

Case No. 1:12-cv-00437-TWP-DKL

walking. Ultimately, the Trident Device failed, resulting in Ms. Gray having to undergo a second hip replacement surgery to replace the Trident Device with a different prosthetic.

Ms. Gray alleges that the defective nature of the Trident Device was demonstrated by wear marks appearing on the bearing that was removed from her hip joint. She claims the defect at issue was caused by manufacturing problems and poor quality control at the manufacturing facility, and that the Food and Drug Administration (“FDA”) made a finding that the Trident prosthetic devices were not manufactured appropriately and recalled the products. Additionally, Ms. Gray alleges that Defendants were aware of the FDA’s findings and the concerns regarding improper wear of the Trident Device, and did not warn Ms. Gray and/or her medical providers of these concerns.

II. LEGAL STANDARD

When reviewing a 12(b)(6) motion, the Court takes all well-pleaded allegations in the complaint as true and draws all inferences in favor of the plaintiff. *Bielanski v. Cnty. of Kane*, 550 F.3d 632, 633 (7th Cir. 2008) (citations omitted). However, the allegations must “give the defendant fair notice of what the . . . claim is and the grounds upon which it rests” and the “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Pisciotta v. Old Nat’l Bancorp.*, 499 F.3d 629, 633 (7th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Stated differently, the complaint must include “enough facts to state a claim to relief that is plausible on its face.” *Hecker v. Deere & Co.*, 556 F.3d 575, 580 (7th Cir. 2009) (citations omitted). To be facially plausible, the complaint must allow “the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). A party’s claim should only be dismissed if it is clear that no set of facts in support of the claim would entitle the party to relief.

Ledford v. Sullivan, 105 F.3d 354, 356 (7th Cir. 1997) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)). “In ruling on a 12(b)(6) motion, a district court may take judicial notice of matters of public record without converting the 12(b)(6) motion into a motion for summary judgment.” *Anderson v. Simon*, 217 F.3d 472, 474–75 (7th Cir. 2000).

III. DISCUSSION

Defendants make several arguments as to why Ms. Gray’s Amended Complaint should be dismissed. First, Defendants argue that the claims against Stryker must be dismissed because Stryker is not a proper party to the lawsuit. Second, Defendants argue that the Amended Complaint must be dismissed in its entirety because Ms. Gray’s claims are preempted by the Medical Device Amendment (“MDA”), 21 U.S.C. § 360k, to the Federal Food, Drug and Cosmetics Act (“FDCA”), 21 U.S.C. § 301 *et seq.* Third, Defendants argue that Ms. Gray’s Amended Complaint fails to meet minimum federal pleading standards.

A. Stryker as a Proper Party

In her Amended Complaint, Ms. Gray alleges that Stryker designed, manufactured, produced, marketed, or sold the Trident Device. Along with its motion to dismiss, Stryker submitted a Certification of Stryker’s Deputy General Counsel, Michael Cartier, certifying that Stryker does not design, manufacture, produce or sell the Trident Device or any of its components. Dkt. 14-1. A motion to dismiss tests the sufficiency of the plaintiff’s complaint, and the court may only consider those documents that were attached to the complaint, as well as matters of which a court may take judicial notice. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). It is well-settled that a court may not consider matters outside the pleadings without converting a motion to dismiss into a motion for summary judgment. *See* Fed. R. Civ. P. 12(d). “Documents that a defendant attaches to a motion to dismiss are considered

part of the pleadings if they are referred to in the plaintiff's complaint and are central to her claim.” *Venture Assoc. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431 (7th Cir. 1993).

Stryker is asking the Court to consider materials outside of the Amended Complaint to determine that Stryker is not a proper party; however, at this stage and for purposes of this Motion, the Court must accept all well-pleaded allegations in the Amended Complaint to be true and construe all reasonable inferences in Ms. Gray’s favor. *See Reed v. City of Chicago*, 77 F.3d 1049, 1051 (7th Cir. 1996). Mr. Cartier’s certification is not a matter of public record of which the Court may take judicial notice, nor does Ms. Gray make any references to Mr. Cartier’s certification in her Amended Complaint; thus, the Court may not construe it as being part of her pleading. Therefore, the Court will not consider Mr. Cartier’s certification and cannot make the determination that Stryker is not a proper party at this stage in the litigation.

B. MDA Preemption

Defendants argue that Ms. Gray’s claims must be dismissed because they are preempted due to the Trident Device’s classification as a Class III device pursuant to the MDA. Under the MDA, medical devices are placed into one of three “classes” that correspond with the level of oversight required by the FDA. Class I devices are those that pose little or no risk of illness or injury, and are subject only to “general controls” applicable to all devices. *See* 21 U.S.C. § 360c(a)(1)(A). Class II devices pose potentially greater risks, and their manufacturers must comply with federal performance regulations known as “special controls.” *See* 21 U.S.C. § 360c(a)(1)(B). Class III devices are subject to the greatest level of oversight because they present a potential unreasonable risk of illness or injury, or are for use in supporting or sustaining human life, or preventing impairment of human health. *See* 21 U.S.C. § 360c(a)(1)(C). Class III medical devices go through a pre-market approval (“PMA”) process, which is a rigorous process

of federal review for safety and effectiveness. *See* 21 U.S.C. § 360e; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-20 (2008).

As an initial matter, Defendants ask the Court to take judicial notice of the fact that the Trident Device is a Class III medical device, a fact which is not pleaded in Ms. Gray's Amended Complaint. A district court may take judicial notice of matters of public record without converting a motion for failure to state a claim into a motion for summary judgment. *See, e.g., Anderson*, 217 F.3d at 474–75; *Doherty v. City of Chicago*, 75 F.3d 318, 325 n.4 (7th Cir. 1996); 5A Wright & Miller § 1357, at 299 (noting the exception applies to “matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint”). Several courts throughout the country have used publically available records from the FDA to determine that the Trident hip implant system is approved as a Class III device.¹ *See Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 530-31 (S.D. Tex. 2009); *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 201 n.3 (W.D.N.Y. 2011); *Bass v. Stryker Corp.*, 669 F.3d 501, 508 (5th Cir. 2012); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 481 (W.D. Pa. 2012); *Phillips v. Stryker Corp.*, No. 3:09-cv-488, 2010 WL 2270683, at *5 n.3 (E.D. Tenn. June 3, 2010); *Covert v. Stryker Corp.*, No. 1:08-CV-447, 2009 WL 2424559, at *1 n.2 (M.D.N.C. Aug. 5, 2009). Ms. Gray does not argue that the Trident Device is not classified as a Class III device, only that the Court should not make such a determination at this preliminary stage. However, because the FDA approval letter for the Trident Device is a publically and readily available “source whose accuracy cannot reasonably be questioned” as required by Federal Rule of Evidence 201(b), the

¹ The Court was able to locate a copy of the Osteonics ABC System and Trident System – P000013 Approval Letter, showing that the application was approved on February 3, 2003, via the FDA's website at http://www.accessdata.fda.gov/cdrh_docs/pdf/p000013a.pdf, as well as a summary of the FDA's approval at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm082655.htm> (last accessed February 14, 2013).

Court will exercise its discretion and take judicial notice that the Trident Device is a Class III medical device subject to the MDA.

The MDA includes an express, but limited, preemption provision for product liability claims against manufacturers of Class III medical devices, which provides:

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). The MDA does not, however, preempt state or local requirements that are equal to, or substantially identical to, requirements imposed by or under the FDCA, also referred to as “parallel” claims. *Riegel*, 552 U.S. at 330 (“State requirements are pre-empted under the MDA only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal law.”) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

The Seventh Circuit in *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), determined that claims for defective manufacture of Class III medical devices in violation of federal law are not expressly preempted by § 360k of the MDA, and that § 360k provides immunity for manufacturers of Class III devices only to the extent that they comply with federal law. 630 F.3d at 553. The plaintiff’s claim in *Bausch* also involved the Trident brand hip replacement system, and she alleged that the defendants violated federal law in the manufacturing of the device. The plaintiff brought a claim under Illinois common law for negligence and strict liability for a defective product, alleging that the failed device was implanted six days after the FDA informed the defendants that a component of the Trident hip system was “adulterated” and that the companies’ manufacturing processes failed to comply with federal standards. The Seventh Circuit concluded that the plaintiff’s claims that she was injured by defendants’ alleged

violations of federal law were not preempted, either expressly or impliedly. *Id.* at 549. The Seventh Circuit determined that the plaintiff could bring a state law claim for breach of duty to use due care in manufacturing a medical device, so long as she could show that she was harmed by a violation of applicable federal law. *Id.* at 558.

Defendants attempt to argue that Ms. Gray has not alleged any violations of federal law in her complaint, thus *Bausch* is inapplicable. However, Ms. Gray's Amended Complaint clearly alleges that the defect was caused by "manufacturing problems and poor quality control" and that its recall was based on "the FDA's finding that the Prosthetic Device was not manufactured properly." Dkt. 10 at 3, ¶¶ 19-20. The claims in Ms. Gray's Amended Complaint reference violations of the requirements set forth by the FDA as the cause of the alleged defects, not that the device violated Indiana products liability laws despite compliance with federal regulations and requirements. It is not necessary that Ms. Gray include the specific federal laws or regulations at issue in her Amended Complaint, only that she put the Defendants on notice that her claims are premised upon allegations that some federal law or regulation was violated. Thus, Ms. Gray has sufficiently pleaded a parallel claim that is not subject to § 360k preemption under *Riegel*.

C. Minimum Federal Pleading Standards

Defendants also argue that Ms. Gray's Amended Complaint must be dismissed because she fails to satisfy minimum federal pleading standards. Defendants believe that Ms. Gray should have included in her Amended Complaint facts showing that the problems with her prosthetic device were the result of manufacturing defects and not physician error, how the FDA's findings relate to the defect that she alleges, and state which specific device components were manufactured inappropriately. Dkt. 14 at 12. Defendants also argue that Ms. Gray should

have identified the applicable federal regulations or requirements that she alleges the Defendants violated. Dkt. 19 at 5. However, this level of specificity is not required to be included in the complaint under the “plausibility” standard applied in *Iqbal* and *Twombly*.

With regard to pleading product liability claims for Class III medical devices, the Seventh Circuit in *Bausch* acknowledged “how difficult it is to plead such a claim sufficiently to survive a motion to dismiss for failure to state a claim” and that “[f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.” *Id.* at 558. Plaintiffs in these medical device defect cases are not expected to plead violations of specific federal laws or product specific information, not only because it is not required under the notice pleading standard of Federal Rule of Civil Procedure 8(a)(2), but also because plaintiffs often do not have access to product-specific information about the manufacturing of these devices, which are kept confidential by federal law, until they are able to obtain this information through discovery. *Id.* The court in *Bausch* stated that “[t]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular.” *Id.* Ms. Gray’s Amended Complaint is sufficient to put Defendants on notice that the basis for her claim is that the Trident Device’s manufacturing process did not comply with the requirements set forth by the FDA, thus Ms. Gray sufficiently alleges a violation of federal law and states a parallel claim that survives a 12(b)(6) motion.

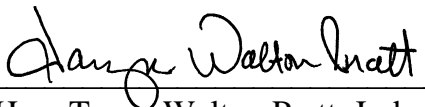
IV. CONCLUSION

For the forgoing reasons, Defendants' Motion to Dismiss the Amended Complaint (Dkt.

13) is **DENIED**.

SO ORDERED.

Date: 02/20/2013


Hon. Tanya Walton Pratt, Judge
United States District Court
Southern District of Indiana

DISTRIBUTION:

Jeffrey S. Zipes
COOTS HENKE & WHEELER, P.C.
jzipes@chwlaw.com

Bruce Benjamin Paul
STITES & HARBISON, LLP
bpaul@stites.com

Douglas B. Bates
STITES & HARBISON, LLP
dbates@stites.com