This Order has been prepared and filed by the Court.

FILED
APR 18 2013
BRIAN R. MARTINOTTI
J.S.C.

IN RE NUVARING® LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION BERGEN COUNTY DOCKET NO. BER-L-3081-09 CIVIL ACTION **ORDER**

THIS MATTER having been opened to the Court on motion by defendants Organon USA Inc., Organon Pharmaceuticals USA Inc., Organon International Inc., and Merck & Co., Inc. (f/k/a Schering-Plough Corporation) ("Defendants") to grant summary judgment in their favor; the Court having considered the moving papers, opposition thereto and the argument of counsel; and good cause having been shown;

For the reasons set forth in the accompanying opinion;

IT IS on this 18th day of April, 2013,

ORDERED:

1. Defendants' motion for summary judgment is GRANTED in the following cases:
    a. Bozicev (BER-L-2869-09)
    b. Mariconda (BER-L-2692-09)
    c. Barrow (BER-L-2707-09)

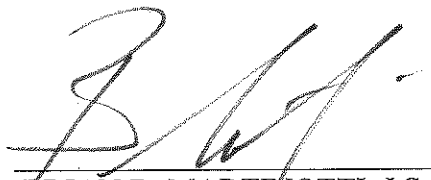
d. Fields (BER-L-2793-09)

e. Wilson-Johnson (BER-L-597-10)

f. Namack (BER-L-2831-09)

g. Ziwange (BER-L-2829-09)

2. A copy of this Order shall be served on all counsel within seven (7) days and posted on the court's website.



BRIAN R. MARTINOTTI, J.S.C.

IN RE NUVARING® LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION BERGEN COUNTY DOCKET NO. BER-L-3081-09 CIVIL ACTION

Argued: March 4-5, 2013 (Decision Reserved)[1]
Transcript Received: March 19, 2013
Decided: April 18, 2013

Melissa A. Geist, Daniel K. Winters, Thomas J. Yoo, and Michael T. Scott, for defendants (Reed Smith, LLP, attorneys).

Thomas Herten, for defendant (Archer & Greiner, P.C., attorneys).

Dan H. Ball, for defendant (Bryan Cave LLP, attorneys).

Hunter Shkolnik, for plaintiffs (Napoli Bern Ripka Shkolnik & Associates, attorneys).

Shelly A. Leonard, Steven Bennett Blau, and Jason T. Brown, for plaintiffs (Blau Brown & Leonard, LLC, attorneys).

Fred Thompson, III, for plaintiff (Motley Rice, LLC, attorneys).

Paul D. Rheingold, and David B. Rheingold, for plaintiffs (Rheingold, Valet, Rheingold, McCartney & Giuffra, LLP, attorneys).

Patrick T. D'Arcy, for plaintiff (D'Arcy, Johnson, Day, attorneys).

Caridad Diego, for plaintiff (Lopez McHugh, LLP, attorneys).

[1] On March 21, 2013, Defendants requested, via email and letter, permission to file a motion to supplement the record with newly acquired evidence. This motion was denied without argument or response from Plaintiffs.

MARTINOTTI, J.S.C.

Before this Court are seven motions filed by defendants Organon USA Inc., Organon Pharmaceuticals USA Inc., Organon International Inc., and Merck & Co., Inc. (f/k/a Schering-Plough Corporation) ("Defendants") for summary judgment of the Group I bellwether cases,[2] which involve the following plaintiffs: Frank Mariconda, General Administrator of the Estate of Rosana F. Mariconda ("Mariconda") (BER-L- 2692-09); Robert Bozicev, individually and as the Executor of the Estate of Jackie Bozicev, and Matthew Bozicev, individually ("Bozicev") (BER-L-2869-09); Tiffany Barrow ("Barrow") (BER-L-2707-09); Febbie Ziwange and Kesson Ziwange ("Ziwange") (BER-L-2829-09); Sharamonda Fields ("Fields") (BER-L-2793-09); Dana Namack ("Namack") (BER-L-2831-09); Anntrinette Wilson-Johnson ("Wilson-Johnson") (BER-L-597-10) (collectively, "Plaintiffs"). These motions were individually opposed by the respective Plaintiffs.

ORGANIZATION OF THE DECISION[3]

FACTS/BACKGROUND APPLICABLE TO ALL PLAINTIFFS

I. The Plaintiffs
   - A. Bozicev (New Jersey)
   - B. Mariconda (New Jersey)
   - C. Barrow (Colorado)
   - D. Fields (California)
   - E. Wilson-Johnson (New York)
   - F. Namack (West Virginia)
   - G. Ziwange (Ohio)

II. NuvaRing®

III. FDA Approval Process

IV. The Approved NuvaRing® Labels
   - A. Main (Physician) Insert

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[2] Counsel agreed on January 28, 2013 to the dismissal, with prejudice, of two Group I bellwether cases: Medina (BER-L-2680-09) and Kippola (BER-L-2705-09).

[3] Since this decision has multiple parties with overlapping facts and law, the Court has prepared this outline to assist the reader.

B. Patient Insert

V. Post-Approval
   A. New Clinical Trial VTEs
   B. Intentional Misrepresentation in Label
   C. Defendants' Instructions To Its Sales Representatives

SUMMARY JUDGMENT STANDARD

CHOICE OF LAW

DECISION

I. Adequacy, generally
   A. Material Issues Of Fact
   B. Defendants' Influence Over Language In Label
   C. Delayed Reporting To FDA
   D. Adequacy Summary

II. Express Warranties, generally

III. Causation, generally
   A. Physicians' Decisions To Prescribe, and Plaintiffs' Decision to Take, NuvaRing®
   B. Plaintiffs' Injuries If Using Another Birth Control
   C. Causation Summary

BOZICEV

I. Adequacy
   A. New Jersey Products Liability Act
      1. Presumption of Adequacy
      2. Rebutting the Presumption
         a. Perez
         b. McDarby
   B. Parties' Arguments
   C. PLA Applied

II. Express Warranty
   A. Legal Standard
   B. Express Warranties

III. Causation
   A. Legal Standard
   B. Causation

IV. Negligent Infliction of Emotional Distress Claim by Matthew Bozicev

MARICONDA

I. Adequacy
   A. New Jersey PLA
   B. Parties' Arguments
   C. PLA Applied

II. Express Warranty

A. Legal Standard
B. Express Warranties

III. Causation

A. Legal Standard
B. Causation

BARROW

I. Adequacy

A. Colorado Legal Standard
B. Parties' Arguments
C. Adequacy

II. Express Warranty

A. Legal Standard
B. Express Warranties

III. Causation

A. Legal Standards
B. Causation

FIELDS

I. Adequacy

A. California Legal Standard
B. Parties' Arguments
C. Adequacy

II. Express Warranty

A. Legal Standard
B. Express Warranties

III. Causation

A. Legal Standard
B. Causation

WILSON-JOHNSON

I. Adequacy

A. New York Legal Standard
B. Parties' Arguments
C. Adequacy

II. Express Warranty

A. Legal Standard
B. Express Warranties

III. Causation

A. Legal Standard
B. Causation

NAMACK

I. Adequacy

A. West Virginia Legal Standard
B. Parties' Arguments

C. Adequacy
II. Express Warranty
A. Legal Standard
B. Express Warranties
III. Causation
A. Legal Standard
B. Causation

ZIWANGE
I. Adequacy
A. Ohio Products Liability Act
B. Parties' Arguments
C. Adequacy
II. Express Warranty
A. Legal Standard
III. Causation
A. Legal Standard
B. Causation
IV. Causes Of Action Not Related To Labeling
A. Defective Design
B. Defective Manufacture
C. Failure To Test

CONCLUSION

FACTS/BACKGROUND APPLICABLE TO ALL PLAINTIFFS

VI. The Plaintiffs[4]

A. Bozicev (New Jersey)

Plaintiffs are Robert Bozicev, husband of decedent Jackie Kelly Bozicev, and Matthew Bozicev, Mrs. Bozicev's son, who was two years old at the time of his mother's injuries. In April 2007, Mrs. Bozicev delivered her second child, and in May 2007, Dr. Leslie Furman prescribed NuvaRing® to Mrs. Bozicev. On December 7, 2007, she

[4] Some claims are being brought by the female patient, while others are brought by third parties or the decedents' husbands on behalf of the estate. For this reason, the Court will generally refer to all plaintiffs using singular female pronouns to prevent confusion.

suffered a pulmonary embolism, witnessed by Matthew, resulting in her death later that morning in the hospital.

B. Mariconda (New Jersey)

Plaintiff is Frank Mariconda as the general administrator of the estate of his wife, decedent Rosana Mariconda. The parties agree that, at the very least, Mrs. Mariconda suffered from "classic migraines." Mrs. Mariconda began seeing Dr. Michael Kuchera for gynecological treatment in 2000 at the age of 25. She had been taking Triphasil, an oral contraceptive, for the previous six or seven years. She had one child in May 2003, and another in May 2005. She visited with her doctor, post-partum, on July 8, 2005, and shortly thereafter filled a prescription for NuvaRing®. On February 24, 2006, Mrs. Mariconda was taken to the hospital and was found to have a left anterior cerebral artery and middle cerebral artery infarct due to a left internal carotid artery thrombosis. She eventually lapsed into a coma and died of a cardiac arrest secondary to her stroke.

C. Barrow (Colorado)

Ms. Barrow was prescribed NuvaRing® by Dr. James Meeuswsen at the age of 20 in January 2006. She had previously used Ortho-Evra for birth control. In 2007, she was diagnosed with a pulmonary embolism, and she discontinued her use of NuvaRing®. She was admitted to the ICU on February 1, 2007 and was treated with Heparin, Lovenox, and Coumadin.

D. Fields (California)

Ms. Fields, at the age of 28, received NuvaRing® from Planned Parenthood on April 11, 2006. Her weight, at a height of 5'5", was recorded to be 260 pounds from April to July 2006. Significant medical history includes migraines, ovarian cysts, uterine

fibroids, and probable sleep apnea, as well as smoking cigars. She has had four children and has lost several pregnancies. On July 2, 2006, she was admitted to the hospital for treatment of a pulmonary emboli. She was hospitalized for five days and treated with Heparin. Upon discharge, she was treated with Coumadin and later, Lovenox.

E. Wilson-Johnson (New York)

Ms. Wilson-Johnson was 30 years old in February 2008 when she began taking NuvaRing®, prescribed by Dr. David Gandel. She has been referred to as "obese" (Wilson-Johnson Opp. 3) at 250 pounds. This was a decrease from 350 pounds, following her gastric bypass surgery prior to using NuvaRing®, at which time she was also diagnosed with hypertension. Before using NuvaRing®, she took ortho-tricyclen, a second generation oral contraceptive. On March 3, 2008, she went to the hospital and was eventually diagnosed with a deep vein thrombosis ("DVT"). She was treated with Coumadin and Lovenox and was discharged, continuing to take both anti-coagulants for two months.

F. Namack (West Virginia)

Ms. Namack was prescribed NuvaRing® by Dr. Erin Stoehr in October 2006 at the age of 34. Significant medical history included amenorrhea, diabetes, endometriosis, hypertension, polycystic ovarian syndrome, obesity, and gastroesophageal reflux disease. She had previously used Yasmin for birth control. In May 2007, she went to the hospital where she was diagnosed with bilateral pulmonary emboli. She was treated with Lovenox and Coumadin and was discharged, continuing the Coumadin treatment after being discharged.

G. Ziwange (Ohio)

Mrs. Ziwange was prescribed NuvaRing® on June 22, 2006, by Dr. Alan Murnane when she was 27 years old. She had previously used Depo-Provera for birth control. On August 10, 2007, she was diagnosed with a pulmonary embolism and treated with Heparin and Coumadin during her three-day stay at the hospital.

VII. NuvaRing®

Defendants' product, NuvaRing®, is a combination hormonal contraceptive ("CHC") which uses a "new delivery system" called a combined contraceptive vaginal ring. (Geist Cert., Ex. 3.[5]) Once every twenty-eight days, the flexible ring is placed in the woman's vagina, where it remains in place for three weeks until it is removed for a one-week period. (Id.) During the three-week period that the ring is in place, it releases a combination of hormones intended to prevent pregnancy. (Id.; Geist Cert., Ex. 2.[6])

CHCs contain two hormones, an estrogen and a progestin. (Defs.' Mot. Exs. 2, 3, supra, notes 5-6.) In the case of NuvaRing®, the estrogen is ethinyl estadiol and the progestin is etonogestrel. (Id.) These hormones are released into the woman's body continuously for the three-week period that the ring remains in the woman's vagina. On average, each ring releases 0.120mg/day of etonogestrel and 0.015mg/day of ethinyl estradiol. (Id.) Plaintiffs dispute that the NuvaRing® releases a steady, continuous dose averaging 0.12mg and 0.015mg per day of etonogestrel and ethinyl estradiol, respectively, asserting that "there were especially high bursts of [ethinyl estradiol] measuring 81 pg/ml and 51 pg/ml, respectively for Subjects 0006 and 0011 [of Clinical Trial 34218], on Day 1 within only 6 hours after initial insertion." (Mariconda Response

[5] FDA Medical Officer's Review, Oct. 6, 2000.
[6] FDA Approved Label.

to Defs.' Facts, Response to ¶ 1 (citing Shelly Leonard Cert., Exs. W, X, Y, Z, II[7]); Bozicev Resp. to Defs.' Facts, Resp. to ¶ 4 (citing Carmen Scott Cert., Exs. 13-16, 41[8]); Barrow Resp. to Defs.' Facts, Resp. to ¶ 4 (citing Leonard Cert., Exs. K, L, M, N[9]); Fields Resp. to Defs.' Facts, Resp. to ¶ 4 (citing Leonard Cert., Exs. I, J, K, L[10]); Wilson-Johnson Opp. to Defs.' Mot. 18-19 (citing Shkolnik Cert., Exs. R, V, W, X[11]); Namack Resp. to Defs.' Facts, Resp. to ¶ 4 (citing Leonard Cert., Exs. I, J, K, L[12]); Ziwange's Opp., Part VI, Section C.[13])

The ring has three main advantages over oral contraceptives: (1) "the more constant steroid levels built up in comparison with oral formulations"; (2) "the avoidance of the hepatic first-pass effects"; and (3) "the potential for better patient compliance." (Geist Cert., Ex. 3, supra, note 5.) Plaintiffs concede advantages (2) and (3), but deny (1). (Mariconda Resp. to Defs.' Facts, Resp. to ¶ 2; Bozicev Resp. to Defs.' Facts, Resp.

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[7] Ex. W: Expert Opinion of Shelley Ann Tishkau, Ph.D.; Ex. X: Study Report Clinical Trial 34218; Ex. Y: Section B.3 of Appendix B for Clinical Trial 34218; Ex. Z: Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude Testimony Related to "Bursts" or "High Variability" in NuvaRing's Estrogen Delivery; Ex. II: Expert Opinion/Report of Kishore Udipi, Ph.D.

[8] Ex. 13: Plaintiff's Memorandum of Law in Opposition to Defendants' Motion to Exclude, dated October 16, 2012; Ex. 14: Expert Report of Dr. Shelley Ann Tischkau; Ex. 15: Study Report Clinical Trial 34218, dated June 1999; Ex. 16: Section B.3 of Appendix D for Clinical Trial 34218, dated June 1999; Ex. 41: Expert Report of Kishore Udipi, Ph.D., dated July 31, 2011.

[9] Ex. K: Expert Opinion of Shelley Ann Tishkau, Ph.D.; Ex. L: Study Report Clinical Trial 34218; Ex. M: Section B. 3 of Appendix B for Clinical Trial 34218; Ex. N: Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude Testimony Related to "Bursts" or "High Variability" in NuvaRing's Estrogen Delivery.

[10] Ex. I: Expert Opinion of Shelley Ann Tishkau, Ph.D.; Ex. J: Study Report Clinical Trial 34218; Ex. K: Section B. 3 of Appendix B for Clinical Trial 34218; Ex. L: Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude Testimony Related to "Bursts" or "High Variability" in NuvaRing's Estrogen Delivery.

[11] Ex. R: NuvaRing® label; Ex. V: Expert Report of Dr. Shelley Ann Tischkau; Ex. W: Clinical Trial Report on Protocol 34218; Ex. X: Section B3 of Appendix B for Clinical Trial Protocol 34218.

[12] Ex. I: Expert Opinion of Shelley Ann Tishkau, Ph.D.; Ex. J: Study Report Clinical Trial 34218; Ex. K: Section B. 3 of Appendix B for Clinical Trial 34218; Ex. L: Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude Testimony Related to "Bursts" or "High Variability" in NuvaRing's Estrogen Delivery.

[13] Plaintiff Ziwange's Opposition to Defendants' Motion did not have page numbers, and will therefore be cited by section references within the brief.

to ¶ 5; Barrow Resp. to Defs.' Facts, Resp. to ¶ 5; Fields Resp. to Defs.' Facts, Resp. to ¶ 5.)

Although NuvaRing® was considered a new delivery system when introduced on the market, both hormones have been used in birth-control pills for years – ethinyl estradiol is widely used in contraceptives (Geist Cert., Ex. 4[14]), while progestin, in its "third generation" form, appeared in the U.S. market in 1993 when it was combined with an estrogen (Geist Cert., Ex. 3, supra, note 5).

Since the use of these hormones, several studies have been released regarding the risk of venous thromboembolism ("VTE")[15] with the use of second and third generation progestin CHCs:

> It has been known for many years that the estrogen component in CHCs creates a risk of thrombosis. However, in 1995 and 1996, three medical journal articles reported unexpected findings that birth control pills with third-generation progestins, such as desogenstrel and gestodene, were associated with a higher incidence of VTE than pills using a second generation progestin.
>
> [Defs.' Undisputed Facts ¶ 11 (admitted by Plaintiffs, but stating that additional reports were published) (emphasis added).]

The parties dispute the exact risk, noting that tests have shown results on both sides:

> In the 1990s, there were at least fifteen (15) epidemological studies addressing the risk of third-generation as compared with second-generation oral contraceptives. Thirteen (13) found higher risks associated with the use of third-generation preparations, with estimates of risk ranging from 1.4 to 4 times as high as that associated with second-generation. Only two (2) studies found no difference.

[14] FDA Group Leader Memorandum, Dec. 22, 2000.
[15] Pulmonary embolisms and DVTs suffered by the Plaintiffs will be collectively referred to as VTEs.

[Parisian Report,[16, 17]; see also Geist Cert., Ex. 2, supra, note 6.]

VIII. FDA Approval Process

Defendants, like every other drug manufacturer, were required to secure approval of NuvaRing® from the United States Food and Drug Administration ("FDA") prior to marketing the drug. 21 U.S.C.A. § 355; Bailey v. Wyeth, 424 N.J. Super. 278, 287, 37 A.3d 549 (2008), aff'd sub. nom. Deboard v. Wyeth, Inc., 422 N.J. Super. 360, 362, 28 A.3d 1245 (App. Div. 2011). In order to secure approval, the drug must be tested for safety and effectiveness, and the results of such tests are submitted to the FDA as a New Drug Application ("NDA"). Id. (citing 21 U.S.C.A. § 393(b)(2)(B)). A NDA will not be approved if the drug is not considered to be safe and effective. Id. at 288 (citing 21 U.S.C.A. § 355). A "safe" drug is defined as one where "the benefits of the drug appear

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[16] Cited as: Bozicev Opp., Scott Cert., Ex 12; Mariconda Opp. 19 & Leonard Cert., Ex. JJ; Barrow Opp., Leonard Cert., Ex. F; Fields Opp., Leonard Cert., Ex. D; Wilson-Johnson Opp., Shkolnik Cert., Ex. H; Namack Opp., Leonard Cert., Ex. D. Plaintiff Ziwange's Opposition only referenced the difference between second and third generation contraceptives when it disputed the label's statement that the difference in risk is unknown between second and third generation oral contraceptives. To that point, Plaintiff states:

> This is another statement which as of the time of the prescription of NuvaRing for Ms Medina [sic] is at best equivocal and misleading and almost surely false. The same literature and adverse reaction report s [sic] just referred to demonstrated that there was a different, i.e., greater, risk of VTE with the ring than t he [sic] comparator second generation pills.
>
> [Ziwange Opp. Part VI(A)(b) (emphasis added).]

The Court notes that no literature or adverse reaction report was previously cited, or "just referred to," in the Opposition, see Ziwange Opp. Part VI(A)(b) (discussing the long term effects of using oral contraceptives with lower doses of estrogen and progestin).

[17] Suzanne Parisian, Ph.D., and her reports and opinions are the subject of the pending Kemp motions. Defendants dispute her reports and the admission of her testimony, in addition to several other expert reports. Similar Daubert motions were pending in the MDL, but were denied around the time of oral arguments on these summary judgment motions. The parties agree that the pending Kemp motions and the decision in the MDL have no bearing on the outcome of these summary judgment motions.

to outweigh the risks." Id. at 287-88 n.8. In addition to the results of required testing, the NDA also includes "reports of investigation into the safety and effectiveness of the drug, the components and production methods used in the drug's manufacturing, and copies of draft labeling proposed for the drug." Id. at 288 (citing 21 C.F.R. § 314.50).

Labeling, with respect to prescription drugs, "means all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C.A. § 321(m). To obtain approval, the FDA requires that the drug's "labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading." 71 Fed. Reg. 3922 (Jan. 24, 2006). If the proposed label needs revisions in order to be approved, the FDA will notify the applicant. Bailey, supra, 424 N.J. Super. at 290, 37 A.3d 549. "Often several versions of the labeling are exchanged between the FDA and the pharmaceutical company before reaching the final approved labeling." Id.

Even after a drug is approved, the drug manufacturer has a continuing obligation to report adverse drug experiences to the FDA, as well as any significant new developments that may affect "the safety, effectiveness, or labeling of the drug product." Id. (quoting 21 C.F.R. § 314.81(b)(2)(i)) (internal citations omitted). This would require the manufacturer to submit a supplemental New Drug Application ("sNDA") seeking the FDA's approval of the additional indications. Id. at 288-89 (citing 21 U.S.C. § 355(d); 21 C.F.R. § 314.125(b)). Like the NDA, the sNDA will be rejected if the drug is not found to be safe or effective for its proposed use. Id. Additionally, under 21 C.F.R. § 314.70(d), a manufacturer can unilaterally change or update a label for specific reasons, however they must notify the FDA of any reasons which justified the change, and the

FDA can, based on information supplied by the manufacturer, later decide to change the label on its own or pull the product from the market. See 21 C.F.R. § 314.70(d).

Plaintiffs emphasize this continuing obligation by noting the flaws in the FDA regulatory system and its limited resources, requiring that manufacturers continue to provide up to date and adequate information to the FDA upon which it can properly base its evaluation. (See Mariconda Resp. to Defs.' Facts, Resps. to ¶¶ 6-10, 13; Bozicev Resp. to Defs.' Facts, Resps. to ¶¶ 16-18; Barrow Resp. to Defs.' Facts, Resps. to ¶¶ 16-18; Fields Resp. to Defs.' Facts, Resps. to ¶¶ 16-18; Wilson-Johnson Opp. 8-10; Namack Resp. to Defs.' Facts, Resps. to ¶¶ 16-18 (all citing Parisian Report, supra, note 16); Ziwange Opp. Part V (all citing Wyeth v. Levine, 555 U.S. 555, 129 S. Ct. 1187 (2009); McDarby v. Merck & Co., Inc., 401 N.J. Super. 10, 64, 949 A.2d 223 (App. Div. 2008)).)

Defendants submitted a NDA for NuvaRing® on December 28, 1999. (Geist Cert., Ex. 5.[18]) The submission included the results of several studies. In sum, 2501 women were treated for a total of 24,391 28-day cycles, or 1870 women-years of exposure.[19] This surpassed the FDA's cycle goal of 10,000 evaluable cycles.

Defendants made over thirty submissions to the FDA regarding NuvaRing® between the time of the initial NDA and September 28, 2001. (Geist Cert., Ex. 6.[20] See also Geist Cert., Exs. 7-9 (showing multiple drafts of the proposed labeling and the

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[18] Organon's NDA Cover Letter, Dec. 28, 1999.

[19] Six studies were conducted total. Studies 680003 and 34219 were identical in design; they were "designed to accumulate information about the contraceptive efficacy, vaginal bleeding patterns, and safety of the NuvaRing® regimen in generally healthy women, age 18 to 41, who elected to use vaginal hormonal contraception for the prevention of pregnancy." (Geist Cert., Ex. 3, supra, note 5.) Study 68003 was conducted in the United States and Canada. It treated 1117 women for a total of 11,188 28-day cycles. (Id.) Study 34219 was conducted in 11 European countries and Israel, and it treated 1145 women for a total of 12,109 28-day cycles. (Id.) Additionally, three smaller European studies were conducted, in which 121 women were treated for a total of 634 28-day cycles. (Id.) Finally, in the "local effects USA study 68004," 58 women were treated over the course of a combined 460 cycles. (Id.)

[20] FDA Approval Letter, October 10, 2001.

FDA's proposed changes).) On October 10, 2001, the FDA approved Defendants' application, finding that "adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text." (Geist Cert., Ex. 6, supra, note 20.) Further instructions stated:

> The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert) and the immediate container and carton labeling submitted September 28, 2001. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.
>
> [(Id.)]

Plaintiffs admit that the label was approved by the FDA, but argue that Defendants' influence in the language of the final label is relevant to certain states' legal standards. Specifically, Plaintiffs argue that Defendants had evidence of an increased risk that they consciously disregarded when marketing the product to physicians and customers, and have provided to the Court internal communications by the Defendants attempting to remove the existence of the clinical trial VTEs from the labels:

- "My major comment on the US [Package Insert ("PI")] relates to including the one case of thrombosis. We should really try to get it out of the text."
- "Or could we use [the animal studies] as a bargaining chip for other, more important issues such as the VTE warning, bleeding data, etc?"
- "I have reviewed the new proposal of the NuvaRing PI made by the FDA. To my satisfaction a number of the critical issues have been implemented in the current proposal (e.g. the deletion of the single VTE case)").

(Parisian Report, supra, note 16; Bozicev Opp. 10-11; Mariconda Opp. 25; Barrow Opp. 21; Fields Opp. 20; Wilson-Johnson Opp. 14; Ziwange Opp. 12 & Ex. 6, and incorporating by reference Mariconda Opp., Leonard Cert. Ex. L.)

IX. The Approved NuvaRing® Labels

The FPL included two texts – one for the main package insert, used primarily by doctors (see Geist Cert., Ex. 5, supra, note 18 (referring to this insert as the "physician labeling")), and the other for the patient's package insert. (Id.; Geist Cert., Ex. 2, supra, note 6.) The main package insert includes sections for description, clinical pharmacology, indications and usage, contraindications, warnings (including 12 subheadings), precautions (including 20 subheadings), information for the patient, adverse reactions, overdosage, dosage and administration, and how the product is supplied. (Geist Cert., Ex. 2, supra, note 6.) The patient package insert includes sections entitled: "What is NuvaRing®?"; "Who should not use NuvaRing®?"; "How should I use NuvaRing®?"; "When should I start NuvaRing®?"; "How do I insert NuvaRing®?"; "How do I remove NuvaRing®?"; "When do I insert a new ring?"; "If NuvaRing® slips out"; "If NuvaRing® is in your vagina too long"; "If you miss a menstrual period"; "Can I use tampons when using NuvaRing®?"; "Overdose"; "What should I avoid when using NuvaRing®?"; "What are the possible side effects of NuvaRing®?" (including several subheadings); "How effective is NuvaRing®?"; and "Other Information."

Between both inserts, there are several warnings of the risk of stroke and VTE. Plaintiffs concede this, but argue that, although the warnings may be accurate, they are not adequate because they are not sufficiently complete. (Bozicev Resp. to Defs.' Facts,

Resps. to ¶¶ 26-28; Mariconda Resp. to Defs.' Facts, Resps. to ¶¶ 17-20; Barrow Resp. to Defs.' Facts, Resps. to ¶¶ 27-28, 32; Fields Resp. to Defs.' Facts, Resps. to ¶¶ 26-28; Wilson-Johnson Opp. 5-8, Exs. D, E, F; Namack Resp. to Defs.' Facts, Resps. to ¶¶ 27-29; Ziwange Opp., Part VI (A), (B), & Part VII.)

A. Main (Physician) Insert

In the main insert, under "Contraindications," the warning states: "NuvaRing® should not be used in women who currently have the following conditions: . . . Headaches with focal neurological symptoms . . . ." (Geist Cert., Ex. 2, supra, note 6.)

Under the heading, "Warnings," the first paragraph indicates that there is no data to determine whether the safety and efficacy of CHCs administered vaginally would differ from CHCs administered orally. (Id.) Consequently, all information under "Warnings" refers to CHCs in the oral form. (See id.)

The second paragraph of the "Warnings" section states:

> The use of oral contraceptives is associated with the increased risks of several serious conditions including venous and arterial thrombotic and thromboembolic events (such as myocardial infarction, thromboembolism, and stroke), hepatic neoplasia, gallbladder disease, and hypertension, although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity or mortality increases significantly in the presence of other underlying risk factors such as certain inherited thrombophilias, hypertension, hyperlipidemias, obesity, and diabetes.
>
> [(Id.) (emphasis added).]

"Warnings" also includes several subheadings, the first of which is entitled "Thromboembolic Disorders and Other Vascular Problems," stating:

a. Thromboembolism

An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well established. . . .

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 that 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.

. . .

c. Cerebrovascular diseases

Oral contraceptives have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (>35 years), hypertensive women who also smoke. . . .

. . . Oral contraceptives also increase the risk for stroke in women with other underlying risk factors . . . . Women with migraine (particularly migraine with aura) who take combination oral contraceptives may be at an increased risk of stroke.

[(Id.) (emphasis added).]

Next, 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 . . . WARNINGS):

. . .

- Thrombophlebitis and venous thrombosis with or without embolism
- . . .
- Pulmonary embolism
- . . .

[(Id.) (emphasis added).]

Finally, under the "Information for the Patient" section of the main insert, the reader is told that "[t]he woman should be instructed regarding the proper use of NuvaRing®" and is directed to the patient insert for more information. (Id.)

Defendants argue that the VTE risk warnings are adequate because the label clearly and unequivocally states that the risk of VTE exists. Additionally, the label clearly states the risk which Plaintiffs assert, that third generation contraceptives, of which NuvaRing® is one, has a two-fold risk. Although the label proceeds by stating that other studies have found otherwise, Defendants argue that this does not make the label inadequate because it is an accurate representation. Further, Defendants argue that their statement regarding the "unknown" risks of NuvaRing® is accurate because Defendants did not have sufficient information to say otherwise.

Regarding the migraine warning in the contraindications and in subheading (c) of the Warnings section, Defendants argue that Plaintiff Mariconda, the only Plaintiff in the Group I bellwether cases asserting the injury of stroke, has not shown a material issue of fact, because any potential material issues of fact are related to VTEs, which do not affect the adequacy of the stroke warning.

Plaintiffs argue that they have raised material issues of fact with respect to these points and this aspect of the label. Plaintiffs argue that the two-fold risk relates only to oral contraceptives, and that Defendants' statement that the difference in risk between

NuvaRing® and oral contraceptives is "unknown" dilutes any statement of an elevated risk of VTEs. Additionally, Plaintiffs assert that Defendants knew or should have known of an increased risk of VTEs, and therefore the risk was not "unknown." Specifically, Plaintiffs point to the discovery of additional VTEs in clinical trials – one before the FDA's approval of the label and three after – which Plaintiffs argue should have demonstrated to Defendants an increased risk, triggering an obligation to update the label or notify physicians.[21, 22]

B. Patient Insert

The patient insert begins by informing the patient that "[t]he leaflet gives you information about the possible serious side effects of NuvaRing®. . . . This information does not take the place of talking with your healthcare provider." (Geist Cert., Ex. 2, supra, note 6 (emphasis added).)

"Blood clots" and "Strokes and heart attacks" are the first two subheadings listed under the "possible risks and side effects":

> - Blood clots
> The hormones in NuvaRing® may cause changes in your blood clotting system which may allow your blood to clot more easily. . . . 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 birth control pills.

[21] Bozicev Resp. to Defs.' Facts, Resps. to ¶¶ 23-24; Mariconda Resp. to Defs.' Facts, Resps. to ¶¶ 13, 21; Barrow Resp. to Defs.' Facts, Resps. to ¶¶ 19, 26; Fields Resp. to Defs.' Facts, Resps. to ¶¶ 18, 25; Wilson-Johnson Opp. 13-16; Namack Resp. to Defs.' Facts, Resps. to ¶¶ 19, 26; Ziwange Opp., Part VI., Sec. C.

[22] In response to the migraine warning under contraindications and subheading (c), Plaintiff Mariconda argues that the warning is vague, ambiguous, and misleading, because "[t]he average patient reading the NuvaRing® label would not understand the meaning of the term 'headache with focal neurological symptoms' or that this description is the equivalent to migraine with aura." (Mariconda Resp. to Defs.' Facts, Resps. to ¶¶ 24-25.)

. . .

- Strokes and heart attacks
  Hormonal contraceptives may increase your risk of strokes (blockage of blood flow to the brain) or heart attacks (blockage of blood flow to the heart). Any of these conditions can cause death or serious disability. . . .

  [(Id.)]

The label also states, "Do not use NuvaRing® if you have any of the following conditions: . . . headaches with neurological symptoms . . . ." The label continues by stating:

> In addition, talk to your healthcare provider about using NuvaRing® if you have any of the following conditions. Women with any of these conditions should be checked often by their doctor or healthcare provider if they choose NuvaRing®:
>
> - . . .
> - Migraine or other headaches or epilepsy
> - . . .
>
> [(Id.)]

Finally, the insert instructs patients to call their healthcare providers "right away" if they experience any one of a number of listed symptoms. Along with each symptom is the "serious problem" of which the symptom may be a sign. On the list is "sudden severe headache or vomiting, dizziness, or fainting, problems with vision or speech, weakness, or numbness in an arm or leg (possible stroke)." (Id.) (emphasis added) The list also includes serious problems such as possible clot in the leg, possible heart attack, and possible clot in eye. (Id.)[23]

X. Post-Approval

[23] Parties assert the same arguments with respect to the patient label as they do with the physician label. See supra "Background," Part IV(A).

A. New Clinical Trial VTEs

Plaintiffs allege that, after the FDA approved the label, additional VTEs were reported to Defendants resulting from clinical trials of NuvaRing®. Defendants confirm the existence of these VTEs, but the parties dispute whether those results were adequately reported, both to the FDA and to physicians. Defendants argue that they reported all clinical trial results to the FDA, including the VTEs, but that they had nothing to report to the physicians, because they did not believe the additional VTEs were sufficient to show an increased risk.

Between October 1997 and April 2004, four VTEs were reported from twenty-four clinical studies, which Plaintiffs assert is a 6.3 fold increase compared to second generation hormonal contraceptives.[24] Parisian Report, supra, note 16; record cited supra note 21 (discussing increased risk).

On or around June 13, 2006, Jan van Emous, an Organon Regulatory Affairs official, issued a confidential memorandum with the subject, "Case of venous thromboembolism in NuvaRing clinical trials," stating:

> Most of the studies that were completed after 2001 (studies 34224, 34229, 34230, and C-1757) have been submitted individually to [Health Agencies] as part of different updates of the product information. The 2005 CER (including the integrated analysis) has been reviewed by the Dutch MEB, but has not been officially submitted in any country worldwide.
>
> [(Mariconda Opp. 19 & Leonard Cert., Ex. L.; Wilson-Johnson Opp. 11 & Shkolnik Cert., Ex. I; Ziwange Opp.

[24] Plaintiffs contend that the "4th" VTE was not calculated, and had it been, the risk would have been higher than the 6.3. (Mariconda Opp. 26 & n.4). However Plaintiffs also state that the "four (4) VTEs reported . . . translates into a rate of . . . a 6.3 fold increase compared to second generation hormonal contraceptives," so it is unclear from Plaintiffs' brief was the exact risk is, or whether all the VTEs were considered in the calculation.

Part VI (C) (citing Mariconda Opp., Leonard Cert., Ex. L.). See Parisian Report, supra, note 16.)]

Plaintiffs allege that this document shows that the results of VTE safety analysis trials were not reported to the FDA. (See Bozicev Opp. 18; Mariconda Opp. 19; Barrow Opp. 23; Fields Opp. 21-22; Namack Opp. 18-19; Wilson-Johnson Opp. 15; Ziwange Opp. Part VI. (C).) Even if they were reported, Plaintiffs argue that Defendants were delayed in their reporting to the FDA, which demonstrates a further attempt to conceal the extent of the risk. Finally, Plaintiffs emphasize the FDA's flawed regulatory process and limited resources, resulting in the manufacturer's obligation (and alleged failure) to keep the FDA apprised of significant or relevant information to ensure the adequacy of the drug's label. (Transcript of Oral Argument [hereinafter "Transcript"], March 4, 2013, at 48:4-17, 137:23-138:9.) Accordingly, Plaintiffs allege that Defendants should have recognized the increased risk and notified physicians, regardless of the FDA's response to Defendants' annual filings. (See Bozicev Resp. to Defs.' Facts, Resps. to ¶¶ 23-26; Mariconda Resp. to Defs.' Facts, Resps. to ¶¶ 13-14; Barrow Resp. to Defs.' Facts, Resp. to ¶ 26; Fields Resp. to Defs.' Facts, Resp. to ¶ 25; Namack Resp. to Defs.' Facts, Resp. to ¶ 26; Wilson-Johnson Opp. 12-20; Ziwange Opp. Part VI (C)) (citing Wyeth, supra, 555 U.S. at 578-79, 129 S. Ct. 1187; McDarby, supra, 401 N.J. Super. at 64, 949 A.2d 223; Parisian Report, supra, note 16).

Defendants argue that the information contained within the 2005 CER – i.e. the results of the clinical trial studies, including the VTEs – was turned over to the FDA through the FDA's required annual Periodic Adverse Drug Experience Report

("PADER").[25] Defendants further state that the clinical trial results were disclosed to the FDA in two other forms.[26] All information was ultimately turned over to the FDA, and Defendants claim that any alleged delay is therefore irrelevant. Finally, Defendants argue that they did not contact physicians because they had no obligation to; not only was the FDA not alarmed by the additional VTEs, Defendants did not find that the VTEs were sufficient to show an increased risk. (See Mariconda Opp., Leonard Cert., Ex. S.[27])

B. Intentional Misrepresentation in Label

Plaintiffs allege that Defendants, since the FDA's approval, have "intentionally misled prescribing physicians into assuming that there are no fluctuations in the NuvaRing's delivery of [ethinyl estradiol] and [etonogestrel], because the label represents that a low steady state of hormones is delivered throughout the cycle."[28] (See, e.g., Mariconda Opp. 21.) Thus, regardless of any FDA-approval, Plaintiffs claim that Defendants continue to deceive physicians and patients/consumers about the drug's implications. (Bozicev Opp. 11-17, 21-24; Mariconda Opp. 21, 29-37; Barrow Opp. 18-22, 24-26; Fields Opp. to Defs.' Mot. 16-20; Namack Opp. 13-17; Wilson-Johnson Opp.

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[25] Defendants also contend that the CER, as a report itself, is a required submission by European authorities, and not the FDA. (Mariconda Rep. 6.)

[26] Defendants reinforced this at oral arguments:

> In three different ways, your Honor, every single VTE raised by the plaintiff in their opposition papers were reported to FDA. First they were reported by way of the IND, NDA annual reports.
>
> Second, they were reported to FDA when Organon provided the clinical trial reports in which these VTEs occurred.
>
> And, finally, your Honor, if there wasn't clear evidence that the company did not deliberately conceal any adverse events after market approval, one only needs to look at the published literature.
>
> [(Transcript of Oral Argument, March 4, 2013, 20:21-21:6.)]

[27] Analyses of the Postmarketing Surveillance of Venous Thromboembolic Events Reported for NuvaRing

[28] The Parties often refer to this fluctuation as a "burst," which is particularly disputed regarding the first day of the drug's use per 21-day period.

7-8, 18-20; Ziwange Opp. Part VI (A).) Plaintiffs also argue that Defendants use of "unknown" with respect to NuvaRing®'s risk is a misrepresentation because Defendants knew or should have know of the risk of the product, if not at the time the product was initially marketed, then at least at the time of Plaintiffs' injuries based on the newly discovered VTEs.

Defendants, on the other hand, argue that the warnings are adequate because the few "bursts" that resulted from clinical studies were revealed to the FDA, and moreover, are not sufficient to show that they occur in all users. Additionally, the increased release on the first day was incorporated in the "average" daily dose stated in the label, making the statement an accurate representation. Defendants argue that Plaintiffs cannot show causation with respect to this issue because, even assuming there is a "burst," the dose on the first day is lower than other third generation contraceptives, meaning that physicians would still be willing to prescribe the NuvaRing® over other contraceptives. Moveover, Defendants argue that Plaintiffs have no evidence linking these "bursts" to strokes or VTEs.

C. Defendants' Instructions To Its Sales Representatives

Plaintiffs also claim that Defendants instructed its sales representatives to defer to less serious side effects when asked about the blood clots. Defendants claim that Plaintiffs have no evidence related to the cases currently before the Court. Defendants also argue that the statements by the representatives were consistent with the statements in the label, which Defendants contend are accurate representations, and that Plaintiffs have not provided evidence that any representatives made statements to Plaintiffs' physicians in the Group I bellwether cases.

SUMMARY JUDGMENT STANDARD

Under the developed governing standard, a summary judgment motion requires "searching review" of the record on the part of the trial court to ascertain whether there is a genuine issue of material fact. R. 4:46-2. Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 541, 666 A.2d 146 (1995). As such, the court must "consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational fact finder to resolve the alleged disputed issue in favor of the non-moving party." Id. at 540. Summary judgment must be granted when the evidence "is so one-sided that one party must prevail as a matter of law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 106 S. Ct. 2505, 2512, 91 L. Ed. 2d 202, 214 (1986). This means that summary judgment cannot be defeated if the non-moving party does not "offer[] any concrete evidence from which a reasonable juror could return a verdict in his favor." Id. at 256, 106 S. Ct. at 2514, 91 L. Ed. 2d at 217. The non-movant has the "burden of producing in turn evidence that would support a jury verdict," and must "set forth specific facts showing that there is a genuine issue for trial." Id. at 256; 106 S. Ct. at 2514; 91 L. Ed. 2d at 217.

"[C]onclusory and self-serving assertions" in certifications without explanatory or supporting facts will not defeat a meritorious motion for summary judgment. Puder v. Buechel, 183 N.J. 428, 440, 874 A.2d 534 (2005) (citing Martin v. Rutgers Cas. Ins. Co., 346 N.J. Super. 320, 323, 787 A.2d 948 (App. Div. 1999)). Competent opposition requires "competent evidential material" beyond mere "speculation" and "fanciful arguments." Merchs. Express Money Order Co. v. Sun Nat'l Bank, 374 N.J. Super. 556,

563, 866 A.2d 189 (App. Div. 2005), appeal dismissed, 183 N.J. 592 (2006); O'Loughlin v. Nat'l Cmty. Bank, 338 N.J. Super. 592, 606-07, 770 A.2d 1185 (App. Div.) (opponent must do more than establish abstract doubt regarding material facts), certif. denied, 169 N.J. 606 (2001). See also James Talcott, Inc. v. Shulman, 82 N.J. Super. 438, 443, 198 A.2d 98 (App. Div. 1964) ("Mere sworn conclusions of ultimate facts, without material basis or supporting affidavits by persons having actual knowledge of the facts, are insufficient to withstand a motion for summary judgment.").

CHOICE OF LAW

The parties concede, as argued in their briefs, that the laws of the individual Plaintiffs' states apply to the issue of liability. The Court is not bound to apply this law to the suit as a whole – meaning that New Jersey's conflict of laws analysis is applied on an issue by issue basis, and "the law of one jurisdiction may apply to one issue in a matter and the law of a second jurisdiction to another." Grossman v. Club Med Sales, Inc., 273 N.J. Super. 42, 51, 640 A.2d 1194 (App. Div. 1994); see In re Consolidated Parlodel Litig., 182 F.R.D. 441, 447 (D.N.J. 1998) ("New Jersey's choice of law rules incorporate the doctrine of depecage whereby the laws of different states may apply in the same case to different issues in the case."). Defendants have also filed a punitive damages motion, in which choice of law is a disputed issue; that motion is still pending before this Court.

DECISION

The Court will take each case in turn, discussing whether Plaintiff was able to demonstrate issues of fact as to the warning's adequacy, express warranties, and

causation. In order to more concisely address the cases-specific issues, the Court will first discuss the "global" issues and arguments applicable to all Group I bellwether cases.

IV. Adequacy, generally

Defendants assert that the label was sufficiently adequate to warn of Plaintiffs' injuries. The statutes and case law of each state set forth various legal standards for this Court to use to determine whether the label was "adequate," with the Court focusing particularly on whether the label was adequate at the time the product was first marketed and at the time of Plaintiff's injuries.

A. Material Issues Of Fact

Plaintiffs raise several issues of fact which they contend are sufficiently material to defeat summary judgment:

- Whether the VTE prior to approval was indicative of a risk, and to what extent Defendants' internal communications shows same (see supra "Background," Part III);
- Whether the three (3) post-approval VTEs were indicative of a risk (see supra "Background," Part IV(A));
- If the VTEs were indicative of an increased risk; was the use of "unknown" an inaccurate statement; and should Defendants' have unilaterally notified label or updated physicians; (see supra "Background," Part IV(A), at 15-16, Part V);
- Whether Defendants adequately updated the FDA with its annual reports (see supra "Background," Part V);
- Whether Defendants' label included the "bursts," and, if not, whether this was an intentional misrepresentation (see supra "Background," Part II);

B. Defendants' Influence Over Language In Label

Plaintiffs further assert that Defendants watered down the label with language like "unknown," claiming that Defendants suggested this language for the label and the FDA merely accepted it. Plaintiffs argue that this alleged attempt to water down the label could be construed as intentional concealment of the risks.

Though there was much discussion at oral argument about this issue, the Court finds it irrelevant as to whether Defendants or the FDA suggested the language of the label. The FDA must ultimately approve all labels, therefore, at the time the product entered the market, the FDA found the language adequate, regardless of who suggested it. With respect to whether such language could be indicative of concealment by Defendants, the Court notes that, based on the FDA approval process, it is irrelevant who – the manufacturer or the FDA – developed the exact language, because the FDA has the authority to ultimately approve the label. Bailey, supra, 424 N.J. Super. at 289-90, 37 A.3d 549. Specifically, the manufacturer submits the NDA, which must comply with a long list of requirements, such as providing a proposed label for prescription drugs. Id. (citing 21 C.F.R. § 201.56, 314.50). The FDA has the authority to advise of necessary revisions, and the label is often revised several times before the FDA approves the final label. Id. Although the Court notes the Supreme Court's recognition of the FDA's limited resources, see Wyeth, supra, 555 U.S. 555, 129 S. Ct. 1187, the Court also notes that the FDA has the authority to create technical and scientific review groups, often referred to as advisory committees, to aid in carrying out its functions, Bailey, supra, 424 N.J. Super. at 295-96, 37 A.3d 549 (citing 21 U.S.C.S. § 393(e)). Importantly, the FDA has taken advantage of this authority with respect to estrogen/progestin contraceptives,

id. at 296-98, and therefore cannot be said to have merely accepted Defendants' version of the label. Moreover, the FDA has the authority to require Defendants to revise the label after it has been approved. Id. at 318. Therefore, "if the FDA had any doubt about the warning it approved . . . , the agency had the authority to revisit that warning and revise it . . . ." Id.

The test is whether the label's language met the standards of adequacy under each jurisdiction. Notably, FDA approval alone does not require a finding of adequacy as a matter of law absent a statute saying otherwise. Comparing the statutes and case law the Court examined in these summary judgment motions, only New Jersey has a presumption of adequacy based on FDA approval. Conversely, in a state that requires an "adequate" label (rather than a state merely requiring approval by the FDA), the Court must evaluate the facts under those relevant standards, regardless of FDA approval. Compare New Jersey's Products Liability Act N.J.S.A. § 2A:58C-1 to -11 (requiring a finding of adequacy as a matter of law if label is approved by the FDA, limited to two exceptions), infra "Bozicev," Part I(A), with Stevens v. Parke, 9 Cal.3d 51, 65, 507 P.2d 653 (1973), infra "Fields," Part I(A) ("[M]ere compliance with regulations or directives as to warnings, such as those issued by the [FDA], may not be sufficient to immunize the manufacturer or supplier of the drug from liability. The warnings required by such agencies may be only minimal in nature and when the manufacturer or supplier knows of, or has reason to know of, greater dangers not included in the warning, its duty to warn may not be fulfilled.").

C. Delayed Reporting To FDA

Plaintiffs assert that Defendants were delayed in reporting the VTEs to the FDA, and that such careless reporting could be viewed as intentional concealment. Defendant counters by stating that all clinical trial results were submitted in full, annually, and notes with particularity that the VTEs were reported several times.

The Court finds that Defendants' alleged delayed reporting is of no consequence. A defendant cannot be found to have intentionally concealed risks where such risks were later disclosed. See Bailey, supra, 424 N.J. Super. at 312, 37 A.3d 549. Moreover, even if the Court were to find that Defendants were delayed in their reporting, all VTEs were eventually revealed to FDA, and FDA made no recommendation to Defendants to update label as of the time of Plaintiffs' injuries. Thus, FDA would not have required an updated label even if Defendants had timely reported their findings, breaking any causal link from Defendants' actions.

D. Adequacy Summary

At this summary judgment stage of the proceedings, the issue is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Anderson, supra, 477 U.S. at 251-52; accord Tomeo v. Thomas Whitesell Constr. Co., 176 N.J. 366, 370, 823 A.2d 769 (2003). Summary judgment is warranted in favor of the movant "if there is no genuine issue as to any material fact and if the moving party is entitled to judgment as a matter of law." Id. at 250. Here, the Court finds there are genuine issues of material fact with respect to adequacy in the cases of Barrow, Fields, Wilson-Johnson, Namack, and Ziwange; only in Bozicev and Mariconda can the Court conclude that no material issues of fact exist with respect to adequacy. The evidence introduced by Plaintiffs is more than

"merely colorable" with respect to adequacy, see id. at 249-50; Plaintiffs have produced testimony of experts supporting Plaintiffs' various positions, and internal communications from Defendants stating that they did not want the VTE in the label which Plaintiffs argue illustrates Defendants knowledge that the additional VTEs indicated an increased risk. (Plaintiffs alternatively assert that, by the fourth VTE, the occurrence of which Defendants admit, Defendants knew or should have known of the increased risk.) This evidence allows the Court to find that all Plaintiffs, except for Bozicev and Mariconda, have met their summary judgment burden on the issue of adequacy.

V. Express Warranties, generally

Each state has its own legal standards with respect to express warranties just as they do for adequate warnings, which the Court will address infra. However, the Court notes at this interval that several Plaintiffs did not specifically allege a breach of an express warranty. Further, when Plaintiffs were asked what express warranties, if any, were made by Defendants, Plaintiffs' counsel could not articulate a response during oral arguments. It was not until prompted by the Court that they recalled their misrepresentation argument.[29] The Court finds that this is not sufficient to defeat

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[29] Transcript, March 5, 2013, at 140:2-25.

> JUDGE MARTINOTTI: One question. With the exception of Mr. Thompson, has anybody spoken about the alleged misrepresentations to the plaintiffs.
> MR. SHKOLNIK: I'm trying to think if misrepresentation is what he talked about, your Honor. I would have to go back.
> MR. BALL: There weren't any.
> JUDGE MARTINOTTI: Okay.
> MR. SHKOLNIK: I don't remember what Mr. Thompson said so I don't want to say yes or no.

summary judgment for those Plaintiffs who did not also allege express warranties in their opposition. Plaintiffs that did raise additional arguments in their oppositions will have them addressed infra.

VI. Causation, generally

In outlining the legal standards of the individual states, the Court is mindful of the two aspects of causation in this case: whether the physicians' decisions to prescribe, or the Plaintiffs' decisions to take,[30] NuvaRing® would have changed had the label been written as Plaintiffs suggest; and whether Plaintiffs' injuries would have been prevented if they had taken another form of birth control.

A. Physicians' Decisions To Prescribe, and Plaintiffs' Decision to Take, NuvaRing®

Plaintiffs have the burden (and they concede such, see Transcript, March 5, 2013, at 34:2-4) to show causation, particularly that the Plaintiff would not have taken the drug, either because the physician would not have recommended it or she would have refused the prescription, if the label indicated the risk to the extent Plaintiffs suggest. Plaintiffs in these cases, have not been able to provide evidence that prescribing physicians'

> JUDGE MARTINOTTI: I think his argument was, it seems like a long time ago, that the fact that the label said unknown was a material misrepresentation.
> MR. SHKOLNIK: Your Honor, I beg to differ with counsel. It may not have been in 2001. That's the point here. Maybe in 2001 we accept FDA acknowledging and accepting that language. But, when time passes, 2001 -- I'm sorry, 2002 to 2006, 2008, when Mrs. Wilson-Johnson took the product up until the present time, at some point it is a misrepresentation as they develop more information and don't disclose it.
> JUDGE MARTINOTTI: Okay.
>
> [Id.]

[30] Depending on applicable case law.

knowledge of the clinical studies' results, including the "bursts" and four (4) VTEs, would have affected their decision to prescribe the drug.

For example, when asked how Plaintiffs will prove this at trial, counsel merely argued that Defendants did not ask particular questions related to causation, and say that Plaintiffs themselves will testify as to whether they would have taken the drug had they known the exact risk. See Transcript, March 5, 2013, 34:7-17.[31] Based on the evidence before the Court at this time, Plaintiffs have not overcome their burden to defeat summary judgment. Plaintiffs have not presented any evidence to the Court of Plaintiffs' response, because the precise question was never asked at the deposition of the Plaintiffs – i.e. whether Plaintiffs would have taken the drug if their doctor informed them of, or the label warned of, the two-fold risk that Plaintiffs allege.

Similarly, Plaintiffs' counsel did not ask the prescribing physicians during their depositions whether their decision to prescribe the drug would be affected if the label were specifically changed to reflect the two-fold risk that Plaintiffs allege. Plaintiffs only asked physicians whether their decision would be affected if the label were "different."

B. Plaintiffs' Injuries If Using Another Birth Control

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31 JUDGE MARTINOTTI: Who has the burden of proving proximate cause?
MS. LEONARD: Plaintiff.
JUDGE MARTINOTTI: Okay. And how would you do that in this case?
MS. LEONARD: How would I prove proximate cause?
JUDGE MARTINOTTI: Yeah.
MS. LEONARD: Well, if this client was adequately warned that there was a double increased risk of a VTE with this product as opposed to the birth control pill, she wouldn't have taken it. They didn't ask that question. Why would they? Because they didn't want to know the answer. They don't want to have that answer before the court.
That's what she's going to say.

[Transcript, March 5, 2013, 34:7-17 (emphasis added).]

Even if Plaintiffs' counsel could overcome summary judgment with respect to each physician's decision to prescribe the medication, Plaintiffs have not been able to provide evidence that the injury would have been prevented if Plaintiffs had used another birth control method.

Plaintiffs assert that the risk of VTEs with NuvaRing® was twice that of oral contraceptives, thus, if a woman affirmatively chose to use an oral contraceptive after being informed of the risks of NuvaRing®, her risks would be cut in half. However, the Court notes that this "half risk" still presents a risk, and parties do not dispute that there is a VTE risk with the alternative, oral contraceptive. Thus, Plaintiffs cannot show that it would have been impossible for Plaintiffs to suffer an injury using another estrogen/progestin birth control method.

C. Causation Summary

Even where Plaintiffs are able to provide sufficient evidence to show that a material issue of fact exist as to the adequacy of the warning, Plaintiffs are not able to defeat summary judgment with respect to causation.

BOZICEV

V. Adequacy

A. New Jersey Products Liability Act

This matter is governed by New Jersey's Products Liability Act ("PLA").[32] N.J.S.A. § 2A:58C-1 to -11. A product liability action is defined as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying

[32] Defendants briefly addressed the common law claims which were placed in Plaintiffs' complaint. However, such claims are subsumed by the PLA, as will be discussed in this section.

the claim, except action for harm caused by breach of an express warranty." N.J.S.A. § 2A:58C-1(b)(3). Consequently, claims for damages caused by an allegedly defective drug must be brought under the PLA. Sinclair v. Merck & Co., Inc., 195 N.J. 51, 66, 948 A.2d 587 (2008). Claims for damages, including negligence, breach of implied warranty, negligent misrepresentation, and fraud by concealment are all subsumed by the PLA. Baker v. APP Pharmaceuticals, LLC [hereinafter Baker I], Civ. A. No. 09-05725 (JAP), 2010 U.S. Dist. LEXIS 126037, at *8-9 (D.N.J. Nov. 30, 2010); see also Tirrell v. Navistar, 248 N.J. Super. 390, 398, 591 A.2d 643 (App. Div. 1991) (negligence and breach of implied warranty); Bailey, supra, 424 N.J. Super. at 335 (fraud and misrepresentation).

For example, in Baker I, the court found that "the potential for harm caused by a drug product, heparin," was "[a]t the heart of th[e] matter," and "it [was] evident that [it was] an action . . . for harm caused by a product[.]" Baker I, supra, Civ. A. No. 09-05725, 2010 U.S. Dist. LEXIS 126037, at *9. Consequently, Plaintiffs' claims for negligence, breach of implied warranty, negligent misrepresentation, and fraud by concealment, alleging that the drug was "manufactured and supplied in a defective and unreasonably dangerous condition and contain[ed] inadequate warnings of the product's dangerous characteristics", were "encompassed by the PLA", "improperly raised and . . . dismissed." Id. Plaintiffs also alleged a failure to warn cause of action, which the court held in a later decision was also covered by the PLA. Baker v. APP Pharmaceuticals LLP [hereinafter Baker II], Civ. A. No. 3:09-cv-05725, at *7 (JAP) (DEA) (D.N.J. Aug. 21, 2012).

Plaintiffs in this case have asserted claims for negligence, strict liability, failure to warn, breach of implied warranty, common law fraud, fraud under the Consumer Fraud Act,[33] breach of express warranty, negligent misrepresentation, fraudulent misrepresentation, fraud by concealment, and wrongful death alleging damages caused by Defendants' product.[34] Although Defendants also contend that Plaintiffs will be unable to prove the causal link from its product to Plaintiffs' injuries, the Court finds it evident that this case stems from a product. As in Baker I and Baker II, the potential for Defendants' drug product to cause harm and the Plaintiff's allegations of such harm are at the heart of this matter. Thus, Plaintiffs' claims for negligence, breach of implied warranty, and common law fraud are subsumed by the PLA and dismissed as individual claims, while Plaintiffs' claim for breach of express warranty stands alone.[35] N.J.S.A. § 2A:58C-1(b)(3); Baker I, supra, Civ. A. No. 09-05725, 2010 U.S. Dist. LEXIS 126037, at *8-9.

Under the PLA, a manufacturer is "not liable for harm caused by a failure to warn if the product contains an adequate warning or instruction . . . ." N.J.S.A. § 2A:58C-4. To avoid liability, the warning must be "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product . . . taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician." Id.

3. Presumption of Adequacy

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[33] The Consumer Fraud Act claims were dismissed with prejudice on February 19, 2010.
[34] In addition, Plaintiff Matthew Bozicev brings a cause of action for negligent infliction of emotional distress.
[35] Plaintiffs' claims for express warranty will be addressed, infra. See infra, "Bozicev," Part II; "Mariconda," Part II.

Warnings for drugs that are approved by the FDA are presumptively adequate. Id. The PLA states, "If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration[,] . . . a rebuttable presumption shall arise that the warning or instruction is adequate." Id. Thus, "[c]ompliance with FDA regulations provides compelling, although not absolute, evidence that a manufacturer satisfied its duty to warn about the dangers of its product." Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 195, 36 A.2d 541 (2012) (citing Perez v. Wyeth Labs., Inc., 161 N.J. 1, 24, 734 A.2d 1245 (1999)). This "super-presumption" instructs courts that "[c]ompliance with the FDA standards should be virtually dispositive of [failure to warn] claims." Kendall, supra, 209 N.J. at 195 (quoting Perez, supra, 161 N.J. at 25) (internal quotation marks omitted).

4. Rebutting the Presumption

There are two ways to rebut this presumption: (1) through the introduction of evidence that the pharmaceutical company "deliberate[ly] conceal[ed] or [did not] []disclos[e]after-acquired knowledge of harmful effects," known as "the Perez exception," Perez, supra, 161 N.J. at 15, 734 A.2d 1245; or (2) through the introduction of evidence of manufacturer's "economically-driven manipulation of the post-market regulatory process," known as "the McDarby exception," McDarby, supra, 401 N.J. Super. at 63, 949 A.2d 223. See Baker II, supra, Civ A. No. 3:09-cv-05725, at *7-13.

a. Perez

The Perez exception requires an intentional withholding of information. Id. at *10; see Perez, supra, 161 N.J. at 25, 734 A.2d 1245. In Perez, the court found that, regardless of whether a drug was distributed to physicians or whether it was marketed

directly to consumers, the same rebuttable presumption should exist – that an FDA approved label will be presumed adequate and "fairly balanced," "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." Id. The court recognized the changes in pharmaceutical practices in which manufacturers had begun to advertise directly to consumers rather than directing all sales efforts at the physicians, after which medical advice was passed from physician to patient. Id. at 4. The Perez court therefore evaluated the duty owed by manufacturers to consumers, specifically Defendant's duty to consumers following its advertisement of its contraceptive drug, Norplant, id. at 5, noting that patient choice is a significant factor in the selection of contraceptives, particularly when such drugs are advertised directly to consumers, id. at 20. Although the Defendant-manufacturer argued that the learned intermediary rule protected it from liability because it had given warnings to the physicians, the court found that this doctrine did not apply as a result of the direct advertising to consumers and a duty was therefore owed by the manufacturer to the consumers. Id. at 21-22 (noting that the learned intermediary rule does not apply and manufacturers may be subject to claims by consumers).

In determining the scope of the duty owed, the court found that the manufacturer was entitled to the same presumption of adequacy governing warnings to physicians, noting that using the same "approach harmonizes the manufacturer's duty to doctors and to the public":

> . . .FDA regulations serve as compelling evidence that a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product.
> We believe that in the area of direct-to-consumer advertising of pharmaceuticals, the same rebuttable

> presumption should apply when a manufacturer complies with FDA advertising, labeling and warning requirements."
>
> [Id. at 24 (emphasis added).]

However, this strong presumption of the warning's adequacy is not overcome "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." Id. at 25. The advertising is presumed to be "fairly balanced." Perez, supra, 161 N.J. at 25, 734 A.2d 1245. In the "rare" case where the presumption is overcome, compensatory damages may be recovered. Id.

b. McDarby

Notably, "circumstances less egregious than deliberate concealment could [also] overcome the presumption." Kendall, supra, 209 N.J. at 196 n.6, 36 A.2d 541 (citing McDarby, supra, 401 N.J. Super. 10, 949 A.2d 223). The McDarby exception is applicable where, after a drug is approved, a manufacturer downplays risks, misrepresents clinical studies, or seeks to conceal after-acquired knowledge of risks from physicians and prevent inclusion of such information on labels. See McDarby, supra, 401 N.J. Super. at 67-69, 949 A.2d 223.

In McDarby, the court rejected the Perez exception as being too narrow, noting the existence of "admitted flaws in the FDA's control over postmarket labeling in the years that [the drug] was on the market." Id. at 66. The court stated:

> Commentators and courts have since recognized that, whereas pre-market approvals of drugs are generally thorough in nature, the ability of the FDA, post-market, "to detect unforeseen adverse effects of [a] drug and to take prompt and effective remedial action" is considerably less.
>
> [Id. at 64 (quoting Kessler & Vladeck, 96 Geo. L. J. at 465).]

As a result, in finding that the Plaintiff overcame the presumption that the warning accompanying Vioxx was adequate, the court relied on Plaintiff's theory of the manufacturer's "economically-driven manipulation of the post-market regulatory process," rather than "claim[s] of fraud on the FDA." Id. at 63. To support this finding, the court noted that Merck, the manufacturer, concealed and downplayed known cardiovascular risks associated with the drug once it was on the market. Id. at 67-69.

B. Parties' Arguments

Defendants assert that, because its NuvaRing® warning was approved by the FDA, it is presumptively adequate under N.J.S.A. § 2A:58C-4. Further, Defendants assert that Plaintiff is unable to rebut this presumption under either the Perez or McDarby theories, and therefore its warnings are adequate as a matter of law. With respect to these exceptions, Defendants state that Plaintiff has not offered any evidence of concealment, nondisclosure, or manipulation.

Alternatively, Defendants claim that, even without the presumption, the summary judgment should be granted because Plaintiff has acknowledged the adequacy of the warning, eliminating this key issue of fact. Defendants highlight depositions in which Plaintiff's experts agree that the label adequately warned of the risk of stroke.[36]

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[36] MR. ALEXANDER: . . . Well, did you look at all of [the label]?
DR. BERLINER: Enough to be concerned that there was an issue related to NuvaRing.

[Berliner Dep., Geist Cert. Ex. 33. at 75:19-21]

MR. ALEXANDER: So when you read the NuvaRing label in something called the Physicians' Desk Reference, it was apparent to you by your reading of the label that there was a disclosed risk of venous thromboembolism with NuvaRing, right?
MS. SCOTT: Objection.
DR. JASON: Yes.
Q: And that was fairly easy for you to read and understand?
A: Yes.

Consequently, Defendants assert that the labels are adequate as a matter of law and therefore it cannot be held liable.

Plaintiff argues that summary judgment cannot be granted because: (1) there are material issues of fact; (2) Defendants' failure to challenge all causes of action, such as design defect, manufacturing defect, and failure to test, preclude summary judgment in Defendants' favor; (3) the warning is equivocal, ambiguous, and dilutes the risks of the drug by use of the word "may" with respect to the potential injuries; (4) Plaintiff can satisfy the Perez exception based on Defendants' failure to disclose studies after the FDA's approval, because, as between the FDA and the manufacturer, research and disclosure was Defendants' responsibility; (5) Plaintiff can satisfy the McDarby exception because Defendants acted in self-economic interest in concealing safety concerns based on VTE risks and misleading prescribing physicians regarding the level of hormones being released, or "bursts;" and (6) NuvaRing® proximately caused the deaths of Plaintiffs' decedents.

C. PLA Applied

The Court starts its analysis by acknowledging the PLA's presumption of adequacy, prior to evaluating the Perez and McDarby exceptions. Through its Opposition, Plaintiff set forth several reasons why Defendants' warnings are inadequate, such as that the warnings are inaccurate regarding the variability of the daily dosage and that it dilutes the increased risk of third generation progestins. Bozicev Opp. 12, 14.

. . .
Q: But when you – when you read that part of the label, the warning section of the label, you came away with it saying there's a risk of venous thromboembolism with NuvaRing.
A: Yes.

[Jason Dep., Geist Cert. Ex. 32 at 178:20-179:5, 179:24-180:3.]

Despite these allegations, the Court is to be guided by the legislature, which allows the Court to presume, as a matter of law, that the warning is adequate based on the FDA's approval. N.J.S.A. 2A:58C-A; Bozicev Opp. 5 Plaintiff can only overcome this "super-presumption" using the Perez or McDarby exceptions.

Plaintiff argues that they are able to satisfy both the Perez and McDarby exceptions to overcome the presumption. Plaintiff alleges that Perez is satisfied because Defendants failed to provide the FDA with an updated integrated safety summary, and admitted such on August 1, 2006. (Bozicev Opp. 19 & Scott Cert., Ex. 32.) Plaintiff asserts that the FDA's flawed regulatory process and limited resources put the responsibility on the manufacturer of drugs that either require approval or have been approved to provide full and accurate information. (Bozicev Opp. 21 (citing Wyeth, supra, 555 U.S. at 578-79, 129 S. Ct. 1187).) Plaintiff asserts that, under Wyeth, supra, upon discovery of increased risks, Defendants should have updated their label or, at the very least, contacted health professionals. (Bozicev Opp. 21 (citing Wyeth, supra, 555 U.S. at 578-79, 129 S. Ct. 1187).) Plaintiff also argues that the presumption is rebutted based on McDarby, because Defendants acted in self-economic interest in concealing safety concerns based on VTE risks and misleading prescribing physicians regarding the level of hormones being released, or "bursts." (See Bozicev Opp. 20.) Additionally, with respect to the "bursts," Plaintiff argues that it is directly related to the increased blot clot risk and that Defendants were aware of same. (See Bozicev Opp. 16.) To support these contentions, Plaintiff has provided the Court with the report of its expert, Dr. Parisian. (See Bozicev Opp., Scott Cert., Ex. 12.)

Defendants contend that they disclosed all they were required to by the FDA, including post-approval VTE studies. For example, Defendants note that they were not required to disclose the 2005 CER to the FDA; under 21 C.F.R. § 314.80(c)(2)(i), they were only required to submit an annual Periodic Adverse Drug Experience Report (PADER). Defendants submitted such in late 2006, which included four pages about the drug's VTE risks. (Defs.' Rep. 5 & Geist Cert. Ex. 40.) Defendants also argue that they had no knowledge of an increased risk, because they deny that such an increased risk exists.

The Court finds that Plaintiff has not shown that issues of material fact exist. New Jersey's PLA establishes a particularly high burden of proof even in the face of Perez and McDarby; the presumption of adequacy is not simply overcome by contrary evidence, as it would be under N.J.R.E. 301. Bailey, supra, 424 N.J. Super. at 314, 37 A.3d 549 (citing William A. Dreier, John E. Keefe, Sr., & Eric D. Katz, New Jersey Products Liability & Toxic Torts Law § 15:4 at 443 (2008)); see also McDarby, supra, 401 N.J. Super. at 71, 949 A.2d 223. With respect to Perez, Defendants have demonstrated that that they revealed all VTEs to the FDA, even if delayed as Plaintiff alleges. Therefore, Plaintiff cannot prove any fraud on the FDA to overcome the presumption of adequacy based on Perez. See Bailey, supra, 424 N.J. Super. at 312 (finding that Perez had not been satisfied where defendants did not withhold any information from the FDA).

Regarding McDarby, the Court finds that the FDA's continued approval of the label prevents the Court from finding that this exception has been satisfied. Although the Parties dispute whether an increased risk existed based on Defendants' knowledge of the

additional VTEs,[37] the Court cannot call this dispute material under New Jersey's PLA. To overcome McDarby, Plaintiff must be able to show that an increased risk existed and that Defendants knew of that risk and concealed it from or downplayed it to physicians once it was on the market. See McDarby, 401 N.J. Super. at 67-69. For example, in McDarby, plaintiffs were able to provide sufficient evidence that defendant knew of the increased risk of thrombotic events, including recognition of the increased risk by the FDA's medical review officer, who also recommended further cardiovascular testing, the risk of which was still unknown. Id. at 67. Additional clinical trials revealed the elevated thrombotic risk, which defendant, in reporting the results to the FDA in an sNDA, attempted to justify by attributing the adverse effects to known effects of naproxen. Id. at 68. The FDA ultimately required that the results of the clinical trials be included in the new label; however the new label took over two years to be approved, during which time, defendant's "marketing personnel engaged in strenuous efforts to ensure that the results of the [clinical trials] were not communicated to prescribing physicians by sales persons, and there is some evidentiary support for a claim of misrepresentation by [defendant] in responding to individual physician inquiries." Id. The court found that the combination of defendant's knowledge of the risk, and the FDA's decision to ultimately revise the label to include the risk "provides powerful evidence that the label [originally] approved . . . , was inadequate, at least from [the date defendant acknowledged that the clinical trial revealed an increased risk]." Id. at 69.

The most glaring distinction between McDarby and this case is that Defendants have not admitted that NuvaRing® has an increased risk of VTE; in fact, they deny it.

[37] The Court notes that the parties agree that: (1) additional VTEs occurred after the FDA's approval of the warning; (2) Defendants have a continuing obligation to update the FDA annually; and (3) there is an obligation to update physicians if an increased risk existed.

Plaintiff has not provided to the Court any evidence that Defendants knew of an increased risk after FDA approval. Cf. id. at 69 (citing defendant's express statement acknowledging increased risk). Although the parties dispute NuvaRing®'s precise risk, this issue of fact is not considered material with respect to McDarby; the issue is whether Defendants knew of a risk, sufficient evidence of which Plaintiff has not provided. In addition, the FDA has never decided to revise the NuvaRing® label despite the results of clinical trials, regardless of how they may be interpreted, which have been published and disclosed to the FDA since the label's initial approval. See id. (citing FDA's decision to revise label as powerful evidence of adequacy); supra, "Decision," Part I(B) (discussing FDA approval process and authority post-approval). Finally, Plaintiff has not provided evidence similar to that submitted in McDarby showing that Defendants engaged in "strenuous efforts" to prevent the results of clinical trials from being revealed to physicians since the FDA's initial approval. See infra "Bozicev," Part II(B). Consequently, Plaintiff Bozicev has not satisfied the exception set forth in McDarby.

Because Plaintiff has not satisfied either Perez or McDarby, the Court is bound by the PLA's presumption of adequacy. Accordingly, summary judgment is GRANTED.

VI. Express Warranty

A. Legal Standard

In New Jersey, a claim for a breach of an express warranty is exempt from the PLA and can be brought separately from those claims which are subsumed by one broad products liability claim. N.J.S.A. § 2A:58C-1(b)(3). Significantly, this claim is derived from a breach of contract claim, and plaintiffs must demonstrate "that they relied upon

labeling or other expressions of promise that could have formed the 'basis of the bargain.' " Bowman v. RAM Med., Inc., No. 10-cv-4403 (DMC) (MF), 2012 U.S. Dist. LEXIS 75218, at *14-15 (D.N.J. May 31, 2012). Plaintiffs must "demonstrate that there was some form of promise or affirmative statement made." Delaney v. Stryker Orthopaedics, Civ. A. No. 08-03210 (DMC), 2009 U.S. Dist. LEXIS 16865, at *13 (D.N.J. Mar. 5, 2009) (citing N.J.S.A. § 12A:2-313). Such allegations must be pled with specificity, describing the statements made and the way on which they were relied. Baker I, 2010 U.S. Dist. LEXIS 126037, at *10 (noting that plaintiffs must "identify a[] specific promise, affirmation, description, or sample which . . . form[s] the basis of the express warranty"); Bowman, No. 10-cv-4403, 2012 U.S. Dist. LEXIS 75218, at *14-15 (finding that plaintiff failed to specifically demonstrate reliance on any express warranties, and that "[s]uch a lack of specificity does not comport with the nature of the theories supporting consumer reliance upon an express warranty").

B. Express Warranties

In Bozicev, Plaintiff relies on statements made to doctors by Defendants' sales representatives, which Plaintiff alleges were misleading representations and affirmations of fact. (Iannone Dep., Scott Cert. Ex. 33; Furman Dep., Scott Cert. Ex. 35). Plaintiff further argues that these representations served as the basis of the bargain because Dr. Furman, Ms. Bozicev's prescribing physician, relied on these statements. Id. Upon review of Dr. Furman's testimony, the Court finds that Plaintiff Bozicev did not meet his burden with respect to express warranties. Plaintiff has the burden to show that Defendants' representations were a basis of the bargain, Dr. Furman's testimony does not confirm that she relied on the sales representatives' statements in prescribing NuvaRing®

to Plaintiff Bozicev, or to even patients generally. She merely recalled speaking with them, and noted that she does trust what pharmaceutical representatives tell her based on what they say. (Furman Dep., Scott Cert. Ex. 35, 101: 6-15.) However, she states that she does not recall the statements made by the NuvaRing® representatives, and does not state that she recalls relying on those statements in prescribing NuvaRing® to her patients. Accordingly, summary judgment is GRANTED with respect to express warranties.

VII. Causation

A. Legal Standard

Assuming, arguendo, Plaintiff were to overcome the PLA's presumption of adequacy, the Court will analyze causation. The applicable law in the New Jersey cases is the PLA, which:

> provides the exclusive remedy for harm caused by a product. A products liability action is defined as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty."
>
> [Bailey, supra, 424 N.J. Super. at 329, 37 A.3d 549 (citing N.J.S.A. 2A:58C-1(b)(3)). See supra "Bozicev" Part I(A).]

Regarding causation, the Supreme Court reversed the appellate court's decision in Strumph v. Schering Corp., 133 N.J. 33, 626 A.2d 1090 (1993), for the reasons stated in the appellate court's dissent:

> Plaintiff has the burden of proving that defendant's alleged inadequate warnings were a proximate cause of her injuries. To satisfy this burden, plaintiff must show that adequate warnings would have altered her doctors' decision

> to prescribe [the drug]. Absent any evidence from which a jury could reasonably make this finding, defendant was entitled to summary judgment.
>
> [Strumph v. Schering Corp., 256 N.J. Super. 309, 323, 606 A.2d 1140 (J. Skillman, dissenting op.) (citing Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806 (5th Cir.1992); Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 209, 485 A.2d 305 (1984)), rev'd based on reasons set forth in dissent, supra, 133 N.J. at 34, 626 A.2d 1090 (emphasis added). Accord Perez, supra, 161 N.J. at 10-11, 734 A.2d 1245.]

New Jersey follows a heeding presumption under which a fact finder may presume that, had plaintiff's doctor received an adequate warning, he would have heeded that warning and not prescribed the drug. McDarby, supra, 401 N.J. Super. at 80-81, 949 A.2d 223. However, this presumption is not applicable where treating physicians testified "that they were aware of the risks of the drug that they prescribed and, having conducted a risk-benefit analysis, nonetheless determined its use to be warranted." Id. at 81 (citing Strumph, supra, 256 N.J. Super. 309, 323-24, 606 A.2d 1140 (J. Skillman, dissenting op.)). See also In re Diet Drug Litig., 384 N.J. Super. 525, 895 A.2d 480 (Law Div. 2005) (finding that the presumption disappears where the heeding presumption is rebutted by evidence that the physician, having appropriate risk information, nevertheless would have prescribed the drug).

B. Causation

Plaintiff Bozicev argues that the learned intermediary rule does not apply because Defendants engaged in direct-to-consumer marketing, and that, as a result, the heeding presumption applies instead. (Bozicev Opp. 31.) Plaintiff therefore argues that the Court should presume that the Plaintiff herself would have heeded the adequate warning had one been present. (Id.) However, Plaintiff misinterprets the application of the heeding

presumption in the case of prescription drugs where the learned intermediary doctrine applies. First, the heeding presumption applies to the physicians rather than the plaintiffs; that is, "whether a physician armed with appropriate risk information concerning the possibility of associated [injury] nevertheless would have prescribed [the medication]." In re Diet Drug Litig., supra, 384 N.J. Super. at 530, 895 A.2d 480 (emphasis added); accord Bozicev Opp. 32. Second, the heeding presumption "vanishes" and is longer applicable if it has been rebutted. In re Diet Drug Litig., supra, 384 N.J. Super. at 530, 895 A.2d 480 (citing N.J.R.E. 301; Sharpe v. Bestop, Inc., 314 N.J. Super. 54, 68-69, 713 A.2d 1079 (App.Div.1998), aff'd o.b., 158 N.J. 329, 730 A.2d 285 (1999)); see also McDarby, supra, 401 N.J. Super. at 81, 949 A.2d 223. The presumption is rebutted where plaintiff's treating physician was "aware of the risks of the drug that [she] prescribed and, having conducted a risk-benefit analysis, nonetheless determined its use to be warranted." McDarby, supra, 401 N.J. Super. at 81, 949 A.2d 223.

Since the Court finds Defendants have rebutted the heeding presumption by demonstrating that Dr. Furman, Ms. Bozicev's treating physician, was aware of the risk of VTE and "nonetheless determined [NuvaRing®'s] use to be warranted." See id.; Furman Dep., Scott Cert. Ex. 35 at 130:2-18; 131:23-132:4. The burden shifts back to the Plaintiff to prove proximate cause. In re Diet Drug Litig., supra, 384 N.J. Super. at 544, 895 A.2d 480 (citing Sharpe, supra, 314 N.J. Super. at 67, 713 A.2d 1079). Plaintiff has not raised a material issue of fact as to proximate cause because she has not presented evidence to the Court as to whether Dr. Furman would have changed her decision to prescribe NuvaRing® had the warning reflected a higher risk of injury. In fact, Dr. Furman testified at her deposition that she continues to prescribe NuvaRing®, and at the

time she prescribed it to Ms. Bozicev, she was aware that third generation contraceptives may have an increased risk over second generation contraceptives. (Furman Dep. at 131:23-132:4, 55:18-56:14, 49:25-50:11.) Even if Plaintiff's counsel could overcome summary judgment with respect to the physician's decision to prescribe the medication, Plaintiff has not been able to provide evidence that the injury would have been prevented if Plaintiff had used another birth control method. Dr. Furman stated that VTEs are an unavoidable risk of taking birth control drugs containing ethinyl estradiol. Further, Dr. Berliner, Plaintiff's case-specific expert, stated that "you never know" if Ms. Bozicev would have had a different outcome if she took a different contraceptive and that, based on the mere existence of a resulting clot while using NuvaRing®, "it's unknown whether the risk [of NuvaRing®] is greater or equal to" other products Ms. Bozicev used. (Berliner Dep., Geist Cert. Ex. 33, at 192-93.)

For the reasons set forth above, and as stated supra, "Bozicev," Part I(C), summary judgment is GRANTED.

VIII. Negligent Infliction of Emotional Distress Claim by Matthew Bozicev

The parties agree that Portee v. Jaffee, 84 N.J. 88, 417 A.2d 521 (1980) governs claims for negligent infliction of emotional distress ("NIED"). The Portee court outlined four elements to this cause of action:

> (1) the death or serious physical injury of another caused by defendant's [***23] negligence; (2) a marital or intimate, familial relationship between plaintiff and the injured person; (3) observation of the death or injury at the scene of the accident; and (4) resulting severe emotional distress. We find that a defendant's duty of reasonable care to avoid physical harm to others extends to the avoidance of this type of mental and emotional harm.

[Portee, supra, 84 N.J. at 101, 417 A.2d 521.]

Plaintiff notes that "[a] Portee action requires all of the same proofs on liability as the underlying negligence/products liability action." Mansour v. Leviton Mfg. Co., Inc., 382 N.J. Super. 594, 604, 890 A.2d 336 (App. Div. 2006); see Bozicev Opp. 40. Based on this, Plaintiff argues that he has satisfied causation as to NIED because he has "provided evidence sufficient to persuade a jury as to the causation element of their products liability actions." As stated supra, "Bozicev," Part III(B), Plaintiff has not met his burden as to causation in the products liability action. Where causation cannot be demonstrated to prove Ms. Bozicev's injury, Plaintiff cannot show that Defendants' alleged failure to warn was a proximate cause of Plaintiff Matthew's injury upon seeing his mother injured. Accordingly, Plaintiff has not raised any issues of material fact as to causation on the NIED claim, and summary judgment is GRANTED on this cause of action.

MARICONDA

IV. Adequacy

A. New Jersey PLA

For the applicable case law, see supra Bozicev, Part I(A).

B. Parties' Arguments

Defendant asserts that all of the Plaintiff's claims, except the claim for breach of warranty, are subsumed by the PLA, under which NuvaRing®'s warning is presumed adequate as a matter of law simply because the FDA approved it. Defendants contend that the Plaintiff did not provide any proof to satisfy the exceptions and overcome this statutory presumption. Additionally, Plaintiff's FDA expert, Dr. Suzanne Parisian, did

not identify any issue regarding concealment of any material information from Defendants to the FDA or any manipulation of the regulation process after NuvaRing® was approved. Dr. Parisian further testified that she did not have any problems with the adequacy of NuvaRing®'s warning. Plaintiff's own neurology expert, Dr. Levine, also testified that the NuvaRing® label provided adequate warning.

Plaintiff argues that summary judgment cannot be granted because: (1) there are material issues of fact; (2) Defendants' failure to challenge all causes of action, such as design defect, manufacturing defect, and failure to test, preclude summary judgment in Defendants' favor; (3) the warning is equivocal, ambiguous, and dilutes the risks of the drug by use of the word "may" with respect to the potential injuries; (4) Plaintiff can satisfy the Perez exception based on Defendants' failure to disclose studies after the FDA's approval, because, as between the FDA and the manufacturer, research and disclosure was Defendants' responsibility; and (5) Plaintiff can satisfy the McDarby exception because Defendants acted in self-economic interest in concealing safety concerns based on VTE risks and misleading prescribing physicians regarding the level of hormones being released, or "bursts." Additionally, Plaintiff specifically denies Defendants' assertion that "[t]here is no evidence that Organon withheld or concealed any information regarding the risk of stroke from the FDA either during the approval process or at any time after approval."[38] (Mariconda Resp. to Defs.' Facts, ¶ 21 and Response.) Finally, Plaintiff asserts that Ms. Mariconda was never diagnosed with migraines with aura by any her prescribing physicians, and that the warning label

[38] The Court notes that, with the exception of stating, "Denied," Plaintiff does not rebut Defendants' "undisputed fact" regarding the risk of stroke; Plaintiff only goes on to address allegedly concealed VTEs.

regarding such is ambiguous and misleading. (Mariconda Resp. to Defs.' Facts, Resps. to ¶¶ 24-25.)

C. PLA Applied

Similar to the analysis in Bozicev, the Court starts its analysis by acknowledging the PLA's presumption of adequacy, prior to evaluating the Perez and McDarby exceptions and the Parties post-approval disputes. Plaintiff asserts several reasons why Defendants' warnings are inadequate, such as that the warnings are:

> . . . equivocal, ambiguous, [and] provide[] the patient/consumer with a diluted variation of the risks associated with the drug and contain warnings of a general nature which do not give the patient/consumer a sufficient understanding of the risks inherent in the product use.
>
> [Mariconda Opp. 12-13.]

The Court is to be guided by the legislature, which allows the Court to presume, as a matter of law, that the warning is adequate based on the FDA's approval. N.J.S.A. § 2A:58C-A; Mariconda Opp. 9.) Plaintiff can only overcome this "super-presumption" using the Perez or McDarby exceptions.

Plaintiff argues that she satisfies both the Perez and McDarby exceptions to overcome the presumption. Plaintiff alleges that Perez is satisfied because Defendants failed to turn over a 2005 Clinical Expert Report ("CER") study and downplayed the VTE risk associated with NuvaRing®. (See Mariconda Opp. 19 & Leonard Cert. Ex. L) Plaintiff asserts that the FDA's flawed regulatory process and limited resources put the responsibility on the manufacturer of drugs that are either seeking approval or have been approved to provide full and accurate information. (Mariconda Opp. 18 (citing Wyeth, 555 U.S. at 578-79, 129 S. Ct. 1187).) Plaintiff asserts that under Wyeth, upon discovery

of increased risks, Defendants should have updated their label or, at the very least, contacted health professionals. (Mariconda Opp. 18.) Plaintiff also argues that the presumption is rebutted based on McDarby, because Defendants acted in self-economic interest in concealing safety concerns based on VTE risks and misleading prescribing physicians regarding the level of hormones being released, or "bursts." (See Mariconda Opp. 21.) To support these contentions, Plaintiff has provided the Court with the report of her expert, Dr. Parisian, stating same. (See Parisian Report, Leonard Cert. Ex JJ.)

Defendants contend that they disclosed all they were required to by the FDA, including post-approval VTE studies. For example, Defendants note that they were not required to disclose the 2005 CER to the FDA; under 21 C.F.R. § 314.80(c)(2)(i), they were only required to submit an annual Periodic Adverse Drug Experience Report (PADER). Defendants submitted such in late 2006, which included 4 pages about the drug's VTE risks. (Defs.' Rep. 5, Geist Cert. Ex. 40.) Defendants also argue that they had no knowledge of an increased risk, because they deny that such an increased risk exists.

Specifically with respect to Plaintiff Mariconda, Defendants reply that, the decedent's cause of death was "cardiac arrest secondary to her stroke" (Mariconda Opp. 5) and therefore (without conceding that it failed to disclose anything), any failure to notify the FDA of increased VTE risks would not affect the adequacy of the warning with respect to the risk of stroke – Ms. Mariconda's cause of death.

The Court finds that Plaintiff was not able to meet her burden to show that a material issue of fact exists. No issues of fact exist that would materially affect the outcome of the decision, as Plaintiff has not put forth any "evidence from which a

reasonable juror could return a verdict in its favor." Anderson, supra, 477 U.S. at 256, 106 S. Ct. 2505. All of Plaintiff's arguments regarding post-approval disputes, in attempt to rebut the "super-presumption" using the Perez or McDarby exceptions, are based on VTE injuries, which are unrelated to Ms. Mariconda's cause of death. Therefore, Plaintiff has not been able to raise any material issues of fact to overcome summary judgment, and summary judgment is GRANTED on this issue.

V. Express Warranty

A. Legal Standard

For the applicable case law, see supra Bozicev, Parts II(A).

B. Express Warranties

Plaintiff's opposition did not raise any specific express warranties, nor did it refute Defendants' argument regarding same. Therefore, summary judgment is GRANTED with respect to Plaintiff's claim for breach of express warranty.

VI. Causation

A. Legal Standard

For the applicable case law, see supra Bozicev, Parts III(A).

B. Causation

In this case, Plaintiff Mariconda is not entitled to the heeding presumption because she has not demonstrated, at minimum, the "basic fact" upon which the "presumed fact" is based. See N.J.R.E. 301 ("[A] presumption discharges the burden of producing evidence as to a fact (the presumed fact) when another fact (the basic fact) has

been established . . . . [T]he presumed fact shall be deemed established if the basic fact is found or otherwise established."). In other words, Plaintiff has not raised a material issue of fact as to the (in)adequacy of the warning regarding Ms. Mariconda's cause of death, which Plaintiff concedes was a stroke. See Mariconda Opp. 5. Because the inadequacy of the warning is the "basic fact" upon which the heeding presumption, or "presumed fact," is based, Plaintiff is not entitled to the heeding presumption.

Even if Plaintiff's counsel could overcome summary judgment with respect to each physician's decision to prescribe the medication, Plaintiff has not been able to provide evidence that the injury would have been prevented if Plaintiff had used another birth control method. Plaintiff essentially argues that Ms. Mariconda was only diagnosed with "classic migraine" – never migraine with aura – and, because classic migraine is not a contraindication, she was prescribed and used NuvaRing®, suffering a stroke as a result thereof. This Court finds that Ms. Mariconda, even suffering from "classic migraines," should have consulted her doctor as advised by the label. See supra "Background," Part IV(B) ("In addition, talk to your healthcare provider about using NuvaRing® if you have any of the following conditions. Women with any of these conditions should be checked often by their doctor or healthcare provider if they choose NuvaRing®: . . . Migraine or other headaches or epilepsy . . . ."). Thus, Plaintiff's argument fails and summary judgment is GRANTED for the reasons set forth above and as stated supra, "Mariconda," Part I(C).

BARROW

IV. Adequacy

A. Colorado Legal Standard

The plaintiff has the burden of proving that the manufacturer gave an inadequate warning of the danger that caused the injury. O'Connell v. Biomet, Inc., 250 P.3d 1278, 1281 (Colo. App. 2010) (citing Peterson v. Parke Davis & Co., 705 P.2d 1001, 1004 (Colo. App. 1985)). Plaintiff would like this court to find that Colorado does not apply the learned intermediary doctrine to prescription drug cases, and requires that "a manufacturer has a duty to warn all foreseeable users of dangers inherent in its products." Barrow Opp. 10 (citing Hiigel v. General Motors Corp., 190 Colo. 57, 63, 544 P.2d 983 (1975) (finding a manufacturer of a motor home liable) (overturned on other grounds)). Plaintiff went on to define a manufacturer's duty by citing cases from other jurisdictions, and spoke generally of the duty owned by a product manufacturer.

Despite Plaintiff's analysis of Colorado law, a prescription drug manufacturer in Colorado satisfies this duty under the learned intermediary doctrine. O'Connell, supra, 250 P.3d at 1281-82. Although the Court is aware that, as of the time of Plaintiff's injury, Colorado appellate courts had not expressly adopted the learned intermediary doctrine, several Colorado courts had found no manufacturer liability based on the manufacturer having provided warnings of the risks to physicians. See Caveny v. CIBA-GEIGY Corp., 818 F. Supp. 1404, 1406 (D. Colo. 1992); Peterson, supra, 705 P.2d 1001. Based on these decisions, a Colorado court of appeals in 2010 found that a trial court did not err by applying the learned intermediary rule. O'Connell, supra, 250 P.3d at 1281-82. Though this decision was not in effect at the time of the Plaintiff's injuries, it is based on those same cases that this Court finds that the learned intermediary doctrine applies in Colorado.

Under the learned intermediary doctrine, defendant need only have adequately warned the prescribing doctor in order to be discharged of its duty. In order for Plaintiff to prove that Defendant failed to provide adequate warning, Plaintiff must show "that reasonable instructions or warnings regarding foreseeable risks . . . [were] not provided to [prescribing] . . . providers who are in a position to reduce the risks of harm in accordance with the warnings or instructions." Defs.' Mot. 15; O'Connell, supra, 250 P.3d at 1281; Caveny, supra, 818 F. Supp. at 1406. "A warning is adequate when it explains to the physician the risk which the plaintiff is asserting to be associated with the drug and which caused the death." Caveny, supra, 818 F. Supp. at 1406.

B. Parties' Arguments

Defendants here assert that, under the learned intermediary doctrine, the Plaintiff's failure to warn claim should be dismissed because the Defendants provided an adequate warning to the physician. Dr. Meeuwsen, Plaintiff's gynecologist and prescribing physician, testified that the NuvaRing label clearly and adequately warned of the dangers associated with it. In addition, Plaintiff's only case-specific expert, Dr. Nitzberg, agreed that the NuvaRing label stated same.

Plaintiff opposes Defendants' motion on the grounds that: (1) genuine issues of material fact exist, precluding summary judgment; and (2) warning was inadequate based on Defendants' duty to warn, the foreseeability of the injury, Defendants' knowledge of the risks, and Defendants' intentional concealment.[39]

C. Adequacy

[39] Plaintiff also asserted that the learned intermediary doctrine is not applicable under Colorado law to bar manufacturer's liability, however this argument was rejected supra, "Barrow," Part I(A).

Plaintiff Barrow must show "that reasonable instructions or warnings regarding foreseeable risks [i.e. VTEs] . . . [were] not provided to [prescribing] . . . providers . . . ." O'Connell, supra, 250 P.3d at 1281. At the time product was initially marketed, Plaintiff has shown, based on internal communications at Organon, that a material issue of fact exists as to whether risks were foreseeable at that point based on the first VTE, and therefore whether a reasonable warning was provided to the physicians under the learned intermediary doctrine. Alternatively, at minimum, by the time of Plaintiff Barrow's injury, there was a material issue of fact as to whether the risk was "unknown;" a total of four VTEs had been discovered, which, despite Defendants' contentions, could reasonably be found by a jury to be a significant number, indicative of an increased risk. The package label states, "In general, these studies [comparing third and second generation CHCs] 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," and therefore a jury could find that even two VTEs can be a significant number indicating a risk. See Geist Cert., Ex. 2, supra, note 6. See also Hawkinson v. A.H. Robins Co., 595 F. Supp. 1290, 1309 (D. Colo. 1984) ("[Physicians] could not reasonably be expected to assume that such a reputable company would be promoting the use of a medical device which should have been considered to be in an experimental state."). Accordingly, the Court finds that Plaintiff Barrow has met her summary judgment burden by demonstrating that a material issue of fact exists, and summary judgment is DENIED on this issue.

V. Express Warranty

A. Legal Standard

In Colorado, claims for breach of express warranty are preempted by FDA regulations. Parker v. Stryker Corp., 584 F. Supp. 2d 1298 (D.C. Colo. 2008). However, a fraud claim requires proof of a specific fraudulent misrepresentation or nondisclosure by the defendant on which the plaintiff relied. Squires v. Goodwin, 829 F. Supp. 2d 1062, 1075; Cent. Masonry Corp, 10-cv-0111-LTB-BNB, 2012 WL 850703, at *6. "Implicit within these elements are the requirements that the claimant demonstrate that it relied on the misrepresentation and that its reliance was justified under the circumstances." Squires, supra, 829 F. Supp. 2d at 1075 (citing Loveland Essential Group, LLC v. Grommon Farms, Inc., 251 P.3d 1109, 1116 (Colo. App. 2010)).

B. Express Warranties

Plaintiff's opposition did not raise any specific express warranties, nor did it refute Defendants' argument regarding same. Therefore, summary judgment is GRANTED with respect to Plaintiff's claim for breach of express warranty.

VI. Causation

A. Legal Standards

In Colorado, the plaintiff must prove causation; in other words, that the "defendant committed an act which caused an injury to that plaintiff." In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1223 (D. Colo. 1998). Accord June v. Union Carbide Corp., 577 F.3d 1234, 1238-39 (10th Cir. 2009); MDC/Wood, Inc. v. Mortimer, 866 P.2d 1380, 1382 (Colo. 1994); Armentrout v. FMC Corporation, 842 P.2d 175, 182 (Colo. 1992); Farmers Truck Ins. v. MagneTek, Inc., No. 00-RB-2218, 2002 US Dist.

Lexis 27262, at *9. Plaintiff must show that the inadequate warning caused plaintiff's injury. See Bartholic v. Scripto-Tokai Corp., 140 F. Supp. 2d 1098, 1115-17 (D. Colo. 2000). Further, plaintiff must show "but-for" causation, which, in most cases, cannot be demonstrated if the injury "would have occurred notwithstanding the [defendant's] conduct." June, supra, 577 F.3d at 1240. No heeding presumption exists to temporarily shift the burden to Defendants, therefore Plaintiff has the burden to prove proximate causation, or, during summary judgment, to raise an issue of fact as to same.

B. Causation

Plaintiff Barrow has not provided any evidence from which the Court could find that an issue of fact exists as to whether the allegedly inadequate label caused Plaintiff's injury. For example, Plaintiff has not shown that the additional warnings she believes are required would have prevented her injuries. To the contrary, Plaintiff's physician, Dr. Meeuwsen, was aware of the risk and prescribed NuvaRing® to Plaintiff regardless, (Meeuwsen Dep., Barrow Reply, Geist Cert. Ex. 30 at 20:24-21:21; 25:20-26:11), continues to prescribe NuvaRing®, (id. at 9:17-19), and would not have (or at the very least, "did not know" whether he would have) changed his decision to prescribe based on Plaintiff's questions at the deposition. (Id. at 87:7-18; 83:6-8; 73:20-74:7.) This evidence does not sufficiently raise any issues of fact as to whether the physician would have changed his decision to prescribe NuvaRing®, therefore Plaintiff has not established issues of material fact.

Even if the Court were to find Plaintiff was correct, namely, that Colorado applies a heeding presumption, Defendants have rebutted the presumption thereby making the presumption inapplicable. Dr. Meeuwsen testified that he was aware of the risks when he

prescribed NuvaRing® to Plaintiff Barrow, and moreover, continues to prescribe it. (Meeuwsen Dep. at 20:24-21:21; 25:20-26:11; 30:2-13; 9:17-19.) Plaintiff would consequently have the burden to prove proximate cause, which the Court already stated she has not done.

Moreover, Plaintiff would not succeed based on the theory that the injury would have been prevented had she used another birth control method. Plaintiff has not defeated summary judgment because she did not address this point in her Opposition. Consequently, Plaintiff has not raised any issues of material fact on this issue, and summary judgment is therefore GRANTED.

FIELDS

IV. Adequacy

A. California Legal Standard

In order to provide an "adequate" warning, a California manufacturer has a duty to warn of "dangers . . . about which it knew or should have known." Dash v. Roche Lab., No. 94-55814, 1996 U.S. App. LEXIS 983, at *3-4 (9th Cir. 1996) (citing Brown v. Superior Court, 44 Cal. 3d 1049, 1058-60, 751 P.2d 470 (1988)).

California applies the learned intermediary doctrine, therefore a manufacturer satisfies its duty where it provides an adequate warning of the risk to the prescribing physician, not the patient, at the time of manufacturing or distribution. Id.; Valentine v. Baxter Healthcare Corp., 68 Cal. App. 4th 1467 (1999) ("In the case of prescription drugs and implants, the physician stands in the shoes of the 'ordinary user' because it is through the physician that a patient learns of the properties and proper use of the drug or implant.

Thus, the duty to warn in these cases runs to the physician, not the patient." (citing Carlin v. Superior Court, 13 Cal.4th 1104, 1116, 1118, 920 P.2d 1347 (1996))); Carmichael v. Reitz, 17 Cal. App. 3d 958, 989 (1971) ("It is the general rule that the duty of adequate warning by the manufacturer of an ethical drug is discharged by its warning of hazards to doctors who may in the exercise of their medical judgments decide to use the drug as a part of their chemotherapy."); Huntman v. Danek Medical, Inc., No. 97-2155-IEG (RBB), 1998 U.S. Dist. LEXIS 13431 (S.D. Cal. Jul. 24, 1998) (applying the intermediary doctrine to fraud and breach of warranty claims arising from prescription drug or device manufacturer's alleged failure to properly warn of product risks). Accord Hill v. Novartis Pharms. Corp, No. 1:06-cv-00939-AWI-DLB, 2012 U.S. Dist. LEXIS 170650, at *13 (E.D. Cal. 2012); Dash, supra, No. 94-55814, 1996 U.S. App. LEXIS 983; Temple v. Velcro USA, Inc., 148 Cal. App. 3d 1090, 1095 (1983); Hayes-Jones v. Ortho-McNeil Pharm., Inc., supra, No. MID-L-3416-10, 2012 WL 3164558, at *5 (New Jersey case applying Virginia law).

Notably, "there is no duty to warn the patient" and cases defining the learned intermediary rule specifically state that the manufacturer's duty is discharged upon providing adequate warnings to doctors. Carmichael, supra, 17 Cal. App. 3d at 989. However, California case law does not provide this Court with any guidance as to a manufacturer's duty where the drug is being provided to patients through a nurse practitioner. Regarding the learned intermediary doctrine generally, California courts note:

> The rationale of the foregoing rule is: "(1) The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the

> manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient."
>
> [Carmichael, 17 Cal. App. 3d at 989 (quoting Rheingold, Paul D., Products Liability -- The Ethical Drug Manufacturer's Liability, 18 Rutgers L. Rev. 947, 987 (1964)).]

Other courts have begun to broaden the class of healthcare providers considered to be "learned intermediaries," including nurse practitioners. Stevens v. Novartis Pharms. Corp., 358 Mont. 474, 492-93 & n.7; 247 P.3d 244 (2010). Courts note that the traditional doctor-patient interaction is no longer present, with nurses administering or providing medication to patients. Id. (citing Mazur v. Merck & Co., 964 F.2d 1348, 1356 (3d Cir. 1992) (finding that the doctrine did not apply to school nurses, but could apply to nonprescribing physicians, physicians' assistants, and nurses acting in an area of special expertise); Walker v. Merck & Co., 648 F. Supp. 931, 934-35 (M.D. Ga. 1986), aff'd, 831 F.2d 1069 (11th Cir. 1987) (finding nurse practitioners to fall within the learned intermediary doctrine); Rohrbough v. Wyeth Labs., 719 F. Supp. 470, 478 (N.D. W. Va. 1989) (finding that registered nurses who administered vaccines are considered learned intermediaries); Wyeth-Ayerst Lab Co. v. Medrano, 28 S.W.3d 87, 92-94 (Tex. Ct. App. 2000) (holding that the doctrine applies to advanced practice nurses who prescribe medication and treat patients without the supervision of a physician); Whitley v. Cubberly, 24 N.C. App. 204, 207, 210 S.E.2d 289 (N.C. 1974) (requiring that warnings be issued to all members within the "medical profession" who use the drug).

Based on this modern trend, and California's rationale that the medical professional is in a better position to weigh the risks and benefits medication, this Court finds that, under the learned intermediary doctrine in California, a nurse practitioner is within the scope of a "learned intermediary." Therefore, once the manufacturer has adequately warned the nurse practitioner of the prescription drug's risks, the manufacturer's duty is discharged; the manufacturer has no duty to warn the patient.

Finally, California follows a "heeding presumption," meaning "[i]f an adequate warning is received by the person to whom the law requires that the warning be given, the manufacturer may assume that it will be read and heeded." Carmichael, supra, 17 Cal. App. 3d at 991.

B. Parties' Arguments

Defendants argue that Plaintiff's failure to warn claim will fail under California's learned intermediary doctrine because NuvaRing®'s label, directed at physicians, clearly and adequately states the risk of VTE. Further, Defendants assert that the risk of VTE associated with the use of all CHCs has been widely known and accepted in the medical community. Plaintiff's prescribing doctor, Nurse Practitioner Marini, understood the warnings on the label and felt they were clear and adequate. Similarly, Plaintiff's causation expert, Dr. Nitzberg, testified, "NuvaRing's warning regarding pulmonary embolism is clear and understandable." (Defs.' Mot. 19.)

Plaintiff argues that Defendants have not adequately conducted necessary post-marketing studies and have failed to monitor the drug in the market. Plaintiff also argues that the label did not provide a full and accurate report of NuvaRing®'s risks consistent

with known risks, and that Defendants further should have updated its label to notify physicians of increased risks.

C. Adequacy

The Court finds that Nurse Practitioner Marini was given permission to provide NuvaRing® to females seeking contraceptives, therefore making her the professional medical intermediary between the Defendants and the patient, and discharging Defendants' duty upon an adequate warning. See Stevens, supra, 358 Mont. at 492-93 & n.7 (citing cases). Defendants have no duty to warn Plaintiff directly, and Marini, not Defendants, was in the best position to weigh the risks and benefits of providing NuvaRing® to Plaintiff.[40]

Defendants' liability to Plaintiff Fields is therefore based on whether the warning to Marini was adequate, meaning that Defendants warned of "dangers . . . about which it knew or should have known." Dash, supra, No. 94-55814, 1996 U.S. App. LEXIS 983, at *3-4 (citing Brown, supra, 44 Cal. 3d 1049, 1058-60, 751 P.2d 470).[41] However, just as in Barrow, Plaintiff has raised sufficient issues of material fact, particularly here where the standard is "knew or should have known." As of the time the product was marketed, and certainly as of the time of Plaintiff Fields' injury, Plaintiff has provided evidence to the Court that it is possible that Defendants knew or should have known of some increased risk. See supra "Decision," Part I(A). Accordingly, the Court finds that

[40] Defendants argued that Plaintiff's failure to warn claim will fail under California's learned intermediary doctrine because NuvaRing®'s label, directed at physicians, clearly and adequately states the risk of VTE. Further, the Defendants assert that the risk of VTE associated with the use of all CHCs has been widely known and accepted in the medical community. Plaintiff's prescribing doctor, Nurse Practitioner Marini, understood the warnings on the label and felt they were clear and adequate. Similarly, Plaintiff's causation expert, Dr. Nitzberg, testified, "NuvaRing's warning regarding pulmonary embolism is clear and understandable." (Defs.' Mot. 19.) The Court rejects this argument for the reasons stated above.

[41] Assuming the warning was adequate, Defendants are permitted to presume that the medical professional would heed such warnings. Defendant "had a duty to warn of dangers . . . about which it knew or should have known." Dash, supra, 1996 U.S. App. LEXIS 983, at *3.

Plaintiff has demonstrated that material issues of fact exist, because the parties dispute whether the risk based on the four VTEs was known or knowable, the precise standard for adequacy in California. Therefore, summary judgment is DENIED on this issue.

V. Express Warranty

A. Legal Standard

In California, express warranties of prescription drugs would likely be preempted by the FDA regulations. A California appellate court distinguished highly regulated class III medical devices from respondents' implants which were exempt from FDA requirements, and found that FDA regulation justified preemption in the case of highly regulated medical devices, but not those which were not typically subject to federal regulation. Evraets v. Intermedics Intraocular, Inc., 29 Cal. App. 4th 779, 789 (1994) (citing King v. Collagen Corp., 983 F.2d 1130, 1135 (1st Cir. 1993)) (noting that plaintiff's express warranty claim in King was preempted because "the FDA 'retains rigid control over the entirety of the labeling and packaging of class III products, largely displacing the ability of manufacturers to make additional claims' "). Consequently, here, where prescription drugs are highly regulated by the FDA, Plaintiff's express warranty claims would likely be preempted under California law.

B. Express Warranties

Plaintiff's opposition did not raise any specific express warranties, nor did it refute Defendants' argument regarding same. Therefore, summary judgment is GRANTED with respect to Plaintiff's claim for breach of express warranty.

VI. Causation

A. Legal Standard

In California, like other states, causation is an element of plaintiff's claim. Nelson v. Superior Ct., 144 Cal. App. 4th 689, 695 (2006); Tietsworth v. Sears, 720 F. Supp. 2d 1123, 1140 (N.D. Cal. 2010); Motus v. Pfizer, Inc., 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001). Plaintiff must show that defendant's conduct was a substantial factor in bringing about her injuries. Rutherford v. Owens-Illinois, Inc., 16 Cal. 4th 953, 968-69, 941 P.2d 1203 (1997). In California, the substantial factor test "generally produces the same results as does the 'but for' rule of causation," however, the substantial factor test "subsumes the 'but for' test while reaching beyond it to satisfactorily address other situations, such as those involving independent or concurrent causes in fact." Id. at 969. The "but for" test requires a showing that that the "injury would not have occurred 'but for' [defendant's] conduct." Id. Thus, California requires a showing of but for causation, but also requires a showing of substantial causation where other factors may have caused the injury. Id. ("Undue emphasis should not be placed on the term 'substantial.' For example, the substantial factor standard, formulated to aid plaintiffs as a broader rule of causality than the 'but for' test, has been invoked by defendants whose conduct is clearly a 'but for' cause of plaintiff's injury but is nevertheless urged as an insubstantial contribution to the injury.")

Although causation is usually a question of fact for the jury, Nichols v. Keller, 15 Cal. App. 4th 1672, 1687 (1993), causation becomes a question of law where no issues of fact exist and only one conclusion may be drawn, Lombardo v. Huysentruyt, 91 Cal. App. 4th 656, 666 (2001).

B. Causation

Plaintiff only addressed in her Opposition the second aspect of causation, and did not discuss the physician's decision to prescribe NuvaRing®. Regarding that second aspect – i.e. likelihood of injury if she used a different drug – Plaintiff argues that she need only show that NuvaRing® was a substantial cause of her injury rather than a "but-for" cause, or cause in fact, as Defendants argue. However, Plaintiff's argument collapses on itself; Plaintiff states, "It has generally been recognized that the 'but for' test contained should not be used when two 'causes concur to bring about an event and either one of them operating alone could have been sufficient to cause the result.' " (Fields Opp. 27 (quoting Thomsen v. Rexall Drug & Chemical Co., 235 Cal. App. 2d 775, 783 (1965)). Plaintiff continues by relying on Rutherford, supra, and Logacz v. Limansky, 71 Cal. App. 4th 1149 (1999), which, in both cases, involve concurrent causes in which the courts attempted to determine which of the events (that actually took place) caused plaintiffs' injuries. These cases are inapplicable because Plaintiff's use of an alternative hormonal contraceptive was not a concurrent cause; in other words, it was not one of multiple "causes [that] concur[red] to bring about an event," barring use of the but-for analysis. See Fields Opp. 27 (quoting Thomsen, supra, 235 Cal. App. 2d at 783). Plaintiff did not use NuvaRing® and another form of CHC birth control, either of which could have caused the injury. Therefore, in applying the but-for test, the Court notes that Plaintiff did not present any evidence to show a material issue of fact as to whether Plaintiff would have suffered "but for" using NuvaRing® – i.e. if she had not taken NuvaRing® and instead taken another CHC.

For the reasons set forth above, summary judgment is GRANTED.

IV. Adequacy

A. New York Legal Standard

New York's highest court, the Court of Appeals, has adopted the learned intermediary doctrine, also referred to in New York as the "informed intermediary doctrine." Martin v. Hacker, 83 N.Y.2d 1, 9, 628 N.E.2d 1308 (1993); accord Dibartolo v. Abbott Labs., 12 Civ. 900 (NRB), 2012 U.S. Dist. LEXIS 182326, at *17-18 (S.D.N.Y. 2012) (referring to New York's rule as both the "informed" and the "learned" intermediary doctrine); Browning v. Wyeth, 38 A.D.3d 1177, 1178 (App. Div. 2007). As such, prescription drug warnings are intended for, and owned only to, the doctor, and it is the doctor's duty as an "informed intermediary" to balance the risks and properly prescribe medication to the patient. Martin, supra, 83 N.Y.2d at 9, 628 N.E.2d 1308.

To satisfy the manufacturer's duty and not be considered defective, the prescription drug must be provided to the physician with "adequate" warnings. Id. at 8; see Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 61, aff'd, 52 N.Y.2d 768 (requiring that prescription drugs be accompanied by "proper directions and warning" (quoting Restatement (Second) of Torts § 402 A, comment k)). "The manufacturer's duty is to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known, to exist." Id. at 8.

New York acknowledges that one way manufacturers attempt to satisfy this duty is through a formal warning included with the package insert. Id. at 10. "Inserts must be

written in accordance with the Food and Drug Administration's recommendation for the proper labeling of prescription drugs . . . ." Id. However, for the insert to be held adequate as a matter of law, it must "provide specific detailed information on the risks of the drug." Id. (citing Wolfgruber, supra, 72 A.D.2d at 61-62; Restatement (Second) of Torts § 402 A, comment k). Specifically, "the factors to be considered in resolving this question include whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk involved," as read and understood by a doctor. Id.; Browning, supra, 38 A.D.3d at 1177-78. Where a label ambiguously warns of or "obscures the nature of the risk," a material issue of fact exists as to adequacy. Forte v. Weiner, 200 A.D.2d 421, 423 (N.Y. 1994) (finding that a material issue of fact exists where defendants' oral contraceptive label ambiguously warned of the risks alleged by stating that the relationship between the drug and various reported risks was "not known").

B. Parties' Arguments

Defendants assert that the warning to Plaintiff's prescribing doctor, Dr. Gandall, was adequate because the risk of VTE was adequately and expressly stated, and the warning was clear and understandable as confirmed by Dr. Gandall. (Defs.' Mot. 11, 15, 18 (citing Gandell Dep., Ex. 30)). In addition, Defendants argue that Plaintiff has not met her summary judgment burden because no expert has stated that the label was inadequate.

Plaintiff alleges that Defendants' warning to Plaintiff's physician was inadequate, particularly by the time of Plaintiff's injury, because the information was no longer accurate. In particular, the Plaintiff alleges that the graph upon which Dr. Gandall relied was no longer accurate once Defendants discovered the additional VTEs. Plaintiff asserts

that Defendants had an obligation to update both the FDA and prescribing doctors with more recent information, such as the additional VTEs, because the insert, which stated that the risk was "unknown" was no longer accurate based on the newly discovered information.

C. Adequacy

The Court finds that Plaintiff Wilson-Johnson has shown a material issue of fact with respect to adequacy. For the insert to be held adequate as a matter of law, it must "provide specific detailed information on the risks of the drug." Martin, supra, 83 N.Y.2d at 10, 628 N.E.2d 1308. "[T]he factors to be considered in resolving this question include whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk involved," as read and understood by a doctor. Id. Although Defendants argue that the label was adequate because Plaintiff's physician stated that the warning was adequate, the Court finds that Plaintiff has raised material issues of fact as to the intensity of the risk and the accuracy of the label (i.e. inclusion of all relevant risks) such that Plaintiff's physician could only opine as to whether the label was adequate on its face. Additionally, Plaintiff has again submitted the report of Dr. Parisian (Wilson-Johnson, Opp., Shkolnik Cert. Ex. H), which Defendants dispute, however, it is not for the Court at this juncture to determine the credibility of the witnesses. Rubanick v. Witco Chemical Corp., 242 N.J. Super. 36, 48, 576 A.2d 4 (App. Div. 1990) ("It is for the jury to determine the credibility, weight and probative value of the expert's testimony . . . ."); see supra note 17 (discussing pending Kemp motions). Accordingly, Plaintiff has raised material issues of fact as to whether the label on which he relied in prescribing the drug was accurate. See Forte, supra, 200 A.D.2d at 423; Smith v. Johnson & Johnson Co., 6

Misc. 3d 1001(A) (N.Y. 2004) ("Plaintiff's submission of an expert opinion as to the inadequacy of defendants' warnings is sufficient to raise an issue of fact precluding summary judgment where the alleged deficiency in the warnings is related to the condition which is alleged to have caused the [injury]."). For the reasons stated above, summary judgment is DENIED on this issue.

V. Express Warranty

A. Legal Standard

In New York, an express warranty claim requires " 'affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase' and that the warranty was relied upon". Schimmenti v. Ply Gem Indus., 156 A.D.2d 658, 659 (N.Y. App. Div. 1989) (quoting Friedman v. Medtronic, Inc., 42 A.D.2d 185, 188 (N.Y. App. Div. 1973)) (finding that statements made by a company's president did not represent an express warranty because they did not form the basis of the bargain; plaintiff had already purchased the product prior to receiving president's letter). See also UCC § 2-313(1)(a); Wojcik v. Empire Forklift, Inc., 14 A.D.3d 63, 65-66 (N.Y. App. Div. 2004) (finding that plaintiffs did not meet their summary judgment burden because they could not show that the alleged express warranty formed the basis of the bargain).

B. Express Warranties

Plaintiff contends that she relied on her physician in using NuvaRing®, but also read the patient insert before using the product. (Wilson-Johnson Opp. 34 & Ex. A.) However, during her deposition, she could not recall any specific "affirmations of fact or promise" on which she relied, which Defendants argue precludes her claim for breach of

express warranty. The Court, based on New York's standard requiring the warranty form a basis for bargain, finds that Plaintiff Wilson-Johnson has not met her summary judgment burden with respect to express warranties. She relied on her physician in choosing NuvaRing®, and merely read the label after making his decision; any alleged warranties within the label did not "induce[] [Plaintiff] to purchase the [product]". Schimmenti, supra, 156 A.D.2d at 659; see Wojcik, supra, 14 A.D.3d at 65-66. Accordingly, summary judgment is GRANTED on this issue.

VI. Causation

A. Legal Standard

Plaintiff must prove "that failure to warn adequately of the potential adverse side effects of the use of the product was a proximate cause of the injury." Banker v. Hoehn, 278 A.D.2d 720, 722 (N.Y. App. Div. 2000) (discussing causation in the context of medical devices); accord Mulhall v. Hannafin, 45 A.D.3d 55, 58 (N.Y. App. Div. 2007) (citing Glucksman v. Halsey Drug Co., 160 A.D.2d 305, 307, 553 N.Y.S. 2d 724 (1990)). In showing proximate causation, "[p]laintiffs have the burden to show that had a different warning been given, this patient would not have used the product that caused her injury." Mulhall, supra, 45 A.D.3d at 60. Because the manufacturer's duty to warn is only owed to the medical community and not the patient,[42] a plaintiff meets this burden by showing that the patient would not have used the product because the learned intermediary "would have departed from her normal practice" had the warning been different. Id. at 61

[42] In Mulhall, the court noted that, even though New York law was clear that a duty to warn was only owed to the doctor, plaintiff failed to satisfy causation under traditional causation standards where a duty to warn is owed directly to the plaintiff. Mulhall, supra, 45 A.D.3d at 61 (citing Sosna v. Am. Home Prods., 298 A.D.2d 158 (2002) (finding plaintiff did not prove proximate causation where he did not read product label)).

(finding that plaintiffs failed to show causation because they failed to provide evidence that plaintiff's doctor "might have used another product under different circumstances").

B. Causation

Plaintiff Wilson-Johnson has not provided evidence sufficient to show a material issue of fact regarding proximate causation. Plaintiff's Opposition provides only argument, no evidence, that Plaintiff's doctor, Dr. Gendel, would have changed his decision to prescribe NuvaRing® or "might have used another product under different circumstances." Mulhall, supra, 45 A.D.3d at 60. Furthermore, even under a basic proximate causation standard, Plaintiff Wilson-Johnson did not state that she would have heeded the warning had it been different; in fact, she states, "I can't say whether or not I would or wouldn't [have used NuvaRing®]." Wilson-Johnson Dep., Wilson-Johnson Opp., Shkolnik Cert. Ex. A at 93:9-12. Accordingly, Plaintiff has not raised any material issues of fact as to causation.

Even if Plaintiff's counsel could overcome summary judgment with respect to physician's decision to prescribe the NuvaRing®, Plaintiff has not been able to provide evidence that the injury would have been prevented if Plaintiff had used another birth control method. Plaintiff Wilson-Johnson argues that she has raised a material issue of fact as to this aspect of causation because, despite being subject to VTE risk factors and previously using other CHCs, she did not suffer from a VTE until she began using NuvaRing®. In addition, Plaintiff's expert, Dr. Jaffe, stated in his expert report that Plaintiff's injury was likely substantially caused by her use of NuvaRing®. (Wilson-Johnson Opp. 38.) However, Dr. Jaffe also testified at his deposition that he would have attributed Plaintiff's injury to whatever CHC, such as an oral CHC, she was taking at the

time of her VTE. (Jaffe Dep., Wilson-Johnson Mot., Geist Cert. Ex. 34 at 93:9-14.) Therefore, Plaintiff's reliance on Dr. Jaffe's expert report is insufficient to establish a genuine issue of material fact, because it does not make it more likely that Plaintiff only suffered a VTE because she was taking NuvaRing®.[43]

Accordingly, summary judgment is GRANTED.

NAMACK

IV. Adequacy

A. West Virginia Legal Standard

West Virginia has rejected the learned intermediary doctrine; therefore a manufacturer has a duty to warn both the doctor and the patient. State ex rel. Johnson & Johnson v. Karl, 220 W.Va. 463, 478, 647 S.E.2d 899 (2007). Manufacturers of prescription drugs are subject to the same standard of care as other manufacturers. Id. The Supreme Court of Appeals has set forth the following for determining whether a product is defective, either through design, structure, or use "arising out of the lack of, or the adequacy of, warnings instructions, and labels":

> In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use. The standard of reasonable safeness is determined not by the particular manufacturer, but by what a reasonably prudent manufacturer's standards should have been at the time the product was made.

[43] Further, Plaintiff's reliance on the theory that NuvaRing® must have caused the VTE based on when it occurred – i.e. after using other birth control methods and despite suffering from risk factors – is rebutted by case law. See Saari v. Merck & Co., 961 F. Supp. 387, 396 (N.D.N.Y. 1997); In re Agent Orange Prod. Liab. Litig., 373 F. Supp. 2d 7, 32 (E.D.N.Y. 2005).

[Wilkinson v. Duff, 212 W.Va. 725, 730, 575 S.E.2d 335 (2002) (quoting Morningstar v. Black & Decker Mfg. Co., 162 W.Va. 857, 888, 253 S.E.2d 666 (1979)).]

In failure to warn cases, the court bases its determination that the product is defective on the manufacturer's failure to adequately warn of the product's dangers, rather than finding that the product is defective simply because it has risks. Wilkinson, supra, 212 W.Va. at 730, 575 S.E.2d 335 (citing Morningstar, supra, 162 W.Va. at 888, 253 S.E.2d 666; Ilosky v. Michelin Tire Corp., 172 W.Va. 435, 307 S.E.2d 603 (1983)). In determining whether the manufacturer has a duty to warn, "the fundamental inquiry is whether it was reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning." Id.

B. Parties' Arguments

Defendants interpret West Virginia's law to merely require that it warn of the risk of VTEs. Thus, Defendants assert that Plaintiff's failure to warn claim fails because NuvaRing®'s label was FDA approved and it provided an adequate, express warning of the VTE risk associated with it. Defendants assert that the burden of proving adequate warning is lower if the prescribing doctor was aware of the risks associated with the drug. See Pumphrey v. C.R. Bard, Inc., 906 F. Supp. 334, 337 (N.D. W. Va. 1995). Here, Defendants assert the testimony of the Plaintiff's physician and expert supports such an argument because Plaintiff's gynecologist, Dr. Stoehr, testified that she was aware of the risk of blood clots associated with NuvaRing® before she prescribed it to the Plaintiff. Dr. Stoehr also testified she relayed information regarding the risks to the Plaintiff and Plaintiff understood those risks before NuvaRing® was prescribed to her. Finally, "Plaintiff's specific causation expert Dr. Scher has likewise conceded that NuvaRing®'s

warning language regarding pulmonary embolism is clear and understandable and that the risk is associated with all the combination hormonal contraceptives." (Defs.' Mot. 20 (citing Scher Dep., Geist Cert. Ex. 35).)

Plaintiff argues that Defendants' labels, both to physician and patient, are "equivocal, ambiguous, provide[] the patient/consumer with a diluted variation of the risks associated with the drug and contain warnings of a general nature which do not give the patient/consumer a sufficient understanding of the risks inherent in the product use." (Namack Opp. 13.) In particular, Plaintiff asserts that, although the label expressly states the risk of VTEs, Defendants weaken and dilute the warning by stating that NuvaRing® "may" have the same risk as oral contraceptives, that the risk is "unknown," and that "no epidemiological data [is] available to determine whether safety and efficacy within the vaginal route of administration of [CHCs] would be different than the oral route." (Namack Opp. 13-14.) Finally, Plaintiff asserts that by the time of her injury, both physicians and patients, including Plaintiff, were entitled to updated information in Defendants' possession, rendering the label inaccurate. (Namack Opp. 14.)

C. Adequacy

The Court finds that there are issues of material fact as to whether Defendants met its duty to adequately warn of reasonably foreseeble risks that would be unreasonably dangerous if not particularly warned of. See Wilkinson, supra, 212 W.Va. at 730, 575 S.E.2d 335. Although the risk of VTEs was expressly included in the label, it was arguably diluted as to the intensity of the warning because the label stated the risk of VTEs, but also noted that the risk was unknown. Plaintiff has raised a material issue of fact as to whether the four VTEs discovered in Defendants' clinical trials should have

reasonably been included to prevent Plaintiff's foreseeable risk. Accordingly, summary judgment is DENIED on this issue.

V. Express Warranty

A. Legal Standard

In West Virginia, an express warranty is created by:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> [W. Va. Code Ann. 46-2-313(1)(a)-(b).]

Therefore, under these two subsections, "an express warranty is created only when the affirmation of fact, promise or description of the goods is part of the basis of the bargain made by the seller to the buyer about the goods being sold." Reed v. Sears, Roebuck & Co., 188 W. Va. 747, 754, 426 S.E.2d 539 (1992).

B. Express Warranties

Plaintiff's opposition did not raise any specific express warranties, nor did it refute Defendants' argument regarding same. Therefore, summary judgment is GRANTED with respect to Plaintiff's claim for breach of express warranty.

VI. Causation

A. Legal Standard

In West Virginia, causation needs to be established. See White v. Dow Chem. Co., 321 Fed. App'x 266, 273 (4th Cir. 2009) (citing Tolley v. Carboline Co., 217 W. Va.

158, 617 S.E.2d 508, 511-12 (W. Va. 2005)). Specifically, "[t]o show proximate causation in a failure-to-warn case based on an allegedly inadequate drug label, a plaintiff must show that a different label or warning would have avoided the plaintiff's injuries." Id. (emphasis added). Plaintiff cites to Stanback v. Parke, Davis & Co., 657 F.2d 642, 645-46 (4th Cir. 1981), and argues that, according to same, West Virginia does not apply the learned intermediary doctrine and instead applies the heeding presumption. (Namack Opp. 22.) Contrary to Plaintiff's argument, a reading of Stanback confirms this Court's prior restatement of West Virginia law; the learned intermediary doctrine, not the heeding presumption, applies. Stanback, 657 F.2d at 644-45 & n.2 (stating that the learned intermediary doctrine applies to prescription drug, failure to warn cases, and that plaintiff could not prove the failure to warn caused plaintiff's injury because manufacturer warned plaintiff's doctor and the doctor, aware of the risks, failed to advise plaintiff of the risks.) In Stanback, the Court held that plaintiff could not prove causation because the plaintiff would not have been informed of the risk even if the manufacturer had fully warned the doctor of any associated risks, because it was "affirmatively established that [the doctor] would not have" responded to the adequate warning. Id. at 645-46.

B. Causation

Plaintiff Namack's only argument to establish causation is that West Virginia applies the heeding presumption, and that under same, Defendants have not met their burden. However, as stated supra "Namack," Part III(A), West Virginia does not apply a heeding presumption. See Stanback, supra, 657 F.2d at 644-46 & n.2. Consequently, plaintiff has a burden to prove causation and, at this stage, to show an issue of material fact. Plaintiff Namack has not provided any evidence to the Court under the relevant law,

as Plaintiff's entire argument relates to the heeding presumption (see Namack Opp. 22-23), and therefore fails to defeat summary judgment with respect to causation.

Moreover, Plaintiff Namack has not defeated summary judgment on the issue of whether her injury would have been avoided had she taken another birth control method, because she did not address this point in her Opposition. Consequently, Plaintiff has not raised any issues of material fact on this issue, and therefore, summary judgment is GRANTED.

ZIWANGE

V. Adequacy

A. Ohio Products Liability Act

Ohio has enacted the Ohio Products Liability Act (OPLA). Ohio Rev. Code Ann. 2307.76. Under this statute, "a product is defective due to an inadequate warning" where the manufacturer either knew or should have known about the risk being alleged by the plaintiff and the manufacturer failed to provide a warning for the risk which a manufacturer exercising reasonable care otherwise would have. O.R.C. § 2307.76 (A)(1); Seley v. G.D. Searle & Co., 67 Ohio St. 2d 192, 423 N.E.2d 831 (1981); Daniel v. Fison Corp., 138 Ohio App. 3d 104, 109, 740 N.E.2d 681 (2000). The exercise of reasonable care is viewed "in light of the likelihood that the product would cause harm . . . and in light of the likely seriousness of that harm." O.R.C. § 2307.76 (A)(1)(b).

The statute further instructs that a product is not defective for failure to warn where the risk is open and obvious, or, in the case of ethical drugs, where "its manufacturer provides otherwise adequate warning or instruction to the physician . . . and

if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it." O.R.C. § 2307.76 (B), (C); Vaccariello v. Smith & Nephew Richards, Inc., 94 Ohio St. 3d 380, 383-84, 763 N.E.2d 160 (2002) (applying the learned intermediary doctrine to prescription drugs and medical devices) (citing Seley, supra, 67 Ohio St. 2d 192, 423 N.E.2d 831).

Both parties rely on Seley, supra. A court must find for the manufacturer where an adequate warning was provided. Seley, supra, 67 Ohio St. 2d at 197, 423 N.E.2d 831 (citing Restatement (Second) of Torts, § 402 A comment k). A warning is adequate where "it reasonably discloses to the medical profession all risks inherent in the use of the drug which the manufacturer knew or should have known to exist." Id. at 198; Daniel, supra, 138 Ohio App. 3d at 109, 740 N.E.2d 681. Failing to give an adequate warning allowing the court to find that a drug is defective and unreasonably dangerous. Seley, supra, 67 Ohio St. 2d at 197, 423 N.E.2d 831.

Adequacy may be determined based on the warning's "factual content, its expression of the facts, or the method or form in which it is conveyed. . . . A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk." Id. at 198; Daniel, supra, 138 Ohio App. 3d at 109, 740 N.E.2d 681. Finally, and most relevant to this case:

> [A]lthough a causal relationship between use of a product and resulting injury may not be clearly established, a manufacturer may not ignore or discount scientific or medical evidence tending to show that a certain danger is associated with use of the drug solely because the manufacturer finds such information unconvincing.

[Daniel, supra, 138 Ohio App. 3d at 109, 740 N.E.2d 681 (citing Seley, supra, 67 Ohio St. 2d at 198, 423 N.E.2d 831).]

B. Parties' Arguments

Defendants assert that all of the Plaintiff's claims are subsumed by the OPLA. Plaintiff's failure to warn claim is unsuccessful because NuvaRing®'s VTE warning is adequate as a matter of law. Mrs. Ziwange's prescriber, Dr. Murnane, understood the increased risk of VTE associated with NuvaRing® because the warning on the label is clear and concise. Plaintiff's case specific expert, Dr. Scher, also testified that the NuvaRing® labeling was clear and understandable.

Plaintiff opposes Defendants' summary judgment motion based on the following grounds: (1) Material issues of fact exist; (2) Defendants did not meet its burden under the OPLA to show that their warning was and is adequate; (3) as an inadequate warning, the drug is presumed to be the proximate cause of Plaintiff's injury; (4) Defendants owed a duty directly to Plaintiff under federal law, which it breached; and (5) Defendants did not bring summary judgment motion against all of Plaintiff's claims, including defective design, defective manufacture, and failure to test.

C. Adequacy

The Court finds, on the issue of adequacy, Plaintiff has shown that material issues of fact exist. See supra "Decision," Part I(A). Plaintiff supports these allegations by providing to the Court the expert report of Dr. Parisian and Dr. Udipi. See supra note 16. Although Defendants contest these reports and disapprove of their use as Plaintiff's

experts, Plaintiff has met her burden by supplying this expert in order to defeat summary judgment on this issue.

Further, Plaintiff has effectively raised an issue under the OPLA regarding the sufficiency of that warning – i.e. whether the label "warns with the degree of intensity demanded by the nature of the risk." – even though the warning disclosed the risk of VTEs to the medical profession. See Seley, supra, 67 Ohio St. 2d at 198, 423 N.E.2d 831; Daniel, supra, 138 Ohio App. 3d at 109, 740 N.E.2d 681. A material issue of fact exists because Defendants assert that there was no increased risk of which to warn, and Plaintiff asserts that Defendants "may not ignore or discount" the four VTEs as evidence of an increased risk "solely because the manufacturer finds such information unconvincing." See Daniel, supra, 138 Ohio App. 3d at 109, 740 N.E.2d 681 (citing Seley, supra, 67 Ohio St. 2d at 198, 423 N.E.2d 831). Consequently, the facts are not "so one-sided that [Defendants] must prevail as a matter of law," see Anderson, supra, 477 U.S. at 252. Therefore summary judgment is DENIED with respect to adequacy.

VI. Express Warranty

A. Legal Standard

In Ohio, the OPLA subsumes Plaintiff's claims for breach of warranty. See Miller v. ALZA Corp., 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010); Boroff v. ALZA Corp., 685 F. Supp. 2d 704, 711 (N.D. Ohio 2010).

B. Express Warranties

Plaintiff Ziwange puts forth three statements that she alleges qualify as misrepresentations. However, Plaintiff's express warranty claim fails for two reasons.

First, all express warranty claims are subsumed by the OPLA. See Miller v. ALZA Corp., 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010); Boroff v. ALZA Corp., 685 F. Supp. 2d 704, 711 (N.D. Ohio 2010). Second, in supporting its express warranty claims, Plaintiff Ziwange's Opposition speaks only of Plaintiffs Medina and Kippola.[44] Therefore, summary judgment is GRANTED on this claim.

VII. Causation

A. Legal Standard

Ohio uses a two-step approach for proximate cause. The plaintiff must prove: "(1) the lack of the adequate warning was a proximate cause of the plaintiff's ingestion of the drug, and (2) that the ingestion of the drug was a proximate cause of the plaintiff's injury." Daniel, supra, 138 Ohio App. 3d 104, 109, 740 N.E.2d 681. Plaintiff argues that summary judgment is premature on the issue of causation, stating, "[Defendants' arguments] are very fact specific and depend upon the type of testimony that would be given at trial." The Court does not find this argument persuasive. Summary judgment is appropriate, even for causation, where a reasonable juror could only find judgment for the nonmoving party. See Kuntz v. Hall Inv. Co., 831 F.2d 295 (6th Cir. 1987) (citing Anderson, supra, 477 U.S. at 248). Where plaintiff has not presented any evidence of causation, summary judgment is appropriate. See id.; accord Reece v. Astrazeneca Pharms., LP, 500 F. Supp. 2d 736, 751 (S.D. Ohio 2007).

The parties also dispute whether a heeding presumption applies in Ohio, with Plaintiff citing Seley, supra, 67 Ohio St. 2d 192, and Defendants countering that Seley was decided before the OPLA was enacted, and that the OPLA did not codify the heeding

[44] See supra note 1.

presumption. Defendants do not cite any cases stating that the heeding presumption is no longer applicable, whereas the Court has found several cases citing Seley's use of the heeding presumption. See Boyd v. Lincoln Elec. Co., 179 Ohio App. 3d 559, 567, 902 N.E.2d 1023 (2008); Kennedy v. Streibel, 2003 Ohio 7241 (2003); accord Hisrich v. Volvo Cars of N. Am., Inc., 226 F.3d 445, 451 (6th Cir. 2000). Therefore, it is this Court's opinion that Ohio continues to apply same. See Seley, supra, 67 Ohio St. 2d at 200, 423 N.E.2d 831 ("[W]here no warning is given, or where an inadequate warning is given, a rebuttable presumption arises, beneficial to the plaintiff, that the failure to adequately warn was a proximate cause of the plaintiff's ingestion of the drug.").

B. Causation

Plaintiff Ziwange argues that summary judgment is premature because causation is fact specific and therefore a jury issue. (Ziwange Opp. Part X.) As explained supra Part A, summary judgment may be used for causation where Plaintiff does not meet her burden to show a genuine issue of material fact. Plaintiff's argument that causation "depend[s] upon the type of testimony that would be given at trial" insinuates that the evidence currently before the Court, such as depositions, expert reports, and exhibits, is either insufficient or will somehow change by the time of trial. (See id.) This argument is insufficient to show a genuine issue of material fact.

Applying Ohio's heeding presumption, the Court finds that Defendants have provided sufficient evidence to rebut the presumption. Under the presumption, "[w]here . . . an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug . . . , the presumption . . . is rebutted, and the required element of proximate cause between the warning and ingestion of the drug is lacking."

Seley, supra, 67 Ohio St. 2d at 201, 423 N.E.2d 831. Plaintiff's Opposition did not dispute Defendants' contentions as to Plaintiff's doctor's knowledge of the risks and his prescribing practices regarding NuvaRing® – i.e. that he continues to prescribe it. (See Ziwange Mot. 25 (citing Murnane Dep.)). Based on evidence put forth by Defendants, particularly testimony from Dr. Murnane that he does not feel differently about NuvaRing® and continues to prescribe it even after learning anything he has about it since prescribing it to the Plaintiff in 2007, Defendants have rebutted the heeding presumption. Thus, "the required element of proximate cause between the warning and ingestion of the drug is lacking." Seley, supra, 67 Ohio St. 2d at 201, 423 N.E.2d 831.

Even if Plaintiff's counsel could overcome summary judgment with respect to her physician's decision to prescribe the medication, Plaintiff has not been able to provide evidence that the injury would have been prevented if Plaintiff had used another birth control method. Plaintiff Ziwange provides no evidence to the Court on this issue to meet its summary judgment burden. In her opposition, she argues only that Defendants have the initial burden to show that NuvaRing® is safer than, or at least that the VTE risk is the same as, second generation pills. She continues by describing what Plaintiff's chief case to be presented to the jury "will be," but fails to cite to any evidence currently before the Court; Plaintiff states only, "To the extent that plaintiff is required now to raise evidence or a fact issue as to the increased risk of VTE with the ring over a second gen [sic] continuing [sic] pill, that is all covered in the first part of this brief and every opposition brief submitted in bellwether cases." (Ziwange Opp. Part X.) This is not sufficient to meet Plaintiff's summary judgment burden. Notably, "the first part of this brief" relates to adequacy arguments, requiring citations to different evidence than would

be required to prove causation. Plaintiff's argument is speculative and unsupported, and therefore summary judgment is GRANTED.

VIII. Causes Of Action Not Related To Labeling

A. Defective Design

Section 2307.75 of the Ohio Revised Code, titled "Product defective in design or formulation," states in pertinent part:

> An ethical drug . . . is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug . . . provides adequate warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect.
>
> [O.R.C. § 2307.75 (D).]

Plaintiff argues that NuvaRing® is not "unavoidably unsafe" because CHCs containing second generation progestins are arguably safer. (Ziwange Opp. Part XI(A) (arguing that second generation CHCs "would have substantially decreased the risk of VTEs"). The Revised Code categorizes a product as "unavoidably unsafe" when, "in the state of technical, scientific, and medical knowledge at the time a product in question left the control of its manufacturer, an aspect of that product was incapable of being made safe." O.R.C. § 2307.71(A)(16); Miller v. Alza Corp., 759 F. Supp. 2d 929, 939 (S.D. Ohio 2010).

In Miller, the court denied defendants' summary judgment motion regarding plaintiff's design defect claim because plaintiff provided "specific evidence showing that Defendants [drug] was not unavoidably unsafe, and that safer designs exist and were/are used. Defendants did not object to this specific evidence and presented no argument in

opposition in their Reply." Miller, supra, 759 F. Supp. 2d at 940 n.12. Here, the Court is faced with just the opposite. Plaintiff does not cite to any proof in her opposition that NuvaRing® is unavoidably unsafe; she states only that "the proof is that second generation progestin would have substantially decreased t he [sic] risk of VTEs," without indicating to what proof she is referring. Even if Plaintiff had cited to such proof, a risk still exists, although arguably decreased as Plaintiff's Opposition states. Therefore, the risk is unavoidable. Further, in response to Plaintiff's Opposition, unlike Miller, Defendants have disputed Plaintiff's argument. Accordingly, the Court finds that NuvaRing® is an "unavoidably unsafe" drug and falls within O.R.C. § 2307.75 (D).

Under O.R.C. section 2307.75 (D), Plaintiff only has a claim if Defendants did not provide an adequate warning and Plaintiff can show causation. O.R.C. § 2307.75 (D); Hickey v. Otis Elevator Co., 163 Ohio App. 3d 765, 769, 840 N.E.2d 637 (2005) (requiring causation). Although the Court has found that Plaintiff met her summary judgment burden with respect to the adequacy of the warning, see supra "Ziwange," Part I(C), Plaintiff is not able to show causation, see supra "Ziwange" Part III(B). Therefore, summary judgment is GRANTED for this cause of action.

B. Defective Manufacture

Section 2307.74 of the Revised Code, titled "When product is defective in manufacture or construction," states:

> A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer

> exercised all possible care in its manufacture or construction.
>
> [O.R.C. § 2307.74.]

Additionally, similar to Plaintiff's claims for design defect and failure to warn, Plaintiff must be able to prove causation. Donegal Mut. Ins. v. White Consol. Indus., 166 Ohio App. 3d 569, 584, 852 N.E.2d 215 (2006) (citing State Farm Fire & Cas. Co. v. Chrysler Corp., 37 Ohio St.3d 1, 523 N.E.2d 489 (1988)).

Plaintiff relies on the expert report of Dr. Udipi in her Opposition, arguing that the product suffers from a manufacturing defect because none of the rings are alike, the ring becomes more unstable over time, and the ring releases an undesirable burst of estrogen. (Ziwange Opp. Part XI(B), XII & Expert Report of Dr. Udipi, attached to Opp. as Ex. 6.)

Viewing the evidence in the light most favorable to the Plaintiff, the Court is unable to find that Plaintiff met her summary judgment burden on this cause of action. Even though, "[i]n manufacturing defect cases, evidence of unsafe, unexpected performance of a product is sufficient to infer existence of defect . . . , said evidence must be accompanied by proof that the alleged defect was present when the product left the hands of the manufacturer and that it proximately caused the plaintiff's injuries." Donegal, supra, 166 Ohio App. 3d 569, 584, 852 N.E.2d 215 (emphasis added). As previously stated, Plaintiff has not been able to provide sufficient evidence of causation, and therefore summary judgment is GRANTED.

C. Failure To Test

Ohio does not have a separate cause of action for "failure to test." Although Plaintiff concedes this (Ziwange Opp. Part XI(C)), she argues that this claim is subsumed under other recognized defect causes of action where evidence of failure to test exists.

Significantly, Plaintiff did not state under which cause of action failure to test should be subsumed. Therefore, having raised no other claim other than one that is nonexistent under Ohio law, summary judgment is GRANTED.

CONCLUSION

For the reasons set forth above, Defendants' summary judgment motion is GRANTED.