UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

SALLIE MANESS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**No. 3:10-CV-178**
	)	**(Phillips)**
BOSTON SCIENTIFIC, *et al.*,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the Court on Defendants' Motion to Dismiss [Doc. 8]. On June 4, 2010, Defendants filed a Motion to Dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Defendants argue that Plaintiff's claims–all based in products liability–do not satisfy the federal pleading requirements, as modified in Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, - - -U.S. - - -, 129 S.Ct. 1937 (2009).

On October 19, 2010, Plaintiff responded in opposition, arguing that: (1) federal pleading requirements do not apply to state law claims removed to federal court; and (2) in any event, Plaintiff satisfied the federal pleading requirements, as modified by Twombly. [Plaintiff's Response to Defendants' Motion to Dismiss, Doc. 13]. On October 28, 2010, Defendants filed a Reply in support of their Motion to Dismiss. [Doc. 15].

Based upon the following, Defendants' Motion to Dismiss [Doc. 8] is **GRANTED**, whereby Plaintiff's complaint is **DISMISSED**. While Plaintiff's complaint is dismissed, Plaintiff has 30 days from entry of this Memorandum and Order to file an amended complaint. If Plaintiff fails to file an

amended complaint within this time period, or if the amended complaint fails to satisfy the federal pleading requirements, judgment shall be entered in favor of the Defendants.

I. BACKGROUND

As an initial matter, the Court notes that it has jurisdiction pursuant to 28 U.S.C. §§ 1332, 1441. The following facts are taken mostly from Plaintiff's complaint, and will be assumed as true for purposes of the 12(b)(6) motion. *See, e.g.*, DIRECTV, Inc. v. Treesh, 487 F.3d 471, 476 (6th Cir. 2007) (in ruling upon motions to dismiss under Rule 12(b)(6), a court must "construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff").

On March 16, 2010, Plaintiff filed a product liability action against defendants Boston Scientific Corporation[1], Advanced Bionics[2], Scott Stewart, and John Does 1-5. [Plaintiff's Complaint, Doc. 1-1]. The complaint was filed in the Circuit Court for Knox County. [Id.]. On April 23, 2010, Defendants removed the case to federal court on the basis of diversity jurisdiction, 28 U.S.C. §§1331, 1441. [Defendants' Notice of Removal, Doc. 1].

In her complaint, Plaintiff alleges that she suffered injuries[3] after having a medical device implanted. [Plaintiff's Complaint, Doc. 1-1, ¶ IX, at 6]. In June 2007, at Fort Sanders Regional

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[1] While Plaintiff sued "Boston Scientific," Defendants argue that the correct party name is "Boston Scientific Neuromodulation Corporation." [*See* Defendants' Reply in Support of their Motion to Dismiss, Doc. 15 at 1 n.1].

[2] While Plaintiff sued "Advanced Bionics," Defendants argue that the correct party name is "Advanced Bionics Corporation." [*See* Defendants' Memorandum of Law in Support of their Motion to Dismiss, Doc. 9 at 1 n.1].

[3] Plaintiff alleges that "[a]s a direct and proximate result of the defendant's negligence, the plaintiff suffered and was injured in health, strength, and activity and sustained injury to her body, and shock and injury to her nervous system causing her physical, mental, and nervous pain and suffering . . ." [Plaintiff's Complaint, Doc. 1-1, ¶ XI, at 9].

Medical Center in Knoxville, Tennessee, Plaintiff had a spinal cord simulation system device implanted. [Id.]. This device, the "Implantable Pulse Generator Advanced Bionics Precision SCS, Model number IPG SC-1110" (hereafter, the "Device"), is used to treat back pain. [Id.]. On October 6, 2007, a recall was issued for the model that Plaintiff had implanted. [Notice of Recall, Doc. 1-1 at 12-15]. According to Boston Scientific, only 8 patients out of 12,700 reported problems with the Device. [Field Safety Notice, Doc. 1-1 at 17]. On March 20, 2009, after "much pain and intense suffering and massive infection," Plaintiff had the Device removed.[4] [Plaintiff's Complaint, Doc. 1-1, ¶ IX, at 7].

Plaintiff has filed product liability claims against Boston Scientific and Advanced Bionics, the corporations which allegedly "designed, manufactured, assembled, distributed and sold" the Device. [Id.¶ V, at 4]. In addition, Plaintiff has sued Scott Stewart, a field sales representative for Boston Scientific, who allegedly "maintained, sold, serviced, controlled, installed and removed" the Device. [Id. ¶ VI, at 5]. Plaintiff has also sued "John Does 1-5," several unidentified defendants [Id.].

Plaintiff has sued Defendants under several theories, including negligence, reckless misconduct, malice, fraud and oppression, and strict liability "in manufacturing, designing, assembling distributing maintaining, repairing, servicing, selling and installation"of the Device," and in "failing to include warnings as to its dangerous propensities and handling characteristics." [Id. ¶X.1, at 7]. While Plaintiff has not clearly identified her causes of action, it appears that she has sued Defendants under theories of defective design, defective manufacturing, and "failure to warn,"

[4] Plaintiff does not explain what pain (or injuries) were allegedly caused by the Device. Instead, Plaintiff alleges that after "much pain and intense suffering and massive infection," Plaintiff had the Device removed. [Plaintiff's Complaint, Doc. 1-1, ¶ IX, at 7].

among others.

On June 4, 2010, Defendants moved to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Defendants argue that Plaintiff failed to satisfy the federal pleading requirements, as modified in Twombly, 550 U.S. 544, and Iqbal, 129 S.Ct. 1937. On October 19, 2010, Plaintiff responded in opposition. [Plaintiff's Response to Defendants' Motion to Dismiss, Doc. 13]. On October 28, 2010, Defendants filed a Reply in support of their Motion to Dismiss [Doc. 16]. The matter is now ripe for adjudication.

II. STANDARD OF REVIEW

Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In 2007, the Supreme Court modified the pleading standard in the context of antitrust cases. Twombly, 550 U.S. at 570. Notably, the Supreme Court held that in order to survive a 12(b)(6) motion to dismiss–which attacks the sufficiency of a complaint–the plaintiff must "state a claim to relief that is *plausible* on its face." Id. (emphasis added). In 2009, the Supreme Court extended the Twombly (or plausibility) standard to all federal civil cases. Iqbal, 129 S.Ct. at 1953.

Under the new standard, a claim is facially plausible if the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. at 1949 (citing Twombly, 550 U.S. at 556). While this is not akin to a "probability requirement," the plaintiff must show "more than a sheer possibility that a defendant has acted unlawfully." Id. (citing Twombly, 550 U.S. at 556). This "requires 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 (citations and quotation marks omitted). In other words, a plaintiff must "plead

factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 129 S.Ct. at 1949. A plaintiff falls short if he pleads facts "merely consistent with a defendant's liability" or if the alleged facts do not "permit the court to infer more than the mere possibility of misconduct . . ." Id.

In ruling upon motions to dismiss under Rule 12(b)(6), a court must "construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff." DIRECTV, 487 F.3d at 476. However, the court "need not accept as true legal conclusions or unwarranted factual inferences." Id. (quoting Gregory v. Shelby Cnty., 220 F.3d 433, 446 (6th Cir. 2000)). *See also* Iqbal, 129 S.Ct. at 1949 ("[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.") (citing Twombly, 550 U.S. at 555). Ultimately, this determination–whether a plaintiff's claim is "plausible"–is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Iqbal, 129 S.Ct. at 1950 (citations omitted).

III. ANALYSIS

A. Twombly Applies to All Civil Cases in Federal Court, Including State Law Claims Removed to Federal Court

As an initial matter, Plaintiff argues that the Court should look to Tennessee law for pleading requirements. [Plaintiff's Response to Defendants' Motion to Dismiss, Doc. 13 at 4]. In other words, Plaintiff wants the Court to apply Tennessee law–instead of Twombly–in ruling upon the 12(b)(6) motion. [Id.]. According to Plaintiff, the Court "should follow state law pleading requirements since this is a claim based upon state law . . ." [Id.].

Plaintiff's argument is without merit. It does not matter whether Plaintiff's claims are based upon state law or federal law: all claims, once removed to federal court, are subject to federal pleading requirements. In Iqbal,. the Supreme Court held that Twombly's plausibility standard applies to *all* civil cases in federal court. 129 S.Ct. at 1953. In Iqbal, the respondents argued that the plausibility standard should be limited to antitrust cases, as in Twombly. Id. The Supreme Court rejected this argument, holding that the plausibility standard applies to all civil cases in federal court:

> Though Twombly determined the sufficiency of a complaint sounding in antitrust, the decision was based on our interpretation and application of Rule 8. That Rule in turn governs the *pleading standard in all civil actions and proceedings in the United States district courts*.

Id. (emphasis added) (citations and quotations omitted). *See also* Minger v. Green, 239 F.3d 793, 799-801 (6th Cir. 2001) (applying federal pleading rules in a case based upon diversity jurisdiction); Wilkey v. Hull, 366 F. App'x 634, 637 (6th Cir. 2010) (applying Twombly pleading standard in a diversity case to determine whether the plaintiff alleged sufficient facts to support state law claims); Foust v. Stryker Corp., No. 2:10-cv-00005, 2010 WL 2572179, at *2 (S.D. Ohio Jun. 22, 2010) (applying Twombly pleading standard to a complaint alleging product liability claims under Ohio law).

Although the complaint was filed in state court, it was eventually removed to federal court. As a result, the complaint is subject to federal pleading requirements, which includes Rule 8(a)(2) of the Federal Rules of Civil Procedure. *See* Granny Goose Foods, Inc. v. Brotherhood of Teamsters & Auto Truck Drivers Local No. 70 of Alameda Cnty., 415 U.S. 423, 438 (1974) ("The Federal Rules of Civil Procedure, like other provisions of federal law, govern the mode of proceedings in

federal court *after removal*.") (emphasis added); Fed R. Civ. P. 81(c) ("These rules apply to civil actions removed to the United States district courts from the state courts and *govern procedure after removal*.") (emphasis added). In Twombly, 550 U.S. at 550, and Iqbal, 129 S.Ct. at 1953, the Supreme Court modified Rule 8(a)(2) by incorporating a "plausibility" standard. Accordingly, the Court must determine whether Plaintiff has "state[d] a claim to relief that is *plausible* on its face." Twombly, 550 U.S. at 570 (emphasis added).

B. Plaintiff's Complaint Does Not Satisfy Twombly's Pleading Requirements

1. Introduction

Defendants argue that Plaintiff's complaint does not satisfy Twombly because it does not "plead sufficient factual allegations concerning how the product was purportedly defective, and how the purported defect caused her alleged injury." [Defendants' Reply in Support of their Motion to Dismiss, Doc. 15 at 3]. In response, Plaintiff argues that her complaint satisfies Twombly because it put Defendants "on notice that this it [sic] is a products liability case, that the Defendants[s] are the maker of a defective product, and that this defective product had to be removed from the Plaintiff's body." [Plaintiff's Response in Opposition to Defendants' Motion to Dismiss, Doc. 14 at 3]. Having reviewed Plaintiff's complaint, the Court finds that it fails to allege sufficient facts to support a product liability action.

While Plaintiff has filed several claims against Defendants, each is covered by the Tennessee Product Liability Act of 1978 ("TPLA"), T.C.A. §§ 29-28-101 *et seq*.[5] *See* Higgs v. Gen. Motors

[5] The TPLA defines "product liability action" to include "all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product." T.C.A. § 29-29-102(6). In addition, the TPLA states that a "'products liability action' includes, but is not limited to, all actions based upon the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or

Corp., 655 F. Supp. 22, 23 (E.D. Tenn. 1985) ("Indeed, it makes no difference whether the complaint is couched in terms of negligence, strict liability or breach of warranty, it has generally been held in the State of Tennessee that in order for a plaintiff to recover under any theory of product liability, the plaintiff must establish that the product was defective and unreasonably dangerous at the time the product left the control of the manufacturer."). Regardless of Plaintiff's theory of recovery–which includes strict liability, defective design, defective manufacturing, failure to warn–Plaintiff must allege facts for the Court to infer that the Device was "defective" or "unreasonably dangerous" at the time it left the control of the manufacturer. *See* King v. Danek Med., Inc., 37 S.W.3d 429, 435 (Tenn. Ct. App. 2000) ("Unless the product was in a defective condition or unreasonably dangerous when it left the control of [the manufacturer], there is no liability pursuant to [the TPLA]"); T.C.A § 29-28-105(a) ("*A manufacturer or seller of a product shall not be liable for any injury to person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous* at the time it left the control of the manufacturer or seller.") (emphasis added). At this stage in the proceeding, Plaintiff must allege facts for the Court to infer that: "(1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product." Sigler v. Am. Honda Motor Co., 532 F.3d 469, 483 (6th Cir. 2008) (citing King, 37 S.W.3d at 435). Under the TPLA, a product is "defective" if it is a "product that renders it unsafe for normal or anticipate handling and consumption." T.C.A. § 29-28-102(2). In addition, a product is "unreasonably dangerous" if it is

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instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever [.] Id.

"dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller assuming that he knew of its dangerous condition." T.C.A. § 29-28-102(8).

In Tennessee, there are two tests for determining whether a product is unreasonably dangerous. *See* T.C.A. § 29-28-102(8). Under the "consumer expectation test," this "requires a showing that the product's performance was below reasonable minimum safety expectations of the ordinary consumer having ordinary, 'common' knowledge as to its characteristics." Jackson v. Gen. Motors Corp., 60 S.W.3d 800, 806 (Tenn. 2001). Under the "prudent-manufacturer test," the Court "imputes knowledge of the dangerous condition to the manufacturer, and then asks whether, given that knowledge, a prudent manufacturer would market the product. As the Tennessee Supreme Court has articulated, '[t]he consumer expectation test is, by definition, buyer oriented; the prudent manufacturer test, seller oriented.'" Johnson v. Manitowoc Boom Trucks, Inc., 484 F.3d 426, 428-29 (6th Cir. 2007) (citations omitted). Only sellers and manufacturers may be held liable under the TPLA.[6] *See* T.C.A. § 29-28-102(4), (7).

In all product liability actions, "[a] plaintiff must show that there was something wrong with the product, and trace the plaintiff's injury to the specific defect." King, 37 S.W.3d at 435 (citations omitted). *See also* Browder v. Pettigrew, 541 S.W.2d 402, 404 (Tenn. 1976) (holding that in order

[6] The TPLA defines "manufacturer" as "the designer, fabricator, producer, compounder, processor or assembler of any product or its component parts." T.C.A. § 29-28-102(4). The TPLA defines "seller" as "a retailer, wholesaler, or distributor, and means any individual or entity engaged in the business of selling a product, whether such sale is for resale, or for use or consumption." TCA § 29-28-102(7).

to establish a defective design claim, the plaintiff must "trace the injury to some specific error in construction or design of the [product]" and that "in a products liability action in which recovery is sought under the theory of negligence, the plaintiff must establish the existence of a defect in the product just as he does in an action where recovery is sought under the strict liability theory or for breach of warranty, either express or implied.") (citations omitted). At this stage in the proceedings, Plaintiff must allege facts for the Court to infer that the Device was defective, and that Plaintiff's injuries were caused by the condition of the Device. In this case, Plaintiff has failed to do both.

2. Plaintiff Failed to Allege Sufficient Facts for the Court to Infer that the Device Was Defective or Unreasonably Dangerous

The fact that Plaintiff allegedly suffered an injury from the Device does not show that the Device was defective. *See* King, 37 S.W.3d at 435 ("[i]n a product liability claim, the fact that a plaintiff is injured is not proof of a defect in the product") (citing Whaley v. Rheem Mfg. Co., 900 S.W.2d 296, 299 (Tenn. Ct. App. 1995); King, 37 S.W. 3d at 435 (recognizing that "the failure or malfunction of the device, without more, will not make the defendant liable") (citing Harwell v. Am. Med. Sys., Inc., 803 F. Supp. 1287, 1298 (M.D. Tenn. 1992)); Allen v. Am. Med. Sys., Inc., 1989 WL 105626 (Tenn. Ct. App. Sept. 15, 1989) (declining to find liability based upon the fact that the device did not function). Even assuming that the Device injured Plaintiff, that is not enough to show that the Device was defective or unreasonably dangerous–an element necessary for each of Plaintiff's claims. Instead of alleging facts for the Court to infer that the Device was defective or unreasonably dangerous, Plaintiff asserts conclusory allegations. For example, Plaintiff alleges that the "defective medical device [the Device] was not fit for the purpose intended and was defective and therefore caused the plaintiff harm." [Plaintiff's Complaint, Doc. 1-1, ¶ IV, at 6].

The facts of the present case are similar to Frey v. Novartis Pharm. Corp, 642 F. Supp. 2d

787 (S.D. Ohio 2009). In Frey, the plaintiff filed a product liability action in state court against the manufacturer of an anti-seizure medication. Id. at 790. The plaintiff alleged that she suffered health complications after ingesting the medication. Id. The plaintiff sued the manufacturer under theories of defective design and manufacturing (under Ohio law). Id. In support of her claims, the plaintiff alleged the following:

> Defendants failed to design, manufacture, test, and control the quality of [the anti-seizure medication] such that when it left the control of the Defendant, it deviated in a material way from the design specification, formula or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula or performance standards.
>
> As a direct and proximate result of the defect in manufacture or construction by Defendants, Plaintiff [] suffered the injuries [] and damages set forth herein.

Id.

The defendant manufacturer removed the action to federal court, and then moved to dismiss under Rule 12(b)(6). Id. In particular, the defendant argued that the complaint failed to satisfy Twombly's pleading requirements. In response, the plaintiff argued that she could not "particularly allege that the scientific makeup of the drug is defective for a specific reason without conducting discovery, which requirement would exceed Twombly's plausibility standard." Id. at 792. The district court dismissed the defective design and manufacturing claims, finding that the complaint failed to satisfy Twombly:

> Plaintiffs' first cause of action for strict liability for defect in the manufacture [and design] of [the anti-seizure medication] . . . must be dismissed pursuant to Rule 12(b)(6) for failure to state a plausible claim for relief. Plaintiffs have done nothing more than provide a formulaic recitation of the elements of a claim under the statute. They have failed to allege any facts that would permit the Court to conclude that a manufacturing defect [or design defect] occurred and

> that the defect was the proximate cause of [the Plaintiffs'] alleged injuries. Plaintiffs' allegations in this regard fall far short of the sufficiency standard set forth in Twombly.

Id. at 795.

Like the plaintiff in Frey, Plaintiff in the present case asserts legal conclusions about the nature of the Device. For example, Plaintiff alleges that Defendants "failed to warn" others of the "dangerous propensities and handling characteristics" of the Device. [Plaintiff's Complaint, Doc. 1-1, ¶ X.1, at 7]. However, Plaintiff does not allege any facts for the Court to infer that the Device was unreasonably dangerous. To plead a "failure to warn" claim[7], Plaintiff must allege facts for the Court to infer that the Device was "unreasonably dangerous" within the meaning of T.C.A. § 29-28-102(8). *See* Evridge v. Am. Honda Motor Co., 685 S.W.2d 632, 636 (Tenn. 1985) (defining an adequate warning–which is a defense to a "failure to warn" claim–as "one calculated to bring home to a reasonably prudent user of the product the nature and the extent of the *danger involved in using the product*") (emphasis added). Regardless of the theory of recovery–whether it be breach of warranty, negligence, defective design–Plaintiff must allege facts for the Court to infer that the Device was defective or unreasonably dangerous. *See, e.g.*, Friedman v. Intervet Inc., No. 3:09CV2945, 2010 WL 2817257, at *3, 4 (S.D. Ohio Jul. 16, 2010) (denying a defendant manufacturer's motion to dismiss a product liability action because "[u]nlike Frey, in this case, *plaintiff alleges specific problems with the product* [a veterinary pharmaceutical used to treat diabetes in animals]; namely, that test results showed the product was out of specification with

[7] There are two types of "failure to warn" claims: post-sale claims, and pre-sale claims. *See* Flax v. DaimlerChrysler Corp., 272 S.W.3d 521, 541-42 (Tenn. 2008) (recognizing that a post-sale "failure to warn" claim "arises when the manufacturer or seller becomes aware that a product is defective or unreasonably dangerous after the point of sale and fails to take reasonable steps to warn consumers who purchased the product," and that a pre-sale "failure to warn" claim arises when "a manufacturer or seller had knowledge of a defect at the time of sale") (citations omitted).

regard to its primary compound, and that this was a deviation from the product's intended characteristics" and that "[p]laintiff's allegations–detailing the product's problem . . . are more than sufficient to nudge [] [his] claims across the line from conceivable to plausible") (emphasis added) (quotations and citation omitted). Like the plaintiff in Frey, Plaintiff failed to satisfy Twombly's plausibility standard because she did not allege facts for the Court to infer that the Device was defective or unreasonably dangerous.

3. Plaintiff Failed to Allege Sufficient Facts for the Court to Infer a Causal Connection Between the Device's Condition and Her Alleged Injuries

Plaintiff's complaint fails for a second reason: she did not allege facts for the Court to infer that the *condition* of the Device–based upon an alleged design or manufacturing defect–caused her alleged injuries. As Tennessee courts make clear, it is not enough that Plaintiff suffered injuries from using (or in this case, having implanted) a product. *See, e.g.,* Browder, 541 S.W.2d at 404 (holding that in order to establish a product liability claim, the plaintiff must "trace the injury to some specific error in construction or design of the [product]"). While Plaintiff alleges that the Device caused her pain, she does not allege facts regarding how an alleged defect–whether it be in design or manufacturing–caused her injuries. The relevant question is not whether the Device caused her pain; the issue is whether the alleged *defective design or manufacturing* of the Device caused her pain. *See* id. Plaintiff has not alleged any facts regarding this issue.

On a final note, the Court finds Plaintiff's allegations regarding a recall insufficient to support her product liability claims. While a Notice of Recall [Doc. 1-1, at 12-15] was issued in February 2008[8], Plaintiff alleges that she was not informed until much later. [Plaintiff's Complaint, Doc. 1-1, ¶ X.2, at 8]. In particular, Plaintiff alleges that "the defective device remained in the

[8] The actual recall was initiated on October 5, 2007. [*See* Notice of Recall, Doc. 1-1 at 12].

plaintiffs' [sic] person causing pain and injury for a period of more than sixteen months after the recall of this defective device, which was unknown and never at anytime published to the plaintiff. Plaintiff believes and avers that the facts and circumstances which lead to the recall of this defective device and that they were known to the defendants at the time, or shortly thereafter, its installment into the plaintiffs' body." [Id.]. In support of her product liability claims, Plaintiff attached the Notice of Recall to her complaint. [Doc. 1-1, at 12-15]

In ruling upon a Rule 12(b)(6) motion to dismiss, courts consider the complaint as well as "*documents incorporated into the complaint by reference*, and matters of which a court may take judicial notice." Bowers v. Wynne, 615 F.3d 455, 470 (6th Cir. 2010) (emphasis added) (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007)). *See also* Bassett v. NCAA, 528 F.3d 426, 430 (6th Cir. 2008) ("When a court is presented with a Rule 12(b)(6) motion, it may consider the Complaint and any exhibits attached thereto . . . so long as they are referred to in the Complaint and are central to the claims contained therein.") (citation omitted). Because the complaint expressly mentions the recall, and because it is central to Plaintiff's product liability claims, the Notice of Recall [Doc. 1-1 at 12-15] will be incorporated by reference. The Notice of Recall, which was issued on February 27, 2008, states that the Device was recalled for the following reason:

> Incorrect Data–Corruption of internal memory component results in an inability for the physician to reprogram the IPG [Implantable Pulse Generator, the type of device that Plaintiff had implanted] with firmware version prior to Revision 3.02. When this occurs, the IPG will report an error code of '10h0' or '00h0' through the Remote Control. Under this condition, the IPG will cease to log in some data that could be used for informational purposes. . . .

[Id. at 14]. In addition, Boston Scientific issued a Field Safety Notice[9] on October 24, 2007, stating the following:

> This condition does not affect routine IPG functionality. The IPG delivers the same therapy as it would without the error, and the Remote Control continues to allow the full range of simulation parameter adjustment. The IPG, however, will cease logging of some data that could be used for informational purposes.

[Field Safety Notice, Doc. 1-1 at 16]. The Field Safety Notice states that only "8 patients out of over 12,7000 implanted IPGs (0.063%)" suffered from the recall problem. [Id. at 17].

While Plaintiff attached the Notice of Recall [Doc. 1-1 at 12-15] and Field Safety Notice [Doc. 1-1 at 16-17] to her complaint, she failed to allege facts for the Court to infer a connection between the recall, the condition of the Device, and her alleged injuries. Notably, Plaintiff does not allege that the Device malfunctioned, or that the Device suffered from the recall problem. Moreover, it does not appear that the recall was even motivated by a safety concern. As Defendants explain, the recall "was related to a software issue in the device's remote control memory, which would result in an error code being displayed on the remote control screen." [Defendants' Memorandum of Law in Support of their Motion to Dismiss, Doc. 9 at 3]. In sum, Plaintiff failed to allege facts regarding: (1) whether the recall was based upon injuries to other persons, or a concern about future injuries; (2) whether the Device suffered from the recall problem; and (3) assuming that the Device suffered from the recall problem, whether such condition caused her alleged injuries.

IV. CONCLUSION

As the Supreme Court stated in Iqbal, "[a] pleading that offers 'labels and conclusions' or

[9] The Field Safety Notice [Doc. 1-1 at 16-17] will also be incorporated by reference for purposes of the 12(b)(6) motion to dismiss.

'a formulaic recitation of the elements of a cause of action will not do.'" Iqbal, 129 S.Ct. at 1949 (quoting Twombly, 550 U.S. at 555). Plaintiff's complaint fails for two reasons. First, Plaintiff failed to allege facts for the Court to infer that the Device was defective or unreasonably dangerous. Second, Plaintiff failed to allege facts for the Court to infer that the product's condition caused Plaintiff's alleged injuries.

Based upon the foregoing, Defendants' Motion to Dismiss [Doc 8] is **GRANTED**, whereby Plaintiff's complaint is **DISMISSED**. However, Plaintiff is granted 30 days from entry of this Memorandum and Order to file an amended complaint. If Plaintiff fails to file an amended complaint within this time period, or if the amended complaint fails to satisfy federal pleading requirements, judgment shall be entered in favor of the Defendants.

IT IS SO ORDERED.

ENTER:

s/ Thomas W. Phillips
United States District Judge