UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

GAYTHRI MURTHY,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO. 4:11-cv-105
	§	
ABBOTT LABORATORIES,	§	
	§	
	§	
Defendant.	§	

MEMORANDUM & ORDER

Before the Court is Plaintiff's Opposed Motion for Leave to File her Second Amended Complaint (Doc. No. 104.) After considering the Motion, the response and reply, and the applicable law, the Court finds that the Motion must be **GRANTED.**

I. FACTS:[1]

This products liability case arises out of Gayathri Murthy's ("Plaintiff" or "Murthy") participation in an Abbott Laboratories ("Defendant" or "Abbott") clinical trial through which she received infusions of Abbott's drug Adalimumab ("Humira") to treat her rheumatoid arthritis.[2] Humira, a member of a class of drugs known as TNF-α blockers, first received approval from the United States Food and Drug Administration for the treatment of moderately to severely active rheumatoid arthritis ("RA") in 2002. Murthy was first diagnosed with RA in late 2004 after her primary care physician referred her to rheumatologist Dr. Jovan M. Popovich. Dr. Popovich initially prescribed Murthy methotrexate, a long standing treatment for RA.

[1] The facts contained in this section are derived from the allegations in the currently active complaint: Murthy's First Amended Complaint. (Doc. No. 7.)
[2] Murthy previously filed suit against Abbott, and one of its subsidiary companies, in the United States District Court for the District of Massachusetts (C.A. No. 2008-00328). That case was dismissed without prejudice pursuant to a stipulation between the parties.

Plaintiff alleges that the methotrexate quickly improved most of the minor symptoms without causing side effects. Later, however, Dr. Popovich approached Murthy about the possibility of her participation in a clinical trial involving Abbott's drug, Humira. In addition to being Murthy's rheumatologist, Dr. Popovich was a "Principal Investigator" for a clinical trial entitled "*Humira Efficacy Response Optimization Study in Subjects with Active Rheumatoid Arthritis*" ("HERO study"). Abbott initiated and paid for the HERO study. In exchange for their participation, Abbott provided participating RA patients with a free supply of Humira throughout the study's duration. Abbott also compensated the physicians involved in the study, including Dr. Popovich.

In January 2005, before participating in the HERO study, Murthy signed a document entitled "Consent to Participate." The document was also signed by Dr. Popovich as the "Person Explaining Authorization." The "Risks of Adalimumab (HUMIRA®)" are discussed on page five of the agreement. With regard to lymphoma or other cancers, it states the following: "Occasionally (about 2%), various types of cancer including lymphoma (cancer of lymph node) are observed in subjects taking adalimumab. The relationship of adalimumab with these cancers is currently unknown." Murthy alleges that, at the time she signed the document, Abbott was aware that Humira could *cause* cancer, a fact not reflected in the "Consent to Participate" agreement. Murthy also alleges that the videotape produced by Abbott that she was shown to explain Humira "paints a rosy picture of therapy with Humira, and does little if anything to alert the patient to the very real risk of life-threatening Humira-induced cancer."

Murthy began participating in the HERO study in February 2005 and received Humira through the study for approximately two months. Following the study's completion, she continued to receive Humira injections until approximately January 2006. In February 2006,

Murthy felt swelling and pain in the right side of her neck and went to her doctor. She was subsequently diagnosed with Stage III large B-cell lymphoma for which she underwent chemotherapy treatment. The rheumatologist who diagnosed Murthy with lymphoma instructed her to immediately cease taking Humira and she complied with these instructions.

Murthy alleges that the direct and actual cause of her lymphoma was her infusion with Humira. In addition to suffering personal physical injury, Murthy alleges that, as a result of her diagnosis of lymphoma, she incurred medical bills and suffered lost wages and other economic injury for which Abbott is liable. In Murthy's First Amended Complaint, she brought claims against Abbott for breach of the Consent to Participate agreement, breach of warranty, strict products liability, and negligence.

On March 6, 2012, this Court issued an Amended Memorandum and Order (Doc. No. 62) dismissing the majority of Plaintiff's claims. Most of Plaintiff's claims (failure to warn, breach of warranty, strict liability, and negligence) were dismissed because they were barred by § 82.007 of the Texas Civil Practices and Remedies Code. The Court found that, because Humira was approved by the FDA, there was a rebuttable presumption under § 82.007 that defendant was not liable with respect to allegations involving failure to provide adequate warnings. At the time that the Memorandum and Order was decided, Murthy had not alleged grounds for rebutting the statutory presumption of § 82.007. On March 30th, 2012, Plaintiff filed a Motion to Reconsider, which this Court denied.

In light of recent discovery, Plaintiff filed a Motion to Vacate on August 8, 2012 because she believed that she fit into two exceptions to § 82.007's presumption—specifically §

82.007(b)(3)[3] and 82.007(b)(4),[4] both exempting off-label use from § 82.007's presumption. Plaintiff alleged that use of the drug was "off-label" and thus not covered by the FDA protection. Humira is only FDA approved if it is prescribed for patients with "moderate to severe active rheumatoid arthritis who have had an inadequate response to one or more DMARDS."[5] Plaintiff alleges that she had "early RA" (early rheumatoid arthritis) and has submitted Doctor Gershwin's deposition (Doc. No. 108-1) as a supplement attesting to the fact that her arthritis should not have been considered moderate or severe. Plaintiff also alleges that she was responding well to the methotrexate, a DMARD and long-standing treatment for RA, and thus did not fulfill the qualification of having an "inadequate response to one or more DMARDS".

As evidence, Plaintiff points to recently discovered call notes from an Abbot Sales representative (Doc. No. 84-2.) One of the call notes details a conversation with Dr. Popovich: "Likes the drug and the results he (Plaintiff's physician) has been getting with Humira. Talked about using it for severe RA pts. stressed to him that Humira can be used in Early RA pts as well. He started talking about the HERO trial, excited to be in the trial. Asked him to use Humira for his RA pts that does not fit the Study criteria. Reiterrated Humira's safety." Based on the call notes and Dr. Gershwin's report, Plaintiff now alleges that use of the drug was "off-label," outside of the study criteria, and not covered by the FDA protection. Based on this newly discovered evidence, the Court vacated the Memorandum and Order issued on March 6, 2012. In its minute order on September 17, 2012, the Court requested Plaintiff to file a motion to amend

---

[3] (3)(A) the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration; (B) the product was used as recommended, promoted, or advertised; and (C) the claimant's injury was causally related to the recommended, promoted, or advertised use of the product;

[4] (4)(A) the defendant prescribed the pharmaceutical product for an indication not approved by the United States Food and Drug Administration; (B) the product was used as prescribed; and (C) the claimant's injury was causally related to the prescribed use of the product;

[5] A DMARD, or disease-modifying antirheumatic drug, is a traditional medication to treat RA.

the complaint, stated that it would extend discovery for 90 days, and that it would issue a new docket control order extending the trial date and dispositive motion deadline.

II. LEGAL STANDARD

The Federal Rules of Civil Procedure provide that "leave (to amend the complaint) shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). "[G]ranting leave to amend is especially appropriate . . . when the trial court has dismissed the complaint for failure to state a claim." *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002) (citation omitted). The Court should generally "afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal." *Id*. On the other hand, the court should deny leave to amend when the proposed amendment "is futile"—meaning "that the amended complaint would fail to state a claim under 12(b)(6)." *Stripling v. Jordan Prod. Co., LLC,* 234 F.3d 863, 872-73 (5th Cr. 2000). To survive a Rule 12(b)(6) motion, a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Accordingly, plaintiff's proposed amended complaint must "plead factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

III. ANALYSIS

Defendant argues that this Court should not grant leave to amend the complaint because Murthy's amended complaint fails to allege facts sufficient to state a plausible claim under 12(b)(6). Specifically, Defendant argues that Plaintiff has failed to establish the Section 82.007(b)(3) and 82.007(b)(4) off-label promotion exceptions. Section 82.007(a) "presumptively

insulates from liability, for failure to warn, defendants who made, prescribe, or sell drugs in accord with FDA standards." *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 379 (5th Cir. 2012). A plaintiff must sufficiently plead at least one of the statutory exceptions to Section 82.007(a) to state a claim and avoid dismissal. *See, e.g.*, *Anderson v. Abbott Labs.*, Civil Action No. 3:11-cv-1825, 2012 WL 4512484, at *5 (N.D. Tex. Sept. 30, 2012) (dismissing all failure-to-warn claims with prejudice for failure to adequately plead an exception); *Phares v. Actavis-Elizabeth LLC*, Civil No. B:11-cv-63, 2012 WL 3779227, at *6-7 (S.D. Tex. Aug. 30, 2012) (concluding that, because "the statutory presumption of nonliability applies," but plaintiff failed to plead an exception, the "failure to warn claims must be dismissed").

Section 82.007(b)(3) requires plaintiff to plead facts establishing that: (A) Abbott promoted Humira to plaintiff's prescribing physician for an indication not approved by the FDA (an "off-label" use); (B) plaintiff used Humira for that off-label use; and (C) the off-label promotion caused the prescribing physician to prescribe the drug to plaintiff for that off-label use. Indeed, in this Court's earlier issued Order, the Court found that Section 82.007 eliminated most of Plaintiff's viable common law causes of action because Plaintiff did not plead facts establishing a statutory exception. *See Del Valle v. Qualitest Pharms. Inc.,* Civil Action No. B-11-113, 2012 WL 2899406, at *2 (S.D. Tex. June 22, 2012).

However, in Plaintiff's amended complaint, she has pled facts sufficient to raise a plausible off-label promotion claim. In her complaint, Plaintiff alleges "Abbott sales representatives repeatedly promoted and encouraged Dr. Popovich to use Humira [1] in patients with 'early' RA and [2] in patients that did not fit the HERO study 'criteria.'" (See Doc. No. 104-1 ¶ 23.) Defendant argues that Murthy alleges no facts establishing that promotion of Humira for "early RA" is necessarily a promotion for an off-label "mild" rheumatoid arthritis

indication. Defendant argues that there is an undisputed medical consensus that "early" rheumatoid arthritis refers to disease duration not disease severity. Thus, RA could be both early and moderate/severe, satisfying the study criteria. However, in the call notes cited by Plaintiff, Abbott's sales representative contrasted "severe" with "early," and thus expressly tied the use of Humira to disease severity. In the sales representative's call notes, he writes that he and Dr. Popovich "[t]alked about using it for severe RA pts. stressed to him [Dr. Popovich] that Humira can be used in Early RA pts *as well*." (emphasis added). (Doc. No. 84-2.) The contrast here between severe and early is sufficient to raise a fact issue, even if most scientific studies do not equate severity and duration.

Plaintiff has also introduced plausible facts that Murthy's RA should not have been considered moderate or severe. (Eric Gershwin Dep. 330:14-23; 343:15-344:14, September 11, 2012.) Dr. Gershwin found that Murthy did not have any new complaints related to morning stiffness, difficulty getting out of a chair or car, heat, redness, or pain. Dr. Gershwin questioned the classification of Murthy's RA as moderate or severe, stating that Ms. Murthy did not have moderate RA. (Gershwin Dep. 330:18-20.) Additionally, there is a fact question as to whether Murthy had an inadequate response to one or more DMARDS, which is another study criterion. The medical records and deposition testimony raise a plausible claim that Murthy's RA was responding to a DMARD, methotrexate, without side effects. Thus, Plaintiff alleges, because her RA was not moderate or severe, and was responding to a DMARD, enrolling her in the HERO study could be considered off-label.

Defendant also argues that Plaintiff has pled no facts establishing that the alleged off-label promotion caused the off-label use. Again, the Court finds the facts alleged to be sufficient. The call notes cited in Plaintiff's complaint state that Abbott's representative **"**[a]sked him [Dr.

Popovich] to use Humira for his RA pts that does not fit the Study criteria." (Doc. No. 84-2.) Additionally, Plaintiff alleges that Dr. Popovich was paid by Defendant to promote Humira and enroll patients in the HERO trial. (*See* Amended Complaint, Doc. No. 104-1, ¶ ¶ 11, 21.) Thus, the Court finds that Plaintiff has provided a number of plausible bases for alleging a statutory exception to Section 82.007(a).

The Court also addresses Plaintiff' argument in the alternative, that her proposed complaint sufficiently pleads Section 82.007(b)(4) off-label prescription exception to the no-liability presumption. That exception requires plaintiff to allege that "the defendant prescribed the pharmaceutical product for an indication not approved by the FDA." The Court agrees with Defendant that Dr. Popovich—not Abbott—ultimately prescribed Humira to Murthy. However, the Plaintiff alleges a plausible claim that, when Dr. Popovich prescribed Humira, he could have been considered an agent of Abbott. Under Texas Law, "[a]gency is the consensual relationship between two parties when one, the agent, acts on behalf of the other, the principal, and is subject to the principal's control." *Indian Harbor Ins. Co. v. Valley Forge Ins. Group*, 535 F.3d 359, 364 (5th Cir. 2008) citing *Happy Indus. Corp. v. Am. Specialties, Inc.*, 983 S.W.2d 844, 852 (Tex. App. 1998). "To prove agency, evidence must establish that the principal has both the right: (1) to assign the agent's task; and (2) to control the means and details of the process by which the agent will accomplish that task." *Id.* Plaintiff alleges that Abbott selected Dr. Popovich as a principal investigator and provided the study materials, medication, protocol, and informed consent forms to him. Additionally, Dr. Popovich agreed to conduct the study in adherence to Defendant's protocol and be bound by Defendant's confidentiality requirements. Even if Dr. Popovich is considered an independent contractor rather than an agent, a general contractor can be held vicariously liable for physical harm caused by an independent contractor "if the

employer controls the details or methods of the independent contractor's work to such an extent that the contractor cannot perform the work as it chooses...control must relate to the activity that actually caused the injury." *Indian Harbor*, 535 F.3d at 364-365. Given the strict study specifications Abbott provided Dr. Popovich, the Court finds that a determination that Dr. Popovich was an agent or independent contractor is plausible. The Court need not make a determination about the ultimate applicability of Section 82.007(b)(4) at this stage, but rather finds that Plaintiff has alleged sufficient facts alleging a plausible claim.

IV. CONCLUSION

The Court **GRANTS** Plaintiff's Motion for leave to file its Second Amended Complaint, and finds that such complaint meets the 12(b)(6) pleading standards, and thus, is not a futile amendment. The Court instructs Defendant to respond within 21 days of this order, as suggested by Fed. R. Civ. P. 12(a)(1). At this time, the Court will not amend the docket control order issued on November 14, 2012. The discovery deadline shall remain February 11, 2013, and the Court orders parties to immediately resume discovery.

IT IS SO ORDERED.

SIGNED in Houston, Texas, on this the 3rd day of December, 2012.

KEITH P. ELLISON
UNITED STATES DISTRICT JUDGE