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

The plaintiffs sued (Doc. 2) in state court for negligence. The defendant removes (Doc. 1) and sufficiently alleges diversity jurisdiction under 28 U.S.C. § 1332. The defendant moves (Doc. 3) to dismiss and argues (1) that the complaint fails to state a claim; (2) that federal law impliedly pre-empts the plaintiffs' claims; and (3) that, to the extent the plaintiffs allege a failure to provide adequate information to the "end-user," the doctor's qualifying as a "learned intermediary" bars the plaintiffs' claim. The plaintiffs respond (Doc. 9) in opposition. Both the plaintiffs and the defendant request (Docs. 4, 8) judicial notice of certain public records of the Food and Drug Administration (the "FDA"), which records evaluate the medical product involved in this action.

Allegations of the 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."[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. Although Genzyme purportedly trained Jurbala in March, 2006, in the proper use of Carticel, the only record of Jurbala's training consists of a May, 2007, FDA registration that identifies Jurbala as a "user of tissue through Genzyme."

In suing Genzyme, Denise claims that Genzyme failed to adequately train Jurbala, one of Genzyme's "certified physicians," to implant Carticel. Additionally, Denise claims that Genzyme (1) failed to "implement an adequate and effective training program"; (2) failed to "implement reasonable and practical safeguards to screen physicians"; (3) failed to "train, educate[,] and instruct physicians . . . as to the medical appropriateness of Carticel"; (4) failed to "provide true, correct[,] and accurate information to physicians and end[-]users of Carticel"; (5) failed to "provide truthful information to physicians and end[-]users about the results and benefits of Carticel"; (6) promoted and marketed Carticel in a manner that exaggerated the efficacy of Carticel; (7) misled both physicians and end-users about the long-term effects of Carticel; (8) failed to "participate in post-marketing studies per [Genzyme's] agreement with the FDA"; and (9) asserted "unsubstantiated comparative claims for Carticel." Denise alleges that as a result of Genzyme's breach of Genzyme's duty, Denise "suffered severe damages." Thomas requests damages for "loss of consortium" resulting from Denise's injury.

[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. 3)

Discussion

1. Judicial Notice

Both the plaintiffs and the defendant request (Docs. 4, 8) judicial notice of certain FDA records and statements about Carticel. Rule 201, Federal Rules of Evidence, governs judicial notice of an "adjudicative fact" such as a fact "not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." A matter in the public record is susceptible to judicial notice and consideration in resolving a motion to dismiss. Oxford Asset Mgmt, Ltd. v. Jaharis, 297 F.3d 1182, 1188 (11th Cir. 2002); Lee v. City of Los Angeles, 250 F.3d 668, 689 (9th Cir. 2001). Accordingly, the FDA's public records and statements about Carticel merit judicial notice.

2. Motion to Dismiss for Failure to State a Claim

In evaluating a motion to dismiss, each factual allegation of the complaint receives both the assumption of truth and a favorable construction. Beck v. Deloitte & Touche, 144 F.3d 732 (11th Cir. 1998) (citing St. Joseph Hosp. Inc. v. Hosp. Corp. of Am., 795 F.2d 948 (11th Cir. 1986)). However, "[f]actual allegations must be enough to raise a right to relief above the speculative level . . . ." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 554-55 (2007), and a plaintiff must "provide the 'grounds' of his 'entitle[ment] to relief[,]' [which] requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action . . . ." Neither a conclusory allegation nor "a legal conclusion couched as a factual allegation" provides support for the sufficiency of a

complaint, Papasan v. Allain, 478 U.S. 265, 286 (1986); South Fla. Water Mgmt. Dist. v. Montalvo, 84 F.3d 402, 408 n.10 (11th Cir. 1996), which derives from the factual allegations, from attached or incorporated documents, and from any matter publicly recorded or judicially noticed. See 5B WRIGHT & MILLER, FEDERAL PRACTICE AND PROCEDURE: CIVIL 3d § 1357.

The defendants argue (1) that the plaintiffs fail to allege a fact showing the causal connection between the defendant's alleged conduct and the alleged damages sustained by the plaintiffs (e.g., that Jurbala negligently performed the implantation because of the defendant's failure to train Jurbala); (2) that the plaintiffs fail to allege that either Carticel or the implantation injured Denise; (3) that the complaint "appears to be generally critical of Genzyme's training program and alleged representations regarding Carticel, without regard to any proximately caused damages." The plaintiffs respond (1) that the complaint satisfies Rule 8, Federal Rules of Civil Procedure; (2) that the defendant, in marketing Carticel, "goes to great lengths to stress how only specially trained surgeons are permitted to perform Carticel implantation;" (3) that, despite the defendant's restriction as to the surgeons qualified to implant Carticel, Jurbala lacked adequate training and competence to perform Carticel surgery and, as a result, could not adequately inform Denise as to the risks and benefits of Carticel implantation; and (4) that the complaint adequately alleges that, as a result of the defendant's failure to train Jurbala, the plaintiffs suffered damages.

In this action, the defendant persuasively argues that the complaint lacks pertinent factual allegations. Although the complaint contains a conclusory allegation as

to both causation and damages, the complaint offers no fact supporting a causal connection between the defendant's alleged failure to train Jurbala and the alleged injury sustained by Denise. In fact, the plaintiff alleges 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). The complaint, which contains a broad, conclusory allegation that Denise suffered "damages," offers no discernable clue as to the source of Denise's alleged injury. As alleged, the complaint fails to state facts showing negligence, causation, or injury and undoubtedly fails to state a discernable claim for relief.

3. Pre-emption, a Private Right of Action, and the Learned Intermediary[2]

The defendant argues (1) that the FDA approved the promotional, marketing, and packaging material for Carticel;[3] (2) that Congress intended for federal law to "occupy the field" of regulating a product such as Carticel;[4] and (3) that, to the extent the

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[2] Because of the limited (and insufficient) briefing on pre-emption and "learned intermediary," this order excludes both.

[3] Section 262 of Title 42, United States Code, provides an exhaustive framework for the licensing, testing, and marketing of biological products. See 21 C.F.R. Part 600 (delineating the general provisions for biological products). The FDA's Center for Biologics Evaluation and Research ("CBER") evaluates and regulates under the Public Health Service Act, 42 U.S.C. Chapter 6A; the Food, Drug, and Cosmetic Act, 21 U.S.C. Chapter 9 (the "FDCA"); 21 C.F.R. Part 600 biological products. See 42 U.S.C. § 262(j) (applying the requirements of the FDCA to biological products).

In 1997, after concluding that Carticel was safe and effective, the FDA approved and licensed the defendant to sell Carticel. (Docs. 3-3, 3-4) The FDA (1) approved the packaging and labeling materials for Carticel, (2) required a post-approval study, (3) required written approval of a change to either the packaging or labeling material, and (4) required pre-approval of either promotional or marketing material for Carticel. (Doc. 3-3)

[4]If state and federal law conflict, federal law governs. Fla. State Conference of N.A.A.C.P. v. Browning, 522 F.3d 1153, 1167 (11th Cir. 2008). Implied pre-emption consists of "field" and "conflict" pre-emption.

> Field preemption occurs when a congressional legislative scheme is 'so pervasive as to make the reasonable inference that Congress left no room for the states to

(continued...)

plaintiffs sue for the defendant's failure to comply with an FDA requirement, the FDCA prohibits a private action. The plaintiffs respond (1) by providing the historical context of the FDA and the FDA's "mission"; (2) by arguing that the plaintiffs' claim is "for simple negligence" and not for a violation of an FDA's requirement; (3) by arguing (at the same time) that the defendant failed to comply with an FDA-approved safeguard;[5] and (4) by "clarifying" that "[t]he type of conduct complained here by Plaintiffs is exactly the type of conduct the FDA is to oversee and regulate."

A person's right to sue for the violation of a statute depends upon legislative intent. Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999). Absent evidence of legislative intent to create a private right of action under the statute, the "violation of a statute creates no civil liability." 55 F. Supp. 2d at 1361 (citing Murthy v. N. Sinha Corp., 644 So. 2d 983, 985-86 (Fla. 1994)). The FDCA unambiguously states that an action for the "enforcement, or to restrain violations, of th[e] [FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a); State of Fla. ex rel. Broward County v. Eli Lilly & Co., 329 F. Supp. 364, 365-66 (S.D. Fla. 1971). Thus, the FDCA strongly evidences legislative intent to prohibit a private right of action for a violation of either the FDCA or the FDA's implementing regulations.

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[4](...continued)
supplement it.' Conflict preemption occurs either when it is physically impossible to comply with both the federal and the state laws or when the state law stands as an obstacle to the objective of the federal law.

[5] In October, 2009, the FDA sent to the defendant a letter (Doc. 9) (1) stating that a "sales aid" and "biopsy letter" (submitted by the defendant for approval) were "false or misleading because [the material] overstate[s] the efficacy and make[s] unsubstantiated comparative claims for Carticel" and (2) concluding that the material violates the FDCA and applicable regulations.

55 F. Supp. 2d at 1361; Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1284 n.9 (11th Cir. 2002). Accordingly, "[a] [p]laintiff cannot use a negligence per se claim to create a private cause of action for [a] [d]efendant's alleged violations of the FDCA." 55 F. Supp. 2d at 1361 (stating that, "[i]In any event, even under a negligence per se theory, a plaintiff must prove causation.") (citing Groh v. Hasencamp, 407 So.2d 949, 953 (Fla. 3d DCA 1981)).

In this action, the claim appears premised on the defendant's failure to comply with an FDA requirement for marketing, promoting, packaging, and training.[6] The complaint (favorably construed) amounts 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.[7] Furthermore, even if the plaintiffs could assert a negligence per se claim, the plaintiffs must allege a fact supporting causation. As stated earlier, the plaintiffs allege no fact supporting the conclusory allegation that either Carticel or the defendant's failure to obey an FDA requirement caused the plaintiffs' injuries. (To the extent that the complaint asserts a "fraud-on-the-FDA" claim,[8] the FDCA "'leaves no doubt'" that the United States possesses exclusive authority to sue for a violation of an FDCA requirement.)[9]

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[6] To the extent that the claim relies on the FDA's conclusion (Docs. 8, 9) that certain promotional material—submitted by the defendant for pre-approval—fails to comply with the FDCA, the claim is misguided.

[7] Because Thomas's "loss of consortium" claim derives from Denise's negligence claim, Thomas's claim receives no evaluation at this time.

[8] See Wheeler v. DePuy Spine, Inc., 706 F. Supp. 2d 1264, 1269-70 n.4 (S.D. Fla. 2010).

[9] 706 F. Supp. 2d at 1269 n.4.

Conclusion

Accordingly, both the plaintiffs' and the defendant's request (Docs. 4, 8) for judicial notice are **GRANTED**. The defendant's motion (Doc. 3) to dismiss is **GRANTED**, and the complaint (Doc. 2) is **DISMISSED** under Rule 12(b)(6), Federal Rules of Civil Procedure. The defendant's motion (Doc. 10) for leave to reply is **DENIED AS MOOT**. The plaintiffs may file an amended complaint no later than **January 3, 2011**.

ORDERED in Tampa, Florida, on December 20, 2010.

STEVEN D. MERRYDAY
UNITED STATES DISTRICT JUDGE