UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

KIRBY KNIGHT and SHIRLEY KNIGHT,

Plaintiffs,

v

ST. JUDE MEDICAL,

Defendant.
_____/

Case No. 1:09-cv-973

HON. JANET T. NEFF

OPINION AND ORDER

Plaintiffs filed this action against Defendant St. Jude Medical, seeking recovery for damages suffered by Plaintiff Kirby Knight when his internal cardiac defibrillator (ICD) failed to fire. The ICD in question was manufactured, distributed and serviced by Defendant. Plaintiffs' Amended Complaint sets forth several claims including claims of defective design, failure to warn of the danger of the device, failure to provide adequate safety procedures, failure to adequately test and inspect, and failure to provide truthful medical data; and a claim that Defendant fraudulently, negligently or wrongfully withheld data and information about the device. On May 24, 2010, Defendant filed a Motion to Dismiss pursuant to FED. R. CIV. P. 12(b)(6), asserting that Plaintiffs' product liability claims are preempted by the Medical Device Amendments (MDA) to the Food, Drug & Cosmetic Act (FDCA) and that Defendant owed no legal duty to Plaintiff (Dkt 25). The Magistrate Judge conducted a hearing on the Motion on August 13, 2010 and subsequently issued a Report and Recommendation (R & R) on January 11, 2011, granting Defendant's Motion and dismissing Plaintiffs' claims except for "(1) Plaintiffs' claims that Defendant failed to 'provide

adequate warnings, instructions, directions, recalls to the public and true information with regard to the safety and danger of the device' to Kirby Knight's care providers; and (2) Plaintiffs' loss of consortium claims" (R & R, Dkt 35 at 23). This matter is before the Court on Defendant's Objections to the Report and Recommendation (Def. Obj., Dkt 37), Plaintiffs' Response to Defendant's Objection (Dkt 38), and Defendant's Reply in Support of Objections (Dkt 41). In accordance with 28 U.S.C. § 636(b)(1) and FED. R. CIV. P. 72(b)(3), the Court has performed de novo consideration of those portions of the Report and Recommendation to which objections have been made. The Court denies the objections and issues this Opinion and Order.

Defendant asserts four objections to the Magistrate Judge's Report and Recommendation, as follows: (1) Plaintiffs' negligence claims, like their product liability claims, are preempted by the MDA; (2) the Magistrate Judge failed to apply the correct legal standard and, as such, did not require Plaintiffs to provide factual allegations to support their negligence claim; (3) Plaintiffs' negligence claims fail to state a claim under applicable state law; and (4) Plaintiffs' claims of fraud fail not only for the reasons stated in the Report and Recommendation, but also because Plaintiffs have not alleged facts that show actual or justifiable reliance by the treating physician (Dkt 37 at 3-4).

A. Objection that Plaintiffs' Negligence Claims are Preempted by the MDA

Defendant's first objection is that Plaintiffs' remaining negligence claims are also preempted by the MDA. Defendant notes that the Magistrate Judge properly found that Plaintiffs' product liability claims are preempted. Defendant asserts that, of the state law negligence claims that the Magistrate Judge found to be sufficient, "one of those negligence claims is wholly redundant to the 'failure to warn' claim that the Magistrate Judge found expressly preempted" (Dkt 37 at 10-11).

Defendant points to the wording of the claim in the Magistrate Judge's conclusion and asserts that "that particular negligence claim ultimately formed the basis of the Magistrate Judge's ruling that St. Jude's motion to dismiss be denied in part" (*id.* at 11).[1]

Defendant's objection is without merit. Defendant is correct that, to the extent that Plaintiffs assert a claim based on a failure to warn about the *inherent* dangers of the device, those claims are preempted by federal law. However, Defendant misconstrues the Magistrate Judge's findings. Although the wording of the claim quoted in the Magistrate Judge's conclusion seems to reflect a products liability failure-to-warn cause of action, when read in the context of the entire opinion, it is clear that these claims are based on the Plaintiffs' assertion that Defendant's representative failed to warn Kirby Knight's treating physician that the *individual unit* implanted in Kirby Knight was not functioning properly (see Dkt 35 at 19).[2] The Magistrate Judge properly noted that "[t]o the extent that Plaintiffs challenge the design, warnings, instructions, directions, procedures regarding the device in question (i.e., the 'form' of the device that was approved by the FDA), such claims are clearly preempted by federal law for the reasons articulated by the *Riegel* Court" (Dkt 35 at 14). The Magistrate Judge then proceeded to address Plaintiffs' "various other negligence claims" (Dkt 35 at 17), including Plaintiffs' assertion "that Defendant withheld relevant information about the

[1]In her conclusion, the Magistrate Judge recommended "that Defendant's motion to dismiss be granted and Plaintiffs' claims dismissed, save for (1) Plaintiffs' claims that Defendant failed to 'provide adequate warnings, instructions, direction, recalls to the public and true information with regard to the safety and danger of the device' to Kirby Knight's care providers; and (2) Plaintiffs' loss of consortium claims" (Dkt 35 at 23).

[2]As stated in Plaintiffs' Amended Complaint, the claim is that Defendant had "information and data indicating that the defibrillator/ICD of the unit would not function, which [Defendant] knew or should have known at that time, and should have revealed to the Plaintiffs and Kirby Knight's health care providers" (Dkt 21 at 4).

functioning of *Knight's pacemaker* from Knight's care providers" (Dkt 35 at 19) (emphasis added). As such, the Magistrate Judge properly found that these claims were not preempted.

B. Objection that Plaintiffs' Claim is Unsupported by Adequate Factual Allegations

Defendant next asserts that Plaintiffs have failed to plead facts that meet the standard established by *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009) (Dkt 37 at 12-15). Defendant asserts that "the Magistrate Judge expressly applied the wrong legal standard abrogated in *Twombly*" (Dkt 37 at 12-13). Defendant specifically asserts that Plaintiffs fail to state a claim because Plaintiffs have not alleged that: (1) the results of the device interrogations were withheld from the treating physician; (2) the treating physician ever discussed the interrogation results with the Defendant's representative; or (3) the treating physician did not review or did not understand the interrogation results or their significance (*id.* at 14). Defendant argues that Plaintiffs have not alleged any facts indicating what medical care was provided by the treating physician or how the physician made the decision to pursue that treatment path (*id.*). Finally, Defendant contends that it had no legal duty to provide the treating physician with "any additional or different information . . . than the interrogation results and the FDA-required literature" (*id.* at 15).

Defendant's argument is without merit. The Magistrate Judge properly noted that *Twombly* requires factual allegations sufficient to "'raise a right to relief above the speculative level'" (Dkt 35 at 6) (quoting *Twombly*, 550 U.S. at 545). The Magistrate Judge also considered the Supreme Court's finding in *Iqbal* that "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face" (Dkt 36 at 6)(quoting *Iqbal*, 129 S. Ct. at 1949) (internal quotation marks omitted). Further, the Magistrate Judge properly noted that a negligence

claim under Michigan law requires a plaintiff to establish (1) that the defendant owed the plaintiff a duty, (2) that the defendant breached that duty, (3) causation, and (4) damages (Dkt 35 at 17). Plaintiffs' Amended Complaint alleges that (1) Defendant's representative knew or should have known that Kirby Knight's ICD would not function (Dkt 21 at 4); (2) Defendant's representative had a duty to provide that information to Kirby Knight's health care providers (*id.*); (3) "knowledge of the dysfunctional status of the defibrillator" was withheld from Kirby Knight's treating physicians (*id.*); (4) Kirby Knight's treating physicians relied upon the representations of Defendant's representative and made "future decisions relating to Kirby Knight's medical care and treatment, including whether or not to replace the unit" based on those representations (*id.*); (4) the ICD "did not function and 'failed to fire'" after Kirby Knight's heart stopped on October 15, 2006 (Dkt 21 at 5); and (5) the ICD failure caused Kirby Knight to "sustain permanent, catastrophic, and debilitating medical consequences" (*id.*). These allegations are sufficient to "raise a right for relief above the speculative level on the assumption that all of the complaint's allegations are true." *Twombly*, 550 U.S. at 545.

C. Objection that Plaintiffs have Failed to State a Negligence Claim Under Michigan Law

Defendant's next argument is that Plaintiffs' negligence claim fails under Michigan's learned intermediary doctrine. In support, Defendant relies on *Mowery v. Crittenton Hosp.*, 400 N.W.2d 633 (Mich. Ct. App. 1986). In *Mowery*, the Michigan Court of Appeals found that "even if [the manufacturer] had completed adequate testing, enabling them to effectively warn [the doctor] of the danger . . . the lack of such a warning was not the proximate cause of the plaintiff's injury" where the doctor was aware of the risk, informed the patient of the risk, and chose to proceed with the treatment. *Mowery*, 400 N.W.2d at 638. Defendant asserts that Plaintiffs have failed to state a claim

under *Mowery* because they have failed to assert that "the treating physician was not fully aware of the risks" (Dkt 37 at 17). Defendant supports this argument by asserting that Plaintiffs have not alleged facts showing that St. Jude failed to "fulfill its obligation to inform the learned intermediary by (a) confirming the interrogation results obtained by the nurse in May 2006, which Plaintiffs claim were similar to the results obtained again in September, and (b) providing the FDA-required warnings, instructions and disclosures" (*id.*).

Defendant's objection is without merit. Defendant's argument as to causation appears to be that, in order to state a claim for relief, Plaintiffs must have alleged facts showing that Kirby Knight's treating physician was *not* fully aware of the risks of low lead impedance. However, the *Mowery* panel was reviewing a decision on a motion for summary disposition, not a Rule 12(b)(6) motion for dismissal, and the *Mowery* panel's opinion was based on its finding that the plaintiff in that case had failed to establish causation. *Mowery*, 400 N.W. 2d at 636. As previously noted, in order to withstand a 12(b)(6) motion for dismissal, the nonmoving party must allege facts that, "accepted as true, [] state a claim to relief that is plausible on its face" *Iqbal*, 129 S. Ct. at 1949. This standard does not require Plaintiffs to allege facts that would *disprove* Defendant's potential defense as to causation. As has been discussed, Plaintiffs allege that Kirby Knight's treating physicians relied on Defendant's representative's representations in making decisions about Kirby Knight's treatment and that Kirby Knight suffered severe injuries as a result. These claims, accepted as true, are sufficient to state a claim under the Rule 12(b)(6) standard.

Defendant also appears to assert that Plaintiffs have failed to state a claim sufficient to establish that Defendant breached any duty to Kirby Knight's physician. Defendant's position appears to be that, as a matter of law, the technician's only legal duty is "to extract data from the

medical device" and that it is the physician's duty "to review and 'interpret' the medical data extracted" (Dkt 41 at 3). Defendant "asks this Court to resolve that a St. Jude sales employee does not owe a duty to 'interpret' those results for the physician" (*id.*). In support of this assertion, Defendant notes that "[Kirby] Knight's ***physician owed a duty*** to his patient to review the interrogation results and, based on those results and the available medical literature, exercise his independent medical judgment" (Dkt 41 at 2). Defendant, however, offers no support for its apparent argument that, because the physician owed this duty to Kirby Knight, Defendant's technician owed no duty to the physician. Defendant's argument appears to more appropriately address the causation element of Plaintiffs' claim (i.e., that it was the physician's breach of duty that was the actual cause of Kirby Knight's injuries). However, for the reasons already stated, the Court finds that Plaintiffs' claim as to causation is sufficient to state a claim under Rule 12(b)(6).

D. Objection that Plaintiffs' Fraud Claims Fail to Show Actual or Justifiable Reliance

Finally, Defendant asserts that, in addition to the reasons already cited in the Magistrate Judge's Report and Recommendation, Plaintiffs' claims based on fraud should be dismissed for failure to plead with specificity facts that establish actual and justifiable reliance by Plaintiffs or the treating physician (Dkt 37 at 18). Defendant does not point to any factual or legal errors in the Magistrate Judge's analysis and, in fact, does not disagree with the Magistrate Judge's ultimate recommendation as to this claim. As such, Defendant has failed to raise a proper objection requiring review by the Court. Rather, Defendant extends an invitation to the Court to conduct additional analysis of the fraud-based claims. The Court declines this invitation and denies Defendant's objection.

Accordingly,

IT IS HEREBY ORDERED that Defendant's Objections (Dkt 37) are DENIED and the Report and Recommendation (Dkt 35) is APPROVED and ADOPTED as the Opinion of the Court.

IT IS FURTHER ORDERED that Defendant's Motion to Dismiss (Dkt 25) is GRANTED IN PART and DENIED IN PART; Defendant's Motion is granted and Plaintiffs' claims dismissed, save for (1) Plaintiffs' claims that Defendant failed to "provide adequate warnings, instructions, directions, recalls to the public and true information with regard to the safety and danger of the device" to Kirby Knight's care providers; and (2) Plaintiffs' loss of consortium claims.

Dated: March 31, 2011

/s/ Janet T. Neff
JANET T. NEFF
United States District Judge