UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

DANIEL JACKSON,

Plaintiff,

v. Case No: 2:14-cv-717-FtM-38DNF

ST. JUDE MEDICAL NEUROMODULATION DIVISION, MEDTRONIC, INC. and ALLSTATE PROPERTY & CASUALTY INSURANCE COMPANY,

Defendants.
_____/

ORDER[1]

Defendants St. Jude Medical Neuromodulation Division and Medtronic, Inc. (collectively "Defendants") have both moved to dismiss Plaintiff's Second Amended Complaint for failure to state a claim. (Doc. #4; Doc. #7). Plaintiff has responded, (Doc. #14; Doc. #15), and thus this matter is ripe for review. Because Defendants' motions raise nearly identical arguments, they are addressed jointly below.

BACKGROUND

At the motion to dismiss stage, the Court must "accept as true the [plaintiff's] factual allegations" set forth in the complaint. Anza v. Ideal Steel Supply Corp., 547 U.S. 451,

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453 (2006); see also Williams v. Mohawk Indus., Inc., 465 F.3d 1277, 1281 n.1 (11th Cir. 2006). However, the facts as recited below may not be the facts later proven.

This action concerns two allegedly defective medical devices: (1) the Eon Mini Neurostimulation System ("Eon Mini") that St. Jude designed, manufactured, and sold; and (2) the SynchroMed II Programmable Drug Infusion System (the "Pump") that Medtronic designed, manufactured, and sold. On or about May 13, 2011, an unidentified physician surgically implanted the Eon Mini into Plaintiff's body to help manage his pain. (Doc. #2 at ¶ 13; Doc. #4 at 1 n.1; Doc. #7 at 2). Sometime thereafter, the Eon Mini allegedly failed and caused Plaintiff bodily injury. (Doc. #2 at ¶ 15). In November 2012, an unidentified physician implanted the Pump into Plaintiff's spine for presumably the same purpose. (Id. at ¶ 44). Subsequent failure of the Pump allegedly also caused Plaintiff bodily injury. (Id. at ¶ 45).

On December 13, 2013, Plaintiff commenced the instant suit in the Circuit Court of the Twentieth Judicial Circuit in and for Lee County, Florida ("State Court"). Defendants removed the case to this Court, (Doc. #1; Doc. #22), and Plaintiff later filed the Second Amended Complaint now at issue, which contains the following claims:

1. Breach of Contract against Defendant Allstate Property and Insurance Company;
2. Products Liability against Defendant St. Jude;
3. Negligence against Defendant St. Jude;
4. Breach of Implied Warranty of Merchantability against Defendant St. Jude;
5. Breach of Implied Warranty for a Particular Purpose against Defendant St. Jude;
6. Strict Liability against Defendant St. Jude;

7. Products Liability against Defendant Medtronic;

8. Negligence against Defendant Medtronic;

9. Breach of Implied Warranty of Merchantability against Defendant Medtronic;

10. Breach of Implied Warranty for a Particular Purpose against Defendant Medtronic; and

11. Strict Liability against Defendant Medtronic.

(Doc. #2 at ¶¶ 10-70).

Defendants have moved to dismiss Plaintiff's claims under Rule 12(b)(6) of the Federal Rules of Civil Procedure. (Doc. #4; Doc. #7). Defendants raise a number of arguments that are discussed in more detail below, but their chief contention is that the Medical Device Amendments Act of 1976, 21 U.S.C. § 360k, et. seq., precludes the instant suit. The framework this Court must employ under Rule 12(b)(6) of the Federal Rules of Civil Procedure is discussed next.

LEGAL STANDARDS

To survive a motion to dismiss under Rule 12(b)(6), "a [c]omplaint must contain sufficient factual matter, accepted as true, to '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 has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. at 678. The issue in resolving such a motion is not whether the non-movant will ultimately prevail, but whether the non-movant is entitled to offer evidence to support his claims. Id. at 678-79.

"Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience

and common sense." Id. at 679 (citations omitted). Although legal conclusions can provide the framework for a complaint, factual allegations must support all claims. See Id. Based on these allegations, the court will determine whether the plaintiff's pleadings plausibly give rise to an entitlement to relief. See Iqbal, 556 U.S. at 678-79. Legal conclusions couched as factual allegations are not sufficient, nor are unwarranted inferences, unreasonable conclusions, or arguments. See Twombly, 550 U.S. at 555; Byrnes v. Small, No. 8:14-CV-1726-T-36MAP, 2015 WL 1243219, at *3 (M.D. Fla. Mar. 18, 2015).

Rule 8 of the Federal Rules of Civil Procedure provides parallel pleading requirements that also must be satisfied. Under this rule, "a pleading must contain a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me-accusation." Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 555). Labels, conclusions, and formulaic recitations of the elements of a cause of action are not sufficient. See id. at 678-79. Mere naked assertions are also inadequate. See id.

DISCUSSION

Defendants ask the Court to dismiss Counts 2 through 11.[2] (Doc. #4; Doc. #7). They first argue that the Medical Device Amendments Act of 1976 ("MDA") expressly preempts Plaintiff's common law claims because the Food and Drug Administration ("FDA") granted premarket approval ("PMA") over the allegedly defective medical devices

[2] Count 1 of the Second Amended Complaint is not at issue because this claim is asserted only against Defendant Allstate Property & Casualty Insurance Company, who has not joined the instant motions.

now at issue. (Doc. #4 at 2, 11-18; Doc. #7 at 2, 6-12). They further argue that the Second Amended Complaint does not satisfy the pleading standards set forth in Rule 8 of the Federal Rules of Civil Procedure, that Plaintiff's breach of warranty claims are improper as no contractual privity exists, and Florida law does not recognized independent claims for "products liability." (Doc. #4 at 9-10; Doc. #7 at 12-15). The Court will address these arguments in turn.

A. The Medical Device Amendments

1. Statutory overview

Before 1976, states had wide latitude to supervise new medical devices. See Stokes v. I–Flow Corp., No. 6:12-cv-991, 2013 WL 1715427, at *2 (M.D. Fla. Apr. 8, 2013). That changed when Congress enacted the MDA, which "swept back some state obligations and imposed a regime of detailed federal oversight" for medical devices. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008).

Under the MDA, medical devices are categorized into three classes based on the risks they pose to the public. See Riegel, 552 U.S. at 316. The strictest regulation category is Class III, and it encompasses devices for which a less stringent classification could not provide reasonable assurance of safety and effectiveness. Id. at 317 (citing 21 U.S.C. § 360c(a)(1)(C)). The devices complained of here – the Eon Mini and the Pump – fall into this category.[3]

All Class III devices undergo the FDA's "rigorous" PMA process. Id.; see also Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996). The FDA grants PMA approval only if

[3] In deciding the instant motion to dismiss, the Court takes judicial notice of the FDA's public records on these medical devices. See Fed. R. Evid. 201(b); see also Kaiser v. DePuy Spine, Inc., 944 F. Supp. 2d 1187, 1192 n.2 (M.D. Fla. 2013) (citations omitted).

there is a "reasonable assurance" of the device's "safety and effectiveness." Riegel, 552 U.S. at 318 (citing 21 U.S.C. § 360e(d)). After the FDA grants PMA approval, manufacturers may not change design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness without the agency's permission. See id. (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Manufacturers also have reporting requirements, including alerting the FDA of new clinical investigations or scientific studies, 21 C.F.R. § 814.84(b)(2), and report incidents where the device may have caused or contributed to death or serious injury, 21 C.F.R. § 803.50(a). See id. at 319.

2. Express preemption of state law claims and parallel claims

The MDA enumerates an express preemption for medical devices. This statutory provision reads:

> [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's decision in Riegel is the seminal case on preemption in the MDA context. In that case, the Supreme Court examined whether the MDA preempted state law claims about an allegedly defective medical device. In doing so, the Supreme Court established a two-pronged test. First, the sitting court must decide whether the

federal government has established requirements applicable to the device in question. 552 U.S. at 321-22. This prong is automatically satisfied when the FDA authorizes commercial distribution of a Class III medical device after the PMA process. See id. at 321-23. Second, the court must decide whether the state law claims are based on requirements, with respect to that device, that are "different from, or in addition to" the federal ones and relate to safety and effectiveness. Id. at 321-22.

Here, the parties agree that the first prong of the Riegel test is satisfied because the Eon Mini and the Pump are PMA approved Class III medical devices. (Doc. #7 at 10; Doc. #14 at 4). The parties, however, dispute the second prong – whether Plaintiff's negligence, strict liability, and breach of implied warranty claims seek to impose state law requirements that are in addition to or inconsistent with the federal requirements. For the following reasons, the Court finds that the MDA expressly preempts these common law claims.

Plaintiff's product liability claims (Counts 2, 3, 6, 7, 8, and 11) nebulously allege that the Eon Mini and the Pump were "negligently designed and/or manufactured." "defective," and "inappropriate for the designed use." (Doc. #2 at ¶¶ 18, 33-35, 49, 51, 64-66). Such claims, however, do not allege that Defendants failed to comply with the federal regulatory scheme for approving these devices. Plaintiff merely questions the FDA's determination that the Eon Mini and the Pump are safe and effective. In essence, Plaintiff claims that Defendants should have designed and manufactured the Eon Mini and the Pump in a manner different from what the FDA required under the PMA. Such claims are clearly preempted under Riegel and its progeny. See Wolicki–Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300 (11th Cir. 2011) (dismissing strict liability and negligence

claims involving Class III pacemaker); McClelland v. Medtronic, Inc., 944 F. Supp. 2d 1193, 1200 (M.D. Fla. 2013) (finding plaintiff's negligence claim to be expressly preempted "because it would impose state law requirements that are different from, or in addition to, the federal requirements under the MDA").

Plaintiff's breach of implied warranty claims (Counts 4, 5, 9 and 10) also run headstrong into the MDA. In summary, these counts allege that Defendants breached warranties regarding the Eon Mini's and the Pump's "merchantable quality" and "warrant for fitness." (Doc. #2 at ¶¶ 25, 30, 55, 61). Such allegations would prompt the Court to evaluate each device's safety and effectiveness, which expressly conflicts with the FDA's finding that both devices had a "reasonable assurance" of the same. Again, this is not permissible under the MDA. Accordingly, the MDA preempts Plaintiff's claims against Defendants.

Recognizing the above hurdle, Plaintiff attempts to sidestep the MDA's express preemption by arguing that his claims "parallel" rather than add to the federal requirements. (Doc. #14); see also Stranifer v. Corin USA Ltd., Inc., No. 6:14-cv-1192, 2014 WL 5823319, at *2 (M.D. Fla. Nov. 10, 2014) (stating that a plaintiff who is injured because of use of a Class III device approved through a PMA can escape preemption if he asserts a "parallel" state law claim).

It is well settled that the MDA's express preemption provision does not apply to a "parallel" claim. See Riegel, 552 U.S. at 330. According to the Supreme Court,

> State requirements are pre-empted under the MDA only to the extent they are "different from, or in addition to the requirements imposed by federal law." § 360k(a)(1). Thus, § 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.

552 U.S. at 330 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996)). The Eleventh Circuit, citing a sister circuit, explained the parallel claim exception as follows:

> "In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are "*genuinely* equivalent." State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law."

Wolicki–Gables, 634 F.3d at 1300 (citing McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir.2005). The Eleventh Circuit further explained, "[p]arallel claims must be specifically stated in the initial pleadings. A plaintiff must allege that '[the] defendant violated a particular federal specification referred to the device at issue. . . . 'To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated.'" Wolicki–Gables, 634 F.3d at 1301 (internal citations omitted); see also Llado–Carreno v. Guidant Corp., No. 09-20971, 2011 WL 6223409, at *5 (S.D. Fla. May 16, 2011). Importantly, the plaintiff "cannot simply incant the magic words '[defendant] violated FDA regulations' in order to avoid preemption." Wolicki-Gables, 634 F.3d at 1301.

Plaintiff relies on Wolicki-Gables to support his parallel claims arguments. (Doc. #14 at 5; Doc. #15 at 5). In that case, the plaintiff asserted Florida state law claims for strict liability and negligence concerning alleged design and manufacturing defects in a pump system for alleviating back pain, as well as a strict liability claim for failure to warn. Wolicki-Gables, 634 F.3d at 1301. According to the plaintiff, defendants "failed to reasonably design the implantable drug delivery system in a manner which would have

prevented injury to those like [plaintiff]; failed to reasonably manufacture the implantable drug delivery system in a reasonable manner; and failed to reasonably provide adequate warnings regarding the defective and unreasonably dangerous implantable drug delivery system, having actual or constructive knowledge of the hazards associated with the product." Id. The district court held the MDA preempted the claims. The Eleventh Circuit affirmed because the plaintiff's allegations did not "'set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged.'" Id. at 1301-02 (citation omitted).

Plaintiff's reliance on Wolicki–Gables is misguided. He does not identify any federal specification or PMA requirement that Defendants violated in the Second Amended Complaint. (Doc. #2). At most, Plaintiff asserts general and conclusory allegations without referencing any specific problem or FDA regulation. These allegations lack the factual detail needed to satisfy the requisite elements of a parallel claim. See Kaiser v. Depuy Spine, Inc., 944 F. Supp. 2d 1187, 1191-92 (M.D. Fla. 2013) (finding the plaintiff's allegation that "the [device] became unsafe and ineffective when it became damaged, displaced, and/or the polyethelene core deteriorated to the point that it was unable to slide and otherwise restore natural motion, which violates the PMA requirements" to be in sufficient to state a parallel claim); Stokes v. I-Flow Corp. No. 6:12-cv-991, 2013 WL 1715427, at *7 (M.D. Fla. Ap. 8, 2013) (finding that plaintiff's allegations were insufficient because they failed to set forth any problem or failure to comply with a federal regulation that could be linked to the injury alleged); Llado–Carreno, 2011 WL 6223409, at *1 (finding general allegations that "the devices did not satisfy the [FDA's] Pre-Market Approval standards for the devices" are insufficient to satisfy the requisite

elements of a parallel claim where the complaint simultaneously lacks any factual detail to substantiate the allegations and does not set forth any specific problem, or failure to comply with any FDA regulation).

Plaintiff tries to correct this deficiency by arguing in his responses that Defendants violated 21 C.F.R. §§ 820.20(a), 820.20(b)(2), 820.70(e). (Doc. #14 at 5-6; Doc. #15 at 5-6). These allegations, however, appear nowhere in the Second Amended Complaint, and the Court declines to consider them as they are raised for the first time in Plaintiff's responses. See Huls v. Liabona, 437 F. App'x 830, 832 n.5 (11th Cir. 2011) (stating that an argument was not properly raised where plaintiff asserted it for the first time in response to defendant's motion to dismiss, instead of seeking leave to file an amended complaint). Thus, absent allegations Defendants violated a particular federal specification, Plaintiff has failed to state a parallel claim to escape express preemption.

3. Implied preemption

In addition to preemption non-parallel claims, the FDCA provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court construed § 337(a) as impliedly preempting suits by private litigants "for noncompliance with the medical device provisions." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001). The interaction between Riegel and Buckman has been explained as follows:

> Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. 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).

McClelland, 944 F. Supp. 2d at 1200 (citing In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010); In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig., 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009) ("[W]hen Sections 337(a) and 360k(a) – as construed in Buckman and Riegel, respectively – are read together, nearly all types of claims concerning FDA-approved medical devices are preempted[.]")).

Here, even if Plaintiff asserted parallel claims, the Court would dismiss Counts 2 through 11 because Florida law does not allow Plaintiff to bring a private cause of action to enforce FDA regulations. "[D]istrict courts in this Circuit have consistently held that private actions like Plaintiff's that seek to enforce violations of FDA regulations are barred because Florida does not recognize such causes of action." Kaiser., 944 F. Supp. 2d at 1192-93) (citing Wheeler v. DePuy Spine, Inc., 706 F. Supp. 2d 1264, 1268 (S.D. Fla. 2010) (plaintiff's claims for negligence and products liability failed because plaintiff did not identify a Florida law that provides a remedy based on an alleged violation of FDA regulations); Cook v. MillerCoors, LLC, 872 F. Supp. 2d 1346, 1351 (M.D. Fla. 2012) (plaintiff cannot rely on allegations regarding FDA violations because no private right of action exists under the FDA); Stokes, 2013 WL 1715427, at *4 ("[T]o the extent Plaintiff bases his strict product liability, negligence, or failure to warn claims on Defendant's alleged violations of the FDCA or FDA's implementing regulations, those claims are dismissed for failure to state a claim [because] the Court cannot hear any claims by private litigants to enforce the regulations of the FDA." (other citations omitted)). Thus, to the extent Plaintiff bases his claims on allegations that the Eon Mini or the Pump failed to meet FDA requirements, such claims are implicitly preempted.

B. Failure to state a claim

In addition to the foregoing, Plaintiff's claims against Defendants fail for the independent reason that he did not plead sufficient facts to satisfy Rule 8 of the Federal Rules of Civil Procedure. The Second Amended Complaint contains perfunctory allegations sounding in products liability theories that amount to nothing more than impermissible "formulaic recitations of elements of a cause of action." Regarding St. Jude, Plaintiff alleges, without providing any support, that the Eon Mini "demonstrated defect/damage when it failed to work properly" and, because "of the negligent design and/or manufacturer of the implant, the implant failed, causing Plaintiff to be injured." (Doc. #2 at ¶¶ 14, 21). He makes no allegations about (1) how and when the Eon Mini acted defectively or failed to work; (2) the character and type of injuries he experienced when the Eon Mini acted defectively or failed; and (3) how the alleged defect caused or contributed to the injuries he allegedly suffered. Such barebones allegations are the "unadorned, the defendant-unlawfully-harmed me accusations" that the Supreme Court has held to be insufficient. See Iqbal, 556 U.S. 678.

Plaintiff's allegations against Medtronic are similarly deficient. Plaintiff baldly concludes that the Pump "failed to work properly" and that he suffered an injury as a result without any supporting factual allegations. He makes no allegations about (1) how and when the Pump acted defectively or failed to work; (2) the character and type of injuries he experienced when the Pump acted defectively or failed; and (3) how the alleged defect caused or contributed to the injuries he suffered. (Doc. #2). Again, such barebones allegations are the "unadorned, the defendant-unlawfully-harmed me accusations" that the Supreme Court has held to be insufficient. See Iqbal, 556 U.S. 678.

As the allegations against Defendants are nothing more than cursory claims devoid of factual support, Plaintiff has submitted the type of pleading that the Federal Rules of Civil Procedure are designed to prevent. Based upon the foregoing, the Court grants Defendants' motions to dismiss. However, it will also grant Plaintiff's request for leave to amend under the liberal standard set forth in Rule 15 of the Federal Rules of Civil Procedure.

Accordingly, it is

ORDERED:

(1) Defendant Advanced Neuromodulation Systems, Inc. d/b/a St. Jude Medical Neuromodulation Division's Motion to Dismiss Plaintiff's Claims for Failure to State a Claim Upon Which Relief Can Be Granted (Doc. #7) is **GRANTED**.

(2) Defendant Medtronic, Inc.'s Motion to Dismiss filed on December 19, 2014. (Doc. #4) is **GRANTED**.

(3) Plaintiff Daniel Jackson may filed a third amended complaint that is consistent with this Order on or before **April 21, 2015**. Defendants shall have fourteen (14) days thereafter to file an answer or other response.

DONE and **ORDERED** in Fort Myers, Florida this 30th day of March, 2015.

SHERI POLSTER CHAPPELL
UNITED STATES DISTRICT JUDGE

Copies: All parties of record