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United States District Court,
N.D. Ohio,
Western Division.

Rachel GIFFEN, Plaintiff,
v.
ORTHO McNEIL PHARMACEUTICAL, INC., et al., Defendant.

No. 3:12 oe 40001.
|
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Attorneys and Law Firms

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MEMORANDUM OPINION

KATZ, District Judge.

I. Introduction

***1** Plaintiff Rachel Giffen, a Missouri resident, brought this action against Defendants OrthoMcNeil Pharmaceutical, Inc., Alza Corporation, Johnson & Johnson Pharmaceutical Research & Development, LLC, and Johnson & Johnson alleging she had been prescribed the Ortho Evra® birth control patch which caused her to have a stroke. (Doc. No. 1). Defendants filed a motion for judgment on the pleadings or in the alternative, summary judgment. (Doc. No. 16). Plaintiff filed a response (Doc. No. 18) and Defendants replied (Doc. 19). On September 23, 2014, the Court heard oral argument on the pending motion in this case and several other cases concerning the Ortho Evra® birth control patch. The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

II. Facts

Plaintiff was given a sample of the FDA approved Ortho Evra® birth control patch in March 2008 and used the patch for one month. As a result, Plaintiff alleges she experienced a stroke. Plaintiff commenced this action in the Northern District of Ohio as part of the Ortho Evra® multidistrict litigation (MDL). In doing so, Plaintiff incorporated by reference portions of the MDL Master Complaint alleging the following causes of action: 1) negligence; 2) negligence per se; 3) strict product liability—failure to warn; 4) breach of express warranty; 5) breach of implied warranties; 6) fraudulent misrepresentation; 7) fraudulent concealment; 8) negligent misrepresentation; 9) fraud and deceit; and 10) gross negligence/malice. (Doc. 1).

From approximately July 2007 to April 2008, Deborah Awoniyi–Obrimah, DNP, RN, WHCNP–BC, worked for Planned Parenthood of Kansas and Mid–Missouri as a licensed nurse practitioner. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 4, 9). She had been working as a nurse or nurse practitioner for approximately fifteen years and was authorized to prescribe hormonal birth control products. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 4). Her knowledge and expertise concerning contraceptives came from multiple sources, including her medical training and education, professional journals, office handouts, and package inserts containing product information about specific medications. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 6, 8).

According to her deposition testimony, Nurse Awoniyi–Obrimah decided what medication to prescribe based on clinical experience, experience with different products, knowledge of products, and patient assessment. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 8–9, 12). After consulting with a patient, Nurse Awoniyi–Obrimah would retrieve the contraceptive from a Planned Parenthood supply room and give it directly to the patient. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 10). She would then counsel the patient about the medicine and encourage them to read the information, or package insert, that came with the specific contraceptive. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 10). As part of this

consultation, the patient also received a pamphlet on various birth control methods, which included the risks and benefits associated with hormonal birth control. (AwoniyiObrimah Aff., Doc. No. 16–3, at 11).

***2** During her employment with Planned Parenthood, Nurse Awoniyi–Obrimah prescribed many different hormonal birth control products, which she concedes have a variety of risks, including clotting events and cerebrovascular events such as strokes. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 11–13). She also acknowledged that warnings about those risks are included in the package inserts, including warnings that smoking increased the risks of adverse events when taking a hormonal birth control. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 12–16, 18).

Nurse Awoniyi–Obrimah was familiar with the risks and benefits associated with the Ortho Evra® patch, including higher estrogen exposure. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 12–16, 18). Nurse Awoniyi–Obrimah confirmed she counseled patients who smoked about the increased risk of a stroke when using the Ortho Evra® birth control patch. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 12–16, 18). She was also familiar with the risks set forth in the Orth Evra® package insert when she prescribed the medication to Plaintiff in March 2008, which included detailed patient labeling containing a warning about increased risk of stroke for smokers. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 12–16, 18). Nurse Awoniyi–Obrimah was also aware the package insert included a specific warning regarding the potential increased risk of venous thromoembolism (VTE) for Ortho Evra® users as compared to the birth control pill. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 16).

In February 2008, Plaintiff met with Nurse Awoniyi–Obrimah at Planned Parenthood for birth control counseling. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 20–21). After consultation, Plaintiff chose the Depo–Provera shot as her preferred method of birth control. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 20–21). In doing so, Plaintiff received the general pamphlet regarding the risks and benefits associated with hormonal birth control. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 21–22).

On March 6, 2008, Plaintiff returned to Planned Parenthood for her scheduled Depo–Provera shot. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 22–23). However, Plaintiff had changed her mind on her preferred birth control method and requested the Orth Evra® birth control patch instead. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 22–23). Nurse Awoniyi–Obrimah prescribed the Orthro Evra® birth control patch and gave Plaintiff a box sample. (Awoniyi–Obrimah Aff ., Doc. No. 16–3, at 22–23). According to Plaintiff, Nurse Awoniyi–Obrimah instructed her on how to use the patch but did not explain the risks associated with that use. (Giffen Aff., Doc. 18–5, at 122–24). Plaintiff admits she received the package insert with the box sample of Ortho Evra®, which included the detailed patient labeling. (Giffen Aff., Doc. 18–5, at 125–26, 133–34). At that time, Plaintiff smoked one pack of cigarettes per day. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 19–20; Doc. 18–2, at 10).

***3** Plaintiff did not use the Ortho Evra® sample right away. Rather, she became pregnant and returned to Planned Parenthood to terminate the pregnancy at six weeks gestation on June 13, 2008. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 23). Subsequently, Plaintiff began using the Ortho Evra® birth control patch sometime in July 2008 and used it for one month or one cycle (three oneweek patches). (Giffen Aff., Doc. 18–5, 123, 129). Plaintiff claims the patch had been "off" for approximately two weeks before she suffered a stroke on September 4, 2008. (Giffen Aff. Doc. 18–5, at 201; Doc. 18–2, at 13).

At her deposition, Nurse Awoniyi–Obrimah testified that before she prescribed Plaintiff the Orth Evra® birth control patch, she considered Plaintiff's personal medical history, family medical history, physical condition based on a physical examination, and desire to obtain birth control. Nurse Awoniyi–Obrimah also took into account all the information she knew about Orth Evra®, including information in the package insert and her knowledge and training as a nurse practitioner, when prescribing Ortho Evra® to Plaintiff. (Awoniyi–Obrimah Aff., Doc. No. 16–3, at 23–24).

In sum, before Plaintiff's stroke, Nurse Awoniyi–Obrimah was aware the Orth Evra® patch could cause a stroke. Nurse Awoniyi–Obrimah was also familiar with the language of the Ortho Evra®'s package insert, including the detailed patient labeling, which warned about the risk of a stroke and increased risks associated with cigarette smoking. Moreover, it was Nurse AwoniyiObrimah's custom and practice to discuss with patients the specific risks associated with each hormonal birth control she prescribed. Despite acknowledging the associated risks of hormonal birth control, Nurse

Awoniyi–Obrimah confirmed the Ortho Evra® birth control patch was a safe and effective product that she prescribed patients on a regular basis.

III. Summary Judgment

Summary judgment is proper where "there is no genuine dispute as to any material fact" and the moving party "is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). A party asserting a genuine issue of material fact must support the argument either by "citing to particular parts of materials in the record" or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed.R.Civ.P. 56(c)(1). The Court views the facts in the record and reasonable inferences that can be drawn from those facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). The Court does not weigh the evidence or determines the truth of any matter in dispute. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 249, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

The party requesting summary judgment bears an initial burden of demonstrating that no genuine issue of material fact exists, which the party must discharge by producing evidence to demonstrate the absence of a genuine issue of material fact or "by showing ... that there is an absence of evidence to support the nonmoving party's case." *Celotex Corp. v. Catrett,* 477 U.S.

***4** 317, 323–25 (1986) (internal quotation marks omitted). If the moving party satisfies this burden, the nonmoving party "may not rest upon its ... pleadings, but rather must set forth specific facts showing that there is a genuine issue for trial." *Moldowan v. City of Warren,* 578 F.3d 351, 374 (6th Cir.2009) (citing Rule 56 and *Matsushita,* 475 U.S. at 586). The party opposing the summary judgment motion must present sufficient probative evidence supporting its claim that disputes over material facts remain; evidence that is "merely colorable" or "not significantly probative" is insufficient. *Anderson,* 477 U.S. at 248–52.

IV. Failure to Warn

Under Missouri law, manufacturers of prescription drugs have "a duty to properly warn the doctor of dangers involved and it is incumbent upon the manufacturer to bring the warning home to the doctor." *Krug v. Sterling Drug, Inc.,* 416 S.W.2d 143, 146 (Mo.1967).

A corollary to this rule is the "learned intermediary doctrine" which provides that a manufacturer of prescription drugs or products discharges its duty to warn by providing physicians with information about risks associated with those products. *Doe v. Alpha Therapeutics Corp.,* 3 S.W.3d 404, 419 (Mo.Ct.App.1999) (citing *Christopher v. Cutter Labs.,* 53 F.3d 1184, 1192 (11th Cir.1995)). Specifically, "[t]he physician acts as a 'learned intermediary' between the manufacturer and the patient and any warning given to the physician is deemed a warning to the patient." *Doe,* 3 S.W.3d at 419 (citing *Kirsch v. Pickler Int'l, Inc.* 753 F.2d 670, 671 (8th Cir.1985); *Johnston v. Upjohn Co.,* 442 S.W.2d 93, 95 (Mo.Ct.App.1969)).

A warning is adequate under Missouri law if it "properly warn[s] the doctor of the dangers involved in [using the medication]" *Doe,* 3 S.W.3d at 419–20. Missouri courts have dismissed failure to warn claims where the manufacturer warns of the specific injury alleged. *Wilson v. Lockwood,* 711 S.W.2d 545, 549 (Mo.Ct.App.1986).

Plaintiff contends the Ortho Evra® package insert was "63 pages long" and Nurse AwoniyiObrimah "could not possibly go over every risk with every patient." (Doc. 18, at 7). Plaintiff also asserts the risk of stroke was "hidden and non-obvious," which precludes it from properly warning the prescriber.

The Ortho Evra® package insert, which was in existence when Nurse Awoniyi–Obrimah prescribed Plaintiff the Ortho Evra® patch, included the following warning:

> **RISKS OF USING HORMONAL CONTRACEPTIVES, INCLUDING ORTHO EVRA®**
>
> ...
>
> **2. Heart Attacks and Strokes**
>
> Hormonal contraceptives, including ORTHO EVRA®, may increase the risk of developing strokes (blockage or rupture of blood vessels in the brain) and angina

> pectoris and heart attacks (blockage of blood vessels in the heart). Any of these conditions can cause death or serious disability. Smoking and the use of hormonal contraceptives including ORTHO EVRA® greatly increase the chances of developing and dying of heart disease. Smoking also greatly increases the possibility of suffering heart attacks and strokes.

***5** Because the detailed patient labeling document explicitly warned that the product could cause strokes, the Court finds the warning is sufficient to meet the Defendants' duty to provide adequate warning to physicians regarding the risks associated with the product. *Doe,* 3 S.W.3d at 419; *Christopher,* 53 F.3d at 119; *Wilson,* 711 S.W.2d at 549; *see also Yates v. Ortho–McNeil Pharm., Inc.,* No. 09–oe–40023, 2014 U.S. Dist. LEXIS 47722, 2014 WL 1369466 (N.D.Ohio Apr. 7, 2014) (this Court, applying New York law, granted summary judgment because Ortho Evra® detailed patient labeling specifically warned of the identical side effect allegedly suffered by the Plaintiff).

The record also establishes that before Plaintiff's stroke, Nurse Awoniyi–Obrimah was aware the Ortho Evra® birth control patch could cause a stroke. In addition, Nurse Awoniyi–Obrimah was familiar with the language of Ortho Evra®'s FDA approved package insert and detailed patient labeling which warned about the risk of stroke. Further, Plaintiff acknowledged receiving a box sample of the Ortho Evra® birth control patch which included the package insert and detailed patient labeling. It was also Nurse Awoniyi–Obrimah's medical opinion that Ortho Evra® was a safe and effective product to prescribe Plaintiff.

The manufacturer's duty of adequate warning is fulfilled by providing sufficient information of the product's risks to the treating physician, not the patient. The record is clear that Nurse Awoniyi–Obrimah was aware of the warnings and risks regarding the patch before she prescribed the product to Plaintiff. Indeed, Nurse Awoniyi–Obrimah testified she was familiar with the Ortho Evra® package insert and detailed patient labeling which included warnings of increased risk of stroke, higher estrogen, and increased potential of stroke for smokers. This belies any allegation that the risk of stroke was hidden and non-obvious, or that Nurse Awoniyi–Obrimah was not properly warned.

Moreover, Missouri law does not require a prescriber to go over every risk with every patient. Rather, Missouri law requires manufacturers to provide adequate warning to physicians regarding the risks associated with the product. *Doe,* 3 S.W.3d at 419; *see also Lemmon v. Wyeth,* LLC, No. 04–cv–1302, 2012 U.S. Dist. LEXIS 95924, at *47–48, 2012 WL 2848671 (E.D.Mo. July 11, 2012) (Missouri law assumes doctors will heed an adequate warning). Thus, whether Nurse Awoniyi–Obrimah directly warned Plaintiff is irrelevant. Defendants have met their burden to warn Nurse AwoniyiObrimah, which is all Missouri law requires. Accordingly, Defendants' motion for summary judgment regarding Plaintiff's failure to warn claims is granted.

V. Remaining Claims

Regarding Plaintiff's remaining claims of negligence, negligence per se, breach of express warranty, breach of implied warranties, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, fraud and deceit, and gross negligence/malice, Defendants have moved to dismiss these claims for failing to state a claim for relief pursuant to Federal Rule of Civil Procedure 12(c). The Defendants argue these theories of recovery are based on conclusory allegations which do not satisfy the requirements of Federal Rule of Civil Procedure 8(a)(2), *Ashcroft v. Iqbal,* 556 U.S. 662, 677–80, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009), and *Bell Atl. Corp. v. Twomby,* 550 U.S. 544, 555–56, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

***6** Defendants further argue their request for judgment on the pleadings comports with the Court's prior decisions dismissing similar claims for failure to state a claim for relief. *James v. Johnson & Johnson,* No. 09–oe–40073, 2011 U.S. Dist. LEXIS 142749, 2011 WL 6153112 (N.D.Ohio Dec. 12, 2011); *Miller v. Ortho–McNeil Pharmaceutical, Inc.,* No. 11–oe–40008, 2013 U.S. Dist. LEXIS 158302, 2013 WL 5939774 (N.D.Ohio Nov. 5, 2013); *Hanhan v. Johnson & Johnson,* No. 11–oe–40007, 2013 U.S. Dist. LEXIS 158301, 2013 WL 5939720 (N.D.Ohio Nov. 5, 2013). However, after review of the complaint, Plaintiff's amended fact sheet, Missouri law, and Plaintiff's reply brief, the Court finds Plaintiff's claims satisfy the requirements of Rule 8(a)(2), *Iqbal,* and *Twomby*. Nevertheless, these claims fail pursuant to Defendants' alternative request for summary judgment, which Plaintiff does not oppose.

A. Negligence, Negligence Per Se, Gross Negligence

To state a claim for negligence, a plaintiff must establish: "(1) a duty owed by defendant to protect plaintiff from the injury of which he complains; (2) a failure by defendant to perform that duty; and (3) injury proximately cause by defendant's failure." *Lavo v. Medlin,* 705 S.W.2d 562, 564 (Mo.Ct.App.1986).

The violation of a statute, which is shown to be the proximate cause of the injury, is negligence per se. *Dibrill v. Normandy Assocs.* 383 S.W.3d 77, 84 (Mo.Ct.App.2012). To establish a claim of negligence per se, the plaintiff must show: (1) the defendant violated a statute or regulation; (2) the injured plaintiff was a member of the class of persons intended to be protected by the statute or regulation; (3) the injury complained of was of the kind the statute or regulation was designed to prevent; and (4) the violation of the statute or regulation was the proximate cause of the injury. *American Mortg. Inc. v. Hardin–Stockton Corp.,* 671 S.W.2d 283, 294 (Mo.Ct.App.1984); *see also Sill v. Burlington N. R .R.,* 87 S.W.3d 386, 392 (Mo.Ct.App.2002).

The moving party may establish a right to judgment as a matter of law by showing "there is no genuine dispute as the existence of each of the facts necessary to support the movant's properly pleaded affirmative defense." (*See* Master Answer, Case No. 06–cv–40000, Doc. 122 at ¶¶ 322–24); *Merramec Valley R–III Sch. Dist. v. City of Eureka,* 281 S.W.3d 827, 835 (Mo.Ct.App.2009).

Here, Plaintiff claims she was injured as a proximate result of Defendants' negligence in failing to adequately warn users of the risks associated with the Ortho Evra® patch. However, for the reasons stated above, Plaintiff's claim for failure to warn is without merit pursuant to Missouri's learned intermediary doctrine. Important here, Plaintiff has not shown any facts to establish a genuine dispute that Defendants were negligent in their failure to warn. Accordingly, Plaintiff's negligence claims fail as a matter of law. *See Krug,* 416 S.W.2d 143.

B. Design Defect

***7** In Missouri, "to prevail in a products liability action under a theory of defective design, an injured plaintiff must establish that 1) defendant sold the product in the course of its business; 2) the product was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use; 3) the product was used in a manner reasonably anticipated; and 4) plaintiff was injured as a direct result of such defective condition as existed when the product was sold." *Jaurequi v. John Deere Co.,* 971 F.Supp. 416, 422 (E.D.Mo.1977); *Waggoner by Waggoner v. Mercedes Benz of N. Am., Inc.,* 879 S.W.2d 692, 694 (Mo.Ct.App.1994).

"To establish liability in a design defect case, the plaintiff bears the burden of demonstrating that the product, as designed, is unreasonably dangerous and therefor 'defective,' and that the demonstrated defect caused his injuries." *Nesselrode v. Exec. Beechcraft, Inc.* 707 S.W.2d 371, 375 (Mo.1986).

Here, while Plaintiff has alleged a defective design, she has put forth no facts to support her claim that the design was defective. Plaintiff "must set forth specific facts showing that there is a genuine issue for trial." *Moldowan,* 578 F.3d at 374. Because Plaintiff has not demonstrated a defect in Ortho Evra®'s FDA-approved design; she has not met this burden.

C. Manufacturing Defect

In Missouri, "a manufacturing defect occurs when something goes wrong in the manufacturing process and the product is not in its intended condition. The product is evaluated against the producers' own standards, and compared to like products." *Richcreek v. Gen. Motors Corp.,* 908 S.W.2d 772, 776 (Mo.Ct.App.1995).

Again, Plaintiff recites factual allegations but fails to put forth any facts creating a genuine issue that shows Defendants' deviated from manufacturing specifications or otherwise identical units. Without more, Plaintiff's allegations fail as a matter of law.

D. Negligent Representation, Fraudulent Representation, Fraudulent Concealment, Fraud and Deceit, Breach of Warranties

Claims of negligent and fraudulent representation, fraudulent concealment, fraud and deceit, and breach of express and implied warranties all require proof of reliance on a false statement, or that goods were not of a certain kind or quality fit for such purpose. *Collins v. Missouri Bar Plan,* 157 S.W.3d 726, 734

(Mo.Ct.App.2005) (negligent misrepresentation); *Mprove v. KLT Telecom, Inc.* 135 S.W.3d 481, 489–90 (Mo.Ct.App.2004) (fraudulent misrepresentation); *Evergreen Nat'l Corp. v. Carr,* 129 S.W.3d 492, 496 (Mo.Ct.App.2004) (fraudulent concealment/fraud and deceit); *Heffernan v. Reinhold,* 73 S.W.3d 659, 664 (Mo.Ct.App.2002) (breach of implied warranty); *Carpenter v. Chrysler Corp.,* 853 S.W.2d 346, 357 (Mo.Ct.App.1993) (breach of express warranty).

Plaintiff alleges she relied on Defendants' "misrepresentations" that the Ortho Evra® birth control patch was "safe, fit, and effective for human consumption." (Doc. 18, at 10). Defendants argue Plaintiff has failed to show she relied on a statement. However, the root of the issue is much simpler; namely, Plaintiff has failed to show Defendants' alleged representation was *false* or that the goods were not fit for a particular purpose. Indeed, Nurse Awoniyi–Obrimah testified the Ortho Evra® birth control patch was a safe and effective birth control method with associated health risks. Moreover, the package insert and detailed patient labeling adequately warned Plaintiff of the very injury she suffered.

***8** Assuming Defendants' represented that Ortho Evra® was a safe and effective method of birth control; they also adequately warned her of the increased risk of stroke, higher estrogen levels, and increased risk of adverse cardiac events in combination with smoking. The Court cannot choose those portions of Defendants' warnings or representations which suit Plaintiff's allegations. Rather, the Court must review the entire record to determine whether there is a "genuine dispute as to any material fact." Fed.R.Civ.P. 56(a). Because Plaintiff has failed to establish she relied on Defendants' representations, or that such representations were false or unsuitable, these claims fail as a matter of law.

E. Miscellaneous Claims

In her reply brief, Plaintiff states she alleged the claims of intentional infliction of emotional distress, loss of consortium, and per quod. (Doc. 18, at 2). However, Plaintiff failed to incorporate these causes of action from the Master Complaint on her Short Form Complaint. Accordingly, to the extent she alleges these claims, they are dismissed.

VI. Conclusion

Accordingly, the Defendants' motion for summary judgment (Doc. 16) is granted and Plaintiff's claims are dismissed.

IT IS SO ORDERED.

All Citations

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