NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: PLAVIX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL No. 2418
This Document Relates to: GARY ARMANTROUT, *et al.*, Plaintiffs, v. BRISTOL-MYERS SQUIBB, *et al.*, Defendants.	Civ. Action No.: 13-4521(FLW)

WOLFSON, District Judge:

This matter is a member case to the Multi-District Litigation ("MDL") entitled, *In Re: Plavix Marketing, Sales Practices and Products Liability Litigation*, which is assigned to the Undersigned. Plaintiff Roger Hopkins ("Plaintiff" or "Hopkins")[1] brings the instant suit against Defendants, Bristol Myers-Squibb Company ("BMS"), Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S.,

[1] Plaintiff's wife, Donna Hopkins, a co-plaintiff in this case, also brought a loss of consortium claim. But, for the purposes of this motion, I will refer only to Plaintiff Roger Hopkins, as all other claims concern him.

Inc., and Sanofi-Synthelabo, Inc. (collectively, "Defendants"), alleging that he suffered injuries as a result of Defendants' design, development, manufacture, promoting, marketing, distributing, labeling and sale of their prescription drug Plavix, an anti-clotting medication. Plaintiff's Complaint asserts various New York state and common law claims against Defendants, including Failure-to-Warn, Defective Design, Manufacturing Defect, Negligence and Loss of Consortium. Before the Court is Defendants' motion for summary judgment based upon a number of theories, including the learned intermediary doctrine under New York law.

BACKGROUND[2]

I. Plavix

Plavix is a drug that inhibits blood platelets from forming clots. The drug was initially approved by the United States Food and Drug Administration ("FDA") for use as monotherapy, *i.e.*, taken without another drug, in patients with recent heart attack, stroke, or diagnosed peripheral arterial disease. See Defs. Statement, ¶ 2. Thereafter, the FDA approved Plavix for dual therapy with aspirin, which also contains antiplatelet effects, in the treatment of patients with particular types of acute coronary syndrome ("ACS").[3] Id. at ¶ 3.

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[2] The following facts are not in dispute unless otherwise noted.

[3] ACS is a set of clinical signs and symptoms occurring when the heart muscle does not receive enough blood because of plaque

Taking Plavix is not without risk. Because it functions by inhibiting the formation of blood clots, it is well known that Plavix increases the risk of bleeding. In that connection, when Plavix entered the market, its labeling included certain information on that risk. When Plaintiff was using Plavix in 2003, the drug label provided:

> **CONTRAINDICATIONS**
>
> The use of PLAVIX is contraindicated in the following conditions:
>
> . . .
>
> - Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.
>
> * * *
>
> **PRECAUTIONS**
>
> **General**
>
> [PLAVIX] prolongs the bleeding time and therefore should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions (particularly gastrointestinal and intraocular). If a patient is to undergo elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery.

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narrowing or blocking of the arteries leading to the heart. Commonly, ACS includes, inter alia, heart attacks and irregular chest pains known as unstable angina. *See, e.g.*, Frederick G. Kushner, *et al.*, *2009 Focused Updates: ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infraction and Guidelines on Percutaneous Coronary Intervention*, 54 J. Am. C. Cardiology 2205, 2212 (2009).

Due to the risk of bleeding and undesirable hematological effects, blood cell count determination and/or other appropriate testing should be promptly considered, whenever such suspected clinical symptoms arise during the course of treatment (see ADVERSE REACTIONS).

GI Bleeding: In CAPRIE, PLAVIX was associated with a rate of gastrointestinal bleeding of 2.0%, vs. 2.7% on aspirin. In CURE, the incidence of major gastrointestinal bleeding was 1.3% vs. 0.7% (PLAVIX + aspirin vs. placebo + aspirin, respectively). PLAVIX should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions should be used with caution in patients taking PLAVIX.

* * *

Information for Patients

Patients should be told that it may take them longer than usual to stop bleeding when they take PLAVIX, and that they should report any unusual bleeding to their physician. Patients should inform physicians and dentists that they are taking PLAVIX before any surgery is scheduled and before any new drug is taken.

* * *

ADVERSE REACTIONS

Hemorrhagic: In CAPRIE patients receiving PLAVIX, gastrointestinal hemorrhage occurred at rate of 2.0%, and required hospitalization in 0.7%. In patients receiving aspirin, the corresponding rates were 2.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for Plavix compared to 0.5% for aspirin.

. . .

In CURE, PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin (see Table 3). There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture sites. The incidence

> of intracranial hemorrhage (0.1%) and fatal bleeding (0.2%), was the same in both groups.
> In patients receiving both PLAVIX and aspirin in CURE, the incidence of bleeding is described in Table 3.

Defs' Facts, ¶ 5.

II. Plaintiff's Medical History

Hopkins is a 69 year old man from Rochester, New York. Dr. Henry Richter, Plaintiff's cardiologist and prescribing physician, explained that Mr. Hopkins had several "cardiac risk factors" that contributed to the risk of him having a heart attack. *See* Richter Dep. at T27:11-28:12; T28:23-T30:2. These included diabetes, a family history of heart disease, hypertension, and high cholesterol. *Id.* at T27:19-24.

In June 2000, Hopkins suffered from acute chest pain, often referred to as unstable angina. Hopkins' Dep. at T85:3-18; Richter's Dep. at T27:11-28:12. Consequently, Hopkins' doctor placed Hopkins on aspirin. *See* Hopkins Dep. at T92:24-T94:5; Richter Dep. at T31:7-15. Hopkins, again, was presented with unstable angina in October 2000. *See* Richter Dep. at T27:11-T28:12. Three years later, in June 2003, Hopkins experienced a third instance of unstable angina which required hospitalization. *See id.* at T31:20-T32:11. Based on his medical history, Hopkins' doctors determined that he required a stent. *See id.* at T32:12-T34:5. As a result of the particular type of stent that Hopkins received, Dr. Richter put Hopkins on double antiplatelet therapy,

which included aspirin and Plavix. *See id.* at T34:25-T35:4. Plaintiff took Plavix for the next eight years, without suffering a heart attack. *See id.* at T47:5-13.

On August 28, 2011, Plaintiff was hospitalized with gastrointestinal bleeding. *See* Karthikeyan Dep. at T19:20-T20:9. His doctors performed an endoscopy, which found a hiatal hernia and two ulcers. It is unclear from the record as to the cause of these conditions, but according to Hopkins, the excessive bleeding was due to taking Plavix, and he was advised to discontinue taking Plavix. After discontinuing Plavix, Mr. Hopkins suffered a heart attack in and around October 2016.

Due to the gastrointestinal bleeding allegedly resulting from taking Plavix, Plaintiff brings the instant suit against Defendants asserting product liability related causes of action, under New York state law, for defective design, manufacturing defect, failure to warn, negligence and loss of consortium.

III. Dr. Richter's Testimony

At his deposition, Dr. Richter testified extensively regarding his decision to prescribe Plavix and aspirin for Plaintiff's condition. In that connection, Dr. Richter explained that he was well aware of the risk of increased bleeding associated with taking Plavix, as well as with the dual therapy.

Q: And what is the principal risk of antiplatelet agents [such as Plavix]?

A: Bleeding.

Q: And is -- do antiplatelet agents carry the risk of bleeding because they -- they work, in effect, by inhibiting clotting?

A: That is true.

Q: And so this is a potential risk of any antiplatelet -- antiplatelet agent; is that correct?

A: That is true.

Q: And is it fair to say that you understood throughout the time that you prescribed Plavix in your practice that it carried with it a bleeding risk?

A: Yes.

Q: The same is true for aspirin, right?

A: Yes.

Q: And when the two are prescribed together, did you understand that that would lead to an increased risk of bleeding because you have two antiplatelet agents?

A: That's been studied and that is definitely true.

Richter Dep. at T15:23-T16:20.

Dr. Richter went on to testify that, knowing such risks, he prescribed Plavix and/or dual therapy to those patients who medically needed such drugs.

Q: And, did you, on occasion, for appropriate patients prescribe Plavix throughout the time that you were practicing

at the University of Rochester say in the years 2002 to when you left your practice?

A: Sure. Yes.

Q: You found that it was a useful medication for appropriate patients?

A: More than useful.

Id. at T16:21-T17:4. In particular, Dr. Richter testified that with the specific type of stent that Plaintiff received, "the community of interventional cardiologists at that time with this particular stent, the CYPHER stent advocated using aspirin and Plavix for the duration of the life of the patient." *Id.* at T19:13-16. And, indeed, Dr. Richter felt that dual therapy was needed in light of Plaintiff's condition and stent placement. *Id.* at T35:2-6. Importantly, Dr. Richter made a medical assessment that "the benefits [of dual therapy] outweighed the risk at that point." *Id.* at T35:20-21.

To this day, Dr. Richter continues to believe that Plavix was the proper prescription for Hopkins:

Q: [S]itting here today, you believe that your prescription to Mr. Hopkins of Plavix during the period that you treated him was appropriate medical therapy for him?

A: I do.

Id. at T51:16-20.

IV. Procedural History

This action, originally filed in Illinois state court, was removed by Defendants to the United States District Court for the Northern District of Illinois. Once removed, the matter was transferred to this MDL litigation by the MDL Panel.

Defendants filed the instant motion for summary judgment on May 19, 2017, and Plaintiff has opposed the motion.[4] The Court held oral argument on June 27, 2017, wherein the parties' counsel appeared. During the hearing, Plaintiff's counsel, Ms. Diane Coffey, Esq., conceded that Plaintiff is not pursuing his manufacturing defect claim, and as such, that claim is dismissed. *See* Motion Tr. T4:22-T5:2. Counsel further conceded that the negligence and strict liability claims with regard to the duty to warn, involve the same analysis. *See id.* at T5:4-13. In other words, if one claim fails, the other one fails as well. Accordingly, on this motion, I will address Plaintiff's failure to warn and design defect claims.

DISCUSSION

I. Summary Judgment

Summary Judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine

[4] The parties agree that New York law applies to Plaintiff's claims.

issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ .P. 56(c). A factual dispute is genuine only if there is "a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party," and it is material only if it has the ability to "affect the outcome of the suit under governing law." *Kaucher v. County of Bucks*, 455 F.3d 418, 423 (3d Cir. 2006); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment. *Anderson*, 477 U.S. at 248. "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004) (quoting *Anderson*, 477 U.S. at 255); *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, (1986); *Curley v. Klem*, 298 F.3d 271, 276-77 (3d Cir. 2002).

The party moving for summary judgment has the initial burden of showing the basis for its motion. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "If the moving party will bear the burden of persuasion at trial, that party must support its motion with credible evidence . . . that would entitle it to a directed verdict if not controverted at trial." *Id.* at 331. On the other hand, if

the burden of persuasion at trial would be on the nonmoving party, the party moving for summary judgment may satisfy Rule 56's burden of production by either (1) "submit[ting] affirmative evidence that negates an essential element of the nonmoving party's claim" or (2) demonstrating "that the nonmoving party's evidence is insufficient to establish an essential element of the nonmoving party's claim." *Id.* Once the movant adequately supports its motion pursuant to Rule 56(c), the burden shifts to the nonmoving party to "go beyond the pleadings and by her own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." *Id.* at 324; *see also Matsushita*, 475 U.S. at 586; *Ridgewood Bd. of Ed. v. Stokley*, 172 F.3d 238, 252 (3d Cir. 1999). In deciding the merits of a party's motion for summary judgment, the court's role is not to evaluate the evidence and decide the truth of the matter, but to determine whether there is a genuine issue for trial. *Anderson*, 477 U.S. at 249. Credibility determinations are the province of the factfinder. *Big Apple BMW, Inc. v. BMW of N. Am., Inc.*, 974 F.2d 1358, 1363 (3d Cir. 1992).

There can be "no genuine issue as to any material fact," however, if a party fails "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322-23. "[A] complete failure of proof

concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Id.* at 323; *Katz v. Aetna Cas. & Sur. Co.*, 972 F.2d 53, 55 (3d Cir. 1992).

II. Failure to Warn

With respect to Plaintiff's failure to warn claim, Defendants argue that the learned intermediary doctrine precludes Plaintiff from suing them because the doctrine excuses drug manufacturers from warning Plaintiff, individually, when these manufacturers have properly and adequately warned the prescribing physicians regarding Plavix's risks. Indeed, the sole basis for Defendants' summary judgment motion on Plaintiff's failure to warn claim is the defense under the learned intermediary doctrine; Defendants do not challenge, on this motion, Plaintiff's position that Plavix's label is inadequate.

In order to establish a *prima facie* case for failure to warn under New York law, a plaintiff must show the following: (1) the manufacturer had a duty to warn; (2) the manufacturer breached the duty to warn in a manner that rendered the product defective, i.e., reasonably certain to be dangerous; (3) the defect was the proximate cause of the plaintiff's injury; and (4) the plaintiff suffered loss or damage. *See McCarthy v. Olin Corp.*, 119 F.3d 148, 156 (2d Cir. 1997) (citing *Becker v. Schwartz*, 46 N.Y.2d 401, 410 (1978)); *see also In re Fosamax Prods. Liab. Litig.*, 924 F. Supp.

2d 477, 486 (S.D.N.Y. 2013); *Mustafa v. Halkin Tool, Ltd.*, No. 00-4851, 2007 U.S. Dist. LEXIS 23096, at *17 (E.D.N.Y. Mar. 29, 2007).

Importantly, these elements of a failure to warn claim remain the same under New York law regardless of whether they sound in negligence or strict liability. *See Martin v. Hacker*, 83 N.Y.2d 1, 8 n.1, (1993); *Fane v. Zimmer, Inc.*, 927 F.2d 124, 130 (2d Cir. 1991) ("'Regardless of the descriptive terminology used to denominate the cause of action . . . where the theory of liability is failure to warn, negligence and strict liability are equivalent.'" (quoting *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 97 (N.Y. App. Div. 1979))).

Generally, a manufacturer has a duty to warn (1) "against latent dangers resulting from foreseeable uses of its product of which it knew or should have known," and (2) "of the danger of unintended uses of a product provided these uses are reasonably foreseeable." *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (1998); *see also State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 Fed. App'x 8, 10 (2d Cir. 2011); *Glucksman v. Halsey Drug Co.*, 553 N.Y.S.2d 724, 726 (App. Div. 1990). "This duty is a continuous one, and requires that the manufacturer be aware of the current information concerning the safety of its product." *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1345-46 (E.D.N.Y. 1992). "Liability for failure to warn may be imposed based upon either the complete failure to warn of a particular hazard or the inclusion of warnings

that are insufficient." *Fisher v. Multiquip, Inc.*, 949 N.Y.S.2d 214, 218 (App. Div. 2012) (citation and internal quotation marks omitted).

Typically, summary judgment is appropriate where a plaintiff has failed to introduce any evidence that a manufacturer knew or should have known of the danger at issue. *See Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 93-94 (S.D.N.Y. 2001); *see also Wolfgruber*, 423 N.Y.S.2d at 97-98 (granting defendant summary judgment in failure to warn case when there were no disputed facts). On the other hand, "the adequacy of a warning generally is a question of fact," best reserved for trial. *Kandt v. Taser Int'l, Inc.*, No. 09-0507, 2012 U.S. Dist. LEXIS 96024, at *3 (N.D.N.Y. July 10, 2012)(quoting *Fisher*, 949 N.Y.S.2d at 218); *see also Urena v. Biro Mfg. Co.*, 114 F.3d 359, 366 (2d Cir. 1997) ("'The adequacy of the instruction or warning is generally a question of fact to be determined at trial and is not ordinarily susceptible to the drastic remedy of summary judgment.'" (quoting *Beyrle v. Finneron*, 606 N.Y.S.2d 465, 465 (App. Div. 1993))).

When evaluating failure to warn liability, a court must conduct an "intensely fact-specific" analysis, "including but not limited to such issues as feasibility and difficulty of issuing warnings in the circumstances; obviousness of the risk from actual use of the product; knowledge of the particular product user; and proximate cause." *Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422,

440 (S.D.N.Y. 1999) (quoting *Liriano*, 92 N.Y.2d at 243) (internal quotation marks omitted). Where a manufacturer owes a duty to warn, it can satisfy this obligation by "warn[ing] of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." *Davids v. Novartis Pharms. Corp.*, 857 F. Supp. 2d 267, 286 (E.D.N.Y. 2012) (quoting *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245 (E.D.N.Y. 1999)) (alternation in original and internal quotation marks omitted).

In the prescription drug context, New York courts have recognized that a manufacturer's duty to warn extends to a patient's doctor (and not to the patient himself) pursuant to the "learned intermediary" rule. *See Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980) (stating that the manufacturer's duty is to warn the doctor, not the patient). The logic underlying this rule is that "[t]he doctor acts as an 'informed intermediary' between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, and prescribing and supervising their use." *Davids*, 857 F. Supp. 2d at 286 (quoting *Glucksman*, 553 N.Y.S.2d at 726) (internal quotation marks omitted). Thus, if a defendant fails to adequately warn a patient's physician of the dangers presented by a given pharmaceutical, and the patient suffers an injury on account of such failure to warn, a failure to warn claim

may lie. In sum, the "learned intermediary doctrine," provides that (1) that manufacturers of prescription drugs and medical devices discharge their duty to of care to patients by providing adequate warnings to prescribing physicians, and (2) that any failure to warn cannot be considered a proximate cause of a subsequent injury if the physician was fully aware of the dangers that would have been included in an alternative warning." *Shepherd v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, No. 04-1596, 2011 U.S. Dist. LEXIS 66664, at *4 (E.D.N.Y. June 23, 2011).

Indeed, nationally, it is well-settled that in prescription drug failure-to-warn cases, courts apply this doctrine. *See, e.g.*, *Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010) (concluding that summary judgment was proper where the "doctor provided explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed [the drug] . . . . Pursuant to Georgia's learned intermediary doctrine, this assertion severs any potential chain of causation"); *Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (holding that "a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician") (citing *Plummer v. Lederle Labs.*, 819 F.2d 349, 358-59 (2d Cir. 1987); *Ebel v. Eli Lilly & Co.*, 536 F.Supp. 2d 767 (S.D. Tex. 2008) (granting summary judgment

for defendant upon finding that prescribing physician was aware of Zyprexa's suicide-related risks that an adequate warning would have provided and that plaintiff had presented no evidence physician would not have prescribed Zyprexa had defendant provided him with an alternate warning label), *aff'd*, 321 Fed. App'x 350 (5th Cir. 2009) (per curiam); *Allgood v. GlaxoSmithKline PLC*, No. 06-3506, 2008 U.S. Dist. LEXIS 12500, at *3 (E.D. La. Feb. 20, 2008) (granting summary judgment to defendant because plaintiff had failed to show (1) that defendant did not adequately warn the physician of a risk associated with the drug that was not otherwise known to the physician and (2) that the "failure to warn the physician was both a cause in fact and the proximate cause of the plaintiffs injury"), *aff'd sub nom. Allgood v. SmithKline Beecham Corp.*, 314 Fed. App'x 701 (5th Cir. 2009) (per curiam).

Here, I note that Plaintiff’s opposition begins by submitting the expert testimony of Dr. Peter Rheinstein, who essentially opines on various inadequacies of Plavix’s label at the time Plaintiff was taking Plavix. Specifically, Dr. Rheinstein found that Plavix’s warnings failed to warn physicians about the lack of published studies evaluating the use of Plavix *for longer than one year* following implantation of a drug eluting stent. Using Dr. Rheinstein’s report, Plaintiff argues that summary judgment is not appropriate since the sufficiency of a warning label is a factual determination to be made by a jury. While Plaintiff is correct

that New York courts have so held, *see Ramirez v. Wyeth Labs., Inc.*, 686 N.Y.S.2d 602, 607 (Sup. Ct. 1999), the question that has been raised by Defendants, here, is not whether Plavix's warning was adequate, but rather, under the learned intermediary doctrine, whether Plaintiff's treating physician — Dr. Richter — would have prescribed Plavix even when provided with the most current research and FDA mandated warnings. This is the relevant inquiry on this motion. Thus, Dr. Rheinstein's report regarding the alleged insufficiencies of Plavix's warnings does not appear to be a relevant consideration on Defendants' defense pursuant to the learned intermediary doctrine. However, during oral argument, Plaintiff's counsel argued, for the first time, that Dr. Rheinstein's report calls into question Dr. Richter's credibility as the learned intermediary. I will address that contention, next.

But, before I discuss Plaintiff's arguments on why summary judgment should be denied despite Dr. Richter's testimony, I note that Plaintiff does not dispute any of his doctor's representations. Indeed, on the issue of causation, it is Plaintiff's burden to prove that a different warning would have changed the physician's decision to prescribe the medication. *See Head v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 649 F. Supp. 2d 18, 32 (E.D.N.Y. 2009); *Alston v. Caraco Pharm, Inc.*, 670 F. Supp. 2d 279, 285 (S.D.N.Y. 2009) ("plaintiff must demonstrate that had a different, more accurate warning[] been

given, his physician would not have prescribed the drug in the same manner."); *Golod v. Hoffman La Roche*, 964 F.Supp. 841, 856 (S.D.N.Y. 1997) ("the plaintiff must generally demonstrate that had appropriate warnings been given, the treating physician would not have prescribed or would have discontinued use of the drug."); *Mulhall v. Hannafin*, N.Y.S.2d 282, 287 (App. Div. 2007) (reversing a denial of summary judgment for defendant where the plaintiff had failed to prove the prescribing physician would have used a different course of treatment had the warnings been different). Stated differently, Plaintiff bears the burden of raising a genuine issue of material fact as to Dr. Richter's testimony, and if Plaintiff fails to do so, summary judgment may be appropriate. *Banker v. Hoehn*, 278 A.D.2d 720, 722 (N.Y. App. Div. 2000) (granting summary judgment in favor of defendant wherein plaintiff failed to create an issue of credibility with the prescribing physician's testimony).

Here, it is clear from the above-referenced testimony of Dr. Richter that he was aware of the serious risks of bleeding when placing Plaintiff on a dual therapy regime of Plavix and aspirin. Indeed, his opinion was unequivocal: because the medical benefits for Plaintiff's condition outweighed the risks, the physician was confident that the treatment he had provided for Plaintiff was medically necessary and appropriate. And, more compellingly, Dr. Richter testified that having reviewed all the relevant studies

regarding Plavix, he believes — even now — that prescribing Plavix to Mr. Hopkins was the most appropriate medical therapy.

In response, Plaintiff has produced no evidence - testimonial or otherwise - to suggest that a different warning would have led his doctor to alter the treatment for Plaintiff. More importantly, Dr. Richter represented that he would have not changed the prescriptions for Plaintiff even understanding the additional risks or questions of efficacy Plaintiff has raised in this litigation.

Rather than meeting his burden, Plaintiff, first, argues that Dr. Richter's uncontradicted testimony is not a sufficient basis to grant summary judgment on causation, because it is the province of the jury to determine that question. Plaintiff reasons that so long as Dr. Richter's testimony is not "self-disserving," his statements must be presented to the factfinder. Having reviewed all the relevant authorities, I reject Plaintiff's position.

Mainly, for his proposition, Plaintiff relies on *Golod*, a decision from the Southern District of New York. In that case, defendant drug manufacturer filed a motion for summary judgment, claiming that plaintiff could not establish that its drug's warning, even if inadequate, caused plaintiff's injuries because the treating physician testified that he would have nonetheless prescribed the drug with stronger warnings. *Golod,* 964 F.Supp. at 857. Admittedly, the court rejected that argument explaining that

because the physician was not a defendant in the action, it was for a jury to decide whether the doctor would indeed have prescribed the drug with different warnings. *Id.* In so finding, the court stated that the doctor's testimony was not self-disserving.[5]

That same line of reasoning was used by the Second Circuit in a relatively older decision of *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71 (2d Cir. 1993). In *Bravman*, the court found that "although the apparently highly qualified Dr. Spencer, [the plaintiff's treating physician,] testified that he would not have" made a different decision regarding treatment even if he knew about the noise issues with an implanted heart valve, "that testimony is insufficient to resolve the proximate cause question." *Id.* at 75. In that court's view, "[i]t is up to the trier of fact to determine whether, and the extent to which, Dr. Spencer's testimony on this point is credible." *Id.* Although Dr. Spencer was not a defendant in that case, the Second Circuit, nonetheless, found that "unless the physician's statement is self-disserving, the issue of credibility of the physician's affidavit should ordinarily be left" to the jury. *Id.* I do not find *Golod* or *Bravman* convincing;

[5] The *Golod* Court also found the doctor's testimony to be equivocal on the issue of whether if he was given a stronger warning, he would have nevertheless continued the plaintiff on the same drug. *Id.* at 857.

in my view, those decisions misstated the law mistakenly extended the reach or prior case law.

The term "self-disserving" was derived from an earlier New York state trial court decision in *Hoffman-Rattet v. Ortho Pharmaceutical Corp.*, 516 N.Y.S. 2d 856 (Sup. Ct. 1987). In *Hoffman-Rattet*, the prescribing doctor had been a defendant in the suit, but the claims against her were dismissed on statute of limitations grounds. Defendant pharmaceutical company sought to use the doctor's testimony that she would not have altered her treatment for the plaintiff. Because the doctor had been a defendant, the court held that the doctor's credibility was in doubt. First, the court explained that if a prescribing doctor is a defendant in suit, his or her testimony must be "self-disserving" — statements that are against the doctor's self-interests — before that testimony could be a sufficient basis upon which to grant summary judgment. In that regard, the court found that because the doctor in that case was "an actor in the transaction in question, [she] is an interested witness, [and] her testimony is subject to attack on credibility.[6]

The takeaway from *Hoffman-Rattet* is that when a treating physician is a defendant in a case brought by the plaintiff, that physician's testimony, in the context of the learned intermediary

[6] Indeed, the court found other reasons to discredit the doctor's testimony, which are not relevant here.

doctrine, must be self-disserving — or against the physician's self-interest — before the testimony can be a sufficient basis to grant summary judgment. Indeed, I agree with that conclusion, since a physician-defendant's credibility is in doubt when he or she is also defending claims brought by the same plaintiff. But, when the treating doctor is not a defendant, but rather a disinterested witness, the same concern regarding credibility is not present. Significantly, both *Bravman* and *Golod* did not discuss this distinction. Instead, those courts relied on *Hoffman-Rattet* and extended the concept of "self-disserving" to testimony from a physician who was not a defendant, without explaining why the credibility of a disinterested witness should be questioned simply because the doctor treated the plaintiff. Importantly, if I were to follow *Bravman*, summary judgment would never be granted in these types of cases, because a third-party prescriber's testimony would always be subject to doubt, unless the prescriber testified he or she would not have prescribed the drug. Such a one-sided result for a disinterested physician's testimony cannot be correct.

Because I am applying New York state law, the Second Circuit's decision in *Bravman* is not binding on this Court. *See Aceto v. Zurich Ins. Co.*, 440 F.2d 1320, 1322 (3d Cir. 1971). Rather, I look to other New York state court decisions to inform me. While I have not found any decision on this issue by the New York Court of Appeals, there is, however, an appellate decision that I find

instructive. *See Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 254 (3d Cir. 2010) ("Where an intermediate appellate state court rests its considered judgment upon the rule of law which it announces, that is a datum for ascertaining state law which is not to be disregarded by a federal court . . . ."). In *Sacher v. Long Island Jewish-Hillaide Medical Center*, 142 A.D.2d 567 (N.Y. App. Div. 1988), the defendant-pharmaceutical company, on summary judgment, sought to use statements from the plaintiff's prescribing physician, who was also named as a defendant in suit, that he was fully aware of risks of the drug and would have acted no differently even if adequate warnings were given. The court denied summary judgment, explaining that "self-serving statements of an *interested* party which refers to matters exclusively within that party's knowledge create an issue of credibility which should not be decided by the court but should be left for the trier of facts." *Id.* (emphasis added). Because the physician in *Sacher* was an interested party, the court found his testimony not sufficient for summary judgment purposes.

As I read *Sacher* and *Hoffman-Rattet*, opinions by state courts interpreting state law, I conclude that so long as a prescribing physician is a defendant in a case brought by a plaintiff, the credibility of that physician's testimony must be decided by a jury. However, if a treating doctor is not a defendant, but merely a third-party witness, his or her testimony, *without any evidence*

of credibility issues, is a sufficient basis to grant summary judgment. I note that no New York state court has endorsed *Bravman*'s holding that a prescribing doctor's testimony is not sufficient to warrant summary judgment. Rather, just the opposite is true; New York's highest court has found summary judgment appropriate where the motion is based on unrebutted deposition testimony. *See Alvarez v. Prospect Hosp.*, 68 N.Y.2d 320, 324-26 (1986)(finding summary judgment appropriate by relying on a treating doctor's unrebutted deposition testimony); *see also Gonzalez v. 98 Mag Leasing Corp.*, 95 N.Y.2d 124, 129 (2000); *Nomura Asset Capital Corp. v. Cadwalader, Wickersham & Taft LLP*, 26 N.Y.3d 40, 50-52 (2015).

Moreover, a district court from the Eastern District of New York, confronted with a similar question, has explained the scope of the effect of a prescriber's testimony by concluding that "[i]n cases where little weight has been accorded to a treating physician's statement that he would have followed the same course of treatment had the warnings been different, the treating physician has been a defendant and the statements found to be self-serving." *Krasnopolsky*, 799 F.Supp. at 1347. Accordingly, like the circumstances here, because the treating physician in *Krasnopolsky* was not a defendant, the court relied on the doctor's testimony to grant summary judgment in favor of the defendant-drug company.

Here, because Dr. Richter is not a defendant in this suit, and Plaintiff has not brought claims against his doctor in other forums, Dr. Richter's testimony does not, on its face, raise any credibility issues.[7] However, as a last ditch effort, Plaintiff's counsel inexplicably contended, during oral argument, that Dr. Rheinstein's Declaration somehow impacts the credibility of Dr. Richter. According to Dr. Rheinstein, because Defendants failed to warn consumers that BMS did not conduct any studies regarding the safety and efficacy of Plavix for a prolonged period of time, Plavix warning labels were insufficient. In that regard, it is Plaintiff's position that Dr. Richter's testimony is simply not

[7] Generally speaking, courts routinely rely on unrebutted testimony, particularly from experts, to grant summary judgment. *See, e.g.*, *Kelly-Brown v. Winfrey*, 659 Fed. Appx. 55 (2d Cir. 2016)(affirming grant of summary judgment based in part on unrebutted expert testimony); *Diaz v. Johnson Matthey, Inc.*, 893 F. Supp. 358, 361 (D.N.J. 1995) (finding that where plaintiff had no expert on exposure to toxin to counter defense experts, he could not "prove causation, and summary judgment . . . must be granted."); *Luby v. Carnival Cruise Lines, Inc.*, 633 F. Supp. 40, 42 n.3 (S.D. Fla. 1986) (noting that, "[w]here, as here, an issue is one of the kind on which expert testimony must be presented, and the affidavit of the expert is uncontradicted, summary judgment is proper"); *Brown v. Kordis*, 46 Fed. Appx. 315, 317 (6th Cir. 2002) (holding that "the district court did not err in granting summary judgment" since the "unrebutted expert testimony" left no genuine issue of material fact); *Evans v. Mentor Corp.*, No. 1:04-CV-1218, 2005 U.S. Dist. LEXIS 37069, at *7 (E.D. Va. Jun. 28, 2005) (finding that the Defendant was entitled to summary judgment because "Plaintiff's speculative evidence [was] countered by [Defendant's] unrebutted expert testimony"); *Sierra Club v. Ga. Power Co.*, No. 3:02-CV-151, 2007 U.S. Dist. LEXIS 100219, at *25 (N.D. Ga. Jan. 11, 2007) (ruling that since the defendant "presented powerful and uncontradicted expert testimony," the defendant is entitled to summary judgment).

"credible" since the doctor had no studies – as to the prolonged use of Plavix – to rely upon when he prescribed Plavix to Plaintiff for over eight years. I find Plaintiff's argument wholly without merit.

First and foremost, it was conceded during oral argument that Plaintiff's counsel never questioned Dr. Richter at his deposition on this issue. *See* Motion Tr., T9:8-10. Indeed, to the extent that counsel believed that Dr. Richter would have given different testimony, or that Dr. Richter would have found it important that Plavix labels lacked any warning that there were no studies conducted regarding the prolonged use of the drug, counsel failed to pose such questions during Dr. Richter's deposition. In fact, to the contrary, according to Dr. Richter, he read and relied upon various studies regarding the efficacy and risks of Plavix. *See* Richter Dep., T21:11-T24:4. More to the point, each of the studies reported the duration of that study which defined the limited time period during which patients were administered Plavix. For example, in the CAPRIE study, patients "received randomized treatment for an average of 1.6 years (maximum of 3 years)", and in the CURE study, patients "were randomized to receive PLAVIX . . . and were treated for up to one year." Rooney Decl., Ex. B, § Clinical Studies. Hence, having reviewed these studies, *see* Richter Dep., T21:16-24, Dr. Richter was well aware of the durations of the available studies, and by extension, the lack of

any studies with prolonged and extended use of Plavix. Yet, knowing these facts, Dr. Richter, nevertheless, unequivocally stated that it was his medical opinion that Plaintiff should remain on Plavix permanently, *see id*. at T45:12-16, and that even today, he believes that Plaintiff's prescription of Plavix was "appropriate medical therapy." *Id.* at T51:16-20.

Under New York law, a treating physician's independent knowledge of a risk associated with a prescription drug is sufficient to preclude a drug manufacturer's liability to an injured plaintiff. *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 406 (S.D.N.Y. 2014) (quoting *Banker*, 278 A.D.2d at 722). *See also Andre v. Mecta Corp.*, 587 N.Y.S.2d 334, 335 (App. Div. 1992) ("existing knowledge of the relevant hazard by the [prescribing doctor] may be so apparent, that liability may be resolved in favor of the manufacturer as a matter of law"). Here, Dr. Richter's uncontradicted testimony of his independent knowledge of the risks associated with Plavix "sever[s] the causal [chain] between an allegedly inadequate warning and a plaintiff's injury." *Id*. (quoting *Glucksman*, 553 N.Y.S.2d at 726) (internal quotations omitted). "The rationale for this rule is that knowledge of the danger is equivalent to prior notice." *Steinman v. Spinal Concepts, Inc.*, No. 05-774S, 2011 U.S. Dist. LEXIS 107286, at *27-28 (W.D.N.Y. Sep. 22, 2011). In fact, even if the drug's warnings were inadequate, the prescribing physician's independent knowledge

of the risks is nonetheless an intervening event that precludes the manufacturer's liability. *Tomaselli v. Zimmer Inc.*, No. 14-04474, 2017 U.S. Dist. LEXIS 9874, at *13 (S.D.N.Y. Jan. 20, 2017); *Steinman*, 2011 U.S. Dist. LEXIS 107286, at *28.

Based on these reasons, I conclude that Plaintiff has failed to present any conflicting evidence to create doubt regarding the credibility of Dr. Richter, and therefore, it is clear that the learned intermediary doctrine applies here.[8]

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[8] The Court is no stranger to the issues raised on this motion. Indeed, I have granted summary judgment based on the learned intermediary doctrine in previous failure to warn cases which also concerned Plavix, brought by various out-of-state plaintiffs. *See, e.g., Begley v. Bristol-Myers Squibb Co.*, No. 06-6051, 2013 U.S. Dist. LEXIS 4849 (D.N.J. Jan. 11, 2013); *Carr-Davis v. Bristol-Myers Squibb Co.*, No. 07-1098, 2013 U.S. Dist. LEXIS 10914 (D.N.J. Jan. 28, 2013); *Cooper v. Bristol-Myers Squibb Co.*, No. 07-885, 2013 U.S. Dist. LEXIS 1768 (D.N.J. Jan. 4, 2013); *LaBarre v. Bristol-Myers Squibb Co.*, No. 06-6050, 2013 U.S. Dist. LEXIS 10082 (D.N.J. Jan. 11, 2013); *Mattson v. Bristol-Myers Squibb Co.*, No. 07-908, 2013 U.S. Dist. LEXIS 58563 (D.N.J. Apr. 22, 2013), *Solomon v. Bristol-Myers Squibb Co.*, 916 F. Supp. 2d 556 (D.N.J. 2013). The Third Circuit affirmed my decisions in that regard. *See LaBarre v. Bristol-Myers Squibb Co.*, 544 Fed. App'x 120 (3d Cir. 2013).

In fact, the circuit court has routinely affirmed causation-based summary judgment pursuant to a treating physician's testimony. *See, e.g.*, *In re Avandia Mktg., Sales Practices, & Prods. Liab. Litig.*, 639 Fed. App'x 874, 876 (3d Cir. 2016) (affirming summary judgment under Pennsylvania law where the prescriber testified that he would have prescribed the same medication to a patient presented with the same medical conditions); *Bock v. Novartis Pharm. Corp.*, 661 Fed. App'x 227, 232 (3d Cir. 2016) (affirming the district court's grant of summary judgment on a failure to warn claim, relying on prescribing physicians' testimony that they "would still prescribe the drug today if presented with a patient such as [plaintiff], because, in their medical judgment, the benefits of the drug significantly outweigh the risks"); *Grobelny v. Baxter Healthcare Corp.*, 341

Accordingly, the Court grants summary judgment on Plaintiff's failure to warn claim, in favor of Defendants.

III. Design Defect

Plaintiff alleges that Defendants are liable under a theory of design defect for injuries that resulted from taking Plavix. Defendants advance three theories why summary judgment should be granted in their favor. First, Defendants argue that comment *k* to § 402(A) of the Restatement (Second) of Torts bars design defect claims where prescription drugs, which are classified as "unavoidably unsafe", are "properly prepared, and accompanied by proper directions and warning." Restatement (Second) of Torts § 402A cmt. K (1965). Second, Defendants contend that the design defect claim fails because Plaintiff has not established that an alternative design is available for Plavix. Third, Defendants claim that Plaintiff's design defect claim is preempted by federal law because any change to Plavix would require further approval and review by the FDA.

In response, Plaintiff argues that comment *k* does not operate to bar design defect claims here. Second, Plaintiff claims that there is no requirement that he must prove an alternative design

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Fed. App'x 803, 808 (3d Cir. 2009) (affirming the district court's grant of summary judgment on a failure to warn claim based on the prescribing physician's testimony at deposition that he was aware of the risks of the drug and prescribed the drug to plaintiff notwithstanding these risks).

is available, but rather, proving an alternative design is only one factor in a balancing test established by the New York Court of Appeals. *See Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 109 (1983). Finally, Plaintiff contends that his design defect claim is not preempted by federal law because Defendants have not provided any evidence on their motion that it was impossible for Defendants to change Plavix' warning label without violating federal law. I turn to these issues.

A. Comment *k* of § 402(A)

Comment *k* to § 402(A) of the Restatement (Second) of Torts states that when an unavoidably unsafe product, such as a prescription drug, is accompanied by proper warnings, that product is not defective. Restatement (Second) of Torts § 402A cmt. K (1965). Use of comment *k* to bar a design defect claim then is unavailable for products unaccompanied by proper warnings. *Martin*, 83 N.Y.2d at 8.

While Defendants invoke comment *k* as a defense to Plaintiff's design defect claim, this defense is unavailable to them because the question of whether Plavix's warning was adequate has not been raised by Defendants on their motion for summary judgment. Rather, Defendants' basis for summary judgment on Plaintiff's failure to warn claim is on the prescribing physician's testimony pursuant to the learned intermediary doctrine. *Id*. at 8 ("The comment *k* defense is unavailable for products . . . unaccompanied by proper

warnings"). Indeed, whether Plavix's warning was adequate is not at issue on this motion. Accordingly, the comment *k* defense is not appropriate to bar Plaintiff's design defect claim on this motion.

B. The Balancing Test

Plaintiff's theory of design defect is based upon the inadequacy of Plavix's warning. Typically, however, design defect claims are based upon the structure and planned design of a particular product. *Voss*, 59 N.Y.2d at 109 (quoting *Robinson v. Reed-Prentice Div. of Package Mach. Co.*, 49 N.Y.2d 471, 479 (1980)) ("a defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use"). Indeed, under New York law, a plaintiff typically brings a defective design claim against a drug company alleging that a particular drug is inherently unsafe due to its composition. *See, e.g.*, *Yates v. Ortho-McNeil-Janssen Pharms, Inc.*, 808 F.3d 281, 296 (6th Cir. 2015) (where plaintiff claimed that there was too high of a level of the active ingredient in a pharmaceutical). Under comment k, if that drug is accompanied by a proper and adequate warning, plaintiff's defective design claim would necessary fail. Conversely, if the warning label of the drug is insufficient, the plaintiff then proceeds to prove

that the design, *i.e.*, composition of the pharmaceutical, is defective.

But, here, Plaintiff's claim is solely based on inadequate warning, not that Plavix is inherently unsafe. I have not found a case, and Plaintiff has not cited to any authority, that permitted a claim of design defect to proceed based on a theory of inadequate warning. *See Wholey v. Amgen*, No. 162934/2015, N.Y. Misc. LEXIS 852, at *1, *20 (N.Y. Sup. Ct. Mar. 8, 2017) (finding a design defect claim based on a theory of failure to warn to be duplicative of the Plaintiffs' failure to warn claims and choosing to only analyze them under a failure to warn standard rather than under the design defect standard).[9]

Indeed, under New York law, in assessing a products liability claim based on design defect, such as a prescription drug, courts use two multifactor balancing tests. *See Wholey*, N.Y. Misc. LEXIS

[9] Indeed, in New York, a cause of action in strict products liability lies where a manufacturer places on the market a product which has a defect that causes injury. *Robinson*, 49 N.Y.2d at 471 (citing *Codling v Paglia*, 32 N.Y.2d 330, 342 (1973)). A defect in a product may consist of one of three circumstances: (1) mistake in manufacturing, *see Victorson v Bock Laundry Mach. Co.*, 37 N.Y.2d 395 (1975); (2) improper design, *see Micallef v Miehle Co., Div. of Miehle-Goss Dexter*, 39 N.Y.2d 376 (1975); *Bolm v Triumph Corp.*, 33 N.Y.2d 151(1973); or (3) by the inadequacy or absence of warnings for the use of the product, *Torrogrossa v Towmotor Co.*, 44 N.Y.2d 709 (1978). Clearly, improper warning is a separate and distinct cause of action from improper design or design defect. *See Liriano*, 92 N.Y.2d at 232.

852, at *11. The first balancing test involves a seven-factor evaluation of the risk and utility of the product to society. *See Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 257 (1995); *Voss*, 59 N.Y.2d at 109; *Wholey*, N.Y. Misc. LEXIS 852, at *11-12. The seven factors include:

> (1) The utility of the product to the public as a whole and to the individual user; (2) the nature of the product -- that is, the likelihood that it will cause injury; (3) the availability of a safer design; (4) the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced; (5) the ability of the plaintiff to have avoided injury by careful use of the product; (6) the degree of awareness of the potential danger of the product which reasonably can be attributed to the plaintiff; and (7) the manufacturer's ability to spread any cost related to improving the safety of the design.

Voss, 59 N.Y.2d at 109. Then, courts must consider whether the product was a proximate cause or "substantial factor" of the plaintiff's injury and use a three-factor test for that analysis. *Voss*, 59 N.Y.2d at 106 (quoting *Codling*, 32 N.Y.2d at 342). The factors for the proximate cause three-factor test include:

> (1) That at the time of the occurrence the product is being used for the purpose and in the manner normally intended, (2) that if the person injured or damaged is himself the user of the product he would not by the exercise of reasonable care have both discovered the defect and perceived its danger, and (3) that by the exercise of reasonable care the person injured or damaged would not otherwise have averted his injury or damages.

Id. None of factors relate to an assessment of warnings on a product. Instead, the multi-factored tests concern the safety of a particular product for its typical usage. Accordingly, I do not find that, under New York law, Plaintiff can bring a design defect claim based on inadequate warning, alone.

Regardless, even if Plaintiff could bring a design defect claim under a theory of inadequate warning, Plaintiff fails to meet his burden of proof. Significantly, Plaintiff has not proffered any alternative, safer design for Plavix. While Plaintiff is correct that such an alternative is not required to prove a strict liability claim of design defect, it is an important factor in the Court's balancing test. *See, e.g.*, *Gaudette v. St.-Gobain Plastics Corp*, No. 11-932, 2014 LEXIS 41790, at *36 (N.D.N.Y. Mar. 28, 2014) ("[t]he showing of a feasible, alternative design is a *sine qua non* of a design defect claim") (citation omitted). Furthermore, under the balancing test, Plaintiff must show that the product ***could*** have been designed more safely even if an alternative design was not offered. *Urena*, 114 F.3d at 365; *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2013). Plaintiff has done neither. Furthermore, while Plaintiff has advocated for a more specific label for Plavix, and while it would arguably be feasible for the manufacturer to include a different label on Plavix, that is the only factor that Plaintiff

has addressed on this motion through the expert report of Dr. Rhinestein.

Ultimately, Plaintiff has plainly failed to satisfy his burden of proving that the design defect balancing factors weigh in his favor. *See Urena*, 114 F.3d at 365 (finding that Plaintiff bears the burden of proving that each of the factors weigh in his favor); *Fane*, 927 F.2d at 129; *Voss*, 59 N.Y.2d at 107. Therefore, given Plaintiff's failure to satisfy his burden of proof, Defendants are entitled to summary judgment on the design defect claim. *See Mathis-Kay v. McNeilus Truck & Mfg.*, No. 06-CV-815S, 2011 U.S. Dist. LEXIS 109677, at *16 ("[i]f, after considering these factors, a reviewing court determines that the plaintiff has failed to establish a prima facie case of design defect, the court may dismiss the claim as a matter of law."); *Scarangella v. Thomas Built Buses, Inc.*, 695 N.Y.S.2d 520, 523 (1999); *Tomaselli*, 2017 U.S. Dist. LEXIS 9874, at *18 (dismissing plaintiffs' design defect claims on summary judgment because they "have failed to meet their burden . . . .").

Because Plaintiff's design defect claims fail on this basis, I need not address Defendants' assertion of federal preemption.

IV. Loss of Consortium

Because all the underlying substantive claims fail, summary judgment is appropriate as to the loss of consortium claim, as

well. *See Liff v. Schildkrout*, 49 N.Y.2d 622, 632 (1980); *Kornicki v. Shur*, 17 N.Y.S.3d 396, 397 (App. Div. 2015).

CONCLUSION

For the reasons expressed above, Defendants' motion for summary judgment is *GRANTED*. Plaintiff's Complaint is, therefore, dismissed.

DATED: August 17, 2017

/s/ Freda L. Wolfson
Freda L. Wolfson
United States District Judge