UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

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

MAGGIE TSAVARIS,

Plaintiff,

vs.

PFIZER, INC., WYETH, Inc. and its divisions WYETH PHARMACUETICALS, INC. AND ESI LEDERLE, and WYETH LLC.; NOVO NORDISK A/S, a Denmark corporation; NOVO NORDISK, INC., a Delaware corporation; BRECKENRIDGE PHARMACUETICAL, Inc., a Delaware corporation,

Defendants.
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OMNIBUS ORDER GRANTING BRECKENRIDGE'S MOTION FOR JUDGMENT ON THE PLEADINGS AND NOVO NORDISK'S MOTION TO DISMISS

This cause is before the Court on Defendant Breckenridge Pharmaceutical, Inc.'s ("Breckenridge") Motion for Judgment on the Pleadings (ECF No. 63) and Defendant Novo Nordisk Inc.'s ("Novo Nordisk") Motion to Dismiss (ECF No. 41). Upon consideration of the motions, pertinent portions of the record, and being otherwise fully advised in the premises, the Court enters the following order.

I. BACKGROUND

This is an action by Plaintiff Maggie Tsavaris against several pharmaceutical companies, including Defendants Novo Nordisk and Breckenridge, for designing, manufacturing, and distributing Hormone Therapy Replacement ("HRT") drugs that Plaintiff alleges caused her to develop breast cancer. Am. Comp. ¶ 1 (ECF No. 30). Specifically, Plaintiff is suing Novo Nordisk as the brand name manufacturer, distributor, and seller of the HRT drug Activella. *Id.* at

¶¶ 1, 5–6. Plaintiff is suing Breckenridge as the manufacturer, distributor, and seller of the generic version of Activella, estradiol/norethindrone acetate (1.0mg/0.5mg). *Id.* at ¶¶ 1, 5, 8. Plaintiff is suing both Defendants for strict products liability based on defective design (Count II), negligence (Count VI), and negligent misrepresentation (Count VIII). And Plaintiff is suing Novo Nordisk individually for strict products liability based on a failure to warn (Count IV). Plaintiff is also suing Pfizer, Inc. and Wyeth LLC (the "Wyeth Defendants") as the manufacturers of the HRT drug Prempro for strict products liability based on defective design and failure to warn (Counts I and III), negligence (Count V), and negligent misrepresentation (Count VII).[1] As relief for her injuries, Plaintiff seeks compensatory and punitive damages, attorney's fees and costs, and a recall of Prempro and Activella. *Id.* at ¶ 72.

While Plaintiff was going through menopause, she experienced severe hot flashes and night sweats. *Id.* at ¶ 14.[2] Plaintiff's physician, Dr. Ellen Schwartzbard, prescribed Plaintiff a combination of HRT drugs to alleviate her symptoms. *Id.* at ¶ 14.

On January 21, 2005, Dr. Schwartzbard gave Plaintiff a prescription for the HRT drug Prempro (0.45mg/1.5mg). *Id.* at ¶ 18. As previously mentioned, Prempro is manufactured and distributed by the Wyeth Defendants. *Id.* at ¶ 3. On or before January 21, 2005, Plaintiff informed Dr. Schwartzbard that her mother had developed breast cancer at age 79 or 80. *Id.* at ¶

[1] The Court will address the motion to dismiss filed by the Wyeth Defendants by separate order. The facts relevant to the Wyeth Defendants are included in this section in order to give Plaintiff's full medical history.

[2] Menopause describes a time in the natural aging process of a woman when her body's production of the natural hormones such as progesterone and several types of human estrogens is dramatically reduced. Am. Compl. at ¶ 13. The physical symptoms of these decreased levels of estrogen and progesterone can include any one or a combination of the following: mood swings, hot flashes, loss of bone density, depression, irritability, night sweats, vaginal dryness, and forgetfulness. *Id.* These symptoms range from severe and disabling in some women to a minor inconvenience or even nonexistent for other women. *Id.*

19. Dr. Schwartzbard informed Plaintiff that her mother's age at the time of her breast cancer was too advanced to be considered a factor as to any family history of breast cancer. *Id.*

On March 28, 2005, Plaintiff was asked by one of the partners in Dr. Schwartzbard's practice to discontinue Prempro because he believed that Plaintiff's ovaries were producing hormones. *Id.* at ¶ 20. Plaintiff discontinued taking Prempro at that time, but at a follow-up visit six weeks later, probably began taking Prempro again because on November 3, 2005, Dr. Schwartzbard wrote during an office visit that Plaintiff "stopped taking Prempro 4 months ago . . . and notices changes in her breasts." *Id.* That would mean that Plaintiff stopped taking Prempro around July 3, 2005. *Id.* Dr. Schwartzbard also noted that, during this office visit, she discussed "[r]isks and benefits of both pill and HRT . . . including heart attack, stroke, and breast cancer." *Id.* According to the Amended Complaint, Dr. Schwartzbard "always advised" Plaintiff "that the studies showing breast cancer risks included an entirely different group of older woman [sic] and that the risks of breast cancer were very remote and insignificant compared to the quality of life that the HRT drugs could provide to [Plaintiff]." *Id.* Plaintiff ceased taking Prempro around July 2005 and did not resume taking the drug again.

From July 2005 to August 2008, Plaintiff did not take any HRT drugs. *Id.* at ¶ 22. On September 17, 2008, and continuing through December 31, 2009, Plaintiff was prescribed Activella (1.0mg/0.5mg). *Id.* at ¶ 23. As previously mentioned, the brand name version of Activella is manufactured and distributed by Novo Nordisk. *Id.* at ¶¶ 1, 6–7. While Plaintiff was prescribed Activella, she never took the brand name version of the drug. *Id.* at ¶ 23. Instead, the pharmacy provided Plaintiff with the generic version of Activella—estradiol/norethindrone

acetate (1.0mg/0.5mg).[3] *Id*. Breckenridge manufactured the generic version of Activella taken by Plaintiff. *Id.* at 8.

Again, when Dr. Schwartzbard prescribed Plaintiff Activella, she advised her "that the studies showing breast cancer risks included a different group of women and that the risks of breast cancer were very remote and insignificant compared to the quality of life that the HRT drugs could provide to [Plaintiff]." *Id.* at ¶ 23.

From December 2009 to February 2010, Plaintiff did not take any HRT drugs. *Id.* at ¶ 25. In March 2010, Plaintiff was again prescribed Activella (1.0mg/0.5mg) and was again given Breckenridge's generic version of Activella, estradiol/norethindrone acetate (1.0mg/0.5mg). *Id*. Plaintiff continued to take Breckenridge's generic from December 2010 through May 2013. *Id.*

On January 31, 2012, Plaintiff's prescription for Activella was reduced from (1.0mg/0.5mg) strength tablets to one (0.5mg/0.1mg) strength tablet once daily, and Plaintiff began to take Breckenridge's generic version of Activella, estradiol/norethindrone acetate (0.5mg/0.1mg). *Id.* at ¶ 26.

On May 15, 2013, Plaintiff was diagnosed with breast cancer and was advised by the diagnosing radiologist to immediately cease taking any HRT drugs, which she did. *Id.* at ¶ 27. Pathology results from tests conducted on or sometime after May 21, 2013, showed that Plaintiff's type of breast cancer was invasive ductal carcinoma and was both estrogen and progesterone receptor positive. *Id.* at ¶ 28. This is commonly referred to as "hormone receptor positive breast cancer." *Id.* The reports also showed negative for HER2 (a gene mutation that is not inherited) and negative for BRCA1 and BRCA2 (genes that are inherited). *Id.*

[3] Pharmacists in most states, including Florida, are under a duty to substitute the generic version of a drug for the brand name version written on the prescription, unless the prescribing physician or the patient specifically request otherwise. *See* Resp. to Mot. to Dismiss, at 6 (ECF No. 48).

Hormone receptor positive breast cancer requires hormones to fuel its growth. *Id.* at ¶ 29. Plaintiff was hormone deficient prior to taking Prempro and Activella, as evidenced by her hormone deficient symptoms, including hot flashes and night sweats. *Id.* at ¶¶ 30–31. Plaintiff claims that she did not have the endogenous hormones to fuel the growth of hormone receptor positive breast cancer prior to taking Prempro and Activella. *Id.* at ¶ 30. Furthermore, had she not ingested exogenous hormones via the HRT drugs, she would not have had the hormones to fuel the growth of hormone receptor positive breast cancer, and she would not have developed hormone receptor positive breast cancer. *Id.* at ¶ 31.

Plaintiff filed the instant case on May 14, 2015 claiming that Defendants' HRT drugs caused her breast cancer and that Defendants knew or should have known of the risk of breast cancer of their HRT drugs. Breckenridge moves for judgement on the pleadings while Novo Nordisk moves to dismiss. The Court will address each motion separately.

II. BRECKENRIDGE'S MOTION FOR JUDGMENT ON THE PLEADINGS

Breckenridge is moving for judgment on the pleadings arguing that Plaintiff's claims for strict products liability, negligence, and negligent misrepresentation are preempted by federal law and further fail to meet the applicable pleading standard. Specifically, Breckenridge argues that "Plaintiff fails to identify *any* action that could have been taken by Breckenridge to cure the alleged defect in the generic version of Activella, or to cure the allegedly defective warnings or misrepresentations made to the prescriber, given that federal law prohibits Breckenridge from making changes to either the chemical composition of the generic version of Activella or its labeling." Mot. for J. on the Pleadings ("Mot. for J."), at 4 (emphasis in original) (ECF No. 63). Plaintiff responds that federal law does not preempt her claims because they are not failure to warn claims. Resp. to Mot. for J., at 3 (ECF No. 65). Plaintiff further focuses on the actions that Breckenridge could have taken "prior to FDA approval" to design a safer drug. *Id.* at 3–4.

A. Legal Standard

Federal Rule of Civil Procedure 12(c) provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). "Judgment on the pleadings is appropriate where there are no material facts in dispute and the moving party is entitled to judgment as a matter of law." *Cannon v. City of W. Palm Beach*, 250 F.3d 1299, 1301 (11th Cir. 2001). When the defendant is the movant, "[a] motion for judgment on the pleadings is governed by the same standard as a motion to dismiss for failure to state a claim on which relief may be granted." *Black v. Kerzner Int'l Holdings Ltd.*, 958 F. Supp. 2d 1347, 1349 (S.D. Fla. 2013).

As a result, all material facts alleged in the non-moving party's pleading are accepted as true and must be viewed in the light most favorable to the non-moving party. *Perez v. Wells Fargo N.A.*, 774 F.3d 1329, 1335 (11th Cir. 2014). "If a comparison of the averments in the competing pleadings reveals a material dispute of fact, judgment on the pleadings must be denied." *Id*.

B. Legal Background

Before turning to the merits of Breckenridge's Motion, the Court will give a brief background of the relevant federal pharmaceutical regulations and how these regulations have impacted claims against generic drug manufacturers.

i. Federal Pharmaceutical Regulations

Federal law heavily regulates the pharmaceutical industry. "Under the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.*, drug manufacturers must gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce." *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013) (citing 21 U.S.C. § 355(a)). In order to gain FDA approval for a new

brand name drug, a manufacturer must prove that the new drug "is safe and effective and that the proposed label is accurate and adequate." *See Pliva v. Mensing*, 131 S. Ct. 2567, 2574 (2011) (citing 21 U.S.C. §§ 355(b)(1), (d); *Wyeth v. Levine*, 555 U.S. 555, 567 (2009)). Meeting these requirements involves "costly and lengthy clinical testing." *Id.* (citing 21 U.S.C. §§ 355(b)(1)(A), (d); D. Beers, Generic and Innovator Drugs: A Guide to FDA Approval Requirements § 2.02[A] (7th ed. 2008)).

For a period of time, all manufacturers had to complete the same approval process, regardless of whether they were the manufacturer of an entirely new pharmaceutical or merely a new, generic version of an existing drug. *See Weeks v. Wyeth, Inc.*, No. 1:10-CV-602-WKW, 2015 WL 4635176, at *6 (M.D. Ala. Aug. 3, 2015) (citing *Mensing*, 131 S. Ct. at 2574). This onerous approval process did not lend itself to a thriving generic pharmaceutical industry. *Id.* Thus, in 1984 Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch–Waxman Amendments, which drastically altered the approval process for new generic pharmaceuticals. *Id.* (citing 21 U.S.C. § 355(j); *Mensing*, 131 S. Ct. at 2574).

The Hatch–Waxman Amendments imposed different obligations on the manufacturers of brand name drugs and the manufacturers of generic drugs seeking federal approval for new pharmaceuticals. Now, generic drug manufacturers may be approved without the same level of clinical testing required for approval of a new brand name drug, provided they show that their drug is identical to an already approved brand name drug in several key respects. *Bartlett*, 133 S. Ct. at 2471. First, the proposed generic drug must be chemically equivalent to the approved brand name drug. *Id.* (citing 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii)). Second, the proposed generic drug must be "bioequivalent" to an approved brand name drug. *Id.* (citing 21 U.S.C. § 355(j)(2)(A)(iv)). Third, the generic manufacturer must show that "the labeling proposed for the

new drug is the same as the labeling approved for the approved brand-name drug." *Id.* (citing 21 U.S.C. § 355(j)(2)(A)(v)) (internal brackets omitted). The impact of this last requirement is that brand name manufacturers seeking approval for a new drug are still responsible for the accuracy and adequacy of their label. *Mensing*, 131 S. Ct. at 2574 (citing 21 U.S.C. §§ 355(b)(1), (d); *Levine*, 555 U.S. at 570–71). However, generic manufacturers seeking approval for a new generic drug are responsible only for ensuring that their label is the same as the brand name drug's label. *Id.* (citing 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7)). Importantly, generic manufacturers are prohibited from making any unilateral changes to a drug's label. *Bartlett*, 133 S. Ct. at 2471.

Once any drug is approved, whether generic or brand name, the manufacturer is prohibited from making any major changes to the formulation of the drug that is provided in the approved application. *Id.* (citing 21 C.F.R. § 314.70(b)(2)(i)).

The Hatch–Waxman Amendments allow manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand name drug. *Mensing*, at 131 S. Ct. at 2574. This presumably allows generic drugs to be sold at a lower price point to more people.

ii. Preemption

While the Hatch-Waxman Amendments have undoubtedly benefitted the general population, they have had the effect of preempting certain claims against generic drug manufacturers. In *Pliva v. Mensing*, 131 S. Ct. 2567 (2011), the Supreme Court addressed whether a state failure to warn claim against a generic manufacturer was preempted based on these federal pharmaceutical regulations. The plaintiffs alleged that long-term use of Pliva's generic drug, metoclopramide, had caused them to develop tardive dyskinesia, a severe neurological disorder. 131 S. Ct. at 2572–73. As a result, the plaintiffs alleged that Pliva was

liable under state tort law for failing to provide adequate warning labels. *Id.* In response, the generic manufacturer argued that the plaintiff's state tort claims were preempted because federal statutes and FDA regulations required them to use the same safety and efficacy labeling as their brand name counterparts. *Id.* at 2573. Thus, it was impossible for them to comply with both federal law and any state tort law duty that required them to use a different label. *Id*. After identifying the relevant state law duties and the federal labeling requirements applicable to the generic manufacturers, the Court determined that it was impossible under federal law for the generic manufacturers to do what state law required of them. *Id.* at 2577–78. Thus, the Court held that federal law preempted the plaintiff's state failure to warn claim. *Id.*

A couple of years later, the Court addressed whether federal law preempted New Hampshire's design defect cause of action in *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013). New Hampshire law imposed a duty on drug manufacturers to ensure that the drugs they marketed were not unreasonably dangerous. 133 S. Ct. at 2474. A drug's safety was evaluated by reference to both its chemical properties and the adequacy of its warnings. *Id.* at 2470. The Court determined that Mutual Pharmaceutical, as a generic manufacturer, was unable to change the drug's composition to make it safer because, as a matter of federal law, a generic drug must be the chemical equivalent and bioequivalent of the brand name drug. *Id.* Because Mutual Pharmaceutical could not change the drug's composition, the Court determined that New Hampshire's design defect claim effectively required Mutual Pharmaceutical to change the drug's labeling to provide stronger warnings. *Id.* However, the Supreme Court had already held that failure to warn claims against generic manufacturers were preempted in *Mensing*. *Id.* Thus, because "state law imposed a duty on Mutual [Pharmaceutical] not to comply with federal law," the Supreme Court determined that New Hampshire's defective design cause of action was preempted. *Id.* at 2470, 2477.

In *Guarino v. Wyeth*, 719 F.3d 1245 (2013), the Eleventh Circuit had the opportunity to apply the Supreme Court's decision in *Mensing*. In *Guarino*, the plaintiff appealed the grant of summary judgment in favor of Teva Pharmaceuticals, the manufacturer of the generic drug metoclopramide, on her claims of negligence, strict liability, breach of warranty, misrepresentation and fraud, and negligence per se.[4] 719 F.3d at 1247. Plaintiff "primarily argue[d]" on appeal that her negligence claim against Teva Pharmaceuticals was not preempted insofar as it alleged a "failure to communicate" a label change to medical providers. *Id.* at 1247, 1249. The Eleventh Circuit found that each of Guarino's claims against Teva Pharmaceuticals were premised upon an "allegedly inadequate warning," and so they were all preempted by federal law. *Id.* Specifically, the Eleventh Circuit stated as follows:

> Guarino's attempt to elude *Mensing* by clothing her allegations as "failure-to-communicate" claims rather than failure-to-warn claims does not alter our analysis. No matter the garb in which she attempts to present them, Guarino's claims are at bottom allegations regarding Teva's failure to warn her of the dangers of long-term metoclopramide use, and they therefore cannot escape *Mensing*'s grasp.

Id.[5]

With this background in mind, the Court turns to Breckenridge's Motion for Judgment on the Pleadings.

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[4] *Guarino v. Wyeth*, 719 F.3d 1245 (2013), also addressed brand name manufacturer liability, which this Court will discuss more *infra* at pages 19–21.

[5] The Eleventh Circuit further found that even if they were to hold that plaintiff's claims against Teva were not preempted by federal law, they would fail on the merits based on the learned intermediary doctrine. *Guarino*, 719 F.3d at 1250–51. While this argument was raised in the Wyeth Defendants' motion, which the Court will address in a subsequent order, neither Novo Nordisk nor Breckenridge raised the argument in their Motions and so there is no reason for the Court to address it here.

C. Discussion

Federal law preempts Plaintiff's claims against Breckenridge for strict products liability, negligence, and negligent misrepresentation because they are premised upon failure to warn and defective design claims. Accordingly, Breckenridge's Motion for Judgment on the Pleadings is granted.

i. Count II: Strict Products Liability – Defective Design

Plaintiff's argues that Breckenridge is liable for defective design because its generic was "not reasonably safe" and contained "unreasonably dangerous design defects" that "far exceeded any utility or benefits of the drug." Am. Compl. at ¶¶ 148–49. As previously mentioned, in *Bartlett*, the Supreme Court held that federal law preempted a cause of action against a generic drug manufacturer for defective design where the defective design claim required that a generic manufacturer either redesign the drug or change the drug's warnings. 133 S. Ct. at 2470. Since federal law preempts state laws imposing a duty to change a drug's design upon generic drug manufacturers, Plaintiff's defective design claim fails.

Plaintiff attempts to circumvent preemption by focusing on the steps that Breckenridge could have taken *prior* to FDA approval. Specifically, Plaintiff argues that "in contrast to the facts of the *Mensing* and *Bartlett* cases," here Breckenridge could have exercised reasonable care in "*the process leading up to placing a drug on the market*." Resp. to Mot. for J., at 7 (emphasis in the original). Plaintiff argues that Breckenridge "can establish neither impossibility of redesign prior to FDA approval and marketing, nor chemical impossibility of redesign." *Id.* (emphasis in the original omitted). However, Plaintiff's argument that Breckenridge could have conducted itself differently prior to FDA approval ignores the nature of a generic drug.[6]

[6] As the Plaintiff outlines in the Amended Complaint, Novo Nordisk applied for an initial new drug application for Activella on November 7, 1997. Am. Compl. at ¶ 89. Activella was

Breckenridge's Reply, at 3 (ECF No. 66). A generic drug must be the chemical equivalent and bioequivalent of its brand name counterpart. *Bartlett*, 133 S. Ct. at 2471. If Breckenridge altered the design of Activella, it would be designing a new drug and Breckenridge would go through an entirely different process of approval, subject to an entirely different set of regulations. Breckenridge's Reply, at 3–4. To find that Plaintiff's defective design claim is not preempted because Breckenridge could have designed an entirely new drug, instead of manufacturing the generic version of Activella, would render *Bartlett* meaningless.[7] It would also undercut Congress' purpose in enacting the Hatch-Waxman Amendments, which was to develop the generic drug market. *See Mensing*, 131 S. Ct. at 2582.

Additionally, Plaintiff's reliance upon *Trahan v. Sandoz, Inc.* No. 3:13-cv-350-j-34MCR, 2015 WL 2365502 (M.D. Fla. Mar. 26, 2015), is misguided. *Trahan* focused on the container

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originally approved by the FDA on or about November 19, 1998 to treat "moderate to severe vasomotor symptoms associated with menopause and in the treatment of vulvar and vaginal atrophy in women with an intact uterus." *Id.* On July 21, 2003, Novo Nordisk announced that it was assuming U.S. marketing activities, including product fulfillment and distribution, for Activella. On March 18, 2004, Novo Nordisk Inc. announced it was "deploy[ing] a force of specialty sales representatives to provide support for hormone therapy Activella (estradiol/norethindrone acetate tables)[.]" *Id.* On or about April 18, 2008, Breckenridge was granted approval for its Abbreviated New Drug Application ("ANDA") to market its generic version of Activella 1.0 mg/0.5mg tablets. *Id.* at ¶ 90. On or about June 10, 2011, Breckenridge was granted approval for its ANDA to market its generic version of Activella 0.5mg/0.1mg tablets. *Id.*

[7] This argument is similar to the argument that the Supreme Court rejected in *Bartlett*. In *Bartlett*, the First Circuit had found that generic drug manufacturer Mutual Pharmaceuticals could escape the impossibility of complying with both its federal and state law duties by choosing to stop selling the drug Sulindac altogether. 133 S. Ct. at 2472. In other words, generic manufacturers facing design defect claims could simply choose not to make the drug at all and thus comply with both federal and state law. *Id*. On appeal, the Supreme Court explicitly rejected the "stop-selling" rationale as "incompatible" with their "pre-emption jurisprudence." *Id.* at 2477. Preemption cases presume that an actor seeking to satisfy both his federal and state law obligations are not required to cease acting altogether to avoid liability. *Id.* Following this reasoning, it would not make sense for this Court to find that Breckenridge could have complied with its state law design defect duty by selling a new drug altogether, instead of the generic version of Activella.

that was used for the drug known as methotrexate. Sandoz, the defendant in *Trahan*, manufactured a generic version of methotrexate and packaged the product in glass vials. *Id.* at *1. Plaintiff's claim was premised on a defect with the glass vials, which led to small pieces of glass being mixed with the drug and administered to the plaintiff in her intravenous injections. *Id.* Sandoz filed a motion to dismiss contending that the design and packaging of the generic methotrexate must be identical to the brand name and Sandoz could not change the packaging to be safer without FDA approval. *Id.* at *2. The plaintiff in *Trahan* "concede[d] that Sandoz [could not] legally alter the chemical composition of methotrexate, but maintain[ed] that her claims [were] premised not on the design of the drug itself, but on Sandoz's decision to use 'substandard glass vials' to package the methotrexate." *Id.* at *5. The court focused on the issue of whether generic drug manufacturers are required "to use exactly the same container for their generic drugs as is used to package the brand-name drug." *Id.* There is not a packaging problem at issue in this case and so *Trahan* is easily distinguishable. The issue here is the composition of the drug itself, and in *Trahan* the plaintiff conceded that the generic manufacturer could not alter the composition of its drug. *See id.*

Because it would be a violation of federal law for Breckenridge, as a generic manufacturer, to change the composition of its drug to be safer, Plaintiff's defective design claim is preempted.

ii. Count IV: Negligence

Plaintiff's negligence claim alleges that Breckenridge owed a duty of care to Plaintiff, which it breached when it failed to "properly conduct adequate pre-clinical testing, failed to properly and safely design, manufacture, produce, discover latent hazards, study, research, and/or distribute [its] HRT drugs," and because it "knew the significant risks of breast cancer of [its] HRT drugs . . . and . . . [it] kept it quiet so that [its] drug sales in [sic] would not suffer."

Am. Compl. at ¶¶ 184–85; *see also* Resp. to Mot. for J., at 8. This breach caused Plaintiff to suffer breast cancer. *Id.* at ¶ 188. Plaintiff's allegations regarding the breach element of her negligence claim are premised on Breckenridge's failure to warn of the risks associated with its drug and the drug's defective design. As a result, Plaintiff's negligence claim is preempted by federal law.

To present a viable state tort negligence claim that falls outside the scope of federal preemption, Plaintiff must allege that Breckenridge: (1) breached its duty to exercise reasonable care and (2) could have taken actions in line with its federal law obligations that would have also allowed it to discharge its duty to exercise reasonable care. *See Bell v. Wyeth, Inc.*, No. 2:10-CV-973-WKW, 2015 WL 4633601, at *8 (M.D. Ala. Aug. 3, 2015). Breaking Plaintiff's negligence claim down, it is clear that there is no action that Breckenridge could have taken to discharge its duty under state negligence law without violating federal law.

First, Plaintiff alleges that Breckenridge breached its duty to exercise reasonable care because it "knew the significant risks of breast cancer of [its] HRT drugs . . . and . . . [it] kept it quiet so that [its] drug sales in [sic] would not suffer." *See* Am. Compl. at ¶ 185. This statement is clearly premised on the notion that Breckenridge was negligent because it failed to warn of the risks associated with ingestion of its generic drug. As the Court already discussed, and as the Supreme Court established in *Mensing* and the Eleventh Circuit found in *Guarino*, claims premised on a generic manufacturer's failure to warn are preempted by federal law.

Plaintiff next alleges that Breckenridge breached its duty to exercise reasonable care when it failed to "properly conduct adequate pre-clinical testing, failed to properly and safely design, manufacture, produce, discover latent hazards, study, research, and/or distribute [its] HRT drugs." Am. Compl. at ¶ 184. Plaintiff's allegation that Breckenridge failed to "properly and safely design, manufacture, produce . . . and/or distribute their HRT drugs" is clearly

premised on the notion that Breckenridge breached its duty of reasonable care because it failed to design a reasonably safe drug. As the Court already discussed, and as the Supreme Court established in *Bartlett*, defective design claims against a generic manufacturer are preempted to the extent that they impose a duty upon the generic manufacturer to redesign a generic drug.

The remainder of Plaintiff's negligence claim, that Breckenridge breached its duty of reasonable care when it failed to "properly conduct adequate pre-clinical testing, failed to properly and safely discover latent hazards, study, [and] research . . . their HRT drugs," also fails to elude preemption. Am. Compl. at ¶ 184. While these allegations focus on the actions that Breckenridge should have taken to discover the alleged hazards associated with ingestion of its drug, it is unclear what action Breckenridge could have taken had it discovered these hazards in light of federal regulations. As this Court has already established, Breckenridge was precluded from strengthening its label and redesigning its generic drug. Accordingly, preemption extends to these allegations as well.

In any event, the duty to test is a subpart of a manufacturer's duty to design a product with reasonable care, and is thus subsumed in a Plaintiff's claims for defective design and failure to warn. *See Trahan v. Sandoz*, 2015 WL 2365502, at *7 (citing *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 730–31 (Fla. Ct. App. 1992). The duty to test was discussed in *Trahan*, a case cited favorably by Plaintiff. *See* Resp. to Mot. for J., at 4, 9–12. In *Trahan*, the plaintiff contended that the inadequate testing of the vials demonstrated negligence because Sandoz, the generic manufacturer, should have detected the defective condition of the glass vials and used a different container. 2015 WL 2365502, at *7. The Middle District found that the plaintiff's contention that the manufacturer failed to adequately test or inspect the drug was a subset of her negligent design and manufacturing claims. *Id.* In *Trahan*, the Middle District had already determined that the plaintiff's defective design and manufacturing claims were not preempted;

thus, the court allowed the plaintiff's inadequate testing allegation to go forward. *Id.* Here, the Court has already concluded that Plaintiff's defective design claims against Breckenridge, as a generic manufacturer, are preempted. Thus, it follows that Plaintiff's allegation that Breckenridge breached its duty of care when it failed to test, study, research, and discover latent hazards is similarly preempted.[8]

iii. Count V: Negligent Misrepresentation

Federal law similarly preempts Plaintiff's negligent misrepresentation claim. Plaintiff alleges that Breckenridge "participated and passively cooperated in the dissemination of misrepresentations and/or concealment, knowing that they were material misrepresentations on which physicians and consumers, including [Plaintiff], would rely and, as such, foreseeably be injured." Am. Compl. at ¶ 219. These misrepresentations failed to communicate the risk of breast cancer associated with Breckenridge's drug. *Id.* at ¶¶ 215, 228. Plaintiff alleges that, were it not for these misrepresentations, she would "never have taken Activella and/or its generic and, as such, [would] not have developed breast cancer." *Id*. at ¶¶ 216–29.

Plaintiff is pleading a failure to warn claim under the guise of a negligent misrepresentation claim. "No matter the garb" Plaintiff presents her claim in, though, it is at bottom an allegation that Breckenridge failed to warn of the dangers associated with its generic drug. *See Guarino*, 719 F.3d at 1249. Plaintiff attempts to ground her claim in a "state law duty not to deceive." But however similar to the failure to communicate claim that the Supreme

[8] To the extent Plaintiff's negligence claim is not preempted by federal law, Breckenridge argues that Plaintiff's Amended failed to meet the *Twombly/Iqbal* standard because Plaintiff's Amended Complaint fails to identify "how Breckenridge failed to exercise reasonable care in the testing, design, manufacture, production, promotion, sales, supply and/or distribution of its generic version of Activella." Mot. for J., at 10. Breckenridge further argues that Plaintiff also does not "make any allegations regarding specific concealments by Breckenridge" and does not allege how Breckenridge's alleged breach of those duties "directly and proximately caused her to suffer breast cancer." *Id.* The Court's grant of Breckenridge's motion for judgment on the pleadings renders this argument moot.

Court rejected in *Bartlett*, this state law duty not to deceive centers around the allegation that Breckenridge had certain information about the increased risk of breast cancer associated with ingestion of its drug and failed to warn consumers and medical practitioners about that risk. *See* Resp. to Mot. for J., at 14.

Plaintiff also attempts once again to focus on what Breckenridge could have, or should have, done before it received FDA approval to make its drug reasonably safe for use by consumers. *Id.* at 17. The Court has already addressed and rejected this argument.[9]

Accordingly, Breckenridge's Motion for Judgment on the Pleadings is granted.[10]

III. NOVO NORDISK'S MOTION TO DISMISS

Novo Nordisk's Motion to Dismiss explores the issue of brand name manufacturer liability. It is the other side of the coin to Plaintiff's suit against Breckenridge. Unfortunately for Plaintiff, her claims against Novo Nordisk fare no better than her claims against Breckenridge. Since Plaintiff never took a HRT drug manufactured or sold by Novo Nordisk, the Court finds that Novo Nordisk is not liable to Plaintiff. Accordingly, Novo Nordisk's Motion to Dismiss will be granted.

A. Legal Standard

A motion to dismiss for failure to state a claim merely tests the sufficiency of the complaint; it does not decide the merits of the case. *Milburn v. United States*, 734 F.2d 762, 765 (11th Cir. 1984). On a motion to dismiss, the Court must accept the factual allegations as true and construe the complaint in the light most favorable to the plaintiff. *SEC v. ESM Group, Inc.*, 835 F.2d 270, 272 (11th Cir. 1988). "To survive a motion to dismiss, a complaint must contain

[9] Breckenridge also argues that Plaintiffs' negligent misrepresentation claim fails to plead facts sufficient to sustain a claim. The Court's grant of Breckenridge's motion renders this argument moot.

[10] Also rendered moot by the Court's grant of judgment on the pleadings is Breckenridge's argument that Plaintiff's request for punitive damages should be dismissed.

sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. v. Twombly*, 550 U.S. 544, 570 (2007)). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* "But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not 'show[n]'-'that the pleader is entitled to relief.'" *Id.* at 679.

A complaint must also contain enough facts to indicate the presence of the required elements. *Watts v. Fla. Int'l Univ.*, 495 F.3d 1289, 1302 (11th Cir. 2007). However, "[a] pleading that offers 'a formulaic recitation of elements of a cause of action will not do.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). "[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).

B. Discussion

Under Florida law, it is clear that Plaintiff does not have a claim against Novo Nordisk "because Florida Law does not permit an injured consumer to recover from the brand name manufacturer of a prescription drug if the consumer is known to have ingested only the generic form of that drug." *See Guarino v. Wyeth*, 719 F.3d 1245, 1253 (11th Cir. 2013). In fact, "[e]very court in Florida" that has considered the question of whether a brand name manufacturer can be held liable if the consumer did not ingest the brand name version of the drug, "has concluded that the brand manufacturer of a prescription drug cannot be held liable for injuries suffered by consumers who ingested only the generic form of the drug." *Id.* at 1251. This approach "is [further] fortified by the fact that the overwhelming national consensus—including decisions of every court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries

caused by the ingestion of the generic form of a product." *Id.* at 1252 (collecting cases); *see also Metz v. Wyeth LLC*, 830 F. Supp. 2d 1291, 1293 (M.D. Fla. 2011), *affirmed*, 525 F. Appx. 893 (11th Cir. 2013) ("The vast majority of courts, in Florida and elsewhere that have addressed the issue now before the Court have consistently held that consumers may not bring claims for negligence, fraud, strict liability, misrepresentation, or breach of warranty against a brand name pharmaceutical manufacturer when the consumers only ingested generic versions of the drug manufactured by third parties.").

Brand name manufacturers are not liable to consumers who did not take their products even though the brand manufacturers are responsible for the label that is on the generic version of their drug and physicians rely upon that label in prescribing the drug. *See, e.g., Smith v. Wyeth, Inc.*, 657 F.3d 420, 423–24 (6th Cir. 2011) ("The plaintiffs' argument—that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs—has been rejected by all but one of the courts that have considered it.").

Plaintiff cites to cases such as *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010), and *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Ct. App. 2008), in support of her argument that Novo Nordisk is liable to Plaintiff. *See* Resp. to Mot. to Dismiss, at 2–3, 7–8, 12. However, these cases are clearly outliers. In fact, they are both cited in *Guarino* as cases that go against the majority. 719 F.3d at 1252–53; *see also Levine v. Wyeth, Inc.*, 684 F. Supp. 2d 1338, 1344 (M.D. Fla. 2010) ("The holding in *Conte* is not binding on this Court, and runs counter to the overwhelming majority of case law, including that of Florida."). Furthermore, there is no reason for the Court to look to the District of Vermont or a state court decision in California when the Eleventh Circuit squarely addressed the issue of brand name manufacturer liability in *Guarino*

and *Metz v. Wyeth LLC*, 830 F. Supp. 2d 1291, 1293 (M.D. Fla. 2011), *affirmed*, 525 F. Appx. 893 (11th Cir. 2013) (per curiam). In both cases, the Eleventh Circuit found that Florida law does not permit an injured consumer to recover from the brand name manufacturer of a prescription drug if the consumer only ingested the generic form of the drug.[11] *See Guarino*, 719 F.3d at 1251; *see also Metz*, 525 F. App'x at 894.

Plaintiff also cites to *Bennett v. Forest Laboratories*, 99 F. Supp. 3d 1360 (M.D. Fla. 2015), for support. *See* Resp. to Mot. to Dismiss, at 8–9. In *Bennett*, Terri Rene was prescribed Lexapro, a selective serotonin reuptake inhibitor ("SSRI") drug. 99 F. Supp. 3d at 1361–62. At the time Rene's physician prescribed her the drug he was aware that SSRI drugs had some relationship to suicidality in certain patients and Rene had suicide risk factors. *Id.* at 1362. Tragically, soon after Rene started to consume Lexapro, she committed suicide. *Id.* Rene's estate brought an action against Forest Laboratories. *Id.* Forest Laboratories moved for summary judgment on the basis that it did not manufacture or design Lexapro. *Id.* at 1363. The Court denied Forest Laboratories' motion because Forest Laboratories was the FDA sponsor of Lexapro and marketed and drafted the warnings for the drug. *Id.* at 1364. The facts in *Bennett* are clearly distinguishable from the facts in this case. The deceased in *Bennett* ingested the drug that Forest Laboratories worked on directly. Here, Novo Nordisk had no direct involvement with Breckenridge's generic version of Activella.

Accordingly, the Court finds that Novo Nordisk is not liable to Plaintiff and its Motion to Dismiss is granted.

[11] Plaintiff's attempt to distinguish *Guarino* from the facts of this case falls short.

IV. CONCLUSION

For the foregoing reasons, it is ORDERED AND ADJUDGED that Defendant Breckenridge Pharmaceutical, Inc.'s Motion for Judgment on the Pleadings (ECF No. 63) is GRANTED and Defendant Novo Nordisk Inc.'s Motion to Dismiss (ECF No. 41) is GRANTED with prejudice.

Done and ordered in Chambers at Miami, Florida, this 7th day of January, 2016.

K. MICHAEL MOORE
CHIEF UNITED STATES DISTRICT JUDGE

c: Counsel of record