NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PATRICIA BEGLEY, Plaintiff, v. BRISTOL-MYERS SQUIBB CO., et al., Defendants.	:	Civil Action No. 06-6051(FLW) **OPINION**

WOLFSON, District Judge:

Plaintiff Patricia Begley ("Plaintiff" or "Mrs. Begley") brings the instant suit against Defendants, Bristol Myers-Squibb Company ("BMS"), Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, "Defendants"), alleging that she suffered injuries as a result of Defendants' design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of their prescription drug Plavix, an anti-clotting medication. Plaintiff's Amended Complaint ("Amended Complaint") asserts various Illinois state and common law claims against Defendants, including Failure-to-Warn, Defective Design, Manufacturing

Defect and Negligence.[1] Before the Court is Defendants' motion for summary judgment based upon a number of theories, including the learned intermediary doctrine under Illinois law. For the reasons that follow, Defendants' motion for summary judgment is GRANTED and all counts in the Amended Complaint are dismissed.[2]

BACKGROUND[3]

A. Plavix

Plavix is a drug that inhibits blood platelets from forming

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[1] In her Original Complaint, Plaintiff initially asserted New Jersey state and common law claims against Defendants. Following two separate decisions rendered by the New Jersey Supreme Court in 2007, Plaintiff voluntarily dismissed those New Jersey claims and amended her Complaint to assert causes of action arising only under Illinois state law. See Opinion dated December 30, 2009, pp. 2-3. Therefore, Illinois law controls on this motion.

[2] Pending before this Court are related cases filed by other plaintiffs who were allegedly injured by ingesting Plavix, albeit their injuries may be different than those suffered by Ms. Begley in this case. In those related cases, Defendants have also filed summary judgment motions. Moreover, the Court is aware that there are numerous cases concerning Plavix brought against Defendants in other state and federal courts across the country. Because each plaintiff's personal circumstances differ, the Court's findings in this Opinion only represent the application of pertinent state law, i.e., Illinois, to the facts presented in this particular case. That said, to avoid unnecessary duplication of effort in my several related cases and to conserve judicial resources, I cite to the analysis of similar legal issues in my published opinion in Solomon v. BMS, Civil Action No. 07-1102 (FLW) (Slip Op.), where appropriate.

[3] The following facts are undisputed unless otherwise noted.

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 vascular disease ("PVD"). 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").[4] Id. at ¶ 3.

Taking Plavix is not without risk. Because it functions by inhibiting the formation of blood clots, Plavix increases the risk of bleeding. In that connection, when Plavix entered the market, labeling on Plavix included certain information on that risk. The label provides:

> **PRECAUTIONS**
>
> **General**
> As with other antiplatelet agents, PLAVIX should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions. If a patient is to undergo

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

elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery.

GI Bleeding: PLAVIX prolongs the bleeding time. In CAPRIE[5], 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.

* * *

ADVERSE REACTIONS

Hemorrhagic: In CAPRIE patients receiving PLAVIX, gastrointestinal hemorrhage occurred at a 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.

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[5] According to BMS, the clinical evidence for the risks of PLAVIX is derived from two double-blind trials: (i) the CAPRIE study (Clopidogrel v. Aspirin in Patients at Risk of Ischemic Events), a comparison of PLAVIX to aspirin, and (ii) the CURE study (Clopidogrel in Unstable Angina to Prevent Recurrent Ischemic Events), a comparison of PLAVIX to placebo, both given in combination with aspirin and other standard therapy. See February 2002 Plavix Labeling, p.3. While Plaintiff contests the accuracy of these clinical trials, its arguments are not relevant to my disposition of this case. They are addressed in detail, however, in my opinion in Solomon.

> In CURE, PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin (see Table 3)[6]. 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.

See, generally, February 2002 Plavix Labeling.

B. Plaintiff's Medical History

Plaintiff Patricia Begley has a history of coronary artery disease and acute coronary syndrome. In December of 2003, she presented to the emergency room at Sherman Hospital in Elgin, Illinois with chest pain. Shah Cert., Exh. 43 (12/31/2003 discharge summary). It was subsequently determined that she had likely suffered a heart attack, id., Exh. 44 (Catherization Report), and that she suffered from severe stenosis - a 76 to 90 percent blockage of her arteries, Nisar Dep. 67:9-22. While she was hospitalized, interventionalist Dr. Asim Nisar, M.D., served as her treating cardiologist. He implanted two stents in her arteries in order to remedy blockages. Nisar Dep. 76:14-23. After implanting the stents, Dr. Nisar placed Plaintiff on dual therapy, specifically, 325 mg of aspirin and 75 mg of Plavix each day, in order to prevent "what's called stent thrombosis, .

[6] Table 3 of the labeling includes certain "incidence of bleeding."

. . . meaning clotting of the stent." Id. at 71:2-73:21.

Once Plaintiff was discharged, she saw Dr. Farzana Hosain for follow-up care through January 2006. Dr. Hosain continued Plaintiff's dual therapy. Hosain Dep. 83:15-22. While under Dr. Hosain's care, Plaintiff experienced bleeding from hemorrhoids in 2004 and gastrointestinal-related bleeding in 2006. Id. at 67:11-68:1; 84:18-85:8; 93:18-94:23. Plaintiff ceased taking Plavix on January 12, 2006. Begley Dep. 142:23-143:1. Altogether, Plaintiff was on dual therapy for a period of several years.

C. Plaintiff's Amended Complaint

Due to the gastrointestinal bleeding allegedly resulting from taking Plavix, Plaintiff brings the instant suit against Defendants asserting product liability related causes of action for defective design, manufacturing defect, failure to warn, and negligence under the Illinois law. See Am. Compl., Count I - Count IV.[7] Although these claims are characterized differently, they essentially turn on whether Defendants adequately warned that Plavix carried a risk of bleeding complications. In that regard, on this motion, Defendants argue that the learned

[7] On December 30, 2009, this Court dismissed Plaintiff's claims for negligent misrepresentation (Count V) and for

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.

DISCUSSION

I. Standard of Review

Summary judgment is "proper if there is no genuine issue of material fact and if, viewing the facts in the light most favorable to the non-moving party, the moving party is entitled to judgment as a matter of law." Pearson v. Component Tech. Corp., 247 F.3d 471, 482 n. 1 (3d Cir.2001) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986)); accord Fed. R. Civ. P. 56(c). For an issue to be genuine, there must be "a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party." Kaucher v. County of Bucks, 455 F.3d 418, 423 (3d Cir.2006); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In determining whether a genuine issue of material fact exists, the court must view the facts and all reasonable inferences drawn from those facts in the light most favorable to the nonmoving party. Matsushita Elec. Indus.

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violation of the Illinois Deceptive Trade Practices Act (Count

Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Curley v. Klem, 298 F.3d 271, 276-77 (3d Cir.2002). For a fact to be material, it must have the ability to "affect the outcome of the suit under governing law." Kaucher, 455 F.3d at 423. Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment.

Initially, the moving party has the burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp., 477 U.S. at 323. Once the moving party has met this burden, the nonmoving party must identify, by affidavits or otherwise, specific facts showing that there is a genuine issue for trial. Id.; Maidenbaum v. Bally's Park Place, Inc., 870 F.Supp. 1254, 1258 (D.N.J.1994). Thus, to withstand a properly supported motion for summary judgment, the nonmoving party must identify specific facts and affirmative evidence that contradict those offered by the moving party. Anderson, 477 U.S. at 256-57. "A nonmoving party may not 'rest upon mere allegations, general denials or ... vague statements...'" Trap Rock Indus., Inc. v. Local 825, Int'l Union of Operating Eng'rs., 982 F.2d 884, 890 (3d Cir. 1992) (quoting Quiroga v. Hasbro, Inc., 934 F.2d 497, 500 (3d Cir. 1991)). Moreover, the non-moving party must

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VI). See Order dated December 30, 2009.

present "more than a scintilla of evidence showing that there is a genuine issue for trial." Woloszyn v. County of Lawrence, 396 F.3d 314, 319 (3d Cir. 2005). Indeed, the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who 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 Corp., 477 U.S. at 322.

Moreover, 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 fact finder. Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992).

II. Illinois Failure-to-Warn Claim

Under Illinois law, a plaintiff must prove the following elements in order to succeed on a failure to warn claim against a prescription drug manufacturer: (1) that there was a duty to warn; (2) the manufacturer knew or should have known that the drug could cause the adverse reaction experienced by the

plaintiff; (3) the manufacturer failed to warn about the drug's potential reaction;(4) omission of this information made the warning inadequate and the drug defective; and (5) this defect proximately caused the plaintiff's injuries. Northern Trust Co. v. Upjohn Co., 572 N.E.2d 1030, 1037 (Ill. App. Ct. 1991); Langer v. Dista Products Co., Div. of Eli Lilly and Co., Civil Action No. 90 C 4598, 1996 WL 526763, at *2 (N.D. Ill. Sept. 12, 1996).

Plaintiff argues here that Defendants failed to adequately warn Plaintiff and her prescribing physicians of the potential for bleeding complications from taking Plavix. More specifically, Plaintiff insists that her prescribing physicians were not warned regarding Plavix's propensity to cause strokes, heart attacks, abnormal bleeding and "other serious issues and side effects." Am. Compl., ¶ 53. The parties agree that the legal sufficiency of Plaintiff's failure to warn claim rests on my application of Illinois' learned intermediary doctrine; thus, to that doctrine I now turn.

A. Illinois' Learned Intermediary Doctrine

Illinois courts have adopted the "learned intermediary" doctrine, which provides that the manufacturers of prescription drugs need not warn patients directly, but must "warn

prescribing physicians . . . of the product's known dangerous propensities." Hansen v. Baxter Healthcare Corp., 764 N.E.2d 35, 42 (Ill. 2002) (citing Kirk v. Michael Reese Hosp. & Med. Ctr., 513 N.E.2d 387, 392 (1987)). Those physicians, in turn, "have a duty to convey the warnings to their patients." Id. The adequacy of the warning "must be judged by whether it sufficiently apprises physicians of the risks associated with the use" of the medical device. See Hernandez v. Schering Corp., 958 N.E.2d 447, 455 (Ill. App. Ct. 2011). This is because "[t]he doctor, functioning as a learned intermediary between the prescription drug manufacturer and the patient, decides which available drug best fits the patient's needs and chooses which facts from the various warnings should be conveyed to the patient ...." Tongate v. Wyeth Laboratories, a Div. of American Home Products Corp., 580 N.E.2d 1220, 1225 (Ill. Ct. App. 1991) (citing Kirk, 513 N.E.2d at 393). "[T]he extent of disclosure is a matter of medical judgment." Id.

As a corollary to the learned intermediary doctrine, drug manufacturers are not obligated to warn prescribing physicians of risks already known to the medical community, see Hansen, 764 N.E.2d at 42 (citation omitted), because "there is no duty to warn of a risk that is already known by those to be warned,"

Proctor v. Davis, 682 N.E.2d 1203, 1211 (Ill. Ct. App. 1997) (citing Kokoyachuk v. Aeroquip Corp., 526 N.E.2d 607 (1988)). In Illinois, "[a] duty to warn exists only when there is 'unequal knowledge and the defendant, possessed of such knowledge, knows or should know that harm might occur if no warning is given.'" Id. (quoting Kokoyachuk, 526 N.E.2d at 610).

Because "[o]nly a physician or someone with specialized knowledge would be qualified to determine whether the warning was inadequate," a plaintiff must present expert testimony to establish that a warning is inadequate. Hernandez, 958 N.E.2d at 455–56; N. Trust Co. v. Upjohn Co., 572 N.E.2d 1030, 1036 (Ill. App. Ct. 1991). See also Sosnowski v. Wright Medical Technology, Inc., Civil Action No. 11 C 59, 2012 WL 1030485, at *7 (N.D.Ill. Mar. 27, 2012); Erickson v. Baxter Healthcare, Inc., 151 F.Supp.2d 952, 962-63 (N.D.Ill. 2001). Expert testimony is not required, however, where the inadequacy of the warning is so obvious that a lay person could "readily understand the insufficiency of the warning." N. Trust Co., 572 N.E.2d at 1036.

With regard to causation, that question is "for the jury to decide unless, viewing the facts in the light most favorable to

[the non-moving party] no jury could reasonably conclude that the defendants' conduct was a cause of [the plaintiff's] injuries or death." Erickson, 151 F.Supp.2d at 967 (quoting Thacker v. UNR Indus., Inc., 603 N.E.2d 449, 455 (Ill. 1992)). See also Baltus v. Weaver Division of Kidde & Co., 557 N.E.2d 580 (Ill. 1990) ("[T]he simple statement that proximate cause is for the jury to decide does not substitute for an affirmative factual base from which to infer such proximate cause.")

In determining whether a plaintiff has demonstrated proximate cause, courts applying Illinois law look carefully at the testimony of the prescribing physician. Summary judgment may be granted on causation grounds "when the physician's testimony shows unequivocally that s/he knew at the relevant time all the information which would have been included in a proper warning." See also Giles v. Wyeth, Inc., 500 F.Supp.2d 1063, 1067 (S.D.Ill. 2007) (emphasis in original). Accord Stephens v. Hook-SuperX, 359 Fed.Appx. 648, 650 (7th Cir. 2009) (affirming grant of summary judgment where there was "no genuine dispute that [the doctor] knew [of the] potential side effect . . . when she prescribed the drug."). Illinois courts have denied summary judgment where the prescribing physician testified that he was not aware that the drug could cause the

adverse reaction experienced by the plaintiff. See, e.g., Tongate, 580 N.E.2d at 1225.

B. Adequacy of Warning Label

Under Illinois law, the question of whether a physician was sufficiently apprised of the harmful effects of a drug is a critical one. "Doctors who have not been sufficiently warned of the harmful effects of a drug cannot be considered 'learned intermediaries' ...." Proctor, 682 N.E.2d at 1215.

"[T]he adequacy of warnings is a question of fact, not law, for the jury to determine ...." Id. (citing Tongate, 580 N.E.2d 1220); Batteast v. Wyeth Laboratories, Inc., 560 N.E.2d 315 (Ill. 1990)). See also Erickson, 151 F.Supp.2d at 962-63. However, "[t]he sufficiency of the warning can become a question of law where the warning is clear, accurate and unambiguous." Hernandez, 958 N.E.2d at 455 (citing Upjohn Co. v. MacMurdo, 562 So.2d 680 (Fla. 1990); Kelso v. Bayer Corp., 398 F.3d 640 (7th Cir. 2005) (applying Illinois law)).

Here, Plaintiff argues that the Plavix label in effect at the time of her injury was inadequate in several ways. While acknowledging that the label discloses that Plavix causes bleeding, she argues that the label did not fully reflect "the risks and benefits (or lack thereof) of Plavix ...." Pl. Opp.

at 23. Specifically, she argues that the label should have reflected: (1) that dual Plavix/aspirin therapy causes a substantial risk of serious bleeding, (2) that genetic testing is required to determine a patient's genetic response to Plavix, (3) that continued use of Plavix beyond one year after a stent is implanted is ineffective, and (4) that dual therapy is no more effective than aspirin alone in preventing clotting. In support of her contentions, she relies on the expert testimony of Dr. Lemuel A. Moye.

As is apparent from this restatement of Plaintiff's arguments, she focuses heavily on the effectiveness of Plavix. However, as I explained in more detail in my recent decision in Solomon, supra, Slip Op. at 16-17, Plaintiff's arguments regarding the effectiveness of Plavix are misguided. Her failure-to-warn claim is premised on the fact that she suffered substantial bleeding as a result of taking both Plavix and aspirin at the same time - not that Plavix was ineffective in preventing her blood from clotting. A failure-to-warn claim under Illinois law involves whether a drug manufacturer adequately warned prescribing physicians of the potential adverse reactions that could be caused by ingesting a drug; manufacturers of prescription drugs must "warn prescribing

physicians . . . of the product's known dangerous propensities." Hansen, 764 N.E.2d at 42 (emphasis added). Hence, although the efficacy of a drug may play a role in a physician's decision to prescribe, the failure-to-warn doctrine is not primarily concerned with a drug's efficacy. In this regard, courts applying the learned intermediary doctrine have held that permitting a plaintiff to pursue a claim for the "failure to warn" of the efficacy of a drug would constitute an unwarranted expansion of liability. See In re Fosomax Prods. Liab. Litig., No. 06-1789, 2010 U.S. Dist. LEXIS 33260, at * 14-15 (S.D.N.Y. Mar. 26, 2010) (applying Florida law). See Needham v. White Laboratories, Inc., 639 F.2d 394, 402 (7th Cir. 1981) (applying Illinois law in concluding that effectiveness of drug not relevant to failure-to-warn claim). So too, here, I find Plaintiff's efficacy arguments unavailing.

Putting aside Plaintiff's efficacy arguments, her failure-to-warn claim boils down to her bare contentions that the Plavix warning label should have better reflected that dual therapy causes a substantial risk of serious bleeding and that genetic testing is required. As will be explained in more detail below, Plaintif fails to present expert testimony to support these contentions, thus, her failure-to-warn claim necessarily fails.

Courts in Illinois, unlike the courts of other states that have been addressed in my recent learned intermediary decisions, repeatedly emphasize the importance of expert testimony in failure-to-warn prescription drug cases. In 1991, in Northern Trust Co., 572 N.E.2d 1030, the Illinois Appellate Division first addressed the issue of expert testimony. Noting that the Illinois Supreme Court had yet to rule on the issue[8], the court looked to the law of other states for guidance. The court distilled from that case law that an expert testimony requirement "is the logical extension of the fact that a prescription drug manufacturer's duty to warn is directed to the prescribing physician. For that reason, only a physician or someone with specialized knowledge would be qualified to determine whether the warning was inadequate." Id. at 1035-36. Further, the court noted, those states found the expert testimony requirement for failure to warn cases involving prescription drugs analogous to the expert testimony requirement

[8] The Illinois Supreme Court has yet to explicitly rule upon whether expert testimony is required in drug manufacturer failure-to-warn cases hence I look to the Illinois Appellate Court for guidance on how the Illinois Supreme Court would rule. See Spence v. ESAB Group, Inc., 623 F.3d 212, 216–217 (3d Cir. 2010). As illustrated below, courts applying Illinois law continue to follow the reasoning of Northern Trust Co. over twenty years after it was issued.

in medical malpractice actions. Id. at 1036. Because Illinois required expert testimony in medical malpractice actions, the Northern Trust Co. court determined that the Illinois Supreme Court would likewise require expert testimony in failure to warn claims against drug manufacturers. It then pronounced that "expert testimony shall be necessary and proper . . . where a drug manufacturer's liability for a prescription drug is based upon its failure to provide adequate warnings." Id.[9]

In terms of the nature of the expert testimony, Northern Trust Co. held that the testimony must establish that the manufacturer breached its duty to warn by failing to include the warnings the plaintiff claims were omitted. Id. at 1038. This is not a simple matter of "whether the [adverse reaction] was listed among the side effects ...." Id. Rather, the question the expert must answer is

[9] The court noted one exception: In its view, the only instance in which expert testimony is not required is where the adequacy of the warning is "so obvious that a lay person could . . . readily understand the insufficiency of the warning." Id. The court held that this exception did not apply to the facts of that case where the "meaning and medical implications of several of the listed adverse reactions [found in the package insert was] outside the knowledge of the ordinary lay person." Id. at 1039. Plaintiff here has not argued that a lay person could understand the similarly complex implications of the bleeding risk-related language at issue in this case. Hence I do not address whether the exception could have applied here, although I would likely conclude that the exception does not apply.

> whether the package insert and other materials designed to warn physicians of the possible risks associated with the drug, were adequate to advise a physician of the potential dangers that were inherent in the use of the product, despite the fact that [the adverse reaction] was not listed specifically as a possible side effect of the drug.

Id. Because the expert testimony presented in Northern Trust Co. did not address this more nuanced question, the Appellate Court held that the plaintiff's claim could not succeed as a matter of law.

Since Northern Trust Co., both state and federal courts in Illinois continue to hold plaintiffs to an exacting expert testimony standard. See, e.g., Hernandez, 958 N.E.2d at 454-55; Sosnowski, 2012 WL 1030485 at *7; Erickson, 151 F.Supp.2d at 962-63. See also 30A Ill. Law and Prac. Prod. Liab. § 17. Recently, in Hernandez, the Appellate Court rejected a plaintiff's failure-to-warn claim based on a lack of expert testimony. In that case, the plaintiff's expert opined that the package insert was inadequate. However, he did not address if "a practicing physician . . . would consider [the insert to be] an adequate warning when determining whether to prescribe [the] medication for a patient." 958 N.E.2d at 456 (emphasis added).

Absent this specific testimony, the court concluded that the plaintiff could not prevail. Id. at 457.[10] Similarly, in a recent federal court decision applying Illinois law, the Sosnowski decision, summary judgment was granted where the "plaintiff offer[ed] no expert evidence that defendant's warning failed to sufficiently apprise physicians of the risks associated with the use of the [drug]."[11] 2012 WL 1030485 at *8. Consistent with this approach, an Illinois court denied summary judgment where the expert testified that the adverse reaction at issue in that case was acknowledged in the medical literature and "should, in fact, be listed as a potential complication." Tongate, 580 N.E.2d at 957.

Because Northern Trust Co. continues to be followed by courts in Illinois, and it has not been undermined by subsequent Illinois Supreme Court law, I treat it as a strong indicator of

[10] To be clear, the expert in that case was not qualified to testify as to how a physician would interpret the package insert because he was not an expert in pharmacology and had no experience as practicing physician who prescribed medicine. Id. at 713. Here, while the competency of Plaintiff's expert is not in question, I nonetheless find Hernandez instructive in defining the nature of the expert testimony required in failure to warn cases.

[11] While this case involved a medical device rather than a pharmaceutical drug, Illinois' learned intermediary doctrine law applies with equal force in medical device failure-to-warn cases. See Hanson, 764 N.E.2d at 42.

how the Illinois Supreme Court would rule on the expert testimony requirement and, therefore, follow it here. Accord Independent Trust Corp. v. Stewart Information Services Corp., 665 F.3d 930, 936 (7th Cir. 2012) (affirming district court's treatment of Illinois appellate court decision as persuasive authority where Illinois Supreme Court had not yet passed on the issue and the appellate court "was the first. . . only Illinois appellate court to discuss the [ ] doctrine . . ., and its holding ha[d] not been undermined by intervening Illinois precedent.")

As in Northern Trust Co. and Hernandez, and Sosnowski, Plaintiff here has failed to present expert testimony that addresses the key questions of how an Illinois physician would have interpreted the Plavix label and whether that label adequately warned physicians of the risks of either dual therapy-induced bleeding or a need for genetic testing. Dr. Moye's expert report renders no conclusions on these issues. Indeed, although his report addresses the long-term use of Plavix in post-stent patients, his comments consist merely of recounting the results of the PRODIGY study. He describes the study as suggesting that dual therapy beyond six months

following the implant of stents creates an increased risk of bleeding.[12] However, as I noted in Solomon, supra at 21, "lacking in Dr. Moye's report is any conclusion as to how . . . Plavix's warning label should have reflected the duration of [the dual] therapy …."[13]

In short, notably absent from Dr. Moye's report is any language addressing how a prescribing physician at the time of Plaintiff's injury would have interpreted the warning label or any other medical information available at that time. Nor does he opine on what additional warning language – in addition to the already-included bleeding language - should have been included in the package insert. Even assuming that Dr. Moye's conclusions with respect to the PRODIGY study are founded, Dr.

[12] Moreover, the Court notes that it is giving Plaintiff the benefit of the doubt in gleaning this excerpt from Dr. Moye's expert report and reading his post-stent conclusions as addressing increased bleeding. In her brief, Plaintiff presents her post-stent, long-term use argument in connection with the efficacy of Plavix, rather than with the incidence of increased bleeding. For the reasons explained above, Plaintiff's efficacy argument cannot and does not carry the day.

[13] The other studies discussed by Dr. Moye do not relate to Plaintiff's medical history in this case, e.g., Plavix studies dealing with stroke survivors, id. at ¶ 132, and are therefore not pertinent to my analysis. In addition, Dr. Moye stresses the inefficacy of Plavix for those patients who have suffered heart attacks or vascular disease. Id. at ¶ 143-44. As noted, Plaintiff's efficacy arguments are unavailing.

Moye renders no opinion on how that study should have been reflected in the warning label. Accordingly, Plaintiff has failed to present the type of expert testimony required by the Illinois cases discussed above, and her claim necessarily fails.

Because her claim fails on adequacy grounds, I do not reach proximate causation. Accord Hernandez, supra at 48. For this reason, I also do not address the parties' arguments regarding whether Illinois recognizes a heeding presumption, and whether that presumption could be rebutted with testimony by Plaintiff's physicians that they would have prescribed Plavix even with the benefit of the sort of increased bleeding warning for which Plaintiff advocates. In a 2007 decision, the Southern District of Illinois noted that the Illinois Supreme Court "has not spoken on this issue clearly." Giles, 500 F.Supp.2d at 1066. However, the district court suggested that the Illinois Supreme Court would likely adopt the presumption, which could have the effect of "reliev[ing] a plaintiff of her burden of proving an important facet of causation whenever a manufacturer of prescription drugs fails to warn doctors adequately." Id. at 1069. In addition, while another district court held that the presumption applies in Illinois, it relied upon an older Illinois Appellate Division case that applied now-outdated Texas

law. See Erickson, 151 F.Supp.2d at 970. Moreover, in arguing that any heeding presumption would be rebutted by the physicians' testimony here, Defendant relies solely on out-of-state law to support its contention. See Def. Reply at 2-3, 2 n.3 (citing Oklahoma and Kansas law on rebuttability). Since my ruling on the inadequacy of the warning alone forecloses Plaintiff's failure to warn claim, I decline to enter this jurisprudential thicket and express my opinion on Illinois' adoption of a heeding presumption.

III. Illinois Defective Design Claim

Plaintiff's design defect claim is premised on Defendants' alleged failure to warn. See Opp. Br. at 37 ("Because there were not proper instructions on the Plavix label, because the label was not properly prepared, and because the benefits of Plavix do not outweigh the risks, the Plaintiff can proceed on a defective design claim.") Under Illinois law, "[a] product bearing an adequate warning is not in [a] defective condition, nor is it unreasonably dangerous." Salerno v. Innovative Surveillance Technology, Inc., 932 N.E.2d 101, 108 (Ill. App. Ct. 2010) (discussing Restatement (Second) of Torts § 402 A (1965)). Moreover, prescription drugs are entitled to the protection of Restatement (Second) of Torts § 402A, Comment k,

at 353 (1965), which "offers an exception to the general rule making a seller strictly liable even when the product was properly prepared." De Bouse v. Bayer, 922 N.E.2d 309, 317 (Ill. 2009) (discussing comment K's applicability to prescription drugs in the context of an Illinois consumer fraud claim). Hence, Plaintiff's defective design claim fails because she has not demonstrated that the Plavix warning was inadequate.

IV. Illinois Manufacturing Defect Claim

Just as with Plaintiff's design defect claim, her manufacturing defect claim is premised on a failure to warn theory. As Illinois law provides that products bearing adequate warnings are not defective, Salerno, 932 N.E.2d at 108, and she has not demonstrated that the Plavix warning was inadequate, her manufacturing defect claim also fails.

V. Negligence Claim

Plaintiff’s negligence claim is nothing more than a restatement of her defective design, defective manufacturing, and failure-to-warn claims. Plaintiff avers that Defendants negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled and/or sold Plavix. See Am. Comp., ¶¶ 65-69. Because the Court

has found that none of her claims have merit, this claim necessarily fails.

VI. Discovery Request Pursuant to Rule 56(d)

As a final note, Plaintiff seeks additional discovery pursuant to Fed. R. Civ. P. 56(d). Based on the Court's ruling herein, there is no basis to provide Plaintiff additional opportunities to seek discovery. Moreover, much of what Plaintiff proposes to discover relates to Plavix's effectiveness, which, is neither relevant nor probative of Plaintiff's claims. Also, Plaintiff has had the opportunity to take the depositions of Plaintiff's treating physicians. Accordingly, Plaintiff's position that the motion is premature and further discovery should be taken is rejected.

CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment is granted in its entirety. As a result, Plaintiff's Amended Complaint is dismissed.

An appropriate Order shall issue.

Dated: January 11, 2013

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