Wholey v Amgen Inc.
2017 NY Slip Op 30468(U)
March 8, 2017
Supreme Court, New York County
Docket Number: 162934/2015
Judge: Eileen A. Rakower

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: PART 15

----------X

Lauren Wholey and Thomas Rosenbluth,

Index No.
162934/2015

Plaintiffs,

- against -

DECISION and ORDER

Amgen Inc., Wyeth, Inc., Wyeth LLC, Wyeth Pharmaceuticals, Inc., and Pfizer, Inc.,

Mot. Seq. 5

Defendants.

----------X

HON. EILEEN A. RAKOWER, J.S.C.

The plaintiffs, Lauren Wholey ("Ms. Wholey") and her husband Thomas Rosenbluth (collectively, "Plaintiffs") filed this action to recover damages for injuries that Ms. Wholey allegedly suffered from her use of the prescription drug Enbrel for the treatment of her rheumatoid arthritis. Ms. Wholey alleges that she developed tongue cancer (squamous cell carcinoma) as the result of her use of Enbrel.

The First Amended Complaint ("Amended Complaint") allege products liability, negligence, fraud, breach of warranty, and unfair and deceptive trade practices causes of action.

Presently before the Court is a motion by Wyeth LLC (incorrectly named as "Wyeth, Inc."), Wyeth Pharmaceuticals Inc., and Pfizer Inc.'s ("Pfizer") (collectively "Defendants") to dismiss the claims in the Amended Complaint, pursuant to CPLR 3211(a)(7) and 3016(b). Plaintiffs oppose.

The following facts are alleged in the Amended Complaint and assumed to be true for the purposes of this motion.

The prescription drug Enbrel is a biologic drug used for the treatment of rheumatoid arthritis. Defendants Wyeth LLC and Wyeth Pharmaceuticals, Inc.

(collectively, "Wyeth"), Amgen Inc. ("Amgen") are alleged to be "the designer, marketer, distributor, and seller of the prescription drug Enbrel." On October 15, 2009, Wyeth was acquired by Pfizer.

Ms. Wholey used Enbrel from 1998 through 2005. Ms. Wholey first used Enbrel in a clinical trial from 1998 through 2000. After the clinical trial concluded in 2000, Ms. Wholey continued to use Enbrel from 2000 to 2005. She stopped taking Enbrel in 2005. In April 2012, Ms. Wholey developed squamous cell carcinoma of the tongue. Ms. Wholey had surgery to remove the tumor and reconstruct her tongue using tissue from her arm, and then had skin graft surgery to repair her arm.

The Amended Complaint alleges, "At no time prior to Plaintiff Lauren Wholey's injuries were doctors and patients warned that Enbrel could cause tongue cancer, despite limited mention concerning malignancies." The Amended Complaint further alleges, "The most recent label at the time of Plaintiff Lauren Wholey's last use included the following language" within its warning section:

> **Malignancies**
>
> In the controlled portions of clinical trials of all the TNFblocking agents, more cases of lymphoma have been observed among patients receiving the TNF blocker compared to control patients. During the controlled portions of ENBREL® trials, 3 lymphomas were observed among 4509 ENBREL® -treated patients versus 0 among 2040 control patients (duration of controlled treatment ranged from 3 to 24 months). In the controlled and open-label portions of clinical trials of ENBREL®, 9 lymphomas were observed in 5723 patients over approximately 11201 patient-years of therapy. This is 3-fold higher than that expected in the general population. While patients with rheumatoid arthritis or psoriasis, particularly those with highly active disease, may be at a higher risk (up to several fold) for the development of lymphoma, the potential role of TNF-blocking therapy in the development of malignancies is not known (see **ADVERSE REACTIONS: Malignancies).**

In addition, the following language was contained within the adverse event section:

Patients have been observed in clinical trials with ENBREL® for over five years. Among 4462 rheumatoid arthritis patients treated with ENBREL® in clinical trials for a means of 27 months (approximately 1000 patient-years. This is 3-fold higher than the rate of lymphomas expected in the general population based on the Surveillance, Epidemiology, and End Results Database.[10] An increased rate of lymphoma up to several fold has been reported in the rheumatoid arthritis patient population, 6 and may be further increased in patients with more severe disease activity[11] [12]. (see WARNINGS:6 Malignancies). Sixty-seven malignancies, other than lymphoma, were observed. Of these, the 700 most common malignancies were colon, breast, lung and prostate, which were similar in type and number to what would be expected in the general population.[10] Analysis of the cancer rates is 6 month intervals suggest constant rates over five years of observation.

In the placebo-controlled portion of the psoriasis studies, 8 of 933 patients who received 704 ENBREL® at any dose were diagnosed with a malignancy compared to 1 of 414 patients who received placebo. Among the 1261 patients with psoriasis who received ENBREL® at any dose in 7 the controlled and uncontrolled portions of the psoriasis studies (1062 patient-years), a total of 22 7 patients were diagnosed with 23 malignancies; 9 patients with non-cutaneous solid tumors, 12 708 patients with 13 non-melanoma skin cancers (8 basal, 5 squamous), and 1 patient with non-Hodgkin's lymphoma. Among the placebo treated patients (90 patient-years of observation) 1 patient was diagnosed with 2 squamous cell cancers. The size of the placebo group and limited duration of the controlled portions of studies precludes the ability to draw firm conclusions.

On November 18, 2009, the following warning and language was added to the Enbrel label:

> WARNINGS: SERIOUS INFECTIONS AND MALIGNANCIES
>
> SERIOUS INFECTIONS
>
> Patients treated with Enbrel are at increased risk for developing serious infections that may lead to hospitalization or death [see Warnings and Precautions (5.1) and Adverse Reactions (6)]. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticorsteroids.
>
> Enbrel should be discontinued if a patient develops a serious infection or sepsis.
>
> Reported infections include:
>
> Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before Enbrel use and during therapy. Treatment for latent infection should be initiated prior to Enbrel use.
>
> Invasive fungal infections, including histoplasmosis, coccidiodomycosts, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systematic illness.

Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.

The risks and benefits of treatment with Enbrel should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Enbrel, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including Enbrel.

Melanoma and Non-melanoma skin cancer (NMSC)

Melanoma and non-melanoma skin cancer has been reported in patients treated with TNF antagonists including etanercept.

Among 14, 401 patients with Enbrel in controlled and open portions of clinical trials representing approximately 23,325 patient-years of therapy, the observed rate of melanoma was 0.043 cases per 100 patient-years.

Among 3306 adult rheumatology (RA, PsA, AS) patients treated with Enbrel in controlled clinical trials representing 2669 patient-years therapy, the observed rate of NMSC was 0.41 cases per 100 patients-years vs 0.37 cases per 100 patient-years among 1,521 control-treated patients representing 1077 patient-years. Among 1245 adult psoriasis patients treated with Enbrel in controlled clinical trials, representing approximately 283 patient-

years of therapy, the observed rate of NMSC was 3.54 cases per 100 patient-years vs 1.28 cases per 100 patient-years among 720 control-treated patients representing 156 patient-years.

Postmarketing cases of Merkel cell carcinoma have reported very infrequently in patients treated with Enbrel.

Pediatric Patients

Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blocking agents (initiation of therapy at $\leq$ 18 years of age), including Enbrel. Approximately half the cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of different malignancies and included rare malignancies usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months of therapy (range 1 to 84 months). Most of the patients were receiving concomitant immunosuppressants. These cases were reported postmarketing and are derived from a variety of sources, including registries and spontaneous postmarketing reports.

In clinical trials of 1140 pediatric patients representing 1927.2 patient-years of therapy, no malignancies lymphoma or NMSC have been reported.

Plaintiffs allege that the information added to the Enbrel label on November 18, 2009 "was known to Defendants before Plaintiff Lauren Wholey stopped taking Enbrel, but was not included in the product label."

Claims Asserted in First Amended Complaint

CPLR § 3211 provides, in relevant part:

> (a) a party may move for judgment dismissing one or more causes of action asserted against him on the ground that:
>
> (7) the pleading fails to state a cause of action.

In determining whether dismissal is warranted for failure to state a cause of action, the court must "accept the facts alleged as true ... and determine simply whether the facts alleged fit within any cognizable legal theory." (*People ex rel. Spitzer v. Sturm, Ruger & Co., Inc.*, 309 AD2d 91 [1st Dep't, 2003] [internal citations omitted]; CPLR § 3211[a][7]).

A. First Cause of Action: Strict Liability – Defective Design and Defective Manufacturing

"A product may be defective when it contains a manufacturing flaw, is defectively designed or is not accompanied by adequate warnings for the use of the product." (*Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 [1998]).

The first cause of action of the Amended Complaint is for strict liability for Defendants' "defective design and defective manufacturing" of Enbrel. Defendants contend that the first cause of action should be dismissed because Plaintiffs have failed to sufficiently allege a defective design or manufacturing claim. Defendants also contend that the cause of action should be dismissed because any claim for defective design of an FDA- approved drug is preempted as a matter of law.

With respect to a strict liability claim for defective manufacturing, "[a] manufacturer who places a defective product on the market that causes injury may be liable for the ensuing injuries." (*Liriano*, 92 N.Y.2d at 237). "Manufacturing defects, by definition, are 'imperfections that inevitably occur in a typically small percentage of products of a given design as a result of the fallibility of the manufacturing process.'" (*Caprara v. Chrysler Corp.*, 52 N.Y.2d 114, 128 [1981]). "A [defectively manufactured] product does not conform in some significant aspect to the intended design, nor does it conform to the great majority of products manufactured in accordance with that design." (*Caprara*, 52 N.Y.2d at 128). "Stated

differently, a defectively manufactured product is flawed because it is misconstructed without regard to whether the intended design of the manufacturer was safe or not." (*Id.*) Manufacturing defects "result from some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction." (*Id.* at 128-29).

In the Amended Complaint, Plaintiffs allege that Enbrel "was manufactured ... by Defendants in a defective and unreasonably dangerous condition." Plaintiffs fail to allege how the manufacture of the Enbrel taken by Ms. Wholey was defective, or how the product "[did] not conform in some significant aspect to the intended design, nor ... to the great majority of products manufactured in accordance with that design." (*Caprara*, 52 N.Y.2d at 128-29). Plaintiffs' conclusory allegations are insufficient to state a manufacturing defect claim.

With respect to a strict liability claim based on a design defect, "[a] defectively designed product 'is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use; that is one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce.'" (*Scarangella v. Thomas Built Buses, Inc.*, 93 N.Y.2d 655, 659 [1999] [citations omitted]). "A manufacturer can be held liable for selling a defectively designed product because the manufacturer 'is in the superior position to discover any design defects and alter the design before making the product available to the public.'" (*Scarangella*, 93 N.Y.2d at 659). "[U]nlike manufacturing defects, design defects involve products which are made in precise conformity with the manufacturer's design but nevertheless result in injury to the user because the design itself was improper." (*Caprara*, 52 N.Y.2d at 129).

"[D]etermining the existence of a design defect has required an assessment of whether 'if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner.'" (*Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 257 [1995] (citations omitted)). "This standard demands an inquiry into such factors as (1) the product's utility to the public as a whole, (2) its utility to the individual user, (3) the likelihood that the product will cause injury, (4) the availability of a safer design, (5) the possibility of designing and manufacturing the product so that it is safer but remains functional and reasonably priced, (6) the degree of awareness of the product's potential danger that can reasonably be

attributed to the injured user, and (7) the manufacturer's ability to spread the cost of any safety-related design changes." (*Denny*, 87 N.Y.2d at 257).

"Under a doctrine of strict products liability, the manufacturer of a defective product is liable to any person injured or damaged if the defect was a substantial factor in bringing about his injury or damages; provided: (1) that at the time of the occurrence the product is being used (whether by the person injured or damaged or by a third person) for the purpose and in the manner normally intended, (2) that if the person injured or damaged is himself the user of the product he would not by the exercise of reasonable care have both discovered the defect and perceived its danger, and (3) that by the exercise of reasonable care the person injured or damaged would not otherwise have averted his injury or damages." (*Codling v. Paglia*, 32 N.Y.2d 330, 342 [1973]).

In the Amended Complaint, Plaintiffs allege that Enbrel was designed by Defendants "in a defective and unreasonably dangerous condition." Plaintiffs further allege that "Enbrel was defective at the time it was placed in the stream of commerce" in various ways, including:

> a. When placed in the stream of commerce, the Enbrel had unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Plaintiff Lauren Wholey to risks which exceeded the benefits of the drugs; b. When placed in the stream of commerce, Enbrel was defective in design and formulation, because making use of the drugs was more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with TNF therapy; c. When placed in the stream of commerce, the warnings accompanying these Enbrel prescriptions—both the Patient Information Sheet ("PIS") distributed direct to the ultimate consumer and the labeling distributed to prescribing physicians through the Physician's Desk Reference ("PDR")—failed to adequately and completely inform such patients and their physicians of the risks associated with the use of said drugs; d. Enbrel was insufficiently tested; e. The benefits of using Enbrel was outweighed by the risks of developing tongue cancer and other injuries similar to that suffered by

> Plaintiff Lauren Wholey. f. Enbrel was distributed in violation of numerous statutory and regulatory provisions designed for the safety of the ultimate consumer and, as such was defective.

Plaintiffs further allege:

> Prior to the approval by the F.D.A., Defendants submitted an application to the FDA to begin testing "Enbrel" in humans. Before seeking approval for Enbrel, defendants developed a product which would ultimately be called Enbrel. Until the application was submitted to the FDA, Defendants had complete control over what constituted Enbrel and evaluated multiple formulations before selecting which would be submitted to the FDA. There were other substances considered by Defendants to be submitted as Enbrel during the development program. Compared to the other substances which could have been submitted as Enbrel, the substance actually submitted as Enbrel's risks outweighed the benefits of the other potential candidates. The FDA does not regulate the development of substance before submission to the FDA.

Plaintiffs further allege that Ms. Wholey experienced serious and permanent injuries from using Enbrel.

Defendants argue that that Plaintiffs' design defect claim fails because there are insufficient facts to support the claim and no alternative design is possible for a biologic drug such as Enbrel. Defendants further argue that any design defect claim would be preempted under *Mutual Pharm Co. v. Bartlett*, 133 S. Ct. 2466, 2475 [2013]).

Concerning Defendants' preemption argument, the Supremacy Clause establishes that federal law "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl.2. "A fundamental principle of the Constitution is that Congress has the power to preempt state law." (*Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 [2000]). State law is preempted by federal law in the following circumstances: (1) "[w]hen Congress intends federal law to 'occupy the field,'" or (2) where state

law conflicts with a federal statute. *Id.* (citation omitted). (*Id.*). Conflict preemption exists "where it is impossible for a private party to comply with both state and federal law." (*Id.*). "Impossibility pre-emption is a demanding defense." (*Wyeth v. Levine*, 555 U.S. 555, 573 [2009]). Courts must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." (*Id.* at 565 [citation omitted)]).

In *Bartlett*, the issue before the Supreme Court was "whether federal law pre-empts the New Hampshire design-defect claim under which respondent Karen Bartlett recovered damages from petitioner Mutual Pharmaceutical, the manufacturer of sulindac, a generic nonsteroidal anti-inflammatory drug (NSAID)." (133 S.Ct. at 2470). The *Bartlett* Court held that plaintiff's state design defect claim asserted under New Hampshire law against Mutual Pharmaceutical, a generic drug manufacturer, was preempted by federal law because: (1) FDA regulations requires "a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based" and therefore prohibits the manufacturer from altering the composition of the generic drug; and (2) "because of sulindac's simple composition, the drug is chemically incapable of being redesigned." (*Id.*).

In *Yates v. Ortho-McNeilJanssen Pharm., Inc.*, 808 F.3d 281, 299 (6th Cir. 2015), the plaintiff seeking to avoid preemption of a design defect claim argued that, notwithstanding *Bartlett*, there was "no federal law that would have prohibited defendants from designing a different drug in the first instance," and that a different, safer design "was possible prior to submitting for FDA approval." The *Yates* Court, applying New York law, held:

> To imagine such a pre-approval duty exists, we would have to speculate that had defendants designed [their product] differently, the FDA would have approved the alternate design. Next, we would have to assume that [plaintiff] would have selected this [alternate product]. Further yet, we would have to suppose that this alternate design would not have caused [plaintiff] to suffer a stroke. This is several steps too far. Even if New York law requires defendants to produce and market a different design, the ultimate availability to [plaintiff] is contingent

> upon whether the FDA would approve the alternate design in the first place.

(*Id.*).

Defendants argue that similar to *Bartlett*, and in accordance with *Yates*, "It is neither legally nor scientifically possible for Defendants to now change the 'design' of an FDA-approved biologic such as Enbrel®...[and] Plaintiffs cannot evade preemption through speculation that in some alternative universe a different design - one never approved by the FDA and not proffered by Plaintiffs here – might have been developed."

Plaintiff, in opposition argues that "[t]he *Bartlett* preemption simply does not apply to brand-name drugs because the FDCA's [Food, Drug, and Cosmetic Act] 'sameness' requirement is not implicated" and that "[t]he Court should reject Defendants' attempt to extend *Bartlett* beyond its limited scope." With respect to *Yates*, Plaintiff argues that the *Yates* Court "rejected the premise that all design defect claims are preempted as a matter of law" and "[i]nstead, the court examined the facts at the summary judgment stage to determine whether compliance with federal law was impossible under those particular circumstances."

In *Small v. Amgen, et. al.*, a case before the United States District Court for the Middle District of Florida, the plaintiff has also asserted that the defendants defectively designed Enbrel which caused her to sustain injuries. Defendants moved for judgment on the pleadings, arguing, *inter alia*, that plaintiff's design-defect claim is preempted by the FDCA based on *Bartlett* and *Yates*. The Florida court held:

> The application of *Bartlett*'s holding to this case will require discovery into Enbrel's chemical formulation and whether that formulation is capable of redesign. Bartlett found that when a drug is "chemically incapable" of being redesigned, it is impossible for a drug manufacturer to make the drug safer and thus state-law design-defect claims are preempted. *Bartlett*, 133 S. Ct. at 2475. Defendants argue that Enbrel is a biologic and incapable of reformulation, but Plaintiffs dispute this contention and must be allowed to take discovery on the issue. Because in this case the preemption question is not one that is purely

> legal, judgment on the pleadings on the basis of preemption is not appropriate.
>
> If, however, Defendants are correct that Enbrel is incapable of redesign, Bartlett would bar any design-defect claim based on an alleged failure to redesign Enbrel. Moreover, it is likely, even if Enbrel is capable of redesign, that any claim that Defendants should have changed Enbrel's design before seeking FDA approval would likewise be preempted. *See Yates v. Ortho–McNeil–Janssen Pharm., Inc.*, 808 F.3d 281, 299-300 (6th Cir. 2015) (holding that a claim for breach of a pre-approval design duty was speculative and was preempted). These issues, however, are matters for post-discovery dispositive-motion practice, not a motion for judgment on the pleadings.

(*Small v. Amgen, Inc.*, Civ. 2:12-476-FTM29-CM, 2016 WL 4942078, at *2 [M.D. Fla. Jan. 25, 2016]).

For the same reasons articulated in *Small*, and at this stage of the proceedings and in the absence of discovery, the Court finds that the allegations that Enbrel could have been designed differently before FDA approval are sufficient to state a strict liability claim based on a design defect.

Lastly, to the extent that Plaintiffs allege that Enbrel was defective because it was not accompanied by adequate warnings of its risks, such a claim is duplicative of Plaintiffs' second cause of action which seeks to impose liability on Defendants for a failure to warn and will be analyzed below.

B. Second Cause of Action: Strict Liability- Failure to Warn

The second cause of action of the Amended Complaint is for strict liability based on a failure by Defendants to adequately warn of the risks and dangers from the use of Enbrel.

The Amended Complaint alleges that Defendants "had a continuing duty to warn the prescribing physicians and users [including Ms. Wholey] of the Enbrel of the dangers associated with said drugs," Defendants "breached that duty" by failing to provide an adequate warning that Enbrel could cause tongue cancer and "the

increased risks inherent in Enbrel," and the failure to warn resulted in Ms. Wholey's use of Enbrel until 2005 and ultimate development of tongue cancer in 2012.

"A manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known" and "has a duty to warn of the danger of unintended uses of a product provided these uses are reasonably foreseeable." (*Liriano*, 92 N.Y.2d at 237). "Although a prescription drug is by its nature an inherently unsafe product and would in the usual case impute strict liability to its manufacturer, a defense is provided against such liability when the drug is 'properly prepared, and accompanied by proper directions and warning.'" (*Martin v. Hacker*, 83 N.Y.2d 1, 8 [1993] [citations omitted]).

To establish a claim for failure to warn, plaintiffs must allege "that the product did not contain adequate warnings and that the inadequacy of those warnings was the proximate cause of the injuries." (*Mulhall v. Hannafin*, 45 A.D.3d 55, 58 [1st Dept 2007]). "Whether the cause of action for failure to warn is based on negligence or strict liability, the courts of this state have consistently held that a manufacturer's duty is to warn only of those dangers it knows of or are reasonably foreseeable." (*Mulhall*, 45 A.D. 3d at 58).

"Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects." (*Martin*, 83 N.Y.2d at 9). "The physician acts as an 'informed intermediary' between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient. The warning must provide sufficient information to that category of prescribing physicians who may be expected to have the least knowledge and experience with the drug." (*Id.*) (citations omitted). "Whether a given warning is legally adequate or presents a factual question for resolution by a jury requires a careful analysis of the warning's language." (*Id.* at 10).

Defendants argue that Plaintiffs' cause of action for strict liability for failure to warn should be dismissed because Defendants did not owe Plaintiffs a duty to warn. Defendants argue that to the extent that Plaintiffs' claims are based on Ms. Wholey's use of Enbrel during a clinical trial, Defendants did not owe a duty to Ms. Wholey because "it is not the pharmaceutical companies that are charged with ensuring trial participants' well being." (*Abney v. Amgen, Inc.*, 443 F.3d 540, 551

[6th Cir. 2006]). Defendants argue that to the extent that the Amended Complaint also alleges that Ms. Wholey continued to take Enbrel after the clinical trial ended, the learned intermediary doctrine applies. Defendants argue that under the learned intermediary doctrine, any duty on Defendants' part to warn of Enbrel's risk and dangers would have been owed to the medical community, not Ms. Wholey, the patient. Lastly, Defendants argues that the warnings for Enbrel were adequate.

Plaintiffs have adequately pled that Defendants breached their duty to Ms. Wholey. Whether Defendants satisfied their duty to warn Ms. Wholey's physicians of the potential adverse effects of Enbrel under the doctrine of learned intermediary is an issue of fact and not one to be resolved at the pleading stage. Lastly, the adequacy of the Enbrel label cannot be determined as a matter of law at the motion to dismiss stage.

Accepting Plaintiffs' allegations as true and drawing all inferences in favor of the non-moving party, the four corners of Plaintiffs' Amended Complaint adequately pleads a cause of action for negligence against Defendants

C. Third Cause of Action: Breach of Implied Warranty of Merchantability and Fourth Cause of Action: Express

The third cause of action of the Amended Complaint is for breach of the implied warranty. The fourth cause of action is for breach of express warranty.

UCC § 2-315, "Implied Warranty: Fitness for Particular Purpose," provides, "Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose." "For an implied warranty of fitness for a particular purpose claim to arise, the buyer must establish that the seller had reason to know, at the time of contracting, the buyer's particular purpose for which the goods are required and that the buyer was justifiably relying upon the seller's skill and judgment to select and furnish suitable goods, and that the buyer did in fact rely on that skill (UCC § 2-315)." (*Saratoga Spa & Bath, Inc. v. Beeche Sys. Corp.*, 230 A.D.2d 326, 331 [3d Dept 1997]).

In the Amended Complaint, Plaintiffs allege that Defendants "impliedly warranted to the public in general, and to Plaintiff Lauren Wholey in particular, that Enbrel designed, manufactured, marketed, distributed, and sold by them, or under their supervision, direction, and control, and when used as intended, was merchantable and reasonably fit and suitable for the ordinary purposes for which such goods are used, and that the product conformed to the standards imposed by law," that "Defendants breached their implied warranties of fitness and merchantability, insofar as Enbrel was placed into the stream of commerce in such a manner as to constitute an unreasonable danger and hazard to Plaintiff Lauren Wholey when used for its intended purpose," "Plaintiff Lauren Wholey and her prescribing physician reasonably relied upon the skill and judgment of Defendants as to whether Enbrel was of merchantable quality and safe and fit for its intended use," and Plaintiffs suffered damages as a result of Defendants' breach.

"In order for an express warranty to exist, there must be an affirmation of fact or promise by the seller, the natural tendency of which is to induce the buyer to purchase." (*Friedman* v. *Medtronic, Inc.*, 42 A.D.2d 185, 190 [2d Dep't 1973](citations omitted)). Therefore, "for a buyer to recover for breach of express warranty, he must show that the warranty was relied on." (*Id.*). *See also* NY U.C.C. § 2-313. "[A]n express warranty may be formed by advertisements and privity is not required to sustain a cause of action seeking to recover damages for breach of an express warranty." (*Murrin* v *Ford Motor Co.*, 303 A.D.2d 475, 477 (2d Dept 2003) (internal citations omitted).

In the Amended Complaint, Plaintiffs allege that that Defendants "expressly warranted to the public in general, and to Plaintiff Lauren Wholey in particular, that Enbrel designed, manufactured, marketed, distributed, and sold by them, or under their supervision, direction, and control, was merchantable and reasonably fit and suitable for the intended or ordinary purposes for which it was used, and that Enbrel conformed to the standards imposed by law, and had a positive risk/benefit ratio when used as intended." Plaintiffs allege that Defendants made these warranties through the following means:

> (i) publicly-made written and verbal assurances of the safety and efficacy of Enbrel by Defendants; (ii) press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create and increase demand for Enbrel, which utterly

> failed to warn of the risks inherent to the ingestion of Enbrel; (iii) verbal assurances made by Defendants regarding Enbrel, (iv) the downplaying of any risk associated with Enbrel; (v) false and misleading written information, supplied by Defendants, and published in the Physicians' Desk Reference on an annual basis, upon which physicians were forced to rely in prescribing Enbrel during the period of Plaintiff Lauren Wholey's ingestion of Enbrel, including but not limited to information relating the recommended duration of the use of Enbrel as well as materials distributed to Plaintiff Lauren Wholey when picking up her prescription; (vi) promotional pamphlets and brochures published and distributed by Defendants and directed to consumers; and (vii) advertisements.

Plaintiffs allege that Defendants breached these warranties, and that Ms. Wholey relied upon the warranties and injured as a result of the breach.

Defendants argue that Plaintiffs' breach of express warranty claim fails because Plaintiffs do not identify or describe any specific warranties. In addition, Defendants argue that Plaintiffs' warranty claims are premised on a failure. Defendants reiterate that the investigator, not the pharmaceutical company, owes the duty to a participant and is the one warranting the "goods" (i.e. Enbrel in this case provided in the clinical trial, and the learned doctrine bars any breach of warranty claim based on the use of Enbrel outside of a clinical trial).

Accepting Plaintiffs' allegations as true and drawing all inferences in favor of the non-moving party which the Court is constrained to do at the motion to dismiss stage, the four corners of Plaintiffs' Amended Complaint adequately pleads a cause of action for breach of implied and express warranties.

D. Fifth Cause of Action: Negligence

To establish negligence, a plaintiff must demonstrate: (1) that a duty of care was owed by the defendant to the plaintiff; (2) breach of the duty; (3) proximate cause; and, (4) damages. (*Alvino v. Lin*, 300 A.D.2d 421 [2002]). In the absence of a duty, there can be no breach and no liability. (*Ruiz v. Griffin*, 71 A.D.3d 1112 [2010]).

To establish a claim for failure to warn, plaintiffs must allege "that the product did not contain adequate warnings and that the inadequacy of those warnings was the proximate cause of the injuries." (*Mulhall*, 45 A.D.3d at 58). "Whether the cause of action for failure to warn is based on negligence or strict liability, the courts of this state have consistently held that a manufacturer's duty is to warn only of those dangers it knows of or are reasonably foreseeable." (*Id.*).

The Amended Complaint alleges that "Defendants had and continues to have a duty to exercise reasonable care to properly prepare, design, research, develop, test, manufacture, inspect, label, market, promote, and/or sell their Enbrel which they introduced into the stream of commerce, including a duty to insure said drugs do not cause users to suffer from unreasonable, dangerous or untoward adverse side effects," "owed a duty to properly warn consumers of the risks, dangers, and adverse side effects of the Enbrel and/or to properly and prudently market Enbrel directly to the consumer," and "has an ongoing duty of pharmacovigilance . . . requir[ing] [Defendants] to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of its marketed drugs, including Enbrel."

The Amended Complaint alleges that "Defendants breached these duties by failing to properly and prudently warn and/or market such Enbrel and, in addition, promoting such drugs for uses beyond that specifically approved by the FDA," and "breached their duty by failing to exercise ordinary care in the preparation, design, research, development, testing, manufacturing, inspection, labeling, marketing, promotion, and/or selling of the Enbrel, which they introduced into the stream of commerce, because Defendants knew or should have known that said drugs created the risk of unreasonable, dangerous or untoward adverse side effect."

The Amended Complaint alleges that Defendants breached their "duty of pharmacovigliance" by *inter alia*, "fail[ing] to comply with the FDA post marketing reporting requirements under 21 C.F.R. § 314.80(c) by, inter alia, failing to report each adverse drug experience concerning Enbrel . . . as soon as possible," "failing to promptly investigate all adverse drug experiences concerning Enbrel that are the subject of these post marketing 15-day Alert reports, failing to submit follow-up reports … ," "failing to maintain records of the unsuccessful steps taken to seek additional information, and "fail[ing] to meet the periodic reporting requirements of 21 C.F.R. § 314(c), 21 C.F.R. § 314.81, and 21 C.F.R. § 312.33."

The Amended Complaint further alleges "[b]ut for Defendants' negligent conduct as described herein, Plaintiff Lauren Wholey's prescribing physician would

have never prescribed Enbrel to Plaintiff Lauren Wholey, Plaintiff Lauren Wholey would not have ingested Enbrel and Plaintiff Lauren Wholey would not have suffered harm."

Accepting Plaintiffs' allegations as true and drawing all inferences in favor of the non-moving party, the four corners of Plaintiffs' Amended Complaint adequately pleads a cause of action for negligence against Defendants.

E. Sixth, Seventh, and Ninth Causes of Action: Fraudulent Misrepresentation, Fraudulent Concealment, and Fraud

The sixth, seventh, and ninth causes of action of the Amended Complaint are for fraudulent misrepresentation, fraudulent concealment, and fraud.

Defendants allege that Plaintiffs' fraud based claims fail because Plaintiffs fail to allege in any detail the circumstances of the alleged fraud or provide any supporting facts to substantiate their allegations. Defendants further allege that to the extent that Plaintiffs' fraud based claims are based on allegations that Defendants mislead the FDA and medical community at large by representing Enbrel® as safe and effective, state law claims for fraud on the FDA conflict with and therefore are preempted by federal law under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 34, 348 [2001]). Plaintiffs, in turn, argue that they have pled all of the elements of fraud with sufficient particularity. Plaintiffs further argue that while Buckman addresses claims for fraud on the FDA, it is not relevant to claims of fraud on the medical community or Ms. Wholey.

In a claim for fraudulent misrepresentation, a plaintiff must allege: (1) a misrepresentation or a material omission of fact; (2) which was false and known to be false by defendant; (3) made for the purpose of inducing the other party to rely upon it; (4) justifiable reliance of the other party on the misrepresentation or material omission; and, (5) injury. (*Mandarin Trading Ltd. v. Wildenstein*, 16 N.Y.3d 173, 178 [2011]) (citations omitted).

With respect to Plaintiffs' claim for fraudulent misrepresentation, the Amended Complaints alleges that "Defendants expressly and/or impliedly represented to Plaintiff Lauren Wholey, Plaintiff Lauren Wholey's physicians, the medical community, and members of the general public that their Enbrel drugs were safe for use," "the representations by Defendants were, in fact, false [because] Enbrel was not safe for its intended use and was, in fact, dangerous to the health and body

of Plaintiff Lauren Wholey," the "misrepresentations or omissions were made to Plaintiff Lauren Wholey, and her physicians, and the medical community, all of whom justifiably and foreseeably relied on those representations or omissions," and Ms. Wholey "would not have suffered injuries but for the above misrepresentations or omissions of Defendants."

"A claim for fraudulent concealment 'requires additionally setting forth that the defendant had a duty to disclose material information.'" (*Id.*) CPLR section 3016 provides that where a cause of action is based upon misrepresentation or fraud, among others, the circumstances constituting the wrong must be stated in detail. *See* CPLR § 3016(b).

With respect to Plaintiffs' claim for fraudulent concealment, The Amended Complaint alleges that "[a]t all times during the course of dealing between Defendants and Plaintiff Lauren Wholey, and/or Plaintiff Lauren Wholey's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Enbrel for its intended use" and "Defendants knew or were reckless in not knowing that its representations were false." The Amended Complaint further alleges, "In representations to Plaintiff Lauren Wholey, and/or Plaintiff Lauren Wholey's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

> a. that Enbrel was not safe; b. that the risks of adverse events with Enbrel were high; c. that the risks of adverse events with Enbrel were not adequately tested and/or known by Defendants; d. that Defendants were aware of dangers in Enbrel, in addition to and above and beyond those associated with alternative medications; e. that Enbrel was defective, and that it caused dangerous side effects; f. that patients needed to be monitored more regularly than normal while using Enbrel; g. that Enbrel was manufactured negligently; h. that Enbrel was manufactured defectively; i. that Enbrel was manufactured improperly; j. that Enbrel was designed negligently; k. that Enbrel was designed defectively; and 1. that Enbrel was designed improperly."

The Amended Complaint further alleges that "Defendants were under a duty to disclose to Plaintiff Lauren Wholey, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Enbrel, including but not limited to the heightened risks of heart attacks, stroke, excessive bleeding and blood disorders and/or death," Ms. Wholey, "as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants," and Ms. Wholey suffered damages as a result of Defendants' acts and omissions.

The elements of fraud are material misrepresentation of a fact, knowledge of its falsity, an intent to induce reliance, justifiable reliance by the plaintiff, and damages. (*Frank Crystal & Co. v. Dillmann*, 84 A.D.3d 704 [1st Dept. 2011]; *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Wise Metals Grp., LLC*, 19 A.D.3d 273, 275 [1st Dept. 2005]). CPLR section 3016 provides that where a cause of action is based upon misrepresentation or fraud, among others, the circumstances constituting the wrong must be stated in detail. *See* CPLR § 3016(b).

With respect to Plaintiffs' claim for fraud, the Amended Complaint alleges that Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and Plaintiff Lauren Wholey, as well as her respective healthcare providers and/or the FDA." The Amended Complaint alleges that Defendants "conducted research and used Enbrel as part of their research," "disregarded test results not favorable to the Defendants, and results that demonstrated that Enbrel was not safe," "intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including Plaintiff Lauren Wholey," and "intentionally made material misrepresentations to the FDA and the public, including the medical profession, and Plaintiff Lauren Wholey, regarding the safety of Enbrel, specifically, but not limited to Enbrel not having dangerous and serious health and/or safety concerns." The Amended Complaint further alleges that these misrepresentations were made "made with the intention of deceiving and defrauding" Ms. Wholey, her healthcare professionals, and/or the FDA, Ms. Wholey and her healthcare providers relied on these false representations, and Ms. Wholey sustained damages as a result of them.

Accepting Plaintiffs' allegations as true and drawing all inferences in favor of the non-moving party which the Court is constrained to do at the motion to dismiss

stage, the four corners of Plaintiffs' Amended Complaint adequately pleads a cause of action for fraudulent misrepresentation, fraudulent concealment, and fraud.

F. Eighth Cause of Action: Negligent Misrepresentation

The eighth cause of action of the Amended Complaint is for negligent misrepresentation.

A claim for negligent misrepresentation requires the plaintiff to demonstrate: (1) the existence of a "special" or "privity-like" relationship of trust and confidence imposing a duty on the defendant to impart correct information to the plaintiff; (2) that the information imparted was incorrect; and, (3) reasonable reliance on the information. (*J.A.O. Acquisition Corp. v. Stavitsky*, 8 N.Y.3d 144, 148 [2007]; *Hudson River Club v. Consolidated Edison Co.*, 275 A.D.2d 218, 220 [1st Dep't 2000]).

The Amended Complaint alleges, "Defendants had a duty to represent to the medical and healthcare community, and to Plaintiff Lauren Wholey, the FDA and the public in general that said product, Enbrel, had been tested and found to be a safe and effective form of therapy," and "[t]he representations made by Defendants were, in fact, false." It alleges that "Defendants failed to exercise ordinary care in the representation of Enbrel, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendants negligently misrepresented Enbrel's high risk of unreasonable, dangerous side effects" and "breached their duty in representing Enbrel's serious side effects to the medical and healthcare community, to Plaintiff Lauren Wholey, the FDA and the public in general." The Amended Complaint alleges that as a result of Defendants' representations, and Ms. Wholey required more health care and services and did incur medical, health, incidental and related expenses."

Accepting Plaintiffs' allegations as true and drawing all inferences in favor of the non-moving party, the four corners of Plaintiffs' Amended Complaint adequately pleads a cause of action for negligent misrepresentation against Defendants.

G. Tenth Cause of Action: Consumer Fraud – Violation of GBL 349 and 350

The tenth cause of action of the Amended Complaint alleges consumer fraud and violations under GBL 349 and 350.

Section 349 of the GBL is a consumer protection statute that prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service" in New York State. GBL § 349(a). The statute is intended to "empower consumers; to even the playing field in their disputes with better funded and superiorly situated fraudulent businesses." (*Teller v. Bill Hayes, Ltd.*, 213 A.D.2d 141, 148 [2d Dept. 1995]). "[S]ection 349 is directed at wrongs against the consuming public," *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 24 [1995], and applies to "virtually all economic activity." (*See Karlin v. IVF Am., Inc.*, 93 N.Y.2d 282, 290 [1999]). Section 350 of the BCL states "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful." "The standard for recovery under General Business Law § 350, while specific to false advertising, is otherwise identical to section 349." (*Goshen v. Mut. Life Ins. Co. of New York*, 98 N.Y.2d 314, 324 [2002]). The broad reach of GBL §§ 349 and 350 "provide[s] needed authority to cope with the numerous, ever-changing types of false and deceptive business practices which plague consumers in our State." [*Karlin*, 93 N.Y.2d at 290 (quoting N.Y. Dept. of Law, Mem. to Governor, 1963 N.Y. Legis. Ann., at 105)]).

To state a claim under GBL § 349, a plaintiff must allege that (1) the deceptive act or practice was consumer-oriented; (2) the deceptive act or practice was misleading in a material respect; and (3) the plaintiff was injured as a result. (*Spagnola v. Chubb Corp.*, 574 F.3d 64, 74 [2d Cir. 2009]; *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris USA Inc.*, 3 N.Y.3d 200, 205-6 [2004] ("[A] plaintiff must allege both a deceptive act or practice directed toward consumers and that such act or practice resulted in actual injury to a plaintiff."). The threshold requirement of consumer-oriented conduct is met by proof that "the acts or practices have a broader impact on the consumer at large" in that they are "directed to consumers" or "potentially affect similarly situated consumers." (*Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 25–27 [1995]). "Private contract disputes, unique to the parties," do not fall within the ambit of the statute. (*Id.* at 25). "Deceptive practices" are "acts which are dishonest or misleading in a

material respect." (*Kramer v. Pollock–Krasner Found.,* 890 F.Supp. 250, 258 [S.D.N.Y. 1995]).

Defendants allege that Plaintiffs' statutory consumer fraud cause of action should be dismissed because the Amended Complaint fails to allege that Defendants engaged in consumer-oriented conduct and Plaintiffs have not identified the allegedly false advertisements that Plaintiffs relied upon under GBL § 350.

The Amended Complaint alleges that Defendants "engaged in consumer-oriented, commercial conduct by selling and advertising" Enbrel, "misrepresented and omitted material information regarding the subject product by failing to disclose known risks," and Ms. Wholey suffered damages as a result.

Accepting Plaintiffs' allegations as true and drawing all inferences in favor of the non-moving party which the Court is constrained to do at the motion to dismiss stage, the four corners of Plaintiffs' Amended Complaint adequately plead a cause of action for consumer fraud under GBL 349 and 350 against Defendants.

H. Eleventh Cause of Action: Punitive Damages

"Punitive damages are not available in the ordinary fraud and deceit case [internal quotation marks and citation omitted]), but are permitted only when a defendant's wrongdoing is not simply intentional but evince[s] a high degree of moral turpitude and demonstrate[s] such wanton dishonesty as to imply a criminal indifference to civil obligations. Mere commission of a tort, even an intentional tort requiring proof of common-law malice, is insufficient; there must be circumstances of aggravation or outrage, or a fraudulent or evil motive on the part of the defendant." (*Hoeffner v. Orrick, Herrington & Stucliffe, LLP*, 85 A.D. 3d 457, 458 [1st Dept 2011]). Defendants allege that Plaintiffs' claim for punitive damages should be dismissed because New York does not recognize a separate cause of action for punitive damages and because Plaintiffs have not alleged any facts to support that punitive damages would be warranted. Here, accepting Plaintiffs' allegations as true and drawing all inferences in favor of the non-moving party, the four corners of Plaintiffs' Amended Complaint plead a basis for punitive damages.

I. Twelfth Cause of Action: Loss of Consortium

As Ms. Wholey's claims are adequately plead, Mr. Rosenbluth's loss of consortium claim stand.

WHEREFORE, it is hereby

ORDERED that Defendants' motion to dismiss is denied.

This constitutes the decision and order of the court. All other relief requested is denied.

DATED: MARCH 8 2017

EILEEN A. RAKOWER, J.S.C.