IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MARILYN J. MIKOS,	*	
Plaintiff,	*	
v.	*	Civil Action No. GLR-21-912
THE ABBOTT LABORATORIES, et al.,	*	
Defendants.	*	

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MEMORANDUM OPINION

THIS MATTER is before the Court on Defendants Abbott Laboratories, Inc. ("Abbott Labs") and St. Jude Medical, LLC's ("St. Jude") Motion to Dismiss (ECF No. 13).[1] The Motion is ripe for disposition, and no hearing is necessary. See Local Rule 105.6 (D.Md. 2021).[2] For the reasons set forth below, the Court will grant in part and deny in part the Motion.

[1] Plaintiff Marilyn J. Mikos's Complaint names "The Abbott Laboratories d/b/a Abbott Laboratories, Inc." as a Defendant. Defendants aver, and Mikos does not contest, that there is no existing entity named "The Abbott Laboratories." Rather, Abbott Laboratories Inc. is a subsidiary of an ultimate parent company, Abbott Laboratories. Accordingly, the Court will direct the Clerk to change the name of Defendant "The Abbott Laboratories d/b/a Abbott Laboratories, Inc." to Defendant "Abbott Laboratories, Inc." Similarly, Mikos's Complaint names "St. Jude Medical Inc. d/b/a St. Jude Medical S.C., Inc." Defendants aver, and Mikos does not contest, that on January 4, 2017, St. Jude Medical, Inc. was acquired by parent company Abbott Laboratories, and thereafter became known as St. Jude Medical, LLC, a wholly owned subsidiary of Abbott Laboratories. Accordingly, the Court will direct the Clerk to change the name of Defendant "St. Jude Medical Inc. d/b/a St. Jude Medical S.C., Inc." to Defendant "St. Jude Medical, LLC."

[2] The Court recognizes that Defendants have filed a Request for Oral Argument on Their Motion to Dismiss (ECF No. 21). Having determined that no hearing is necessary to understand the issues underlying the Motion, the Court will deny Defendants' Request.

I. BACKGROUND[3]

A. Factual Background

Plaintiff Marilyn J. Mikos suffers from Complex Regional Pain Syndrome ("CRPS") in her right leg. (Compl. ¶ 8, ECF No. 2). CRPS "is an array of neuropathic pain conditions that has been known by many names such as Sudeck's Atrophy, Reflex Sympathetic Dystrophy Syndrome and Causalgia." (Id. ¶ 22). The disease "can be very painful and often arises after trauma, surgery, or a limb immobilization. It is believed that about 10-20% of cases become chronic and resistant to any treatment. . . . [T]he hallmarks of CRPS are continuous pain and mechanical hyperalgesia which are disproportionate to the inciting event." (Id.).

To treat her CRPS, on March 1, 2018, Mikos's treating physicians placed an Implanted Generator Proclaim Dorsal Root Ganglion ("DRG") Model 3664 (the "Proclaim DRG") into her back. (Id. ¶ 14). DRGs are "structures along the spinal column made up of densely populated sensory nerves, and they act like traffic lights, regulating signals and sensations that travel through nerve fibers along the spinal column to the brain." (Id. ¶ 23). DRG therapy works by stimulating DRGs, which "can reduce pain in specific locations in the body." (Id.). The Proclaim DRG is a neurostimulator system designed to treat chronic pain in the foot, knee, or groin in patients with CRPS. (Id. ¶ 8). Neurostimulator systems like the Proclaim DRG "consist of electrical leads, an optional extension, and an implantable pulse generator," and work by threading the leads "into the epidural space and

[3] Unless otherwise noted, the Court takes the following facts from the Complaint and accepts them as true. See Erickson v. Pardus, 551 U.S. 89, 94 (2007).

from there, into the intervertebral foramen, in which the DRG lies." (Id. ¶ 26). Patients are provided a small hand-held controller to program the leads to provide stimulation. (Id.).

Days after having the Proclaim DRG installed, Mikos began to experience "throbbing, dull, aching, shooting, [and] stabbing" pain, with a pain level of nine out of ten. (Id. ¶ 16). Over the following two years, the Proclaim DRG caused Mikos to experience "significant pain and discomfort and incur[] significant medical bills from multiple physician visits, including the ultimate removal of the defective unit from her body on July 15, 2020." (Id. ¶ 17). Mikos alleges that her pain was caused in part by the fact that Defendants provided her health care providers the incorrect leads with the Proclaim DRG. (Id. ¶¶ 14, 17, 34).

In 2016, the U.S. Food and Drug Administration ("FDA") granted approval for the Proclaim DRG device through its Premarket Approval process. (See Feb. 26, 2016 FDA Premarket Approval Letter ["Axium PMA"] at 1, ECF No. 14-1; Nov. 28, 2016 FDA Premarket Approval Letter ["Proclaim DRG PMA"] at 1–2, ECF No. 14-2).[4] Mikos alleges

[4] The Premarket Approval documents provided by Defendants are also available on the FDA website. See FDA, Axium Neurostimulator System, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150004 (Nov. 15, 2021); FDA, Proclaim Dorsal Root Ganglion Neurostimulation System, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150004S002 (Nov. 15, 2021). Courts in this circuit "routinely take judicial notice of information contained on state and federal government websites." United States v. Garcia, 855 F.3d 615, 621 (4th Cir. 2017). Indeed, this Court has also taken judicial notice of a Class III device's status as a premarket-approved device. See Smith v. St. Jude Med. Cardiac Rhythm Mgmt. Div., No. CCB-12-1746, 2013 WL 1104427, at *3 (D.Md. Mar. 13, 2013). Mikos has not objected to Defendants' request that the Court take judicial notice of the Proclaim DRG Premarket Approval documents. Accordingly, the Court takes judicial notice of ECF Nos. 14-1 and 14-2.

that around that same time, Defendants became aware that the failure rates of the Proclaim DRG had reached "exceedingly high[]" levels and "failed to warn consumers of this fact." (Compl. ¶¶ 35–36). Mikos further alleges that despite knowledge of these risks, Defendants continued to market the device as being safe for use and "failed to provide adequate warnings or instructions for use regarding said risks." (Id. ¶ 38). Mikos also alleges that Defendants failed to adequately instruct physicians regarding the implant and use of the Proclaim DRG, (id. ¶ 58), and that Defendants failed to manufacture the Proclaim DRG in compliance with current Good Manufacturing Practices ("cGMPs"), (id.).

B. Procedural History

On February 26, 2021, Mikos filed this lawsuit against Defendants in the Circuit Court for Baltimore County, Maryland. (ECF No. 2). Defendants removed the action to this Court on April 12, 2021. (ECF No. 1). Mikos's seven-count Complaint alleges: Negligence (Count I); Strict Products Liability based on Failure to Warn (Count II); Strict Products Liability based on Design Defect (Count III); Strict Products Liability based on Manufacturing Defect (Count IV); Breach of Express Warranty (Count V); Breach of Implied Warranty of Merchantability (Count VI); and Negligent Misrepresentation (Count VII). (Compl. ¶¶ 50–114). Williams seeks compensatory damages, payment for medical costs and expenses, punitive and exemplary damages, prejudgment and post-judgment interest, and attorneys' fees and costs. (Id. at 30).

On May 27, 2021, Defendants filed a Motion to Dismiss (ECF No. 13). Mikos filed an Opposition on June 15, 2021, (ECF No. 17), and Defendants filed a Reply on July 13,

2021, (ECF No. 20). Defendants filed Notices of Supplemental Authority on August 18, 2021, and November 4, 2021. (ECF Nos. 22, 23).

II. DISCUSSION

A. Standard of Review

The purpose of a Rule 12(b)(6) motion is to "test[] the sufficiency of a complaint," not to "resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." King v. Rubenstein, 825 F.3d 206, 214 (4th Cir. 2016) (quoting Edwards v. City of Goldsboro, 178 F.3d 231, 243 (4th Cir. 1999)). A complaint fails to state a claim if it does not contain "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed.R.Civ.P. 8(a)(2), or does not "state a claim to relief that is plausible on its face," Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (citing Twombly, 550 U.S. at 556). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. (citing Twombly, 550 U.S. at 555). Though the plaintiff is not required to forecast evidence to prove the elements of the claim, the complaint must allege sufficient facts to establish each element. Goss v. Bank of Am., N.A., 917 F.Supp.2d 445, 449 (D.Md. 2013) (quoting Walters v. McMahen, 684 F.3d 435, 439 (4th Cir. 2012)), aff'd, 546 F.App'x 165 (4th Cir. 2013).

In considering a Rule 12(b)(6) motion, a court must examine the complaint as a whole, consider the factual allegations in the complaint as true, and construe the factual

allegations in the light most favorable to the plaintiff. Albright v. Oliver, 510 U.S. 266, 268 (1994); Lambeth v. Bd. of Comm'rs of Davidson Cnty., 407 F.3d 266, 268 (4th Cir. 2005) (citing Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). But the court need not accept unsupported or conclusory factual allegations devoid of any reference to actual events, United Black Firefighters v. Hirst, 604 F.2d 844, 847 (4th Cir. 1979), or legal conclusions couched as factual allegations, Iqbal, 556 U.S. at 678.

B. Analysis

1. Preemption Standard

The preemption doctrine is based on the Supremacy Clause of the United States Constitution.[5] Duvall v. Bristol-Myers-Squibb Co., 103 F.3d 324, 328 (4th Cir. 1996). Preemption is the standard by which a state law is invalid to the extent it conflicts with federal legislation. Id. It can be either express or implied. Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373, (2000). Express preemption is "present when Congress's intent to preempt state law is 'explicitly stated in the statute's language.'" Mills v. Giant of Md., LLC, 441 F.Supp.2d 104, 106 (D.D.C. 2006) (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)), aff'd, 508 F.3d 11 (D.C. Cir. 2007). Implied preemption is "applicable 'where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution

[5] The Supremacy Clause states: "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . 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.

of the full purposes and objectives of Congress.'" Id. (quoting Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992)).

The Supreme Court has provided "two cornerstones" to guide the lower courts' preemption analysis. Wyeth v. Levine, 555 U.S. 555, 565 (2009). First, courts must presume that "the purpose of Congress is the ultimate touchstone in every pre-emption case." Id. (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)). Second, courts should operate from a "presumption against pre-emption," id. at 565 n.3, cognizant that "Congress does not cavalierly pre-empt" state law claims, Lohr, 518 U.S. at 485. Courts should begin their analysis with the assumption 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)). But where a "statute contains an express pre-emption clause, we do not invoke any presumption against pre-emption." Puerto Rico v. Franklin Cal. Tax-Free Tr., 136 S.Ct. 1938, 1946 (2016) (cleaned up). And in the medical device context, the Supreme Court has recognized Congress' apparent intent to displace "the tort law of 50 States." Riegel v. Medtronic, Inc., 552 U.S. 312, 326 (2008).

The Proclaim DRG is known as a "Class III" medical device pursuant to the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360c–360f, 360k) ("MDA"). Judge Catherine Blake of this Court has described in detail the structure of the federal oversight process implemented by the MDA:

The Medical Device Amendments of 1976

In 1976, in response to "mounting consumer and regulatory concern" about the health risks posed by new medical devices, the FDA passed the MDA. Medtronic, Inc. v. Lohr, 518 U.S. 470, 475–76, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996); Riegel v. Medtronic, Inc., 552 U.S. 312, 315–16, 128 S.Ct. 999, 169 L.Ed.2d 892 (20[0]8). Expanding the scope of the Federal Food, Drug, and Cosmetic Act[, 21 U.S.C. § 301 et seq.] (the "FDCA"), the MDA established federal requirements for the introduction of new devices and included an express preemption provision that preempts conflicting state law. See Medical Device Amendments of 1976, Pub. L. No. 94-295, sec. 2, §§ 513-516, 521, 90 Stat. 539, 540-60, 562 (codified as amended at 21 U.S.C. §§ 360c-360f, 360k). The MDA established three classes of medical devices, tiering devices based upon the potential risk posed to human health: Class I, Class II, and Class III. 21 U.S.C. § 360c. Class I medical devices are the most benign, while Class III medical devices pose the most potential risk to human life and welfare and, therefore, are subject to the most stringent regulations. Id.; see Riegel, 552 U.S. at 317, 128 S.Ct. 999.

Premarket Approval Process

Before a manufacturer can release a Class III device to the public, it must proceed through the premarket approval ("PMA") process. See 21 U.S.C. § 360c(a)(1)(C). A device will receive premarket approval only if the FDA determines, after considering "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," that "there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" Riegel, 552 U.S. at 318, 128 S.Ct. 999 (quoting 21 U.S.C. §§ 360c(a)(2)(C), 360e(d)). The premarket approval process is demanding. On average, before rendering a decision on any Class III device, the FDA spends 1,200 hours reviewing the manufacturer's submissions and data related to the device's safety and efficacy. Lohr, 518 U.S. at 477, 116 S.Ct. 2240 (first citing Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy & Commerce, 100th Cong., 1st Sess. (Ser. No. 100-34), p. 384 (1987) (hereinafter 1987 Hearings), and then citing Kahan, Premarket Approval Versus Premarket

Notification: Different Routes to the Same Market, 39 FOOD DRUG COSM. L.J. 510, 512–14 (1984)).

Manufacturers must provide the FDA with a range of information, including "a full statement of the [device's] components, ingredients, and properties," 21 U.S.C. § 360e(c)(1)(B); Riegel, 552 U.S. at 317–18, 128 S.Ct. 999, and a "specimen of the proposed labeling" that details "conditions of use," Riegel, 552 U.S. at 318, 128 S.Ct. 999; 21 U.S.C. § 360e(c)(1)(F). The FDA also reviews the manufacturer's proposed labeling to ensure that it is not false or misleading. Riegel, 552 U.S. at 318, 128 S.Ct. 999; 21 U.S.C. § 360e(d)(1)(A). "Once approved, the device may be manufactured, advertised, and distributed to the public, but those marketing activities may not be done in a manner 'inconsistent with . . . the [premarket] approval order for the device.'" Shuker v. Smith & Nephew, PLC, 885 F.3d 760, 766 (2018) (quoting 21 C.F.R. § 814.80).

And manufacturers are required to inform the FDA of "new clinical investigations or scientific studies concerning the device which the [manufacturer] knows of or reasonably should know of," and to "report incidents in which the device may have caused or contributed to death or serious injury." Riegel, 552 U.S. at 319, 128 S.Ct. 999 (first citing 21 C.F.R. § 814.84(b)(2), and then citing § 803.50(a)). Manufacturers of premarket-approved products are also required to investigate adverse reports to determine if remedial action is required to prevent substantial harm to the public health, 21 C.F.R. § 803.50, and to report these findings to the FDA within five days, 21 C.F.R. § 803.53. If manufacturers want to make changes to a PMA approved device, they must submit an application for "supplemental premarket approval" to the FDA. § 360e(d)(5); 21 C.F.R. § 814.39(c). Finally, the FDA may withdraw premarket approval if it "determines that a device is unsafe or ineffective." Riegel, 552 U.S. at 319–20, 128 S.Ct. 999 (first citing § 360e(e)(1), and then citing § 360h(e)).

In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig., 401 F.Supp.3d 538, 548–49 (D.Md. 2019) [hereinafter "BHR II"], motion to certify appeal

denied, No. 1:17-MD-2775, 2019 WL 6345746 (D.Md. Nov. 26, 2019). Judge Blake went on to describe the requirements for express or implied preemption under the MDA:

> The MDA's Express Preemption Provision . . . .
>
> The MDA contains an express preemption provision, which reads: "no State . . . may establish or continue in effect with respect to a device . . . any requirement which is different from, or in addition to," any federal requirement that relates either "to the safety or effectiveness of the device" or "to any other matter" included in a federal requirement applicable to the device. 21 U.S.C. § 360k(a). The Supreme Court has held that premarket approval establishes federal "requirement[s]" under the MDA. Riegel, 552 U.S. at 322–23, 128 S.Ct. 999. . . . Accordingly, state law may not impose requirements on PMA approved devices that depart from, or expand upon, federal requirements. But parallel state-law claims that mirror the federal requirements established by the MDA are not preempted. Lohr, 518 U.S. at 494–95, 116 S.Ct. 2240. Importantly, state claims need not be identical to federal requirements to survive explicit preemption, they need only be "narrower, not broader" than existing federal requirements. See Lohr, 518 U.S. at 495, 116 S.Ct. 2240 ("While such a narrower requirement might be 'different from' the federal rules in a literal sense, such a difference would surely provide a strange reason for finding preemption of a state rule insofar as it duplicates the federal rule."); see also id. (Breyer, J., joining the Court's opinion as to Part V).
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> Accordingly, determining whether state-law claims are preempted under § 360k(a) requires a two-step analysis: (1) has the federal government established requirements applicable to the specific device?; and (2) if so, do the plaintiffs' state-law claims impose state requirements "with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and efficacy"? See Riegel, 552 U.S. at 321–22, 128 S.Ct. 999 (quoting 21 U.S.C. § 360k(a)). Claims will be preempted only if both of these questions are answered in the affirmative.

> Implied Preemption
>
> State-law causes of action may also be impliedly preempted by the MDA. See Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 348 n.2, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). Buckman held that state-law claims will be impliedly preempted under the MDA if the claim "exist[s] solely by virtue of the FDCA . . . requirements" and is not a "traditional state tort law which had predated the federal enactments in question." Id. at 353, 121 S.Ct. 1012. The claim at issue in Buckman was a "fraud-on-the-FDA" claim. Id. at 350, 121 S.Ct. 1012. The Supreme Court reasoned that the MDA grants the FDA flexibility to prosecute fraud. Id. at 349–50, 121 S.Ct. 1012. Allowing litigants to bring a state-law fraud-on-the-FDA claim might undercut the FDA's enforcement power. Id. Buckman, therefore held that the claim was impliedly preempted.
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> But as this court has previously held, Buckman cannot be read to mean that Smith & Nephew cannot be held liable for a violation of FDA regulations under state law. In re Smith & Nephew Hip Resurfacing (BHR) Hip Implant Products Liability Litigation ["In re BHR"], 300 F.Supp.3d 732, 747 (D. Md. 2018) (first citing Riegel, 552 U.S. at 330, 128 S.Ct. 999, and then citing Buckman, 531 U.S. at 352–53, 121 S.Ct. 1012). After Buckman the operative question is whether a traditional state law cause of action imposes the duty a litigant seeks to enforce, or whether the duty arises solely from the MDA. If the former, the claim will survive implied preemption. If the latter, the claim will be impliedly preempted.

Id. at 550–51. The Court will apply these frameworks to the case at bar.

2. Choice of Law

The parties appear to agree that Maryland law governs this case. The Court concurs. Mikos alleges that she was injured in Maryland. (Compl. ¶ 6). As a federal court sitting in diversity, this Court is obligated to apply Maryland's choice of law rules. Colgan Air, Inc. v. Raytheon Aircraft Co., 507 F.3d 270, 275 (4th Cir. 2007). Under Maryland's choice of

law rules, Maryland substantive law applies to Plaintiff's claims. See McNulty v. Casero, 479 F.Supp.3d 200, 211 (D.Md. 2020) ("Maryland courts must 'apply the law of the State where the injury – the last event required to constitute the tort – occurred.'" (quoting Lab. Corp. of Am. v. Hood, 911 A.2d 841, 845 (Md. 2006))); see also Smith v. MTD Prod., Inc., No. CCB-19-1592, 2019 WL 5538273, at *2 (D.Md. Oct. 24, 2019) ("It is undisputed that [Plaintiff] was injured in Maryland. Under lex loci delicti, Maryland substantive law thus applies.").

3. Express Preemption

There is, of course, no doubt that the federal government has established requirements applicable to the Proclaim DRG; it is a Class III medical device subject to the MDA and FDA regulations. See Walker v. Medtronic, Inc., 670 F.3d 569, 577 (4th Cir. 2012) ("[B]ecause all Class III devices are required to undergo the [PMA] process, federal requirements exist with respect to all Class III devices."). Claims involving the Proclaim DRG therefore satisfy the first Riegel condition.

The Court must then turn the second part of the inquiry: whether state requirements exist "with respect to" the Proclaim DRG that are different from, or in addition to the federal ones. This step may be better conceptualized as two subparts: (1) are there state requirements "with respect to" the Proclaim DRG; and (2) are those requirements different from, or in addition to the federal ones. As to the first subpart, the Court concludes that the Maryland tort law duties Mikos alleges are "with respect to" the Proclaim DRG. See Riegel, 552 U.S. at 327–28 (rejecting argument that "the duties underlying

negligence, strict-liability, and implied-warranty claims . . . are not requirements maintained 'with respect to devices'").

As to the second subpart, the Supreme Court has provided a helpful gloss to the "different from, or in addition to" analysis. The Riegel Court explained that "§ 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). Thus, the Court will consider whether the state laws underlying the Complaint parallel or are different from MDA requirements.

In the context of express preemption, this Court has repeatedly held that to state a claim that parallels federal requirements, a complaint must include allegations that the defendant's conduct violated the MDA or FDA regulations. See, e.g., Diodato v. Mentor Worldwide LLC., No. JKB-20-762, 2020 WL 3402296, at *2–3 (D.Md. June 19, 2020) ("Here, each of Plaintiff's claims falls before the preemption bar, because the Complaint does not include any allegation that [the defendant's] conduct violated the MDA."); Winkler v. Medtronic, Inc., No. PX-18-865, 2019 WL 6052702, at *3 (D.Md. Nov. 15, 2019) ("[M]erely stating that the precise alleged failure of this device which allegedly caused Winkler's death also generally violated some non-specific FDA 'standards' is simply insufficient for this Court to infer plausibly that the claims are parallel, and not in addition, to the pertinent FDA regulations."), appeal dismissed, No. 19-2437, 2020 WL 3246285 (4th Cir. Apr. 23, 2020). Other courts in this circuit have imposed similar requirements. See Ellis v. Smith & Nephew, Inc., No. CV 6:15-545-TMC, 2016 WL

7319397, at *3 (D.S.C. Feb. 16, 2016) ("To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated." (quoting Gelber v. Styker Corp., 788 F.Supp.2d 145, 155 (S.D.N.Y. 2011))). Here, the Complaint's only reference to the MDA or FDA regulations is a broad allegation that Defendants "fail[ed] to comply with FDA good manufacturing regulations." (Compl. ¶ 58). Under this standard, then, the Court would be compelled to find that Mikos's claims are preempted by federal law.

Respectfully, however, the Court disagrees with applying this unforgiving approach toward the preemption analysis at the motion to dismiss stage. Instead, the Court views as a better model the one employed by this Court in two of its earlier decisions, Williams v. Smith & Nephew, Inc., 123 F.Supp.3d 733 (D.Md. 2015), and In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation, 300 F.Supp.3d 732 (D.Md. 2018) [hereinafter "BHR I"]. In Williams, this Court analyzed a serious of tort claims brought under Maryland law relating to a Class III medical device. 123 F.Supp.3d at 741–44. Rather than determining whether the plaintiff identified specific federal laws or regulations that defendant's conduct violated, the Williams Court analyzed plaintiff's actual allegations to determine whether the claims were essentially parallel to FDA requirements. Id. Similarly, the BHR I Court was faced with a series of state tort claims relating to the alleged failure of a Class III medical device. 300 F.Supp.3d at 742–46. Rather than reviewing the complaint for specific references to FDA regulations, the BHR I Court compared the substance of plaintiffs' claims to the FDA regulations necessarily implicated by those allegations to determine whether the claims were parallel

to, rather than differing from or adding to, federal requirements. Id. This Court finds the analytical structure reflected in these decisions persuasive and agrees with the BHR I Court finding that "[t]he state law reliance on a federal regulation need not be explicit. Rather the elements of traditional state laws need only be satisfied by conduct leading to a violation of a federal regulation." Id. at 743.

The Court will thus review the tort claims presented by Mikos to determine if those claims parallel, rather than differing from or adding to, federal requirements. As set forth above, Mikos's seven-count Complaint alleges: Negligence (Count I); Strict Products Liability based on Failure to Warn (Count II); Strict Products Liability based on Design Defect (Count III); Strict Products Liability based on Manufacturing Defect (Count IV); Breach of Express Warranty (Count V); Breach of Implied Warranty of Merchantability (Count VI); and Negligent Misrepresentation (Count VII). (Compl. ¶¶ 50–114). Of these, the Court finds that Count I is not expressly preempted by federal law, while the remainder of Mikos's claims are expressly preempted.

a. Negligence Claim (Count I)

Much of Mikos's negligence count involves allegations of conduct that would violate FDA regulations. As the BHR I Court held, "[i]t is undisputed that under FDA regulations and the PMA[,] [a Class III medical device manufacturer] has duties to disseminate truthful information, to report adverse incidents, and to adequately train surgeons working with the [device]." BHR I, 300 F.Supp.3d at 744. Mikos's negligence claim includes several allegations that Defendants failed to comport with these regulations.

(See, e.g., Compl. ¶ 58 (alleging, inter alia, that Defendants failed to adequately instruct physicians regarding the implant and use of the Proclaim DRG).[6]

Mikos also alleges that Defendants failed to manufacture the Proclaim DRG in compliance with cGMPs. (Id.). Courts have held that such allegations are sufficient to state a claim for negligence. See, e.g., Howard v. Sulzer Orthopedics, Inc., 382 F.App'x 436, 442 (6th Cir. 2010). Further, Mikos alleges that Defendants provided incorrect leads to her health care providers to support her Proclaim DRG implant. This alleged act would cause Defendants to be using the Proclaim DRG outside its FDA-approved specifications and therefore acting in violation of federal regulations. See 21 U.S.C. §§ 360e(c)(1)(B), (F) (requiring device manufacturers seeking premarket approval to provide "a full statement of the [device's] components, ingredients, and properties" and a "specimen of the proposed labeling" that details "conditions of use").

"[I]nsofar as the plaintiffs pin their negligence claims to conduct that breached those preexisting federal requirements, they avoid express preemption." BHR I, 300 F.Supp.3d at 744. In this respect, Mikos's negligence claim—and, indeed, virtually any negligence claim in the medical device context—is more accurately framed as a negligence per se claim, as it is a negligence claim premised on a violation of federal law. At the summary judgment stage, Mikos will be required to demonstrate a genuine issue of material fact regarding the specific federal laws or regulations Defendants' allegedly negligent conduct

[6] The Court notes that to the extent Mikos's negligence claim is premised on Defendants' alleged failure to warn or instruct Mikos or her physicians about the dangers of the Proclaim DRG, such a claim is expressly preempted for the reasons detailed infra in Section II.B.3.d.

violated. At the motion to dismiss stage, Mikos's negligence claim survives to the extent it alleges conduct on the part of Defendants that violated federal law.

b. Strict Liability Claims (Counts II, III, & IV)

Strict liability claims arising under Maryland law cannot proceed against manufacturers of Class III medical devices. This is because an element of strict liability claims in Maryland requires the plaintiff to establish that the product was "unreasonably dangerous." AIG Prop. Cas. Co. v. Eaton Corp., No. JKB-18-1853, 2019 WL 1586253, at *3 (D.Md. Apr. 12, 2019) (noting that "[a] product may be defective because of its design, a manufacturing error, or the manufacturer's failure to warn of certain risks"). But "as the Supreme Court made clear in Riegel, premarket approval is FDA recognition of a particular medical device's fitness for the market. Having received that approval, the [device] cannot be labeled unreasonably dangerous by state law without imposing requirements on medical devices different from or in addition to federal regulations." BHR I, 300 F.Supp.3d at 743. Under the MDA, "the FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information." Id. (citing 21 U.S.C. §§ 360e(e)(1)(A)–(B)). "[A]llowing state tort law claims to proceed that would require finding a device unreasonably dangerous would undermine Congress's decision to leave such questions to the FDA." Id. Accordingly, the Court finds that Mikos's strict liability claims are expressly preempted by federal law. The Court will therefore dismiss Counts II, III, and IV for failure to state a claim for which relief may be granted.

c. Breach of Implied Warranty Claim (Count VI)

Similarly, Mikos's claim that Defendants breached the implied warranty of merchantability is expressly preempted. In Maryland, the implied warranty of merchantability imposes a requirement on sellers of goods that, inter alia, the goods are "fit for the ordinary purposes for which such goods are used." Md. Code Ann., Com. Law § 2-314. But "the FDA, through the PMA process, expressly defines the scope of a device's intended use and determines all representations [a device manufacturer] is obligated to make concerning the [device]." Williams, 123 F.Supp.3d at 742 (internal quotation marks and citations omitted). "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." Id.; see also 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[.]"). The Court must therefore dismiss Count VI because it is expressly preempted by federal law.

d. Breach of Express Warranty and Negligent Misrepresentation Claims (Counts V & VII)

Mikos's claims for breach of express warranty and negligent misrepresentation are different from or in addition to FDA regulations and therefore are expressly preempted by federal law. These claims are essentially rooted in allegations that Defendants failed to adequately warn patients and physicians of the unreasonably high risk of harm associated with the Proclaim DRG. (See, e.g., Compl. ¶¶ 86, 88–89, 105–06). But "[b]ecause the

MDA does not impose any requirement that a manufacturer warn the public or the medical community about adverse events, these claims are preempted." BHR II, 401 F.Supp.3d at 557–58. Indeed, "[a] manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means." BHR I, 300 F.Supp.3d at 745. In BHR I, the Court found that the plaintiffs' negligent misrepresentation and breach of express warranty claims survived preemption because the plaintiffs in that case alleged that the defendant was essentially engaging in off-label marketing by making claims about its device that had not been approved by the FDA. Mikos makes no such allegation here. Moreover, Mikos makes no allegation that Defendants failed to accurately report adverse events to the FDA, as required by federal regulations. Rather, Mikos's breach of express warranty and negligent misrepresentation claims essentially ask the Court to impose liability for conduct in addition to, or different from, activity that would violate FDA regulations. Accordingly, these claims are expressly preempted by federal law.

4. Implied Preemption

As set forth above, "state-law claims will be impliedly preempted under the MDA if the claim 'exist[s] solely by virtue of the FDCA . . . requirements' and is not a 'traditional state tort law which had predated the federal enactments in question.'" Smith & Nephew, 401 F.Supp.3d at 551 (quoting Buckman, 531 U.S. at 353). All Mikos's claims arise from traditional tort causes of action that long predate the MDA or related FDA regulations. Accordingly, none of Mikos's claims are subject to dismissal under the doctrine of implied preemption.

5. Failure to State a Claim

Defendants argue that even if Mikos's claims are not preempted, the Court should dismiss Counts II, III, IV, V, and VII for failure to state a claim. As set forth above, these counts are expressly preempted by federal law. Accordingly, the Court declines to address whether they would otherwise state a claim for which relief may be granted.

III. CONCLUSION

For the foregoing reasons, the Court will grant in part and deny in part the Motion to Dismiss (ECF No. 13). A separate Order follows.

Entered this 18th day of November, 2021.

/s/
George L. Russell, III
United States District Judge