UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE NUVARING® PRODUCTS LIABILITY LITIGATION	)	Case No. 4:08-MD-1964 RWS
MARIANNE PRATHER,	)	
Plaintiff	)	
v.	)	Case No. 4:08-cv-00558-RWS
ORGANON USA, INC. *et al.*	)	
Defendants.	)	

MEMORANDUM AND ORDER

Plaintiff Marianne Prather claims that she suffered a pulmonary embolism caused by the NuvaRing combined hormonal contraceptive. Defendants ("Organon") bring this motion for summary judgment against Prather's claims of negligence and strict liability. Prather fails to establish a genuine issue of material fact as to the defective manufacture of NuvaRing as well as the successor liability of Merck as to that claim. Prather establishes genuine issues of material fact as to her claims of inadequate warning, fraud, misrepresentation, design defect, breach of express warranty, breach of implied warranty, and violation of the Missouri

Merchandising Practices Act. Organon's motion for summary judgment will be granted, in part, and denied, in part.

I. BACKGROUND FACTS

NuvaRing is a combination hormonal contraceptive, or "CHC," that contains two hormones: estrogen and progestin. The progestin inhibits ovulation, while the estrogen component primarily mitigates breakthrough bleeding. The most common estrogen in CHCs is ethinyl estradiol ("EE"), which has been used with various progestins over the years to form combination oral contraceptives. CHCs are typically grouped by "generation." Each generation of CHC typically uses the following progestins: first-generation contains norethynodrel; second-generation contains levonorgestrel; and third-generation CHCs contain desogestrel, gestodene, or norgestimate. NuvaRing uses the active metabolite of desogestrel, etonogestrel, and is therefore considered a third-generation progestin

All CHCs can cause venous thromboembolism ("VTE"), including deep vein thrombosis ("DVT") and pulmonary embolism.[1] First-generation CHCs use high levels of EE and are associated with high incidence rates of VTE. Second-generation CHCs use a reduced amount of EE and are associated with less risk of VTE. It is generally accepted that risk of thrombosis is correlated with estrogen

[1] Venous thromboembolism is a blood clot that forms within a vein. Deep vein thrombosis is a blood clot that forms in a vein not externally visible, typically in the veins of the lower extremities. A pulmonary embolism forms when part or all of a blood clot breaks free and lodges in one of the lungs. These conditions have varying severity and can be life threatening.

dose. Third-generation CHCs use lower amounts of estrogen than prior generations; however, some studies have found an increased risk of VTE with some third-generation oral CHCs as compared to second-generation oral CHC, despite the decrease in estrogen dose.

In contrast with oral contraceptives, which are daily pills, NuvaRing is a flexible vaginal ring that is inserted every 28 days. On day 21 of the cycle, the ring is removed, and a new ring is inserted on the 28th day to continue treatment.

The Food and Drug Administration approved NuvaRing and its labeling. NuvaRing's label contains two parts, a main package insert and a portion designated specifically for patients. The main package insert contains numerous sections that provide information on NuvaRing, including its chemical composition, pharmacological data, indications for use, contraindications (patient conditions that preclude NuvaRing use), warnings, reported adverse reactions, overdosage, dosage and administration, and storage.[2] The patient information section contains some of the same information in layperson terms and includes additional information on how to use and dispose of NuvaRing. (Id.).

The main package insert states that NuvaRing should not be used in women who currently have certain conditions, including "[t]hrombophlebitis or

[2] (Doc. 32, Geist Decl. Exh. 1, FDA Approved Label for NuvaRing).

thromboembolic disorders." (Id.). The label has an entire section devoted to warnings:

> **WARNINGS**
>
> NuvaRing and other contraceptives that contain both an estrogen and a progestin are called combination hormonal contraceptives. There is no epidemiologic data available to determine whether safety and efficacy with the vaginal route of administration of combination hormonal contraceptives would be different than the oral route.
>
> The use of oral contraceptives is associated with increased risks of several serious conditions [,] including venous and arterial thrombotic and thromboembolic events (such as . . . thromboembolism . . .) . . . , although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as certain inherited thrombophilias . . . .
>
> The information contained in this package insert is principally based on studies carried out in women who used oral contraceptives with formulations of higher doses of estrogens and progestogens than those in common use today. The effect of long-term use of oral contraceptives with lower doses of both estrogens and progestogens remains to be determined.
>
> . . . .
>
> **1. THROMBOEMBOLIC DISORDERS AND OTHER VASCULAR PROBLEMS**
>
> a. Thromboembolism
>
> An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well established. Case control studies have found the relative risk of users compared to

non-users to be three for the first episode of superficial venous thrombosis, four to 11 for deep vein thrombosis or pulmonary embolism, and 1.5 to six for women with predisposing conditions for venous thromboembolic disease. Cohort studies have shown the relative risk to be somewhat lower, about three for new cases and about 4.5 for new cases requiring hospitalization. The risk of thromboembolic disease associated with oral contraceptives is not related to length of use and disappears after pill use is stopped.

Several epidemiology studies indicate that third generation oral contraceptives, including those containing desogestrel (etonogestrel, the progestin in NuvaRing, is the biologically active metabolite of desogestrel), are associated with a higher risk of venous thromboembolism than certain second generation oral contraceptives. In general, these studies indicate an approximate two fold in-creased risk, which corresponds to an additional one or two cases of venous thromboembolism per 10,000 women-years of use. However, data from additional studies have not shown this two-fold increase in risk. It is unknown if NuvaRing has a different risk of venous thromboembolism than second generation oral contraceptives.

(Doc. 32-1, FDA Approved Label).

Under the heading, "Adverse Reactions," the label states:

Listed below are adverse reactions that have been associated with the use of combination hormonal contraceptives. These are also likely to apply to combination vaginal hormonal contraceptives, such as NuvaRing.

An increased risk of the following serious adverse reactions has been associated with the use of combination hormonal contraceptives (see CONTRA-INDICATIONS and WARNINGS):

- Thrombophlebitis and venous thrombosis with or without embolism
- Arterial thromboembolism
- Pulmonary embolism

(Doc. 32-1, FDA Approved Label).

The label's "Patient Information" section presents additional information:

> **What is NuvaRing?**
>
> . . . .
>
> Contraceptives that contain both an estrogen and progestins are called combination hormonal contraceptives. Most studies on combination contraceptives have used oral (taken by mouth) contraceptives. NuvaRing may have the same risks that have been found for combination oral contraceptives. This leaflet will tell you about risks of taking combination oral contraceptives that may also apply to NuvaRing users. . . .
>
> . . . .
>
> **What are the possible risks and side effects of NuvaRing?**
>
> - **Blood Clots**
>
> The hormones in NuvaRing may cause changes in your blood clotting system which may allow your blood to clot more easily. If blood clots form in your legs, they can travel to the lungs and cause a sudden blockage of a vessel carrying blood to the lungs. Rarely, clots occur in the blood vessels of the eye and may cause blindness, double vision, or other vision problems. *The risk of getting blood clots may be greater with the type of progestin in NuvaRing than with some other progestins in certain low-dose birth control pills. It is unknown if the risk of blood clots is different with NuvaRing use than with the use of certain blood control pills.*[3]

Prather is a resident of Missouri. Organon sold and marketed NuvaRing in Missouri, which included the use of sales representatives. Dr. Evelyn Schuetz prescribed NuvaRing to Prather in Missouri, and Prather began using NuvaRing in

[3] (Id.) (emphasis added).

late August 2003. At the end of September 2003, Prather began to experience leg discomfort and shortness of breath. On October 4, 2003, Prather visited the emergency room in St. Charles, Missouri, where an ultrasound revealed a deep vein thrombosis in her left leg, and a CT scan revealed multiple pulmonary emboli.

Prather claims that NuvaRing presents an undisclosed risk of VTE, including both DVT and pulmonary embolism, that is higher than second- and third-generation oral contraceptives. Prather cites evidence that progestins "counterbalance" the blood-clotting tendencies of estrogen, and that the progestin in NuvaRing does not counterbalance as well as some earlier generations.[4] Prather contends that NuvaRing's use results in occasional bursts of estrogen that are unopposed by progestin, and this increases the blood-clotting propensities of NuvaRing. Prather further alleges that the progestin component of NuvaRing reaches optimum levels more slowly than the estrogen component and that this also increases the risk of blood clots. Prather alleges that Organon knew of these issues and that these properties of NuvaRing are not reflected in the drug's label and packaging inserts. Prather further alleges that Organon failed to timely disclose the occurrences of VTEs in NuvaRing clinical patients and that Organon's sales representatives misrepresent NuvaRing's hormonal "burst" propensity by

[4] Discovery motions brought as part of this multi-district litigation have addressed the admissibility of much of Prather's evidence. See Order dated March 4, 2013 (denying Organon's motion to exclude testimony on hormone counterbalancing); Order dated March 5, 2013 (denying Organon's motion to exclude testimony on estrogen bursts and hormone variability).

telling doctors that the ring "releases a steady dose" of estrogen and progestin per day. (See Doc. 46-3, NuvaRing Sales Support, at 16).

Organon presents several arguments which it believes establish a right to summary judgment. First, Organon argues that Prather's failure-to-warn, breach-of-warranty, and fraud claims fail, because NuvaRing's warnings are adequate as a matter of law. Second, Organon alleges that Prather's express warranty, misrepresentation, and Missouri Merchandising Practices Act claims fail, because Prather has not shown that Organon made any warranty or representation. Third, Organon alleges it is entitled to summary judgment as to Prather's implied warranty claims. Fourth, Organon argues alleges that Prather has provided no evidence in support of her defective manufacturing claims. Fifth, Organon argues that Prather fails to support her defective design claims and that it is entitled to protection from strict liability arising from defective design pursuant to Comment k of the Restatement (Second) of Torts, Section 402A. Sixth, Organon argues that all of Prather's claims fail, because Prather lacks evidence of causation. Finally, Organon argues that it is entitled to summary judgment as to Defendant Merck's successor liability deriving from Prather's claims. Missouri's substantive law governs.[5]

[5] Because this is a diversity case, see 28 U.S.C. § 1332(a), Missouri law applies. See Prudential Ins. Co. of America v. Kamrath, 475 F.3d 920, 924 (8th Cir. 2007) (district court sitting in diversity applies the law of the state in which it sits).

II. SUMMARY JUDGMENT STANDARD

Pursuant to Federal Rule of Civil Procedure 56(c), a court may grant a motion for summary judgment only if all of the information before the court shows "there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Rule 56(c)(1) "provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for judgment; the requirement is that there be no *genuine* issue of *material* fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247–48 (1986). Material facts are those "that might affect the outcome of the suit under the governing law," and a genuine material fact is one such that "a reasonable jury could return a verdict for the nonmoving party." Id. Further, if the non-moving party has failed to "make a showing sufficient to establish the existence of an element essential to that party's case, . . . there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Celotex, 477 U.S. at 322–23.

The initial burden of proof in a motion for summary judgment is placed on the moving party to establish the non-existence of any genuine issue of fact that is material to a judgment in its favor. City of Mt. Pleasant, Iowa v. Assoc'd Elec. Coop., Inc., 838 F.2d 268, 273 (8th Cir. 1988). Once this burden is discharged, if

the record reflects that no genuine dispute exists, the burden then shifts to the non-moving party who must set forth affirmative evidence and specific facts showing there is a genuine dispute on that issue. Anderson, 477 U.S. at 249. When the burden shifts, the non-moving party may not rest on the allegations in its pleadings, but by affidavit and other evidence must set forth specific facts showing that a genuine issue of material fact exists. Fed. R. Civ. P. 56(e). The non-moving party must show there is sufficient evidence favoring the non-moving party that would enable a jury to return a verdict for it. Anderson, 477 U.S. at 249; Celotex, 477 U.S. at 324. "If the non-moving party fails to produce such evidence, summary judgment is proper." Olson v. Pennzoil Co., 943 F.2d 881, 883 (8th Cir. 1991). The evidence must be viewed in the light most favorable to the non-moving party and give to that party the benefit of all favorable inferences. Adickes v. S. H. Kress & Co., 398 U.S. 144, 157 (1970).

III. ANALYSIS

A. The Record Presents a Genuine Issue of Material Fact as to Whether NuvaRing's Warnings of VTE Risk Were Inadequate

Counts III and VIII of Prather's amended complaint assert negligence and strict-liability claims against Organon for failure to warn of VTE risk.

To prevail on a negligent failure-to-warn claim, Prather must prove that Organon manufactured or designed NuvaRing; that NuvaRing did not contain an adequate warning of its alleged defect or hazard; that Organon failed to use

ordinary care to warn of the risk of harm from the alleged defect or hazard; and that, as result of such failure, Prather sustained damage. Moore v. Ford Motor Co., 332 S.W3d 749, 764 (Mo. banc 2011).

To recover under the theory of strict failure-to-warn liability, Prather must prove that NuvaRing was unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics; that Organon did not give an adequate warning of the danger; that NuvaRing was used in a manner reasonably anticipated; and that Prather was damaged as a direct result of NuvaRing being sold without an adequate warning. Pollard v. Ashby, 793 S.W.2d 394, 397–98 (Mo. App. E.D. 1990) (en banc). Admissible expert testimony that additional or other warnings might have altered the plaintiff's behavior is required in failure-to-warn cases. See Bryant v. Laiko Int'l Co., Inc., No. 05-00161, 2006 U.S. Dist. LEXIS 73682, 2006 WL 2788520 at *9–10 (E.D. Mo. Sept. 26, 2006); Davidson v. Besser Co., 70 F. Supp. 2d 1020, 1023 (E.D. Mo. 1999).

"Missouri courts have held that in cases involving manufacturers of prescription drugs, the manufacturer has 'a duty to properly warn the doctor of the dangers involved and it is incumbent upon the manufacturer *to bring the warning home* to the doctor.'" Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. App. 1999) (emphasis added) (quoting Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 146 (Mo. 1967)).

Organon argues that the NuvaRing label provides adequate warnings as to the risk of VTE and that no material fact exists as to that issue. Prather responds that the warnings fail to adequately address the difference in risk between NuvaRing and oral CHCs, including second-generation oral CHCs. I have already allowed testimony from Prather's experts as to the inadequacy of the NuvaRing label as it pertains to variability and bursts of estrogen and how those issues affect the risk of VTE.[6]

NuvaRing's label provides:

> Several epidemiology studies indicate that third generation *oral* contraceptives, including those containing desogestrel (etonogestrel, the progestin in NuvaRing, is the biologically active metabolite of desogestrel), are associated with a higher risk of venous thromboembolism than certain second generation *oral* contraceptives. In general, these studies indicate an approximate two fold increased risk, which corresponds to an additional one or two cases of venous thromboembolism per 10,000 women-years of use. However, data from additional studies have not shown this two-fold increase in risk. *It is unknown if NuvaRing has a different risk of venous thromboembolism than second generation oral contraceptives.*

(Doc. 32-1, FDA Approved Label).

Prather argues that Organon knew that NuvaRing presented a risk of VTE greater than second-generation oral contraceptives. In 1995, Prather notes, a study funded by one of the Defendants reported an increased risk of VTE in third-

[6] See Order dated March 5, 2013, at *10–12 (denying Organon's motion to exclude all testimony related to "bursts" or "high variability" in NuvaRing's estrogen delivery); Order dated March 4, 2013 (denying Organon's motion to exclude testimony by Dr. Shelly Ann Tischkau regarding adequacy of NuvaRing's VTE warnings and pharmacokinetic data).

generation progestins when compared to second-generation progestins. (Doc. 49-4, Dr. Buncher Expert Report at *3 (citing Jick H. et al., "Risk of Idiopathic Cardiovascular Death and Nonfatal Venous Thromboembolism in Women Using Oral Contraceptives with Differing Progestagen Components," 346 *The Lancet*, 1589 (1995)).[7] Prather cites to the occurrences of VTEs in NuvaRing clinical trial subjects as evidence that the increased risk presented by third-generation progestins in oral CHCs had manifested in NuvaRing prior to Prather's injury. (Doc. 50-1, Parsian Report at ¶¶ 141 & 196). Prather alleges that these VTEs reflect an incidence rate for NuvaRing at nearly double the calculated rate (10.1/10,000 women-years versus 5.35/10,000 women-years). Prather further cites to communications by Organon personnel resisting the inclusion of VTE information in the label.[8]

Missouri law places the burden on the manufacturer to "bring the warning home" to a prescribing physician. Alpha Therapeutic, 3 S.W.3d at 419. The

[7] See also id. at *2 (noting consensus opinion as to third- and second-generation progestin risk differentials) (citing Vendenbroucke J.P. et al., "Oral Contraceptives and the Risk of Venous Thrombosis, 344 *New England Journal of Medicine* 1527 (2001)).

[8] "My major comment on the U.S. [Package Insert] relates to including the one case of thrombosis. We should really try to get it out of the text." (Doc. 50-1, Parisian Report at ¶ 144). "It is unclear to me why we are s opposed to including the animal data . . . could we use this as a bargaining chip for other, more important issues such as the VTE warning, bleeding data, etc.?" (Id.). "[T]he label change looks much better, however, I am still unhappy with the VTE section of the label. Obviously, the case that we presented to them has made some impact, in that they have added the statement about being unknown if NuvaRing has this increased risk. What are the chances that this section can be removed all together?" (Id.). "To my satisfaction a number of critical issues have been implemented in the current proposal of the FDA (e.g. the deletion of the single VTE case)." (Id.).

record contains admissible expert testimony regarding the inadequacy of warnings Organon placed upon NuvaRing and tends to show that the NuvaRing label does not disclose a known difference in risk between NuvaRing and second-generation CHCs. Cf. Parke-Davis & Co. v. Stromsodt, 411 F.2d 1390, 1401 (8th Cir. 1969) (affirming inadequacy of undisclosed difference in risk with comparator drug). I find that Prather's evidence presents a genuine issue of material fact as to whether Organon's warnings were inadequate.

Finally, Organon argues that, regardless of the warning's adequacy, Prather cannot establish causation as a matter of law because her prescribing physician, Dr. Schuetz, knew of the allegedly undisclosed risks.[9] A corollary to the prescription drug manufacturer's duty to warn a prescribing doctor is the "learned intermediary doctrine," which recognizes the role of a physician as a "learned intermediary" between a drug manufacturer and a patient. See Alpha Therapeutic, 3 S.W.3d at 420 (citation omitted). Under the learned intermediary doctrine, any warning given to the physician is deemed given to the patient. Id. (citations omitted). A manufacturer's failure to provide an adequate warning "is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warnings should have communicated." Id. (citations omitted).

[9] Organon's remaining arguments as to causation are addressed below.

Dr. Schuetz acknowledged that she was aware that all "combined hormonal contraceptive products that contain estrogen, . . . as a class, carry an inherent risk of blood clots." (Doc. 50-5, Schuetz Dep. at 29). Dr. Schuetz admitted that she learned of this risk during residency. (Id. at 30). Dr. Schuetz stated that she had read the portion of the NuvaRing label that addressed the risk differential between third-generation oral contraceptives and second-generation oral contraceptives.[10] Dr. Schuetz testified that she understood the label to convey that "we don't know conclusively whether there's a difference in risk between NuvaRing and second-generation birth control pills." (Id. at 146). Dr. Schuetz further testified that at the time she prescribed NuvaRing to Prather, she understood that NuvaRing had the same risk as birth control pills or other products on the market. (Id. at 127).[11]

Contrary to Organon's argument, this testimony does not tend to show that Dr. Schuetz possessed independent knowledge that NuvaRing presented a greater

[10] The portion of the NuvaRing label to which Dr. Schuetz refers states:

> Several epidemiology studies indicate that third generation *oral* contraceptives, including those containing desogestrel (etonogestrel, the progestin in NuvaRing, is the biologically active metabolite of desogestrel), are associated with a higher risk of venous thromboembolism than certain second generation oral contraceptives. In general, these studies indicate an approximate two fold increased risk, which corresponds to an additional one or two cases of venous thromboembolism per 10,000 women-years of use. However, data from additional studies have not shown this two-fold increase in risk. It is unknown if NuvaRing has a different risk of venous thromboembolism than second generation oral contraceptives.

(Doc. 32-1, FDA Approved Label).

[11] See also (id. at 130) ("[Q] Just assuming . . . there's an increased risk with NuvaRing of causing thrombotic events in comparison with second-generation birth control products . . . would you agree that the label does not clearly tell you that NuvaRing is any more likely to cause thrombotic events than other birth control products available on the market?" . . . A: Correct.").

VTE risk than second-generation oral contraceptives. Rather, when viewed in the light most favorable to Prather, Dr. Schuetz's testimony supports Prather's claim that the VTE warning was inadequate. I will, therefore, **DENY** Organon's motion for summary judgment as to Counts III and VIII of Prather's complaint.

B. Prather's Claims for Breach of Express Warranty, Intentional and/or Negligent Misrepresentation, and Violation of the Missouri Merchandising Practices Act (Counts IV, IX, and X) Do Not Fail Due to any Lack of Proof that Organon Made a Warranty or Misstatement to Prather or Dr. Schuetz

A plaintiff seeking to recover for breach of an express warranty must establish that the defendant represented to the plaintiff that the goods were of certain kind or quality. Carpenter v. Chrysler Corp., 853 S.W.2d 346, 357 (Mo. Ct. App. 1993) (citing Rev. Stat. Mo. 400.2-313). To state a claim for negligent misrepresentation, a plaintiff must show, among other elements: the speaker supplied information in the course of his or her business and because of a failure by the speaker to exercise reasonable care, the information was false. Renaissance Leasing, LLC v. Vermeer Mfg. Co., 322 S.W.3d 112, 134 (Mo. banc 2010). Similarly, a Missouri fraud claim requires a representation. Joel Bianco Kawasaki Plus v. Meramec Valley Bank, 81 S.W.3d 528, 536 (Mo. banc 2002). To establish a claim under the Missouri Merchandising Practices Act ("MMPA"), a plaintiff must "allege facts establishing that defendants used or employed a deception, fraud, false pretense, false promise, [or] misrepresentation . . . ." Chochorowski v.

Home Depot U.S.A., Inc., 295 S.W.3d 194, 197–98 (Mo. Ct. App. 2009) (citing Rev. Stat. Mo. § 407.020.1).

Organon contends that it is entitled to summary judgment because Prather fails to allege that a particular representation was made to her by a defendant. However, Prather alleges that Organon sales personnel represented to Dr. Schuetz that NuvaRing is a new product and carries the same risks as birth control pills with respect to blood clots. (Doc. 50-5, Schuetz Dep. at 141–42).[12] Dr. Schuetz further testified that she would have informed Prather of the increased risk for pulmonary embolism if it had been disclosed. (Doc. 50-5, Schuetz Dep. at 132–33). Likewise, Prather testified that if she had known of the increased VTE risk presented by NuvaRing, she would not have used the product. (Doc. 50-6, Prather Dep. at 21–22).

Prather has set forth an allegedly false statement made by Organon upon which she relied. Prather establishes a genuine issue of material fact as to Counts

[12] Under the "learned intermediary doctrine," warnings given to a physician are deemed given to the patient. See Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 420 (Mo. App. 1999). Prather does not cite any Missouri cases applying the doctrine to breach of warranty, fraud, or misrepresentation claim, though she cites holdings from numerous other jurisdictions. See, e.g., Allen v. G.D. Searle & Co., 708 F. Supp. 1142, 1161 (D. Or. 1989); Boles v. Merck & Co. (In re Fosamax Prods. Liab. Litig.), 647 F. Supp. 2d 265, 283 (S.D.N.Y. 2009) ("A fraud on the physician is a fraud upon the patient."). Physicians are the gatekeepers to prescription medicine in America, and common sense dictates that any representations made to a doctor would foreseeably influence their prescribing practices. Cf. Plubell v. Merck & Co., Inc., 289 S.W.3d 707, 714 (Mo. Ct. App. 2009) (noting that under the MMPA, a plaintiff need not prove she or her physician relied upon the misrepresentation). In any case, Organon does not challenge the application of the doctrine as to Prather's claims in Counts IV, IX, and X.

IV, IX, and X, and I will **DENY** Organon's motion for summary judgment as to those counts.

C. Prather Established Her Claim for Implied Warranty (Count V)

Missouri has adopted the Uniform Commercial Code ("UCC"). See Rev. Stat. Mo. § 400.1-101; see also Bracey v. Monsanto Co., Inc., 823 S.W.2d 946, 947 (Mo. banc 1992). In order to recover under the UCC's breach of an implied warranty of merchantability theory, "a plaintiff must prove (1) that a merchant sold goods, (2) which were not 'merchantable' at the time of the sale, (3) injury and damages to the plaintiff or his property (4) which were caused proximately or in fact by the defective nature of the goods, and (5) notice to the seller of the injury." Ragland Mills, Inc. v. General Motors, Corp., 763 S.W.2d 357, 360 (Mo. Ct. App. 1989) (citing Rev. Stat. Mo. § 400.2-314). In order to be merchantable, goods must, among other requirements, be "fit for the ordinary purposes for which such goods are used." Rev. Stat. Mo. § 400.2-314.

Organon argues that it is entitled to summary judgment for two reasons: (1) there can be no breach of an implied warranty where a product warns of the precise risk giving rise to plaintiff's claim; and (2) Prather fails to prove that NuvaRing was not fit for its ordinary and intended purposes.

Organon cites Haddix v. Playtex Family Prods. Corp. for the proposition that the warranty of merchantability is not breached when a user is harmed by a

specific risk against which the product warns. 964 F. Supp. 1242, 1246–47. However, Haddix requires that the warning not only be specific, but adequate. See id. at 1247. As discussed above, Prather has shown that a genuine issue of material fact exists as to the adequacy of NuvaRing's warnings.

Under Section 2-314 of the UCC, a manufacturer may breach its implied warranty of merchantability, based on lack of fitness for ordinary purposes, by failing to provide adequate instructions or warnings. See Madsen v. Am. Home Prods. Corp., 477 F. Supp. 2d 1025, 1037–38 (E.D. Mo. 2007) (applying Iowa codification of UCC § 2-314); Grinage v. Mylan Pharms., Inc., 840 F. Supp. 862, 871 (D. Md. 2011) (applying Maryland adoption of UCC § 2-314).[13] Prather has shown that a question of fact exists as to the adequacy of Organon's warnings. I cannot, as a matter of law, hold that Organon is entitled to summary judgment as to

[13] Compare Barkley Clark & Christopher Smith, The Law of Product Warranties, ¶ 5.01 [2][a], at 5–9 (1984) ("For a product to flunk the merchantability test, it must contain an inherent defect. . . . The cases indicate that the courts find goods to be unfit for their ordinary purposes when they can identify one of three general types of defects: manufacturing defects, design defects, and failure to give the buyer proper instructions with respect to the goods. This tripartite test for defect is essentially the same as that required when the theory is strict tort liability under Section 402A of the Restatement (Second) of Torts, except that goods may violate Section 2-314 without being 'unreasonably dangerous' . . . .") with Hill v. Searle Labs, Inc., 884 F.2d 1064, 1066 (8th Cir. 1989) ("[A] product is 'defective' when it is properly made according to an unreasonably dangerous design, or when it is not accompanied by adequate instructions and warning of the dangers attending its use.") (citing Prosser, Law of Torts, 659 (4th ed. 1971)).

Prather's claim for breach of implied warranty.[14] Organon's motion for summary judgment as to breach of implied warranty will be **DENIED.**

D. Prather Has Not Shown a Genuine Issue of Material Fact as to Defective Manufacturing (Counts I and VIII)

"[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) (internal quotation marks omitted).

Prather has provided no evidence that anything has "gone wrong" in the manufacturing process, which caused the NuvaRing she used to deviate from Organon's specifications. Because Prather fails to show that a genuine issue of material fact exists as to defective manufacturing, I will **GRANT** Organon's motion for summary judgment as to those issues.

E. Prather's Claims for Negligent Design and Strict Liability (Counts II and VIII) Do Not Fail Due to any Lack of Proof of a Design Defect and Comment K to Section 402A of Restatement (Second) of Torts Does Not Preclude Prather's Strict Liability Claims

Organon argues it is entitled to summary judgment as to Prather's design-defect claims. Organon asserts that Prather's strict liability design-defect claims

[14] As discussed later, Prather has presented a colorable claim for defective design. The evidence supporting that claim would equally support her argument that NuvaRing was not merchantable. See Hill, 884 F.2d at 1066.

are barred pursuant to Missouri's adoption of comment k to the Restatement (Second) of Torts, Section 402A ("comment k"). Organon also alleges that Prather has failed to establish that any defect in the Design of NuvaRing proximately caused her pulmonary embolism.

Comment k to section 402A specifically addresses the application of strict liability to unavoidably unsafe products such as prescription drugs. Comment k states:

> k. Unavoidably unsafe products. There are some 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. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Missouri courts limit the application of comment k to drugs "shown to be incapable of being made safe given the present state of human knowledge but which have such a high degree of social need that their use is warranted, so long as there are sufficient warnings." Pollard v. Ashby, 793 S.W.2d 394, 399–400 (Mo. Ct. App. 1990) (en banc).

Comment k is an affirmative defense, and the manufacturer of a prescription drug bears the burden of showing that the drug falls under the protection of comment k. Id. at 400. Organon fails to show that NuvaRing is incapable of being made safe and that there is such a need for the drug that its use is warranted. Organon makes no showing in its initial brief; in reply to Prather, Organon merely points to evidence that all CHCs present some risk of VTE and that some oral CHC users have difficulty remembering when to take their pills.[15] Organon fails to identify and quantify NuvaRing's risks, and further fails to respond to Prather's argument that NuvaRing might have been made safer by employing a second-generation progestin.[16] I find that Organon has failed to establish the applicability of comment k.

[15] It should be noted that there are an abundance of other contraceptive methods available, not all of which involve combinations of hormones.

[16] Organon argues that prescription CHCs as a class fall under the protection of comment k, and that I should not follow an Eighth Circuit decision that held that the comment requires an individualized inquiry as to the drug's risks and benefits. See Hill v. Searle Labs., 884 F.2d 1064, 1068–70 (8th Cir. 1989) (evaluating a hormonal contraceptive and declining to apply

Organon also argues that Prather fails to show a design defect and, therefore, it is entitled to summary judgment as a matter of law. However, Prather alleges that NuvaRing is defective due to use of a third-generation progestin in lieu of a second-generation progestin; due to the failure of NuvaRing's progestin component to properly counterbalance its estrogen component; and due to the use of a vaginal delivery system that results in unopposed "bursts" of estrogen.[17] Prather has also provided admissible expert evidence of causation stemming from these defects.[18] I find that Prather has established a genuine issue of material fact as to whether a design defect in NuvaRing caused her pulmonary embolism. As a result, I will **DENY** Organon's motion for summary judgment as to Prather's design defect claims.

F. Prather's Claims Do Not Fail for Lack of Causation

Organon argues that Prather's claims fail to establish causation for several reasons. First, Organon argues that Prather cannot show she would not have used NuvaRing if it had been accompanied by an adequate warning. Second, Organon also alleges that Prather's claims are all barred as a matter of law because there is

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comment k). Organon argues that Hill is distinguishable "because Missouri law does not limit application of comment k to exceptional circumstances." (Doc. 60, Def. Reply at *18 & n.13). Organon ignores Missouri case law that is directly on point and which Organon itself cites in its immediately preceding paragraph. See Pollard, 793 S.W.2d at 400 ("This court holds that comment k is an affirmative defense and its applicability must be determined by the trial courts on a case-by-case basis.") (citing Hill, 884 F.2d at 1069).

[17] See supra, notes 4, 6 & 7 and accompanying text.

[18] See Order dated April 10, 2013 (admitting expert causation testimony from Dr. John Richart); see also (Doc. 50-3, Richart Dep. at 249); (Doc. 49-5, Richart Report at *2, 7–10).

no evidence of a causal link between any alleged wrongdoing by Organon and Prather's pulmonary embolism.

Organon argues that Prather cannot establish that a different warning would have altered the decision of Dr. Schuetz to prescribe NuvaRing for her. However, Missouri aids plaintiffs in proving that a warning would have altered the behavior of their prescribing physicians by presuming that a warning will be heeded. Arnold v. Ingersoll-Rand Co., 834 S.W.2d 192, 194 (Mo. banc 1992). This "heeding presumption" may be rebutted by the defendants. Grady v. Am. Optical Corp., 702 S.W.2d 911, 918 (Mo. Ct. App. 1985).

Organon argues that it has rebutted the heeding presumption because Dr. Schuetz testified that up until her deposition, she still prescribed NuvaRing. (Doc. 50-5, Schuetz Dep. at 34). However, Organon's argument requires an impermissible inference: that Dr. Schuetz was at that point in time aware of all of NuvaRing's risks. See Schilf v. Eli Lilly & Co., 687 F.3d 947, 951 (8th Cir. 2012).

Even if Organon could show that Dr. Schuetz still prescribes NuvaRing with full knowledge of its risks, the record shows that Prather would not have used NuvaRing had the warning been adequate. Dr. Schuetz testified that Prather had the right to know that a drug being considered has increased risk of blood clots. (Doc. 50-5, Schuetz Dep. at 133). Dr. Schuetz stated that had she understood that NuvaRing was more likely to cause a pulmonary embolism, she would have

disclosed that fact to Prather. (Id. at 132–133). Prather testified that had she known of the increased risk for blood clots, she would not have taken NuvaRing. (Doc. 50-6, Prather Dep. at 21). Regardless of Dr. Schuetz's prescribing practices, there exists evidence that Prather would not have taken NuvaRing had the risks been adequately disclosed. Viewing this information in the light most favorable to the non-moving party, I find that Prather has raised a genuine issue of material fact as to whether she would have taken NuvaRing had its warning been adequate.

Organon also alleges that Prather's claims are all barred as a matter of law because there is no evidence that Prather have avoided her pulmonary embolism had she not taken NuvaRing. I have already ruled that Prather's expert, Dr. John Richart, may testify that but for Prather's use of NuvaRing, she would not have suffered her pulmonary embolism.[19] Organon's argument that Prather's claims fail for lack of causation will be **DENIED**.

G. Successor Liability (Count XI)

Organon finally argues that Prather's claim for successor liability against Merck fails for want of an underlying claim. A successor liability claim is predicated upon the existence of liability on the part of a predecessor entity. See Santa Maria v. Owens-Illinois, Inc., 808 F.2d 848, 851 n.5 (1st Cir. 1986). Because Prather has introduced genuine issues of material fact, as discussed above,

[19] See Order dated April 10, 2013 (denying Organon's Daubert motion to exclude testimony of Dr. Richart).

I will deny Organon's motion for summary judgment as to successor liability deriving from those claims. However, I have found that Prather fails to introduce evidence in support of her manufacturing defect claim. I will, therefore, **GRANT** Organon's motion for summary judgment regarding successor liability as to manufacturing defect.

IV. CONCLUSION

In conclusion, I will grant Organon's motion for summary judgment as to Prather's manufacturing defect claims and as to Merck's successor liability deriving from those dismissed claims. Prather has introduced genuine issues of material fact as to her remaining counts.

Accordingly,

IT IS HEREBY ORDERED that Organon's motion for summary judgment [Doc. 30] is **GRANTED, in part, and DENIED, in part.** Organon's motion for summary judgment is **GRANTED**, as to Counts I (Strict Products Liability—Defective Manufacturing) and as to the portions of Count VIII (Negligence) of Prather's Amended Complaint that address defective manufacturing, and **GRANTED** as to Count XI (Successor Liability Against Defendant Merck) of Prather's Amended Complaint, as it applies to those derivative claims.

IT IS FURTHER ORDERED that Organon's motion for summary judgment is **DENIED** as to Counts II, III, IV, V, VII, VIII, IX, X, and XI

RODNEY W. SIPPEL
UNITED STATES DISTRICT JUDGE

Dated this 12th day of July, 2013.