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-29MRM

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

Defendants.

OPINION AND ORDER

This matter comes before the Court on the defendants' Motion for Summary Judgment (Doc. #82) filed on December 23, 2014. Plaintiffs filed a Response in Opposition (Doc. #89) on January 20, 2015. Defendants filed a Reply (Doc. #92) on February 2, 2015, and plaintiffs filed a Sur-Reply (Doc. #95) on February 10, 2015.

I.

Plaintiffs Rebecca and Lawrence Small filed this action against defendants Amgen, Inc., Wyeth, Inc., Pfizer, Inc., and Does 1-20 to recover damages for the injuries Ms. Small allegedly sustained as a result of her use of the prescription drug Enbrel. Plaintiffs allege that Ms. Small started using Enbrel in 2002 to treat her rheumatoid arthritis. Ms. Small continued her treatment with Enbrel 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 allegedly caused by her use of Enbrel. Plaintiffs allege that multiple surgeries were required to treat the infection.

In their Fourth Amended Complaint, filed on December 23, 2014, plaintiffs set forth the following five claims against Amgen, Inc., Wyeth, Inc., and Pfizer, Inc.: (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.) On March 6, 2014, the Court entered an Opinion and Order dismissing Count IV to the extent plaintiffs asserted a claim for the negligent failure to test or inspect, and to the extent that plaintiffs asserted a claim of negligence per se. (Doc. #66.) Defendants now move for summary judgment on the remaining claims, arguing that they are barred by Florida's learned intermediary doctrine.

II.

Summary judgment is appropriate only when the Court is satisfied that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "An issue of fact is 'genuine' if the record taken as a whole could lead a rational trier of fact to find for the nonmoving party." Baby Buddies, Inc. v. Toys "R" Us, Inc., 611 F.3d 1308, 1314 (11th Cir. 2010). A fact is "material" if it may affect the outcome of the suit under governing law.

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "A court must decide 'whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.'" Hickson Corp. v. N. Crossarm Co., Inc., 357 F.3d 1256, 1260 (11th Cir. 2004) (citing Anderson, 477 U.S. at 251).

In ruling on a motion for summary judgment, the Court views all evidence and draws all reasonable inferences in favor of the non-moving party. Scott v. Harris, 550 U.S. 372, 380 (2007); Tana v. Dantanna's, 611 F.3d 767, 772 (11th Cir. 2010). However, "if reasonable minds might differ on the inferences arising from undisputed facts, then the court should deny summary judgment." St. Charles Foods, Inc. v. America's Favorite Chicken Co., 198 F.3d 815, 819 (11th Cir. 1999) (quoting Warrior Tombigbee Transp. Co. v. M/V Nan Fung, 695 F.2d 1294, 1296-97 (11th Cir. 1983) (finding summary judgment "may be inappropriate even where the parties agree on the basic facts, but disagree about the factual inferences that should be drawn from these facts")). "If a reasonable fact finder evaluating the evidence could draw more than one inference from the facts, and if that inference introduces a genuine issue of material fact, then the court should not grant summary judgment." Allen v. Bd. of Pub. Educ., 495 F.3d 1306, 1315 (11th Cir. 2007).

III.

A. Rheumatoid Arthritis

Rheumatoid arthritis is an autoimmune disease that occurs when the body's immune system mistakenly attacks joints, cells, tissues, and other organs of the body. (Doc. #82-1, p. 10.) Rheumatoid arthritis typically causes inflammation in the body's joints, but can also cause symptoms such as fatigue, joint stiffness, low grade fevers, rashes, ulcerations in the mouth, shortness of breath, and chest pains. (Id.) If left untreated, rheumatoid arthritis can lead to "[t]otal disability, and also a decrease in quality of life as well as a decrease in life expectancy." (Id. at 11.) Early rheumatoid arthritis treatment options carried substantial risks, such as increased risk of lymphoma and nonmelanoma skin cancers, stomach ulcers, kidney disease, bone marrow depression, thinning of the skin, hypertension, and avascular necrosis. (Id. at 13-14.)

In 1998, the Food and Drug Administration ("FDA") approved the release of Enbrel, a drug credited with revolutionizing the treatment options for those suffering from rheumatoid arthritis. (Doc. #82, p. 3.) Enbrel is a "biologic" drug and is "alleged to be a recombinant human IcGI antibody that neutralizes and/or blocks the activity of TNFs [Tumor Necrosis Factor]," a naturally occurring substance in the human body. (Doc. #54, ¶¶ 14-15.) Enbrel was 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.)

B. Enbrel's Warning Label and Medication Guide

Throughout the relevant time period, defendants distributed an FDA-approved package insert to physicians to inform them about how Enbrel should be used and what risks were associated with its use. (Doc. #82-3.) The package insert issued in July 2001 identified infections as the primary risk of taking Enbrel. (Id.) Specifically, the warning, which was in capitalized and bold font, stated:

> **WARNINGS**
>
> **INFECTIONS**
>
> **IN POST–MARKETING REPORTS, SERIOUS INFECTIONS AND SEPSIS, INCLUDING FATALITIES, HAVE BEEN REPORTED WITH THE USE OF ENBREL. MANY OF THE SERIOUS INFECTIONS HAVE OCCURRED IN PATIENTS ON CONCOMITANT IMMUNOSUPPRESSIVE THERAPY THAT, IN ADDITION TO THEIR UNDERLYING DISEASE COULD PREDISPOSE THEM TO INFECTIONS. RARE CASES OF TUBERCULOSIS (TB) HAVE BEEN OBSERVED IN PATIENTS TREATED WITH TNF ANTAGONISTS, INCLUDING ENBREL. PATIENTS WHO DEVELOP A NEW INFECTION WHILE UNDERGOING TREATMENT WITH ENBREL SHOULD BE MONITORED CLOSELY. ADMINISTRATION OF ENBREL SHOULD BE DISCONTINUED IF A PATIENT DEVELOPS A SERIOUS INFECTION OR SEPSIS. TREATMENT WITH ENBREL SHOULD NOT BE INITIATED IN PATIENTS WITH ACTIVE INFECTIONS INCLUDING CHRONIC OR LOCALIZED INFECTIONS. PHYSICIANS SHOULD EXERCISE CAUTION WHEN CONSIDERING THE USE OF ENBREL IN PATIENTS WITH A HISTORY OF RECURRING INFECTIONS OR WITH UNDERLYING CONDITIONS WHICH MAY PREDISPOSE PATIENTS TO INFECTIONS, SUCH AS ADVANCED OR POORLY CONTROLLED DIABETES (see PRECAUTIONS and ADVERSE REACTIONS, Infections).**

(Doc. #82-3, p. 12.) Defendants also distributed an FDA-approved medication guide that warned patients of various potential risks associated with Enbrel, including the risk of serious infection. (Doc. #82-8, p. 2.)

C. Ms. Small's Treatment with Enbrel

Ms. Small first visited her rheumatologist, Catherine Nina Kowal, M.D. (Dr. Kowal), on September 24, 2001.[1] (Doc. #82-1, p. 37.) Dr. Kowal determined that Ms. Small's rheumatoid arthritis was very active and tried to treat Ms. Small's condition with non-biologic medications such as Leflunomide and Methotrexate. (Id. at 37.) Ms. Small, however, continued to experience joint swelling and pain, predominantly in her hands, and was unable to really function. (Id. at 38.) Dr. Kowal then decided to treat Ms. Small with a biologic. Because Ms. Small could not afford Enbrel, Dr. Kowal asked her if she wanted to participate in a clinical study on Enbrel for which Dr. Kowal was a principal investigator. (Id.) After a thorough discussion with Dr. Kowal, Ms. Small voluntarily decided to enroll in the Enbrel study. (Id. at 43-44.)

[1]Dr. Kowal has been practicing medicine in Naples, FL since 1992, and about 50 to 60 percent of her current patients suffer from rheumatoid arthritis. (Doc. #81, p. 8.) Dr. Kowal is very familiar with all of the treatments available for rheumatoid arthritis, and is part of the American College of Rheumatology and the Florida Society of Rheumatology. (Id.)

Before starting her treatment with Enbrel, Ms. Small was given a Research Subject Information and Consent Form that contained information about the study, including the potential risks, hazards, and discomforts associated with Enbrel. (Id.) As to the increased risk of infection, the consent form stated that:

> It is possible that Enbrel® may make infections worse or could lead to life-threatening infections. These infections may occur in any body system. In some patients[,] very low blood cell counts have been reported. If you develop signs and symptoms of a significant infection, or persistent fever, bruising, bleeding, or very pale skin, you should immediately contact your study doctor to determine whether you should stop taking Enbrel®.

(Doc. #82-4, p. 4.) Dr. Kowal talked to Ms. Small about the information in the Research Subject Information and Consent Form and explained that the serious conditions identified in the form are rare. (Doc. #82-1, p. 44.) Ms. Small also reviewed the package insert and medication guide that accompanied Enbrel before starting her treatment. (Doc. #89-1, ¶ 2.)

Ms. Small treated her rheumatoid arthritis with Enbrel from 2002 until August 29, 2008. Ms. Small's use of Enbrel, however, was not without interruption. In May 2003, Ms. Small took Dr. Kowal's recommendation and temporarily went off Enbrel before undergoing surgery on her thumb. (Doc. #82-1, p. 48.) In October 2003, Dr. Kowal stopped Ms. Small's treatment with Enbrel and monitored her for infections because Ms. Small had swollen glands. (Id.) Dr. Kowal also stopped treatment and monitored for

infections in December 2004 because Ms. Small had bronchitis. (Id. at 50.) No other incidents were recorded.

During a visit on August 25, 2008, Dr. Kowal noted that Ms. Small's rheumatoid arthritis was "stable," meaning she had no new synovitis, her energy level was okay, and the Enbrel was working. (Id. at 53.) On August 29, 2008, Ms. Small was admitted to the hospital on an emergency basis and was diagnosed with a perforated bowel from a diverticulitis infection. (Doc. #54, ¶ 26.) Until a few days before her hospitalization, Ms. Small was asymptomatic. Multiple surgeries were required to treat the infection. (Id. ¶ 26.) Ms. Small was instructed to stop using Enbrel until she recovered from the infection. (Doc. #89-1, ¶ 4.)

On February 24, 2009, Ms. Small met with Dr. Kowal to discuss whether it was appropriate to resume treatment with Enbrel. (Id. ¶ 5.) Ms. Small claims that Dr. Kowal consulted with defendants' sales representative during the appointment and was assured by the representative that it was safe to resume Ms. Small's treatment with Enbrel. (Doc. #89-1, ¶ 6.) Ms. Small asserts that she relied of the sales representative's assurances and agreed to restart Enbrel. (Doc. #89-1, ¶ 7.) Dr. Kowal, however, does not recall speaking to a sales representative. (Doc #82-1, p. 68.)

Within approximately 60 days of restarting Enbrel, Ms. Small developed another serious round of complications requiring additional surgeries and treatments, which are still affecting her

today. (Doc. #54, ¶ 28; Doc. #89-1, ¶ 8.) Dr. Kowal subsequently advised Ms. Small to stop taking Enbrel, and Ms. Small complied. Ms. Small has not taken Enbrel since this incident. (Id.)

At no time prior to Ms. Small's injuries were doctors and patients warned that Enbrel could cause asymptomatic serious infections, nor were doctors and patients instructed on how to mitigate and manage the risks associated with the use of Enbrel. (Doc. #54, ¶ 61.)

IV.

It is well settled that "summary judgment should not be granted until the party opposing the motion has had an adequate opportunity for discovery." Snook v. Trust Co. of Ga. Bank, N.A., 859 F.2d 865, 870 (11th Cir. 1988). Rule 56(d) provides that a court may deny a motion for summary judgment as premature "[i]f a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition." Fed. R. Civ. P. 56(d)(1).

Here, plaintiffs contend that defendants' motion is premature because "no discovery from Defendants has taken place and discovery is still open."[2] (Doc. #89, p. 19.) Plaintiffs, however, failed to submit an affidavit or declaration showing that they are unable

[2]Although this case is more than three years old, plaintiffs have not yet served a single discovery request upon defendants. (Doc. #89, pp. 1-2.)

to defend against the pending motion for summary judgment. Furthermore, defendants' motion focuses upon a single issue – whether Dr. Kowal would have prescribed Enbrel to Ms. Small if Enbrel's package insert warned of asymptomatic infections. As discussed in more detail below, no additional evidence is necessary to resolve this issue. The Court, however, finds that defendants' motion for summary judgment is premature to the extent that it addresses claims that are not covered by the learned intermediary doctrine.

V.

Florida tort law provides that the manufacturer of a defective product may be subject to liability under two theories: negligence and strict liability. To prevail on a products liability claim sounding in negligence, a plaintiff must establish: (1) a duty or obligation recognized by the law requiring the defendant to protect others from 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. Coop., Inc. v. Johnson, 873 So. 2d 1182, 1185 (Fla. 2003)). As to a claim for strict liability, a plaintiff must establish (1) the manufacturer's relationship to the product in question, (2) the defective and unreasonably dangerous condition of the product, and (3) the existence of a proximate causal connection between such

condition and 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)).[3]

In order to prevail under either theory, the plaintiff must establish that the product was defective or unreasonably dangerous. Colville v. Pharmacia & Upjohn Co. LLC, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008) (citing Marzullo v. Crosman Corp., 289 F. Supp. 2d 1337, 1342 (M.D. Fla. 2003)). Under Florida law, "a product may be defective by virtue of a design defect, a manufacturing defect, or an inadequate warning." Jennings c. BIC Corp., 181 F.3d 1250, 1255 (11th Cir. 1999) (quoting Ferayorni v. Hyundai Motor Co., 711 So. 2d 1167, 1170 (Fla. 4th DCA 1998)). In this case, plaintiffs assert all three defects.

A. Failure to Warn

A plaintiff seeking to recover damages for the failure to warn must prove that the defendant (1) is a manufacturer or distributor of the product at issue, and (2) did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and

[3]Strict liability differs from negligence in that the plaintiff does not have to prove specific acts of negligence. See West v. Caterpillar Tractor Co., 336 So. 2d 80, 90 (Fla. 1976) (Strict liability is defined as "negligence as a matter of law or negligence per se, the effect of which is to remove the burden from the user of proving specific acts of negligence").

medical knowledge available at the time of the manufacture and distribution. Thomas v. Bombardier Recreational Prods., Inc. 682 F. Supp. 2d 1297, 1300 (M.D. Fla. 2010). The plaintiff must also establish that the inadequate warning was a proximate cause of her injury. Hoffmann-La Roche, Inc. v. Mason, 27 So. 3d 75, 77 (Fla. 5th DCA 2009).

When the product is a prescription drug, as is the case in this matter, the manufacturer's duty to warn is directed to physicians rather than patients under Florida's "learned intermediary doctrine." Id. (citing Felix v. Hoffmann-La Roche, Inc., 540 So. 2d 102, 104 (Fla. 1989)). Thus, a drug manufacturer's duty to warn is satisfied if it gives an adequate warning to the physician who prescribes the drug.[4] Buckner v.

[4]The rationale behind the learned intermediary doctrine is as follows:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

Allergan 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.

The learned intermediary doctrine further provides that "the failure of the manufacturer to provide the physician with an adequate warning is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that an adequate warning should have communicated." Tillman v. C.R. Bard, Inc., F. Supp. 3d. , 2015 WL 1456657, at *21 (M.D. Fla. 2015) (citing Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995)). Accordingly, "the adequacy of the warning is irrelevant if the prescribing physician, as opposed to the patient, has knowledge of the risks and benefits of the drug and would have prescribed the drug anyway had the warnings been different." Chase v. Novartis Pharm. Corp., 740 F. Supp. 2d 1295, 1297 (M.D. Fla. 2006).

Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 822 (Fla. 5th DCA 1981) (quoting Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974)).

In this matter, defendants contend that plaintiffs' failure to warn claims are barred by the learned intermediary doctrine because Dr. Kowal would have prescribed Enbrel to Ms. Small even if the package insert had warned of asymptomatic infections. In response, plaintiffs assert that the learned intermediary doctrine is not implicated in this matter because defendants had a duty to warn Ms. Small of the risks associated with Enbrel pursuant to 21 C.F.R. § 208. Alternatively, plaintiffs argue that the learned intermediary doctrine is pre-empted by 21 C.F.R. § 208.24, and that defendants' motion for summary judgment should be denied because there are disputed issues of material fact.

1. The Duty to Warn

In 1998, the FDA implemented regulations requiring the distribution of "patient labeling for human prescription drug products, including biological products, that the [FDA] determines pose a serious and significant public health concern." 21 C.F.R. § 208.1(a). Patient labeling, also known as a medication guide, is required when the FDA determines that the "patient labeling could help prevent serious adverse effects;" the safety information regarding the drug's "serious risk(s) (relative to benefits) . . . could affect patients' decision to use, or to continue to use, the product;" or the drug "is important to health and patient adherence to directions for use is crucial to the drug's effectiveness." 21 C.F.R. § 208.1(c).

The manufacturer of a drug for which a medication guide is required must obtain FDA approval of the medication guide prior to distribution. 21 C.F.R. § 208.24(a). The medication guide will only be approved if it includes certain information, such as the name of the drug, a specific description of what the patient should do or consider before taking the drug, the circumstances under which the drug should not be used, the instructions on how to properly use the drug, and the possible or reasonably likely side effects of the drug. 21 C.F.R. § 208.20(b). After the medication guide is approved, the manufacture must ensure that medication guides are available for distribution to patients by either providing medication guides in sufficient numbers to distributors, packers, or authorized dispensers, or providing the means to produce medication guides in sufficient numbers to distributors, packers, or authorized dispensers. 21 C.F.R. § 208.24(b).

Plaintiffs contend that these regulations (the "medication guide regulations") were implemented "with the express goal of allowing the FDA to impose a duty upon manufacturers to provide pertinent safety information directly to consumers where special circumstances existed that required it." (Doc. #89, p. 6.) Because this duty was expressly created by the FDA, plaintiffs

assert that the learned intermediary doctrine is not implicated by their failure to warn claims.[5] The Court disagrees.

Florida law clearly provides that the duty to warn of a drug's dangerous propensities runs to the physician, not the patient. See Mason, 27 So. 3d at 77. The fact that federal law requires drug manufacturers to warn patients of the risks associated with certain drug products does not change the analysis under Florida law. Indeed, "[d]istrict 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." Small v. Amgen, Inc., 2 F. Supp. 3d 1292, 1299-1300 (M.D. Fla. 2014) (citing 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). Furthermore, the FDA explicitly stated that it did not intend to change or expand state tort law when it promulgated the medication guide regulations. Specifically, the FDA stated that it "does not believe that this rule would adversely affect civil tort liability" because it "does not alter the duty, or set the standard of care for manufacturers," and because "courts have not recognized an exception to the 'learned intermediary' defense in [other] situations where FDA has

[5]The undisputed evidence shows that Enbrel was distributed with a medication guide. (Doc. #82-8.)

required patient labeling." Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998). See also Bartlett v. Mutual Pharm. Co., No. 08-cv-00358-JL, 2010 WL 3659789, at *6 (D.N.H. Sept. 14, 2010).

To the extent that plaintiffs are asking the Court to create a special exception to the learned intermediary doctrine, the Court declines to do so.[6] Plaintiffs have not identified, nor has this Court found, any cases supporting their theory that FDA regulations "inactivate" the learned intermediary doctrine. In fact, the courts that have addressed similar arguments have all concluded that the learned intermediary doctrine is not abrogated by the medication guide regulations. See Dreher v. Wyeth Pharms., Inc., No. 2:14-cv-280-KOB, 2015 WL 3948961, at *8 (N.D. Ala. June 29, 2015); Frazier v. Mylan Inc., 911 F. Supp. 2d 1285, 1290 (N.D. Ga. 2012); Bartlett, 2010 WL 3659789, at *5-7. Accordingly, the Court concludes that defendants' duty to warn of the risks associated with the use of Enbrel ran to Ms. Small's physician, not Ms. Small.

[6] "[F]ederal courts must be cautious when making pronouncements about state law and '[w]hen given a choice between an interpretation of [state] law which reasonably restricts liability, and one which greatly expands liability, we should choose the narrower and more reasonable path.'" Germain v. Teva Pharms., USA, Inc. (*In re* Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.), 756 F.3d 917, 937 (6th Cir. 2014). See also Three Palms Pointe, Inc. v. State Farm Fire & Cas. Co., 362 F.3d 1317, 1318 (11th Cir. 2004).

2. Preemption of the Learned Intermediary Doctrine

Plaintiffs also argue that the medication guide regulations preempt the learned intermediary doctrine. Again, the Court disagrees.

The Supremacy Clause, U.S. Const. Art. VI, cl. 2, invalidates state laws that "interfere with, or are contrary to," federal law. Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 712 (1985). The Supreme Court has identified three types of preemption: (1) express preemption; (2) field preemption; and (3) conflict preemption. Cliff v. Payco General Am. Credits, Inc., 363 F.3d 1113, 1122 (11th Cir. 2004) (citing Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 604-05 (1991)). Here, plaintiffs assert that learned intermediary doctrine is preempted by both field preemption and conflict preemption.

i. Field Preemption

Field preemption occurs when state law occupies a "field reserved for federal regulation," leaving no room for state regulation. United States v. Locke, 529 U.S. 89, 111 (2000). It can also be inferred when "an Act of Congress 'touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" Wiersum v. U.S. Bank, N.A., 785 F.3d 483, 486 (11th Cir. 2015) (quoting English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990)). Nonetheless, for field preemption to be applicable,

"congressional intent to supersede state laws must be 'clear and manifest.'" English, 496 U.S. at 79.

Plaintiffs argue that field preemption exists because "21 C.F.R § 208 gives the FDA exclusive power to determine whether a manufacturer has a duty to warn consumers by way of a medication guide" and "there is no room for a state to determine whether such a duty exists." (Doc. #89, p. 8.) The Court disagrees.

In Wyeth v. Levine, 555 U.S. 555 (2009), the Supreme Court held that state common law failure to warm claims against manufacturers of brand name drugs are not preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, or the regulations promulgated by the FDA. 555 U.S. at 581. In reaching its conclusion, the Supreme Court noted that, as the FDA's powers to ensure the safety of prescription medications expanded, "Congress took care to preserve state law." Id. at 567. Specifically, the Court underscored the fact that while Congress had the opportunity to expressly preempt state law governing the labeling of prescription medication, it declined to do so. Id. The Court further noted that "Congress has not authorized the FDA to pre-empt state law directly." Id. at 576. Because "Congress has repeatedly declined to pre-empt state law," id. at 581, the Court concluded that neither Congress nor the FDA intended the FDA's drug labeling requirements to occupy the field, see Lefaivre

v. KV Pharm. Co., 636 F.3d 935, 941 (6th Cir. 2011). Accordingly, the Court finds that there is no field preemption in this case.

ii. Conflict Preemption

"'Conflict preemption,' as it is commonly known, arises in two circumstances: when it is impossible to comply with both federal and state law and when state law stands as an obstacle to achieving the objectives of the federal law." Cliff, 363 F.3d at 1122 (citing Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372-73 (2000)). Plaintiffs do not argue that it is impossible for a drug manufacturer to comply with the medication guide regulations and the state law duty to provide the prescribing physician with an adequate warning. Instead, plaintiffs assert that "the learned intermediary doctrine is an obstacle to achieving the objectives of 21 C.F.R. § 208 because it relieves the manufacturer of the exact duty that § 208 was constructed to impose." (Doc. #89, p. 9.)

As previously stated, the learned intermediary doctrine provides that a drug manufacturer has a duty to warn the prescribing physician of the possibility that the drug may cause the injury alleged by the plaintiff. See Mason, 27 So. 3d at 77. If the manufacturer complies with this duty, Florida law provides that a plaintiff cannot recover damages under a failure to warn theory. Id. In no way does this doctrine relieve drug manufacturers of their obligations under the medication guide

regulations. Nor does the learned intermediary doctrine stand as an obstacle to fulfilling the purposes and objectives of the medication guide regulations. Indeed, the FDA explicitly stated the learned intermediary doctrine is not at odds with the medication guide regulations. Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998). Furthermore, plaintiffs' obstruction theory is undercut by the fact that the learned intermediary doctrine and the medication guide regulations have coexisted since 1998. See Wyeth, 555 U.S. at 581. As such, the Court concludes that learned intermediary doctrine is not preempted by the medication guide regulations.

3. Application of the Learned Intermediary Doctrine

Defendants maintain that plaintiffs' failure to warn claims are barred by the learned intermediary doctrine because the undisputed evidence demonstrates that Dr. Kowal knew of the risks associated with the use of Enbrel, and would have prescribed Enbrel to Ms. Small regardless of whether the package insert specifically warned of asymptomatic infections. The Court agrees.

Dr. Kowal, as the prescribing physician, served as the learned intermediary between defendants and Ms. Small. See Guarino v. Wyeth, LLC, 719 F.3d 1245, 1250 (11th Cir. 2013) ("[T]he prescribing physician, acting as a 'learned intermediary' between the manufacturer and consumer of the drug, weighs the drug's benefits against its potential harms in deciding whether it is

appropriate to the patient's course of treatment."); Buckner, 400 So. 2d at 822 (same). Thus, the issue before the Court is whether Dr. Kowal was aware of the risk of serious asymptomatic infections and would have prescribed the drug anyway had the warnings been different. See Chase, 740 F. Supp. 2d at 1297.

The undisputed evidence shows that Dr. Kowal's knowledge of the risks and benefits associated with the use of Enbrel was extensive. Dr. Kowal was the principal investigator in a clinical study on Enbrel and was privy to all of the available information regarding the drug's potential side effects. (Doc. # 82-1, pp. 22-23.) Dr. Kowal testified that she understood that Enbrel's warnings of infection included all types of infection and that these infections may occur in any body system. (Id. at 35-36.) She also knew that Enbrel may cause abdominal abscesses and digestive system disorders, including intestinal perforations, and that a patient with a history of infections should be closely monitored for recurrent infections. (Doc. #82-1, pp. 33-34, 75; Doc. #82-3, pp. 17, 20; Doc. #82-5, p. 5.) This knowledge was used by Dr. Kowal when she weighed the risks and benefits of prescribing Enbrel to Ms. Small. (Doc. #82-1, pp. 35-37.)

With respect to her decision to prescribe Enbrel to Ms. Small in 2002, Dr. Kowal testified as follows:

> Q. So you're aware that there could be an asymptomatic infection?

> A. Absolutely . . . .
>
> Q. And if the package insert had said that infections, including asymptomatic infections may be possible with Enbrel, would you still have made the decision to prescribe Enbrel to Ms. Small?
>
> A. Yeah, because it still works, and asymptomatic infections, I mean, how can you -- I mean, are you going to scan everybody? We don't have MRI scan that we can just do body scans to see if an infection is brewing, so you take that risk.
>
> Q. And you -- would you have changed your counseling to Ms. Small in any way if the package insert had said asymptomatic infections?
>
> A. No, not at this time, absolutely not.

(Id. at 46-47.) As to her decision to resume Ms. Small's treatment with Enbrel in 2009, Dr. Kowal testified that her decision would not have been altered by additional warnings regarding the risk of asymptomatic infections. (Id. at 78, 85.)

Based on this testimony, it is clear that Dr. Kowal was aware of the risk of asymptomatic infections and would not have changed her decision to treat Ms. Small's rheumatoid arthritis with Enbrel, even if the package insert had warned of asymptomatic infections. Thus, defendants' purported failure to warn of asymptomatic infections could not have been the proximate cause of Ms. Small's injuries. See Mason, 27 So. 3d at 77.

Plaintiffs attempt to avoid the impact of the learned intermediary doctrine by arguing that Dr. Kowal cannot be treated as a learned intermediary because defendants' pharmaceutical sales

representative advised Dr. Kowal that it was safe to resume Ms. Small's treatment with Enbrel. As previously stated, "the failure of the manufacturer to provide the physician with an adequate warning is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that an adequate warning should have communicated." Tillman, 2015 WL 1456657, at *21. Thus, any representations made by defendants' sales representative are irrelevant if Dr. Kowal had independent knowledge of the possibility that Enbrel could cause the injuries sustained by Ms. Small. Dr. Kowal's testimony clearly shows that she knew of the risks associated with the resumption of Enbrel before she spoke to the sales representative. (Doc. #82-1, pp. 33-34, 75; Doc. #82-3, pp. 17, 20; Doc. #82-5, p. 5.) Accordingly, the Court finds that the representations allegedly made by defendants' sales representative are irrelevant.

Plaintiffs' failure to warn claim is also premised on the theory that defendants failed to provide guidance on resuming treatment with Enbrel after an infection. The problem with this theory is that manufacturers are only required to warn the prescribing physician of the possibility that the drug may cause the injury alleged by the plaintiff. MacMurdo, 562 So. 2d at 683. There is no duty to provide guidance under Florida law. Furthermore, Dr. Kowal testified that requested guidance would not have changed her decision to resume Ms. Small's treatment with

Enbrel.[7] (Doc. #82-1, pp. 78-79, 84-86, 96.) Accordingly, plaintiffs cannot show that defendants' purported failure to provide guidance as to when it was appropriate to resume treatment with Enbrel was the proximate cause of her injuries. See Chase, 740 F. Supp. 2d at 1298.

In conclusion, the Court finds that summary judgment is warranted as to plaintiffs' failure to warn claims. Judgment shall be entered in favor of defendants as to Count II and Count IV, to the extent it asserts a claim for the negligent failure to warn.

B. Design and Manufacturing Defects

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, 74.) Plaintiffs also allege that Enbrel was negligently manufactured. (Id.) Defendants assert that plaintiffs' design and manufacturing defect claims are barred by the learned intermediary doctrine because unavoidably unsafe products are exempt from design defect liability if the benefits

[7]Dr. Kowal also testified that a warning label cannot tell a physician when and how to start treatment with a drug because every patient is unique. (Doc. #82-1, pp. 64, 75.)

of the product outweigh the risks and the product is accompanied by an adequate warning.

Defendants are essentially seeking the protection of comment k in § 402A of the Restatement (Second) of Torts. Comment k addresses "[u]navoidably unsafe products," described "as products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs." Restatement (Second) of Torts § 402A, cmt. k. "Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous." Id. (emphasis in original). Accordingly, the seller of an unavoidably unsafe product that was properly prepared and accompanied by proper directions and warnings will not be strictly liable "for unfortunate consequences attending its use merely because he or she has undertaken to supply the public with an apparently useful and desirable product." Id. In order to be protected under comment k, "a defendant must show that the product is as safe as current testing and research permit, and that the product's benefits outweigh the known risks as of the date the product is distributed." Tillman, 2015 WL 1456657, at *26 (citing Adams v. G.D. Searle & Co., Inc., 576 So. 2d 728, 732-33 (Fla. 2d DCA 1991)).

Here, defendants assert that Dr. Kowal's testimony clearly shows that the benefits of Enbrel outweigh its risk. Defendants

have not, however, proffered any evidence showing that Enbrel was as safe as it could be at the time of Ms. Small's injuries. Furthermore, defendants' arguments are premature as the discovery period has yet to close. Accordingly, defendants' motion for summary judgment is denied as to plaintiffs' design and manufacturing defect claims.

VI.

In Count III of the Fourth Amended Complaint, 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. (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.)

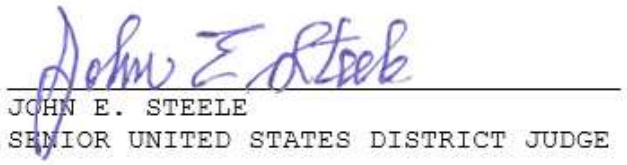
Defendants assert that this claim is barred by the learned intermediary doctrine because it is presumably based upon the failure to warn of asymptomatic infections. The Court disagrees. Nowhere in Count III do plaintiffs allege that defendants made an affirmation or promise as to the adequacy of Enbrel's warnings. As such, defendants' motion for summary judgment is denied as to Count III of the Fourth Amended Complaint.

Accordingly, it is now

Defendants' Motion for Summary Judgment (Doc. #82) is **GRANTED** in part and **DENIED** in part. The Clerk shall enter judgment in favor of defendants as to Count II and Count IV, to the extent it asserts a claim for the negligent failure to warn. The motion is otherwise denied.

ORDERED:

DONE AND ORDERED at Fort Myers, Florida, this 25th day of September, 2015.



JOHN E. STEELE
SENIOR UNITED STATES DISTRICT JUDGE

Copies:

Counsel of record