UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

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

MEMORANDUM AND ORDER

Pending before the Court is Defendant Abbott Laboratories' ("Defendant" or "Abbott") Motion to Dismiss Complaint for Failure to State a Claim. (Doc. No. 16.) After considering the parties' filings, all responses and replies thereto, and the applicable law, the Court concludes that Abbott's motion should be **DENIED.**

I. BACKGROUND[1]

This products liability case arises out of Gayathri Murthy's ("Plaintiff" or "Murthy") participation in an 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 ("FDA") 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.

[1] The facts contained in this section are derived from the allegations in 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.

Popovich. Dr. Popovich initially prescribed Murthy Methotrexate to treat her RA. 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 claims that the FDA-approved full package insert in effect during the relevant period was incomplete and misleading. For example, in the "Warnings" section, Murthy alleges that it stated, in part, that in controlled portions of the clinical trials of all TNF-blockers, "more lymphoma cases were observed in patients receiving the TNF-blockers" and that "2 lymphomas were observed among 1380 Humira-treated patients

with moderate to severe rheumatoid arthritis versus 0 among 690 control patients." Murthy alleges that the increased risk of lymphoma was statistically significant. According to Murthy, the labeling further informed the consumer that, "in the controlled and open-label portions of the clinical trials, 10 lymphomas were observed in 2,468 patients" and warned that this incidence "is approximately 5-fold higher than expected in the general population." Murthy alleges that this "is presumptively causal."

At or about the time that she began participating in the HERO study, Murthy was shown a 14 minute, 50 second videotape, produced and provided by Abbott to Dr. Popovich. Murthy claims that the video was designed for patients who might potentially participate in the HERO study. According to Murthy, the video, which was not approved by the FDA, "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 Humura 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. Murthy brings claims against Abbott for breach of the Consent to Participate agreement, breach of warranty, strict products liability, and negligence. Abbott has moved to dismiss all of Murthy's claims under Federal Rule of Procedure 12(b)(6).

II. LEGAL STANDARD

A. Rule 12(b)(6)

"To survive a Rule 12(b)(6) motion to dismiss, a complaint 'does not need detailed factual allegations,' but must provide the plaintiff's grounds for entitlement to relief—including factual allegations that when assumed to be true 'raise a right to relief above the speculative level.'" *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). That is, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 570). A claim has facial plausibility "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). The plausibility standard is not akin to a "probability requirement," but asks for more than a sheer possibility that a defendant has acted unlawfully. *Id.* A pleading need not contain detailed factual allegations, but must set forth more than "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citation omitted).

Ultimately, the question for the court to decide is whether the complaint states a valid claim when viewed in the light most favorable to the plaintiff. The court must

accept well-pleaded facts as true, but legal conclusions are not entitled to the same assumption of truth. *Iqbal*, 129 S. Ct. at 1950 (citation omitted). The court should not "'strain to find inferences favorable to the plaintiffs'" or "accept 'conclusory allegations, unwarranted deductions, or legal conclusions.'" *R2 Investments LDC v. Phillips*, 401 F.3d 638, 642 (5th Cir. 2005) (quoting *Southland Sec. Corp. v. Inspire Ins. Solutions, Inc.*, 365 F.3d 353, 362 (5th Cir. 2004)).

Importantly, the court should not evaluate the merits of the allegation, but must satisfy itself only that the plaintiff has adequately pled a legally cognizable claim. *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004). "Motions to dismiss under Rule 12(b)(6) are viewed with disfavor and are rarely granted." *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 231 (5th Cir. 2009) (internal citation omitted).

B. Choice-of-Law

As a threshold matter, this Court must determine which state's law applies to Murthy's claims. District courts sitting in diversity apply the choice-of-law rules of the state in which they sit. *Klaxon v. Stentor Elec. Mfg., Inc.*, 313 U.S. 487, 496 (1941); *Mayo v. Hartford Life Ins. Co.*, 354 F.3d 400, 403 (5th Cir. 2004); *Smith v. EMC Corp.*, 393 F.3d 590, 597 (5th Cir. 2004). Texas courts determine the appropriate choice of law by determining which state, with respect to the issues, has the most significant relationship to the occurrence and the parties. In doing so, they apply the "most significant relationship" test provided by Sections 145 and 6 of the Restatement (Second) of Conflict of Laws.[3] *Torrington Co. v. Stutzman*, 46 S.W.3d 829, 848 (Tex. 2000);

[3] All references to the Restatement are to the Restatement (Second) of Conflict of Laws unless otherwise indicated.

Gutierrez v. Collins, 583 S.W.2d 312, 318 (Tex. 1979). For tort cases, the Restatement instructs courts to consider the following contacts in determining which state possesses the most significant relationship:

> (a) the place where the injury occurred,
> (b) the place where the conduct causing the injury occurred,
> (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and,
> (d) the place where the relationship, if any, between the parties is centered.

Restatement (Second) of Conflict of Laws § 145 (1971). These contacts are to be evaluated according to their relative importance with respect to the particular issue before the court. *Spence v. Glock, Ges.m.b.H*, 227 F.3d 308, 312 (5th Cir. 2000). The number of contacts is less important than the qualitative nature of those contacts as affected by the policy factors of Section 6 of the Restatement. *See Gutierrez*, 583 S.W.2d at 319. Indeed, Section 6 directs courts to consider the contacts involved in the case in light of the following general principles:

> (a) the needs of the interstate and international systems,
> (b) the relevant policies of the forum,
> (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,
> (d) the protection of justified expectations,
> (e) the basic policies underlying the particular field of law,
> (f) certainty, predictability and uniformity of result, and
> (g) ease in the determination and application of the law to be applied.

Spence, 227 F.3d at 311-312.

The Fifth Circuit has held that the location of injury is an "important factor" in determining the most appropriate law to apply. *Huddy v. Fruehauf Corp.*, 953 F.2d 955, 957 (5th Cir. 1992). Indeed, under the Restatement, in tort cases, "the applicable law will usually be the local law of the state where the injury occurred." Restatement (Second) of Conflict of Laws § 156(2) (1971).

Texas courts also look to the Restatement (Second) of Conflict of Laws when determining choice-of-law for contract disputes. *Sonat Exploration Co. v. Cudd Pressure Control, Inc.*, 271 S.W.3d 228, 231 (Tex. 2008). The Restatement provides that "an issue in contract [is] determined by the local law of the state which, with respect to that issue, has the most significant relationship to the transaction and the parties." Restatement (Second) of Conflict of Laws § 188(1). Specifically, in a contract action, the court should consider five factors: (1) the place where the contracting occurred, (2) the place where the contract was negotiated, (3) the place where the contract was performed, (4) the subject matter locations, and (5) the parties' domicile, place of incorporation, and place of business. *Advanced Environmental Recycling Technologies Inc.*, 399 Fed.Appx. 869, 872 n.1 (5th Cir. 2010) (citing *Sonat Exploration Co.*, 271 S.W.3d at 231; Restatement (Second) of Conflict of Laws § 188(2) (1971)).

Abbott argues that Texas law should apply because Murthy participated in the Abbott study, received Humira, and developed and was treated for lymphoma while resident in Texas. Murthy has not raised any arguments to the contrary. Given Murthy's lack of opposition, the Court will apply Texas law to the resolution of Abbott's Motion to Dismiss. [4]

III. APPLICATION

For the reasons explained below, Murthy's claims survive Abbott's Motion to Dismiss. Murthy's negligent failure to warn claim is not barred by the learned intermediary doctrine or § 82.007 of the Texas Civil Practices and Remedies Code. As Murthy pleads facts showing a failure to warn, she has stated a plausible claim for relief

[4] Murthy's response states that it will "assume arguendo" for purposes of this motion that Texas substantive law applies. Accordingly, she does not advance an argument that Texas law does not apply for purposes of this Motion.

under a strict liability theory. Murthy's breach of warranty claim also survives the Motion to Dismiss, as Abbott's argument for dismissal of that claim is exclusively based on the learned intermediary doctrine and § 82.007. Because Abbott does not address Murthy's remaining negligence claim in its Motion, the Court will not dismiss it at this time. Finally, Murthy's contract claim is not barred by the statute of limitations, as it "relates back" to her original pleading. Therefore, Abbott's Motion to Dismiss is denied in its entirety.

A. Murthy's Claims for Breach of Warranty, Strict Liability, and Negligence

The Court will first examine Murthy's claims for negligent failure to warn. Abbott alleges that the learned intermediary doctrine and § 82.007 of the Texas Civil Practice and Remedies Code provide independent bases for dismissal of these claims. The Court disagrees with Abbott's arguments. The Court concludes, first, that the learned intermediary doctrine does not apply to the unique circumstances of Murthy's case. Second, § 82.007 does not require dismissal of Murthy's failure-to-warn claim at this stage.

i. Learned Intermediary Doctrine

The Court finds that the learned intermediary doctrine does not shield Abbott from liability for failure to warn Murthy of Humira's adverse effects. First, Abbott directly marketed to Murthy by creating a promotional video. Second, Murthy's doctor was compensated by Abbott. For these two reasons, the learned intermediary doctrine does not preclude Murthy's failure-to-warn claims. Before analyzing Murthy's allegations, the Court will examine the learned intermediary doctrine and its theoretical foundations.

1. Foundations of the Learned Intermediary Doctrine

"Under Texas law, a manufacturer must instruct consumers as to the safe use of its product and warn consumers of dangers of which it has actual or constructive knowledge at the time the product is sold." *Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 276 (5th Cir. 2010) (citing *Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330, 338 (5th Cir. 1984)). But where a plaintiff sues the manufacturer of a prescription drug for failing to adequately warn of the drug's effects, Texas courts employ the learned-intermediary doctrine. *Id*. "The learned-intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn consumers." *Ackermann v. Wyeth Pharmaceuticals*, 526 F.3d 203, 207 (5th Cir. 2008) (citing *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591-92 (Tex. 1986)). Under the doctrine, a patient-purchaser's doctor acts as a conduit between the patient and the manufacturer, professionally evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use. *Id.* "If the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided." *Id*. Accordingly, the doctrine excuses a drug manufacturer "from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers." *Id*. (citing *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467-68 (5th Cir. 1999)). Conversely, "when the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user." *Id*.

"Texas law generally holds that the adequacy of a product's warning is a question of fact to be determined by the jury." *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006)

(citing *Williams v. Upjohn Co.*, 153 F.R.D. 110, 114 (S.D. Tex. 1994); *Alm*, 717 S.W.2d at 591-92). "In prescription drug cases involving the learned intermediary doctrine, however, when 'a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law.'" *Id*. (quoting *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.-Waco 1993, writ denied)). Merely mentioning in the label the condition of which the plaintiff complains, however, is not necessarily sufficient for a finding of adequacy of as a matter of law, at least where the plaintiff's contention is not that the warning is inadequate because her condition was not mentioned, but that the label is misleading as to the *risk level* for developing the condition. *Id*. Indeed, "[w]arning the learned intermediary of a much lower risk than the actual risk could render the warning not just misleading, but ineffective." *Id*. "Thus, if the manufacturer decides to label a risk as 'comparatively rare' and also to provide a numerical quantification of that risk, that number must be within a certain degree of accuracy." *Id.* The learned intermediary doctrine may apply to a number of different causes of action, including strict liability, negligence, misrepresentation, and breach of warranty, where the crux of the allegation is based on a failure to adequately warn. *Ebel v. Eli Lilly & Co.*, 536 F.Supp.2d 767, 773 (S.D. Tex. 2008) (citing *In re Norplant Contraceptive Products Liab. Lit.*, 955 F.Supp. 700, 709 (E.D. Tex. 1997), *aff'd* 165 F.3d 374 (5th Cir. 1999)).

The learned intermediary doctrine is premised on the assumption that "the physician understands the potential dangers involved in the use of a given drug and, as the prescriber, stands between the drug and the ultimate consumer." *Wyeth-Ayerst Laboratories Co. v. Medrano*, 28 S.W.3d 87, 91 (Tex.App.-Texarkana 2000) (citing *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex.Civ.App. 1973)). *See also*

Gerber v. Hoffmann-La Roche Inc., 392 F.Supp.2d 907, 915 (S.D. Tex. 2005) ("Under the learned intermediary doctrine in Texas, 'a physician stands as an intermediary between a product manufacturer and the patient.'" (quoting *Porterfield*, 183 F.3d at 468)). Under the doctrine, "it is assumed that a patient-purchaser's doctor stands between the patient and the manufacturer, professionally evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use." *Ackermann*, 526 F.3d at 207. In other words, the choice the prescribing physician "makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative." *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974).

In *Reyes v. Wyeth Laboratories*, the Fifth Circuit recognized an exception to the learned intermediary doctrine when a vaccine is "dispensed without the sort of individualized medical balancing of the risks to the vaccinee that is contemplated by the prescription drug exception." *Id.* at 1277. The drug company "had ample reason to foresee the way in which its vaccine would be distributed," in other words, "without prescription drug safeguards." *Id.* The Court held the drug manufacturer "to the skill of an expert in his field," and presumed it "possess[ed] an expert's knowledge of the arts, materials, and processes of the pharmaceutical business." *Id.* The Court determined that "[i]ncluded in such expertise must be a familiarity with practices and knowledge common in the drug industry as to distribution and administration of pharmaceutical products." *Id.* As the pharmaceutical company well knew, vaccination clinics dispensed the Sabin vaccine "to all comers in an assembly line fashion; there is often neither time nor personnel to make an individualized medical judgment of the vaccinee's needs or susceptibilities." *Id.* The Court concluded that the pharmaceutical company "knew or had

reason to know that the vaccine would not be administered as a prescription drug, and therefore was required to warn foreseeable users, or see that the Texas Department of Health warned them." *Id.*

Other courts have developed similar rationales when finding exceptions to the learned intermediary doctrine. The Supreme Court of New Jersey has determined that the foundations justifying the learned intermediary doctrine—"(1) reluctance to undermine the doctor patient-relationship; (2) absence in the era of 'doctor knows best' of need for the patient's informed consent; (3) inability of drug manufacturer to communicate with patients; and (4) complexity of the subject"—"are all (with the possible exception of the last) absent in the direct-to-consumer advertising of prescription drugs." *Perez v. Wyeth Laboratories Inc.*, 161 N.J. 1, 18 (N.J. 1999). Based on this reasoning, the Supreme Court of New Jersey concluded that the learned intermediary doctrine did not apply to the direct marketing of drugs to consumers. *Id.* at 21. When carving out an exception to the learned intermediary doctrine, the Supreme Court for New York County concluded that "[w]here vaccines are administered prophylactically by a physician in connection with overseas travel, an in-depth analysis of the benefits and risks to the individual of the vaccine's administration appears to be unlikely." *Samuels v. Am. Cyanamid Co.*, 495 N.Y.S.2d 1006, 1013 (N.Y. Sup. 1985). Some courts have also held that the learned intermediary doctrine should not apply to contraceptives because the physician is largely relegated to a passive role in their prescription and dissemination. *MacDonald v. Ortho Pharmaceuitical Corp.*, 394 Mass. 131, 138 (Mass. 1985), *cert. denied*, 474 U.S. 920 (1985). The West Virginia Supreme Court recently declined to adopt the learned intermediary doctrine altogether, finding the justifications for the doctrine "to be largely

outdated and unpersuasive." *State ex rel. Johnson & Johnson Corp. v. Karl*, 220 W.Va. 460, 470 (W.Va. 2007). The court was concerned specifically with "the initiation and intense proliferation of direct-to-consumer advertising, along with its impact on the physician/patient relationship, and the development of the internet as a common method of dispensing and obtaining prescription drug information." *Id.* at 471.

Nonetheless, many state courts have declined, in recent years, to find any exceptions to the learned intermediary doctrine. *See Beale v. Biomet, Inc.*, 492 F.Supp.2d 1360, 1376 (S.D. Fla. 2007) ("Since *Perez* was decided, no court—including any Florida court—has recognized the DTC exception to the learned intermediary doctrine, and several courts have expressly rejected the DTC exception."); *Cowley v. Abbott Labs., Inc.*, 476 F.Supp.2d 1053, 1060 n.4 (W.D. Wis. 2007); *Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514, 517 n.30 (E.D. Pa. 2006). The Fifth Circuit has expressed that it is "skeptical that a Texas court would adopt [an over-promotion] exception" to the doctrine. *Ebel*, 321 Fed.Appx. at 356. *See also In re Norplant Contraceptive Products Litigation*, 165 F.3d at 379 (citing *Hurley v. Lederle Lab.*, 863 F.2d 1173, 1178 (5th Cir. 1988); *Swayze v. McNeil Lab.*, 807 F.2d 464 (5th Cir. 1987)).

Recently, however, a Texas state appellate court recognized an exception to the learned intermediary doctrine in cases where a drug manufacturer practices "consumer marketing that fraudulently touts the drug's efficacy while failing to warn of the risks." *See Centocor, Inc. v. Hamilton*, 310 S.W. 3d 476, 499 (Tex. App.-Corpus Christi 2010). The court reasoned that "[t]he changes in the delivery of healthcare brought about by direct marketing and managed care demonstrate that the theoretical underpinnings of the 'learned intermediary' doctrine do not apply when a drug manufacturer directly markets

to its consumers, the patients." *Id.* at 507-08. First, the court determined that "although a doctor must still write a prescription for prescription drugs, it is clear that many doctors are not spending the amount of time necessary to pass along warnings by pharmaceutical companies." *Id.* at 509. Second, the court opined, "by directly marketing to consumers and providing warnings in those advertisements, drug manufacturers have completely undermined their own arguments" that consumers cannot understand the warnings and that the companies "lack effective means to communicate directly with consumers." *Id.* Third, "consumer-directed advertising encroaches on [the physician-patient] relationship by encouraging consumers to ask for advertised products by name." *Id.* (internal quotations omitted). The court thus concluded that "when a pharmaceutical company directly markets to a patient, it must do so without fraudulently misrepresenting the risks associated with its product." *Id. Centocor, Inc.* has been appealed to the Texas Supreme Court.

2. Learned Intermediary Doctrine in Murthy's Case: Direct-to-Consumer Advertising and Pharmaceutical Companies' Compensation of Physicians

"The central theme, consistent among all of the cases finding an exception to the learned intermediate doctrine, is that the physician-patient relationship is not the same as in typical treatment scenarios." Jeffrey J. Wiseman, *Another Factor in the "Decisional Calculus": The Learned Intermediary Doctrine, the Physician-Patient Relationship, and Direct-to-Consumer Marketing*, 52 S.C. L. REV. 993, 1007 (2001). Murthy's situation departs from the typical treatment scenario in two respects. First, Abbott directly marketed to Murthy by creating and disseminating a promotional video. Second, Abbott compensated Murthy's physician.

The Texas Supreme Court has not directly addressed either of these unique circumstances in the learned intermediary context. Murthy's case thus requires this Court to determine unsettled issues of state law. "'When confronted with an unsettled issue of state law, a federal court sitting in diversity must make its best effort to predict how the state courts would decide the issue.'" *Haralson v. State Farm Mut. Auto. Ins. Co.*, 564 F.Supp.2d 616, 621 (N.D. Tex. 2008) (quoting *Batts v. Tow-Motor Forklift Co.*, 666 F.3d 743, 750 (5th Cir. 1995)). "'While decisions of intermediate state appellate courts provide guidance, they are not controlling.'" *Id.* (quoting *United Teacher Associates Ins. Co. v. Union Labor Life Ins. Co.*, 414 F.3d 558, 565 (5th Cir. 2005)). "If a state's highest court has not ruled on the issue in question, a federal court must determine, to the best of its ability, what the highest court of the state would decide." *United Teacher Associates Ins. Co.*, 414 F.3d at 565. "In making an *Erie*-guess, the court can consider, among other sources, 'treatises, law review commentaries, decisions from other jurisdictions whose doctrinal approach is substantially the same, and the majority rule.'" *Haralson*, 564 F.2d at 621 (quoting *Jackson v. Johns-Manville Sales Corp.*, 781 F.2d 394, 398 (5th Cir. 1986), *cert denied*, 478 U.S. 1022 (1986)).

Given the underlying justifications for the learned intermediary doctrine, the Court believes that the Texas Supreme Court will likely agree with the Court of Appeals' reasoning in *Centocor, Inc.* The learned intermediary doctrine in Texas assumes that "the physician understands the potential dangers involved in the use of a given drug and, as the prescriber, stands between the drug and the ultimate consumer." *Wyeth-Ayerst Laboratories Co.*, 28 S.W.3d at 91 (citing *Gravis*, 502 S.W.2d at 870). In other words, Texas courts have applied the doctrine because "[t]he doctor stands as a learned

intermediary between the manufacturer and the ultimate consumer." *Alm*, 717 S.W.2d at 591. By creating a video about Humira, Abbott Laboratories directly marketed its product to Murthy. The video painted "a rosy picture of therapy with Humira" and did "little if anything to alert the patient to the very real risk of life-threatening Humira-induced cancer." (Pl's Am. Compl. ¶ 20.) The Complaint contains sufficient facts to state a plausible claim that the Humira video "fraudulently tout[ed] the drug's efficacy" or "fraudulently misrepresent[ed] the risks associated with its product." *Centocor, Inc.*, 310 S.W. at 499, 509. By creating and disseminating a promotional video that, according to Murthy, fraudulently touted Humira's efficacy, Abbott circumvented the doctor-patient relationship. Therefore, the Court concludes, Abbott is not released from its duty to warn Murthy of Humira's potentially dangerous side effects.

Similarly, when a physician is compensated by a drug company, some of the assumptions underlying the learned intermediary doctrine no longer hold. The doctrine is premised on the notion that the physician is an objective intermediary who will draw an independent judgment about the best course of treatment for his or her patient. *Ackermann*, 526 F.3d at 207; *Reyes*, 498 F.2d at 1276. In part, the doctrine assumes that physicians do not have an incentive to choose one drug over another, and thus make an indifferent determination about the proper treatment plan. For example, in the first case ever to hold that a manufacturer's duty to warn was satisfied by providing warnings to a prescribing physician, the Supreme Court for New York County noted that "[t]here is no reason to believe that a physician would care to disregard his own knowledge of the effects of drugs and hence of the quantity to be administered, and substitute for his own judgment that of a drug manufacturer." *Marcus v. Specific Pharms.*, 191 Misc. 285, 287

(N.Y. Sup. Ct. 1948). *See also Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 462 (Tex.App.-Austin 2002) (observing that the physician relies "on his medical training, experience, and knowledge of the individual patient" to choose "the type and quantity of drug to be prescribed").

Studies have documented, however, that gifts or compensation from drug companies influence medical professionals' treatment decisions.[5] Conflicts of interest

[5] The responsibilities of pharmaceutical companies and physicians are, according to the Accreditation Council on Graduation Medical Education, irreconcilably different: "[T]he responsibility of the pharmaceutical industry [is] to act in the best interests of its shareholders by maximizing their return on investment. In contrast, however, the altruism expected of medical professionals dictates that doctors put patients first. The doctor-patient relationship … is the foundation of medical professionalism; the good of the patient must be preeminent." Accreditation Council on Continuing Medical Education, *Principles to Guide the Relationship Between Graduate Medical Education and Industry* 2 (Sept. 10, 2002), *available at* http://www.acgme.org/acWebsite/positionpapers/pp_index.asp (accessed Nov. 1, 2011). This conflict of interest has led to concerns that medical industry may influence medical decision-making. *Id.* These fears are well founded: Researchers have documented that gifts and drug-company sponsored continuing medical education are associated with increased prescription rates of the sponsor's medication. Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. AM. MED. ASS'N 373 (2000). *See also* Institute of Medicine, *Report Brief: Conflict of Interest in Medical Research, Education, and Practice* (April 2009). According to researchers, physicians may even be influenced by "token gifts": "Social science research continues to show that the impulse to reciprocate from even a token gift can be a powerful influence on behavior, thereby producing a possible conflict of interest for the recipient (physician)." David W. McFadden, *The Devil is in the Details: The Pharmaceutical Industry's Use of Gifts to Physicians as Marketing Strategy*, 140 J. SURGICAL RESEARCH 1, 2 (June 1, 2007). This is because even a small gift giving encourages reciprocity: "Reciprocity is one of the key tools of persuasion that is used in the interaction between physician and the pharmaceutical industry. In that all societies subscribe to a norm that obligates individuals to repay in kind what they have received, when a physician receives a gift, irrespective of its value, the beginning of a relationship of psychological indebtedness is established." Ashley Wazana, *Ethical Considerations in the Relationship between Physicians and the Pharmaceutical Industry*, 25 PSYCHATR. CLIN. N. AM. 647, 652 (2002).

Physicians, of course, may be unaware of any bias. "[P]romotional support has been proven to influence medical decision-making, and studies have found decision makers unable to recognize its impact." Accreditation Council on Continuing Medical Education, *supra*, at 2. Indeed, the number of promotional items received by physicians is correlated with the belief that pharmaceutical representatives have little impact on their prescribing behavior. Catherine A. Marco, et al., *Gifts to Physicians from Pharmaceutical Industry: An Ethical Analysis*, 48 ANNALS OF EM. MED. 513, 517 (Nov. 2006). Strangely, most physicians (61%) believe that they are not influenced by pharmaceutical company gifts, but believe the same is true for only 16% of their colleagues. McFadden, *supra*, at 2. Despite most physicians' assumptions, "there is strong evidence that bias behaviors exist." *Id.* Thus, "[a]s with many instances of conflict of interest, the bias created in physicians by pharmaceutical promotions tends to be unintentional and unconscious." Susan Poser, *Unlabeled Drug Samples and the Learned Intermediary: The Case for Drug Company Liability without Preemption*, 62 FOOD & DRUG L. J. 653, 668 (2007). Therefore, even if physicians do not acknowledge the bias, it may nonetheless exist; indeed, physicians' self-interest may affect their choices indirectly. Jason Dana & George Lowenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 J. AM. MED. ASS'N 252, 254 (2003).

also arise when clinicians stand to gain from enrolling their own patients as subjects in clinical trials.[6] Indeed, a doctor who receives gifts or compensation from a drug company may no longer, "as the prescriber, stand[] between the drug and the ultimate consumer," as the doctor has an incentive to prescribe a particular drug or, in this case, enroll a patient in a clinical trial. *Wyeth-Ayerst Laboratories Co.,* 28 S.W.3d at 91 (citing *Gravis*, 502 S.W.2d at 870). As the Restatement of Torts recognizes, "in certain limited therapeutic relationships the physician or other health-care provider has a much-diminished role as an evaluator or decisionmaker. In these instances it may be appropriate to impose on the manufacturer the duty to warn the patient directly." Restatement (Third) of Torts (1998), comment b. When a physician receives compensation or gifts from drug companies, his or her role as the neutral decision-maker is diminished. The Texas Supreme Court would surely not apply the learned intermediary doctrine when the physician's prescribing practice is compromised by a conflict of interest as overt as compensation by the defendant drug company. The Court thus concludes that because Murthy's doctor was compensated by Abbott at the time he enrolled Murthy in the

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[5] Researchers have also documented that conflicts of interest may arise when clinicians stand to gain from enrolling their own patients as subjects in clinical trials:

> Extensive literature demonstrates the shortcomings of the current informed consent process in the experimental setting. The informed consent might be compromised even further when the physician/investigator who is responsible for enrolling participants in the trial and obtaining their consent stands to gain financially from each participant who is enrolled. The physician/investigator may be less inclined to emphasize how the experimental treatment differs from the care that is ordinarily provided, the additional risks involved, or lack of direct benefit to the participant.

K. Morin, et al., *Managing Conflicts of Interest in the Conduct of Criminal Trials*, 287 J. AM. MED. ASS'N 78, 80 (2002). Indeed, Morin observed that "the physician who has treated a patient on an ongoing basis should not be responsible for obtaining that patient's informed consent to participate in a trial to be conducted by the physician." *Id.* Murthy's doctor appears to have obtained her consent to participate.

clinical trial and prescribed her Humira, Abbott cannot avail itself of the learned intermediary doctrine.

ii. Section 82.007 of the Texas Civil Practice and Remedies Code

1. Legal Standard

In 2003, the Texas legislature enacted Texas Civil Practice and Remedies Code § 82.007 as part of a broader tort reform effort. This section provides, in relevant part:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended….

Tex. Civ. Prac. Rem. Code § 82.007. For purposes of § 82.007, a "products liability action" is defined as

> any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories.

Tex. Civ. Prac. Rem. Code § 82.001(2).

Where a fact is a "presumption" or "presumed," it means that the trier of fact must presume the existence of the fact unless and until evidence is introduced to support a finding of its nonexistence. Tex. Bus. & Com. Code Ann. § 1.201(29). The effect of a presumption "is to shift the burden of producing evidence to the party against whom it

operates." *Gen. Motors Corp. v. Saenz*, 873 S.W.2d 353, 359 (Tex. 1993). Once evidence contradicting the presumption has been offered, the presumption disappears and is not to be weighed or treated as evidence. *Id*.

Section 82.007(b) enumerates specific ways in which a claimant may rebut the presumption set out in Subsection (a):

> (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;
> (2) the pharmaceutical product was sold or prescribed in the United States by the defendant after the effective date of an order of the United States Food and Drug Administration to remove the product from the market or to withdraw its approval of the product;
> (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)(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; or
> (5) the defendant, before or after pre-market approval or licensing of the product, engaged in conduct that would constitute a violation of 18 U.S.C. Section 201 and that conduct caused the warnings or instructions approved for the product by the United States Food and Drug Administration to be inadequate.

Tex. Civ. Prac. Rem. Code § 82.007(b).

Although Subsection (b)(1) still appears in the statute as a valid avenue to rebut the presumption articulated in Subsection (a), drug manufacturers, including Abbott in this case, frequently argue that Subsection (b)(1) is preempted.

Whether the exception articulated § 82.007(b)(1) is preempted is an issue that has not yet been decided by the Supreme Court or the Fifth Circuit, and there is a split of authority among the courts that have addressed it. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965-66 (6th Cir. 2004) (finding provision similar to § 82.007 preempted); *accord In re Aredia and Zometa Products Liability Litigation*, No. 3:06-MD-1760, 2008 WL 2944910 (M.D. Tenn. July 25, 2008) (finding § 82.007(b)(1) preempted); *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 682 F.Supp.2d 662, 675 (N.D. Tex. 2010) (finding section 82.007(b)(1) preempted, at least where plaintiffs asked the court to reach the conclusion opposite of that reached by FDA—that defendants did not withhold information or mislead it). *But see Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 98 (2d Cir. 2006), *aff'd*, 552 U.S. 440, 128 S.Ct. 1168, 170 L.Ed.2d 51 (2008) (explicitly rejecting the result in *Garcia* and finding a similar provision not preempted);[7] *accord Yocham v. Novartis Pharmaceuticals Corp.*, 736 F.Supp.2d 875, 883 (D.N.J. 2010) ("[W]hile a tort based exclusively on fraud on the FDA is preempted by federal law, the exception contained in the Texas statute providing a defense to traditional tort claims is not preempted."); *Ackermann v. Wyeth Pharmaceuticals*, 471 F.Supp.2d 739, 749 (E.D. Tex. 2006) (denying summary judgment on the basis of § 82.007(a) in light of material issue of fact regarding the applicability of Subsection (b)(1)).

Defendant argues that Murthy's products liability claims should be dismissed under § 82.007 because it is undisputed that Humira's warnings were approved by the

[7] *Desiano* was affirmed by an equally-divided Supreme Court without an opinion. 552 U.S. 440, 128 S.Ct. 1168, 170 L.Ed.2d 51 (2008). The Court's decision is therefore not binding on this court. *Hertz v. Woodman*, 218 U.S. 205, 213-14, 30 S.Ct. 621, 54 L.Ed. 1001 (1910) ("[A]n affirmance by an equally divided court is, as between the parties, a conclusive determination and adjudication of the matter adjudged; but the principles of law involved not having been agreed upon by a majority of the court sitting prevents the case from becoming an authority for the determination of other cases, either in this or in inferior courts."); *Lofton*, 682 F.Supp.2d at 675 n.5.

FDA for an FDA-approved indication, the treatment of RA, and Murthy has not alleged grounds for rebutting the statutory presumption. Murthy responds that § 82.007 does not bar her tort claims for five reasons. First, she argues, "by its terms, § 82.007 does not apply to an 'indication not approved' by the FDA. Therefore, it is highly questionable whether it applies to patients enrolled in any kind of clinical trial." (Pl.'s Resp., Doc. No. 23 at 8-9.) Second, Murthy argues, § 82.007 does not apply because she has made plausible allegations that not all of the information given to her was FDA approved. Third, Murthy contends, her allegations that the FDA subsequently mandated stricter warnings rebut the statutory presumption. Fourth, Murthy maintains, the cases Abbott cites in support of its argument that the case should be dismissed involved motions for *summary judgment* where the court concluded that the record lacked sufficient evidence to create a fact issue vis-à-vis rebuttal of the presumption. Because § 82.007 is a defensive statutory presumption, Murthy argues, it is not necessary for her to anticipate and negate it in her *complaint*. Finally, Murthy argues that Subsection (b)(1) is not preempted and that, if it were preempted, the entirety of § 82.007 would be constitutionally invalid because the remaining sections are not severable. As Murthy anticipates being able to rebut the presumption by demonstrating that Abbott withheld evidence from the FDA sufficient to rebut the presumption within the ambit of Subsection (b)(1), she argues, her case should not be dismissed.

2. Analysis

The Court can easily dispose of two of Murthy's arguments against dismissal. Murthy's first contention that, by its terms, § 82.007 does not apply to an "indication not approved" by the FDA fails for two reasons. First, it is not a correct statement of the law.

Section 82.007 applies to all products liability actions "alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product." Under § 82.007(b)(3)(A), a plaintiff may *rebut* § 82.007(a)'s presumption by proving, among other facts, that "the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by" the FDA, but it erroneous to say that § 82.007 does not "apply to an indication not approved" by the FDA. Second, it is undisputed that, at the time of the HERO study, Humira was approved for the treatment of moderately to severely active RA, the condition for which Murthy was treated with Humira. Murthy has presented no authority suggesting that the mere fact that Murthy received Humira in a clinical trial setting changes the Court's analysis.

Murthy's argument that she may rebut the statutory presumption with evidence that the FDA subsequently mandated stricter warnings also fails. Murthy reasons that, because a plaintiff can rebut the presumption by showing that the relevant pharmaceutical product was sold or prescribed after the effective date of an order of the FDA to remove the product from the market or to withdraw its approval of the product, a plaintiff should also be able to rebut the presumption with evidence of subsequent FDA-mandated direct-to-patient warnings. Murthy presents no authority, however, for what would represent a considerable expansion of the means by which a plaintiff may rebut the statutory presumption. Furthermore, Abbott presents case law suggesting that, under general principles of Texas statutory interpretation, the exceptions to § 82.007(a) enumerated in § 82.007(b) should be treated as exclusive. *See McCalla v. State Farm Mut. Ins. Co.*, 704 S.W.2d 518, 519 (Tex. App.-Houston [14 Dist.] 1986, ref. n.r.e.) ("When specific

exclusions or exceptions to a statute are stated by the Legislature, the intent is usually clear that no other shall apply.").

Murthy's argument that § 82.007(a) does not apply because "not *all*" of the information given to her was FDA approved is similarly unpersuasive. As Abbott points out, Murthy's argument is based solely on *dicta* from a recent state appellate court opinion. *See Centocor, Inc.*, 310 S.W.3d at 505 n.7. The *Centocor* court opined, "[I]t is not clear that [§ 82.007] was intended to cover something other than a package insert, which accompanies a prescription drug in its distribution," but noted that § 82.007 did not apply to that suit because it was filed after the statute's effective date and the statute did not apply retroactively. The Court declines to apply the *Centocor* court's unsupported conjecture that § 82.007(a) does not apply where, in addition to the FDA-approved warnings on the package insert, the plaintiff is exposed to non-FDA approved marketing materials. Murthy cites no other authority in support of her argument.

Murthy's remaining arguments present thornier issues. Indeed, they require the Court to decide whether, in order to avoid dismissal on a Rule 12(b)(6) motion, a plaintiff must plead facts in her complaint sufficient to make it plausible that she could rebut the statutory presumption once the record is developed. Indeed, if such allegations are required, Murthy's complaint must be dismissed. Murthy does not attempt to argue that she pleaded adequate facts to raise the "fraud on the FDA" rebuttal to the statutory presumption.[8] Rather, she argues that she will be able to show that Abbott withheld evidence from the FDA *once evidence is developed*, and that analysis of the presumption

[8] The Court need not determine at this stage whether § 82.007(b)(1) is preempted. Murthy has not included factual allegations related to fraud on the FDA and, thus, if such allegations are necessary, her complaint must fail. On the other hand, if the Court concludes that a plaintiff need not anticipate and rebut the statutory presumption, such factual allegations are not necessary at this stage.

is not appropriate until summary judgment. Thus, Murthy essentially argues that, notwithstanding her failure to plead any of the available means to rebut the statutory presumption against liability, she should be permitted to proceed with discovery.

Abbott counters that Humira's warnings were adequate as a matter of law. Indeed, it argues that § 82.007(a)'s rebuttable presumption applies because it is undisputed that the warnings accompanying Humira at the relevant time were FDA approved. A plaintiff, Abbott argues, may rebut the presumption only by alleging sufficient facts showing that her claims fall within one of the several narrowly-drawn ways to rebut the presumption under § 82.007(b). To support this position, Abbott cites *Thurston v. Merck & Co. Inc.*, a recent, unpublished Fifth Circuit opinion. No. 10-20485, 2011 WL 817520, at *1 (5th Cir. Mar. 9, 2011). In that case, without analysis, the Fifth Circuit affirmed a Rule 12(b)(6) dismissal of the plaintiff's failure-to-warn claims, in the alternative, under § 82.007(a) because the complaint did not plead facts sufficient to meet any of the statutory exceptions. This unpublished decision has no precedential effect, however, and is entitled to less weight, given the lack of analysis on the issue. Moreover, the Court did not need to reach § 82.007, having held that the plaintiff's complaint did not point to any medical evidence confirming his alleged injuries or connecting them to his use of the relevant drug. *Id*.

Thurston is the only case of which the Court is aware that even mentions the issue of whether, in order to avoid dismissal, a plaintiff must plead one of the enumerated ways to rebut the statutory presumption. In its supplemental briefing, Abbott argues that "[b]ecause Section 82.007 presumptively immunizes manufacturers from liability unless plaintiffs can meet at least one of the limited statutory exceptions, it is properly

understood as creating an additional element that plaintiffs must allege in order to state a valid claim." (Def.'s Resp. to Pl.'s Supp. Mem., Doc. No. 31 at 2.) Abbott points out that the Texas Product Liability Act "'represent[s] the state's policy preference to limit manufacturers' liability for injuries caused by their products.'" (*Id.* (quoting *Harris v. Philip Morris Inc.*, 232 F.3d 456, 458 (5th Cir. 2000)).). Abbott further relies on case law interpreting § 82.003, which provides that "[a] seller that did not manufacture a product is not liable for harm caused to the claimant by that product unless the claimant proves that a statutory exception applies." Tex. Civ. Prac. & Rem. Code § 82.003. Abbott points to two cases in which courts have dismissed actions under § 82.003 because the plaintiff had failed to make factual allegations that would invoke an exception to non-liability under the statute. *Gonzalez v. Estes, Inc.*, No. SA-10-CA-0038-XR, 2010 WL 610778, at *5 (W.D. Tex. Feb. 18, 2010) (finding that allegations in plaintiff's amended complaint "would be insufficient to overcome a motion to dismiss under Rule 12(b)(6)" because "[t]here are no factual allegations that would invoke any exception to nonliability on the part of [the defendant]"); *Harris v. New Werner Holding, Co., Inc.*, No. 3:08-CV-1750-L, 2009 WL 1211409, at *3 (N.D. Tex. May 1, 2009) ("Plaintiff's claims as pleaded in Plaintiff's Original Petition do not set forth a cause of action as permitted under section 82.003. Plaintiff wholly fails to state why any of his claims would fall within any of the exceptions set forth in 82.003."). Although provided with the opportunity to file additional briefing on the matter, Murthy was unable to cite any cases to illuminate whether she was required to plead one of the statutory presumptions.

The Court observes that many potential plaintiffs may lack sufficient facts to rebut the presumptions in § 82.007 without first conducting discovery. Until it receives

guidance from the Fifth Circuit, the Court will not erect what could be an insurmountable barrier for many plaintiffs seeking to bring actions under § 82.007. The Court concludes that Murthy need not, in her Complaint, plead one of the enumerated ways to rebut the statutory presumptions outlined in § 82.007.

Neither the learned intermediary doctrine nor § 82.007 provides a basis for dismissing Murthy's failure-to warn-claim. The Court therefore determines that Murthy's negligent failure-to-warn claims survive the Motion to Dismiss.

iii. Murthy's Remaining Claims

Having determined that Murthy's claims resting on allegations that Abbott failed to warn of Humira's dangerous side effects survive Abbott's Motion to Dismiss, the Court must analyze whether any of Murthy's remaining claims survive. In addition to breach of contract, which the Court will deal with separately, Murthy brings strict liability, breach of warranty, and negligence claims.

The Court determines that Murthy's strict liability claim survives the Motion to Dismiss. Texas courts refuse to recognize a cause of action for negligence per se based on violations of the Food and Drug Cosmetic Act and FDA regulations. *Id.* at 594; *see also Talley v. Danek Medical, Inc.*, 179 F.3d 154, 161 (4th Cir. 1999) (refusing to allow plaintiff to enforce the FDCA through state law negligence per se action). Under Texas law, however, Abbott can be held "strictly liable if the drug was not properly prepared or marketed or accompanied by proper warnings." *Hackett v. G.D. Searle & Co.*, 246 F.Supp.2d 591, 595 (W.D. Tex. 2002) (citing Restatement (Second) Torts § 402A, comment k). Murthy has not pleaded facts suggesting that Abbott did not properly prepare or market the drug. She has, however, pleaded that Abbott did not adequately

warn consumers of Humira's potentially dangerous side effects. As she has pleaded facts demonstrating a failure to warn, Murthy states a plausible claim for relief on a negligence per se theory. Thus Murthy's strict liability claim survives the Motion to Dismiss.

The Court also finds that Murthy's remaining claims for negligence and breach of warranty should not be dismissed. Murthy alleges negligence based on Abbott's failure to adequately and properly test Humira before and after placing it on the market. Abbott does not raise any arguments about why this particular claim should be dismissed. The Court thus declines to dismiss Murthy's remaining negligence claim at this stage. Abbott's only grounds for dismissing Murthy's breach of warranty claim are § 82.007 and the learned intermediary doctrine. As the Court explains above, neither § 82.007 nor the learned intermediary doctrine precludes Murthy's claims. Thus Murthy's breach of warranty claim survives the Motion to Dismiss.

B. Murthy's Contract Claims

In addition to her products liability claims, Murthy alleges in her Amended Complaint that Abbott breached the terms of the Consent to Participate agreement she signed before participating in the HERO study. Abbott argues in its Motion to Dismiss that this claim should be dismissed as untimely because the statute of limitations has run.[9] Murthy contends that her contract claim is not untimely because the statute of limitations was tolled. Furthermore, Murthy argues, her breach of contract claim is an amendment that relates back to the initial filings in her lawsuit. The Court finds that Murthy cannot

[9] In it reply, Abbott raises for the first time the argument that Murthy's breach of contract is factually insufficient under Rule 12(b)(6). Abbott argues that Murthy fails to allege facts to show that Abbott breached the agreement. The Fifth Circuit deems arguments raised for the first time in a reply brief to be forfeited. *See Yohey v. Collins*, 985 F.2d 222, 225 (5th Cir. 1993). "Some district courts follow the same approach." *Home Builders Ass'n of Northwest Louisiana v. Martin*, Civil Action No. 09-cv-1679, 2010 WL 5109987, at *1 (W.D. La. Dec. 8, 2010). As Abbott did not raise its factually insufficiency argument until its reply, and Murthy was therefore unable to respond, the Court finds that it has been waived and will not consider it when determining whether Murthy's breach of contract claim should be dismissed.

avail herself of either the fraudulent concealment or discovery doctrines. However, her contract claim is not barred by the statute of limitations because it relates back to her original pleadings.

i. Fraudulent Concealment and the Discovery Rule

The statute of limitations for breach of contract is four years, and begins to accrue once a plaintiff is provided with sufficient facts from which to seek a judicial remedy. Tex. Civ. Prac. & Rem. Code § 16.051; *Johnson & Higgins v. Kenneco Energy Inc.*, 962 S.W.2d 507, 514 (Tex. 1998). "It is well-settled law that a breach of contract claim accrues when the contract is breached." *Stine v. Stewart*, 80 S.W.3d 586, 592 (Tex. 2002) (citing *Smith v. Fairbanks, Morse & Co.*, 101 Tex. 24, 102 S.W. 908, 909 (1907)).

The Court finds that the statute of limitations for Murthy's contractual cause of action was not suspended because of fraudulent concealment. The doctrine of fraudulent concealment "suspend[s] the running of limitations until such time as the plaintiff learned of, or should have discovered, the deceitful conduct or the facts giving rise to the cause of action." *Earle v. Ratliff*, 998 S.W.2d 882, 888 (Tex. 1999). Furthermore, "[f]or fraudulent concealment to apply, the plaintiff must prove the defendant: '(1) had actual knowledge of the wrong; (2) had a fixed purpose to conceal the wrong; and (3) did conceal the wrong from the plaintiff.'" *Doe v. St. Stephen's Episcopal Sch.*, 382 Fed.Appx. 386, 390 (5th Cir. 2010) (quoting *Quigley v. Bennett*, 256 S.W.3d 356, 360-61 (Tex.App. 2008) (citing *Shah v. Moss*, 67 S.W.3d 836, 841 (Tex. 2001))). *See also BP Am. Production Co. v. Marshall*, 342 S.W.3d 59, 67 (Tex. 2011) ("A party asserting fraudulent concealment must establish an underlying wrong, and that 'the defendant actually knew the plaintiff was in fact wronged, and concealed that fact to deceive the plaintiff.'" (quoting *Earle*,

998 S.W.2d at 888)); *AT&T Corp. v. Rylander*, 2 S.W.3d 546, 557 (Tex.App.-Austin 1999, pet. denied) ("Fraudulent concealment requires either the active suppression of truth or the failure to disclose when there is a duty to speak."). Murthy has not pleaded facts sufficient to show that Abbott had knowledge of the wrong, had a fixed purpose to conceal the wrong, and did conceal the wrong. The statute of limitations on Plaintiff's contractual claim was therefore not suspended because of fraudulent concealment.

Murthy also alleges that "her cause of action did not necessarily accrue for limitations purposes when she was diagnosed with cancer," as "[t]he mere diagnosis did not put her on notice that Humira probably caused her lymphoma." (Pl.'s Resp. at 16.) She further alleges that Abbott did not "do[] anything to tell her that Humira was a likely culprit." (*Id.*) Murthy is presumably raising a discovery rule issue here. The discovery rule applies when "the nature of the injury … [is] inherently undiscoverable and the injury itself … [is] objectively verifiable." *Barker v. Eckman*, 213 S.W.3d 306, 312 (Tex. 2006) (citing *HECI Exploration Co. v. Neel*, 982 S.W.2d 882, 886 (Tex. 1998)). Under these circumstances, a cause of action does not accrue "until the plaintiff knew or, by exercising reasonable diligence, should have known of the facts giving rise to a cause of action." *Truman Arnold Co. v. Hammond*, No. 12-09-00099-CV, 2010 WL 2982912, at *2 (Tex.App-Tyler July 30, 2010, pet. denied) (citing *Barker*, 213 S.W.3d at 312).

A contract cause of action normally accrues when the contract is breached. *Id.* (citing *Slusser v. Union Bankers Ins. Co.*, 72 S.W.3d 713, 717 (Tex.App.-Eastland 2002, no pet.)). However, the discovery rule may serve to delay the commencement of the limitations period for a breach of contract action. *Id.* (citing *Barker*, 213 S.W.3d at 311-12). Yet "'limitations begin to run when the fact of injury is known,' not when the

alleged wrongdoers are identified." *Russell v. Ingersoll-Rand Co.*, 841 S.W.2d 343, 344 n.2 (Tex. 1992) (quoting *Moreno v. Sterling Drug, Inc.*, 787 S.W.2d 348, 351 (Tex. 1990)). Indeed, "[t]he discovery rule exception defers accrual of a cause of action until the plaintiff knew or, exercising reasonable diligence, should have known of the *facts* giving rise to the cause of action." *Computer Assocs., Int'l v. Altai, Inc.*, 918 S.W.2d 453, 455 (Tex. 1996) (emphasis added). The discovery rule does not toll statute of limitations when "some injury is known but the full extent of injury and cause are unknown." *Yalamanchili v. Mousa*, 316 S.W.3d 33, 38 (Tex.App-Houston [14 Dist.] 2010, reh'g denied). The party need not know "the specific cause of the injury; the party responsible for it; the full extent of it, or the chances of avoiding it." *PPG Industries, Inc. v. JMB/Houston Centers Partners Ltd. Partnership*, 146 S.W.3d 79, 93 (Tex. 2004) (internal citations omitted).

Murthy does not offer facts to support her contention that the limitations period was tolled beyond her diagnosis with cancer. Indeed, Murthy's rheumatologist even instructed Murthy to cease taking Humira when she was diagnosed, which suggests she may have known at that time that Humira may have been a contributing cause of her cancer. (Pl.'s Am. Compl. ¶ 29.) "A statute of limitations may support dismissal under Rule 12(b)(6) where it is evident from the plaintiff's pleadings that the action is barred and the pleadings fail to raise some basis for tolling or the like." *Jones v. Alcoa, Inc.*, 339 F.3d 359, 366 (5th Cir. 2003). *See also LaChapelle v. Berkshire Life Ins. Co.*, 142 F.3d 507, 509 (1st Cir. 1998) ("In the case of the affirmative defense of statute of limitations, dismissal is entirely appropriate when the pleader's allegations leave no doubt that an asserted claim is time barred."); *Kansa Reinsurance v. Congressional Mortg. Corp.*, 20

F.3d 1362, 1366-70 (5th Cir. 1994) (dismissing, under Rule 12(b)(6), a claim as time barred where the claim was clearly filed after the applicable statute of limitations had run and it was evident that the plaintiff could not benefit from the discovery rule); *Jablon v. Dean Witter & Co.*, 614 F.2d 677, 682 (9th Cir. 1980) ("When a motion to dismiss is based on the running of the statute of limitations, it can be granted only if the assertions of the complaint, read with the required liberality, would not permit the plaintiff to prove that the statute was tolled." (citing *Leone v. Aetna Casualty & Surety Co.*, 599 F.2d 566 (3rd Cir. 1979))). On the face of her Complaint, Murthy's contract claim is barred by the statute of limitations, and she does not plead facts suggesting that she may avail herself of the discovery rule. Murthy's breach of contract claim is not, therefore, saved by the discovery rule.

ii. Relation-Back Doctrine

Under federal law, an amendment to a pleading relates back to the date of the original pleading when "the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading." Fed. R. Civ. P. 15(c)(1)(B). By contrast, under Texas law, the "relation back" doctrine provides that new facts or claims raised in subsequent pleadings relate back to timely filed pleadings "unless the amendment or supplement is wholly based on a new, distinct, or different transaction or occurrence." Tex. Civ. Prac. Rem. Code § 16.068. "A transaction is defined as a set of facts that gives rise to the cause of action premised thereon." *Brewster v. Columbia Medical Center of McKinney Subsidiary, L.P.*, 269 S.W.3d 314, 317-18 (Tex. App.-Dallas 2008, no pet.) (internal quotations omitted).

Relation back is determined by whichever is more forgiving between state law or federal law. Thus, if state limitations law "affords a more forgiving principle of relation back than" Rule 15(c), such state law "should be available to save the claim." Fed. R. Civ. P. 15(c) Comm. N. to 1991 Amendment. "If there is a difference between Texas and federal relation-back law, the federal rule appears to be more lenient." *Schirle v. SOKUDO USA, LLC*, Action No. 4:08–CV–555–Y, 2011 WL 2881422, at *7 (N.D. Tex. July 19, 2011). "The federal rule allows relation back if the proposed amendment arose out of the same 'conduct, transaction, or occurrence' as the claim asserted in the original petition. Texas law provides that the amendment relates back unless it 'is wholly based on a new, distinct, or different transaction or occurrence.'" *Id*.

The Court concludes that, under either Texas or federal law, Murthy's breach of contract claim does in fact relate back to her initial pleadings. The rationale for Rule 15(c) "'is that, once litigation involving a particular transaction has been instituted, the parties should not be protected [by the statute of limitations] from later asserted claims that arose out of the same conduct set forth in the original pleadings.'" *Flores v. Cameron County, Tex.*, 92 F.3d 258, 272 (5th Cir. 1996) (quoting *Kansa Reinsurance Co.*, F.3d at 1366-67). Thus "'if a plaintiff seeks to correct a technical difficulty, state a new legal theory of relief, or amplify the facts alleged in a prior complaint, then relation back is allowed.'" *Id.* at 273 (quoting *F.D.I.C. v. Conner*, 20 F.3d 1376, 1386 (5th Cir. 1994)). "The theory that animates this rule is that 'once litigation involving particular conduct or a given transaction or occurrence has been instituted, the parties are not entitled to the protection of the statute of limitations against the later assertion by amendment of defenses or claims that arise out of the same conduct, transaction, or occurrence as set

forth in the original pleading.'" *F.D.I.C.*, 20 F.3d at 1385 (quoting 6A Charles A. Wright et al., Federal Practice and Procedure: Civil 2d § 1496, at 64 (1990)). Murthy's breach of contract claim arises out of the same transaction, conduct, or occurrence as her original pleading: her participation in the Abbott clinical trial and eventual development of cancer. Her amendment merely "seeks to identify additional sources of damages that were caused by the same pattern of conduct identified in the original complaint." *Id.* at 1386. For the purposes of 15(c), then, Murthy's breach of contract claim relates back to her original pleadings.

Under Texas law, "'[a] transaction is defined as a set of facts that gives rise to the cause of action premised thereon.'" *Brewster*, 269 S.W.3d at 317-18 (quoting *Texas Disposal Sys. Landfill, Inc. v. Waste Mgmt. Holdings, Inc.*, 219 S.W.3d 563, 587 (Tex.App.-Austin 2007, pet. denied)). "Thus, an amended pleading alleging a new cause of action relates back to the original filing and is not subject to a limitations defense if the original pleading was filed within the limitations period and if the amendment is not based on a wholly new, distinct, or different transaction." *J.K. and Susie L. Wadley Research Institute & Blood Bank v. Beeson*, 835 S.W.2d 689, 697 (Tex.App.-Dallas 1992). Murthy's new cause of action is not based on a wholly new, distinct, or different transaction. Her new allegations are rooted in her participation in the Abbott study and her subsequent development of cancer. The breach of contract claim shares the same actors and the same underlying operative facts. *White v. Baylor All Saints Medical Center*, No. 07-08-0023-CV, 2009 WL 1361612, at *2 (Tex.App.-Amarillo May 13, 2009). "Since section 16.068 is a remedial statute, designed to protect litigants from loss of their claims by a plea of limitation in cases where that would otherwise occur, [it]

should be liberally construed and applied to effect that purpose." *Milestone Properties, Inc. v. Federated Metals Corp.*, 867 S.W.2d 113, 116 (Tex.App.-Austin 1993). Construing the Texas doctrine liberally, as it is required to do, the Court finds that Murthy's breach of contract claim relates back to her original pleadings.

As Murthy's breach of contract claim relates back under either federal or Texas law, it is not barred by the statute of limitations. Therefore, the Court determines that it should not dismiss Murthy's breach of contract claim.

IV. CONCLUSION

For the reasons stated above, Murthy's claims for negligence, breach of warranty, breach of contract, and strict liability survive Abbott's Motion to Dismiss. Abbott's Motion to Dismiss is therefore **DENIED.**

IT IS SO ORDERED.

SIGNED this the 7th day of November, 2011.

KEITH P. ELLISON
UNITED STATES DISTRICT COURT JUDGE