IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

LEWIS WILLIAMS, JR., et al.	:	
	:	
	:	
v.	:	Civil No. CCB-14-3138
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	:	
SMITH & NEPHEW, INC.	:	

MEMORANDUM

Lewis Williams, Jr., and his wife, Angela Williams, filed this lawsuit against Smith & Nephew, Inc.—maker of the Birmingham Hip Resurfacing System ("BHR System") at the center of this lawsuit—alleging state law claims of negligence, strict liability, breach of warranty, and loss of consortium. The Williamses allege Smith & Nephew deviated, in several ways, from the requirements the Food and Drug Administration ("FDA") set in its order approving the BHR System for commercial distribution. In their view, these deviations ultimately caused Mr. Williams, the recipient of a BHR System implant, permanent and irreversible harm. Presently pending is Smith & Nephew's motion to dismiss for failure to state a claim, which invokes, as defenses, express preemption under 21 U.S.C. § 360k of the Medical Device Amendments of 1976 ("MDA"), implied preemption under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and Rule 8 insufficiency. For the reasons stated below, Smith & Nephew's motion will be granted in part and denied in part.

BACKGROUND

In 1976, Congress passed the MDA "[i]n response to the mounting consumer and regulatory concern" over medical devices, which had not previously been subject to federal regulation. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). The MDA changed that by

imposing on medical devices "a regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).

The level of oversight established by the MDA regime varies according to a medical device's safety risks. Class I devices—such as elastic bandages and examination gloves—are least risky, and are therefore "subject to the lowest level of oversight: 'general controls,' such as labeling requirements." *Id.* (quoting 21 U.S.C. § 360c(a)(1)(A)). Class II devices—such as powered wheelchairs and surgical drapes—are subject to "heightened oversight mechanisms, such as 'performance standards [and] postmarket surveillance[.]'" *Walker v. Medtronic, Inc.*, 670 F.3d 569, 572 (4th Cir. 2012) (quoting 21 U.S.C. § 360c(a)(1)(B)). Class III devices—such as replacement heart valves and pacemaker pulse generators—are the most risky, and are subject to "the highest level of federal oversight." *Id.* Accordingly, "[b]efore a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a 'reasonable assurance' that the device is both safe and effective" by completing the premarket approval ("PMA") process. *Lohr*, 518 U.S. at 477 (citing 21 U.S.C. § 360e(d)(2)).

PMA is a "rigorous" process. *Riegel*, 552 U.S. at 317 (quoting *Lohr*, 518 U.S. at 477). It requires a device-maker to provide, among other things: information concerning a device's safety and effectiveness; "a full statement of [its] components, ingredients, and properties"; the methods and facilities used to manufacture it; and examples of proposed labeling. 21 U.S.C. § 360e(c)(1). "This typically requires a 'multivolume application.'" *Walker*, 670 F.3d at 573 (quoting *Riegel*, 552 U.S. at 317). The FDA then reviews the device, and, after "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use[,]" 21 U.S.C. § 360c(a)(2)(C), decides whether to grant premarket approval. Further, "the FDA may condition its grant of premarket approval upon certain requirements."

Walker, 670 F.3d at 573. The PMA process takes, on average, 1,200 hours. *Riegel*, 552 U.S. at 318.

After a device receives FDA approval, the MDA "forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing process, labeling, or any other attribute, that would affect safety or effectiveness." *Walker*, 670 F.3d at 573 (quoting *Riegel*, 552 U.S. at 319). To make any such change, a manufacturer must submit a supplemental application that is "evaluated under largely the same criteria as an initial application." *Riegel*, 552 U.S. at 319; *see also* 21 U.S.C. § 360e(d)(6)(A)(i).

PMA also imposes reporting requirements after a device has been approved. *See Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360i). A device-maker has, for example,

> the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the [device-maker] knows of or reasonably should know of, 21 C.F.R. § 814.84(b)(2), and 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 if it recurred, § 803.50(a).

Id. at 319. The FDA "has the power to withdraw premarket approval based on newly reported data or existing information and must [do so] if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Id.* at 319-20 (citing 21 U.S.C. § 360e(e)(1)).

As will be described further below, *infra* section I.A, the MDA also includes an "express pre-emption provision[,]" *Riegel*, 552 U.S. at 316, which is codified at 21 U.S.C. § 360k.

* * *

The Williamses' complaint alleges the following. Smith & Nephew designs, manufactures, and sells the BHR System, a "metal-on-metal hip resurfacing prosthesis" made from a cobalt chromium and molybdenum alloy. (Compl. ¶ 5, ECF No. 1.) The BHR System is a Class III device under the MDA. (Compl ¶ 6.) Accordingly, it is subject to the PMA process.

In 2004, Smith & Nephew submitted an application to the FDA for premarket approval of the BHR System. (Compl. ¶ 7.) On May 9, 2006, the FDA "conditionally approv[ed]" the BHR System for commercial distribution. (Compl. ¶ 8; *see also* Pls.' Opp'n Ex. 1, Approval Order, ECF No. 11-1.) As a "condition for distribution," the FDA's Approval Order required Smith & Nephew to comply with specific regulations and provisions of the Food, Drug, and Cosmetic Act ("FDCA").[1] (Compl. ¶¶ 8a-8b.) The Approval Order also outlined other post-approval requirements for Smith & Nephew including, for example, studies of the longer-term safety and effectiveness of the BHR System for patients in the United Kingdom and United States; a training program for doctors using the BHR System; submission of adverse reaction and device defect reports to the FDA; and labeling and warning obligations. (Compl. ¶¶ 8c-8l.) The Approval Order warned that failure to comply with any of these conditions would be grounds for the withdrawal of FDA approval. (Compl. ¶ 9.) Upon receiving FDA approval, Smith & Nephew began distributing the BHR System. (Compl. ¶ 10.)

On September 21, 2006, Mr. Williams received an implant of the BHR System. (Compl. ¶ 11.) Over half a decade later, in April 2013, he was admitted to a hospital with coughing, shortness of breath, fatigue, weakness, and other symptoms of cardiomyopathy. (Compl. ¶ 12.) His ejection fraction was 15-20%.[2] (*Id.*) In May 2013, Mr. Williams's cardiologist evaluated Mr. Williams and, after blood testing, confirmed that he had cobalt and chromium poisoning. (Compl. ¶ 13.) The cardiologist believed erosion of the BHR System had released metal ions into, and poisoned, Mr. Williams's bloodstream. (*Id.*) Accordingly, the decision was made to

[1] These include 21 C.F.R. §§ 801.109, 814.82, and 814.84, and §§ 520(e), 502(q), and 502(r) of the FDCA.
[2] Ejection fraction is "a measurement of the percentage of blood leaving [the] heart each time it contracts." Martha Grogan, *Ejection Fraction: What Does it Measure?*, Mayo Clinic (Feb. 20, 2013), http://www.mayoclinic.org/ejection-fraction/expert-answers/faq-20058286. "A normal heart's ejection fraction may be between 55 and 70." Am. Heart Ass'n, *Ejection Fraction Heart Failure Measurement*, Heart.org (Mar. 24, 2015), http://www.heart.org/HEARTORG/Conditions/HeartFailure/SymptomsDiagnosisofHeartFailure/Ejection-Fraction-Heart-Failure-Measurement_UCM_306339_Article.jsp. "A measurement under 40 may be evidence of heart failure or cardiomyopathy." *Id.*

remove the BHR System as soon as possible. (Compl. ¶ 14.) By June 2013, Mr. Williams's ejection fraction was 8%. (*Id.*) On July 9, 2013, Mr. Williams's BHR System was removed and replaced with a ceramic hip replacement system. (Compl. ¶ 15.) The removed BHR System showed signs of wear and tear. (Compl. ¶ 16.) After removal, Mr. Williams's cobalt levels, cardiomyopathy, and ejection fraction immediately began to improve. (Compl. ¶ 17.) But the "long term toxic exposure" had caused "permanent, irreversible damage." (*Id.*)

On October 6, 2014, the Williamses filed their four-count complaint. Count I alleges negligence. The Williamses allege that, with respect to its development and distribution of the BHR System, Smith & Nephew had the "duty to comply with and not deviate from the PMA requirements contained in the BHR System's FDA approval order[,]" the conditions of approval attached to that order, and "other federal statutory and regulatory requirements" applicable to the BHR System. (Compl. ¶¶ 19-21.) These duties were ongoing—that is, they existed even after the FDA had issued its Approval Order. (*See* Compl. ¶¶ 22-25.) "In parallel with" these duties, Maryland law imposed on Smith & Nephew "post-sale duties": to monitor the sale and use of the BHR System; discover defects associated with the BHR System's use; and warn the government, doctors, and users about those defects. (Compl. ¶ 26.) Furthermore, "Maryland law treats violations of federal statutes and regulations as evidence of common law negligence . . . ." (Compl. ¶ 27.) Smith & Nephew allegedly "failed to comply with and not deviate from the[se] conditions . . . ."[3] (Compl. ¶ 28.) And those failures meant that "the FDA, doctors implanting BHR [S]ystems, and the public" did not know about the difficulties doctors and patients had with

[3] The Williamses allege, for example, that Smith & Nephew failed to conduct required studies; collect required clinical data; report to the FDA its awareness of many patients experiencing adverse reactions to the BHR System; warn the medical community or Mr. Williams's doctors about those adverse reactions and the potential dangers associated with metal poisoning; implement an adequate training program; follow up on patient-reported adverse events; issue PMA supplements or updated labels; and use a metal of a "different hardness" than that approved by the FDA. (*See* Compl. ¶¶ 28a-l.)

the BHR System, as well as the metal poisoning risks associated with the device. (Compl. ¶ 29.) Had the FDA or Mr. Williams's doctors known about these risks, Mr. Williams would not have experienced the "longstanding exposure to high levels of cobalt and other metals in [his] blood" that ultimately harmed him. (*Id.*) Moreover, had the FDA or Mr. Williams's doctors been "fully informed" of the metal poisoning risks associated with the BHR System, other preventive action could and would have been taken. (Compl. ¶¶ 30-31.) As a proximate result of Smith & Nephew's failures, Mr. Williams received a BHR System implant that "released high levels of cobalt and other metal ions into [his] bloodstream and caused him to develop metal poisoning, cardiomyopathy, heart damage, and other injuries." (Compl. ¶ 32.) The Williamses clarify that this count is "based solely on Smith & Nephew's failure to comply with the PMA approval order and the conditions and requirements set by federal regulatory and statutory law" and that they seek damages for violations of these duties "to the extent, and only to the extent, that they run parallel to the federal conditions and requirements." (Compl. ¶ 34.)

Count II alleges strict liability on the theory that the BHR System was "defective and unreasonably dangerous," both when it entered the stream of commerce and when it was implanted into Mr. Williams's body, as a result of deviations from the FDA's requirements. (Compl. ¶ 36.)[4] As a result of these design and manufacturing defects, Mr. Williams suffered and continues to suffer harm. (Compl. ¶¶ 37-38.) The Williamses again clarify they allege strict liability only insofar as state requirements under that claim parallel federal ones. (Compl. ¶ 39.)

Count III alleges breach of both express and implied warranty based on repeated assurances to Mr. Williams's doctors that the BHR System "was a safe medical device, free from known or unknown defects and hazards." (Compl. ¶ 41.) Smith & Nephew's sales materials

[4] Specifically, the BHR System was allegedly designed and manufactured with a different "material hardness" than that approved by the FDA; a material that "could not withstand the foreseeable wear and tear forces and expected usage by patients"; and a different "material composition" than that approved by the FDA. (Compl. ¶¶ 36a-f.)

allegedly referred to the BHR System's durability in relation to other hip replacement systems. (*Id.*)

Count IV alleges loss of consortium based on the "interfere[nce] with and injur[y] [to]" The Williamses' marital relationship. (Compl. ¶ 47.)

On November 21, 2014, Smith & Nephew moved to dismiss for failure to state a claim.

ANALYSIS

When ruling on a motion under Rule 12(b)(6), the court must "accept the well-pled allegations of the complaint as true," and "construe the facts and reasonable inferences derived therefrom in the light most favorable to the plaintiff." *Ibarra v. United States*, 120 F.3d 472, 474 (4th Cir. 1997). "Even though the requirements for pleading a proper complaint are substantially aimed at assuring that the defendant be given adequate notice of the nature of a claim being made against him, they also provide criteria for defining issues for trial and for early disposition of inappropriate complaints." *Francis v. Giacomelli*, 588 F.3d 186, 192 (4th Cir. 2009). "The mere recital of elements of a cause of action, supported only by conclusory statements, is not sufficient to survive a motion made pursuant to Rule 12(b)(6)." *Walters v. McMahen*, 684 F.3d 435, 439 (4th Cir. 2012) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). To survive a motion to dismiss, the factual allegations of a complaint "must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted). "[A] plaintiff need not 'forecast' evidence sufficient to prove the elements of the claim. However, the complaint must allege sufficient facts to establish those elements . . . . [and] advance the plaintiff's claim 'across the line from conceivable to plausible.'" *Walters*, 684 F.3d at 439 (citations omitted) (quoting *Twombly*, 550 U.S. at 570).

In its motion to dismiss, Smith & Nephew argues: (1) section 360k of the MDA expressly preempts the Williamses' claims; (2) even were it otherwise, the Williamses' claims are impliedly preempted; and (3) the Williamses' claims are insufficient under Rule 8. The court considers Smith & Nephew's two preemption arguments first, and then its Rule 8 argument.

I. Preemption

The Supremacy Clause provides 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. "Consistent with that [Clause's] command . . . state laws that conflict with federal law are 'without effect[]'"—they are preempted. *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). Preemption can occur either expressly or impliedly. Express preemption occurs when Congress "define[s] explicitly the extent to which its enactments pre-empt state law." *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990). Implied preemption occurs: (1) when state law "regulates conduct in a field that Congress intended the Federal Government to occupy exclusively[,]" or (2) when state law "actually conflicts with federal law[,]" which exists "where it is impossible for a private party to comply with both state and federal requirements, . . . or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 79 (citations and internal quotation marks omitted).

"[T]wo cornerstones of [the Supreme Court's] pre-emption jurisprudence" guide the preemption analysis. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009); *see also Lohr*, 518 U.S. at 485-86. First is the presumption that "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth*, 555 U.S. at 565 (quoting *Lohr*, 518 U.S. at 485). Second is the "presumption against pre-emption[,]" *id.* at 565 n.3, under which "Congress does not cavalierly

pre-empt" state law claims, *Lohr*, 518 U.S. at 485. Instead, the starting "assumption" is that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).[5]

Smith & Nephew invokes both express and implied preemption arguments here.

A. Express Preemption

Smith & Nephew first argues that section 360k of the MDA expressly preempts all of the plaintiffs' claims. That section of the MDA states:

> [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). Though the parties agree that section 360k expresses Congress' intent to preempt state requirements, they disagree about the scope of that clause's preemptive effect.

Riegel established a two-part inquiry to decide when a plaintiff's state common law requirements were "different from, or in addition to," federal ones and would therefore be preempted by section 360k. 552 U.S. at 321; *see also Walker*, 670 F.3d at 577-81 (discussing and applying *Riegel*'s "two-part inquiry"). The first part of the inquiry asks "whether the Federal Government has established requirements applicable to" the device at issue. *Riegel*, 552 U.S. at 321. The second part asks "whether the [plaintiff's] common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22 (quoting 21 U.S.C. § 360k(a)).

[5] Although a close reading of *Lohr* suggests these presumptions might not apply to claims of implied preemption, the Supreme Court has "long held to the contrary." *Wyeth*, 555 U.S. at 565 n.3 (collecting cases recognizing the presumption against preemption).

In elaborating on this second part, the *Riegel* Court held that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties." *Id.* at 324. *Riegel* also reaffirmed what *Lohr* had previously decided: "§ 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[,]" *id.* at 330 (quoting *Lohr*, 518 U.S. at 495)[6]; *accord Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc) ("The rule that emerges from [the Supreme Court's MDA preemption] cases 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.").

Here, the federal government has established requirements "applicable to" the BHR System, which satisfies the first part of the inquiry. As the Supreme Court held in *Riegel*, "[u]nlike general labeling duties" applicable to Class I and Class II devices, PMA "is specific to individual devices" and is "focused on safety[.]" *Id.* at 322-23. And, "because all Class III devices are required to undergo the [PMA] process, federal requirements exist with respect to all Class III devices[,]" including the BHR System at issue here. *Walker*, 670 F.3d at 577.

As to the second part of the inquiry—whether state requirements exist "with respect to" the BHR System that are not parallel to the federal requirements—the court concludes that some of the Williamses' claims are preempted by section 360k, but others are not.

As an initial matter, the court concludes that the Maryland tort law duties the Williamses allege are "with respect to" the BHR System. *Riegel* said as much. *See* 552 U.S. at 328 (rejecting argument that "the duties underlying negligence, strict-liability, and implied-warranty claims . . . are not requirements maintained 'with respect to devices.'"). And the Williamses do

[6] Because, however, the *Riegel* plaintiffs had failed to argue before the Second Circuit that their claims were parallel, the Supreme Court did not decide the contours of what constituted a parallel claim.

not dispute that Maryland common law duties are, in every material respect, analogous to those asserted under New York common law in *Riegel*. But even if all of the Williamses' claims are "with respect to" the BHR System, the question remains: are they parallel, such that they evade section 360k's preemptive effect?

The Williamses' design defect claim is not parallel. That claim alleges Smith & Nephew was required to use a different design for the BHR System, even though the FDA approved that design in its Approval Order. In other words, the Williamses "seek[] to impose a more demanding standard than that of the FDA, rather than a parallel one." *Walker*, 670 F.3d at 580. 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*." *Id.* at 580 (citing *Riegel*, 552 U.S. at 324-25); *see also Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1043-44 (D. Ariz. 2014) (collecting cases holding design defect claims preempted). Section 360k expressly preempts this claim.

Nor is their breach of implied warranty claim parallel. That claim alleges Smith & Nephew violated warranties, imposed by operation of Maryland law, that goods are either "fit for the ordinary purposes for which such goods are used[,]" Md. Code, Com. Law § 2-314, or fit for the "particular purpose" expressed by the device's buyer, *id.* § 2-315. Yet the FDA, through the PMA process, expressly defines the scope of a device's "intended use," 21 U.S.C. § 360e(c)(2)(A)(iv), and determines all representations Smith & Nephew "is obligated to make concerning" the BHR System, *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 707 (S.D. Tex. 2014). Accordingly, a claim for breach of an implied warranty relies on requirements imposed by Maryland law that are more burdensome than those imposed by the MDA. Such a claim is expressly preempted. *See McCormick v. Medtronic, Inc.*, 101 A.3d 467, 491 (Md. Ct. Spec.

App. 2014) ("To the extent that the [plaintiffs] allege the breach of the implied warranties of merchantability or fitness for a particular purpose, their claims are expressly preempted[.]").

On the other hand, the Williamses' failure to warn claim is parallel. Maryland tort law recognizes that a "duty to warn can undergird a negligence case in . . . a product liability action . . . ." *Gourdine v. Crews*, 955 A.2d 769, 779 (Md. 2008).[7] Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make "reasonable efforts" to convey an effective warning. *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633, 646 (Md. 1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA. The Williamses' failure to warn claim tracks Maryland law's elements: Smith & Nephew learned new information about the BHR System's risks, yet failed to make reasonable efforts to issue an effective post-sale warning. And this claim is parallel to several federal duties imposed by the PMA including, for example, the duty to provide the FDA with "Adverse Reaction" and "Device Defect" reports, (Approval Order Attach. 1, Conditions of Approval, at 2 (citing 21 C.F.R. § 814.82(a)(9))), and the duty under the Medical Device Reporting Regulation to "report to the FDA whenever [manufacturers] receive or otherwise become aware of information . . . that reasonably suggests that a device marketed by the manufacturer . . . [m]ay have caused or contributed to a death or serious injury[,]" (*id.* at 3). So section 360k does not preempt this claim. *Accord Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) ("To the extent that [plaintiff] asserts a failure to warn claim based only on [the device-maker]'s failure to comply with FDA regulations, . . . such a claim is not expressly preempted.").[8]

[7] The Maryland Court of Appeals has stated that "in the products liability domain a duty to warn is imposed on a manufacturer if the item it produces has an inherent and hidden danger about which the producer knows, or should know, could be a substantial factor in bringing injury to an individual . . . ." *Id.* at 780 (quoting *Moran v. Faberge, Inc.*, 332 A.2d 11, 20 (Md. 1975)).

[8] The Williamses assert negligence based on breach of other duties, including the duties to train physicians, conduct studies, and recall the BHR System. As described below, claims based on these duties are impliedly preempted. *See infra* Section I.B.

The same is true for their manufacturing defect claim.[9] Maryland law provides for recovery on a strict liability theory for unreasonably dangerous products sold in a defective condition. *See, e.g.*, *Phipps v. Gen. Motors Corp.*, 363 A.2d 955, 958 (Md. 1976). One way of proving a product defect is by showing "a deficiency in its manufacture[.]" *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 407 (D. Md. 2001) (citing *Simpson v. Standard Container Co.*, 527 A.2d 1337, 1339-40 (Md. Ct. Spec. App. 1987)). The Williamses assert such a theory here: the BHR System, as manufactured, deviated from its intended design, and that deviation caused Mr. Williams harm. And because the FDA approved that design—and *only* that design—any such deviation would also violate the federal requirements outlined in the PMA Approval Order. *Accord Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010) (concluding that "[plaintiff]'s claims for defective manufacture in violation of federal law are not expressly preempted by section 360k"); *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 933 (5th Cir. 2006) (concluding that the district court "properly limited [the plaintiff]'s negligence claims to a claim that the [medical device] used in her surgery was defectively manufactured because it did not comply with the FDA-approved specifications" (citation omitted)); *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 105 (D. Conn. 2014) (holding that manufacturing defect claim survived express preemption based on allegation that medical device "was not manufactured in accordance with federal standards and that the failure to meet these standards resulted in the defect observed on the device . . . ."). This claim is not preempted.

The Williamses' breach of express warranty claim is partly parallel and partly not. It is parallel to the extent that it is based on those statements "made in voluntary communications with the medical profession or the public[.]" *McCormick*, 101 A.3d at 487, 491. This is so

[9] Smith & Nephew does not appear to argue section 360k preempts the Williamses' manufacturing defect claim. (*See* Def.'s Mot. Dismiss 15, ECF No. 8.)

because federal law "already requires [Smith & Nephew] to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law."[10] *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 788 (D. Minn. 2009); *see also Schouest*, 13 F. Supp. 3d at 707. But the claim is not parallel to the extent that the claim is "based solely on alleged warranties in the FDA-approved labeling[.]" *McCormick*, 101 A.3d at 491. To hold Smith & Nephew liable "for making the statements that the FDA required it to make, or . . . for not making statements that the FDA required it not to make," would be to impose state law requirements "different from, or in addition to," federal ones. *Id.* at 487; *see also Riley*, 625 F. Supp. 2d at 787 ("[E]xpress-warranty claims that are based solely on the contents of an FDA-approved label are expressly preempted by § 360k(a).").

Finally, "[b]ecause the loss of consortium claim is derivative of [the Williamses'] claims, it survives to the extent that the other claims survive." *McCormick*, 101 A.3d at 492 n.19 (citations omitted).

* * *

Walker—the Fourth Circuit's only post-*Riegel* decision interpreting the MDA—supports this court's conclusions, even though the *Walker* majority ultimately affirmed the district court's holding that the West Virginia common law tort claims at issue were preempted. *See Walker*, 670 F.3d at 571. That holding was premised on the plaintiff's "concession that the device [at issue] was designed, manufactured, and distributed *in compliance with* the terms of its premarket approval . . . ." *Id.* (emphasis added). The FDA's approval letter "contained a number of specific 'Conditions of Approval[,]' . . . [but] did *not* include the plus or minus 15 percent specification" plaintiff alleged the defendant was required to comply with. *Id.* at 579 (emphasis

[10] The PMA Approval Order states that the FDA "does not evaluate information related to contract liability warranties[.] [H]owever you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws." (Approval Order, at 3.)

in original). "[W]ithout an express statement in the FDA's approval materials" that the device at issue was subject to that specification, the plaintiff's was an "attempt to impose one through civil tort liability [that] would impose additional requirements in violation of the MDA as interpreted by *Riegel*." *Id.* at 579 n.5.

Here, unlike in *Walker*, the bulk of the Williamses' claims assert that the BHR System was manufactured and distributed *out of compliance* with the terms of its PMA.[11] That takes those claims outside the scope of section 360k's protections. *See, e.g.*, *Bausch*, 630 F.3d at 553 ("Section 360k provides immunity for manufacturers . . . to the extent that they comply with federal law, but it does not protect them if they have violated federal law."). The Williamses have pointed to numerous "Conditions of Approval" and other requirements in the PMA that they claim Smith & Nephew violated. These are valid predicates because, as the *Walker* majority noted, "the FDA's [premarket] approval and the Conditions of Approval, taken together, . . . establish[] the specific federal requirements for" Class III devices like the BHR System here. 670 F.3d at 579 n.5 (alterations in original) (quoting *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 228 (6th Cir. 2000)). And the Williamses rely on state law duties that parallel these federal law duties. Section 360k does not preempt claims based on those duties.

A survey of other district court cases applying section 360k to claims against Smith & Nephew for harm caused by the BHR System further supports the court's conclusions.[12]

In *Comella v. Smith & Nephew, Inc.*, for example, the Northern District of Illinois held that section 360k did not expressly preempt plaintiffs' claim that Smith & Nephew had "breached a common law duty by failing to advise the FDA about dangers that became manifest after the product was put on the market." No. 13 C 1850, 2013 WL 6504427, at *2 (N.D. Ill.

[11] As noted, although the Williamses also assert design defect and implied warranty claims, they are preempted.
[12] Unpublished cases are cited for the soundness of their reasoning, and not for any precedential value.

Dec. 11, 2013). This was so because Illinois common law's duty to warn was "sufficiently parallel" to requirements "under the [MDA] and CGMPs to make certain reports and disclosures to the FDA . . . ." *Id.*; *see also Elmore v. Smith & Nephew, Inc.*, No. 12 C 8347, 2013 WL 1707956, at *2-3 (N.D. Ill. Apr. 19, 2013) (rejecting Smith & Nephew's express preemption argument); *Tillman v. Smith & Nephew, Inc.*, No. 12 C 4977, 2013 WL 3776973, at *3 (N.D. Ill. July 18, 2013) ("This court agrees with and adopts *Elmore*'s [express preemption] analysis."). Likewise here, the Williamses allege a violation of the Maryland common law duty to warn, which parallels the federal duties under the MDA.

Although the Southern District of New York, in *Gale v. Smith & Nephew, Inc.*, dismissed several of plaintiff's claims—including for manufacturing and design defect and a general post-sale duty to warn—the court did so because plaintiff "d[id] not so much as reference the FDA, federal law, or federal regulation" for the former claim, and "neither specifie[d] the legal basis for any such duty, nor to whom the duty [wa]s allegedly owed" for the latter. 989 F. Supp. 2d 243, 249-50 (S.D.N.Y. 2013). Here, by contrast, the Williamses have pointed to a variety of specific PMA requirements that Smith & Nephew allegedly violated and have a valid parallel basis in Maryland negligence law.

In *Herron v. Smith & Nephew, Inc.*, the Eastern District of California ultimately dismissed the plaintiff's complaint with leave to amend because, while "[c]ertainly, some portion of [plaintiff's] claims are not preempted," the allegations were "so ambiguous" that the court could not decide which specific theories escaped express preemption. 7 F. Supp. 3d 1043, 1052 (E.D. Cal. 2014). Here, the Williamses' complaint is far less ambiguous. As noted below, the complaint asserts plausible claims.

B. Implied Preemption

Even if the Williamses' claims evade section 360k's preemptive scope, Smith & Nephew argues they are impliedly preempted. But, with one small exception, the court finds that the Williamses' claims are not impliedly preempted under either a field or conflict preemption theory. In fact, Smith & Nephew does not invoke field preemption in its briefing,[13] so the court addresses only its conflict preemption argument under *Buckman*.

In *Buckman*, plaintiffs sued for damages under state law based on injuries allegedly caused by orthopedic bone screws, which were Class III devices. 531 U.S. at 343. Instead of suing the screws' manufacturer, however, the plaintiffs sued the consulting company that helped that manufacturer navigate the federal regulatory process on the theory that it "made fraudulent representations to the [FDA] in the course of obtaining approval to market the screws." *Id.* The *Buckman* Court held that these "fraud-on-the-FDA" claims were impliedly preempted because they "inevitably conflict[ed] with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. In enacting the FDCA, the Court noted, Congress "le[ft] no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions . . . ." *Id.* at 349 n.4 (citing 21 U.S.C. § 337(a)).

In light of *Buckman*, Smith & Nephew argues the Williamses' claims are impliedly preempted because they "seek to enforce the MDA and . . . second-guess the FDA's regulatory decisions . . . ." (Def.'s Mot. Dismiss 9.) There are two problems with Smith & Nephew's reliance on *Buckman*.

The first problem is that *Buckman* does not apply to the tort claims asserted here. Simply put, none of the Wiliamses' claims resembles the state law "fraud-on-the-FDA" claim asserted

[13] Smith & Nephew argues that this court should "consider implied preemption under principles of conflict preemption." (Def.'s Mot. Dismiss 8.) But it never mentions field preemption.

by the plaintiff in *Buckman*. *See* 531 U.S. at 348. "[Plaintiffs'] claims, like those in *Lohr*, and unlike those in *Buckman*, are tort law claims based on manufacturing defects, not fraud on a federal agency." *Bausch*, 630 F.3d at 557; *see also, e.g.*, *Hughes*, 631 F.3d at 775 ("The plaintiffs in *Buckman* were attempting to assert a freestanding federal cause of action based on violation of the FDA's regulations; the plaintiffs did not assert violation of a state tort duty."). Accordingly, the federal interference rationale followed in *Buckman* does not apply.

The second problem is that, even were it applicable here, *Buckman* does not support a finding of implied preemption. *See Stengel*, 704 F.3d at 1235 (Watford, J., concurring) (explaining how "accepting that argument would require an unwarranted expansion of *Buckman*'s rationale"). Indeed, 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.

Buckman itself forecloses such an expansive reading of its holding. It is true that the *Buckman* Court was concerned about state law's interference in "the relationship between a federal agency and the entity it regulates[.]" *Buckman*, 531 U.S. at 347. But the Court shielded claims "relying on traditional state tort law which had predated the federal enactments" at issue. *Id.* at 353. In other words, *Buckman* left a gap—albeit a "narrow gap"—for some state law claims. *In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley*, 625 F. Supp. 2d at 777). As long as a plaintiff's alleged state law claim does not "exist solely by virtue" of the federal requirements, a claim threads that gap. *Buckman*, 531 U.S. at 353. "For a state-law claim to survive, then, the claim must be premised

on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." *Riley*, 625 F. Supp. 2d at 777.

The majority of the Williamses' remaining claims properly thread that gap. These claims do not exist solely because the PMA process exists; as already noted, they have an independent basis in Maryland tort law that predates the requirements outlined in the PMA process. *See, e.g.*, *McCormick*, 101 A.3d at 492 ("The claim for breach of express warranty has a long and venerable history in Maryland . . . ."). And this is true even if proving those independent state law claims will rely, in part, on evidence that a federal requirement was violated.[14]

Some claims, however, do not thread the gap. As noted, *supra* note 9, the Williamses allege negligence based on Smith & Nephew's violation of federal duties other than a failure to warn the FDA. Although it may be true that Smith & Nephew violated those federal duties, the Williamses do not cite a single authority in their opposition brief showing that these are actionable under state law. They do not suggest that Maryland law, for example, independently provides a remedy for the failure to "conduct a study on the learning curve and training program of doctors in the United States[,]" (Compl. ¶ 8f), or the failure to "initiat[e] a voluntary recall[,]" (Compl. ¶ 28g). Without a freestanding basis in state law, such claims are impliedly preempted.

In sum, the only claims impliedly preempted are those that are based on the violation of federal duties but that have no freestanding basis in Maryland tort law. The Williamses' remaining claims, based on the failure to warn, are not impliedly preempted under *Buckman* insofar as they do not remain premised solely on Smith & Nephew's violation of federal duties.

II. Rule 8 Sufficiency

[14] Maryland law permits reliance on statutory violations to prove negligence. *See Absolon v. Dollahite*, 831 A.2d 6, 11 (Md. 2003) ("[T]he settled rule in Maryland is that a statutory violation is evidence of negligence.").

Smith & Nephew's final argument is that the Williamses have not pled claims that are sufficient under Rule 8. "There are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular." *Bausch*, 630 F.3d at 558. The Williamses must simply meet the plausibility standard applied in *Iqbal* and *Twombly*. With one exception, they have done so here.

The exception is the Williamses' manufacturing defect claim. The Williamses make a blanket statement that Smith & Nephew deviated from the design approved by the FDA. But they do not indicate what that design is, nor do they point to any specific facts tending to show such deviation. The Williamses allege that the device had a "different hardness in metal and a variance in other metallurgical properties that caused or allowed it to break down sooner" than it should have, (Compl. ¶¶ 28h-i), but at the same time admit they have no information regarding "the specific material composition and hardness requirements of the metal used in the BHR System[,]" (Opp'n 22-23, ECF No. 11). This claim is too speculative. The court will grant the Williamses leave to seek to amend this claim, as they request, but they must add sufficiently specific factual allegations to make their claim plausible.

On the other hand, the Williamses' failure to warn claim is plausible. The Williamses allege that Smith & Nephew "knew or should have known that its BHR System was causing or contributing to serious injuries and were failing in the field." (Compl. ¶ 28f.) In making this claim, they allege that Smith & Nephew received over 600 adverse event reports through September 2011, yet delayed production of these reports to the FDA and followed up on only two percent of them. (*Id.*) This allegation is sufficiently specific to make it plausible. Smith & Nephew responds with a causation argument: even had it warned relevant third parties like the FDA or Mr. Williams' doctor, Smith & Nephew's warnings would not have affected Mr.

Williams' doctor's decision to implant the BHR System. (*See* Def.'s Mot. Dismiss 11.) Even if that is so, it is still plausible that, had he been warned, Mr. Williams' doctor would have removed the device earlier. "[A]t this juncture"—on a motion to dismiss—"the [Williamses]' allegations of causation are adequate." *Stengel*, 704 F.3d at 1234-35 (Watford, J., concurring).

The Williamses' breach of express warranty claim also is plausible. Although the Williamses "do[] not identify the sales representatives" who allegedly made the alleged representations and do not "identify when these statements were supposedly made[,]" (Def.'s Reply 14, ECF No. 12), they do specify "the product literature at issue: sales literature, warranties, [and] sales representations . . . ." *Frederick v. Smith & Nephew, Inc.*, No. 1:13 CV 1220, 2013 WL 6275644, at *4 (N.D. Ohio, Dec. 4, 2013). Moreover, they specify what aspects of the BHR System were the subject of these warranties, including "safety," "effectiveness," and "durability." (Compl. ¶ 41.) Smith & Nephew's sales representatives allegedly "repeatedly warranted" that the BHR System did not have "the same wear and tear problems" that faced other systems, and that it used a manufacturing process that "prevented cobalt and other metal ion release." (*Id.*) Those allegations are sufficiently specific to make the claim plausible.

Finally, Smith & Nephew notes the Williamses' loss of consortium claim is "derivative of" the other three counts, and thus rises and falls with those other claims. (Def.'s Reply 5 n.3.) It does not argue that that claim fails to satisfy the Rule 8 standard on any independent ground. Accordingly, the loss of consortium claim survives alongside those claims on which it depends.

With the exception of the manufacturing defect claim, the Williamses' claims meet the Rule 8 standard. The Williamses have done far more than "simply incant[ing] the magic words '[Smith & Nephew] violated FDA regulations' . . . ." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634

F.3d 1296, 1301 (11th Cir. 2011) (quoting *In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)).

CONCLUSION

Section 360k expressly preempts the Williamses' design defect and implied warranty claims. Their remaining manufacturing defect, failure to warn, and express warranty claims are parallel to the federal requirements applicable to the BHR System and therefore evade the reach of that preemption clause. Further, with a small exception, these remaining claims are not impliedly preempted under *Buckman* insofar as they are independently supported by Maryland tort law. Finally, only the manufacturing defect claim fails to meet the Rule 8 pleading standard. Accordingly, the court will: (1) grant Smith & Nephew's motion to dismiss with respect to the design defect and implied warranty claims; (2) deny Smith & Nephew's motion with respect to the remaining claims insofar as they are parallel to the requirements imposed by the federal MDA and independently cognizable under Maryland law, and (3) grant the Williamses leave to seek to amend their manufacturing defect claim.

A separate Order follows.

August 18, 2015
Date

/s/
Catherine C. Blake
United States District Judge