**UNITED STATES DISTRICT COURT**
**DISTRICT OF MINNESOTA**

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| David A. Reed and Georgia Gerard-Reed,<br><br>Plaintiffs,<br><br>v.<br><br>St. Jude Medical,<br><br>Defendant. | Civil No. 17-5560 (JRT/HB)<br><br><br><br>**REPORT AND RECOMMENDATION** |

HILDY BOWBEER, United States Magistrate Judge

This matter is before the Court on Defendant St. Jude Medical's Motion to Dismiss [Doc. No. 11] and Plaintiffs David A. Reed and Georgia Gerard-Reed's Motion to Add Exhibit K [Doc. No. 42]. Plaintiffs are proceeding pro se. The motion to dismiss was referred to the undersigned for a report and recommendation by the Honorable John R. Tunheim, Chief Judge, United States District Court. (Order of Reference, Feb. 7, 2018 [Doc. No. 19].)

## I. Background and Procedural History

Plaintiffs David A. Reed and Georgia Gerard-Reed are suing Defendant St. Jude Medical[1] for injuries allegedly caused by a mechanical heart valve manufactured by St. Jude and implanted in Mr. Reed in 2011. (Compl. ¶ 1 [Doc. No. 1-1].)

[1] The formal corporate name of St. Jude Medical is now St. Jude Medical, LLC. (Wirth Decl. ¶ 3 [Doc. No. 2].)

### A. Allegations in the Complaint

Plaintiffs allege the following facts in their complaint. Five years after a St. Jude mechanical heart valve was implanted in Mr. Reed, he experienced heart and lung complications, including a heart attack. (Compl. ¶¶ 2-3.) One of his providers opined that the heart valve was not defective, but another provider opined it was leaking and should be repaired or replaced. (*Id.* ¶¶ 3-4.) A third provider agreed the valve was leaking and recommended that the mechanical valve be replaced with a tissue valve. (*Id.* ¶ 5.) Mr. Reed was scheduled to undergo surgery in December 2017 to replace the heart valve. (*Id.*)

Though Plaintiffs describe the valve as "defective" in the complaint (*id.* ¶ 4), they do not identify a particular defect in design, manufacture, or warnings, nor do they use words that would specify a particular theory of liability or cause of action (*e.g.*, strict liability, negligence, breach of warranty, fraud, or misrepresentation). Plaintiffs are seeking $4,000,000 in damages, plus $20,000 a year for the remainder of Mr. Reed's life. (*Id.* at 2.)

### B. St. Jude's Notice of Removal and Motion to Dismiss

St. Jude removed the case from Ramsey County District Court to the United States District Court for the District of Minnesota on the basis of diversity jurisdiction. (Ntc. Removal ¶ 3 [Doc. No. 1].) On February 1, 2018, St. Jude filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), seeking dismissal on the grounds of express preemption under 21 U.S.C. § 360k(a) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008); implied preemption under 21 U.S.C. § 337(a) and *Buckman Co. v.*

*Plaintiffs' Legal Committee*, 531 U.S. 341 (2001); and failure to state a claim on which relief can be granted. (Def.'s Mot. Dismiss [Doc. No. 11]; Def.'s Mem. Supp. Mot. Dismiss at 1-3 [Doc. No. 14].)

Plaintiffs filed an opposition to the motion to dismiss, but did not address Defendant's legal arguments. (Pls.' Mot. Deny Mot. at 1 [Doc. No. 20]; David Reed Aff. [Doc. No. 21].) Instead, Plaintiffs accused St. Jude of committing "medical fraud" by directing a medical facility, Wilmington Health, to perform a scan "off the record for their benefit to see how severe the damage was." (David Reed Aff. at 2.) Mr. Reed further claims that the scan was not provided to his doctor and that Wilmington Health denies the scan was even performed. (*Id.*)

The hearing on the motion to dismiss was originally scheduled on May 2, 2018, but was rescheduled at Plaintiffs' request to May 30, 2018, and was postponed again at Plaintiffs' request to June 22, 2018.

**C. Plaintiffs' Motion to Add Exhibit K and Other Filings**

On April 13, 2018, Plaintiffs filed an unsolicited, supplemental response to the motion to dismiss. [Doc. Nos. 30-36.] In that filing, Plaintiffs asked the Court to invalidate the premarket approval of the St. Jude mechanical heart valve at issue on the basis that the FDA did not perform studies on left-handed individuals. Plaintiffs also repeat the accusation of "medical fraud." (Pls.' Request ¶ 2.)

On May 18, 2018, Plaintiffs filed a motion to add Exhibit K, a purported "confession of guilt" by St. Jude. [Doc. No. 42.] The document designated as Exhibit K is a typewritten statement that is not signed or sworn and appears to be drafted by

Mr. Reed. [Doc. No. 43.] Submitted with the typewritten statement is a letter from Farah Tabibkhoei, an attorney with the law firm of Reed Smith LLP. [Doc. No. 44.] Reed Smith LLP represents Abbott Laboratories, the parent company of St. Jude. [Doc. No. 44.] St. Jude opposes the motion to add Exhibit K to the record. [Doc. No. 47.]

## II. Discussion

### A. Legal Standards

On a motion to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court "must take the well-pleaded allegations of the complaint as true, and construe the complaint, and all reasonable inferences arising therefrom, most favorably to the pleader." *Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). "To survive a 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 Alt. 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.*

Generally, a court may not consider matters outside the pleadings in assessing the sufficiency of a complaint under the Rule 12(b)(6) standard. *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999) (citations omitted). A court may make exceptions to this rule for matters of public record, materials "necessarily embraced by" the complaint, and exhibits submitted with the complaint. *Id.* (citations omitted).

A court has the duty to construe liberally a pro se party's pleadings. *Estelle v. Gamble*, 429 U.S. 97, 106 (1976). But, although courts "grant deference to pro se

litigants, the court will not assume the role of advocate for the pro se individual and the court will not allow defective or insufficiently pled pro se claims to proceed." *Sneh v. Bank of N.Y. Mellon*, No. 12-cv-954 (MJD/JSM), 2012 WL 5519690, at *5 (D. Minn. Oct. 30, 2012), *R. & R. adopted*, 2012 WL 5519682 (D. Minn. Nov. 14, 2012).

**B. Express Preemption**

St. Jude argues that the product defect claim alleged in Plaintiffs' complaint is expressly preempted under 21 U.S.C. § 360k(a) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008). St. Jude has submitted materials outside the pleadings to show that the mechanical heart valve at issue was approved through the Food and Drug Administration's ("FDA") Premarket Approval ("PMA") process. (Wells Decl. Exs. 1, 2.) Plaintiffs do not dispute that the device at issue was approved through the PMA process, and the Court will consider the materials attached to the Wells declaration as matters of public record. Alternatively, the Court takes judicial notice of the FDA's PMA. *See Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 984 n.1 (E.D. Mo. 2014).

The express preemption provision of the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") provides that no state may establish "any requirement . . . which is different from, or in addition to" a federal requirement, and "which relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). This provision operates as a broad preemption of state-law claims that purport to challenge the safety or performance of a PMA device but that add to or otherwise differ from federal requirements. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322, 330 (2008). The MDA do not, however, "prevent a State from providing a damages remedy for claims premised on

a violation of FDA regulations"; in that circumstance, the state duties are parallel to the federal requirements. *Riegel*, 552 U.S. at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

The test for express preemption is two-part: (1) "whether the Federal Government has established requirements applicable to" the device, and if so, (2) whether the "common-law claims are based upon [a state's] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22. With respect to the first factor, *Riegel* established as a matter of law that the PMA of a medical device necessarily imposes requirements under the MDA that are applicable to the specific device. 552 U.S. at 322-23. The first express preemption factor is therefore satisfied here because the FDA has imposed requirements through the PMA process that are applicable to the medical device at issue.

As to the second factor, *Riegel* described the inquiry as whether the state-law claim relies on "any requirement" of state law "that is 'different from, or in additional to,' federal requirements." *Id.* at 323. Thus, any state law cause of action that would impose requirements concerning the safety or effectiveness of a PMA device that are "different from, or in addition to" the requirements imposed by federal law are expressly preempted. *Riegel*, 552 U.S. at 321. *Riegel* recognized that state-law claims for negligence, strict liability, and breach of implied warranty impose different or additional "common-law duties" requirements and are preempted by federal requirements. *Id.* at 323-24, 327-28. Since *Riegel*, courts have determined that state law claims of failure to warn, design defect, manufacturing defect, negligence per se, breach of express warranty,

misrepresentation, fraud, false advertising, and consumer fraud are also expressly preempted. *See In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205-08 (8th Cir. 2010) (finding failure to warn, design defect, manufacturing defect, and breach of express warranty claims preempted); *Morton v. Medtronic, Inc.*, No. 14-cv-3263 (DWF/JJK), 2015 WL 12778750, at *1, *4-6 (D. Minn. Jan. 5, 2015), *R. & R. adopted*, 2015 WL 12780468 (D. Minn. Feb. 19, 2015) (finding negligence, strict liability, breach of express warranty, breach of implied warranty, misrepresentation, fraud, false advertising, and consumer fraud preempted); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157-64 (D. Minn. 2009) (finding negligence per se, breach of implied warranty, breach of express warranty, manufacturing defect, design defect, and failure to warn claims preempted), *aff'd*, 623 F.3d 1200. Indeed, the only state-law claims that are *not* preempted are those "alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA." *In re Medtronic*, 592 F. Supp. 2d at 1152. "Such claims are not preempted because they merely 'parallel' federal requirements—that is, they do not add to or differ from federal requirements, which is the cornerstone of FDCA preemption." *Id.* (citing *Riegel*, 552 U.S. at 330).

Here, Plaintiffs allege in their complaint that the medical device was defective, but they do not identify the state-law cause or causes of action for which they are suing. At the hearing, Mr. Reed mentioned breach of warranty, design defect, manufacturing defect, failure to warn, false advertising, and fraud as possible underlying causes of action; there are also accusations of fraud elsewhere in the record. But nowhere in the

complaint, in the written response to this motion, or even in his oral argument, did Mr. Reed describe how the alleged defect violates a specification of the device's PMA. Without, for example, an allegation that St. Jude violated a specific manufacturing or labeling requirement imposed by the FDA, Plaintiffs' existing or prospective claims are expressly preempted. *See Zaccarello v. Medtronic, Inc.*, 38 F. Supp. 3d 1061, 1067 (W.D. Mo. 2014).

Rather, Plaintiffs' action is based simply on the premise that because the mechanical heart valve leaked and had to be replaced sooner than Plaintiffs (and perhaps their doctors) expected, it must have been defective. Simply alleging that a product was defective or that it malfunctioned, without alleging how a federal requirement was violated, does not state a plausible claim for relief. *See In re Medtronic*, 592 F. Supp. 2d at 1158. Consequently, Plaintiffs' claims for breach of warranty, design defect, manufacturing defect, failure to warn, and false advertising are expressly preempted. Plaintiffs' fraud claim, which does not relate to the valve itself or the PMA process but rather to St. Jude's alleged attempt to obtain a scanned image of his heart valve, is not expressly preempted.

The above discussion also forecloses Plaintiffs' arguments during the hearing that the FDA did not adequately study left-handed individuals or individuals with AB negative blood as part of the PMA. "[A] valid parallel claim cannot challenge the [PMA] process itself or the requirements imposed by the FDA pursuant to that process." *Raab v. Smith & Nephew, Inc.*, 150 F. Supp. 3d 671, 687 (S.D.W. Va. 2015) (citing *In re Medtronic*, 623 F.3d at 1206).

In sum, the Court recommends that—to the extent any particular claims can be sussed from the existing complaint—Plaintiffs' claims be dismissed with prejudice because it is not likely that Plaintiffs could allege additional facts that would save the claims. *See Jackson v. Walgreens Co.*, No. 16-0398 (JRT/FLN), 2016 WL 4212258, at *2 (D. Minn. Aug. 10, 2016). To the extent any of Plaintiffs' filings or oral arguments could be construed as a motion for leave to amend, the Court recommends that leave be denied because amendment would be futile.

**C. Implied Preemption**

St. Jude argues that Plaintiffs' claims are also subject to implied preemption under 21 U.S.C. § 337(a). The MDA provides that all actions to enforce FDCA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court remarked that "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provision. 531 U.S. 341, 349 n.4 (2001). Thus, if a state law claim exists solely because of a federal requirement, it is impliedly preempted. *Id.* at 353. Stated another way, to avoid implied preemption under *Buckman*, Plaintiffs' claim must be based on a state tort law that predated the FDCA and that would have given rise to liability even if the FDCA had never been enacted. *See Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

St. Jude cites two cases for the general proposition that claims for fraud and failure to warn are impliedly preempted. In *Kinetic Co. v. Medtronic, Inc.*, the plaintiff premised the failure to warn claim on the defendant's violation of an FDCA regulation. No. 08-cv-

6062 (PJS/AJB), 2011 WL 1485601, at *3 (D. Minn. Apr. 19, 2011). The court characterized the claim as "simply an attempt by private parties to enforce the MDA," which was impliedly preempted under *Buckman*. *Id.* (quoting *In re Medtronic*, 623 F.3d at 1205-06). At the hearing on the motion to dismiss in this case, Mr. Reed said that his failure to warn claim was based on St. Jude's failure to warn left-handed individuals that their electromagnetic fields were different from left-handed individuals. This prospective claim is not based on a violation of the FDCA, and thus, it is not impliedly preempted.

In *Riley v. Cordis Corp.*, the court found impliedly preempted a claim that "but for the defendant's fraudulent statements to the FDA, the [device] would not have been approved." 625 F. Supp. 2d 769, 777 (D. Minn. 2009). Here, Plaintiffs do not accuse St. Jude of committing fraud during the PMA process, but of committing fraud to obtain a scanned image of his heart years after the device at issue was implanted. This claim does not relate to the PMA process, to any requirements imposed by the MDA, or to the safety or effectiveness of the device. Therefore, the claim is not subject to implied preemption.

**D. Failure to State a Claim**

St. Jude's third basis for dismissal is that Plaintiffs have not adequately pleaded a plausible claim for relief. St. Jude argues that Plaintiffs have neither identified a particular cause of action nor pleaded facts sufficient to state a claim for relief. In light of the Court's conclusion that Plaintiffs' actual or potential claims for breach of warranty, design defect, manufacturing defect, failure to warn, and false advertising are expressly preempted, the Court addresses only the plausibility of the prospective fraud claim raised

by Plaintiffs in response to the instant motion.

Plaintiffs accuse St. Jude of committing fraud by directing a medical facility to perform a scan of Mr. Reed's heart for St. Jude's sole benefit and without providing the results to Mr. Reed. These allegations are not included in the complaint, but set forth elsewhere in the record. To the extent the allegations could be construed as a request to amend the complaint, the Court finds that amendment would be futile and recommends that leave to amend be denied.

To state a claim of fraud under Minnesota law, Plaintiffs must allege that St. Jude

> made a false representation of a past or present fact, susceptible of knowledge, knowing it to be false or without knowing whether it was true or false, with the intention of inducing the plaintiffs to act in reliance upon it or under such circumstances that plaintiffs were justified in so acting and was thereby deceived or induced to so act to their damage.

*Thompson v. Campbell*, 845 F. Supp. 665, 681 (D. Minn. 1994) (quoting *Davis v. Re-Trac Mfg. Corp.*, 276 Minn. 116, 117 (1967)). Plaintiffs have not described the false representation allegedly made by St. Jude, alleged that St. Jude made the statement without knowing whether it was true or false, alleged that St. Jude intended for Plaintiffs to rely on the statement, alleged that Plaintiffs actually relied on the statement, or alleged that Plaintiffs were damaged by their reliance. Consequently, the fraud claim—if actually pleaded—could not withstand a Rule 12(b)(6) motion to dismiss.

**E. Plaintiffs' Motion to Add Exhibit K**

The Court recommends that Plaintiffs' motion to add Exhibit K be denied. The typewritten statement is neither signed nor sworn. In addition, the statement and the letter are materials outside the pleadings that should not be considered on a motion to

dismiss.

Accordingly, **IT IS HEREBY RECOMMENDED** that:

1. Defendant's Motion to Dismiss [Doc. No. 11] be **GRANTED**;

2. Plaintiffs' complaint be **DISMISSED WITH PREJUDICE**;

3. Plaintiffs' Motion to Add Exhibit K [Doc. No. 42] be **DENIED**; and

4. Leave to amend not be granted.

Dated: July 24, 2018

s/ *Hildy Bowbeer*
HILDY BOWBEER
United States Magistrate Judge

## NOTICE

**Filing Objections:** This Report and Recommendation is not an order or judgment of the District Court and is therefore not appealable directly to the Eighth Circuit Court of Appeals. Under Local Rule 72.2(b)(1), "a party may file and serve specific written objections to a magistrate judge's proposed finding and recommendations within 14 days after being served a copy" of the Report and Recommendation. A party may respond to those objections within 14 days after being served a copy of the objections. D. Minn. LR 72.2(b)(2). All objections and responses must comply with the word or line limits set forth in LR 72.2(c).