

Mikelle Mabey (“Mabey”) are St. Jude representatives who allegedly “assist surgeons to implant the medical products, and assist patients who receive the medical products.”² Either one or both representatives were present during McCartney’s surgeries.

On May 17, 2011, McCartney underwent a surgery to implant a permanent stimulator in his back. Dr. Paul Amstutz (“Dr. Amstutz”), a neurosurgeon at the VA performed the surgery. Initially, the stimulator worked well to control Plaintiff’s pain, which was located in the top rear of his left leg down to his left foot, but the effectiveness decreased progressively. By mid-August 2011, the stimulator did not work at all. On December 16, 2011, an X-ray indicated that at least one of the stimulator wires was fractured.

On April 17, 2012, McCartney underwent another surgery at the VA to correct the problem with the permanent stimulator. A St. Jude representative was present during the surgery and allegedly called McCartney’s wife during the surgery to inquire about the location of McCartney’s pain. McCartney’s wife indicated that she was unsure which leg was afflicted. After the surgery, the stimulator was turned on but did not address McCartney’s pain. McCartney could feel the device working on the upper front side of his right leg. Allegedly, St. Jude representatives told McCartney that the stimulator was placed in an incorrect location. McCartney saw a different VA physician, Dr. Isani, in November 2012. Dr. Isani allegedly told McCartney that the stimulator paddle was placed on the wrong side of Plaintiff’s spinal cord.

In February 2013, McCartney underwent another surgery to replace the spinal stimulator yet again. Dr. Levitt, a private doctor not associated with the VA, conducted the surgery to replace the stimulator. The surgery was successful.

² Docket No. 2, at 2.

This suit arises out of the two surgeries performed by Dr. Amstutz. Plaintiff brings two causes of action for negligence against both St. Jude and the United States of America. St. Jude seeks dismissal.

II. MOTION TO DISMISS STANDARD

In considering a motion to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6), all well-pleaded factual allegations, as distinguished from conclusory allegations, are accepted as true and viewed in the light most favorable to Plaintiff as the nonmoving party.³ Plaintiff must provide “enough facts to state a claim to relief that is plausible on its face,”⁴ which requires “more than an unadorned, the-defendant-unlawfully-harmed-me accusation.”⁵ “A pleading that offers ‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action will not do.’ Nor does a complaint suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’”⁶

“The court’s function on a Rule 12(b)(6) motion is not to weigh potential evidence that the parties might present at trial, but to assess whether the plaintiff’s complaint alone is legally sufficient to state a claim for which relief may be granted.”⁷ As the Court in *Iqbal* stated,

only a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not

³ *GFF Corp. v. Associated Wholesale Grocers, Inc.*, 130 F.3d 1381, 1384 (10th Cir. 1997).

⁴ *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007).

⁵ *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

⁶ *Id.* (quoting *Twombly*, 550 U.S. at 557) (alteration in original).

⁷ *Miller v. Glanz*, 948 F.2d 1562, 1565 (10th Cir. 1991).

permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not show[n]—that the pleader is entitled to relief.⁸

III. DISCUSSION

Plaintiff asserts two negligence claims against Defendants collectively, one for each allegedly negligently performed surgery. A claim for negligence requires four elements: a duty, breach of that duty, causation, and damages.⁹ St. Jude argues that Plaintiff's claims fail because medical device manufacturers owe no duty to patients to ensure their devices are properly implanted. St. Jude further argues that the complaint in this case fails to satisfy *Twombly's* plausibility requirement and fails to identify which wrongful acts were committed by which Defendant, thus violating notice requirements. Plaintiff argues that medical device manufacturers owe a general duty of care to ensure that physicians properly implant their devices. Plaintiff further argues that, regardless of any such common law duty, his second cause of action is properly pleaded because he alleges a voluntary undertaking by St. Jude.

There is a relatively new, yet now common practice, of having medical device company representatives attend surgeries.¹⁰ As a result, courts have seen claims alleging liability based on the actions or omissions of the company representative during the medical procedure. At issue in the first cause of action is whether the medical device representative who attended Plaintiff's surgery owed a duty of care to the patient to ensure the device was implanted properly and at

⁸ *Iqbal*, 556 U.S. at 679 (alteration in original) (citations and internal quotation marks omitted).

⁹ *Williams v. Melby*, 699 P.2d 723, 726 (Utah 1985).

¹⁰ Michael J. Summerhill & Aaron M. Chandler, *Company Representatives in the Operating & Treatment Room: How to Navigate the Ever-Expanding Theories of Liability for Medical Device & Pharmaceutical Companies*, 12 DePaul J. Health Care L. 253, 253–54 (2009).

issue in the second cause of action is whether the medical device representative affirmatively undertook a duty through Mabey's affirmative acts during the surgery. The issues can be resolved by determining what duties if any that St. Jude owed to Plaintiff during each surgery.

“Duty must be determined as a matter of law and on a categorical basis for a given class of tort claims.”¹¹ These duty factors include (1) whether the defendant's allegedly tortious conduct consists of an affirmative act or merely an omission, (2) the legal relationship of the parties, (3) the foreseeability or likelihood of injury, (4) public policy as to which party can best bear the loss occasioned by the injury, and (5) other general policy considerations.¹² The first two factors are typically “plus factor[s]—used to impose a duty where one would otherwise not exist, such as where the act complained of is merely an omission.”¹³ The final three factors are typically “minus factors—used to eliminate a duty that would otherwise exist.”¹⁴

In determining whether a duty exists between medical device manufacturers and patients, *B.R. ex rel. Jeffs v. West* is particularly instructive. In *Jeffs* the Utah Supreme Court determined that physicians owe nonpatients a duty to exercise reasonable care in prescribing medications that pose a risk of injury to third parties.¹⁵ The defendants in that case argued that there was no duty because there was no special legal relationship between a healthcare provider and nonpatients.¹⁶ The plaintiffs argued that a special relationship was required only where the claim

¹¹ *B.R. ex rel. Jeffs v. West*, 275 P.3d 228, 234 (Utah 2012).

¹² *Id.* at 230.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.* at 229.

¹⁶ *Id.* at 231.

was based on an omission or failure to act.¹⁷ The Utah Supreme Court agreed with the plaintiffs, noting that the “[t]he long-recognized distinction between acts and omissions—or misfeasance and nonfeasance—makes a critical difference and is perhaps the most fundamental factor courts consider when evaluating duty.”¹⁸ Acts of misfeasance typically carry a duty of care while nonfeasance “generally implicates a duty only in cases of special legal relationships.”¹⁹

1. First Cause of Action—Negligence

In support of the first cause of action, which corresponds to the May 2011 surgery, Plaintiff alleges, “On information and belief, the Company’s employees instructed Dr. Amstutz as to how to implant the permanent spinal cord stimulator in Plaintiff’s back.”²⁰ Further, Plaintiff alleges that “Defendants failed to ensure that the stimulator device was properly implanted in Plaintiff’s back, . . . failed to place the electrodes of the stimulator in the original spot shown to be effective by the trial implant, . . . and the improper placement of the stimulator device caused the stimulator device’s wires to fracture.”²¹

Defendant argues that allegations “on information and belief” constitute conclusory allegations that should be disregarded by the Court. “The mere fact that a plaintiff uses the language ‘information and belief’ does not make an allegation conclusory but, instead, the Court

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ Docket No. 2, at 4.

²¹ *Id.* at 9.

must consider the content of the allegation itself.”²² In considering the content, however, the Court finds that the allegation is totally conclusory because it completely lacks factual support. The Complaint alleges that St. Jude representatives instructed Dr. Amstutz as to how to implant the permanent spinal cord stimulator but pleads no facts to allow the Court to reach such a conclusion.

Plaintiff is left only with the allegation that Defendants failed to ensure that the physician properly implanted the stimulator device and electrodes. This cause of action is one for St. Jude’s nonfeasance during McCarney’s surgery. Upon a review of the duty factors in the case at hand, the Court concludes that there is no special legal relationship between medical device manufacturers and patients such that medical device manufacturers owe a duty of care for their nonfeasance during a physician’s surgery. St. Jude did not owe Plaintiff a duty to ensure the physician properly implanted the medical device at issue. The Court will therefore grant St. Jude’s Motion to Dismiss regarding Plaintiff’s first count of negligence.

2. Second Cause of Action—Negligence

In support of the second count of negligence, which corresponds to the April 2012 surgery, Plaintiff alleges that during Plaintiff’s surgery, St. Jude, “voluntarily undertook the duty to ensure that the electrodes would be placed in the proper location in Plaintiffs’ [sic] back.”²³ In support of that allegation, Plaintiff alleges that Mabey, who was assisting Dr. Amstutz during McCartney’s surgery, called Plaintiff’s wife during the surgery and asked in which leg

²² *ArCzar, Inc. v. Navico, Inc.*, No. 11-CV-805-PJC, 2012 WL 3150815, at *2 (N.D. Okla. Aug. 2, 2012) (citing *Dorf v. City of Evansville*, No. 11-CV-351-S, 2012 WL 1440343, at *4 n.2 (D. Wyo. Apr. 22, 2012)).

²³ Docket No. 2, at 10.

McCartney was suffering his nerve pain.²⁴ McCartney's wife said she did not know. Plaintiff further alleges that Defendants placed the electrodes of the stimulator in a manner that had no effect on Plaintiff's pain.

While St. Jude as a medical device manufacturer would ordinarily have no duty to ensure the physician placed the electrodes in the proper location, Plaintiff has alleged that by Mabey's communication with McCartney's wife during the surgery, St. Jude voluntarily undertook the duty to act reasonably. Plaintiff argues that this phone call establishes that St. Jude involved itself in medical decision-making in some affirmative way and therefore voluntarily undertook a duty. This cause of action is for St. Jude's alleged misfeasance during McCartney's surgery.

Liability for such an undertaking is outlined in the *Restatement (Second) of Torts* § 324A. Section 324A states,

One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if . . . he has undertaken to perform a duty owed by the other to the third person, or . . . harm is suffered because of reliance of the other or the third person upon the undertaking.²⁵

The parties disagree about whether Section 324A is applicable. Even if the Court assumes that Section 324A applies, Plaintiff's claim still fails because there are no facts alleged that St. Jude acted unreasonably in its undertaking nor are there any facts alleged that anyone relied on St. Jude's undertaking.

Plaintiff's Complaint does not identify the wrongful acts allegedly committed by each Defendant. The use of the collective term "Defendants" fails to inform individuals what

²⁴ *Id.* at 5.

²⁵ *Restatement (Second) of Torts* § 324A (1965).

wrongful acts they allegedly committed.²⁶ These allegations are not helpful in “figuring out what *facts*”²⁷ McCartney means to allege about St. Jude’s specific conduct.

Section 324A requires St. Jude to have acted unreasonably. Plaintiff does not allege any action by St. Jude other than Mabey having gathered information during a telephone call with McCartney’s wife. As outlined above, Section 324A requires that harm be suffered “because of reliance of the other or the third person upon the undertaking.” In the case at hand, that means that the harm caused by improperly implanting electrodes during the surgery must be suffered because Dr. Amstutz relied on the information Mabey provided. Plaintiff does not allege that Mabey gave Dr. Amstutz misinformation regarding Plaintiff’s pain, nor does Plaintiff allege that Dr. Amstutz relied on said misinformation. Therefore, Plaintiff’s allegations fail to demonstrate a claim under § 324A.

The Court is mindful that the exact conduct of St. Jude’s representatives and Dr. Amstutz during the second surgery is not yet fully known. Discovery is necessary to determine each actor’s conduct during the surgery. To that end, the Court will dismiss Plaintiff’s second cause of action without prejudice so that if discovery reveals facts sufficient to show that Plaintiff suffered harm because the physician relied on St. Jude’s failure to exercise reasonable care, Plaintiff may amend his Complaint to reassert claims against St. Jude.

²⁶ *Gray v. Univ. of Colo. Hosp. Auth.*, 672 F.3d 909, 919 n.9 (10th Cir. 2012).

²⁷ *Bryson v. Gonzales*, 534 F.3d 1282, 1290 (10th Cir. 2008) (explaining that “allegations that simply name the ‘Defendants’ generically” do not state facts about each individual defendant’s conduct).

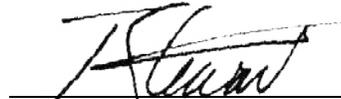
IV. CONCLUSION

Based on the foregoing, it is hereby

ORDERED that Defendant St. Jude's Motion to Dismiss (Docket No. 8) is granted.

DATED this 16th day of July, 2014.

BY THE COURT:



Ted Stewart
United States District Judge