UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 1:15-cv-21826-KMM

MAGGIE TSAVARIS,

Plaintiff,

v.

PFIZER, INC.; WYETH, INC. and its divisions WYETH PHARMACEUTICALS, INC., ESI LEDERLE, and WYETH LLC.; NOVO NORDISK A/S, a Denmark corporation; NOVO NORDISK INC, a Delaware corporation; and BRECKENRIDGE PHARMACEUTICAL, INC., a Delaware corporation,

Defendants.
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ORDER GRANTING THE WYETH DEFENDANTS' MOTION TO DISMISS

This cause is before the Court on Defendants Pfizer, Inc. and Wyeth LLC's (collectively, the "Wyeth Defendants") Motion to Dismiss Plaintiff Maggie Tsavaris's First Amended Complaint [D.E. 40]. For the reasons discussed below, the motion is granted.

I. BACKGROUND

Tsavaris brings this action against several pharmaceutical companies, including the Wyeth Defendants, for personal injuries she allegedly sustained after consuming their products. The First Amended Complaint [D.E. 30] asserts claims against the Wyeth Defendants for strict products liability–design defect (Count I), strict products liability–failure to warn (Count III), negligence (Count V), and negligent misrepresentation (Count VII) based on the design, manufacture, and distribution of Prempro, a hormone replacement therapy drug Tsavaris claims caused her breast cancer. First Am. Compl. ("FAC") ¶¶ 1–229. As relief, Tsavaris seeks

compensatory and punitive damages, attorney's fees and costs, and a recall of Prempro. *Id*. at 72.

The First Amended Complaint alleges as follows. In 2005, Tsavaris's gynecologist, Dr. Ellen Schwartzbard, prescribed her Prempro. *Id*. ¶ 18. Before receiving the prescription, Tsavaris disclosed to Dr. Schwartzbard her mother's breast cancer diagnosis at the age of 79 or 80. *Id*. ¶ 19. Nevertheless, Dr. Schwartzbard gave Tsavaris a prescription for Prempro, believing that Tsavaris's mother's advanced age at the time of diagnosis meant that hormone therapy did not pose an increased risk of breast cancer for Tsavaris. *Id*.

A few months later, a partner in Dr. Schwartzbard's practice advised Tsavaris to discontinue use of Prempro because her ovaries were producing hormones. *Id*. ¶ 20. Tsavaris did so. *Id*. Tsavaris, however, "probably" resumed taking Prempro sometime after, but discontinued the drug altogether about four months later. *Id*. She did not use Prempro or any other hormone therapy product manufactured by the Wyeth Defendants again.

Tsavaris claims that Dr. Schwartzbard's decision to prescribe Prempro, despite her family history of breast cancer, was the result of the Wyeth Defendants "misrepresenting, downplaying, and/or concealing material facts . . . from the Plaintiff, the public, and the medical profession [regarding] the nature and scope of the serious side effects of the risk of breast cancer from their [hormone therapy] drugs." *Id*. ¶ 32. She maintains that the Wyeth Defendants "minimized the risk in its package inserts by assuring physicians that while some studies indicated an increased risk [of breast cancer], other studies did not." *Id*. ¶ 41. The falsity of this statement, Tsavaris contends, is demonstrated by scientific studies available at the time she was prescribed Prempro. *Id*. Even so, Tsavaris acknowledges that the Wyeth Defendants received approval from the Food

and Drug Administration ("FDA") for inclusion of a black box warning on the Prempro packaging concerning the risks of breast cancer. *Id*. ¶ 47.

The Wyeth Defendants move to dismiss the First Amended Complaint under Rule 12(b)(6) for failure to state a claim on which relief can be granted.

II. LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). It must also contain enough facts to suggest the required elements of a cause of action. *Watts v. Fla. Int'l Univ*., 495 F.3d 1289, 1302 (11th Cir. 2007). "[C]onclusory allegations, unwarranted deductions of fact or legal conclusions masquerading as facts will not prevent dismissal." *Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1188 (11th Cir. 2002). The purpose of this requirement is "to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Id*. When considering a motion to dismiss, the court must accept all of the plaintiff's allegations as true in determining whether the plaintiff has stated a claim for relief. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984).

III. DISCUSSION

As shown more fully below, the claims against the Wyeth Defendants do not survive dismissal. Tsavaris does not allege enough facts to sustain her strict products liability and negligence claims, and she does not plead her negligent misrepresentation claim with the requisite specificity. Accordingly, the Wyeth Defendants' motion to dismiss is granted.

A. Count I (Strict Products Liability–Defective Design) and Count III (Strict Products Liability–Failure to Warn) Are Dismissed Without Prejudice For Failure To State A Claim

Tsavaris fails to put the Wyeth Defendants on notice of how Prempro is defective or how the warnings she received were insufficient. Accordingly, her strict products liability claims in Counts I and III are dismissed without prejudice.

1. Count I (Strict Products Liability–Design Defect)

The manufacturer of a defective product can be held liable if the plaintiff shows that (1) the defendant manufactured or distributed the product in question, (2) the product has a defect that renders it unreasonably dangerous, and (3) the unreasonably dangerous condition is the proximate cause of the plaintiff's injury. *Jennings v. BIC Corp.*, 181 F.3d 1250, 1255 (11th Cir. 1999). In the context of an allegedly defective hormone therapy drug, the plaintiff must make clear "what the alleged defect(s) of each drug is and how each drug is unreasonably dangerous," show "how each drug caused her particular form of breast cancer," and identify "potential defects in each of the drugs that could have caused her cancer." *Kaufman v. Pfizer Pharm., Inc.*, No. 1:02-CV-22692, 2010 WL 9438673, at *3 (S.D. Fla. Nov. 23, 2010). Merely concluding that the drug is defective is insufficient. *See id*.

Tsavaris fails to plead any facts identifying Prempro's purported design defect. Rather, she merely declares that the product was "unreasonably dangerous," that its "risks of breast cancer exceeded any benefits or utility associated with the design or formulation," and that the drug is "much more dangerous than other available and safe alternative HT drugs." FAC ¶¶ 137, 139. Such conclusory allegations, without more, fail to state a design defect claim.

The Court rejects Tsavaris's "shotgun" form of pleading. The allegations in a complaint "must be simple, concise, and direct," Fed. R. Civ. P. 8(d)(1), and the complaint must "state its claims . . . in numbered paragraphs, each limited as far as practicable to a single set of

circumstances," Fed. R. Civ. P. 10(b). A "shotgun pleading"—one in which "it is virtually impossible to know which allegations of fact are intended to support which claim(s) for relief"—does not comply with the pleading standards for a complaint. *Taft v. The Dade Cty. Bar Ass'n, Inc.*, No. 1:15-CV-22072-KMM, 2015 WL 5771811, at *2 (S.D. Fla. Oct. 2, 2015) (citing *Anderson v. Dist. Bd. of Trs. of Ctr. Fla. Cmty. Coll.*, 77 F.3d 364, 366 (11th Cir. 1996)). It forces the district court to sift through the facts presented and decide for itself which are material to the particular claims asserted. *See Anderson*, 77 F.3d at 366–67. The Eleventh Circuit "has addressed the topic of shotgun pleadings on numerous occasions in the past, often at great length and always with great dismay." *Strategic Income Fund, L.L.C. v. Spear, Leeds & Kellogg Corp.*, 305 F.3d 1293, 1297 n.9 (11th Cir. 2002) (citations omitted). While the allegations set forth under Count I do little more than recite the bare elements of a design defect claim, Tsavaris argues this is enough, pointing to allegations scattered throughout the facts section of the First Amended Complaint, which spans 36 pages, to show how Prempro was defectively designed. In doing so, Tsavaris expects the Court to dig through the almost 80 pages of her submission to discover and puzzle together the grounds for her claim. Such shotgun pleading is unacceptable.

For these reasons, Count I is dismissed without prejudice.

2. Count III (Strict Products Liability–Failure to Warn)

Count III fails for the same reasons. To state a strict liability failure to warn claim, the plaintiff must plead that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution. *Bailey v. Janssen Pharmaceutica, Inc.*, No. 06-80702 CIV, 2006 WL 3665417, at *4 (S.D. Fla. Nov. 14, 2006) (citing *Ferayorni v. Hyundai Motor Co.*, 711 So. 2d 1167, 1172 (Fla. 4th DCA 1998)). This requires the plaintiff to plead the content of the warning label or otherwise describe the manner

in which the warning was inadequate. *Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 602 (11th Cir. 2008).

The First Amended Complaint, however, does not identify the content of the warnings in question or adequately present the alleged defects in the warnings. Although Tsavaris maintains that the Wyeth Defendants should have warned that "certain symptoms or family history could lead to breast cancer," of "the symptoms, scope or severity of the potential risk of breast cancer," and "that a safe alternative was available that should be tried first," FAC ¶ 158, she fails to identify what risks the Wyeth Defendants actually warned of, including whether those warnings accompanied the Prempro she received, and exactly how those warnings should have been rewritten to avoid any alleged inaccuracy. As such, Tsavaris has not pleaded enough facts to state a claim under a failure to warn theory.

Tsavaris's attempt to rescue her deficient failure to warn claim fails. Tsavaris relies almost exclusively on the 2005 Prempro label she included with her response, but which she never referenced nor attached to the First Amended Complaint. A plaintiff, though, cannot amend the complaint in a response to a motion to dismiss, for a court's review on dismissal is limited to the four corners of the complaint. *See, e.g., St. George v. Pinellas Cnty.*, 285 F.3d 1334, 1337 (11th Cir. 2002)). In addition, Tsavaris argues that her failure to warn claim is sufficient by pointing to allegations spread throughout the introductory paragraphs of the First Amended Complaint. She also tries to establish the sufficiency of her claim by relying on allegations asserted in other causes of action but not incorporated by reference into Count III. A shotgun pleading of this sort will not do.

For these reasons, Count III is dismissed without prejudice.

B. Count V (Negligence) Is Dismissed Without Prejudice For Failure To State A Claim

To state a negligence claim, a "plaintiff must allege (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 causal connection between the conduct and the resulting injury, and (4) actual loss or damages." *Williams v. Davis*, 974 So. 2d 1052, 1056 (Fla. 2007).

Tsavaris alleges that the Wyeth Defendants owed her a duty of care, which they breached by (1) failing to conduct adequate pre-clinical testing and research to determine the safety of Prempro; (2) failing to conduct adequate post-marketing surveillance to determine the safety and risks of Prempro; (3) failing to warn of the risks of Prempro; and (4) continuing to "dismiss and distract" the consuming public, including Tsavaris, through deceptive marketing and media campaigns designed to downplay the risk of breast cancer associated with Prempro, despite knowing of the significant risks of breast cancer associated with the product. FAC ¶¶ 173–174.

First, Tsavaris's allegation of inadequate testing and post-market surveillance are problematic, at least as currently pleaded. Under Florida law, a manufacturer's duty to test is a subpart of its duty to design a product with reasonable care and, therefore, is subsumed in the plaintiff's claims for defective design and failure to warn. *See, e.g., Adams v. G.D. Searle & Co., Inc.*, 576 So. 2d 728 (Fla. 2d DCA 1991). On that basis, the Court cannot analyze Tsavaris's inadequate testing allegation as supporting her negligence count, only as corroborating her design defect and failure to warn counts.[1]

As for Tsavaris's allegation of insufficient post-market surveillance, the Wyeth Defendants argue that this is effectively a fraud-on-the-FDA claim, which is preempted by federal law. According to the Wyeth Defendants, by alleging that they failed to conduct

[1] Even then the design defect and failure to warn claims fail.

adequate post-market surveillance of Prempro, Tsavaris is in effect claiming that they misled or defrauded the FDA by providing the agency false information. This position is unavailing. A fraud-on-the-FDA claim, like the name suggests, requires allegations of fraud. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001). But Tsavaris makes no such accusations. Instead, she asserts what purports to be a purely state law cause of action for negligence.

That alone does not avoid preemption, however. Federal law impliedly preempts state law when state and federal law "conflict"—that is, when "it is impossible for a private party to comply with both state and federal law" or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2587 (2011)); *see also* William Hochul III, *Enforcement in Kind: Reexamining the Preemption Doctrine In Arizona v. United States*, 87 Notre Dame L. Rev. 2225 (2012). Stated differently, if complying with a state's laws would require a "party to violate federal law," then the state laws "are preempted and, thus, are 'without effect.'" *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013) (citation omitted). So, to present a viable state tort claim that falls outside the scope of federal preemption, Tsavaris would have to allege that (1) the Wyeth Defendants violated a state tort duty and (2) the Wyeth Defendants could have acted in line with their federal obligations while lawfully discharging their state duty. Based on the allegations in the First Amended Complaint, Tsavaris fails to make this showing. That being said, the Court is not ready to dismiss with prejudice her negligence claim based on inadequate post-market surveillance. Tsavaris will have another opportunity to avoid preemption should she choose to file an amended complaint.

Second, Tsavaris's negligence claim based on inadequate warnings fails for the same reasons as her strict products liability failure to warn claim discussed in section III(A)(2) above.

Given these points, and to avoid the piecemeal pleading of claims, the Court will dismiss the entire negligence claim without prejudice so that Tsavaris can amend her complaint to cure the deficiencies discussed above. *See, e.g.*, *Architectural Ingenieria Siglo XXI, LLC v. Dominican Republic*, No. 1:13-CV-20544-KMM, 2015 WL 7760057, at *6 (S.D. Fla. Dec. 2, 2015) (dismissing the entire complaint in the interest of judicial economy to exclude certain claims barred under the law of the case doctrine).

For these reasons, Count V is dismissed without prejudice.

C. Count VII (Negligent Misrepresentation) Is Dismissed Without Prejudice For Failure To State A Claim

A plaintiff may establish negligent misrepresentation by proving (1) a misrepresentation of a material fact; (2) the representor made the representation without knowledge as to its truth or falsity, or under circumstances in which the representor ought to have known of its falsity; (3) the representor intended to induce another to act on the misrepresentation; and (4) injury resulted to the party acting in justifiable reliance on the misrepresentation." *Souran v. Travelers Ins. Co.*, 982 F.2d 1497, 1503 (11th Cir. 1993) (citation omitted). Negligent misrepresentation, like fraud, must be pleaded with specificity. *See, e.g.*, *Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1324 (M.D. Fla. 2013). Adequate pleading of a negligent misrepresentation claim requires allegations of who made the false statement, the substance of the false statement, when the statement was made, and the context in which the statement was made. *See Bailey*, 2006 WL 3665417, *7.

Tsavaris alleges that the Wyeth Defendants misrepresented material facts regarding the "serious risk of breast cancer . . . on the Prempro label and through their sales force." FAC ¶ 193. One such misrepresentation, according to Tsavaris, is a statement made on the 2012 warning label for Prempro that "studies have not found significant variation in the risk of breast

cancer among different estrogen plus progestin combinations, doses, or routes of administration." *Id*. ¶ 196. Tsavaris claims that this was a material misrepresentation because several studies available at the time undermined this assertion. *Id*. But even if the statement on the 2012 warning label was a material misrepresentation, it was made approximately seven years after Tsavaris last used Prempro. As a result, Tsavaris cannot allege that her physician relied on this statement in prescribing the drug.[2] Because Tsavaris is unable to show any justifiable reliance on the alleged misrepresentation, she fails to state a claim for negligent misrepresentation based on the 2012 warning label.

Another misrepresentation Tsavaris cites is a statement on the Prempro package insert that "the risk of breast cancer was 'unknown' and did not exceed that of the general population." FAC ¶ 198. Tsavaris, however, does not specify whether this was the package insert distributed with the Prempro she received from Dr. Schwartzbard. Nor does she state whether Dr. Schwartzbard relied on this statement in prescribing her the drug. By failing to allege critical facts like when the misrepresentation was made, as well as the context in which the statement was made, Tsavaris fails to state a claim for negligent misrepresentation based on the contents of the Prempro package insert.

[2] In Florida, manufacturers of prescription drugs have a duty to warn consumers of known risks or be subject to strict liability for any resulting harm. *Dimieri v. Medicis Pharm. Corp.*, No. 2:14-CV-176-FTM-38, 2014 WL 3417364, at *2 (M.D. Fla. July 14, 2014) (citing *Horrillo v. Cook Inc.*, No. 10–15327, 2012 WL 6553611, at *2 (11th Cir. Nov. 7, 2012)). When a physician is involved, however, the physician serves as a learned intermediary between the patient and the manufacturer, and the learned intermediary doctrine might apply. *Id*. (citing *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir.1995)). Under that doctrine, if the manufacturer properly warns the physician regarding known risks, the manufacturer's duty to warn the consumer is discharged. *Id*. (citing *Christopher*, 53 F.3d at 1192). But even where the manufacturer fails to warn the physician properly, the learned intermediary doctrine will still discharge the manufacturer's duty to warn if the physician had independent knowledge of the risks associated with the drug. *Id*. (citing *MacMorris v. Wyeth, Inc.*, 2:04CV596FTM–29DNF, 2005 WL 1528626, at *2 (M.D. Fla. June 27, 2005)).

Like some of the other causes of action, the Court rejects Tsavaris's shotgun pleading of her negligent misrepresentation claim. Tsavaris tries to cure her inadequate claim by citing introductory paragraph 41 of her 232-paragraph, 79-page complaint, buried in the facts section of the First Amended Complaint and incorporated by reference into Count VII. Again, the Court will not entertain such shotgun pleading.

The Court also rejects Tsavaris's effort to save her claim through her response. Tsavaris points to three statements contained on the 2005 Prempro label, which, together with the allegations set forth under Count VII, she contends make out a negligent misrepresentation claim. The 2005 label, however, was neither referenced in nor attached to the First Amended Complaint. Because a plaintiff cannot amend the complaint when responding to a motion to dismiss, the Court cannot consider the contents of the 2005 Prempro label.

For these reasons, Count VII is dismissed without prejudice.

IV. CONCLUSION

For the foregoing reasons, it is ordered and adjudged that the Wyth Defendants' Motion to Dismiss [D.E. 40] is granted. Counts I, III, V, and VII are dismissed without prejudice.

All pending motions, if any, are denied as moot.[3] The Clerk of Court is instructed to close this case.

Done and ordered in Chambers at Miami, Florida, this 1st day of February, 2016.

Kevin Michael Moore
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K. MICHAEL MOORE
CHIEF UNITED STATES DISTRICT JUDGE

c: Counsel of record

[3] This includes the Wyeth Defendants' motion to strike Tsavaris's request for attorney's fees and for a recall of Prempro.