UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

DENISE ROUNDS and THOMAS ROUNDS,

Plaintiffs,

v. CASE NO: 8:10-cv-2479-T-23TBM

GENZYME CORPORATION,

Defendant.
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ORDER

A December 20, 2010, order (Doc. 16) grants both the plaintiffs' and the defendant's requests (Docs. 4, 8) for judicial notice and grants the defendant's motion (Doc. 3) to dismiss. The order (Doc. 16) finds (1) that the complaint offered no fact supporting a causal connection between the defendant's alleged failure to train Jurbala and the alleged injury sustained by Denise; (2) that the complaint contained a conclusory allegation as to both causation and damages; (3) that the complaint alleged neither a defect in the product nor a defect in the defendant's training program (a defect without which Jurbala presumably would have performed the implantation correctly and without injury to Denise); (4) that the complaint failed to state facts showing negligence, causation, or injury and undoubtedly failed to state a discernable claim for relief; and (5) that the complaint (favorably construed) amounted to no more than a per se negligence claim based on the defendant's violation of the FDCA and FDA regulations, which claim the law prohibits. The plaintiffs file an amended complaint (Doc. 17), and

the defendant again moves (Doc. 18) to dismiss. The plaintiff requests (Docs. 20, 21) leave to file a reply and oral argument.

Allegations of the Amended Complaint

Denise and Thomas Rounds are married and reside in Lakeland, Florida. In August, 2005, Denise, forty-two and a patient of Dr. Brian Jurbala, developed a problem with her knees. Jurbala recommended to Denise a treatment involving Carticel, a "biological product" manufactured and sold by the defendant Genzyme Corporation and applied as a component of an "autologous chondrocyte implantation" ("ACI").[1] In May, 2006, Denise received an implantation in her left knee, and in May, 2007, Denise received an implantation in her right knee. Jurbala performed each implantation. Because neither operation succeeded, Denise received an arthroscopy of each knee followed by a total replacement of each knee.

The plaintiffs sued Jurbala for medical malpractice and in discovery learned that Jurbala "did not receive reasonable, adequate[,] and proper training regarding Carticel." Specifically, the plaintiffs learned that Jurbala received "custom training" from John Toale, a Genzyme sales executive with no medical background. The training consisted of meetings with Jurbala at Jurbala's office over lunch and Toale's providing Jurbala with information and training material. "Nothing was done to determine whether Dr. Jurbala was qualified or competent to perform the ACI procedures and even whether he had been involved in any prior ACI surgeries, seminars[,] or other training as to ACI." Jurbala admitted both that he lacked knowledge of whether he received the required

[1] As part of the implantation, the surgeon uses Carticel (combined with cells extracted from the patient) to "regenerate the articular cartilage in a knee." (Doc. 18)

training from Genzyme before operating on Denise and that he failed to read the Carticel package insert.[2]

The plaintiffs allege that Jurbala lacked the necessary skill and training to use Carticel and that Genzyme's "custom training" program is "defective, inadequate[,] and deficient."

Discussion

1. Failure to State a Claim

In moving to dismiss under Rules 8 and 12, Federal Rules of Civil Procedure, the defendant argues (1) that the plaintiffs fail to allege either that Jurbala performed the procedure incorrectly or negligently or that with better training Jurbala would have performed differently; (2) that the plaintiffs fail to allege an injury to Denise as a result of the procedure; (3) that the plaintiffs fail to allege that Jurbala would have followed a different course of treatment if Jurbala received better training; (4) that the plaintiffs fail to state why Denise was an improper candidate for Carticel; (5) that the defendant cannot determine what information the defendant failed to provide Jurbala about selecting a proper candidate for Carticel; and (6) that, assuming the truth of each allegation, the plaintiffs fail to allege facts showing that the defendant's conduct injured the plaintiffs—rather, the allegations amount to "an indictment of Dr. Jurbala's judgment in using Carticel with this patient." The plaintiffs respond (Doc. 19) and state (1) that expert testimony in the state court malpractice action established that Denise was not a suitable candidate for Carticel; (2) that "as to the specifics" of why Denise was not a

[2] The December 20, 2010, order (Doc. 16) grants judicial notice of the Carticel package insert.

suitable candidate "the parties are entitled to perform discovery to flush out those facts"; (3) that the plaintiffs malpractice action against Jurbala provides sufficient support for the plaintiffs' assertion that Jurbala acted negligently; and (4) that the plaintiffs' claim "is very simple—Genzyme permitted Dr. Jurbala to perform this particular ACI on the [p]laintiff without properly training and certifying him as to Carticel."

In this instance, the defendant again persuasively argues that the amended complaint lacks a pertinent and necessary factual allegation supporting causation. Assuming that Denise was an improper candidate for treatment with Carticel, the plaintiffs fail to allege a causal connection between Jurbala's decision to treat Denise with Carticel and the defendant's training program. Furthermore, the plaintiffs fail to allege a causal connection between the allegedly deficient training program and Denise's alleged injury, which apparently consists of arthroscopic and total knee replacement surgeries. In other words, the complaint lacks a necessary factual connection between the defendant's alleged inadequate training for Carticel and Denise's alleged injury. Additionally, neither the existence of a malpractice action against Jurbala nor the opinion of an expert (who testified in state court) provide the necessary factual connection between the defendant's alleged conduct and the alleged injury to Denise.

2. The Learned Intermediary

The duty of a manufacturer to warn of the risk associated with a prescription drug or medical device runs to a physician, the so-called "learned intermediary," rather than the patient. See Christopher v. Cutter Laboratories, 53 F.3d, 1184, 1192 (11th Cir.

1995) (stating that "a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products."); Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102 (Fla. 1989); Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1365 (S.D. Fla. 2007). "[T]he causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." 53 F.3d at 1192. "Whether the physician in fact reads the warning, or passes its contents along to the recipient of the drug is irrelevant." E.R. Squibb and Sons, Inc. v. Farnes, 697 So. 2d 825, 827 (Fla. 1997); Felix, 540 So. 2d at 102-05. The adequacy of a warning, i.e., the existence of a "learned intermediary," is an issue of law if the warning is accurate, clear, and unambiguous. Felix, 540 So. 2d at 105; Beale, 492 F. Supp. 2d at 1368-69; Buckner v. Allergan Pharm., Inc., 400 So. 2d 820 (Fla. 5th DCA 1981).

In this instance, the defendant argues that the Carticel package insert[3] (1) "contained warnings, precautions, and contraindications regarding patient evaluation and use, including identifying as unsuitable patients who have certain medical conditions"; (2) specifically warned of the likelihood of subsequent surgical procedures, "primarily arthroscopic" in forty-nine percent of patients; and (3) precludes the plaintiffs' claim notwithstanding Jurbala's failing to read the warning. The plaintiffs respond and argue (1) that the defendant assumed a duty to train physicians; (2) that the defendant

[3] The package insert is available at www.fda.gov/downloads/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/ucm109339.pdf.

permitted only a certified physician to implant Carticel; (3) that, although Jurbala received training, Jurbala lacked the knowledge and education to implant Carticel effectively; (4) that Jurbala's lack of training caused Jurbala's failure to identify Denise as an improper Carticel candidate; and (5) that, as a result, Denise must receive "knee replacement procedures for the rest of her natural life."

In this instance, the defendant undoubtedly provides in the package insert an accurate, clear, and unambiguous warning to Jurbala of the need for additional surgery (unrelated to Carticel) after treatment with Carticel in approximately half of all patients. The package insert also describes the risk associated with the use of Carticel in certain patients. Contrary to the plaintiffs' assertion, the adequacy of the warning is both relevant to, and dispositive of, the plaintiffs' "failure to train" claim. The difference between a "failure to train" and a "failure to warn" is semantic. The manufacturer (i.e., the defendant) of a prescription product owes a duty to the doctor to provide adequate information about the risk associated with a product. The doctor (i.e., Jurbala) owes a duty to the patient to apprise himself of the risk associated with a product and to exercise judgment in both prescribing the product and informing the patient of the risk. The plaintiffs cannot overcome an unambiguous and adequate warning to Jurbala and somehow attribute Jurbala's alleged negligence to the defendant.

Conclusion

Accordingly, the defendant's motion (Doc. 18) is **GRANTED**, and this action is **DISMISSED WITH PREJUDICE**. Both the motion (Doc. 21) for leave to file a reply and the request (Doc. 20) for oral argument are **DENIED AS MOOT**. The Clerk is directed to (1) terminate any pending motion and (2) close the case.

ORDERED in Tampa, Florida, on February 18, 2011.

STEVEN D. MERRYDAY
UNITED STATES DISTRICT JUDGE