *Hofts* court would demand); *but see Bass*, 2012 U.S. App. LEXIS at *34-37 (adopting the reasoning in *Hofts* when analyzing whether implied warranty claims are preempted). The *Hofts* court allowed the plaintiff's manufacturing defect claim to withstand dismissal as a parallel claim, reasoning that to hold otherwise is "an unusually stringent application of *Twombly* and Rule 8 of the Federal Rules of Civil Procedure at the motion to dismiss stage." *Hofts*, 597 F. Supp. 2d at 838. Like the courts in *Lewkut*, *Ilarraza*, and *Covert*, this Court declines to agree with the holding in *Hofts* and, instead, requires a greater level of pleading specificity to allege a parallel claim in accordance with *Iqbal*, *Twombly*, and *Fowler.*

In *Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777-M, 2008 WL 3874713, 2008 U.S. Dist. LEXIS 62131 (N.D. Tex. Aug. 13, 2008), the plaintiffs successfully pled parallel claims but premised them on specific violations of the PMA process in addition to violations of CGMPs. Notably, in *Purcel*, the FDA had filed a prior suit against the defendant for these same alleged violations. *Id.* at 4. No such facts are pled in the instant case, so the outcome in *Purcel* is distinguishable. (*See* Docket No. 1-3).

Additionally, a prescription drug rather than a device was at issue in another case cited by Plaintiff, *Bolin v. Smithcline Beecham Corp.*, No. 08-60523-CIV-COHN, 2008 WL 3286973, 2008 U.S. Dist. LEXIS 60241 (S.D. Fla. Aug. 7, 2008). Express preemption under the MDA

does not apply to prescription drugs. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1196 (2009). *Bolin*, therefore, has no application to this case. (*See* Docket No. 1-3).

In support of his parallel claims argument, Plaintiff also quotes from *Heisner*, 2008 U.S. Dist. LEXIS 60569, at *12-13, a case in which the defendant's Rule 12(b)(6) motion was granted for failing to properly allege parallel claims not preempted by the MDA. Stryker agrees with the dicta Plaintiff quoted from *Heisner*, 2008 U.S. Dist. LEXIS 60569, at *12-13, which states, "Defendant's action or inaction in its efforts to take part in the PMA process or implement its results" serve as the basis for a parallel claim. (*See* Docket No. 11 at 9). This Court has discussed previously that Plaintiff failed to allege any violation of the PMA process by Stryker, and thus, the Court could not find that Plaintiff properly pled a parallel claim. Therefore, this quote from *Heisner* does not support Plaintiff's position.

In sum, this Court finds that Plaintiff has not adequately pled a parallel violation of federal law in his negligence and *res ipsa loquitur* state law claims at Count II. Plaintiff has even conceded that his *res ipsa loquitur* claim fails as a purported parallel claim. (Docket No. 16 at 6). This Court has already determined that Plaintiff's breach of implied warranty claim at Count III has been expressly preempted because it imposes requirements that are different, or in addition to, the applicable federal requirements. Consequently, Plaintiff's negligence and *res ipsa loquitur* (Count II) and breach of implied warranty (Count III) claims are dismissed, with prejudice.

C. Breach of Express Warranty (Count III)

Stryker next argues that Plaintiff's Complaint failed to state a claim for breach of express warranty, thus demanding its dismissal.[43] (*See* Docket No. 8 at 22-24). Although the first

[43] The Court notes that Stryker offers an alternative argument for the dismissal of Plaintiff's breach of express warranty claim based on express preemption grounds under 21 U.S.C. § 360k of the Medical Device Amendments

paragraph of Count III purports to assert a claim for both breach of express warranty and breach of implied warranty, the remaining three subparagraphs and two paragraphs of Count III only refer to the breach of implied warranty of merchantability. (*See* Docket No. 1-3 at 17-18). No other assertion of an express warranty is made in Count III. (*See id.*). Thus, there are no specific factual averments supporting Stryker's express warranty claim. (*See id.*). Furthermore, Plaintiff does not offer any counterargument in response to Stryker's Motion to Dismiss his express warranty claim. (*See* Docket. No. 10). Because this bare allegation of a breach of express warranty is deficient, this claim must be dismissed.

Under the Pennsylvania Commercial Code, "[a]ny 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." 13 Pa.C.S. § 2313(a)(1). A promise becomes the basis of the bargain if the plaintiff can prove "that she read, heard, saw or knew of the advertisement containing the affirmation of facts or promise." *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 752 (W.D. Pa. 2004) (quoting *Cipollone v. Liggett Group, Inc.*, 893 F.2d 541, 567 (3d Cir. 1990), *rev'd on other grounds*, 505 U.S. 504 (1992)). "[A]n express warranty must be 'directed at consumers in order to induce purchases of the product.'" *Sowers v. Johnson & Johnson Med.*, 867 F. Supp. 306, 314 (E.D. Pa. 1994) (quoting *Kenepp v. Am. Edwards Lab.*, 859 F. Supp. 809, 817 (E.D. Pa. 1994)).[44] Absent

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of 1976. (*See* Docket No. 8 at 22-24). Because the claim for breach of express warranty can be dismissed on the basis of its inadequate pleading, analysis of this claim in the context of the alternative argument is unnecessary.

[44] It is unlikely that Stryker made an express warranty that induced Plaintiff to select the Trident System hip prosthesis for his hip replacement procedure. Rather, Plaintiff's orthopedic surgeon read or should have read any warranties on the Trident System's labels or package inserts when selecting and prescribing this prosthesis to Plaintiff. Under Pennsylvania's "learned intermediary doctrine," a prescription drug or prescription medical device manufacturer has a duty "to exercise reasonable care to inform the one for whose use the product is supplied of the facts which make the product is supplied of the facts which make the product likely to be dangerous." *Rosci v. AcroMed, Inc.,* 669 A.2d 959, 969 (Pa. Super. 1995) (citations omitted). The intended user in the learned intermediary doctrine is the prescribing doctor and not the general public or the patient. *See id.; Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 748-49 (W.D. Pa. 2004) (citation omitted). Although the learned intermediary

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. *See Delaney*, 2009 U.S. Dist. LEXIS 16865, at *13-14 (identifying deficiencies in plaintiff's breach of express warranty claim regarding the Trident System under both New Jersey and Pennsylvania law). 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. *See Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, 2010 U.S. Dist. LEXIS 59869, at *27-31 (W.D. Pa. June 16, 2010) (dismissing a breach of express warranty claim against a pain pump manufacturer for failing to state a claim under Pennsylvania law).

Plaintiff has not alleged any "affirmation of fact or promise" made by Stryker that relates to the Trident System that would amount to an express warranty. (*See* Docket No. 1-3). Additionally, Plaintiff has not pled any details regarding the content of any express warranty, how it was made, that it became the basis of the bargain, or that it was directed at Plaintiff. (*See id.*). Moreover, Plaintiff has not responded to Stryker's challenge to his breach of express warranty claim in any fashion. (*See* Docket No. 10; Docket No. 11 at 5).

Even construing Plaintiff's claim liberally, he has not set forth the elements of a breach of express warranty cause of action. (*See id.*). As was previously discussed, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Iqbal*, 129 S. Ct. at 1950

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doctrine has barred claims sounding in breach of implied warranty, it not been applied to breach of express warranty claims "to bar an action by an injured consumer . . . since such a claim is unrelated to the issue of the warnings given to the prescribing physician and instead is based solely upon the express affirmation of fact made by the manufacturer." *Rosci*, 669 A.2d at 969. Regardless, Plaintiff has not pled any facts to illustrate that he had knowledge of any promises or affirmative statements made by Stryker regarding his Trident System hip prosthesis such that they became the basis of the bargain. *See Parkinson*, 315 F. Supp. 2d at 752.

(emphasis added). Furthermore, "a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 127 S. Ct. at 1964-65. Plaintiff's passing mention of a breach an express warranty, without factual allegations supporting this claim, demonstrates that the claim does not rise above the level of a mere "label" or "conclusion." Without any indication that an express warranty was made and without providing the content of any alleged warranty, it is impossible to find that an express warranty exists, let alone that a breach occurred.

Because Plaintiff has failed to state a plausible claim for breach of express warranty under Pennsylvania law and has not provided the court with any argument to the contrary, his claim for breach of express warranty at Count II is likewise dismissed, with prejudice.

D. Punitive Damages

Plaintiff's Complaint contains a request for punitive damages[45] arising from Stryker's alleged gross negligence or, alternatively, Stryker's "fraud, oppression, and malice."[46] (Docket No. 1-3 at 18-22). As no claims against Stryker remain before the Court, Plaintiff's request for punitive damages is dismissed, with prejudice.

E. Discovery

[45] Pennsylvania has adopted Restatement (Second) of Torts § 908 and the accompanying comments regarding punitive damages. *See Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1096-70 (Pa. 1985), *rev'd on other grounds sub nom.*, *Kirkbride v. Lisbon Contractors, Inc.*, 555 A.2d 800 (Pa. 1989). Section 908(1) defines punitive damages as "damages, other than compensatory or nominal damages, awarded against a person to punish him for his outrageous conduct and to deter him and others like him from similar conduct in the future." REST. (2D) TORTS § 908(1). Punitive damages are "an 'extreme remedy' available in only the most exceptional matters." *Phillips v. Cricket Lighters*, 883 A.2d 439, 445 (Pa. 2005). They are "awarded only when the plaintiff has established that the defendant has acted in an outrageous fashion due to either the defendant's evil motive or his reckless indifference to the rights of others." *Id.* (internal quotations and citations omitted).

[46] To the extent that Plaintiff alleges fraud, he "must state with particularity the circumstances constituting fraud" in accordance with FED. R. CIV. P. 9(b). Plaintiff fails to do so in his Complaint. (*See* Docket No. 1-3).

In Plaintiff's Response brief, he asks the Court to convert Stryker's Motion to Dismiss into a motion for summary judgment and defer ruling on the motion until Plaintiff has obtained discovery. (Docket No. 10 at 14-16). Plaintiff seeks discovery on the PMA application and "other documents which are in the exclusive possession, custody, and control of Defendants Stryker that would provide definitive information on the approval process"; documents and depositions related to the testimony of Stryker's representatives who testified before the PMA panel; and information related to manufacturing processes utilized for the Trident acetabular cup and safety analyses conducted by Stryker in response to the FDA warnings. (*Id.* at 15-16).

No discovery is necessary here because, even after discovery, Plaintiff would still not be able to allege any viable claims against Stryker. In fact, numerous district courts across the country have dismissed very similar actions in their entirety at the motion to dismiss stage. *See e.g.*, *inter alia*, *Rhynes*, 2011 U.S. Dist. LEXIS 58286; *Cornwell*, 2010 U.S. Dist. LEXIS 116824; *Lewkut*, 724 F. Supp. 2d 648; *Anthony*, 2010 U.S. Dist. LEXIS 31031. Additionally, in *Delaney*, 2009 U.S. Dist. LEXIS 16865, at *10, the court declined to grant the plaintiff an opportunity to obtain additional discovery "to determine if all or only part of the Trident [System] was subject to the PMA process," because the defendant "ha[d] sufficiently demonstrated" that the entire Trident System received premarket approval.

Additionally, Plaintiff has already accessed some information from the FDA regarding the Trident System, as evidenced by the direct reference Plaintiff makes to "FDA documents" in his Complaint. (*See* Docket No. 1-3 at ¶ 14). To obtain additional information from the FDA to aid in drafting his Complaint, Plaintiff could have submitted a Freedom of Information Act ("FOIA") request. *See* 5 U.S.C. § 552; *see also* FDA, *Freedom of Information*, *available at* http://www.fda.gov/RegulatoryInformation/foi/default.htm (last visited Feb. 26, 2012)

(providing an overview of how FOIA requests are made to the FDA).[47] "[U]nless the requested material falls within one of [ ] nine statutory exemptions, FOIA requires that records and material in the possession of federal agencies be made available on demand to any member of the general public." *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 221 (1978).

Plaintiff also had an opportunity to conduct pre-complaint discovery when he commenced this action in the Court of Common Pleas of Allegheny County by filing a Praecipe for Writ of Summons. (*See* Docket No. 1-1 at ¶ 1). Pre-complaint discovery is contemplated in Rule 4001(c) of the Pennsylvania Rules of Civil Procedure[48] and is directly addressed in Rule 4003.8. According to Rule 4003.8(a), "[a] plaintiff may obtain pre-complaint discovery where the information sought is material and necessary to the filing of the complaint and the discovery will not cause unreasonable annoyance, embarrassment, oppression, burden or expense to any person or party." If an objection to pre-complaint discovery follows, then "the court may require the plaintiff to state with particularity how the discovery will materially advance the preparation of the complaint." PA. R. CIV. P. 4003(b). The trial court has "undisputed discretion to grant or deny pre-complaint discovery requests," *McNeil v. Jordan*, 894 A.2d 1260, 1279 (Pa. 2006), and the court exercises this discretion by balancing the interests of the parties involved, PA. R. CIV. P. 4003(b).

Finally, the Court finds Plaintiff's request for discovery to be inapposite to Rule 8 and Rule 11(b) of the Federal Rules of Civil Procedure. Rule 8, which requires a pleading to contain

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[47] Plaintiff's attorney could have also called the phone number listed on the FDA's official website to inquire about obtaining the information that he sought. *See* FDA, *U.S. Food and Drug Administration*, *available at* http://www.fda.gov/default.htm (last accessed Jan. 30, 2012).

[48] Pa. R. Civ. P. 4001(c) provides:

> Subject to the provisions of this chapter, any party may take the testimony of any person, including a party, by deposition upon oral examination or written interrogatories for the purpose of discovery, or *for preparation of pleadings*, or for preparation or trial of a case, or for use at a hearing upon petition, motion or rule, or for any combination of the foregoing purposes.

(emphasis added).

"a short and plain statement of the claim showing that the pleader is entitled to relief," "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 129 S. Ct. at 1953; *see also Timmons v. Linvatec Corp.*, 263 F.R.D. 582, 585 (C.D. Cal. 2010) (stating, "[A] plaintiff who fails to meet the pleading requirements of *Rule 8* is not entitled to conduct discovery with the hope that it might permit her to state a claim"). In addition, Rule 11(b) requires a pleading to be a representation of "the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances." FED. R. CIV. P. 11(b); *see also Haniotakis v. Nassan*, 727 F. Supp. 2d 388, 411 (W.D. Pa. 2010) (stating, "An attorney must conduct a reasonable inquiry before filing a lawsuit, and cannot pursue the action unless he or she reasonably believes that facts exist to support the allegations"). Allowing Plaintiff to "file first and investigate later," contradicts the reasonable inquiry requirement in Rule 11(b). *See Timmons*, 263 F.R.D. at 585; *Kester*, 2010 U.S. Dist. LEXIS 59869, at *22-23; *see also Oswell v. Morgan Stanley Dean Witter & Co.*, 507 F. Supp. 2d 484, 488 (D.N.J. 2007) (quoting *Lieb v. Topstone Indus.*, 788 F.2d 151, 157 (3d Cir. 1986)).

Even though Plaintiff requests the opportunity to conduct discovery in this matter, this Court has already established that the Trident System is a Class III medical device receiving premarket approval in its entirety. Consequently, this Court declines to convert Stryker's Motion to Dismiss into a motion for summary judgment and will not defer its ruling until Plaintiff has obtained discovery.

F. Leave to Amend

As indicated, the Court has ruled that all of Plaintiff's claims and his request for punitive damages are dismissed, with prejudice. Plaintiff has not sought leave to amend his Complaint. (*See* Docket No. 10).

Rule 15(a) of the Federal Rules of Civil Procedure dictates that "[a] party may amend its pleading once as a matter of course" if "the pleading is one to which a responsive pleading is required." The "grant or denial of an opportunity to amend is within the discretion of the District Court." *Foman v. Davis*, 371 U.S. 178, 182 (1962). "Among the grounds that justify a denial of leave to amend are undue delay, bad faith, dilatory motive, prejudice and futility." *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997)). Allowing an amendment would be futile if "the complaint, as amended, would fail to state a claim upon which relief could be granted." *Shane*, 213 F.3d at 115 (citing *In re Burlington Coat Factory Sec. Litig*., 114 F.3d at 1434). "In assessing 'futility,' the District Court applies the same standard of legal sufficiency as applies under Rule 12(b)(6)." *Shane*, 213 F.3d at 115 (citing, *inter alia*, *In re Burlington Coat Factory Sec. Litig*., 114 F.3d at 1434).

In this Court's estimation, leave to amend is not required because any amendment of Plaintiff's Complaint would be futile. Plaintiff's strict liability claims against Stryker are not viable under Pennsylvania law. He has not set forth *any* facts supporting a breach of express warranty claim. Finally, his remaining claims are expressly preempted, do not meet the narrow exception of parallel claims, or are conceded. For these reasons, the Court declines to grant Plaintiff the opportunity to amend.

V. CONCLUSION

Based on the foregoing, Stryker's Motion to Dismiss is granted and Plaintiff's claims are dismissed, with prejudice. The Court dismisses with prejudice all of Plaintiff's claims: strict liability based on manufacturing defect and marketing defect theories (Count I), negligence and *res ipsa loquitur* (Count II), and breach of express and implied warranties (Count III), as well as

Plaintiff's request for punitive damages. Finally, the Court declines to grant Plaintiff the opportunity to obtain discovery and amend his Complaint given the facts of this case and controlling authority. An appropriate Order follows.

s/Nora Barry Fischer
Nora Barry Fischer
United States District Judge

Date: March 14, 2012

cc/ecf: All counsel of record