

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION**

**JANET ADAMS
and RANDY ADAMS,**

Plaintiffs,

v.

MEDTRONIC, INC. *et al.*,

Defendants.

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Civil Action No. 4:19-cv-870-SDJ-KPJ

MEMORANDUM OPINION AND ORDER

Pending before the Court is Plaintiffs Janet Adams and Randy Adams’s (together, “Plaintiffs”) Opposed Motion for Leave to File Third Amended Complaint (the “Motion”) (Dkt. 81). Defendants Medtronic, Inc., Covidien LP, Covidien Sales LLC, and Covidien Holding, Inc. (together, “Defendants”) filed a response in opposition to the Motion, *see* Dkt. 83, to which Plaintiffs filed a reply, *see* Dkt. 84. Upon consideration, the Motion (Dkt. 81) is hereby **GRANTED.**

I. BACKGROUND

On October 14, 2019, Plaintiffs filed this suit against Defendants in the 429th Judicial District Court of Collin County, Texas. *See* Dkts. 1-1, 1-2. Defendants removed the case, *see* Dkt. 1, and then filed a motion to dismiss Plaintiffs’ Original Complaint, *see* Dkt. 5. Plaintiffs filed a First Amended Complaint (Dkt. 9) as a matter of course, asserting the following causes of action: (1) defective design, sounding in negligence and strict liability; (2) manufacturing defect, sounding in negligence and strict liability; (3) failure to warn, sounding in strict liability; (4) breach of implied warranty; (5) breach of express warranty; and (6) loss of consortium. *See* Dkt. 9. With respect to their manufacturing defect claim, Plaintiffs alleged the EEA Stapler was “manufactured

without a component that resulted in a failure to ‘fire’ the staples” which, “in turn, resulted in Ms. Adam’s [sic] tissue being cut, but not sealed with staples.” *Id.* at 15. Plaintiffs did not identify the missing component that allegedly caused Mrs. Adams’s alleged injuries.

Defendants filed two additional motions to dismiss, both of which were granted in part. On February 5, 2020, Defendants moved to dismiss each claim asserted in Plaintiffs’ First Amended Complaint, including Plaintiffs’ manufacturing defect claim. *See* Dkt. 12. On October 1, 2020, the District Judge granted the motion to dismiss in part, dismissed each of Plaintiffs’ claims without prejudice, provided Plaintiffs with notice of the proper pleading standards for each claim asserted, and ordered Plaintiffs to file an amended complaint. *See* Dkt. 24. As to Plaintiffs’ manufacturing defect claim, the District Judge stated as follows:

[Plaintiffs] allege only that certain EEA staplers manufactured by Covidien were manufactured “without a component that resulted in a failure to ‘fire’ the staples.” Even taking this allegation as true, as the Court must, the Adamses have not plausibly alleged a manufacturing defect because they have not specified which component was missing from the stapler or how that component’s absence caused the EEA stapler to misfire. Alleging that some component was missing, without specifying which component, is no more specific than merely alleging there was a “manufacturing flaw” because the EEA stapler “malfunctioned and did not perform as intended or designed.”

See Dkt. 24 at 8.

Plaintiffs then filed the Second Amended Complaint, asserting claims for defective design, failure to warn, and loss of consortium. *See* Dkt. 25 at 12–21. Notably, Plaintiffs omitted their manufacturing defect claim. Defendants moved to dismiss Plaintiffs’ Second Amended Complaint, *see* Dkt. 26, which the District Judge granted in part. *See* Dkt. 75. Plaintiffs’ design defect claim was dismissed with prejudice, leaving only Plaintiffs’ failure to warn and loss of consortium claims. *See* Dkt. 75.

Subsequently, the Court entered the Second Amended Scheduling Order (Dkt. 80), which controls the disposition of this case. As set forth therein, Plaintiffs' deadline to file amended pleadings was June 20, 2022;¹ the discovery deadline is February 1, 2023; the dispositive motion deadline is March 1, 2023; the final pretrial conference is July 19, 2023; and trial is set for August 2023. *See* Dkt. 80. Notably, the parties jointly proposed the February 2023 discovery deadline. *See* Dkt. 77.

On June 21, 2022, Plaintiffs filed the Motion, which seeks to amend Plaintiffs' complaint to assert a manufacturing defect claim based on information learned during a June 2022 deposition and through a May 2022 product recall letter issued by Defendants. *See* Dkt. 81. Defendants filed a response in opposition, *see* Dkt. 83, to which Plaintiffs filed a reply, *see* Dkt. 84.

II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 15,² courts must “freely give leave [to amend] when justice so requires.” FED. R. CIV. P. 15(a)(2). “[T]he language of this rule ‘evinces a bias in favor of granting leave to amend,’” and “[a] district court must possess a ‘substantial reason’ to deny a request.” *SGK Props., L.L.C. v. U.S. Bank Nat’l Assoc. for Lehman Bros. Small Balance Comm. Mortg. Pass-Through Certificates, Series 2007-3*, 881 F.3d 933, 944 (5th Cir. 2018) (quoting *Smith v. EMC Corp.*, 393 F.3d 590, 595 (5th Cir. 2004)). In deciding whether to grant leave to amend,

¹ Because June 20, 2022, was an observed federal holiday, Plaintiffs' deadline to request leave to amend was June 21, 2022. *See* Dkt. 80 at 1 n.1 (“If a deadline falls on a Saturday, Sunday, or a legal holiday as defined in Federal Rule of Civil Procedure 6, the effective date is the first business day following the deadline imposed.”).

² “When a trial court imposes a scheduling order, Federal Rules of Civil Procedure 15 and 16 operate together to govern the amendment of pleadings.” *Tex. Indigenous Council v. Simpkins*, 544 F. App’x 418, 420 (5th Cir. 2013). If a party requests to amend his pleadings before his deadline to amend has passed, the Court considers the party’s request under Rule 15 only. *See* FED. R. CIV. P. 15(a). If the deadline to amend has passed, the Court must first consider whether to extend the party’s deadline to amend under Rule 16 before considering whether, under Rule 15, it is appropriate to grant leave to amend. *See S&W Enters., L.L.C. v. SouthTrust Bank of Ala., N.A.*, 315 F.3d 533, 535 (5th Cir. 2003). Here, because Plaintiffs’ Motion was timely filed, the Court considers Plaintiffs’ request under Rule 15 only.

the district court may consider a variety of factors, including undue delay, bad faith or dilatory motive on the part of the movant, repeated failures by the movant to cure pleading deficiencies by amendments previously allowed, undue prejudice to the non-movant, and futility of the amendment. *Strickland v. Bank of N.Y. Mellon*, 838 F. App'x 815, 821 (5th Cir. 2020) (per curiam) (citing *Schiller v. Physicians Res. Grp., Inc.*, 342 F.3d 563, 566 (5th Cir. 2003)).

III. ANALYSIS

Defendants argue the Motion should be denied as futile and as unduly prejudicial. Having considered Defendants' arguments, the Court finds there is no substantial reason to deny Plaintiffs' Motion.

A proposed amendment is futile if it would fail to survive a Rule 12(b)(6) motion to dismiss. *Marucci Sports, L.L.C. v. N.C.A.A.*, 751 F.3d 368, 378 (5th Cir. 2014). Here, Defendants argue amendment would be futile because, "The manufacturing defect claim alleged in Plaintiffs' proposed Third Amended Complaint is identical to the (dismissed) manufacturing defect claim alleged in Plaintiffs' [First Amended Complaint]" and likewise fails to "plead facts to support the required elements of a manufacturing defect claim." *See* Dkt. 83 at 3. The Court disagrees, as Plaintiffs' proposed manufacturing defect claim cures the deficiencies of its prior, dismissed manufacturing defect claim. As noted by Defendants, Plaintiffs' prior manufacturing defect claim generally alleged that "certain units among the stapler(s) manufactured by Defendants - including the stapler used in Plaintiff's surgery - were manufactured without a component that resulted in a failure to 'fire' the staples," which in turn resulted in Mrs. Adams's injuries. *See* Dkt. 9 at 15. The District Judge found this allegation to be too generic to withstand scrutiny under Rule 12(b)(6) because Plaintiffs did not specify "which component was missing from the stapler or how that component's absence caused the EEA stapler to misfire." *See* Dkt. 24 at 8. Plaintiffs' proposed

amended complaint cures this deficiency by alleging specifically that the stapler at issue was manufactured with “a stapler guide [that] could come loose from the stapler and cause the device to cut but not staple a sealed anastomosis” and that such defect caused Mrs. Adams’s alleged injuries because the stapler cut Mrs. Adams’s tissue but did not seal an anastomosis. *See* Dkt. 82 at 22.

Further, the Court finds Plaintiffs have alleged sufficient facts to support their manufacturing defect claim. “A manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous.” *Gharda USA, Inc. v. Control Sols., Inc.*, 464 S.W.3d 338, 352 (Tex. 2015) (quoting *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004)). “A plaintiff must prove that the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff’s injuries.” *Id.* To succeed on a manufacturing defect claim, the plaintiff must “identify a specific defect by competent evidence and rule out other possible causes of the damage.” *Id.* (citing *Nissan Motor Co. Ltd. v. Armstrong*, 124 S.W.3d 131, 137 (Tex. 2004)). The proposed amended complaint alleges a specific defect that made the stapler unreasonably dangerous; it alleges the defect existed when the stapler left the manufacturer, as the stapler “arrived in the surgical suite in its original package, unchanged from when it left Defendants [sic] manufacturer”; and it alleges the defect was the producing cause of Plaintiffs’ injuries, as Dr. Novosad allegedly used the stapler as instructed, yet the stapler allegedly cut Mrs. Adams’s tissue without sealing an anastomosis. *See* Dkt. 82 at 22–24. Accepting these allegations as true, the Court finds Plaintiffs have adequately pled a manufacturing defect claim. As such, amendment would not be futile.

Turning to Defendants' second argument, the Court finds amendment would not unduly prejudice Defendants. "A defendant is prejudiced if an added claim would require the defendant to 'reopen discovery and prepare a defense for a claim different from the [one] . . . that was before the court.'" *Smith*, 393 F.3d at 596 (quoting *Duggins v. Steak 'N Shake, Inc.*, 195 F.3d 828, 834 (6th Cir. 1999)). And denial based on undue prejudice is justified if amendment would cause the defendant to incur "considerable delay and expense." *Id.* In this case, Defendants claim they will be required to prepare additional written discovery and re-depose an unidentified number of previously-deposed witnesses. *See* Dkt. 53 at 5–6. Defendants have not identified the extent to which they would be prejudiced, let alone shown they would incur "considerable delay and expense" if Plaintiffs' Motion is granted. *See Smith*, 393 F.3d at 596. And, as noted, the discovery deadline in this case is not until February 2023, which was set based on a proposed scheduling order jointly submitted by the parties. *See* Dkt. 77 (joint proposed scheduling order); Dkt. 80 (Second Amended Scheduling Order).

Further, the Court is not persuaded by Defendants' assertion that "Plaintiffs allowed Defendant to litigate this case for almost two years without having to defend against a manufacturing defect claim or discover facts in support of such a defense." *See* Dkt. 83 at 3 n.2. Plaintiffs contend they learned of the allegedly defective component during Dr. Novosad's June 2022 deposition and based on a May 2022 product recall letter issued by Defendants. *See* Dkt. 81. Plaintiffs argue "it is likely that Defendants knew of this information prior to this litigation and of its relevance to this case throughout litigation" and so "[a]ny burden[s] suffered by Defendants are of their own doing." *See* Dkt. 84 at 5. Defendants did not respond to this argument.

All things considered, the Court does not find a substantial reason to deny the Motion (Dkt. 81), as required to deny leave to amend under Rule 15. *See Stripling v. Jordan Prod. Co., LLC*,

234 F.3d 863, 872 (5th Cir. 2000) (“In the context of motions to amend pleadings, ‘discretion’ may be misleading, because FED. R. CIV. P. 15(a) ‘evinces a bias in favor of granting leave to amend.’ Unless there is a ‘substantial reason to deny leave to amend, the discretion of the district court is not broad enough to permit denial.’”).

IV. CONCLUSION

IT IS ORDERED that Plaintiffs’ Motion (Dkt. 81) is **GRANTED**. The Third Amended Complaint (Dkt. 82) is deemed filed and is the live complaint in this matter.

So ORDERED and SIGNED this 10th day of August, 2022.

A handwritten signature in black ink, appearing to read 'K. Priest Johnson', written over a horizontal line.

KIMBERLY C. PRIEST JOHNSON
UNITED STATES MAGISTRATE JUDGE