UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

EVA WESTMORELAND,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 4:17-CV-01626-AGF
	)	
MEDTRONIC, INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This wrongful death action is before the Court on Defendants' motion to dismiss for failure to state a claim, under Federal Rule of Civil Procedure 12(b)(6). For the reasons set forth below, Defendants' motion will be denied in large part, and granted in part, without prejudice to Plaintiff filing a motion for leave to file an amended complaint.

BACKGROUND

Plaintiff Eva Westmoreland filed this action against Defendants Medtronic, Inc., Medtronic USA, Inc., (jointly, "Medtronic"), and Jeff Belkowski, a Medtronic employee and agent (sales representative), seeking damages for the wrongful death of her mother. The record establishes that Decedent died following heart surgery in which her surgeon implanted a Medtronic Endurant II 25 mm graft in her aorta. Plaintiff alleges that Decedent's surgeon selected the Medtronic 25 mm graft after Belkowski performed an "Endovascular Stent Planning procedure . . . for the purpose of 'sizing' [Decedent's] aortic anatomy" and recommended the Endurant II 25 mm graft, even though use of a Medtronic graft was contraindicated and Medtronic's own sizing documents indicated the

25 mm graft was too large for Decedent's aorta. "[F]ollowing the recommendations" of Belkowski, Decedent's surgeon "attempt[ed] to place the contraindicated graft," and her left renal artery was "ripped apart," causing Decedent's death. Plaintiff claims Belkowski, and Medtronic as his employer, were negligent because they recommended a "contraindicated graft" and this recommendation was the direct and proximate cause of Decedent's death. Plaintiff seeks compensatory damages and "aggravating circumstances damages" for Defendants "knowingly" recommending a contraindicated graft procedure and "a graft that was clearly too large . . . according to [Medtronic's] own" guidelines. ECF No. 1 at 3-4.

In support of their motion to dismiss, Defendants first argue that Plaintiff has not pled sufficient facts to support a negligence cause of action. Defendants argue no duty was owed to Decedent because "medical device companies, operating through sales representatives, generally do not provide direct care to patients and thus do not owe a duty to people using their devices." ECF No. 10 at 12. Defendants also assert the complaint fails to demonstrate Medtronic is liable for the actions or omissions of Belkowski, because the complaint does not state facts suggesting Belkowski was acting within the scope of his employment at the time of Decedent's injury. Additionally, according to Defendants, even if Defendants owed a duty to Decedent, the complaint does not sufficiently allege a breach of that duty or that such a breach was the direct and proximate cause of Decedent's death because Plaintiff has not shown "whether or not the alleged recommendations had anything to do with the events that occurred during [Decedent's] surgery, and her subsequent death." *Id*.

Defendants next argue that Plaintiff's cause of action is preempted by the Medical Device Amendments Act of 1976 ("MDA") to the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 360k. It is undisputed that Medtronic's Endurant II Stent is subject to Food and Drug Administration ("FDA") pre-market approval, which imposes federal requirements. According to Defendants, federal law requires pre-market approval of the device's "specifications, intended uses, and warnings" regarding the stent's "contraindications" and "recommended device sizing," as well as of "physician training requirements." ECF No. 10 at 17-18. In particular, Defendants ask this Court take judicial notice of Medtronic's "Patient Information Booklet" and its "Endurant II/Endurant IIs Stent Graft System Instructions for Use," which they assert were subject to pre-market approval.[1] Defendants argue that these documents contain "specific physician training requirements" regulating Belkowski's communications with Decedent's surgeon. As such, Defendants assert that Plaintiff's negligence claim based on Belkowski's communications and recommendations is preempted, characterizing Plaintiff's claim as "essentially a warnings claim." Finding Defendants were negligent would, according to Defendants, require finding Defendants had a duty to provide "different or additional information or instructions to the surgeon than those approved or required by the FDA." *Id.* at 18.

[1] Defendants refer the Court to the Medtronic Patient Information Booklet at https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100021C.pdf, and the "Endurant II/Endurant IIs Stent Graft System Instructions for Use" at http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@cardio/documents/documents/contrib_200054.pdf.

Lastly, Defendants argue that Plaintiff's request for aggravating circumstances damages should be dismissed because, under Missouri law, she is not entitled to recover such damages based on a negligence claim. Defendants further contend that Plaintiff is not entitled to punitive damages because she has failed to allege facts demonstrating that Defendants showed deliberate indifference or conscious disregard for the rights of others.[2]

Plaintiff responds that the complaint alleges sufficient facts demonstrating that Defendants assumed a duty of care, that the duty was breached when Belkowski recommended a stent too large for Decedent's anatomy, that Belkowski was acting as the agent and employee of the Medtronic Defendants when he negligently recommended the wrong-sized stent graft, and that his actions caused Decedent's death. Second, Plaintiff contends her claim is not preempted because she is not alleging the design, manufacture, or warnings approved by the FDA were inadequate. Instead, she is alleging Belkowski undertook to measure the proper stent size and negligently recommended the wrong size, and federal law does not regulate such "interactions between corporate representatives and physicians." ECF No. 11 at 8-9. Third, Plaintiff argues that she has sufficiently alleged that Defendants knowingly recommended an oversized graft and, if that allegation is proven at trial, she would be entitled to aggravating circumstances damages under Missouri law. Plaintiff asks that, should the Court decide that she has not

[2] Defendants also contend that the complaint should be dismissed because Plaintiff has not adequately asserted a claim for "fraudulent misrepresentation." But Plaintiff's claim for aggravated damages does not require that she claim fraud, and the Court finds no basis for characterizing Plaintiff's complaint as a claim for fraud.

sufficiently pled any matter raised in Defendants' motion to dismiss, she be granted leave to file an amended complaint setting forth additional facts.

DISCUSSION

For a plaintiff 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 Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The reviewing court must accept the plaintiff's factual allegations as true and construe them in the plaintiff's favor, but the court is not required to accept the legal conclusions the plaintiff draws from the facts alleged. *Id*.; *Retro Television Network, Inc. v. Luken Commc'ns, LLC*, 696 F.3d 766, 768-69 (8th Cir. 2012).

"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." *Iqbal*, 556 U.S. at 678. A court must draw on its judicial experience and common sense, and consider "the plausibility of the plaintiff's claim as a whole, not the plausibility of each individual allegation." *Zoltek Corp. v. Structural Polymer Grp.*, 592 F.3d 893, 896 n.4 (8th Cir. 2010).

Alleged Failure to State Negligence Claim

Because this is a diversity case, Plaintiff's negligence claim is governed by Missouri law. This Court is bound by the decisions of the Supreme Court of Missouri, and if there is no decision from that court on point, this Court must predict how the state supreme court would rule, and "follow decisions from the intermediate state courts when

they are the best evidence of Missouri law." *United Fire & Cas. Co. v. Titan Contractors Serv., Inc.*, 751 F.3d 880, 883 (8th Cir. 2014).

The Court concludes that Plaintiff has pled sufficient factual allegations demonstrating a plausible negligence claim. In any action for negligence, the plaintiff must establish that the defendant had a duty to protect the plaintiff from injury, the defendant failed to perform that duty, and that failure proximately caused injury to the plaintiff. *Lopez v. Three Rivers Elec. Coop., Inc.*, 26 S.W.3d 151, 155 (Mo. 2000). "[W]hether a duty exists in a given situation depends on whether a risk was foreseeable" and a risk was foreseeable if there was some probability of harm sufficiently serious that the ordinarily prudent person would take precautions to avoid that risk of harm. *Id*. at 156. Even if one does not ordinarily owe a particular duty of care, one can assume such a duty when gratuitously undertaking to render services if failure to exercise reasonable care in that undertaking would foreseeably increase the risk of harm. *Standurf v. Sipes*, 447 S.W.2d 558, 561 (Mo. 1969). Thus, even if medical device companies generally owe no duty to patients because they do not provide direct care, they can assume such a duty by volunteering to offer assistance to a patient's treating physician. *Medtronic, Inc. v. Malander*, 996 N.E.2d 412, 420–21 (Ind. Ct. App. 2013); *see also Chamian v. Sharplan Lasers, Inc*., No. 200000171, 2004 WL 2341569, at *8 (Mass. Super. Ct. Sept. 24, 2004) (holding that owner of a medical instrument owed a duty of care to a patient because, by providing a technician to assist in the operating room, it assumed a duty to provide knowledgeable and competent assistance to the treating physician).

Here, the complaint alleges that Belkowski undertook to assist the Decedent's surgeon in a stent sizing procedure, which would support finding Belkowski assumed a duty to provide competent assistance. The Court concludes that Defendants' arguments regarding breach of duty and causation similarly do not support dismissal of the complaint for failure to state a claim.

The Court, however, agrees with Defendants that Plaintiff did not adequately allege that Belkowski was acting within the scope of his employment with Medtronic when he engaged in the conduct at issue in this case, such that Medtronic could be held liable for those actions under a respondeat superior theory. On this matter, the Court will grant Plaintiff's request to be allowed to seek leave to file an amended complaint setting forth additional allegations.

Preemption

The MDA preempts any common-law claims that would impose requirements in addition to those imposed by the FDA pre-market approval process, such as additional manufacturing, design, or labeling requirements. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-323 (2008). But Plaintiff is not bringing a products liability action based on deficient design, manufacturing, or warnings. Instead, the complaint alleges a negligence claim based on communications between Belkowski and Decedent's surgeon in which Belkowski recommended a contraindicated device. The FDA's pre-market approval process does not regulate such communications and, therefore, federal law does not preempt Plaintiff's claim. *See Malander*, 996 N.E.2d at 416-19 (holding no preemption where the plaintiff claimed a manufacturer's employee negligently assisted a physician in

testing a malfunctioning medical device and recommended the physician use it); *Adkins v. Cytyc Corp.*, No. 4:07CV00053, 2008 WL 2680474, at *2 (W.D. Va. July 3, 2008) (holding no preemption of a negligence claim based on recommendations of the defendant's employee given to the plaintiff's surgeon during her operation that it was safe to use a certain device; granting the plaintiff leave to amend her complaint to plead such a claim).

Defendants argue, however, that these communications were regulated, since Medtronic's Patient Information Booklet and Endurant II Instructions for Use documents contained "physician training requirements" and were subject to pre-market approval. Even assuming the Court can consider these documents on a motion to dismiss, they do not alter the Court's above conclusion. The "physician training requirements" section of the Endurant II Instructions for Use document provides for the minimum recommended training practitioners should complete before using an Endurant System.[3] It states "[a]ll physicians should complete in-service training" prior to using an Endurant System and warns, "Caution: The Endurant II/IIs stent graft system should only be used by physicians and teams trained in vascular interventional techniques, and in the use of this device." The document then goes on to list the minimum "knowledge and skill requirements" of such physicians. In a section titled "Recommended Device Sizing," the document

[3] Endurant II/Endurant IIs Stent Graft System Instructions for Use, at 76.

provides a "Sizing Chart" indicating the system size recommended for vessels of different diameters and lengths.[4]

These documents thus provide warnings and recommendations for physicians planning to use an Endurant II system. But, again, Plaintiff's claim is not that any warnings, whether given on the labeling of the product itself or by Medtronic's documents, were deficient. Her claim is that Belkowski undertook to recommend a particular sized stent appropriate for Decedent's anatomy, and did so negligently, and also recklessly. In sum, Plaintiff's claims are not preempted by the MDA.

Claim for Aggravating Circumstances Damages

Plaintiff has also stated a claim for aggravating circumstances damages. Under Missouri law, a plaintiff bringing a wrongful death action may request damages based on "aggravating circumstances." Mo. Rev. Stat. §§ 537.080, .090. The Missouri Supreme Court has explained that aggravating circumstance damages in wrongful death cases are the equivalent of punitive damages. *Bennett v. Owens–Corning Fiberglas Corp*., 896 S.W.2d 464, 466 (Mo. 1995). In order to submit the issue of aggravating circumstances to the jury, the plaintiff must show "willful misconduct, wantonness, recklessness, or want of care indicative of indifference to consequences must be shown." *Letz v. Turbomeca Engine Corp*., 975 S.W.2d 155, 164 (Mo. Ct. App. 1997). Plaintiff has alleged that Belkowski suggested the wrong size stent for Decedent, even though Medtronic's own materials suggested this was improper, and that he did so "knowingly." The determination of the propriety of aggravating circumstances damages as claimed is

[4] *Id.* at 77-78.

premature at this stage in the proceedings. The facts as alleged sufficiently state a claim for such damages.

CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that Defendants' motion to dismiss Plaintiff's complaint is **DENIED**, except with respect to her claims against the Medtronics Defendants, without prejudice to Plaintiff's right to file, on or before **November 16, 2017**, a motion for leave to file an amended complaint setting forth additional facts with regard to Defendant Belkowski's scope of employment. Such a motion must include, as an attachment, the proposed amended complaint.

Audrey G. Fleissig

AUDREY G. FLEISSIG
UNITED STATES DISTRICT JUDGE

Dated this 6th day of November, 2017.