IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

ANNA RAAB, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:14-cv-30279

SMITH & NEPHEW, INC.,

Defendant.

MEMORDANUM OPINION AND ORDER

Pending before the Court is Defendant's Motion to Dismiss the Amended Complaint (the "Motion to Dismiss"). (ECF No. 22.) For the reasons discussed herein, the Motion to Dismiss is **GRANTED IN PART**, and **DENIED IN PART**.

I. Background

In early 2010, Plaintiff Anna Raab underwent two hip surgeries at St. Francis Hospital in Charleston, West Virginia, pursuant to which she was implanted with medical device components developed and manufactured by the defendant, Smith & Nephew, Inc. This is a lawsuit seeking redress, under various state law causes of action, for the severe and permanent injuries that Mrs. Raab and her husband allege resulted from the failure of the defendant's products.

The defendant is a developer and manufacturer of joint replacement systems. (ECF No. 21 (Plaintiff's Amended Complaint) ¶ 5.) As relevant to this case, the defendant manufactures the Birmingham Hip Resurfacing System ("BHR System"), a metal-on-metal hip resurfacing

prosthesis that consists of two constituent components: (1) a Birmingham Resurfacing Femoral Head (the "femoral head"); and (2) a Birmingham Hip Resurfacing Acetabular Cup (the "acetabular cup"). (*Id.*) As will be fully discussed below, the BHR system is a Class III medical device and as such was required to receive premarket approval ("PMA") pursuant to a rigorous review process administered by the Food and Drug Administration ("FDA"). This process was completed on May 9, 2006, on which day "the FDA conditionally approved the BHR for commercial distribution." (*Id.* ¶ 6.)

On January 12, 2010, Mrs. Raab underwent the first of her surgeries, a right hip resurfacing performed by Dr. Jason Castle. (*Id.* ¶ 8.) During this surgery, "Dr. Castle utilized and implanted the Defendant's Birmingham resurfacing system." (*Id.*) Accordingly, Mrs. Raab was implanted with both components, the femoral head and the acetabular cup, of the BHR System. About a month later, on February 17, 2010, "it was discovered through diagnostic studies at St. Francis Hospital that Plaintiff suffered a right periprosthetic fracture of the femoral neck." (*Id.* ¶ 9.) As a result, Mrs. Raab went forward with a second procedure, a revision surgery intended to convert her right hip resurfacing into a "right total hip arthroplasty." (*Id.* ¶ 10.) Pursuant to this procedure, Dr. Castle left the acetabular cup in place but "revis[ed]" the femoral head. (*Id.*) Specifically, Dr. Castle implanted the following three components, all manufactured by the defendant, into Mrs. Raab's hip: (1) Synergy Porous High Offset Femoral Component; (2) Modular Head Sleeve; and (3) Modular Femoral Head. (*Id.*) These femoral components are not part of the BHR System approved by the FDA, and the defendant does not dispute that they were cleared by the FDA as Class II devices not subject to any PMA process. (*See* ECF No. 23 at 13.)

In the months following the revision surgery, Mrs. Raab began suffering complications. In response, she went to the University of Pittsburgh Medical Center for the purpose of undergoing a second right hip revision procedure. (ECF No. 21 ¶ 11.) Plaintiffs allege that it was pursuant to this surgery that they were notified, on May 8, 2014, that Defendant's metal-on-metal hip components "had failed." (*Id*.) Plaintiffs further allege that this failure caused several medical complications, as well as the presence of metal debris "in the Plaintiff's surrounding bone and tissue of the right hip, including the presence of pseudotumors." (*Id*.) Ultimately, Mrs. Raab's Pittsburgh physician, Dr. Edwin McClain, III, replaced the BHR acetabular cup, as well as the Modular Femoral Head implanted in the first revision surgery. (*Id*.)

Based on these factual allegations, the plaintiffs filed a complaint in this Court on December 18, 2014. (ECF No. 1.) In response to the defendant's initial motion to dismiss, (ECF No. 15), Plaintiffs sought leave to file an amended complaint, (ECF No. 17). This Court granted that request by Order entered April 20, 2015, (ECF No. 20), and Plaintiff's Amended Complaint (the "Amended Complaint") was filed the same day, (ECF No. 21).

The Amended Complaint asserts five claims for relief against the defendant manufacturer. The first four causes of action seek to assert "parallel state common law claims" based on the defendant's alleged violation of federal statutory and regulatory requirements. (*Id*. ¶¶ 16, 27, 40, 53.) The first two claims arise out of the original surgery on January 12, 2010. One asserts strict products liability and the other negligence, and both seek to impose liability on the premise that the BHR System, including both the femoral head and the acetabular cup, did not comply with the requirements imposed by the Federal Food, Drug and Cosmetic Act ("FDCA") and the regulations promulgated pursuant thereto. (*Id*. ¶¶ 13–14, 24–25). To support the products liability claim,

Plaintiffs allege that the BHR System was "designed and/or manufactured," (*id*. ¶ 13), in violation of the Act and regulations, and that as a result was "unreasonably dangerous," (*id*. ¶ 14). In support of the negligence claim, Plaintiffs again claim that the device was "designed and/or manufactured," (*id*. ¶ 24), in violation of the Act and regulations, and that this violation breached Defendant's duty to comply with that Act and those regulations, (*id*. ¶ 25). In support of both claims, the Amended Complaint references an identical list of specific federal regulations that the defendant allegedly violated, all located within 21 C.F.R. § 820, a quality system regulation prescribing current good manufacturing practice for manufacturers of medical devices.

Plaintiffs' allegations with respect to their third and fourth claims follow a similar pattern. Again, state law strict products liability and negligence are asserted based on the defendant's alleged violation of federal statutes and regulations governing medical devices. These claims, however, are based exclusively on the revision surgery performed on February 17, 2010, and allege violations of a different, and smaller, set of statutory and regulatory requirements. Again, the plaintiffs support their claims for both strict products liability and negligence with reference to the same set of federal requirements. This time, though, the plaintiffs use identical language to support both claims. (*Compare id*. ¶¶ 34–46, *with id*. ¶¶ 47–59.) Plaintiffs' strict products liability claim does not allege that the defendant created an unreasonably dangerous product, as in the first claim for relief. Rather, it borrows the duty-based language of a negligence claim, alleging that the defendant should be liable because "[i]t was the duty of Defendant . . . to comply with the Act, and the regulations promulgated pursuant to it, yet, notwithstanding this duty, Defendant . . . violated the Act in one or more of the following ways . . . ." (*Id*. ¶ 38.) In support

of both claims, Plaintiffs allege violations of 21 U.S.C. §§ 352, 360h-360j, and 360l, as well as 21 C.F.R. § 814.39. (ECF No. 21 ¶¶ 38, 51.)

Pursuant to each of the first four claims, Plaintiff Anna Raab asserts the same measure of harm incurred:

> As a direct result, Plaintiff, Anna Raab, endured pain and suffering, including, but not limited to pseudotumor formation, recurrent dislocations and subluxations with swelling, proximal thigh enlargement, lumps in her groin, pain in her buttocks and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress, both past and future, including, but not limited to, humiliation, embarrassment, annoyance and aggravation.

(*Id*. at ¶¶ 15, 26, 39, 52.)

The fifth claim for relief differs from the first four in that it is not based on violations of federal law. Rather, it asserts a variety of "state law and common law claims" based on the defendant's failures exclusively with respect to the Class II devices implanted in Mrs. Raab on February 17, 2010. (*Id*. at 17.) Specifically, the plaintiffs allege strict products liability under the doctrine of manufacturers' products liability, breach of implied and express warranties, including the implied warranties of merchantability and fitness for a particular purpose, and failure to warn. Mrs. Raab alleges the same measure of harm and damages for these claims as the other parallel claims. (*Id*. ¶ 63.) Pursuant to this overarching fifth claim for relief Plaintiff Terry Raab, Mrs. Raab's husband, asserts a claim for loss of consortium. (*Id*. ¶ 64.) Both Plaintiffs also seek punitive damages based on the "willful, wanton, intentional acts, reckless and/or the willful, wanton, intentional and reckless failures to act by Defendant." (*Id*. ¶ 65.)

On May 4, 2015, the defendant filed the instant Motion to Dismiss, pursuant to Federal Rules of Civil Procedure 8 and 12(b)(6). (ECF No. 21.) Defendant asserts three bases for

dismissal: (1) that claims one through four, seeking to impose liability based on alleged deficiencies in the BHR System, are expressly preempted pursuant to 21 U.S.C. § 360k(a); (2) that the same claims, to the extent they seek to privately enforce the FDCA, are impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); and (3) an overarching argument that all five claims lack sufficient factual detail to state a claim with the specificity required by the Supreme Court decisions in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). (ECF No. 23 at 2.)

II. Standard of Review

Rule 12(b)(6) affords a defendant the opportunity to test the legal sufficiency of the complaint. A motion to dismiss under that rule does not "resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Republican Party v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992). Rather, it serves the crucial role of "defining issues for trial and for early disposition of inappropriate complaints." *Francis* v. *Giacomelli*, 588 F.3d 186, 192 (4th Cir. 2009) (citing 5 Charles Alan Wright & Arthur Miller, *Federal Practice and Procedure*, § 1202 (3d ed. 2004)).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, 'to state a claim for relief that is plausible on its face.'" *Ashcroft*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). This requires the Court to utilize a two-pronged approach. First, it must separate the legal conclusions in the complaint from the factual allegations. Second, assuming the truth of only the factual allegations, the Court must determine whether the plaintiff's complaint permits a plausible inference that "the defendant is liable for the misconduct alleged." *Id*. A sufficient complaint must do more than plead factual allegations that

are "merely consistent with" liability. *Id*. (quoting *Twombly*, 550 U.S. at 557). Labels, conclusions, and a "formulaic recitation of the elements of a cause of action" will not do. *Twombly*, 550 U.S. at 555.

Nonetheless, while well-pleaded factual allegations are essential, a court's inquiry is not so onerous as to require a plaintiff to "'forecast' evidence sufficient to prove the elements of the claim." *Walters v. McMahen*, 684 F.3d 435, 439 (4th Cir. 2012) (quoting *Robertson v. Sea Pines Real Estate Cos.*, 679 F.3d 278, 291 (4th Cir. 2012)). "Th[e] plausibility standard requires only that the complaint's factual allegations 'be enough to raise a right to relief above the speculative level.'" *Houck v. Substitute Tr. Servs., Inc.*, 791 F.3d 473, 484 (4th Cir. 2015) (quoting *Twombly*, 550 U.S. at 555). A motion to dismiss will be granted if, "after accepting all well-pleaded allegations in the plaintiff's complaint as true and drawing all reasonable factual inferences from those facts in the plaintiff's favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief." *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999).

III. Applicable Law

A. The Medical Device Amendments

This case, asserting injuries allegedly stemming from an FDA-approved medical device, arises within a complex and highly regulated area of federal law pursuant to which the contours of permissible private enforcement suits are carefully circumscribed. The starting point is the federal Medical Device Amendments of 1976 ("MDA"), which imposed a "regime of detailed federal oversight" over the market for medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Regulation of medical devices, an expansive field encapsulating everything from

"bedpans to brainscans," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996) (citation omitted), had traditionally been left largely to state supervision. However, rapid technological change and highly publicized instances of medical device failure led many to doubt the ability of the "common-law tort system to manage the risks associated with dangerous devices." *Riegel*, 552 U.S. at 315. In response to this "mounting consumer and regulatory concern," *Lohr*, 518 U.S. at 476, Congress entered the field and enacted the MDA, which "intentionally 'swept back some state obligations' in favor of uniform federal regulation." *Walker v. Medtronic, Inc.*, 670 F.3d 569, 572 (4th Cir. 2012) (quoting *Riegel*, 552 U.S. at 315).

The MDA utilized a two-pronged approach to achieve its purpose. On the one hand, it imposed an intricate regulatory scheme to increase oversight and promote uniformity at the federal level. Correspondingly, as will be discussed below, it eliminated the potential for state enforcement interference by enacting an express preemption clause, 21 U.S.C. § 360k. A key feature of the federal scheme is a graduated classification system designed to tailor the level of FDA oversight to the safety risks posed by a given medical device; the higher the safety risk, the more regulatory requirements apply. *See* 21 U.S.C. § 360c(a)(1). Class I devices present the lowest safety risk and accordingly are subject only to "general controls," such as labelling requirements, imposed by the FDCA and the regulations promulgated pursuant to its authority. *Riegel*, 552 U.S. at 316. Such devices need not adhere to device-specific regulations because general quality controls, applicable to "any finished device . . . intended for human use," 21 C.F.R. § 820.1, are "sufficient to provide reasonable assurance of the safety and effectiveness of the device," 21 U.S.C. § 360c(a)(1)(A)(i).

The safety and effectiveness of Class II devices cannot be guaranteed by these generally applicable controls, and so these devices require further oversight, including device-specific "special controls," such as the promulgation of performance standards, postmarket surveillance, patient registries, and the dissemination of guidelines. *Id.* § 360c(a)(1)(B). Where not even such special controls can ensure the device's safety, and where the device is either useful in supporting or sustaining human life, substantially important in preventing the impairment of human health, or presents an unreasonable risk of illness or injury, the device is given a Class III classification. *Id.* § 360c(a)(1)(C). "Because of the risks associated with them, Class III devices are required to go through pre-market approval 'to provide reasonable assurance of [their] safety and effectiveness.'" *Walker*, 670 F.3d at 573 (quoting 21 U.S.C. § 360c(a)(1)(C)).

Premarket approval is a "rigorous process," *Riegel*, 552 U.S. at 317, designed to fully vet and secure safety and effectiveness "[b]efore a new Class III device may be introduced to the market." *Williams v. Smith & Nephew, Inc.*, ---F.Supp.3d---, Civil No. CCB-14-3138, 2015 WL 4984531, at *1 (D. Md. Aug. 18, 2015) (quoting *Lohr*, 518 U.S. at 477). The PMA process for new devices is governed by 21 U.S.C. § 360e, as well as regulations promulgated under its authority. Where PMA is required, the device's proponent must file with the Secretary of the FDA an application providing a wide variety of information: reports of all investigations into the safety and effectiveness of the device, a statement of its components, a full description of the methods used to manufacture and produce the device, device samples, and specimens of proposed labelling. 21 U.S.C. § 360e(c)(1). This application process "typically requires a 'multivolume application.'" *Walker*, 670 F.3d at 573 (quoting *Riegel*, 552 U.S. at 317). Within 180 days of receipt of such application, the FDA is required to making a decision regarding approval. "The

FDA will grant premarket approval only if it finds that there is 'reasonable assurance' of the device's safety and effectiveness.'' *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 100 (D. Conn. 2014) (quoting 21 U.S.C. § 360e(d) and *Riegel*, 552 U.S. at 319).

The FDA has broad authority to condition its approval in a number of ways, including requiring that the device meet formal performance standards, 21 C.F.R. § 861.1(b)(3), or any other post-approval requirement "necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device" imposed either in "a PMA approval order or by regulation at the time of the approval of the PMA or by regulation subsequent to approval," *id*. § 814.82(a). These post-approval requirements can include restrictions on the sale, distribution, or use of the device, continuing reporting and recordkeeping requirements, and requirements related to labelling and advertising of the restricted device. *Id*.

Once a medical device successfully obtains PMA approval, the MDA "forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing process, labelling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. §360e(d)(6)(A)(i). In order to get FDA permission to make such changes, a device manufacturer must submit a supplemental application, pursuant to 21 U.S.C. § 360e(d)(6)(A)(1). This application must "describ[e] the change in detail and summarize[e] the findings supporting the change," *Walker*, 670 F.3d at 573 (citing 21 U.S.C. § 360e(d)(6)(A)(1)), and is to be evaluated under "largely the same criteria as an initial application." *Riegel*, 552 U.S. at 319.

Moreover, the FDCA and its accompanying regulations impose continuing requirements on medical devices and their manufacturers after they receive PMA. These include several

reporting requirements, imposing a general obligation to inform the FDA about the known adverse consequences of the device. The "rigorous oversight regime" following approval generally requires that:

> Approved medical devices are also subject to continuing recording and reporting requirements, including the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device of which the manufacturer knows or reasonably should know, and the obligation to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury were it to recur. 21 U.S.C. § 360i; 21 C.F.R. §§ 814.84(b)(2), 803.50(a); *Riegel,* 552 U.S. at 319, 128 S.Ct. 999.

McConologue, 8 F. Supp. 3d at 101.

Finally, in addition to these ongoing requirements specific to Class III devices, "[m]edical devices in general, not just Class III devices, are subject to the FDA's current good manufacturing practice requirements (CGMP requirements)." *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 152 (S.D.N.Y. 2011) (citing 21 U.S.C. § 360j(f) and 21 C.F.R. §§ 820 *et seq*.). These CGMP requirements, promulgated under the authority of several MDA provisions, are located within a regulatory provision that sets forth a quality control system for all medical devices. *See* 21 C.F.R. § 820.1; *see also Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 278–79 (E.D.N.Y. 2009) (noting that CGMP requirements serve as "an umbrella quality system" that leave it up to individual manufacturers to "institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective"). Specifically, the requirements are applicable to "any finished device, as defined in this part, intended for human use," and as such form the kind of "general controls," described above, that are sufficient to regulate Class I medical devices. 21 C.F.R. § 820.1(a)(2).

Though not sufficient to ensure the safety and effectiveness of such devices, CGMP requirements are nonetheless applicable to Class III devices. *Bausch v. Stryker Corp.*, 630 F.3d 546, 554 (7th Cir. 2010) ("[M]anufacturers of Class III medical devices are required by federal law to comply with Quality System Regulations established by the FDA. The Quality System Regulations also set forth Current Good Manufacturing Practices.") This remains true, "[e]ven after PMA is granted," *Elmore v. Smith & Nephew, Inc.*, No. 12 C 8347, 2013 WL 1707956, at *1 (N.D. Il. Apr. 19, 2013), and the purpose of the CGMP requirements is to "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). Accordingly, the CGMP regulations set forth comprehensive standards with which a device manufacturer must comply or be "subject to regulatory action." *Id*. § 820.1(c). "To comply with CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action." *Gelber*, 788 F. Supp. 2d at 152 (citing 21 C.F.R. §§ 820.1–.250).

B. Preemption

Here, the defendant argues that this federal regulatory scheme both expressly and impliedly preempts Plaintiffs' claims. The express preemption argument is based on the MDA's express preemption clause, mentioned above. The argument for implied preemption is based on the structure of the FDCA, which provides that an action "for the enforcement, or to restrain violations [of the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Defendant

argues that this statute, taken together with the Supreme Court's decision in *Buckman*, 531 U.S. 341, sets forth the broad principle that, outside narrow circumstances, "a claim based on breach of federal regulations . . . constitutes an impliedly preempted attempt to privately enforce the FDCA." (ECF No. 23 at 10 n.3.)

The Court agrees that a narrow gap exists for private lawsuits in this area, but notes that courts, including this one, have struggled to define the boundaries of this gap.

i. General Principles

The notion that state law will be preempted to the extent it conflicts with federal law is a well-established principle grounded in the Supremacy Clause's command that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. Simply stated, "a state law that 'interferes with, or is contrary to' federal law is invalid." *Pinney v. Nokia, Inc.*, 402 F.3d 430, 453 (4th Cir. 2005) (quoting *Free v. Bland*, 369 U.S. 663, 666 (1962)). Preemption analysis is essentially an exercise in statutory interpretation, and the Supreme Court has recently re-emphasized that "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Lohr*, 518 U.S. at 485). "Congress may indicate pre-emptive intent through a statute's express language or through its structure and purpose. *See Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). As such, there are two general types of preemption, express and implied.

Further, within the category of implied preemption, there are two distinct theories for determining Congress' implied intent to preempt: (1) field preemption, under which theory federal law is said to "so thoroughly occup[y] a legislative field as to make reasonable the inference that

Congress left no room for the states to supplement it," *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); and (2) conflict preemption, a narrower theory under which state law is not wholesale preempted in a given field, but only preempted "when it 'actually conflicts with federal law.'" *Pinney*, 402 F.3d at 453 (quoting *Hillsborough Cnty. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 713 (1985)). Express preemption, on the other hand, "arises 'when Congress has clearly expressed an intention' to preempt state law," *Smith v. BAC Home Loans Servicing, LP*, 769 F. Supp. 2d 1033, 1039 (S.D. W. Va. 2011) (quoting *College Loan Corp. v. SLM Corp.*, 396 F.3d 588, 595–96 (4th Cir. 2005)), usually through the passage of an express preemption clause such as § 360k(a) of the MDA. Where such a clause exists, a court's task is to determine "the substance and scope of Congress' displacement of state law," *Altria Grp.*, 555 U.S. at 77, guided by the assumption that "the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

ii. MDA Express Preemption

The MDA's express preemption clause provides, in relevant part, that:

> [N]o 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 Supreme Court addressed the scope of this provision in both *Lohr* and *Riegel*. In particular, it highlighted the fact that not all federal law carries the force and specificity necessary to establish "requirements" and preempt state law, and that, even where federal law does carry such preemptive force, it only preempts state law that imposes requirements "different from,

or in addition to" those federal requirements. *See Lohr*, 518 U.S. at 472 ("State requirements must be 'with respect to' medical devices and 'different from, or in addition to,' federal requirements . . . Federal requirements must be 'applicable to the device' in question, and, according to the regulations, pre-empt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'"). Accordingly, *Reigel* established a "two-part inquiry" to determine which types of state "requirements" are preempted. *Walker*, 670 F.3d at 577. First, from the federal perspective, a court asks whether the federal government has established any requirements applicable to the device in question. *Riegel*, 552 U.S. at 321. If so, the next inquiry is into the state requirement sought to be imposed with respect to the device: whether it is related to safety and effectiveness and "different from, or in addition to," any device-specific federal requirements. *Id*. at 321–22.

In applying this test to a case like the present one, involving a claim sounding in state common law and challenging a Class III device subject to PMA, three baseline principles apply. First, with respect to the step one inquiry, the PMA process imposes federal requirements carrying preemptive force. Accordingly, "because all Class III devices are required to undergo the premarket approval process, federal requirements exist with respect to all Class III devices." *Walker*, 670 F.3d at 577. Second, pertinent to the step two determination, common law (as opposed to statutory) liability is sufficiently authoritative to constitute a state requirement subject to preemption under the MDA. *Riegel*, 552 U.S. at 324. Thus, several of the state tort claims at issue here are subject to preemption, both because they impose state requirements and because those requirements are "with respect to" a Class III medical device to which the MDA's express preemption clause always applies. *See Walker*, 670 F.3d at 577 (noting that the "terms of a Class

III device's premarket approval constitute federal requirements and that a common law tort claim premised on different or additional requirements is preempted by the MDA"). The third principle follows as a corollary of the first two: "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (quoting *Lohr*, 518 U.S. at 495).

The above-quoted language forms the basis for the "parallel claims" doctrine on which the plaintiffs in this case explicitly rely. In this area of the law, Supreme Court precedent "has made clear that Section 360k protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law." *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010); *see also Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5th Cir. 2012) ("[S]tate common law claims 'are not preempted, provided that such claims are premised entirely on violation of the applicable federal requirements.'" (quoting *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 770 (5th Cir. 2011))); *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) ("The rule that emerges from [Supreme Court cases interpreting the MDA preemption clause] is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA.").

Thus, the parallel claims doctrine recognizes that a litigant may use state tort law as a mechanism for enforcing federal requirements. At the same time, however, it enforces §360k's fundamental prohibition on a litigant's ability to challenge the validity of the federal requirements themselves or impose liability on device manufacturers notwithstanding their compliance with federal law. *See, e.g., In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d

1200, 1204 (8th Cir. 2010) ("[A]ny state law imposing an additional requirement is preempted by § 360k. 'Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted.'" (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005))); *Bausch*, 630 F.3d at 553 ("Section 360k provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law."). For Class III devices undergoing the PMA process, this means that a valid parallel claim cannot challenge the process itself or the requirements imposed by the FDA pursuant to that process. *See In re Medtronic*, 623 F.3d at 1206 (noting that, in a challenge to a PMA approved Class III device, complaint must allege nonconformity with the FDA-approved design or be preempted as an "attack[] on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device").

Thus, Section 360k(a) does not preempt state law tort claims when those claims are "premised on a violation of FDA regulations." *Walker*, 670 F.3d at 577 (quoting *Riegel*, 552 U.S. at 330). However, under the argument forwarded by the defendant in this case, a plaintiff must be careful when asserting a parallel claim based on alleged violations of federal law. To the extent such claims are truly parallel and impose no additional state law requirements, they run the risk of impermissibly seeking to privately enforce the FDCA, a federal statute for which Congress has provided no private right of action. *See Shuker v. Smith & Nephew PLC*, Civil Action No. 13-6158, 2015 WL 1475368, at *13 (E. D. Pa. Mar. 31, 2015) ("While a parallel claim must be based on the manufacturer's violation of federal law in order to avoid express preemption, the claim must not arise '*solely* from the violation of FDCA requirements,' less it be impliedly preempted as an

attempt to privately enforce the FDCA." (quoting *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352–53 (2001))); *In re Medtronic*, 623 F.3d at 1204 (noting the "narrow gap" for state common law claims created by *Riegel* and *Buckman* and specifically recognizing that "the plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)") (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009))). The defendant here argues that such attempts are impliedly preempted pursuant to the decision in *Buckman*.

iii. Implied preemption under *Buckman*

In *Buckman*, the plaintiffs had suffered personal injuries from the use of orthopedic bone screws in the pedicles of their spines. *Buckman*, 531 U.S. at 344. Importantly, the plaintiffs did not sue the manufacturer of the bone screws at issue, but rather a consulting company employed by that manufacturer to help it navigate the regulatory landscape governing medical devices and secure FDA approval. *Id*. Although ostensibly suing under state tort law, the crux of the claim was that the consulting company made fraudulent misrepresentations to the FDA, and that, "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id*. Characterizing the asserted tort actions as "fraud-on-the-FDA-claims," *id*. at 348, the Supreme Court found them impliedly preempted by the structure of the FDCA. Specifically, it referenced the provision of the FDCA which requires that all "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States," 21 U.S.C. § 337(a), and in it found "clear evidence that Congress

intended that the MDA be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352.

Although using this broad language, the Court was careful to distinguish the case from *Lohr*, the prior case recognizing the parallel claim exception to the MDA's express preemption clause. Specifically, it noted:

> In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although [*Lohr*] can be read to allow certain state-law causes of actions [sic] that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

Id. at 352–53. Central to the Court's holding was its recognition that "petitioner's dealings with the FDA were prompted by the MDA, and the very subject matter of petitioner's statements were dictated by that statute's provisions." *Id*. at 347–48. In such a situation, involving disclosure duties arising solely by the operation of federal law governing the relationship between a federal agency and its regulated entities, the Court determined that the traditional presumption against preemption did not apply. *Id*.; *see also Bausch*, 630 F.3d at 557 (noting that the *Buckman* court "specifically distinguished such 'fraud-on-the-agency' claims, *i.e.*, claims not related to a field of law that states had traditionally occupied, from claims based on state law tort principles"). Because the claims did not rely on "traditional state tort law which had predated the federal enactments in question[]," *Buckman*, 531 U.S. at 353, the Court found the freestanding claim preempted.

Thus, an analysis of *Buckman* itself prevents the expansive reading the current defendant would assign it. Indeed, if the parallel claims doctrine (explicitly recognized by *Buckman*) is to exist at all, a plaintiff must have *some* room to enforce federal requirements imposed by the MDA and related regulations. *See Williams*, 2015 WL 4984531, at *10 (noting, in a case involving the

same defendant making the same implied preemption argument, that "crediting Smith & Nephew's reading of *Buckman* would essentially require the implied preemption of *every* claim not already expressly preempted; this would be so because a 'parallel' state law claim is, almost by definition, one that will, in effect, seek to enforce the federal requirements to which it corresponds").

For these reasons, courts have generally been willing to distinguish claims premised on traditional state law duties, such as negligence or products liability, and remove them from the preemptive scope of *Buckman*. So long as the plaintiff asserts a state law claim that exists independently and not as the sole result of the federal regulations allegedly violated, the claim properly "threads the gap" between *Riegel* and *Buckman*. *Id*.; *see also Bausch*, 630 F.3d at 558 (distinguishing *Buckman* on the basis that the plaintiffs "did not have an implied right of action under federal law, and they were not claiming the breach of a recognized state-law duty for their benefit," and finding no preemption where "the plaintiff claims breach of a well-recognized duty owed to her under state law—the duty of a manufacturer to use due care in manufacturing medical devices"); *Bass*, 669 F.3d 501, 514 (noting that "there is a difference between the 'freestanding federal cause of action based on violation of the FDA's regulations' presented by the plaintiffs in *Buckman* and a state-law tort claim" (quoting *Hughes*, 631 F.3d at 775)); *Tillman v. Smith & Nephew*, No. 12 C 4977, 2013 WL 3776973, at *4 (N.D. Ill. July 18, 2013) ("[C]laims involving FDCA violations are not impliedly preempted where liability is independent of the FDCA, *i.e.*, where plaintiffs claim 'breach of a recognized state-law duty' for their benefit and harm arising from violation of applicable federal law." (quoting *Bausch*, 630 F.3d at 558)).

As noted above, parallel claims, by their very nature, seek to impose state law liability based on violations of federal regulatory requirements. If such claims were not grounded in

federal law, they would be expressly preempted to the extent they imposed duties different from or in addition to those prescribed by the FDA. The key to avoiding implied preemption is that these claims, while incorporating federal standards, must also be grounded in state law causes of action, unlike the "fraud-on-the-FDA" theory rejected in *Buckman*, that exist and impose duties outside of the FDCA's operation. Claims such as negligence and strict products liability often use the violation of safety statutes to demonstrate that traditional state law duties, such as the duty of reasonable care or the duty to not produce an unreasonably dangerous product, have been breached. *See Bausch*, 630 F.3d at 557 (noting that federal safety standards with respect to medical devices are "tied directly to the duty of manufacturers to avoid foreseeable dangers with their product by complying with state law," such that the violation of federal law "goes a long way toward showing that the manufacturer breached a duty under state law toward the patient"); Syl. Pt. 7, *Shaffer v. Acme Limestone Co.*, 524 S.E.2d 688 (W. Va. 1999) ("When a statute imposes a duty on a person for the protection of others, it is a public safety statute and a violation of such a statute is prima facie evidence of negligence unless the statute says otherwise."). Thus, state law causes of action can assert viable parallel claims "even if proving those independent state law claims will rely, in part, on evidence that a federal requirement was violated." *Williams*, 2015 WL 4984531, at *10.

To put it even more simply, implied preemption is inapplicable when state law causes of action existing independently of federal law are asserted, even though they happen to be based on federal law as alleged in a particular case.

IV. Discussion

In the current action, Plaintiffs' complaint can be categorized into three general types of claims. The first set, comprising the first and second claims for relief, seeks damages based on the failure of the BHR System, a Class III medical device that received premarket approval from the FDA, and was wholesale implanted within Mrs. Raab on January 12, 2010. These claims are expressly styled as parallel claims and are "based on an exclusively federal statutory and regulatory set of requirements." (ECF No. 21 at 7.) The plaintiffs' asserted basis for liability on this set of claims is the defendant's non-compliance with an enumerated set of CGMP requirements.

The second category of claims, comprising the plaintiffs' third and fourth claims for relief, are also explicitly pled as parallel claims but refer to the revision surgery on February 17, 2010, and the resulting combination of a Class III BHR part with several Class II components. Although not entirely clear, these claims appear to be alleging that the defendant did not abide by a number of federally mandated post-approval, devise-specific requirements relating to the marketing and labelling of Class III devices. Specifically, this category of claims seeks to hold the defendant liable for its failure to discourage the use of a Class III device in conjunction with outside parts and components. Plaintiffs aver that Defendant's failure to comply with federal requirements resulted in its BHR System being used in an unauthorized way and, ultimately, caused Plaintiffs' alleged injuries.

The final category of claims relates only to the Class II components used during the revision surgery on February 17, 2010. Because not related to a Class III device, Plaintiffs argue that these claims are not subject to the MDA's express preemption clause and accordingly do not plead them as parallel claims. With respect to this set of claims, the defendant does not argue for

preemption, either express or implied. Instead, it argues for dismissal based on the failure of the fifth claim for relief to state a claim with the specificity required by *Twombly* and *Iqbal*.

This area of the law has engendered much litigation, and the current plaintiffs are certainly not the first to attempt to plead a parallel claim against the manufacturer of a medical device, against this current manufacturer, Smith & Nephew, or even as a challenge to the very device at issue in this case, the BHR System. *See Williams*, 2015 WL 4984531, at *9 (surveying "other district court cases applying section 360k to claims against Smith & Nephew for harm caused by the BHR System"). Here, it appears that the plaintiffs have learned from the mistakes of previous litigants and taken great care, at least with respect to their first four claims, to tie their state law claims closely to the defendant's violation of specific FDA standards, expressly invoking the parallel claim doctrine. As such, as largely conceded by the defendants in this case, the main issue raised by the current complaint is one of pleading rather than preemption. (*See* ECF No. 23 at 15–16.)

As with any other claim in federal court, a plaintiff's parallel claim must comply with certain basic requirements in order to withstand a motion to dismiss for failure to state a claim. Importantly, "[t]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular. The federal standard of notice pleading applies, so long as the plaintiff alleges facts sufficient to meet the new 'plausibility' standard announced applied in *Iqbal* and *Twombly*." *Bausch*, 630 F.3d at 558; s*ee also Bass*, 669 F.3d at 509 (collecting cases for the proposition that "a plaintiff's allegations that the manufacturer violated FDA regulations must meet the *Twombly* plausibility standard").

Although this area of the law is fluid, one factor that consistently distinguishes a successful parallel claim is an allegation of a manufacturer's noncompliance with specific requirements imposed by the FDA, as opposed to an allegation that the manufacturer was required to do more despite compliance with the FDA-approved process. *See Walker*, 670 F.3d at 580–81 (collecting cases for the proposition that "common law tort claims based on the failure of devices that were designed, manufactured, and sold in accordance with the terms of their premarket approval [are] preempted under *Riegel*"); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) ("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.'" (quoting *Heisner ex rel. Heisner v. Genzyme Corp*, No. 08-C-593, 2008 WL 2940811, at *5 (N.D. Ill. July 25, 2008)); *Williams*, 2015 WL 4984531, at *6 ("But 'a common law tort claim that presupposes a Class III device should have been designed in a manner other than that contemplated by its premarket approval is . . . expressly preempted by the MDA as interpreted by *Riegel*.'" (quoting *Walker*, 670 F.3d at 580)).

Predictably, courts have required varying degrees of specificity when applying the plausibility standard to parallel claims alleging noncompliance with federal requirements. *Compare Wolicki-Gables v. Arrow Intern, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011), and *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 494 (W.D. Pa. 2012), *with Bausch*, 630 F.3d at 558–59, and *Elmore*, 2013 WL 1707956, at *6. These disagreements are derivative of the larger debate over the proper application of *Twombly* and *Iqbal*. For purposes of this decision, however, the Court merely notes that while no heightened pleading standard applies to assess the claims at issue, two important considerations do factor into a court's assessment of the pleadings in a medical device

case. First, and most importantly, "much of the product-specific information about manufacturing needed to investigate [a claim relating to medical devices] is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." *Bausch*, 630 F.3d at 558; *see also* 21 C.F.R. § 814.9. Second, although a plaintiff must plausibly allege a violation of federal requirements, the plaintiff need not go so far as to demonstrate that the FDA has found the manufacturer to be in violation of federal requirements. *See Hughes*, 631 F.3d at 772.

In this case, although a close call, the plaintiffs have sufficiently pled allegations of federal law to avoid preemption, both express and implied, and state valid parallel claims with respect to their first two claims for relief. Claims three and four, on the other hand, are utterly devoid of factual allegations, and thus insufficient to state a parallel claim.

A. Claims I and II: Strict Liability and Negligence Based on Noncompliance with CGMP Requirements

As noted above, Plaintiffs' first two claims for relief are based on alleged violations of the FDA's CGMP requirements. Specifically, the plaintiffs allege that the defendant failed to comply with various design controls established by 21 C.F.R. § 820.30, failed to adequately conduct the inspecting and verification activities required under 21 C.F.R. § 820.80, failed to establish appropriate procedures to ensure it could take necessary corrective and appropriate action, as required by 21 C.F.R. § 820.100, and failed to conduct appropriate investigations into adverse incident reports and returned device parts in violation of 21 C.F.R. § 820.198.

Whether or not the generally applicable CGMP requirements can form the basis for a parallel claim, especially a claim challenging a Class III medical device subject to the stringent

and specifically-tailored requirements of the PMA process, has been the subject of considerable dispute among the courts that have considered the issue. Some courts, concerned about the potential for state courts (and particularly state juries) to apply these intentionally vague and flexible standards differentially, have determined that the regulations lack the specificity necessary to support a parallel claim. *See Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) (noting that the "intentionally vague and open-ended nature" of the CGMP requirements "is the precise reason why they cannot serve as the basis for a parallel claim . . . allowing them to serve as the basis for a claim would lead to differing safety requirements that might emanate from various lawsuits"); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009) (determining that a claim based on CGMP requirement are "simply too generic, standing alone" to form the basis for a parallel claim); *Cline v. Advanced Neuromodulation Systems, Inc.*, 921 F. Supp. 2d 1374, 1380–81 (N.D. Ga. 2012) ("Generally, violations of the CGMPs alone are insufficient to state a parallel claim. This is because CGMPs apply to many different types of devices and are thus not specific to any one device.").

This Court is not persuaded by such arguments. It is not immediately clear why the generality of the federal regulation at issue should make a difference in determining whether a plaintiff has stated a parallel claim. The Supreme Court, in its interpretation of § 360k, has certainly not drawn any distinction between allegations implicating general or specific law. Instead, the distinction has been between federal and state law: state law claims based on alleged violations of federal law are not preempted because they would, by definition, not impose any different or additional requirements on device manufacturers. *See Riegel*, 552 U.S. at 330 (emphasizing that Section 360k "does not prevent a State from providing a damages remedy for

claims premised on a violation of FDA regulations"). Accordingly, many courts facing this issue have allowed violations of CGMP requirements to state parallel claims, provided they are adequately pleaded. *See Bausch*, 630 F.3d at 555 (refusing to draw a distinction "between general requirements and 'concrete, device-specific' requirements" and finding such a distinction incompatible with a statutory provision designed to "provide preemption for medical device manufacturers to the extent they actually comply with stringent requirements of federal law"); *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440 (6th Cir. 2010) (rejecting the defendant's argument that the particular CGMP at issue was "categorically unenforceable" and finding it "not so vague as to be incapable of enforcement"); *Gelber v. Stryker Corp.*, 788 F.2d 145, 156 (S.D.N.Y. 2011) (finding no basis on which to conclude that "alleging that the device was defective because it was not manufactured in accordance with the CGMP requirements set forth in the Act, imposes a different or additional requirement on the device within the meaning of section 360k(a)").

This Court agrees with the reasoning of this latter set of courts. Violations of the CGMP requirements are undoubtedly violations of federal law and, as noted above, the regulations impose continuing federal requirements on all device manufacturers, including Class III devices that have already received PMA approval. *See, e.g.*, *Elmore*, 2013 WL 1707956, at *2. Thus, Plaintiffs' CGMP-premised claims are not expressly preempted simply because they rely on those regulations. As the Fifth Circuit has noted, "[t]he key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on CGMPs, but rather 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." *Bass*, 669 F.3d at 511–12. Thus, Plaintiffs' first two claims will proceed to the extent they plausibly tie the federal violations to their injuries in a traditional state law cause of action. To the extent, however, that the plaintiffs are "pursing a claim that the BHR system design, as approved by the FDA in the PMA, is defective, such claim is preempted." *Tillman v. Smith & Nephew*, No. 12 C 4977, 2013 WL 3776973, at *3 (N.D. Ill. July 18, 2013).[1]

In West Virginia, a plaintiff can establish a claim for strict products liability in tort by showing that the "involved product is defective in the sense that it is not reasonably safe for its intended use." Syl. Pt. 4, *Morningstar v. Black and Decker Mfg. Co.*, 253 S.E.2d 666 (W. Va. 1979). Under the heading of a defective product claim, three "broad, and not necessarily mutually exclusive" categories of defects exist: "design defectiveness; structural [or manufacturing] defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions, and labels." *Mullins v. Ethicon, Inc.*, ---F. Supp. 3d---, Civil Action No. 2:12-cv-02952, 2015 WL 4635573, at *1 (S.D. W. Va. Aug. 4, 2015) (quoting *Morningstar*, 253 S.E.2d at 682). Importantly, a plaintiff "is not required to establish a strict products liability cause of action by identifying the specific defect that caused the loss, but instead may permit a jury to infer the existence of a defect by circumstantial evidence." *Bennett v. Asco Servs., Inc.*, 621 S.E.2d 710, 717 (W. Va. 2005). Under the "malfunction theory" recognized by this state, "[c]ircumstantial

[1] Plaintiffs' complaint alleges that the BHR device was "designed and/or manufactured" in violation of the CGMP requirements discussed above. (*See* ECF No. 21 ¶ 14.) As opposed to claims alleging manufacturing defects, which often allege deviations from FDA requirements and state valid parallel claims, challenges to the design of a PMA-approved Class III medical device are generally preempted. *See, e.g.*, *In re Medtronic*, 623 F.3d at 1206 (noting that the design of Class III medical devices is determined by the FDA and that absent some allegation that the actual product sold deviated from the PMA-approved design, design defect claims "are attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. Such claims are expressly preempted by §360k."). This Court determines that the plaintiffs' first two claims for relief are not preempted only to the extent they allege noncompliance with federal regulations and the FDA approval process. *See Bausch*, 630 F.3d at 560 (allowing claims to proceed to discovery but noting that "[i]f the problem turns out to be a design feature that the FDA approved, section 360k will protect the manufacturer.").

evidence may be sufficient to make a *prima facie* case in a strict liability action, even though the precise nature of the defect cannot be identified, so long as the evidence shows that a malfunction in the product occurred that would not ordinarily happen in the absence of a defect." Syl. Pt. 3, *Anderson v. Chrysler*, 403 S.E.2d 189 (W. Va. 1991).

Moreover, the violation of a statute, ordinance, or regulation is *prima facie* evidence of negligence where it "imposes a duty on a person for the protection of others." *Hersh v. E-T Enterprises, Ltd. P'ship*, 752 S.E.2d 336, 343 (W. Va. 2013) (quoting Syl. Pt. 7, *Shaffer v. Acme Limestone Co, Inc.*, 524 S.E.2d 688 (W. Va. 1999)). Accordingly, Plaintiffs' allegations that the defendant violated safety regulations promulgated by the FDA[2] and, as a result, produced an unreasonably dangerous product fit squarely within well-recognized causes of action in West Virginia. Critically, although expressly premised on violations of federal law, these claims allege that the same activity that violated the federal standards also made the defendant negligent and strictly liable for creating an unreasonably dangerous product. This independent basis in West Virginia law prevents a finding of implied preemption, notwithstanding the fact that "proving those independent state law claims will rely, in part, on evidence that a federal requirement was violated." *Williams*, 2015 WL 4984531, at *10.

Finally, at this stage of the litigation, the Court concludes that Plaintiffs' first two claims for relief are sufficient to state a claim that is plausible on its face and, more importantly, to give the defendant fair notice of the nature of the claims against it. *See Elmore*, 2013 WL 1707956, at

[2] 21 C.F.R. § 820.1(a)(1) provides that all the CGMP requirements set forth in that quality system regulation, including those relied upon by Plaintiffs in this case, "are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." The clear thrust of the CGMP requirements are to protect people, like Mrs. Raab, who have been implanted with medical devices, and as such, she, as a "member of a class protected by a public safety statute has a claim against anyone who violates such a statute when the violation is a proximate cause of injury to the claimant." Syl. Pt. 7, *Shaffer*, 524 S.E.2d 688.

*5. A plaintiff's pleading burden must "be commensurate with the amount of information available to them." *Bausch*, 630 F.3d at 561 (quoting *In re Medtronic*, 623 F.3d at 1212 (Melloy, J., dissenting)). In this case, the plaintiffs have identified a specific medical device, the BHR System, that was manufactured and produced by the defendant. In addition, they have alleged that the device components (in addition to those added in the February 17, 2010 revision surgery) "failed," specifically asserting that "metal debris from the Defendant's metal-on-metal components was present in the Plaintiff's surrounding bone and tissue of the right hip, including the presence of pseudotumors." (ECF No. 21 ¶ 11.)

Most importantly, the plaintiffs set forth specific allegations that this medical device was unreasonably dangerous and that the defendant was negligent in allowing it to be so, citing several violations of specific provisions of federal law promulgated to promote the safety of medical devices and prevent injuries to those implanted with such devices. For example, allegations that the defendant "[f]ailed to accurately establish the in vivo life expectancy of the BHR," (*id.* ¶ 14), and "failed to validate the anticipated wear of the acetabular cup prior to its release into commercial distribution," (*id.*), taken as true, suggest a defect in the BHR System as manufactured, namely that its acetabular cup component did not meet federal standards related to durability. Given Mrs. Raab's allegations about undergoing two revision surgeries within four years of initial implantation of the BHR system—the second of which revealing that the device as a whole had failed—the complaint plausibly ties the defendant's violation of federal law to an identified defect making the product unreasonably dangerous and ultimately causing the alleged injuries suffered.

Further, the plaintiffs allege that the defendant failed to establish procedures to respond to complaints regarding the BHR, failed to respond to adverse incident reports "strongly" indicating

that the acetabular component in particular was malfunctioning, and failed to conduct investigations into acetabular cup components that had been returned. (*Id*.) Taken together, these allegations create an inference that the BHR system, and in particular the acetabular cup, was not functioning safely and in accordance with its PMA requirements, and that the defendant was negligent in not taking the corrective action required by the regulations. Given Plaintiffs' further allegations of injury—suggesting the malfunction of the acetabular cup—reference to these alleged federal violations make plausible Plaintiffs' state law claims that Defendant produced an unreasonably dangerous product, negligently disregarded federal requirements designed to prevent such products from harming consumers, and injured the plaintiffs as a result.

Plaintiffs have thus plausibly alleged that the defendant's product was unreasonably dangerous and defective, insofar as they have raised an inference of the existence of "a malfunction in the product occurred that would not ordinarily happen in the absence of a defect." Syl. Pt. 3, *Anderson*, 403 S.E.2d 189. Moreover, by alleging the violation of federal safety standards designed to promote public safety, the plaintiffs have at least plausibly alleged the defendant's negligence under West Virginia law. Given the difficulty plaintiffs face, prior to discovery, in alleging specific violations related to Class III medical devices that undergo the PMA process, attributable to the fact that "certain premarket approval documents are confidential and the public does not have access to the complete versions of these documents," *Gelber*, 788 F. Supp. 2d at 157, the Court determines that the plaintiffs have carried their pleading burden. *See Bausch*, 630 F.3d at 561 (noting that, in order for a plaintiff to plead a parallel claim with specificity, she would "need access to the confidential materials in the premarket approval application setting forth the medical device's specifications. This is simply not possible without discovery."); *Gelber*, 788 F.

Supp. 2d at 156 ("By pleading the conduct which plaintiffs allege violated the CGMP requirements, describing evidence of the alleged violation, and directing [defendants] to the CGMP requirements generally, plaintiffs have given defendants more than ample notice of the alleged violation of federal law."); *Tillman*, 2013 WL 3776973, at *5 (allegations of medical complications occurring after implantation, combined with allegations of numerous CGMP violations, sufficient to state claim for negligence and strict products liability).

To the extent Plaintiffs claims allege that the BHR system, as approved by the FDA, was defective in design, such claims are **DISMISSED** as expressly preempted. Accordingly, Defendant's Motion to Dismiss with respect to any such expressly preempted claims is **GRANTED**. In all other respects, Defendant's Motion to Dismiss the first and second claims for relief is **DENIED**.

B. Claims III and IV: Strict Liability and Negligence Based on Violations of Federal Labelling and Advertisement Requirements

The central allegation of the plaintiffs' third and fourth claims for relief is that the defendant contributed to a portion of the Class III BHR System (the acetabular cup) being used in combination with certain Class II components in a manner not approved by the BHR's PMA and in violation of other post-approval federal requirements specific to the BHR System. Specifically, Plaintiffs allege that the defendant's "marketing, distribution and/or permitted use of its Synergy Porous High Offset Femoral Component, Modular Head Sleeve and Modular Femoral Head with its BHR acetabular cup" violated the FDCA and various regulations promulgated pursuant to its authority. (ECF No. 21 ¶ 37.) In marked contrast to the allegations supporting the plaintiffs' first two claims for relief, these allegations fail to specify any actual conduct on the part of the

defendant demonstrating either how any specific federal regulations were violated or how the defendant's alleged violating behavior made it negligent or created an unreasonably dangerous product.

As an initial matter, the Court notes that while Plaintiffs' third claim for relief is ostensibly labelled as a claim based on "strict products liability," it does not actually make any allegation that the defendant's action created an unreasonably dangerous product. Unlike the first claim for relief, which included such an allegation, the third claim for relief uses language identical to the Plaintiffs' count four negligence claim, including describing the defendant's offending conduct as a violation of its "duty" to comply with the FDCA. (*See* ECF No. 21 ¶ 38.) Accordingly, Plaintiffs' third claim is **DISMISSED** for failing to state a claim for strict products liability and as duplicative of Plaintiff's fourth claim for relief. The rest of the analysis will focus on whether Plaintiffs have sufficiently pled a parallel claim for negligence, pursuant to their fourth asserted claim for relief.

As before, Plaintiffs allege noncompliance with specific provisions of federal law, taking care to confine their claims to an "exclusively federal statutory and regulatory set of requirements." (*Id*. ¶¶ 44, 57.) The first allegation, in contrast to the rest, actually points to an instance of specific conduct by the defendant: that it failed to submit a PMA supplement to the FDA, in violation of 21 C.F.R. § 814.39. As noted above, once a device receives PMA approval, the manufacturer of that device is forbidden to make, "without FDA permission, changes in design specifications, manufacturing process, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319. If a manufacturer seeks to make such change, it must submit a PMA supplement, subject to the same stringent review and approval standards as the original PMA.

Here, the complaint does not allege that the defendant made any such change to the design of the Class III BHR system. Instead, the claims are based on the allegation that Mrs. Raab's doctor used the PMA-approved device in combination with non-PMA approved, Class II components. Such "off-label" use, however, is not prohibited or even regulated by the FDCA, which focuses on the product as produced by device manufacturers. *See* 21 U.S.C. § 396 (providing a rule of construction to prevent the FDCA from interfering with "the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship"); *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977, 988 (D. Ariz. 2013) ("The MDA does not seek to control how physicians use regulated devices . . . ."); *Shuker v. Smith & Nephew PLC*, Civil Action No. 13-6158, 2015 WL 1475368, at *9 (E.D. Pa. Mar. 31, 2015) ("[B]y granting premarket approval, the FDA requires the manufacturer of an approved device to place the device on the market in the form—and accompanied by the warnings and indications for use—approved by the agency, but does not prevent physicians from using the device in a different manner."). Accordingly, to the extent the plaintiffs seek to impose liability on the defendant based on Dr. Castle's off-label use of the BHR system, they seek to impose a requirement that is in addition to any provision of federal law and are expressly preempted from doing so. *See Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779 (D. Minn. 2009) (noting that a manufacturer does not lose the protection of § 360k when its device is used in an off-label way and finding claims imposing liability for such use, despite "scrupulous[] adhere[nce] to the FDA's every command," preempted).

The rest of Plaintiffs' fourth claim appears related to the defendant's off-label promotion, as opposed to off-label use, of the BHR system. To begin with, any state law claim challenging

the labels and warnings associated with a Class III device having received PMA raises the specter of express preemption because the "FDA's PMA approval includes specific language for Class III device labels and warnings." *In re Medtronic*, 623 F.3d at 1205. Thus, any state law claim seeking to challenge a Class III device's warning labels is expressly preempted to the extent it seeks to impose warning requirements in addition to those imposed by the FDA during the PMA process. *See Horn v. Thoratec Corp.*, 376 F.3d 163, 177 n.22 (3d Cir. 2004) (noting that PMA approval "expresses the FDA's determination that the proposed labelling meets the detailed labelling requirements set forth in its regulations" and concluding that any claim "premised on the adequacies of the warnings reviewed and approved by the FDA in its PMA approval order" is expressly preempted); *Riley*, 625 F. Supp. 2d at 782 (noting that the terms of a Class III medical device's PMA "severely limit[]" a device manufacturer's ability to alter its labels, including in situations where the manufacturer "becomes aware of a new off-label use of the device").

To the extent that a plaintiff can avoid express preemption and state a valid parallel claim based on off-label promotion, however, the law governing such a claim is far from settled. *See Shuker*, 2015 WL 1475368, at *14 (noting that, while off-label promotion can form the basis for a non-preempted parallel claim, the "precise contours of such a claim are not clear, as the law in this area is continuing to evolve"); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 701 (S.D. Tex. 2014) (noting that the status of off-label promotion under federal law is "not clear"). In fact, "[f]ederal law does not expressly define, or ban, off-label promotion; rather the FDCA prohibits '[t]he adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.'" *Id.* (quoting 21 U.S.C. § 331(b)). Accordingly, there has been some dispute over the extent to which federal law actually prohibits a manufacturer's promotion that is

not false and misleading but that nonetheless fails to comply with federal regulatory requirements. *See id*. at 702 (noting that federal law clearly "bars off-label promotion when it is false and misleading" but that more doubt exists with respect to whether "federal law bans truthful off-label promotion," an issue "on which courts have come to differing conclusions"); *Houston v. Medtronic, Inc.*, 13 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013) (concluding that "federal law forbids device manufacturers to promote any off-label uses, and certainly prohibits false or misleading off-label promotion"); *Dawson v. Medtronic, Inc.*, C/A No. 3:13-cv-663-JFA, 2013 WL 4048850 (D.S.C. Aug. 9, 2013) ("This Court is not convinced that off-label promotion violates the FDCA.").

This Court need not determine the precise contours of a parallel claim based on off-label promotion, however, for purposes of resolving the present motion. Even assuming that off-label promotion that is neither false nor misleading could support a valid parallel claim, the plaintiffs have not pled sufficient facts to allow this Court to determine whether the state law action would impose requirements "different from" or "in addition to" those imposed by federal law. The claim for relief neither identifies a specific federal standard applicable to any device manufactured by the defendant nor describes how such violation supports a negligence claim under West Virginia law. As such, the fourth claim for relief does not sufficiently plead a valid parallel claim. *See White v. Stryker Corp.*, 818 F. Supp. 2d 1032, 1040 (W.D. Ky. 2011) (finding complaint insufficient where the allegations were "so general and so absent any reference to federal standards, that the Court has no basis for determining whether they plausibly assert 'parallel' claims").

Plaintiffs rely on two provisions of 21 U.S.C. §§ 352, a statute providing a list of circumstances under which a drug will be deemed misbranded by the FDA. Specifically, they cite §§ 352(q) and 352(r), which allow the FDA to impose restrictions on certain types of devices it defines as "restricted," under 21 U.S.C. § 360j(e). That latter statute, in turn, permits the Secretary of the FDA to enact regulations restricting the sale, distribution, or use of a device to the extent she determines "that there cannot otherwise be reasonable assurance of its safety and effectiveness." As relevant in a case like this, where the plaintiffs do not allege that the defendant engaged in any false or misleading advertising, § 352(q) merely deems a device misbranded to the extent its sale, distribution, or use violates a regulation prescribed under § 360j(e). In other words, it does not proscribe any substantive conduct, but merely make it a violation of the FDCA for a device manufacturer not to comply with whatever device-specific regulations the FDA chooses to impose under its § 360j(e) authority. Section 352(r) further requires that restricted devices carry certain warnings and use labels, including a "brief statement of the intended uses of the device, and relevant warnings, precautions, side effects, and contradindications."

Finally, Plaintiffs allege wholesale noncompliance with the requirements of 21 U.S.C. §§ 360h, 360i, and 360l, a series of statutory provisions equipping the FDA Secretary with a variety of tools to ensure the continued safety and effectiveness of medical devices, including the authority to require manufacturers to notify health care professionals of the risks associated with a given device, to keep such records as are deemed necessary by the Secretary, and to engage in postmarket surveillance of their devices. What all of these these asserted violations have in common is an allegation that the defendant was negligent because it failed—in unspecified ways—to market its product in accordance with statutory provisions that merely empower the FDA to impose

regulations of its choosing on devices it chooses to define as "restricted." Critically though, Plaintiffs do not allege that any of the devices at issue were actually classified as restricted devices under § 360j(e), nor do they specify any regulation or restriction enacted by the FDA under any of the cited statutory provisions and made applicable to any device manufactured by the defendant.

Unlike with the first two claims for relief, where the plaintiffs identified specific regulatory provisions actually applicable to the defendant and described in some detail how the defendants actually violated those regulatory provisions, the fourth claim for relief simply fails to do anything more than "incant the magic words '[defendant] violated FDA regulations.'" *Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (citation omitted). The plaintiffs do not allege how any of the defendant's promotional activities violated federal law because they neither identify any specific conduct on the part of the defendant in marketing its products nor any substantive federal regulation, restriction, or standard capable of being violated because actually made applicable to any of the defendant's devices. On such allegations, the defendant (and this Court) are left to guess as to the manner in which the defendant was negligent under state law. More is required of a valid parallel claim. *See, e.g.*, *Bass*, 669 F.3d at 510 (finding that plaintiff sufficiently pled a parallel claim where the complaint "specifie[d] what went wrong in the manufacturing process and cite[d] the relevant FDA manufacturing standards [defendant] allegedly violated" (quoting *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011)).

Plaintiffs' "blanket statement," *Williams*, 2015 WL 4984531, at *11, that the defendant marketed, distributed, and/or permitted the use of Class II components with the Class III BHR System fails to create an inference that any federal law was violated because it does not identify any substantive federal requirement made applicable to any device at issue. Further, it fails to

give rise to a plausible claim for negligence under West Virginia law because it does not identify any conduct on the part of the defendant that would support the allegations that federal safety standards were violated and that the defendant was negligent on the basis of such violations. Accordingly, Defendant's Motion to Dismiss with respect to Plaintiffs' third and fourth claims for relief is **GRANTED**.

C. Claim V: State Common Law Claims Based on Failure of Class II Devices

Plaintiff's fifth claim for relief is based exclusively on the defendant's alleged failures with respect to the Class II devices inserted as part of the February 17, 2010 revision surgery. As the Defendant has admitted, these devices were not part of the PMA-approved BHR system, instead gaining approval under the less stringent Section 510(k) process applicable to Class II devices. (ECF No. 23 at 13.) The Section 510(k) process, so named because of the original numbering of the provision within the MDA, imposes a "limited form of review on every manufacturer intending to market a new device," including all new Class I and Class II devices, by requiring the manufacturer to "submit a 'premarket notification' to the FDA." *Lohr*, 518 U.S. at 478. Because this 510(k) process is not focused on safety, its approval requirements do not impose device-specific "requirements" for purposes of the MDA's express preemption clause. *Id*. at 494; *see also Riegel*, 552 U.S. at 322–23. Accordingly, this set of claims is not subject to the express preemption clause of § 360k. Further, because they are not based on any violations of federal law, and thus do not seek to enforce the provisions of the FDCA, there is no issue of implied *Buckman* preemption. Defendant recognizes this fact and argues only that Plaintiffs' fifth claim for relief lacks sufficient factual detail to state a claim because it fails to "identify the alleged defect in these Class II devices and how this defect caused Mrs. Raab's alleged injuries. It also fails to

identify the express or implied warranties allegedly breached or the nature of the warning allegedly not provided." (ECF No. 23 at 5.)

Pursuant to the fifth claim, Plaintiffs allege strict products liability, failure to warn, and breach of express and implied warranties. This Court has already detailed, with respect to the above claims for relief, the requirements necessary to state a claim for strict products liability in West Virginia. For present purposes, the Court reiterates that, under West Virginia law, a plaintiff need not identify a specific defect, but can prevail by demonstrating circumstantial evidence demonstrating a malfunction. *See, e.g.*, *Bennett*, 621 S.E.2d at 717. Here, the plaintiffs allege that the defendant's product was unreasonably dangerous because it failed, releasing metal debris into Mrs. Raab's body and creating myriad other health problems. At the pleading stage, this is sufficient to create an inference that the malfunction "would not ordinarily happen in the absence of a defect," Syl. Pt. 3, *Anderson*, 403 S.E.2d 189, and state a plausible claim that Defendant's Class II devices were defective.

Plaintiffs also assert a state law claim based on the defendant's failure to provide appropriate warnings with respect to the Class II devices. In West Virginia, failure to warn is a subset of the larger category of strict products liability. *See, e.g.*, *Morningstar*, 253 S.E.2d at 682. "In ascertaining whether a duty to warn exists, the basic inquiry is whether it was reasonably foreseeable to the manufacturer that the product would be unreasonably dangerous if distributed without a warning." *Church v. Wesson*, 385 S.E.2d 393, 396 (W. Va. 1989). Here, the defendant operates in a highly regulated industry in which, as noted above, there have been sufficient well-documented failures associated with medical devices to give rise to the comprehensive federal scheme embodied in the MDA. Moreover, Plaintiffs allege that the defendant should have

provided warnings relating to the specific injuries that Mrs. Raab suffered. At this stage of the litigation, that is enough to create a plausible inference that the defendant should have done more in the way of warning, and establish a claim for failure to warn. *See Woodcock v. Mylan, Inc.*, 661 F. Supp. 2d 602, 611 (S.D. W. Va. 2009) (rejecting the defendant's argument that a West Virginia plaintiff asserting a failure to warn claim was required to plead that an adequate warning would have averted the plaintiff's injury and concluding that allegation that defendant "failed to warn [the plaintiff] of the risks attendant to using [the allegedly defective product] . . . satisfies the requirements of a failure-to-warn claim in West Virginia").

Relatedly, Plaintiffs allege breach of "applicable implied and express warranties, including warranties of merchantability and fitness for a particular purpose." (ECF No. 21 ¶ 62.) West Virginia has codified two types of implied warranties in its version of the Uniform Commercial Code ("UCC"), the implied warranty of merchantability and the implied warranty of fitness for a particular purpose. *See* W. Va. Code 253 §§ 46–2–314, 46–2–315. "For goods to be 'merchantable,' they must be, among other things, 'fit for the ordinary purposes for which such goods are used,' and 'adequately contained, packaged, and labeled as the agreement may require.'" *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 542 (S.D. W. Va. 2011) (quoting W. Va. Code §§ 46–2–314(2)(c) & 46–2–314(2)(e)). Although the West Virginia Supreme Court has not addressed the issue, this Court, based upon a nationwide survey of cases interpreting the UCC implied warranty of merchantability, has previously determined that "claims for strict liability and breach of the implied warranty of merchantability are essentially coextensive in products liability actions." *Id.* at 545. The Court finds this conclusion persuasive in this case and determines that, for the same reasons Plaintiffs have sufficiently stated a claim for strict products liability based on the alleged

defective Class II devices, they have also stated a claim for breach of the implied warranty of merchantability. The allegation that the devices failed, while implanted inside of Mrs. Raab, gives rise to a plausible claim that the Class II components were not fit for the ordinary purpose for which they are used.

The implied warranty of fitness for a particular purpose, on the other hand, provides that:

> Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.

W. Va. Code § 46-2-315. As interpreted by the West Virginia Supreme Court, this warranty arises when (1) the seller at the time of the contracting had reason to know the particular purpose for which the goods were required; (2) the buyer relied upon the seller to select suitable goods; and (3) the goods were unfit for the particular purpose intended. Syl. Pt. 2, *Jones, Inc. v. Wiedebusch Plumbing & Heating Co.*, 201 S.E.2d 248 (W. Va. 1973). To distinguish this warranty from that described above, the official commentary to the statute emphasizes that the warranty of fitness for a particular purpose "envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question." W. Va. Code § 46–2–315 cmt. 2.

Here, Plaintiff Anna Raab has not distinguished a particular purpose for which she intended to use the Class II medical components at issue that in any way differs from the ordinary purpose of such devices, which is to resurface her right hip. Without any indication of a further purpose, specific to Mrs. Raab and differentiating her use of the components from the class of other purchasers, this claim must be dismissed for failure to state a claim. *See Wilson v. Brown &*

Williamson Tobacco Corp., 968 F. Supp. 296, 302 (S.D. W. Va. 1997) (dismissing plaintiff's implied warranty of fitness for a particular purpose claim against a cigarette manufacturer where the plaintiff failed to allege any intended use for the cigarette other than "smoking the product," which, the court determined "is its ordinary purpose, and [the] purpose for which [the plaintiff] purchased the product"); *Keffer*, 791 F. Supp. 2d at 547 (noting that implied warranty of fitness for a particular purpose claim requires a showing of a "particular purpose that differs from the ordinary purpose for which the goods are generally used" and finding that claim against drug manufacturer failed as a matter of law where it failed to establish such particular use).

Plaintiffs' claim for breach of express warranty must also fail. Express warranties, like the implied warranties discussed above, are covered by the West Virginia UCC. Specifically, "West Virginia Code § 46–2–313(1)(a) and (b) mandates that an express warranty is created *only* when [a seller's] affirmation of fact, promise or description of the goods is part of the basis of the bargain made by the seller to the buyer about the goods being sold." *Reed v. Sears, Roebuck & Co., Inc.*, 426 S.E.2d 539, 546 (W. Va. 1992). "To succeed on a breach of express warranty claim, a plaintiff must show the existence of an express warranty, breach of the express warranty, and damages proximately caused by the breach." *Tyree v. Boston Sci. Corp.*, Civil Action No. 2:12-cv-08633, 2014 WL 5359008 (S.D. W. Va. Oct. 20, 2014) (quoting *Michael v. Wyeth, LLC*, No. 2:04-0435, 2011 WL 2150112, at *7 (S.D. W. Va. May 25, 2011)). Here, unlike the claims regarding defective products, the Plaintiffs' assertion of injury resulting from the defendant's product failure does not sustain a claim. Evidence of an injury resulting from a defective product does not, by itself, give rise to an inference that the seller of the product made any contrary affirmations of fact or descriptions of the goods in question before placing them "into the stream

of interstate commerce." (ECF No. 21 ¶ 61.) Plaintiffs have simply not alleged that the defendant made any representations as to the quality of the Class II components at issue, or that any such representations became the basis of any bargain between the parties.

Plaintiffs' failures here are highlighted when contrasted with the allegations at issue in *Williams*, 2015 WL 4984531. There, in a case brought against this defendant for injuries resulting from this same BHR System, the Court found the plaintiffs' breach of express warranty claim plausible where it identified specific representations as to the quality of the BHR system. *Id*. at *12 (highlighting fact that plaintiffs were able to "specify 'the product literature at issue: sales literature, warranties, [and] sales representations . . ." (quoting *Frederick v. Smith & Newphew, Inc.*, No 1:13 CV 1220, 2013 WL 6275644, at *4 (N.D. Ohio Dec. 4, 2013)). No such literature is identified in this case, nor is there even any conclusory allegation asserting that the defendant made any express warranties. There is nothing in the complaint to give plausible rise to the existence of an express warranty between the parties, and Plaintiffs' claim for breach of express warranties must as a result be dismissed.

The final claim for relief is Plaintiff Terry Raab's claim for loss of consortium. "It is generally recognized that '[i]n a procedural context, the derivative claim for loss of consortium is a mere incident to a cause of action and not the subject of an action itself.'" *State ex rel. Small v. Clawges*, 745 S.E.2d 192, 201 (W. Va. 2013) (quoting *Stokes v. Southeast Hotel Properties, Ltd.*, 877 F. Supp. 986, 1000 (W.D.N.C. 1994)). Defendant does not appear to challenge this theory of recovery independently, and accordingly "the loss of consortium claim survives alongside those claims on which it depends." *Williams*, 2015 WL 4984531, at *12.

Accordingly, with respect to Plaintiffs' fifth claim, Defendant's motion to dismiss is **GRANTED**, insofar as it seeks to dismiss Plaintiffs' claims for breach of implied warranty of fitness for a particular purpose and breach of express warranties. It is **DENIED** insofar as it seeks dismissal of Plaintiffs' claims for strict products liability, failure to warn, breach of implied warranty of merchantability, and loss of consortium.[3]

V. Conclusion

For the reasons discussed herein, Defendant's Motion to Dismiss is **GRANTED IN PART**, and **DENIED IN PART**. With respect to Plaintiffs' first and second claims for relief, Plaintiffs' claims are expressly preempted to the extent they allege that the BHR System, as approved by the FDA, was defectively designed. Defendant's Motion to Dismiss any such expressly preempted claims is **GRANTED**. With respect to Plaintiffs' third and fourth claims for relief, asserting strict products liability and negligence arising out of the February 17, 2010 revision surgery, the Motion to Dismiss is **GRANTED**. With respect to Plaintiffs' fifth claim for relief, asserting state law claims for injuries suffered as the result of Defendant's Class II device components, the Motion to Dismiss is **GRANTED** insofar as Plaintiffs fail to state a claim for breach of the implied warranty of fitness for a particular purpose and breach of express warranties.

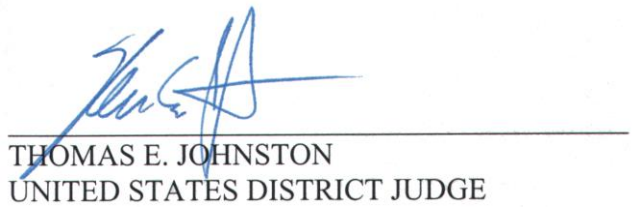
In all other respects, the Motion to Dismiss is **DENIED**.

IT IS SO ORDERED.

[3] Plaintiffs style their fifth claim for relief as asserting "state and common law claims of strict liability and negligence for Class II devices." (ECF No. 21 at 17.) However, no specific allegations of negligence are ever alleged therein. As such, to the extent the complaint seeks to assert a state law cause of action for negligence relating to the Class II devices at issue, it fails to state a claim on that ground upon which relief can be granted.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: December 15, 2015



THOMAS E. JOHNSTON
UNITED STATES DISTRICT JUDGE