UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

REBECCA A. SMALL and
LAWRENCE W. SMALL

Plaintiffs,

v. Case No: 2:12-cv-476-FtM-29DNF

AMGEN, INC., PFIZER, INC.,
and WYETH, INC.,

Defendants.

OPINION AND ORDER

This matter comes before the Court on review of defendants' Motion to Dismiss (Doc. #55) filed on May 17, 2013. Plaintiffs filed a Response in Opposition (Doc. #59) on June 14, 2013. Defendants filed a Reply (Doc. #62) on June 28, 2013, and plaintiffs filed a Sur-Reply (Doc. #65) on July 5, 2013.

I.

Under Federal Rule of Civil Procedure 8(a)(2), a Complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This obligation "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)(citation omitted). To survive dismissal,

the factual allegations must be "plausible" and "must be enough to raise a right to relief above the speculative level." Id. at 555. See also Edwards v. Prime Inc., 602 F.3d 1276, 1291 (11th Cir. 2010). This requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)(citations omitted).

In deciding a Rule 12(b)(6) motion to dismiss, the Court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff, Erickson v. Pardus, 551 U.S. 89 (2007), but "[l]egal conclusions without adequate factual support are entitled to no assumption of truth," Mamani v. Berzain, 654 F.3d 1148, 1153 (11th Cir. 2011)(citations omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678. "Factual allegations that are merely consistent with a defendant's liability fall short of being facially plausible." Chaparro v. Carnival Corp., 693 F.3d 1333, 1337 (11th Cir. 2012) (internal quotation marks and citations omitted). Thus, the Court engages in a two-step approach: "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Iqbal, 556 U.S. at 679.

II.

On August 29, 2012, plaintiffs Rebecca and Lawrence Small filed a six count complaint against Amgen, Inc., Wyeth, Inc., Pfizer, Inc., and Does 1-20.[1] Plaintiffs amended their complaint on October 30, 2012, but it was subsequently dismissed as an impermissible shotgun pleading. (Doc. #53.) Plaintiffs are now relying on their Fourth Amended Complaint which sets forth the following five claims based on injuries allegedly caused by the prescription drug Enbrel: (I) strict liability based on a design defect; (II) strict liability based on a failure to warn; (III) breach of an express warranty; (IV) negligence; and (V) loss of consortium. (Doc. #54.) In support, plaintiffs allege the following:

The prescription drug Enbrel is a "biologic" drug used to treat rheumatoid arthritis.[2] (Doc. #54, ¶¶ 15, 19.) Enbrel was originally developed by Amgen and, at all relevant times, the drug was marketed and sold by both Amgen and Wyeth. (Id. ¶¶ 16-17.) On October 15, 2009, Wyeth was acquired by Pfizer. (Id ¶ 18.)

[1]Does 1-20, unknown defendants, are no longer parties to this action.

[2]A "biologic" drug is a medicine that has been constituted or reconstituted from natural substances in the body. (Doc. #54, ¶ 15.)

In 2002, Ms. Small began receiving two subcutaneous injections of Enbrel a week to treat her rheumatoid arthritis. (Id. ¶ 22.) Ms. Small continued the treatment until August 29, 2008, when she was admitted to the hospital on an emergency basis and was diagnosed with a perforated bowel from a diverticulitis infection that was caused by her use of Enbrel. Until a few days before her hospitalization, Ms. Small was asymptomatic. Multiple surgeries were required to treat the infection. (Id. ¶ 26.)

Following her release from the hospital, Ms. Small visited her rheumatologist, Dr. Catherine Kowal. Dr. Kowal consulted with a sales representative regarding Enbrel and was ensured by the representative that it was appropriate to resume Ms. Small's treatment with Enbrel three months after the serious adverse effects occurred. (Id. ¶ 27.) Ms. Small experienced another round of complications associated with her use of Enbrel requiring additional surgeries and treatment. (Id. ¶ 28.)

At no time prior to Ms. Small's injuries were doctors and patients warned that Enbrel could cause asymptomatic serious infections. The label accompanying Enbrel at the time of Ms. Small's injuries included the following boxed warning:

> Infections, including serious infection leading to hospitalization or death, have been observed in patients treated with ENBREL® (see **WARNINGS** and **ADVERSE REACTIONS**). Infections have included bacterial sepsis and tuberculosis. Patients should be

> educated about the symptoms of infection and closely monitored for signs and symptoms of infection during and after treatment with ENBREL®. Patients who develop an infection should be evaluated for appropriate antimicrobial treatment and, in patients who develop a serious infection, ENBREL® should be discontinued.

(Id. ¶ 29.) In addition to the boxed warning, a patient information sheet or medication guide accompanying the drug contained the following instructions to patients:

> **After starting ENBREL®**, if you get an infection, any signs of an infection including a fever, cough, flu-like symptoms, or have any open sores on your body, **call your doctor right away**. ENBREL® can make you more likely to get infections or make any infection that you may have worse.

(Id. ¶ 30.) Although the warnings for Enbrel have mentioned "infections" since at least 2002, the Food and Drug Administration (FDA) has required that additional warnings covering histoplasmosis and other fungal infections be added to the label. (Id. ¶ 37.)

III.

Defendants' assert in their Motion to Dismiss that the Fourth Amended Complaint still constitutes a shotgun pleading, plaintiffs were adequately warned about the potential side effects of Enbrel, plaintiffs failed to allege any facts to support their defective design claim, plaintiffs failed to identify an express warranty, and plaintiffs failed to identify

any negligent conduct. (Doc. #55.) The Court will address each argument in turn.

A. Shotgun Pleading

Defendants contend that the Fourth Amended Complaint still constitutes a shotgun pleading because plaintiffs simply removed the language incorporating the preceding paragraphs into each count and replaced it with a section titled "Factual Allegations Relevant to All Causes of Action." In response, plaintiffs argue that the Fourth Amended Complaint does not constitute a shotgun pleading because the offending language was removed and the facts are relevant to all of their claims.

A typical shotgun pleading is a pleading that "incorporate[s] every antecedent allegation by reference into each subsequent claim for relief or affirmative defense." Wagner v. First Horizon Pharm. Corp., 464 F.3d 1273, 1279 (11th Cir. 2006). A complaint incorporating a long list of general allegations into each claim for relief will also constitute a shotgun pleading if it fails to specify which facts are relevant to each claim. Johnson Enters. of Jacksonville, Inc. v. FPL Group, Inc., 162 F.3d 1290, 1333 (11th Cir. 1998). The problem with a shotgun complaint is that most of the counts "contain irrelevant factual allegations and legal conclusions." Strategic Income Fund, L.L.C. v. Spear, Leeds & Kellogg Corp., 305 F.3d 1293, 1295 (11th Cir. 2002); see also Anderson v. Dist.

Bd. of Trs. of Cent. Fla. Cmty. Coll., 77 F.3d 364, 366 (11th Cir. 1996) (The general problem with shotgun pleadings is that "it is virtually impossible to know which allegations of fact are intended to support which claim(s) for relief.")

The Eleventh Circuit has routinely and explicitly condemned "shotgun pleadings," Davis v. Coca-Cola Bottling Co. Consol., 516 F.3d 955, 979 n.54 (11th Cir. 2008), and has stated that neither the district courts nor the defendants are required to "sift through the facts presented and decide for itself which were material to the particular cause of action asserted." Beckwith v. Bellsouth Telecomms. Inc., 146 F. App'x 368, 372 (11th Cir. 2005) (quoting Strategic Income Fund, LLC v. Spear, Leeds & Kellogg Corp., 305 F.3d 1293, 1296 n.9 (11th Cir. 2002) (citations omitted)).

The Fourth Amended Complaint is far from exemplary, but does not amount to an impermissible shotgun pleading. The problem with a shotgun pleading is that each subsequent count is replete with irrelevant factual allegations and legal conclusions. Here, the complaint simply contains a section of general factual allegations that are relevant to all of plaintiffs' claims. The legal conclusions are not incorporated into each subsequent count. Given that all of the claims are based upon Ms. Small's use of Enbrel, the Court finds that the use of general factual allegation section is not problematic.

Therefore, defendants' motion to dismiss the Fourth Amended Complaint as a shotgun pleading is denied.

B. Count I: Strict Liability – Defective Design

In order to state a claim in Florida for strict products liability, a plaintiff must allege (1) the manufacturer's relationship to the product in question, (2) the unreasonably dangerous condition of the product, and (3) the existence of a proximate causal connection between such condition the user's injuries or damages. Bailey v. Janssen Pharmaceutica, Inc., 288 F. App'x 597, 604 (11th Cir. 2008) (citing West v. Caterpillar Tractor Co., 336 So. 2d 80, 87 (Fla. 1976). Defendants contend that Count I should be dismissed because plaintiffs have failed allege a single fact in support of the products unreasonably dangerous condition. The Court disagrees.

Plaintiffs allege that "Enbrel® contained an unreasonably dangerous defect in design or formulation in that, when it left the hands of the Defendants, an average consumer could not reasonably anticipate the dangerous nature of Enbrel® nor fully appreciate the attendant risk of injury associated with Enbrel®." (Doc. #54, ¶ 46.) Plaintiffs further allege that Ms. Small experienced severe and significant infections due to the design defect. (Id. ¶¶ 23, 49-50.) The Eleventh Circuit has observed that "[t]he very nature of a products liability action-where the cause or source of the defect is not obvious to the

consumer-would make it difficult for [a plaintiff] to pinpoint a specific source of defect against one entity along the chain of distribution prior to discovery." Bailey, 288 F. App'x at 605. Although plaintiffs do not set forth the precise chemical, biological, or other process by which Enbrel causes asymptomatic infections, they do place defendants on notice of the type of harm allegedly caused by the design defect. At this stage of the proceedings, the Court finds that the allegations of an unreasonably dangerous defect are sufficient to plausibly state a strict liability claim based on a design defect. See Bailey, 288 F. App'x at 608. Therefore, defendants' motion to dismiss Count I of the Fourth Amended Complaint is denied.

C. Count II: Strict Liability - Failure to Warn

"As a general rule, drug companies have the duty to warn of a drug's dangerous side effects; however, the duty to warn is directed to physicians rather than patients under the 'learned intermediary' doctrine." Hoffmann-La Roche, Inc. v. Mason, 27 So. 3d 75, 77 (Fla. 5th DCA 2009) (citing Felix v. Hoffmann-La Roche, Inc., 540 So. 2d 102, 104 (Fla. 1989)). The duty to warn is satisfied if the drug manufacturer gives an adequate warning to the physician who prescribes the drug. Buckner v. Allegran Pharms, Inc., 400 So. 2d 820, 822 (Fla. 5th DCA 1981). In determining the adequacy of a warning, the critical inquiry is whether it was adequate to warn the physician of the possibility

that the drug may cause the injury alleged by the plaintiff. Upjohn Co. v. MacMurdo, 562 So. 2d 680, 683 (Fla. 1990). The sufficiency and reasonableness of a warning is generally a question of fact, but "can become a question of law where the warning is accurate, clear, and unambiguous." Felix, 540 So. 2d at 105.

Plaintiffs allege that defendants failed to adequately warn health care providers that Enbrel was associated with an increased risk of complications arising from serious and significant infection and failed to adequately instruct doctors and patients how to mitigate risks of infections, including asymptomatic infections, associated with the use of Enbrel. (Doc. #54, ¶¶ 54, 56.) Defendants contend that Packaging Insert accompanying Enbrel was adequate as a matter of law because it broadly and clearly warned Ms. Small's physician of the risk of infection. In support of their position, defendants rely on Salvio v. Amgen, Inc., No. 2:11-cv-00553, 2012 WL 517446 (W.D. Pa. Feb. 15, 2012). In Salvio, the court dismissed a failure to warn claim brought under Pennsylvania law because it determined that the "broad" warning of infection accompanying Enbrel adequately warned the decedent's doctors of the injury that occurred, a serious infection resulting in death. Id. at *5-6. Defendants requests that this Court follow the holding in Salvio by finding that the broad warning of infection accompanying

Enbrel adequately warned Ms. Small's physicians of the risk of a serious asymptomatic infection.

A review of the warning label reveals that it not only provides a broad and general warning of infection, but also includes warnings regarding specific types of infections ("Infections have included bacterial sepsis and tuberculosis"). Because the warning label does not specifically warn of asymptomatic infections, however, the Court finds that a determination as to the adequacy of such a broad warning of infection is best left for a later stage of the proceedings. Plaintiffs have plausibly stated a cause of action. Accordingly, defendants' motion to dismiss Count II is denied.

D. Count III: Breach of Express Warranty

Defendants assert that plaintiffs' breach of express warranty claim should be dismissed because it is conclusory in nature. The Court disagrees. An express warranty is "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes a basis of the bargain[.]" Fla. Stat. § 672.313(1)(a). However, "an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." Fla. Stat. § 672.313(2). The existence of an express warranty is a factual issue for the

jury to decide. State Farm Ins. Co. v. Nu Prime Roll-A-Way of Miami, 557 So. 2d 107, 109 (Fla. 3d DCA 1990).

Plaintiffs allege that defendants expressly warranted in the package inserts, the Physicians' Desk Reference, other marketing literature, and documents provided to the FDA, that Enbrel was of merchantable quality, fit, safe, and otherwise not injurious to the health and well-being of Ms. Small.[3] (Doc. #54, ¶ 66.) Plaintiffs further allege that these representations were material to Ms. Small's decision to use Enbrel and that product did not conform to the representations. As a result of the product's nonconformity, she was injured. (Id. ¶¶ 67-71.) The Court finds that these allegations are sufficient to plausibly state a claim for breach of an express warranty. Therefore, defendants' motion to dismiss Count III of the Fourth Amended Complaint is denied.

E. Count IV: Negligence

In order to state a claim for negligence under Florida law, the plaintiff must allege (1) a duty or obligation recognized by the law requiring the defendant to protect others from

[3]In response to defendants' motion to dismiss, plaintiffs attempt to include the promises made by defendants' sales representative in their breach of express warranty claim. Plaintiffs, however, have failed to include any allegations regarding the representative's promises in Count III. Accordingly, the Court declines to include them among the alleged warranties.

unreasonable risks; (2) a breach of that duty; (3) a reasonably close casual connection between the conduct and the resulting injury; and (4) actual loss or damages. Williams v. Davis, 974 So. 2d 1052, 1056 (Fla. 2007) (citing Clay Elec. Corp. v. Johnson, 873 So. 2d 1182, 1185 (Fla. 2003)). Here, plaintiffs allege that "Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Enbrel® . . . ." (Doc. #54, ¶ 74.) Defendants assert that there is not a single fact in the Fourth Amended Complaint to support the assertion that Enbrel was negligently designed or manufactured.[4] For the reasons set forth in Section 3.B above, the Court finds that plaintiffs have plausibly stated a claim for a design defect, and for the same reasons, the Court finds that the allegations are sufficient to support a claim of negligent manufacturing. See Hosler v. Alcon Labs., Inc., No. 12-60025-CIV, 2012 WL 4792983, at *6 (M.D. Fla. Oct. 9, 2012) (citing Bailey, 288 F. App'x at 605). Defendants also assert that a claim for negligent testing is subsumed by plaintiffs' claims for defective design and failure to warn. To this the

[4]Defendants also assert that the negligent failure to warn claim fails under the learned intermediary doctrine, but, as discussed above, the Court is unable to determine if the warning label is adequate as a matter of law. Therefore, plaintiffs may proceed on their negligent failure to warn claim.

Court agrees. In Florida, no separate duty or claim exists for testing or inspecting a product because it is part of the manufacturer's duty to design a product with reasonable care; thus, it is subsumed in claims for defective design and failure to warn. Hall v. Sunjoy Indus. Grp., Inc., 764 F. Supp. 2d 1297, 1302 (M.D. Fla. 2011) (citing Adams v. G.D. Searle & Co., Inc., 576 So. 2d 728, 730-31 (Fla. 2d DCA 1991)). Accordingly, plaintiffs' claim for negligence cannot rest on defendants' alleged failure to test or inspect.

Plaintiffs also allege that defendants breached the duty of pharmacovigilance, which includes the duties to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of Enbrel. (Doc. #59, ¶¶ 85-86.) In support of the alleged breach, plaintiffs assert that defendants learned through clinical trials and adverse event reports that there was a serious problem associated with Enbrel, but failed to adequately inform doctors, regulatory agencies, and the public of the risk. (Id. ¶ 86.) Plaintiffs further allege that defendants' failure to comply with the post marketing requirements of FDA regulations is evidence of defendants' negligence and also constitutes negligence per se. (Id. ¶ 91.)

Defendants contend that plaintiffs cannot assert a claim of negligence per se for the failure to comply with FDA regulations because Florida law does not recognize a claim for negligence

per se for the alleged violation of the Federal Food, Drug, and Cosmetic Act (FDCA). District courts in this Circuit have consistently held that private actions based on the violation of FDA regulations are barred because Florida does not recognize such causes of action. Kaiser v. Depuy Spine, Inc., 944 F. Supp. 2d 1187, 1192 (M.D. Fla. 2013). See also Cook v. MillerCoors, LLC, 872 F. Supp. 2d 1346, 1351 (M.D. Fla. 2012). Thus, Count IV is dismissed to the extent that plaintiffs assert a negligence per se claim based on defendants' alleged violations of FDA regulations.

Accordingly, it is now

ORDERED:

Defendants' Motion to Dismiss (Doc. #55) is **GRANTED** in part and **DENIED** in part. Count IV is dismissed in part to the extent that plaintiffs assert a claim for the negligent failure to test or inspect, and to the extent that plaintiffs assert a claim of negligence per se. The motion is otherwise denied.

DONE AND ORDERED at Fort Myers, Florida, this 6th day of March, 2014.

JOHN E. STEELE
UNITED STATES DISTRICT JUDGE

Copies:

Counsel of record