

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

RON MIKESELL, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Case No. 3:16-CV-304 JD
)	
ST. JUDE MEDICAL, INC., <i>et al.</i> ,)	
)	
Defendants.)	

ORDER

On April 19, 2016, Plaintiffs Ron and Beverly Mikesell filed a complaint in state court alleging that Ron Mikesell was injured as the result of manufacturing defects in a St. Jude cardiac defibrillator component implanted in him in 2005. [DE 6]. The Defendants removed that complaint to federal court, [DE 1], and then filed a motion to dismiss [DE 10] all four of the Plaintiffs’ claims. They contend that the Plaintiffs’ three substantive claims are preempted by federal law and fail to satisfy Rule 8 pleading requirements. Further, they say that the Plaintiffs’ loss of consortium claim cannot survive alone. The Plaintiffs responded in opposition, arguing that their claims are not preempted and satisfy federal pleading requirements. [DE 12].

On October 7, 2016, the undersigned referred this motion to Magistrate Judge Michael G. Gotsch for a report and recommendation, pursuant to 28 U.S.C. § 636(b)(1)(B), Federal Rule of Civil Procedure 72(b) and Northern District of Indiana Local Rule 72.1(c). [DE 14]. On February 2, 2017, Magistrate Judge Gotsch issued his Report and Recommendation [DE 15], which recommends that the Court dismiss the Plaintiffs’ complaint in its entirety, though permit the Plaintiffs an opportunity to file an amended complaint.

The Court’s review of a Magistrate Judge’s report and recommendation is governed by

28 U.S.C. § 636(b)(1), which provides in part:

A judge of the court shall make a *de novo* determination of those portions of the report or specified proposed findings or recommendations to which objection is made. A judge of the court may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge. The judge may also receive further evidence or recommit the matter to the magistrate judge with instructions.

Under Fed. R. Civ. P. 72(b), however, the Court must only make a *de novo* determination of those portions of the Magistrate Judge's report and recommendation to which specific written objection has been made. *Johnson v. Zema Sys. Corp.*, 170 F.3d 734, 739 (7th Cir. 1999); Fed. R. Civ. P. 72(b). If no objection or only a partial objection is made, the Court reviews those unobjected portions for clear error. *Id.* In addition, failure to file objections with the district court "waives the right to appeal all issues addressed in the recommendation, both factual and legal." *Id.* Under the clear error standard, the Court can only overturn a Magistrate Judge's ruling if the Court is left with "the definite and firm conviction that a mistake has been made." *Weeks v. Samsung Heavy Indus. Co., Ltd.*, 126 F.3d 926, 943 (7th Cir. 1997).

Both 28 U.S.C. § 636(b)(1) and Fed. R. Civ. P. 72(b) require the parties to file objections to a report and recommendation within fourteen days of being served with a copy of the same. *See* 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(2). More than 14 days have passed since the parties were served with Magistrate Judge Gotsch's Report and Recommendation and no party has filed an objection. Consequently, because the time period for objections has passed, the Court considers there to be no objection to Magistrate Judge Gotsch's Report and Recommendation.

Having reviewed that Report and Recommendation, the Court finds no clear error therein. The Court concurs that, at the pleadings stage, it would be premature to conclude that

Counts I (strict liability - manufacturing defect) and II (negligence in manufacturing) of the complaint are expressly preempted by 21 U.S.C. § 360k(a). However, the Plaintiffs do not offer sufficient factual allegations to substantiate those claims. In particular, they do not plausibly allege that the specific leads implanted in Mikesell were defective, or that a defect in those leads actually increased Mikesell's dependence on his pacemaker. As to Count III (negligence per se), the Magistrate Judge correctly concluded that this claim is distinguishable from the fraud claims in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 344 (2001) and thus is not impliedly preempted by federal regulations. Nevertheless, this claim too lacks the factual heft required by *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007). The Plaintiffs provide conclusory allegations that St. Jude violated numerous federal regulations, though make no effort to explain how it did so. That simply fails to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir. 2009). The Court thus finds that the Magistrate Judge did not clearly err in concluding that the Plaintiffs failed to sufficiently plead their first three claims. Since the remaining loss of consortium claim is not independently actionable, it too must be dismissed. *Miller v. Cent. Ind. Cmty. Found., Inc.*, 11 N.E.3d 944, 963 (Ind. Ct. App. 2014).

As such, the Court **ADOPTS** Magistrate Judge Gotsch's Report and Recommendation [DE 15] in its entirety and incorporates that Report and Recommendation into this order. The Court accordingly **GRANTS** the Defendants' motion to dismiss and dismisses all four of the Plaintiffs' claims. The Plaintiffs may file an amended complaint no later than March 15, 2017.

SO ORDERED.

ENTERED: February 17, 2017

 /s/ JON E. DEGILIO
Judge
United States District Court