UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CALI LONTIN,	*	
	*	
Plaintiff,	*	
	*	
v.	*	
	*	Civil Action No. 15-30014-MGM
ORGANON USA, INC., N.V. ORGANON,	*	
SCHERING CORPORATION,	*	
MERCK & CO., INC., and	*	
MERCK SHARP & DOHME,	*	
	*	
Defendants.	*	

MEMORANDUM AND ORDER REGARDING
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT
(Dkt. No. 90)

November 27, 2018

MASTROIANNI, U.S.D.J.

I. INTRODUCTION

Cali Longtin ("Plaintiff") brings this action against Organon USA, Inc., N.V. Organon, Schering Corp., Merck & Co., Inc., and Merck Sharp & Dohme ("Defendants"), for claims related to a stroke she suffered in New Jersey following her use of NuvaRing, a prescription contraceptive.[1]

[1] Specifically, Plaintiff asserts claims for Strict Products Liability/Defective Manufacturing (Count I); Strict Products Liability/Defective Design (Count II); Strict Products Liability/Defect Due to Inadequate Warning (Count III); Breach of Express Warranty (Count IV); Breach of Implied Warranty (Count V); Strict Products Liability/Defect, Nonconformance With Representations (Count VI); Strict Products Liability/Defect, Failure to Adequately Test (Count VII); Negligence (Count VIII); Intentional and/or Negligent Misrepresentation (Count IX); Successor Liability (Count X); and Violation of Mass. Gen. Laws Ch. 93A (Count XI). (Dkt. No. 1.) Each claim is asserted against Organon USA, Inc., N.V. Organon, and Schering Corporation, except Count X, which is brought against Merck & Co., Inc. and Merck Sharp & Dohme Corp., and Count XI, which is only brought against Merck & Co., Inc. (*Id.*) As discussed below, most of these claims are subsumed by the New Jersey Product Liability Act.

Presently before the court is Defendants' motion for summary judgment as to all counts. (Dkt. No. 90.) For the following reasons, the court will grant Defendants' motion.

II. BACKGROUND AND PROCEDURAL HISTORY

The following facts, which are construed in a light most favorable to Plaintiff, are not disputed, except as otherwise noted. In 2008, while living in Massachusetts, Plaintiff began using NuvaRing following an appointment with Mary Casartello, a certified nurse midwife at Riverbend Medical Group. (Dkt. No. 98, Pl's Resp. to Def's Statement of Material Facts ("Pl's Resp. to Def's SOF") ¶ 33; Dkt. No. 104, Def's Resp. to Pl's Statement of Additional Material Facts ("Def's Resp. to Pl's SOF") ¶¶ 10-11.) NuvaRing is a combination hormonal contraceptive ("CHC") containing the hormones estrogen and progestin. (Pl's Resp. to Def's SOF ¶ 1.) Unlike oral contraceptives, NuvaRing is a flexible ring that is inserted in a woman's vagina once every 28 days and is removed after day 21 for a seven-day ring-free interval, after which a new NuvaRing is inserted and the 28-day process begins again. (*Id.* ¶ 5.) Between 2008 and 2010, while living in Massachusetts, Plaintiff used NuvaRing as prescribed and did not use any other form of hormonal contraceptive. (Def's Resp. to Pl's SOF ¶ 15.)

In October of 2010, Plaintiff moved to New Jersey for a new job, where she continued using NuvaRing. (*Id.* ¶¶ 17-19.)[2] On September 27, 2013, Plaintiff saw Dr. Kimberlee Austin, an obstetrician/gynecologist in New Jersey, for an appointment. (*Id.* ¶ 22.) At that appointment, Dr. Austin prescribed Plaintiff NuvaRing, recognizing Plaintiff was using the medication, and provided samples. (*Id.* ¶¶ 23-24; Pl's Resp. to Def's SOF ¶ 39.) From September 27, 2013 to January 16, 2014,

[2] Plaintiff testified at her deposition that, following her move to New Jersey until September of 2013, she continued seeing Mary Casartello during visits to Massachusetts, and Ms. Casartello would directly send the NuvaRing prescriptions to be filled at a pharmacy in Agawam, Massachusetts. (Dkt. No. 90-19 at 76-78.) However, the medical records of Ms. Casartello's treatment of Plaintiff, reviewed during Ms. Casartello's deposition, only spanned from January of 2007 until November of 2009, and Ms. Casartello stated she had no specific recollection of Plaintiff before or after November of 2009. (Dkt. No. 90-21 at 9-10, 14-15.) Ms. Casartello also testified that in 2011 she left her practice at Riverbend Medical Group and began working at Baystate Medical Center, where she provided emergency-type OB/GYN treatment and care in a hospital setting. (*Id.* at 29-32.)

Plaintiff used the NuvaRing samples Dr. Austin provided, as instructed. (Def's Resp. to Pl's SOF ¶ 27.)

On January 16, 2014, Plaintiff suffered a left middle cerebral artery stroke, resulting in cognitive and physical deficits. (*Id.* ¶ 28.) In May of 2014, Plaintiff moved back to Massachusetts to live with her parents. (Dkt. No. 90-19 at 66, 96.) Plaintiff has since remained in Massachusetts, but moved to her own apartment in June of 2016. (*Id.* at 65-66.)

Organon had submitted a New Drug Application ("NDA") for NuvaRing on December 28, 1999, seeking the approval of the Federal Drug Administration ("FDA") to market the product in the United States. (*Id.* ¶ 9.) The NDA included proposed language for the labels addressed to both doctors and patients warning of the risk of stroke, among other complications. (*Id.* ¶¶ 12, 14.) Following some minor changes to the proposed stroke warning labels requested by the FDA and accepted by Organon, those warnings ultimately provided as follows. The label addressed to doctors stated, in relevant part:

> NuvaRing® (etonogestrel/ethinyl estradiol ring) and other contraceptives that contain both an estrogen and a progestin are called combination hormonal contraceptives. There is no epidemiologic data available to determine whether safety and efficacy with the vaginal route of administration of combination hormonal contraceptives would be different than the oral route. Practitioners prescribing NuvaRing® should be familiar with the following information relating to these risks.
>
> The use of oral contraceptives is associated with increased risks of several serious conditions including myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease, although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. . . .
>
> **1. THROMBOEMBOLIC DISORDERS AND OTHER VASCULAR PROBLEMS**
>
> * * * *
>
> 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. . . . In a large study, the relative risk of thrombotic strokes has been shown to range from 3 for normotensive users to 14 for users with severe hypertension. The relative risk of hemorrhagic stroke is reported to be 1.2 for non-smokers who used

> oral contraceptives, 2.6 for smokers who did not use oral contraceptives, 7.6 for smokers who used oral contraceptives, 1.8 for normotensive users and 25 for users with severe hypertension. The attributable risk is also greater in older women.

(Dkt. No. 90-2 at 15-16, 18-19.) The label addressed to patients stated, in relevant part:

> NuvaRing® contains a combination of a progestin and estrogen, two kinds of female hormones. . . .
>
> Contraceptives that contain both an estrogen and a progestin are called combination hormonal contraceptives. Most studies on combination contraceptives have used oral (taken by mouth) contraceptives. NuvaRing® may have the same risks that have been found for combination oral contraceptives. This leaflet will tell you about risks of taking combination oral contraceptives that may also apply to NuvaRing® users.
>
> * * * *
>
> **What are the possible risks and side effects of NuvaRing®?**
>
> * * * *
>
> - **Heart attacks and strokes**
>
> 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.* at 37, 46.) The FDA approved NuvaRing and its doctor and patient labels on October 10, 2001. (*Id.* at 2.)[3]

Plaintiff commenced this action on January 29, 2015. (Dkt. No. 1.) On March 2, 2015, the United States Judicial Panel on Multidistrict Litigation ("JPML") issued a Conditional Transfer Order transferring this action to MDL No. 1964 in the Eastern District of Missouri for consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. (Dkt. Nos. 6-7.) On November 1, 2016, the JPML

[3] In October of 2013, the FDA approved updated labeling for NuvaRing. (Pl's Resp. to Def's SOF ¶ 25.) The updated labeling included formatting changes required by the Physician Labeling Rule as well as additional information, obtained from studies conducted after NuvaRing's FDA approval in 2001, regarding the risk of venous thromboembolic events ("VTEs") with NuvaRing compared to other CHCs. (Dkt. No. 90-16; Dkt. No. 90-18 at 6.) The updated labeling explained: "In these studies, which were required or sponsored by regulatory agencies, NuvaRing users had a risk of VTE similar to [combined oral contraceptive] users . . . ." (*Id.* at 8.) The court addresses differences between VTE and stroke below. In any event, as Defendants argue (and Plaintiff has not disputed), because Plaintiff received her last NuvaRing prescription and samples in September of 2013, before the updated labeling went into effect, the October of 2013 updated labeling is not relevant to Plaintiff's claims.

remanded this action from the MDL to this court for case-specific discovery and further proceedings. (Dkt. Nos. 9-10.) Defendants filed a motion for summary judgment on July 9, 2018, Plaintiff filed an opposition on August 16, 2018, and Defendants filed a reply on August 30, 2018. (Dkt. Nos. 90, 97, and 103.) This court held a hearing on Defendant's motion on October 18, 2018. (Dkt. No. 105.)

III. STANDARD OF REVIEW

"Summary judgment is appropriate 'if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Bellone v. Southwick-Tolland Reg'l Sch. Dist.*, 748 F.3d 418, 422 (1st Cir. 2014) (quoting Fed. R. Civ. P. 56(a)). "[A] nonmovant can forestall summary judgment by 'present[ing] definite, competent evidence' demonstrating the existence of a genuine dispute about a material fact." *Murray v. Kindred Nursing Ctrs. W. LLC*, 789 F.3d 20, 25 (1st Cir. 2015) (quoting *Mesnick v. Gen. Elec. Co.*, 950 F.2d 816, 822 (1st Cir. 1991)). "'A dispute is genuine if the evidence about the fact is such that a reasonable jury could resolve the point in the favor of the non-moving party.' . . . 'A fact is material if it has the potential of determining the outcome of the litigation.'" *Patco Constr. Co. v. People's United Bank,* 684 F.3d 197, 206-07 (1st Cir. 2012) (quoting *Rodríguez-Rivera v. Federico Trilla Reg'l Hosp. of Carolina*, 532 F.3d 28, 30 (1st Cir. 2008)).

IV. ANALYSIS

A. Choice of Law

Defendants assert New Jersey law applies because Plaintiff was a New Jersey resident when she suffered her stroke, she obtained the NuvaRing which allegedly caused her stroke in New Jersey from a New Jersey physician, and New Jersey is Defendants' principal place of business and the location where Defendants engaged in the labeling and marketing of NuvaRing. In contrast, Defendants assert, Massachusetts has a minimal connection to this case. Plaintiff, on the other hand,

argues Massachusetts law applies, citing that Plaintiff first started using NuvaRing in Massachusetts and she obtained most of the medication in Massachusetts. Plaintiff also points out that she lived in Massachusetts most of her life and moved back to Massachusetts shortly after her stroke. In addition, Plaintiff's counsel asserted at the hearing it was not clear whether the NuvaRing Plaintiff was using at the time of her stroke was obtained from Massachusetts or New Jersey.

Where, as here, a federal court exercises diversity jurisdiction, "[t]he question of which state's law applies is resolved using the choice of law analysis of the forum state—in this case, Massachusetts." *Reicher v. Berkshire Life Ins. Co. of Am.*, 360 F.3d 1, 4 (1st Cir. 2004). Massachusetts courts "consider choice-of-law issues 'by assessing various choice-influencing considerations,' . . . including those provided in the Restatement (Second) Conflict of Laws (1971)." *Cosme v. Whitin Mach. Works, Inc.*, 632 N.E.2d 832, 834 (Mass. 1994) (quoting *Bushkin Assocs., Inc. v. Raytheon Co.*, 473 N.E. 2d 832, 835 (1985)). "Under § 146 [of the Restatement], the law of . . . the 'state where the injury occurred' . . . applies unless Massachusetts has a 'more significant relationship' to the parties and the occurrence under the considerations provided in § 6." *Id.* at 835 (quoting Restatement (Second) Conflict of Laws § 146); *see also Cohen v. McDonnell Douglas Corp.*, 450 N.E.2d 581, 585 (Mass. 1983) ("The law of Massachusetts is that ordinarily the substantive law governing an action of tort for physical injury is that of the place where the injury occurred." (internal quotation marks omitted)); *Watkins v. Omni Life Sci., Inc.*, 692 F. Supp. 2d 170, 174 (D. Mass. 2010) ("Under Massachusetts choice-of-law rules, tort claims are governed by the law of the state in which the injury occurred, unless another state has a more significant relationship to the underlying cause of action.").[4] The Supreme Judicial Court has also explained: "The place where the injury occurred is

[4] The Supreme Judicial Court in *Cosme*, after stating it was "guided by the Restatement," explained that "[s]ection 145 of the Restatement provides the general principle 'applicable to all torts and to all issues in tort,' . . . and § 146 of the Restatement provides a principle applicable in issues concerning causes of action involving person injury." *Cosme*, 632 N.E.2d at 834-35 (quoting Restatement (Second) Conflict of Laws § 145, cmt. a).

Section 145 of the Restatement, entitled "The General Principle," provides:

the place where the last event necessary to make an actor liable for an alleged tort takes place." *Cohen*, 450 N.E.2d at 585 (internal quotation marks omitted).

In this case, the injury (Plaintiff's stroke) clearly occurred in New Jersey, where Plaintiff had been living and working for over three years. Contrary to Plaintiff's counsel's point raised at the hearing, there is no evidence to support the assertion that the NuvaRing Plaintiff was using on the day of her stroke was obtained in Massachusetts. In Plaintiff's affidavit, filed in support of her opposition to Defendants' motion for summary judgment, she attests: "From September 27, 2013 to the date of my stroke, I used the NuvaRing® samples Dr. Austin gave me, as instructed." (Dkt. No. 98-1 ¶ 27.)[5] Therefore, both the injury and the conduct causing the injury occurred in New Jersey. *See Ogburn-Sisneros v. Fresnius Med. Care Holdings, Inc.*, 2015 WL 6437773, at *4 (Mass. Super. Ct. Oct. 19, 2015) ("[T]he conduct causing injury in a prescription drug products liability case, including failure to warn and warranty cases, occurs primarily where the injured party was prescribed and ingested the drug." (quoting *Yocham v. Novartis Pharm. Corp.*, 736 F. Supp. 2d 875, 882 (D.N.J. 2010))). As a result, New Jersey has the "dominant interest" in both regulating Defendants' conduct and in determining whether, as a result of the injury, Plaintiff is entitled to recourse. *See* Restatement

> (1) The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.
> (2) Contacts to be taken into account in applying the principles of § 6 to determine the law applicable to an issue include: (a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicil, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered.
> These contacts are to be evaluated according to their relative importance with respect to the particular issue.

Section 6 of the Restatement, entitled "Choice of Law Principles," provides in relevant part:

> [T]he factors relevant to the choice of the applicable rule of law include (a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of results, and (g) ease in the determination and application of the law to be applied.

[5] There is also no support in the record for a theory, raised by the court at the hearing, that NuvaRing has a cumulative effect such that a woman is more susceptible to a stroke the longer she takes the medication.

(Second) of Conflict of Laws (1971) § 146, cmt. d (explaining that when the "conduct and injury" occur in the same state, that state "will usually be the state of dominant interest"); *see also Ricci v. Alternative Energy Inc.*, 211 F.3d 157, 165-66 (1st Cir. 2000).

Given that New Jersey is also Defendants' principal place of business—where the relevant decisions regarding labeling occurred—no other factors outweigh New Jersey's interest in this action. This is not a case, for example, where Plaintiff's contacts with New Jersey were merely "fortuitous" or fleeting. *See* Restatement (Second) of Conflict of Laws § 145, cmt. e ("Situations do arise, however, where the place of injury will not play an important the selection of the state of the applicable law. This will be so, for example, when the place of injury can be said to be fortuitous or when for other reasons it bears little relation to the occurrence and the parties with respect to the particular issue . . . ."). Moreover, the fact that Plaintiff first started using NuvaRing in Massachusetts and subsequently moved back to the state does not, under these circumstances, give Massachusetts a more significant relationship to the underlying claims. The court will therefore apply New Jersey law.

A. Merits

1. Counts I, IV, and IX

As an initial matter, Plaintiff has not set forth any opposition to Defendants' arguments that the Defective Manufacturing (Count I), Breach of Express Warranty (Count IV), and Intentional and/or Negligent Misrepresentation (Count IX) claims all should be dismissed. Accordingly, Defendants' motion will be allowed and summary judgment granted in their favor as to these claims.

2. Counts II, III, V, VI, VII and VIII

Plaintiff agrees that, if the court finds New Jersey substantive law applies, all of her remaining claims—except Count X (Successor Liability) and Count XI (Violation of Chapter 93A)—are subsumed by the New Jersey Products Liability Act ("PLA"), *N.J.S.A.* § 2A:58C-1. *See In*

re Lead Paint Litig., 924 A.2d 484, 503 (N.J. 2007) (explaining that the PLA, which created "one unified, statutorily defined theory of recovery for harm caused by a product," encompasses "virtually all possible causes of action relating to harms caused by consumer and other products" (internal quotation marks omitted)); *N.J.S.A.* § 2A:58C-1b(3) (defining "Product Liability action" as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except for harm caused by breach of an express warranty").[6]

Under the PLA, a manufacturer

> shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction . . . . An adequate product warning or instruction is 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 persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.

N.J.S.A. § 2A:58C-4. The statute further provides that warnings approved by the FDA are presumed adequate. *See id.* ("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 under the 'Federal Food, Drug, and Cosmetic Act' . . . or the 'Public Health Service Act' . . . a rebuttable presumption shall arise that the warning or instruction is adequate."). 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.*, 36 A.3d 541, 554 (N.J. 2012). The New Jersey Supreme Court has described this as a "super-presumption," explaining that "only in the 'rare case[]' will damages be assessed against a manufacturer issuing FDA-approved warnings." *Id.* at 554-55 (quoting *Perez v. Wyeth Labs, Inc.*, 734 A.2d 1245, 1259 (N.J. 1999)); *see also*

[6] Moreover, under the PLA, the parties only specifically address a failure-to-warn theory of liability. The court does the same.

Perez, 734 A.2d at 1259 ("[C]ompliance with FDA standards should be virtually dispositive of such claims.").

New Jersey courts recognize only two exceptions to this super-presumption. First, under the "*Perez/Rowe* exception," a plaintiff may rebut the statutory presumption in favor of an FDA-approved warning label by presenting evidence of "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." *Perez*, 734 A.2d at 1259; *Rowe v. Hoffman-La Roche, Inc.*, 917 A.2d 767, 774 (N.J. 2007); *see also Bailey v. Wyeth, Inc.*, 37 A.3d 549, 569-70 (N.J. Super. Ct. Law Div. 2008), *aff'd sub nom DeBoard v. Wyeth, Inc.*, 28 A.3d 1245 (N.J. App. Div. 2011). Second, under the "*McDarby* exception," the presumption may be rebutted by evidence of "economically-driven manipulation of the post-market regulatory process." *McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 256 (N.J. Super. Ct. App. Div. 2008); *see also Baker v. App Pharms. LLP*, 2012 WL 3598841, at *5 (D.N.J. Aug. 21, 2012).

Plaintiff argues the *McDarby* exception applies in this case.[7] In support, she principally relies on the expert opinions of Suzanne Parisian, MD and Gerald McGwin, Jr., M.S., Ph.D. As Defendants point out, however, Dr. Parisian only addressed matters that preceded FDA's approval of NuvaRing, making her opinion irrelevant under the *McDarby* exception, which requires "manipulation of the *post-market* regulatory process." *McDarby*, 949 A.2d at 256 (emphasis added); *see In re NuvaRing Litig.*, 2013 WL 1874321, at *22-23 (N.J. Super. Ct. Law Div. Apr. 18, 2013)

[7] Although Plaintiff's counsel made arguments at the hearing regarding alleged deliberate concealment or nondisclosure of certain harmful effects, these arguments were based on studies conducted *after* NuvaRing was already approved by the FDA. Accordingly, these arguments relate to the *McDarby* exception, which focuses on the "post-market regulatory process," and not the *Perez/Rowe* exception, which focuses on concealment or nondisclosure in the "pre-market" approval process. *See McDarby*, 949 A.2d at 256 (explaining that the *Perez/Rowe* exception was insufficient because "close scrutiny of the FDA and its regulatory power in a labeling context" disclosed "flaws in the post-marketing oversight process that provide the foundation for the further exception"; "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 effect remedial action is considerably less" (internal quotation marks omitted)). Furthermore, as discussed below, Plaintiff's expert's analysis of these post-market NuvaRing studies improperly conflates VTE and stroke injuries without an adequate basis for doing so.

("Plaintiff's FDA expert, Dr. Suzanne Parisian, did not identify . . . any manipulation of the regulation process after NuvaRing® was approved.").[8]

Dr. McGwin, an epidemiologist, opined that NuvaRing users have a "1.3-times increased rate of cardiovascular events, including stroke, compared to . . . users of combined oral contraceptives," based on a review of several studies. (Dkt. No. 98-13 at 10.) Dr. McGwin combined the results of these studies—some of which addressed the risk of VTE and some addressed stroke—into "a meta-analysis in order to estimate a combined, quantitative result" using a broad composite injury he describes as "cardiovascular events." (*Id.* at 5.) But Dr. McGwin admitted at his deposition that he was not aware of any drug study that combined VTE and arterial stroke into one calculation, that the "generally-accepted . . . universal practice is to always report those separately," and that combining "different types of clinical injuries into one analysis" can introduce "bias." (Dkt. No. 90-23 at 47, 54, 56, 60.) In fact, Dr. McGwin admitted he is not an expert in strokes or VTEs; he does not know "how arterial strokes are different from VTE"; and he did not consult "any medical doctors to see if it would be medically appropriate, clinically relevant to combine the risk of VTE and arterial strokes into one end point." (*Id.* at 29, 36, 60.) Dr. McGwin also conceded he did not have "any opinion to a reasonable degree of scientific certainty that NuvaRing has an increased risk of arterial stroke compared to other combined hormonal contraceptives," and none of the studies he included in his meta-analysis "found a statistically-significant increased risk of arterial stroke with NuvaRing compared with other combined hormonal contraceptives." (*Id.* at 34, 152.) Moreover, Plaintiff's own expert, Stephen Shohet, MD, a hematologist, disavowed Dr. McGwin's meta-analysis of combining VTE and stroke into one composite injury. (Dkt. No. 90-21 at 93-94, 96-97, 100-01.)

[8] In addition, Dr. Parisian only opined as to the risk of VTE and conceded that she was not offering any opinions regarding NuvaRing's stroke warnings. (Dkt. No. 90-28 at 127.)

Granted, as Plaintiff's counsel pointed out at the hearing, Defendants have not yet challenged the admissibility of Dr. McGwin's expert opinion under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Nevertheless, in light of the "fatal gaps" in Dr. McGwin's analysis (and thus Plaintiff's evidence), that does not preclude summary judgment in Defendants' favor. *Kearney v. Philip Morris, Inc.*, 916 F. Supp. 61, 66 (D. Mass. 1996) (explaining that "the opinions in plaintiff's expert affidavits, even if assumed to pass the threshold of admissibility, do not fit the facts of this case in a way that would enable a finder of fact, even after taking all of the proffered evidence into account, to make a finding favorable to the plaintiff"). As the Supreme Court itself explained in *Daubert*, even if expert evidence is not barred under Rule 702, "in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free . . . to grant summary judgment." *Daubert*, 509 U.S. at 596; *see also Nat. Res. Def. Council v. Metro. Water Reclamation Dis. of Greater Chicago*, 175 F. Supp. 3d 1041, 1056-57 (N.D. Ill. 2016) ("[T]o the extent that one side's expert opinions are substantially incomplete or inaccurate, they do not create a genuine issue of material fact that precludes summary judgment."). Thus, even if admissible, Dr. McGwin's analysis is still insufficient to defeat summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986) ("[T]here is no issue for trial unless there is sufficient evidence favoring the non-moving party for a jury to return a verdict for that party. . . . If the evidence is merely colorable . . . or is not significantly probative . . . summary judgment may be granted." (internal citations omitted)).

What is missing in this case is any medical expert testimony supporting the lumping together of stroke and VTE, as Dr. McGwin has done. One of Defendants' experts, Mitchell S. V. Elkind, MD, MS, who is both a medical doctor and a stroke epidemiologist, explained that Dr. McGwin's analysis

> inappropriately combines venous and arterial thrombotic events. Venous and arterial events, however, are very distinct, with different risk factors and causes, and combining them in an analysis of the risk of stroke associated with a medication, such as NuvaRing, is not reliable. The event rates for arterial events are much lower than for venous events among users of hormonal contraceptives. Folding together arterial events with venous events is not helpful to clinicians as it does not allow one to draw independent conclusions about those arterial events if the effects are driven by the outcome of venous events. Other studies on the effect of hormonal contraceptives do not combine venous and arterial events.

(Dkt. No. 90-12 ¶ 101.)[9] This evidence, regarding the medical differences between arterial strokes and VTEs and the flaws in combining the two injuries, has not been contested. In fact, Plaintiff's own experts agree with Dr. Elkind that stroke and VTE are distinct injuries. (*See* Dkt. No. 90-24 at 83-89; Dkt. No. 90-25 at 99.) Moreover, the FDA-approved label for NuvaRing discusses stroke and VTE separately, as do the various studies relied upon by the FDA and the experts in this case. The court also notes that most of the previous NuvaRing cases dealt with VTE, not stroke, and the one case that did address stroke specifically rejected a similar attempt to conflate the two injuries. *See In re NuvaRing Litig.*, 2013 WL 1874321, at *23 ("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.").

Accordingly, the court concludes Plaintiff has not met her burden of demonstrating that the *McDarby* exception applies. The "super-presumption" in favor of the FDA-approved warning label is therefore dispositive of these claims under the PLA. *See Perez*, 734 A.2d at 1259.

There is also an independent reason to dismiss these claims. Even if Plaintiff could somehow surmount the "super-presumption," she has presented no expert testimony that the NuvaRing warning label was inadequate. "Pursuant to New Jersey law, in a case involving the adequacy of a prescription medication's label and warnings, expert testimony is necessary for

[9] Dr. Elkind's criticism of Dr. McGwin's analysis echoes that of Dr. Shohet, one of *Plaintiff's* experts: "There's mixed data of arterial and venous data in here. And so it's very hard to tease out what he's really talking about." (Dkt. No. 90-24 at 97.)

Plaintiff to prove his case." *Nelson v. Biogen Idec, Inc.*, 2018 WL 1960441, at *12 (D.N.J. Apr. 26, 2018); *see also Grobelny v. Baxter Healthcare Corp.*, 2008 WL 2186417, at *2 (D.N.J. May 23, 2008) ("Because the product here is a complex pharmaceutical compound . . . with a complicated warning insert, testimony of a physician would be necessary in order to aid the jury in determining whether the warning was adequate."), *aff'd* 341 F. App'x 803 (3d Cir. 2009). None of Plaintiff's experts opined the NuvaRing label was inadequate to warn against the risk of stroke—the injury Plaintiff suffered. Rather, her experts made clear they either held no opinion on that question or agreed with Defendants that the warning *was* sufficient. (Dkt. No. 90-23 at 34; Dkt. No. 90-24 at 46; Dkt. No. 90-25 at 150-51; Dkt. No. 90-29 at 65; Dkt. No. 90-30 at 25; Dkt. No. 90-31 at 93.) As a result, Plaintiff's claims under the PLA fail for this reason as well.

3. Counts X and XI

In Count X, Plaintiff asserts a claim for violation of Mass. Gen. Laws ch. 93A. The court agrees with Defendants, however, that Plaintiff cannot maintain a claim under Chapter 93A for essentially the same reasons discussed in the choice-of-law analysis above. *See, e.g.*, *Cornwell Entertainment, Inc. v. Anchin, Block & Anchin, LLP*, 830 F.3d 18, 34 (1st Cir. 2016) (affirming district court's decision that Chapter 93A claim could not proceed based on choice-of-law analysis guided by Restatement (Second) Conflict of laws); *see also* Mass. Gen. Laws Ch. 93A, § 11 ("No action shall be brought or maintained under this section unless the actions and transactions constituting the alleged unfair method of competition or the unfair or deceptive act or practice occurred primarily and substantially within the commonwealth.").

Lastly, Plaintiff's claim for Successor Liability (Count XI) also fails because none of her underlying claims survive summary judgment. *See In re Emoral, Inc.*, 740 F.3d 875, 882 (3d Cir. 2014) ("[A]ny cause of action asserting successor liability necessarily contemplates some underlying damage or liability for which the claimant is seeking recourse from a third party.").

IV. CONCLUSION

For these reasons, the court ALLOWS Defendants' motion for summary judgment in its entirety. (Dkt. No. 90.) The clerk shall enter judgment for Defendants, and this case may now be closed.

It is So Ordered.

/s/ Mark G. Mastroianni
MARK G. MASTROIANNI
United States District Judge