IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF OKLAHOMA

RITA KEIM-BACON,

Plaintiff,

v. No. 4:22-CV-00383-WPJ-MTS

STRYKER CORPORATION,

MEMORANDUM OPINION AND ORDER GRANTING DEFENDANT STRYKER CORPORATION'S MOTION TO DISMISS

THIS MATTER is before the Court[1] on Defendant Stryker Corporation's Motion to Dismiss (**Doc. 14**). The Court, having considered the parties written arguments and the applicable law, finds that Defendant's Motion to Dismiss is well-taken and is therefore **GRANTED.**

BACKGROUND

This case involves claims arising from the implantation of an artificial ankle prosthetic device known as the Scandinavian Total Ankle Replacement System ("STAR device"). The STAR device "is indicated for use as a non-cemented total ankle prosthetic ('artificial joint') and used to replace a painful arthritic ankle joint due to osteoarthritis, post-traumatic arthritis, or rheumatoid arthritis." **Doc. 2-1 ("Exhibit 1") at 2**. The United States Food and Drug Administration ("FDA") classified the STAR device as a Class III medical device and evaluated it under the Premarket Approval Process.

On October 21, 2014, podiatrist physician, Dr. Raymond L. Smith surgically implanted the STAR device into Plaintiff Rita Keim-Bacon's right leg. **Doc. 2 ("Complaint"), ¶ 3**. On January

[1] Chief United States District Court Judge William P. Johnson of the District of New Mexico was assigned this case as a result of the Tenth Circuit Order designating Judge Johnson to hear and preside over cases in the Northern District of Oklahoma.

31, 2021, Plaintiff began experiencing symptom of instability, inability to bear weight, pain, new grinding in the STAR device, and noise in her right ankle. ***Id.* ¶ 4.** On March 26, 2021, the FDA issued a Safety Communication regarding the STAR device. ***Id.***

In the Safety Communication, the FDA advised patients, caregivers, and health care providers about a higher-than-expected rate of fractures in the polyethylene (plastic) component of the STAR device as early as three to four years after implantation. **Ex. 1 at 1**. The FDA further explained that the breaking of the plastic component of the STAR device may lead to surgery to repair or replace the device. ***Id.*** On June 29, 2021, Plaintiff had the STAR device removed from her right leg. **Compl. ¶ 5.**

Following the removal of the STAR device from her right leg, Plaintiff filed a complaint against Stryker Corporation. Plaintiff asserts claims for strict products liability (Count I) and negligence/gross negligence/negligence per se (Count II). Under Count I, Plaintiff alleges that the STAR device was defective and unreasonably dangerous. ***Id.* ¶ 6**. Under Count II, Plaintiff alleges, based on the FDA's safety communication, that Stryker breached its duty of ordinary care to Plaintiff by failing to design, manufacture, and sell the STAR device in a safe and careful manner. ***Id.* ¶ 7**. Defendant Stryker then filed the instant motion, seeking to dismiss all Plaintiff's claims against it pursuant to Fed. R. Civ. P. 12(b)(6). **Doc. 14**.

12(b)(6) STANDARD

To survive a Rule 12(b)(6) motion to dismiss "a complaint 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 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). This does not mean that the complaint needs detailed factual

allegations; however, it is not enough merely that there might be some conceivable set of facts that entitles the Plaintiff to relief. *Twombly*, 550 U.S. at 555. Naturally, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

In reviewing a motion to dismiss, the Court must assume all the complaint's factual allegations are true, but it is not bound to accept as true legal conclusions, including any "legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555 (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). Accordingly, the Court "should disregard all conclusory statements of law and consider whether the remaining specific factual allegations, if assumed to be true, plausibly suggest the defendant is liable." *Kan. Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1214 (10th Cir. 2011). In deciding whether the plaintiff's stated claim for relief is adequate, the Court views "the totality of the circumstances as alleged in the complaint in the light most favorable to [the plaintiff]." *Jones v. Hunt*, 410 F.3d 1221, 1229 (10th Cir. 2005). The essential question is whether the plaintiff has nudged his or her claim "across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570.

Generally, courts may only consider the complaint when deciding a 12(b)(6) motion to dismiss. However, there are three limited exceptions to this rule: (i) "documents that the complaint incorporates by reference," (ii) "documents referred to in the complaint if the documents are central to the plaintiff's claim and the parties do not dispute the documents' authenticity," (iii) "matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

DISCUSSION

Congress heavily regulates the production and use of medical devices. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetics Act

("FDCA"). With the MDA, "Congress standardized and regulated the safety and effectiveness of medical devices." *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1276 (10th Cir. 2021).

The medical devices that receive the most federal oversight are those in Class III. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). Class III devices are subject to the premarket approval ("PMA") process. *Id.* During the PMA process, a manufacturer must submit a multivolume application. *Id.* This application includes the following:

> a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

Id. at 318 (internal citations and quotations omitted). "The FDA spends an average of 1,200 hours reviewing each application and grants premarket approval only if it finds there is a reasonable assurance of the device's safety and effectiveness" *Id.* (internal citations and quotations omitted).

After a device receives premarket approval, the MDA prohibits manufacturers from making changes to its design, manufacturing, labeling without FDA approval. *Id.* at 319. To make such changes, the manufacturer must submit, and the FDA must approve, an application for supplemental premarket approval. *Id.* Devices must also comply with reporting requirements, including notifying the FDA of new clinical studies and reporting incidents that may have caused or contributed to death or serious injury. *Id.*

With regards to preemption, the MDA contains the following express preemption provision:

> (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k. The Supreme Court, in *Riegel*, set forth a two-part test to determine whether a state law claim is expressly preempted by this provision. 552 U.S. at 321. Under this test, courts first determine whether the federal government has established requirements applicable to the medical device at issue. *Id.* If so, courts then determine whether the state-law claims would impose device requirements "different from, or in addition to, any requirement applicable . . . to the device under federal law." *Id.*

In addition to the express preemption provision, the MDA also contains an implied preemption provision, "[e]xcept as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States" 21 U.S.C. § 337. This provision requires that the MDA be enforced solely by the federal government. *Brooks*, 985 F.3d at 1279.

In short, to avoid express and implied preemption under the MDA and FDCA, a plaintiff asserting claims related to a failed Class III medical device must allege conduct that: (1) "violates the FDCA (because state law may not impose additional or different duties)," (2) "would be actionable under state law independently of the FDCA (because a plaintiff may not seek to enforce the FDCA)." *Id.* Claims meeting both requirements are known as "parallel claims."[2]

[2] To provide more context for parallel claims: If a manufacturer fully complies with all PMA and other FDA requirements, a plaintiff cannot pursue a claim for a defect in a Class III medical device. However, if a defect in a Class III medical device arises from the manufacturer's violation of a PMA or other FDA requirement, the plaintiff may pursue a claim against the manufacturer, provided the claim is based on a state law cause of action that parallels the federal requirements (*i.e.*, a parallel claim). *Brooks*, 985 F.3d at 1279 (10th Cir. 2021) (explaining that parallel claims "must be predicated on conduct that violates the FDCA but may not be brought solely because that conduct violates the FDCA – the conduct must also violate a parallel state-law requirement"); *see also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1343 (10th Cir. 2015) ("Once a device endures the premarket approval process . . . any state safety requirement differing from or adding to the body of federal regulations is preempted, even if that requirement comes in the guise of a general tort suit . . ." (internal citation omitted)).

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Considering these requirements, to properly plead a parallel claim at the 12(b)(6) stage, plaintiff cannot simply identify a defect or malfunction in a Class III device and rely "on *res ipsa loquitur* to suggest only . . . that the thing speaks for itself." *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1112 (9th Cir. 2019) (citing *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011)). Instead, as set forth in *Weber*, "a plaintiff must show that the defendant deviated from a particular pre-market approval or other FDA requirement applicable to the Class III medical device." *Id.* Moreover, a plaintiff must, "specifically identify a state law claim that is parallel to the federal requirements and . . . causally connect the simultaneous violations of federal and state law and to the alleged injury. *Kubicki ex rel. Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 172 (D.D.C. 2018) (citing *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1214 (W.D. Okla. 2013), *aff'd*, 784 F.3d 1335 (10th Cir. 2015)).

A. Plaintiff's strict products liability and negligence claims are expressly preempted by the MDA.

To determine whether the MDA expressly preempts Plaintiff's claims against Defendant, the Court applies the two-part test from *Riegel.* Here, there is no question that the federal government imposed requirements on the STAR device because the device underwent the PMA process. In *Riegel*, the Supreme Court determined that this process imposes "requirements" under the MDA, satisfying the first step of the *Riegel* test. 552 U.S. at 322.

The second part of the *Riegel* test examines whether Plaintiff's state-law tort claims would impose device requirements different from, or in addition to, any requirement applicable to the device under federal law.

Although only persuasive authority, *Skinner v. Small Bone Innovations Inc.*, where an Arizona district court addressed similar claims regarding the STAR device, is instructive here. No. CV-23-01051-PHX-MTL, 2023 WL 6318014, at *4 (D. Ariz. Sept. 28, 2023).

In *Skinner*, the plaintiff experienced complications akin to those of Plaintiff Keim-Bacon. After implantation of the STAR device, the plaintiff reported pain and instability in the affected ankle. *Id.* at *1. A CAT scan on June 13, 2022, revealed that the STAR device was defective. *Id.* During the scan, doctors informed the plaintiff that the device had degraded and was shedding plastic into his body. *Id.* Armed with this information, the plaintiff filed a complaint against Small Bones Innovations Inc. ("SBI"), a STAR device manufacturer, alleging:

1. "[T]he STAR ankle replacement was defective, unreasonably dangerous and unfit for its intended use and purposes because of its design, manufacture, testing, inspection, warranty, marketing, lack of warnings and packaging;" and

2. "Defendant SBI negligently designed, manufactured, tested, inspected, stored, marketed, warned about, distributed, repaired, maintained, prepared and packaged the STAR device, which constituted a breach of the standard of care."

Id. at *6, *4 (internal quotations omitted). The plaintiff relied largely on the FDA's Safety Communication to support these claims. *Id.* at *1.

The *Skinner* court concluded that the plaintiff's strict liability and negligence claims were expressly preempted by the MDA because the plaintiff did not allege specifically how the STAR device deviated from PMA requirements. *Id.* at *4. The *Skinner* court observed that the plaintiff merely relied on general allegations of defect (specifically, material degradation of the polyethylene component) and *res ipsa loquitur*, which the Court explained was insufficient to state a parallel claim. *Id.* at *4, *6.

Similarly, in the present case, Plaintiff's Complaint fails to allege that Defendant violated or deviated from any PMA or other FDA requirements, either during the PMA process or after. Plaintiff's Complaint merely references an FDA safety communication advising of a higher-than-expected rate of fractures—or breakage—of a plastic component in the STAR device, as early as three to four years post-implantation. The safety communication does not indicate that this newly

identified issue with the STAR device results from any violation of or deviation from PMA or other FDA requirements. Like the plaintiff in *Skinner*, Plaintiff identified a defect in the STAR device and expects the defect to speak for itself (*i.e.*, *res ipsa loquitor*).[3] However, as the court held in *Skinner*, a plaintiff cannot simply allege a defect in a medical device and assume that the existence of the defect in the device alone establishes a parallel claim. *See also Weber* 940 F.3d at 1112; *supra* at pp. 5–6.

Since Plaintiff failed to allege[4] that Defendant violated a particular PMA or other federal requirement, Plaintiff essentially alleges that Defendant acted improperly/negligently, even though Defendant complied with PMA and other federal requirements. Thus, for Plaintiff to prevail on her strict liability, negligence and gross negligence claims, a factfinder would have to conclude that the PMA requirements were inadequate —an impermissible finding under the law, as it would impose device requirements different from, or in addition to any requirement applicable to the device under federal law. Consequently, Plaintiff's strict liability and negligence claims fail the second part of the *Riegel* test and are therefore expressly preempted by the MDA.

B. <u>Plaintiff failed to allege a plausible negligence per se claim.</u>

Plaintiff also failed to allege a plausible negligence per se claim because she failed to identify a particular statute or regulation that Defendant breached.[5]

To state a plausible negligence per se claim under *Iqbal* and *Twombly*, the complaint must "identify a specific regulation and then allege facts plausibly suggesting a violation of that specific

[3] *Res ipsa loquitur* is a Latin phrase meaning "the thing speaks for itself." "[A]n inference of negligence can be drawn from the doctrine of *res ipsa loquitor*." *Stevens v. Barnard*, 512 F.2d 876, 880 (10th Cir. 1975).
[4] When the Court refers to Plaintiff's failure to allege, it clarifies that this refers to Plaintiff's counsel failing to make such allegations. The Court recognizes that Plaintiff did not draft the Complaint personally.
[5] Plaintiff's negligence per se claim also fails for the same reasons that her strict products liability and negligence claims fail, namely that Plaintiff did not plausibly allege that Defendant violated or deviated from a particular PMA requirement.

statute; otherwise, a right to relief on such a claim is merely possible, and not plausible." *Young ex rel. Young v. Kerr-McGee Corp.*, 658 F. Supp. 3d 1028, 1040 (E.D. Okla. 2023) (emphasis in original); *see also Bristow First Assembly of God v. BP p.l.c.*, 210 F. Supp. 3d 1284, 1294 (N.D. Okla. 2016) (reasoning that plaintiff did not satisfy the *Twombly* plausibility standard for a negligence per se claim where the plaintiff did not identify the statutory or regulatory violation). Plaintiff's complaint alleges a general breach of ordinary care in Defendant's design, manufacture, and sale of the STAR Device, without identifying a breach of any particular statute or regulation. Thus, Plaintiff has not met the requirements to state a plausible negligence per se claim under *Iqbal* and *Twombly*.

Additionally, even if Plaintiff had pointed to a specific statute or regulation violated by Defendant, the claim would still be preempted—whether expressly or impliedly—under the MDA. A negligence per se claim based on a violation of a state statute would face express preemption under the MDA, as Plaintiff has not plausibly alleged any violation of or deviation from PMA requirements. And permitting a claim premised on a violation of a state statute to proceed would invite the same impermissible finding that PMA or other FDA requirements are inadequate.

On the other hand, if Plaintiff's negligence per se claim was premised on a violation of the MDA, such a claim would be impliedly preempted under the MDA. As pointed out by the Tenth Circuit in *Brooks*, "[a]ny negligence per se action premised on an MDA violation necessarily seeks to enforce the MDA rather than a parallel state law duty." 985 F.3d at 1280.

C. <u>Plaintiff's proposed amendments are futile.</u>

In Plaintiff's Response to Defendant's Motion to Dismiss, Plaintiff introduces new claims not alleged in her Complaint and seeks leave to amend to include these claims in her Complaint. **Doc. 18 at 6–7**. Under Fed. R. Civ. P. 15(a), courts should "freely give" leave to amend "when justice so requires." However, district courts may deny leave to amend if the amendment would

be futile. *Lind v. Aetna Health, Inc.,* 466 F.3d 1195, 1199 (10th Cir. 2006). "A proposed amendment is futile if the complaint, as amended, would be subject to dismissal." *Id.* (quoting *Bradley v. J.E. Val–Mejias,* 379 F.3d 892, 901 (10th Cir. 2004)).

Before considering whether Plaintiff's proposed claims would survive dismissal, the Court highlights that it may consider "matters of which a court may take judicial notice" when deciding if granting leave to amend would be futile. *Hansen v. Harper Excavating, Inc.*, 641 F.3d 1216, 1219 n.2 (10th Cir. 2011) (citation omitted) (explaining that under Federal Rule of Evidence 201, judicial notice may be taken "whether requested or not," and "at any stage of the proceeding"). Courts may take judicial notice of facts "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned," such sources include but are not limited to court documents and matters of public record. *Id.* Here, the Court takes judicial notice of facts cited by Defendant from the FDA website, specifically the definition of an FDA warning letter, Defendant's application for supplementary PMA approval for inner-packaging changes to the STAR device, and the absence of any FDA warning letters or recalls related to the STAR device.

Turning to Plaintiff's proposed amendments, Plaintiff suggests she would amend her Complaint to add a strict products liability claim, alleging that the Star Device's new "inner-pouch foil packaging" was defectively designed and lacked adequate warnings.[6] **Doc. 18 at 6**. However, Plaintiff's allegations are conclusory and lack specifics on how Defendant allegedly violated any PMA or other federal manufacturing or warning requirements. This claim, therefore, would be subject to dismissal for the same reason Plaintiff's current claims are subject to dismissal the—express preemption. Allowing this claim would permit a finding that PMA and any other FDA

[6] In her response, Plaintiff argues that this claim is already alleged in the Complaint. However, the Court agrees with Defendant that the claim is not alleged in the Complaint and constitutes a new claim that Plaintiff must assert through an amended Complaint. Accordingly, the Court construes this as a proposed amendment to the Complaint.

requirements were inadequate—an impermissible finding under federal law as previously explained.

Plaintiff seeks to add a claim that Defendant failed to test the STAR device under realistic or simulated conditions in violation of 21 C.F.R. § 820.30(g), arguing that proper testing would have prevented premature product failure. **Doc. 18 at 6**. Yet, this claim is unsupported by specific facts and assumes that the defect "speaks for itself," which is insufficient to establish a plausible, non-preempted claim at the Rule 12(b)(6) stage. *See In re: Medtronic Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010) ("Plaintiffs cannot simply incant the magic words '[defendants] violated FDA regulations' to avoid preemption."); *see also Brooks*, 985 F.3d 1272, 1282 (concluding that conclusory allegations of non-compliance with federal regulations are insufficient to establish a parallel claim).

Additionally, Plaintiff seeks to add a claim that the STAR device was adulterated, alleging Defendant made unauthorized changes to the inner-pouch packaging in August 2014. **Doc. 18 at 6–7**. However, Defendant obtained FDA approval for this modification via a supplemental PMA for the STAR sliding core component.[7]

Lastly, Plaintiff references *Purcel v. Advanced Bionics Corp*, No. 3:07-CV-1777-M, 2010 WL 2679988 (N.D. Tex. 2010) and *Littlebear v. Advanced Bionics*, LLC, 896 F. Supp. 2d 1085 (N.D. Okla. 2012), arguing that these cases establish that her proposed claims are not preempted by the MDA and would survive a motion to dismiss. **Doc. 18 at 3–5**. Both cases involved the same Class III cochlear implant, and although the district courts in both cases found that claims of strict products liability, deviation from FDA-approved specifications, adulteration, and inadequate testing were not preempted by the MDA, these cases differ significantly from the present one.

[7] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050050S006 [https://perma.cc/ZD5B-JU26].

Unlike Plaintiff in this case, the plaintiffs in *Purcel* and *Littlebear* included specific, substantiated allegations of PMA violations, backed by FDA warning letters, inspection reports, and administrative complaints identifying particular PMA violations discovered by the FDA. *See, e.g., Littlebear*, 896 F. Supp. 2d at 1085 & 1088; *Purcel*, 2010 WL 2679988 at *2.

Unlike in *Purcel* and *Littlebear*, Plaintiff's proposed claims—while referencing particular PMA violations—are conclusory, as they lack supporting factual allegations that, if true, would establish a violation of a PMA requirement, as well as documentation like FDA warning letters or inspection reports. The only FDA "warning" related to the STAR device is a safety communication noting an unexpectedly high fracture rate in the STAR device's plastic component. However, this communication, unlike the FDA warning letters and inspection reports in *Purcel* and *Littlebear*, does not detail any violation of a PMA requirement or issue a recall of the STAR device. Consequently, Plaintiff's reliance on cases like *Purcel* and *Littlebear* is unpersuasive, as her proposed claims lack the necessary factual allegations or documentation to substantiate her claim that the newly discovered high rate of fractures in the Star Device's plastic component detailed in the FDA safety communication was the result of any violation of or deviation from a PMA or other FDA requirement.

For all these reasons, the Court finds that Plaintiff's proposed amendments to her Complaint would be futile. The Court therefore denies Plaintiff leave to amend her Complaint.

On a final note, the Court does not intend to downplay the complications, pain, and suffering experienced by Plaintiff. Nevertheless, the Court is constrained by the stringent federal regulations and requirements governing Class III medical devices. Had the FDA safety communication cited by Plaintiff demonstrated that Defendant violated an FDA-imposed requirement under the PMA process, and that such a violation caused the newly discovered fracture rate in the STAR device's plastic component, Plaintiff's claims might have been viable. However,

based on the Complaint and judicially noticed facts from the FDA website, Defendant Stryker has complied with all applicable PMA and FDA requirements. Without evidence of a violation of an FDA-imposed requirement, Plaintiff cannot assert state law claims that "parallel" an FDA-imposed requirement and therefore cannot proceed. Simply stated, the Court's hands are tied.

CONCLUSION

In sum, Plaintiff's Complaint fails to allege any parallel/non-preempted claims. Further, Plaintiff's proposed amendments to her Complaint are subject to the same deficiencies as her current claims, rendering any amendment futile. Accordingly, the Court **GRANTS** Defendant's Motion to Dismiss under Rule 12(b)(6) (**Doc. 14**).

IT IS THEREFORE ORDERED that all claims against Defendant Stryker Corporation are **DISMISSED** pursuant to Rule 12(b)(6) and leave to amend the Complaint is **DENIED**.

/s/
WILLIAM P. JOHNSON
UNITED STATES DISTRICT JUDGE