UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

CARY MASSA,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. H-11-70
	§	
GENENTECH INC, *et al*,	§	
	§	
Defendants.	§	

OPINION AND ORDER

Pending before the Court is Defendants Genentech Inc. ("Genentech") and XOMA US Inc.'s ("XOMA") motion for partial dismissal of Plaintiff Cary Massa's amended complaint.[1] Doc. 37. Specifically, Defendants move to dismiss Counts Two (Strict Products Liability against Genentech), Four (Breach of Implied Warranty against Genentech), Five (Breach of Express Warranty against Genentech), Six (Fraud by Concealment against Genentech), Nine (Strict Products Liability against XOMA), Eleven (Breach of Implied Warranty against XOMA), Twelve (Breach of Express Warranty against XOMA), and Thirteen (Fraud by Concealment against XOMA) on the grounds that Massa fails to state a claim for which relief can be granted. Massa has responded to the Defendants' motion (Doc. 41-1) and the Defendants have filed a reply. Doc. 42.

After considering the parties' arguments, the facts of this case, and the applicable law, the Court finds that Defendants' motion should be granted as to Counts Two, Four, Five, Nine, Eleven, and Twelve and denied as to Counts Six and Thirteen.

Background

[1] Genentech and XOMA are pharmaceutical drug developers and manufacturers. Massa's amended complaint states that they collaborated on the development, testing, licensing, manufacture, and sale of Raptiva, the prescription drug at issue in this case. Doc. 21 at 6.

The factual allegations set forth in this prescription drug product liability action necessarily are complex and detailed. For the purpose of this motion to dismiss, the Court sets forth an abbreviated version of the related facts as alleged in Massa's amended complaint. Doc. 21.

Psoriasis is a chronic, non-contagious auto-immune disease that causes "inflamed patches of skin . . . topped with silvery white scales." Doc. 21 at 2. Relatively recently, research has revealed that psoriasis is caused or influenced by "the aberrant activation and migration of T-cells into the skin." *Id.* Massa identifies "conventional treatment[s]" for psoriasis including topical agents, ultraviolet therapy, cyclosporine, and methotrexate. *Id.* Recently, pharmaceutical companies have developed a class of treatments called "biologics," "medications that are produced by means of biological processes involving recombinant DNA technology," to treat psoriasis. *Id.* at 2-3.

In April, 1996, XOMA and Genentech entered into a collaboration agreement to develop Raptiva as a biologic psoriasis treatment. *Id.* at 4. Massa describes Raptiva as

> . . . a recombinant humanized monoclonal antibody that binds to human CD11a, one of the two components which form lymphocyte function-associated antigen 1 (LFA-l). LFA-l is an important molecule in lymphocyte adhesion, activation, and migration of tissues. It is involved in the recruitment of inflammatory cells to the site of infection. The skin lesions that occur in psoriasis are caused by the actions of T-cells that are attracted to the site of inflammation. LFA-1 is found on all T-cells, and also on B-cells, macrophages and neutrophils.
>
> [Raptiva] was designed to inhibit the function of the T-cell by interfering with the ability of the LFA-1 to bind to the endothelium adhesion molecule ICAM-1 and migrate from the blood into the skin where it would promote an inflammatory response and the growth of skin lesions.
>
> *Id.* at 3.

The mechanism of action also poses a risk, however, because

> [Raptiva's] prevention of adhesion of LFA-1 (i) diminishes T-cell adhesion to the lining of blood vessels; (ii) decreases the migration of T-cells to sites of inflammation; (iii) reduces the potentia1 of T-cells to kill malignant cells;

> and, (iv) contributes to the inhibition of activation of T-lymphocytes which are needed to fight infection.
>
> It is generally accepted in the medical community that suppression of T-cell function predisposes the body to serious life-threatening infections (encephalitis, meningitis, and progressive multifocal leukoencephalopathy (PML), a rare brain infection) neurological complications, and the development of lymphoma, malignancy and possibly death.
>
> It is generally accepted in the medical community that prolonged inhibition of (LFA-1) would impair the body's defenses against infection resulting in increased risk of infection, malignancy, lymphoma and death.
>
> It is generally accepted in the medical community that the role of LFA-1 and its relationship to the body's immune system was well known long before [Raptiva] was approved in October 2003 for use in the management of patients with psoriasis.

Id.

In September, 1996, XOMA filed an Investigational New Drug (IND) application with the Food and Drug Administration ("FDA") for Phase I clinical testing of Raptiva in patients with moderate to severe psoriasis. *Id.* at 4. In 1998, XOMA successfully completed Phase II trials. *Id.* In December, 1999, Defendants "announced initiation of Phase III clinical trials." *Id.* at 5.

On April 5, 2002, Defendants "reported that a [Raptiva] pharmacokinetic study failed." *Id.* As a result, Defendants "decided to relocate the [Raptiva] manufacturing facilities from XOMA to [Genentech] in order to allow for production of large-scale commercial quantities of [Raptiva]." *Id.* Massa alleges that the pharmacokinetic study "suggested that the [Genentech]-sourced material achieved a higher serum concentration than the XOMA-material. The FDA [then] asked [Genentech] to conduct a study of the 'new' [Raptiva] in psoriasis patients due to the difference in [Raptiva] serum concentration that was previously tested in patients." *Id.*

On December 27, Genentech submitted its Biologic License Application ("BLA") to the FDA's Center for Biologics Evaluation and Research and, Massa alleges, based that application "on efficacy and safety data from three Phase III studies . . . conducted by XOMA." *Id.* "In

August 2003, XOMA and [Genentech] reported that the FDA's Dermatologic and Ophthalmic Drug Advisor Board Committee would review their Biologics License Application. . . . The [Raptiva BLA] consisted of information, data, testing, design formulation, and the clinical studies of [Raptiva] conducted by both" Defendants and "FDA approval of the [Raptiva BLA] was based in part on the clinical studies involving *XOMA manufactured RAPTIVA*." *Id.* at 9.

Massa alleges that of the thirteen clinical trials that Defendants submitted to the FDA with their BLA, "more than half were XOMA-conducted with XOMA-manufactured [Raptiva]. Only XOMA conducted all three clinical trial phases, and XOMA carried out the single, critical Phase II trial." *Id.* at 10. These data formed the basis for the "warnings, precautions[,] and adverse reaction information in the [Raptiva] packaged inserts (warning labels) and patient package inserts" on which Massa and his physician relied. *Id.* at 11. On October 23, 2003, the FDA approved Xoma and Genentech's BLA for Raptiva, "conditional on D[efendants'] commitment to conduct several post marketing surveillance studies," and the Defendants "launched" Raptiva for sale on November 17, 2003. *Id.*

The parties agree that Raptiva carries numerous health risks including undesirable "rebound effects." *Id.* at 12; Doc. 38 at 2-4. Rebound effects are the re-occurrence and sometimes worsening of a patient's psoriatic symptoms experienced when he stops taking Raptiva. Massa alleges that the rebound effects of Raptiva sometimes caused "a more aggressive form [of psoriasis] than a patient's original baseline or pre-[Raptiva] treatment status. The rebounds . . . occurred at new sites on the body where patients had never experienced psoriasis before. . . . In several patients who discontinued [Raptiva], their plaque psoriasis turned into debilitating erythrodermic, guttae[,] or pustular types of the disease; some even required hospitalization." Doc. 21 at 12.

Massa alleges that, because of the risk of "rebound effects," Defendants "made a strategic decision to promote and market [Raptiva] as safe for 'continuous treatment,'" rather than marketing it as originally planned as a 12-week treatment course. *Id.* To secure approval from the FDA for this decision, Massa claims that the Defendants "made multiple material misrepresentations and omissions to the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA, falsely and deceptively reporting that [Raptiva] was safe for continuous usage." *Id.*, at 13. Specifically, Massa points to statements to the Advisory Committee made by Genentech representatives in which the representatives claimed that "[e]xtended therapy with [Raptiva] provides increased clinical efficacy with no increase in adverse events. Overall, there were few serious adverse events associated with [Raptiva] therapy. . . . [Raptiva] was well tolerated and safe for continuous use. . . . [T]he efficacy of [Raptiva] improves with continuous treatment past 12 weeks . . . [and that Raptiva's] safety profile over the extended period appears as favorable as its safety profile over the short period." *Id.* Defendants also "provided no information regarding duration of treatment . . . in their product labeling for [Raptiva] and/or in D[efendants'] marketing materials." *Id.* As a result, "prescribing physicians and the consumer public, including Plaintiff, were grossly under-informed regarding the risks of serious health effects." *Id.* at 14.

Massa also alleged that the distribution of Raptiva increased the likelihood of adverse health effects. *Id.* Massa alleged that Defendants "failed to implement a patient monitoring program in order to provide early detection of serious life-threatening infection, neurological complications, lymphomas, and malignancies. . . [Defendants] made a strategic business decision not to require any baseline blood work or physical exams prior to commencing" Raptiva. *Id.* Massa claims that Defendants forewent patient monitoring in order "to undermine the reporting

by physicians and patients of the adverse health risks associated with [Raptiva] . . . [and] for strategic marketing purposes." *Id.* at 15. Defendants also supplied Raptiva through a direct mailing system from "specialized pharmacies" which sent Raptiva directly to patients for self-injection. *Id.* at 16.

Massa contends that Defendants engaged in a long-term and sustained advertising campaigning touting the safety of Raptiva while "falsely and deceptively fail[ing] to inform physicians and the public that by March 5, 2008, [they] had knowledge and receipt of approximately 60 adverse event reports of patient deaths while on [Raptiva], and over one hundred adverse event report[s] of serious life-threatening infections leading to hospitalizations." *Id.* Despite these adverse event reports, Defendants failed to update the product labeling until October 2008, at which time "the FDA finally issued a boxed warning for [Raptiva] highlighting the risk of life-threatening neurological complications, bacterial and viral infections . . . [and] increased risk of cancer." *Id.* at 19.

In February 2009, "the FDA issued a Public Health Advisory concerning three deaths in patients treated with Raptiva. Two [of the reports] involved people with confirmed cases of progressive multifocal leukoencephalopathy. The third death was a person believed to have contracted the brain infection." *Id.* At approximately the same time, "the European Medicines Agency recommended to the European Commission the suspension of the marketing for [Raptiva] . . . [and shortly after] physicians were advised not to issue *any* new prescriptions for [Raptiva]." *Id.* At the same time, "Canada suspended the sales of [Raptiva] due to safety concerns." *Id.* On June 8, 2009, Genentech withdrew Raptiva from the US market. *Id.*

Massa suffers from psoriasis. *Id.* at 24. From February 2006 to January 2008, Massa's physician prescribed him Raptiva. *Id.* Massa alleged that "[b]ecause of the misleading

information that [Defendants] . . . provided to physicians and the FDA about the true risks . . . of [Raptiva] . . . [Massa's physicians] never informed him of the risk of developing serious and permanent injuries, including Hodgkin's lymphoma." *Id.*

Masse "began experiencing a persistent cough in approximately 2007. He also experienced nausea and vomiting, general malaise, reflux and weight loss. In approximately February 2009, Plaintiff Massa presented to the emergency department at the Crispus St. Catherine Hospital . . . with a painful left neck lymphadenopathy. . . Massa was diagnosed with Classic Hodgkin's lymphoma in approximately March 2009." *Id.* Massa alleges that Raptiva caused his cancer and other permanent and disabling injuries. *Id* at 25.

Legal Standard

Rule 12(b)(6) allows dismissal if a plaintiff fails "to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b) (6). In *Bell Atlantic Corp. v. Twombly,*550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009), the Supreme Court confirmed that Rule 12(b)(6) must be read in conjunction with Rule 8(a), which requires "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2).

To withstand a Rule 12(b)(6) motion, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Twombly,* 550 U.S. at 570; *see also Elsensohn v. St. Tammany Parish Sheriff's Office,* 530 F.3d 368, 372 (5th Cir. 2008). Under Rule 8(a)(2), plaintiffs are not required to include "'detailed factual allegations,' but more than 'an unadorned, the-defendant-unlawfully-harmed-me accusation' is needed." *Id.* (quoting *Twombly,* 550 U.S. at 555). "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."

Iqbal, 129 S.Ct. at 1949. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556.

Analysis

Defendants move for partial dismissal of Massa's complaint. Defendants contend that Massa's claims for design defect, fraud by concealment, breach of implied warranty, and breach of express warranty against both Defendants are insufficient or inapplicable under Texas law and therefore must be dismissed.

Design Defect

Defendants move to dismiss Massa's design defect claim on the grounds that 1) in Texas, the Restatement (Second) of Torts, section 402A, comment k, effectively exempts FDA-approved prescription drugs from strict-liability claims for design defect; and 2) Massa has no evidence of a safer alternative design as required under Texas law. Doc. 38 at 7.

In Texas, prescription drug design defect claims are governed by comment k to Section 402A of the Restatement (Second) of Torts. *See Brockert v. Wyeth Pharmaceuticals, Inc.*, 287 S.W.3d 760, 769 (Tex.App.–Houston [14 Dist.] 2009); *Keene Corp. v. Yeager*, 1994 WL 34159, *5 (Tex.App.-Dallas 1994). Comment k "recognizes that '[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use,' and that some drugs 'for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.' Under [comment k], a prescription drug is unreasonably dangerous in design if it is not 'accompanied by proper directions and warning.'" *Gerber v. Hoffmann-La Roche Inc.*, 392 F.Supp.2d 907, 922 (S.D.Tex. 2005)(quoting *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 (Tex. 1998)).

Additionally, "Texas courts . . . require a plaintiff asserting a design defect cause of action to demonstrate 'that the defendant could have provided a safer alternative design.' If no safe alternative can be established, the product is not defective as a matter of law." *Id.* "The Texas Supreme Court has . . . confirmed the 'common-law jurisprudence [that identifies] the availability of a safer alternative design [as not only] a factor to be considered in the risk-utility analysis [but also] a requisite element of a cause of action for defective design'" *Dyer v. Danek Medical, Inc.*, 115 F.Supp.2d 732, 738 (N.D.Tex. 2000) (quoting *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999)). Massa attempts to satisfy the "safer alternative design" requirement by contending that Defendants could have designed Raptiva "to require closer physician supervision . . . [by using] the original, XOMA-produced Efalizumab[2] rather than switching to Genetech-produced product with a higher serum concentration as the basis for commercial Raptiva . . . [or by] using an alternative chemical compound in their psoriasis treatment." Doc. 41-1 at 3.

Massa's proposed alternatives are insufficient to satisfy the requirements under Texas law. Initially, Raptiva, as a prescription drug, necessarily was designed to require at least some physician oversight. Patients could not obtain the drug without a prescription obtained during a physician visit. Additionally, the "patient information sheet" that is the subject of Massa's failure to warn claim states that Raptiva "is intended for use under the guidance and supervision of a physician." Doc. 38-1 at 21. Raptiva was designed to be a once-a-week self-administered injection. Massa's principal contention appears to be that it would have been safer if Defendants had designed the drug to be administered only by a physician because physician administration would result also in physical exams and diagnostic monitoring including x-rays, blood work, and CT scans. Doc. 21 at 16. Beyond the drastic increase in cost and difficulty posed by weekly visits

[2] Raptiva is the trade name for the monoclonal antibody Efalizumab.

to a physician, the essence of Massa's complaint is not that the drug itself was defective, but that Defendants' distribution system allowed for insufficient oversight by physicians whom Defendants failed to warn of the need for close supervision of patients taking Raptiva. While this allegation may support Massa's claim for failure to warn, it does not make out the "safer alternative design" requirement for his design defect claim.

Massa also asserts that "Defendants could have used the original, XOMA-produced Efalizumab rather than switching to Genentech-produced product with a higher serum concentration." Doc. 41-1 at 3. Massa does not allege how the lower concentration serum would be safer than the Raptiva that he took, nor whether a lower concentration would be as effective. Massa's speculation that a lower concentration of Efalizumab in Raptiva would be a "technically feasible" alternative is insufficient to satisfy the requirement for a "safer alternative design."

Finally, Massa points to the existence of "a number of competitive psoriasis treatments" on the market to demonstrate that "Defendants always had the option of using an alternative chemical compound in their psoriasis treatment." *Id.* A plaintiff cannot demonstrate the existence of a "safer alternative design" "by pointing to a substantially different product, even when the other product has the same general purpose as the allegedly defective product." *Brockert v. Wyeth Pharmaceuticals, Inc.*, 287 S.W.3d at 770 (citing *Theriot v. Danek Med., Inc.*, 168 F.3d 253). "[A] safer alternative design must be one for the product at issue," not a different product. *Id.* Massa's argument that "Raptiva could have been formulated with a number of alternative underlying compounds" is not an argument that Raptiva should have been *safer*; it is an argument that Raptiva should have been *a different product*. The argument is insufficient to satisfy Texas' requirement that a plaintiff demonstrate a "safer alternative design." Because Massa has not demonstrated the availability of a safer alternative design for Raptiva, his design

defect claim must be dismissed.

Fraudulent Concealment

"In Texas, fraud occurs when: (1) the defendant misrepresented a material fact; (2) the defendant knew the material representation was false or made it recklessly without any knowledge of its truth; (3) the defendant made the false material representation with the intent that it should be acted upon by the plaintiff; and (4) the plaintiff justifiably relied on the representation and thereby suffered injury." *United Teacher Associates Ins. Co. v. Union Labor*, 414 F.3d 558, 566 (5th Cir. 2005) (citing *Ernst & Young, L.L.P. v. Pacific Mut. Life*, 51 S.W.3d 573, 577 (Tex. 2001). "The first requirement of this test can be met if the defendant concealed or failed to disclose a material fact when a duty to disclose existed." *Id.* (citing *New Process Steel Corp., Inc. v. Steel Corp. of Texas, Inc.*, 703 S.W.2d 209, 214 (Tex.App.-Houston [1st Dist.] 1985).

Claims of fraud are held to the heightened pleading standard of Rule 9(b). "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). In the Fifth Circuit, the Rule 9(b) standard requires "specificity as to the statements (or omissions) considered to be fraudulent, the speaker, when and why the statements were made, and an explanation of why they were fraudulent." *Plotkin v. IP Axess, Inc.*, 407 F.3d 690, 696 (5th Cir. 2005).

Here, Defendants contend that Massa's "Amended Complaint fails to specify any material fact about Raptiva that Defendants allegedly concealed" and therefore fails to state a claim for fraudulent concealment. Defendants have raised no argument pertaining to the other elements. Massa contends that his complaint "identifies numerous material facts Defendants failed to disclose." Doc. 41-1 at 5. Specifically, Massa states that Defendants failed to disclose to

him or to his prescribing physician "the extent and severity of psoriasis rebound effects caused by Raptiva[,] . . . the motivation behind Defendants' effort to position Raptiva as safe for continuous use[,] . . . the lack of research on the effect of long-term Raptiva use[, and] . . . the frequency and seriousness of possible adverse events." *Id.*

The first two "material facts" fail to state a claim for fraudulent concealment and must be dismissed. Massa does not allege that he suffered "rebound effects" from his use of Raptiva and cannot, therefore, show that he "justifiably relied on the representation" that Raptiva had a lower risk of rebound effects than it actually did and "thereby suffered injury." Nor does the Court consider "the motivation behind Defendants' effort to position Raptiva as safe for continuous use" a "material fact" for purposes of this cause of action. Defendants, private corporations engaged in the business of pharmaceutical drug development, undoubtedly were motivated by the prospect of increased profits if Raptiva were sold for long term use. Massa does not allege, and the Court will not stretch to imagine, that he acted in the belief that Defendants were entirely benevolent, not-for-profit entities. Whether Massa states a claim for fraudulent concealment therefore turns on whether his complaint adequately alleges that Defendants failed to disclose research and safety information on Raptiva relating to the illness that Massa actually suffered.

In their motion to dismiss, Defendants aver that Massa's complaint "alleges generally that Defendants failed to disclose the "facts" that Raptiva 'would cause injuries,' including 'debilitating rebound effects, serious life-threatening infections (encephalitis, meningitis, and PML), lymphomas, malignancies and death.'" Doc. 38 at 12 (quoting Doc. 21 at 31, 39). Defendants, however, contend that the "Raptiva labeling specifically warned of those risks," and that "the Amended Complaint itself acknowledges that the risks of Raptiva were well known in the medical community during the entire time Plaintiff was taking it." *Id.* To the extent that

Massa claims that Defendants failed to disclose that Raptiva posed any risk of "serious life-threatening infections," he has failed to demonstrate that Defendants concealed a material fact.

Nevertheless, Massa additionally alleges that Defendants' distributed marketing materials to Massa's physician that "downplayed" the risks that existed from long-term use of Raptiva, failed to disclose the paucity of "significant studies on long-term usage," and, subsequent to FDA approval of Raptiva, failed publicly to disclose numerous adverse event reports of serious side effects and deaths from patients taking Raptiva. Doc. 21 at 13-14, 18-19, 21-23. Defendants contend that "it is not plausible that Defendants committed fraud by [not disclosing adverse event reports to prescribing physicians or patients when those events] . . . were fully disclosed to the FDA." Doc. 38. As Massa states in his response, however, "FDA adverse event reports are not independently transmitted to physicians, and in fact are extremely difficult for private parties to access." Doc. 41-1 at 5-6. Contrary to Defendants' assertion, this Court can find no authority for the proposition that disclosure of adverse event reports to the FDA satisfies a prescription drug manufacturer's common law duty to disclose material facts.

Relatively recently, the Supreme Court considered a similar issue and determined that state-law "failure to warn" claims against pioneer drug manufacturers (not generic manufacturers) were not pre-empted by the FDA's labeling-approval authority pursuant to the FDCA. *Wyeth v. Levine*, 555 U.S. 555, 129 S.Ct. 1187 (2009). Here, Defendants have not raised a pre-emption issue, but seem to suggest that compliance with FDA reporting requirements is sufficient to satisfy a purported common law duty of disclosure. The Court disagrees. In the face of an otherwise well-pleaded claim for fraudulent concealment, Defendants cannot discharge their duty to disclose material facts to the Plaintiff simply by disclosing those facts to the FDA when that disclosure is not publicly available and readily accessible to the Plaintiff. The

Defendants' motion to dismiss Massa's claim for fraudulent concealment as it relates to the extent and validity of the studies relating to long-term use of Raptiva and adverse event reports is denied.

Breach of Warranty Claims

Finally, Defendants move to dismiss Massa's breach of express and implied warranty claims on the grounds that Defendants at no time "expressly warranted that Raptiva was safe" and that Massa's failure to state a claim for design defect equally is fatal to his implied warranty claim. Doc. 42 at 14-17.

To state a claim for breach of an express warranty in Texas, "a plaintiff must prove: (1) an express affirmation of fact or promise by the seller relating to the goods; (2) that such affirmation of fact or promise became a part of the basis of the bargain; (3) that the plaintiff relied upon said affirmation of fact or promise; (4) that the goods failed to comply with the affirmations of fact or promise; (5) that the plaintiff was injured by such failure of the product to comply with the express warranty; and (6) that such failure was the proximate cause of plaintiff's injury." *Morris v. Adolph Coors Co.*, 735 S.W.2d 578, 587 (Tex.App.–Fort Worth 1987) (citing *Gen. Supply & Equip. Co. v. Phillips*, 490 S.W.2d 913, 917 (Tex.Civ.App.—Tyler 1972); TEX BUS. & COM. CODE ANN. §. 2.313 (Vernon 1968)).

Massa asserts that Defendants "expressly warranted [Raptiva] to be safe for use by Plaintiff . . . [and warranted Raptiva] to be in all respects, [sic] fit, safe, and effective and proper for" the treatment of psoriasis. Doc. 21 at 30. Massa's assertions are directly contradicted by the Raptiva labeling, which warned patients that Raptiva "can cause serious side effects . . . [that Raptiva] can affect your immune system and might cause . . .[s]erious infections[,] . . . [c]ancers[, or] . . . [w]orsening of psoriasis." Doc. 38-1 at 28. Defendants point out that the label

also warned patients that "[t]he safety and efficacy of [Raptiva] therapy beyond 1 year have not been established" and that "[t]he long-term immunogenicity of [Raptiva] is unknown." *Id.* at 8, 20. In light of the warnings contained in the Raptiva patient and physician labeling, Massa's contention that Defendants' publicity campaigns touting the safety of Raptiva formed an "express affirmation of fact or promise" that Raptiva was safe is erroneous.

Massa also fails to state a claim for breach of implied warranty. "In a products liability case [under Texas law], the implied warranty of merchantability is breached if the product was defective when it left the manufacturer's or seller's possession and was unfit for the ordinary purposes for which it is used because of a lack of something necessary for adequacy." *Sipes v. General Motors Corp.*, 946 S.W.2d 143, 158 (Tex.App.–Texarkana 1997) (citing *Hyundai Motor Co. v. Chandler*, 882 S.W.2d 606, 612 (Tex.App.-Corpus Christi 1994)). *See also Nobles v. Sofamor, S.N.C.*, 81 F.Supp.2d 735, 741 (S.D.Tex. 1999) ("A plaintiff in an implied warranty of merchantability case must prove that the good complained of was defective at the time it left the manufacturer's or seller's possession."). Because the Court already has found that Massa failed to demonstrate that Raptiva was defectively designed, his claim for breach of implied warranty also must fail. Massa's claims for breach of express and implied warranty are dismissed.

Conclusion

For the foregoing reasons, the Court hereby

ORDERS that Defendants Genentech Inc. and XOMA US Inc.'s motion for partial dismissal of Plaintiff Cary Massa's amended complaint is **GRANTED** as to Counts Two, Four, Five, Nine, Eleven, and Twelve and **DENIED** as to Counts Six and Thirteen.

SIGNED at Houston, Texas, this 19th day of March, 2012.

MELINDA HARMON
UNITED STATES DISTRICT JUDGE